

# Automated Microbiology System User's Manual







The BD Phoenix reagents and BD Phoenix software are intended for *in vitro* diagnostic use and comply with the European IVD Directive 98/79/EC.

The BD Phoenix 100 instrument manufactured as of 22 July 2016 continues to be compliant with the European IVD Directive 98/79/EC.

However, the BD Phoenix 100 instrument manufactured as of 22 July 2016 does not comply with the requirements set forth in RoHS Directive 2011/65/EU.



Becton, Dickinson and Company 7 Loveton Circle Sparks, Maryland 21152 USA

#### **Australian Sponsor:**

Becton Dickinson Pty Ltd. 66 Waterloo Road Macquarie Park NSW 2113Australia

> L-003342(23) 2020-04 448021



English Not For Sale in USA



bd.com/e-labeling

# **Change History**

Revision	Date	Page and/or Sections	Reason
21	2016/09	Cover, Section 3.6, Section E, Section F, Section H	Remove CE mark and EC Rep address, add USB functionality, update performance tables
22	2017/10	Section 1, 8.1, 14.1, 15.1	Addition of resistance mechanisms, CPO Detect test, and performance for new drug formulations.
Revision	Date	Change Summary	
23	2020/04	Content flow changed; Updated Chapter 1: Introduction; Updated Preparing Panels in chapter 4; Updated Chapter 8: Performance and Limitations; Updated Chapter 9: Panel Information; Updated Chapter 13: International Contacts; Updated 16: Glossary.	

ATCC is a trademark of American Type Culture Collection.

BD, BD Logo, BBL, Cefinase, CrystalSpec, EpiCenter, Phoenix, PhoenixSpec, and Trypticase are trademarks of Becton, Dickinson and Company or its affiliates. All other trademarks are the property of their respective owners. © 2020 BD. All rights reserved.

No part of this publication may be reproduced, transmitted, transcribed, stored in retrieval systems, or translated into any language or computer language, in any form or by any means, electronic, mechanical, magnetic, optical, chemical, manual, or otherwise, without the prior written permission of BD, 7 Loveton Circle, Sparks, Maryland, 21152, USA.

1 – Introducti	ion	11
1.1 Intended	d Use	11
1.2 Summar	ry and Explanation of the Test	11
1.3 Principle	es of the Procedure	12
1.3.	1 Overview of the BD Phoenix ID/AST System	12
	1.3.1.1 Organism Identification	13
	1.3.1.2 Antimicrobial Susceptibility Testing	13
1.4 Precauti	ons	17
1.5 System	Overview	17
1.5.	1 Instrument Overview	17
	1.5.1.1 Instrument Optical System and Drive Mechanism	17
	1.5.1.2 Carousel Assembly	18
	1.5.1.3 Incubation System	18
	1.5.1.4 Panel Status and Internal Barcode Scanner Assembly	18
	1.5.1.5 Front-Panel and External Barcode Scanners	19
	1.5.1.6 Control Electronics Assembly	19
1.5.	2 Software and Operation Overview	20
1.5.	3 Panel Overview	20
1.5.	4 Testing Overview	22
1.5.	5 Normalizers	22
1.6 Use of the	his Manual	23
1.7 Convent	tions	23
	1 Keys	
1.7.	2 Symbols Used on the Equipment	24
1.7.	3 Notes, Cautions, and Warnings	25
1.8 Summar	ry of Cautions and Warnings	25
2 – Installatio	on	27
2.1 General		27
2.1.	1 Installation	28
2.2 Instrume	ent Specifications	28
2.3 Software	e Setup	30
2.3.	1 Instrument Configuration	33
	2.3.1.1 General Instrument Configuration	33
	2.3.1.2 More Configuration Options	37
	2.3.1.3 Password Administration	39

	2.3.2 Communications Configuration	41
	2.3.2.1 Organism Configuration	45
	2.3.2.2 Antimicrobial Configuration	47
	2.3.3 Custom Interpretation Rule Set	49
	2.3.4 BDXpert Rule Configuration	58
	2.3.5 Rapid Reporting Configuration	60
	2.3.6 Panel Lot Definition	64
	2.4 System Startup	69
	2.5 Software Installation	69
3 -	- Controls and Indicators	71
	3.1 General	71
	3.2 Power Switch	73
	3.3 Keypad and LCD Display	74
	3.3.1 DOWN /UP ARROW Keys	74
	3.3.2 TAB Key	74
	3.3.3 Soft Keys	75
	3.3.4 UNLOAD PANELS Key	75
	3.3.5 LOAD PANELS Key	75
	3.3.6 SILENCE ALARM Key	75
	3.3.7 System Alert/Door Unlocked Indicator	75
	3.3.8 Display Area	76
	3.4 Barcode Scanners	76
	3.5 Floppy Disk Drive	76
	3.5.1 Floppy Disk Indicator	76
	3.5.2 Floppy Disk Eject Button	76
	3.6 USB Functionality	77
	3.7 Station Indicators	77
	3.8 Audible Tones and Alarms	78
	3.9 Keyboard	79
	3.10 Printer	79
4 -	– Operation	81
	4.1 General	81
	4.2 Daily System Maintenance	82
	4.3 Storage and Handling	82
	4.4 Preparing Panels	82

4.4.1 General Panel Pre	eparation	86
4.4.2 ID Inoculum Dens	ity Flexibility	89
4.4.3 Preparing BD Pho	enix Strep Panels	91
4.4.4 Preparing BD Pho	penix Yeast ID Panels	92
4.4.5 Preparing BD Pho	penix Emerge Panels	94
4.4.6 Using BD Phoenix	Inoculum Broth	96
4.4.7 Quality Control		96
4.5 Panel Login		99
4.5.1 Using the Instrume	ent Interface	99
4.5.2 Logging in Panels		100
4.5.3 Associating and R	temoving LIS Orders	102
4.6 Inserting Panels in the Instru	ument	104
4.7 Panel Testing		106
4.8 Responding to Needs Attent	tion Panel	106
4.9 Automatic Association of Pa	nels	110
4.9.1 Overview		110
4.9.2 Panel Types		110
4.9.3 When Auto Assoc	iation Is Not Performed	110
4.9.4 Organism ID Conf	flict Checking	111
4.9.5 Auto Association a	and Related Actions	111
4.9.6 Typical Auto Asso	ciation Examples	112
4.10 Obtaining Results		114
4.10.1 Adding/Modifying	g ID Results	118
4.10.2 Modifying AST R	esults	119
4.10.3 BDXpert Triggere	ed Rules Display	120
4.10.4 Resistance Mark	er Display	120
4.11 Panel Finalization		121
4.12 Responding to Alarms and	Errors	124
4.13 Printing Reports		125
4.14 Unloading and Discarding	Panels	127
4.15 LIS Operations		128
4.15.1 General		128
4.15.2 Important Conce	pts	129
4.15.3 Processing Pane	el Orders	129
4.15.4 Routine System	Operation	130

<b>5</b> ·	- Reference	131
	5.1 General	131
	5.2 Software Tree	132
	5.3 Main Status Screen	133
	5.4 Panel Login	136
	5.5 Panel Results	140
	5.5.1 BDXpert Triggered Rules Display	149
	5.5.2 Resistance Marker Display	152
	5.5.3 Special Messages Display	153
	5.5.4 Lab Report	155
	5.6 Finalization	158
	5.7 Configuration/Maintenance	160
	5.8 Reports	161
	5.8.1 Completed Lab Report	162
	5.8.2 Accession Lab Report	165
	5.8.3 Needs Attention List Report	167
	5.8.4 Resident Panel Report	168
	5.8.5 QC Lab Report	169
	5.8.6 Cumulative QC Report	172
	5.8.7 Daily Instrument Report	173
	5.8.8 Interpretation Rule Set Report	176
	5.8.9 BDXpert Rule Set Database Report	178
	5.8.10 Organism ID Code List Report	180
	5.8.11 Antimicrobial Code Report	181
	5.8.12 Lab Report/QC Lab Report	182
	5.8.13 Finalization Summary Report	182
	5.8.14 Custom Breakpoint Difference Report	182
	5.8.15 Current QC Panel Lot Report	182
	5.8.16 Historical QC Panel Lot Report	182
	5.8.17 Panel Lot Report	182
	5.8.18 Panel Lot Database Report	184
	5.9 Panel Inventory	185
	5.10 System Alerts	187
	5.11 Needs Attention	189

6 – Maint	tenance	195
6.1 G	eneral	195
6.2 R	outine Maintenance	196
	6.2.1 Daily Maintenance	196
	6.2.2 Weekly Maintenance	196
	6.2.3 Periodic Maintenance	198
	6.2.3.1 Air Filter Replacement	198
	6.2.3.2 Cleaning the Barcode Scanner Window	201
	6.2.3.3 Cleaning/Decontamination	201
	6.2.4 Maintenance Menu	202
	6.2.4.1 Save User Data to Disk or USB	203
	6.2.4.2 Restore User Data from Disk	205
	6.2.4.3 Save LIS Codes to Disk	206
	6.2.4.4 Restore LIS Codes from Disk	208
	6.2.4.5 Save Panel Lot Definitions	210
	6.2.4.6 Restore Panel Lot Definitions	212
	6.2.4.7 Save Panel Configuration	213
	6.2.4.8 Install Panel Configuration	215
	6.2.4.9 BD Phoenix Update Disk	216
	6.2.4.10 Modify Panel Usage	218
	6.2.4.11 Write Light Source to Disk	220
	6.2.4.12 Read Light Source from Diskette	221
	6.2.4.13 View Syslog	223
	6.2.4.14 Save Syslog to Network	227
	6.2.4.15 Display UV and RGB Status	228
	6.2.4.16 Force Front UV Bulb Adjustment	229
	6.2.4.17 Force Rear UV Bulb Adjustment	231
	6.2.4.18 Force RGB LED Adjustment	233
	6.2.4.19 Front Panel Reader Setup	234
6.3 M	odule Replacement	236
	6.3.1 General	236
	6.3.2 Barcode Scanner Replacement	236
	6.3.3 Thermometer Removal	
	6.3.4 Reuniting Separated Liquid in the Thermometer	237

7 – Troubleshooting	239
7.1 General	239
7.1.1 Instrument Service	239
7.2 Error/Alert Messages	239
7.3 Save System Data to Disk Function	263
7.4 Save Syslog to Disk Function	264
8 – Performance and Limitations	267
8.1 Performance Characteristics	267
8.1.1 Gram Negative Performance	267
8.1.2 Gram Positive Performance	272
8.1.3 Streptococci Performance (with the BD Phoenix SMIC/ID, SMIC Panels)	276
8.1.4 Yeast Performance	277
8.2 Limitations of the Procedure	278
8.3 Limitations of the BD Phoenix CPO detect test	279
9 – Panel Information	281
9.1 List of Antimicrobial Agents in BD Phoenix Panels	281
9.2 List of Reagents and Principles Employed in the BD Phoenix System	288
9.2.1 Gram Negative	288
9.2.2 Gram Positive	290
9.2.3 Streptococci	292
9.2.4 Yeast	294
9.3 Taxa for ID/AST Determination	296
9.3.1 Gram Negative (0.5 McFarland)	296
9.3.2 Gram Negative (0.25 McFarland)	306
9.3.3 Gram Positive (0.5 McFarland)	312
9.3.4 Gram Positive (0.25 McFarland)	319
9.3.5 Streptococci	322
9.3.6 Yeast	326
10 – Limited Warranty	329
11 – Replacement Parts	331
12 – Software Update Log	333
13 – International Contacts	335

14 – Bibliography	337
15 – Event Log Messages	339
15.1 LIS Related Messages	339
16 – Glossary	349
16.1 Definitions	350
16.2 Organism Names and Abbreviations	354
16.3 Supplemental Id Test Abbreviations	376
16.4 Interpretation Codes	377
17 – Index	379

# 1 - Introduction

## 1.1 Intended Use

The BD Phoenix<sup>™</sup> Automated Microbiology System is intended for the rapid identification (ID) and antimicrobial susceptibility testing (AST) of clinically significant bacteria. The BD Phoenix system provides rapid results for most aerobic and facultative anaerobic Gram-positive bacteria as well as most aerobic and facultative anaerobic Gram-negative bacteria of human origin. The BD Phoenix system is also intended for the rapid identification of yeast and yeast-like organisms.

## 1.2 Summary and Explanation of the Test

Micromethods for the biochemical identification of microorganisms were reported as early as 1918.¹ Several publications reported on the use of the reagent-impregnated paper discs and micro-tube methods for differentiating enteric bacteria.¹-9 The interest in miniaturized identification systems led to the introduction of several commercial systems in the late 1960s, and they provided advantages in requiring little storage space, extended shelf life, standardized quality control, and ease of use.

The modern broth microdilution test used today has origins in the tube dilution test used in 1942 by Rammelkamp and Maxon to determine *in vitro* antimicrobial susceptibility testing of bacterial isolates from clinical specimens.<sup>12</sup> The broth dilution technique involves exposing bacteria to decreasing concentrations of antimicrobial agents in liquid media by serial two-fold dilution. The lowest concentration of an antimicrobial agent in which no visible growth occurs is defined as the minimal inhibitory concentration (MIC).

In 1956, the introduction of a microtitrator system (using calibrated precision spiral wire loops and droppers for making accurate dilutions) rapidly allowed Marymont and Wentz to develop a serial dilution AST test.<sup>13</sup> The microtitrator system was accurate and allowed the reduction in volumes of antimicrobial agents. The term microdilution appeared in 1970 to describe the MIC tests performed in volumes of 0.1 mL or less of antimicrobial solution.<sup>14</sup>

## 1.3 Principles of the Procedure

Many of the tests used in the BD Phoenix ID panels are modifications of the classical methods. These include tests for fermentation, oxidation, degradation and hydrolysis of various substrates. In addition to these, the BD Phoenix System utilizes chromogenic and fluorogenic substrates as well as single carbon source substrates in the identification of organisms.<sup>10,11, 26–28</sup>

The BD Phoenix AST is a modified miniaturized version of the micro-broth doubling dilution technique. Susceptibility testing in the BD Phoenix System is performed through determination of bacterial growth in the presence of various concentrations of the antimicrobial agent tested with the aid of the AST indicator in continuously incubated and read micro-wells in the BD Phoenix panels.

### 1.3.1 Overview of the BD Phoenix ID/AST System

A maximum of 100 identification and antimicrobial susceptibility tests can be performed in the BD Phoenix instrument at a time using BD Phoenix combination panels. A sealed and self-inoculating molded polystyrene tray, with 136 micro-wells containing dried reagents, serves as the BD Phoenix disposable. The combination panel includes an ID side with dried substrates for bacterial or yeast identification and an AST side with varying concentrations of antimicrobial agents, growth and fluorescent controls at appropriate well locations. The BD Phoenix System utilizes an optimized colorimetric redox indicator for AST, and a variety of colorimetric and fluorometric indicators for ID. The AST broth is cation-adjusted (e.g., Ca<sup>++</sup> and Mg<sup>++</sup>) to optimize susceptibility testing performance.



Figure 1-1 – Example of ID/AST Panel

The BD Phoenix Panel is comprised of a 51 well ID side and an 85 well AST side. The ID side contains 45 wells with dried biochemical substrates and 2 fluorescent control wells. The AST side potentially contains up to 84 wells with dried antimicrobial agents and 1 growth control well. Panels are available as ID only, AST only, or ID/AST combination. Unused wells are reserved for future use. BD Phoenix panels are inoculated with an organism suspension adjusted to a specific McFarland standard. Organism suspensions must be prepared only with the BD BBL™ CrystalSpec™ Nephelometer, the BD PhoenixSpec™ Nephelometer, or the BD Phoenix™ AP instrument.

Once inoculated, panels are placed into the instrument and continuously incubated at 35 °C. The instrument tests panels every 20 minutes: on the hour, at 20 minutes past the hour, and again at 40 minutes past the hour for up to 16 hours if necessary. BD Phoenix panels are read only by the BD Phoenix instrument. BD Phoenix panels cannot be read manually.

### 1.3.1.1 Organism Identification

The ID portion of the BD Phoenix panel utilizes a series of conventional, chromogenic, and fluorogenic biochemical tests to determine the identification of the organism. Both growth-based and enzymatic substrates are employed to cover the different types of reactivity within the range of taxa. The tests are based on microbial utilization and degradation of specific substrates detected by various indicator systems. Acid production is indicated by a change in phenol red indicator when an isolate is able to utilize a carbohydrate substrate. Chromogenic substrates produce a yellow color upon enzymatic hydrolysis of either *p*-nitrophenyl or *p*-nitroanilide compounds. Enzymatic hydrolysis of fluorogenic substrates results in the release of a fluorescent coumarin derivative. Organisms that utilize a specific carbon source reduce the resazurin-based indicator. In addition, there are other tests that detect the ability of an organism to hydrolyze, degrade, reduce, or otherwise utilize a substrate.

A complete list of taxa that comprises the BD Phoenix Database is provided in Section 9.3 Taxa for ID/AST Determination. Reactions employed by various substrates and a brief explanation of the principles employed in the BD Phoenix Gram Negative, Gram Positive, *Streptococcus*, and Yeast ID reactions are described in Section 9.2 List of Reagents and Principles Employed in the BD Phoenix System.

### 1.3.1.2 Antimicrobial Susceptibility Testing

The AST method used by the BD Phoenix System is a broth based microdilution test. The BD Phoenix system utilizes a redox indicator for the detection of organism growth in the presence of an antimicrobial agent. Continuous measurements of changes to the indicator as well as bacterial turbidity are used in the determination of bacterial growth. Each AST panel configuration contains several antimicrobial agents with a wide range of two-fold doubling dilution concentrations. Organism identification is used in the interpretation of the MIC values of each antimicrobial agent.

A complete list of taxa for which the BD Phoenix panels can provide AST results is shown in Section 9.3 Taxa for ID/AST Determination. The list of antimicrobial agents and concentrations available for susceptibility testing in the BD Phoenix System is provided in Section 9.1 List of Antimicrobial Agents in BD Phoenix Panels.

#### Principles of BD Phoenix AST Tests for the Detection of Resistance Markers

The following sections outline the principles of the BD Phoenix AST System in the detection of resistance markers in gram-negative or gram-positive organisms, including:

- 1. detection of ESBL production among species of Enterobacterales;
- 2. detection of vancomycin resistance in *Enterococcus* species (VRE);
- 3. detection of high-level aminoglycoside resistance in *Enterococcus* and *Streptococcus* species (HLAR);
- 4. detection of methicillin-resistance in staphylococci (MRS);
- 5. detection of β-lactamase production in *Staphylococcus* species (BL);
- 6. detection of macrolide resistance in *Streptococcus* species (MLSb);
- 7. detection of mecA-mediated Resistance with S. aureus (mecA) and S. lugdunensis (mecA);
- 8. detection of Vancomycin Resistant Staphylococcus aureus (VRSA);
- 9. detection of BD Phoenix Inducible Macrolide Resistance (iMLSb) in Staphylococcus spp.;
- 10. detection of BD Phoenix high level Mupirocin resistance (HLMUPH);
- 11. detection of Carbapenemase-Producing Organism (CPO) detect test for *Enterobacterales, Pseudomonas aeruginosa,* and *Acinetobacter baumannii.*

#### BD Phoenix Extended Spectrum β-Lactamase (ESBL) Test<sup>16</sup>

The BD Phoenix ESBL test evolved from published data of known ESBL antibiogram patterns in the current literature. <sup>18,19,20,21</sup> Selected strains of various species with known β-lactamase genotype/phenotypes in the family *Enterobacterales*, including *Escherichia coli, Klebsiella* species (spp.), *Citrobacter* spp., *Enterobacter* spp., *Proteus* spp., and *Serratia* spp., were used to develop the BD Phoenix ESBL test. The BD Phoenix ESBL test is based on the principle of a differential response between the inhibitory effect of selected second or third generation cephalosporins in the presence or absence of a β-lactamase inhibitor, clavulanic acid. The principles of BD Phoenix ESBL test is similar to the CLSI ESBL broth microdilution confirmatory test. <sup>22</sup> The BD Phoenix ESBL test is applied to *E. coli, K. pneumoniae* and *K. oxytoca*. When a test result of ESBL is positive, the categorical interpretation of all penicillins, cephalosporins (except cephamycins), and aztreonam on the same BD Phoenix panel will be changed to **R** (resistant) with BDXpert rule 1529. <sup>22</sup> Carbapenem results will not change for positive ESBL tests. Customers can enable specific rules to report listed drugs as tested.

#### **BD Phoenix Vancomycin Resistant Enterococci (VRE) Test**

The BD Phoenix VRE test is based on the SIR interpretation of vancomycin. The breakpoint selected in the instrument configuration is used for the categorical interpretation. The BD Phoenix VRE test was developed and optimized to match the CLSI standard broth microdilution test.<sup>22,23</sup> Selection of a breakpoint other than CLSI may result in less than optimal performance due to differences in categorical interpretations. Only *Enterococcus faecalis* and *E. faecium* with acquired resistance (vanA or vanB) will be reported as positive.<sup>22</sup>

#### **BD Phoenix High-Level Aminoglycoside Resistance (HLAR) Tests**

The BD Phoenix HLAR tests for *Enterococcus* are based on the growth response in a single well containing either a high-level concentration of gentamicin or streptomycin. These tests were developed and optimized against both the CLSI standard broth microdilution and the CLSI screening agar test.<sup>22</sup> The BD Phoenix HLAR tests for *Streptococcus* are based on the growth response in a single well containing gentamicin, kanamycin, or streptomycin. These tests were developed and optimized using the CLSI recommended standard broth microdilution.

#### BD Phoenix Methicillin-Resistance in Staphylococci (MRS) Test

The BD Phoenix MRS test is based on the SIR interpretation of oxacillin with *Staphylococcus* species. When an MRS test result is positive, several BDXpert rules are designed to handle the reporting and the interpretations of all beta-lactam drugs. A special BDXpert rule is designed to report MRS using cefoxitin results for *Staphylococcus aureus*. The surrogate drug, cefoxitin, has been validated as a better indicator for the presence of mecA in staphylococci. The breakpoint selected in the instrument configuration is used for the categorical interpretation.

#### BD Phoenix Gram-Positive β-lactamase (BL) Test<sup>16</sup>

The BL test available in the BD Phoenix AST System is a nitrocefin based β-lactamase test. The nitrocefin based test is a direct detection method located on the ID side of the BD Phoenix panel. The performance of this test was established against the results of testing with BD BBL™ Cefinase™ Discs (Cat. No. 231650) as the reference method. Currently, only *Staphylococcus* species will be evaluated with these tests. When the result of BL test is positive, the categorical interpretation of all penicillinase labile penicillins on the same BD Phoenix panels will be changed to resistant.<sup>22</sup>

#### BD Phoenix Macrolide Resistance in Streptococci (MLSb) Test

The BD Phoenix Macrolide Resistance test is based on SIR interpretation of erythromycin and clindamycin. The breakpoint selected in the instrument configuration is used for the categorical interpretation. Erythromycin resistant and clindamycin resistant *Streptococcus* isolates will be reported as macrolide/lincosamide/streptogramin B (MLSb) phenotype.

#### BD Phoenix mecA-mediated Resistance Marker for Staphylococcus aureus (mecA)

The BD Phoenix *mecA* test is used to predict *mecA*-mediated resistance in *Staphylococcus aureus* and *S. lugdunensis*. The principle is similar to the CLSI-recommended Disk Diffusion test, which uses a cefoxitin (FOX) disk to predict *mecA*-mediated resistance. The performance of the test was established against multiplex PCR methods<sup>25</sup> as well as the Disk Diffusion test. With the BD Phoenix *mecA* test, the *mecA*-specific FOX breakpoints used for detection of the resistance marker will be configured in the instrument. When the *mecA* resistance marker is detected, the interpretations for all beta-lactam drugs on the same BD Phoenix panel are changed to resistant,<sup>22</sup> and the BD Phoenix *mecA* resistance marker is set.

#### BD Phoenix Vancomycin Resistant Staphylococcus aureus (VRSA) Test

The BD Phoenix VRSA detection is based on the SIR interpretation of vancomycin when testing *Staphylococcus aureus*. The breakpoint selected in the instrument configuration is used for the categorical interpretation. The BD Phoenix VRSA test was developed and optimized to match the CLSI standard broth microdilution test, and verified with known VRSA isolates. Selection of a breakpoint other than those found in CLSI M100-S15 may result in less than optimal performance due to differences in categorical interpretations. Only *Staphylococcus aureus* with true resistance (isolates containing resistance marker such as vanA gene) will be reported as VRSA. Strains of *S. aureus* with vancomycin intermediate results (GISA/VISA) will be identified and reported by separate BDXpert rules. The BD Phoenix Gram Positive AST panel detected vancomycin resistance in the VRSA *S. aureus* strains available at the time of comparative testing. The ability to detect resistance in other *S. aureus* strains is unknown due to the limited number of resistant strains available for comparative testing.

#### BD Phoenix Inducible Macrolide Resistance (iMLSb) Test in Staphylococcus species

The BD Phoenix Inducible Macrolide Resistance (iMLSb) Test is used to detect inducible macrolide-lincosamide-streptogramin B (iMLSb) resistance in *Staphylococcus* species. iMLSb resistance, usually encoded by *ermA* or *ermC* genes, may be either constitutive (always expressed) or inducible after exposure to a macrolide antibiotic (e.g. erythromycin, clarithromycin, etc.). The BD Phoenix Inducible Macrolide Resistance Test is based on the same principle as the CLSI-recommended Disk Approximation Test (D-Test) for the detection of inducible clindamycin resistance. When the BD Phoenix Inducible Macrolide Resistance Test result is positive, the categorical interpretation of clindamycin on the same BD Phoenix panel will be reported as resistant and accompanied by a separate BDXpert message. *Staphylococcus* isolates resistant to both erythromycin and clindamycin on initial testing will be reported as constitutive iMLSb resistance to distinguish them from isolates that are resistant to macrolides alone by efflux mechanism.

#### **BD Phoenix high level Mupirocin resistance (HLMUPH)**

The BD Phoenix high level Mupirocin resistance test is based on the growth response in a single well containing 256 mcg/mL of the topical antibiotic Mupirocin that is frequently used for eradication of *Staphylococcus* colonization, particularly for nasal carriage of MRSA. The breakpoint selected in the instrument configuration is used for the categorical interpretation of Susceptible (no growth in 256 mcg/mL well) or Resistant (growth in 256 mcg/mL well). High level Mupirocin resistant *Staphylococcus* isolates will be reported as the (HLMUPH) phenotype resistance marker.

#### **BD Phoenix CPO detect Test**

#### Intended Use:

BD Phoenix<sup>TM</sup> CPO detect is a qualitative confirmatory test that uses a growth-based algorithm intended to phenotypically detect carbapenemase production in *Enterobacterales*, *Pseudomonas aeruginosa*, and *Acinetobacter baumannii* on Gram-negative ID/AST or AST only BD Phoenix panels. The test also provides the Ambler classification (Class A, Class B, and Class D) of the carbapenemase produced. One of three test configurations is available per panel for carbapenemase detection with or without Ambler classification for the target organism groups. BD Phoenix CPO detect does not report multiple classes of carbapenemases from a single isolate.

#### Description:

Carbapenem non-susceptibility among *Enterobacterales*, *Pseudomonas aeruginosa* and *Acinetobacter baumannii* can result from two main mechanisms: production of a β-lactamase (carbapenemase) or production of a β-lactamase (cephalosporinase or ESBL) coupled with decreased permeability through porin mutations.<sup>(1,2)</sup> World-wide, the most common Ambler classification of carbapenemases with corresponding genes in the *Enterobacterales* are: Class A (*bla*KPC), Class B (*bla*NDM, *bla*VIM, *bla*IMP) and Class D (blaOXA-48).<sup>2</sup> The most common in *Pseudomonas aeruginosa* are Class B (*bla*VIM and *bla*IMP).<sup>3,4</sup> The most common in *Acinetobacter baumannii* are Class D (*bla*OXA-23, *bla*OXA-24, *bla*OXA-58).<sup>2,5</sup>

The BD Phoenix CPO detect test uses the principles of Ambler-class specific  $\beta$ -lactamase inhibition and Ambler-class specific antibiotic resistance to detect the presence of a carbapenemase and to derive the Ambler class of the carbapenemase. In some isolates, the presence of multiple resistance mechanisms, including more than one carbapenemase, may result in a "CPO Positive" test result with no Ambler classification (i.e., "unclassified").

Test performance was established utilizing multiple reference methods, which included, but was not limited to, the modified Carbapenem Inactivation Method (mCIM), MIC Screen (utilizing carbapenem threshold values), and multiplex PCR testing. Multiplex PCR testing for *Enterobacterales* included *bla*KPC, *bla*NDM, *bla*IMP, *bla*VIM, and OXA-48-like genes. Multiplex PCR testing for *P. aeruginosa* and *A. baumannii* included *bla*KPC, *bla*NDM, *bla*IMP, *bla*VIM, OXA-23-like, OXA-24-like, OXA-48-like, and OXA-58-like genes.

The test is offered on Phoenix Gram Negative panels in one of three configurations:

- CPO 2 well configuration provides detection of carbapenemase-producing organisms (CPO) in *Enterobacterales, Pseudomonas aeruginosa*, and *Acinetobacter baumannii*.
- CPO 6 well configuration provides detection of carbapenemase-producing organisms (CPO) in Enterobacterales, Pseudomonas aeruginosa, and Acinetobacter baumannii and Ambler classification of the carbapenemase in Enterobacterales.
- CPO 9 well configuration provides detection and Ambler classification of the carbapenemase in *Enterobacterales*, *Pseudomonas aeruginosa*, and *Acinetobacter baumannii*.

#### References for BD Phoenix CPO detect test

- 1. Jorgensen, James H., et al. ed., *Manual of Clinical Microbiology*, 11th Edition, ASM Press, Washington, D.C., 2015.
- 2. Djahmi, N., C. Dunyach-Remy, A. Pantel, M. Dekhil, A.Sotto, and J. Lavigne. 2014. "Epidemology of Carbapenemase-Producing Enterobacterales and Acinetobacter baumannii in Mediterranean Countries," BioMed Research International. Article ID 305784, 11 pages.
- 3. Liakopoulos, A., A. Mavroidi, E.A. Katsifas, A. Theodosiou, A.D. Karagouni, V. Miriagou and E. Petinaki. 2013. "Carbapenemase-producing Pseudomonas aeruginosa from central Greece:

molecular epidemiology and genetic analysis of class I integrons," BCM Infectious Diseases, 13:505.

- Maya, J.J., S.J. Ruiz, V.M. Blanco, E. Gotuzzo, M. Guzman-Blanco, J. Labarca, M. Salles, J.P. Quinn, and M.V. Villegas. 2013. "Current Status of Carbapenemaseses in Latin America," Expert Rev Anti Infect Ther. 11(7):657–667.
- Naas, T., M. Levy, C. Hirschauer, H. Marchandin and P. Nordmann. 2005. "Outbreak of Carbapenem-Resistant Acinetobacter baumannii Producing the carbapenemase OXA-23 in a Tertiary Care Hospital of Papeete, French Polynesia," Journal of Clinical Microbiology. 43(9):4826–4829.

## 1.4 Precautions

For in vitro Diagnostic Use.

All patient specimens and microbial cultures are potentially infectious and should be treated with universal precautions. Please refer to CDC manual *Biosafety in Microbiological and Biomedical Laboratories*, 5<sup>th</sup> Edition, 2009, as well as other recommended literature.

Panels once inoculated should be handled carefully until placed in the instrument.

For a patient/user/third party in the European Union and in countries with identical regulatory regime; if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to BD and/or its authorized representative and to your national authority managing health products.

## 1.5 System Overview

#### 1.5.1 Instrument Overview

### 1.5.1.1 Instrument Optical System and Drive Mechanism

Within the main instrument incubation bay, the cylindrical carousel and its drive are the only moving parts. The carousel assembly is supported and permitted to rotate by three large V-groove bearing assemblies, which accept the carousel V-ring. The carousel is normally driven at either 1.0 RPM or 2.0 RPM. The drive speed, acceleration and deceleration are controlled by the central processor.

The carousel is divided vertically into four tiers, each of which functions as a relatively independent optical source and detection system for panels placed on that tier. Each tier has its own microcontroller to control data acquisition and transmission. The four microcontrollers communicate with the central processor over a serial communications link.

Visible illumination in the red, green and blue spectral regions for each tier is provided by a Light Emitting Diode (LED) source board. The LED source currents are programmable in order to compensate for signal loss at the panel extremes due to parallax and other factors. A source monitor system averages signal from two onboard photodiodes to monitor visible source output. A fluorescent UV (ultraviolet) lamp containing a selected phosphor provides UV illumination. The active length of the lamp spans all four tiers vertically, producing UV illumination constant to 10% over the useful lamp length. A second UV lamp is maintained as a spare.

#### 1.5.1.2 Carousel Assembly

The Carousel Assembly is a cage-like structure comprising of aluminum rings and vertical ribs bolted together to form a circular cylinder. The carousel has 104 panel holders in four tiers, where each tier has one normalizer panel and 25 sample panels. The carousel rotates counterclockwise. Following a door closure, an inventory scan is performed to identify panels within the instrument.

Under normal conditions, the carousel is driven at either 1.0 RPM or 2.0 RPM for the current/ongoing operation. During panel location, it can rotate at up to 10.0 RPM. A complete test cycle requires 7 minutes.



Figure 1-2 - BD Phoenix 100 Instrument

### 1.5.1.3 Incubation System

The Incubation System maintains the carousel, panel carriers, and panels at a constant nominal temperature of 35 °C. The system is a recirculating forced-air convection design, and has a single filter to remove dust. The system consists of a squirrel cage blower powered by a brushless DC motor, a coil-style heater section with automatic over-temperature shut-off, thermoformed inlet and return ductwork, and a user-replaceable polyester fiber air filter.

#### 1.5.1.4 Panel Status and Internal Barcode Scanner Assembly

Panel status indication and panel identification is accomplished on the same tower in the instrument, mounted directly behind the carousel in the door area. Panel Status is indicated by tri-color LEDs mounted on a panel behind the carousel that shine through light pipes in the panel carriers. Five columns of the carousel are exposed when the instrument door is open; there are five LED boards with four indicator LEDs on each.

Four barcode scanners capable of reading panel barcodes are located on the same tower as the indicators. Each scanner reads panel barcodes on its respective tier of the carousel. Panel barcodes are affixed at the top of the panel on the base (bottom) side of the panel, facing inward on the carousel when placed in the instrument.

#### 1.5.1.5 Front-Panel and External Barcode Scanners

External barcode scanners are located on the front panel and the right side of the instrument. These scanners can be used to read barcoded accession numbers that have been placed on the panels, as well as the panel's own sequence number barcodes. The accession barcodes can be used to link specimen identification information to specific panels in the instrument.

#### NOTE

The placement of customer barcode labels must not interfere with panel reading.

### 1.5.1.6 Control Electronics Assembly

The control electronics assembly consists of the boards: I/O (Input/Output) Interface, CPU and memory, Ethernet, and LCD (Liquid Crystal Display) Driver. Other control electronics include user interface components such as the front panel barcode scanner, the floppy disk drive, the LCD display, the custom keypad, the keyboard, and the speaker for audible alarm notification.

The control electronics are primarily responsible for the following functions:

- scheduling and monitoring panel testing
- · acquiring panel test data
- illuminating the panel (station) status indicators
- processing data from the external and internal barcode scanners
- interpreting data from organism identification panels to produce an organism identification
- interpreting data from antimicrobial susceptibility panels to produce either MIC results or, via guidelines, SIR results
- sending information to the LCD display
- · processing commands from the keypad and keyboard
- controlling door switch status and door interlock
- · controlling cabinet incubation
- communications with external devices (such as a BD EpiCenter™ workstation)
- · generating alarm signals
- performing the Built-In-Test (BIT)

### 1.5.2 Software and Operation Overview

The Liquid Crystal Display (LCD) presents all the information needed to monitor instrument status, to enter and remove panels, set up the instrument, print reports, and perform routine instrument maintenance. The information is presented in the form of screens and icons that graphically represent the information (e.g., a clock indicates the current time). The top region of the Main Status display presents instrument status information that is updated every few seconds. The middle region of the display initially presents station status information. As you access different screens and functions, they appear in place of the top and middle status windows. At the bottom of the displays, a series of icons shows the current software (soft) key definitions. Each of the displays are discussed in detail in Section 5 – Reference.

Most of the operations you perform at the instrument are initiated by pressing soft keys. Soft key definitions change as you select their related functions and access different displays and operations.

In addition to the soft keys, six hard keys, themselves marked with screened icons, perform fixed functions regardless of the current display or operation. The LOAD PANELS key is used to prepare the instrument for loading panels for testing; the UNLOAD PANELS key is used to remove panels from the instrument; the SILENCE ALARM key quiets any audible alerts; the UP and DOWN ARROW keys are used to scroll through lists or to increase or decrease values; and the TAB key is used to move the cursor to the next field on a display.

#### 1.5.3 Panel Overview

The BD Phoenix panel is available in four formats: EMERGE, ID only, AST only, and combination ID/ AST testing. The "pour and seal" serpentine design is optimized for safety and leak-resistance. Each well in the disposable contains approximately 50  $\mu$ L of inoculum in an environment that prevents significant evaporation during the course of incubation.



Figure 1-3 – Components Used for Panel Inoculation

Panel Inoculation Components	
Number	Description
1	ID and AST broth tubes
2	Panels
3	Empty Inoculation Station

Table 1-1 - Components Required for Panel Inoculation

A panel inoculation station holds six tubes of broth (ID, AST) and three panels held at an angle of 24° in order to provide proper gravity-driven inoculum flow through the panel. See Figure 1-4 – Panel Inoculation Station.



Figure 1-4 - Panel Inoculation Station

A Panel Transportation Caddy is a molded plastic tray used to transport filled and sealed BD Phoenix panels from the preparation bench to the BD Phoenix instrument. The caddy capacity is 20 panels. See Figure 1-5 – Panel Transportation Caddy.



Figure 1-5 – Panel Transportation Caddy

### 1.5.4 Testing Overview

After a door-opening/-closing event, the instrument reads panel barcode labels and then performs a scan using the red LEDs to determine if panels are present, and to locate or "map" well positions. Panel readings are made on the hour and at 20 and 40 minutes after the hour. The instrument test sequence begins with the system checking that the door is locked. Tiers perform dark readings, then the UV bulb is turned on and allowed to warm up. UV readings are then taken for one revolution. The UV bulb is turned off. Next the red LEDs are turned on, allowed to warm up, and red LED readings are taken. Then the green LEDs go through the same sequence. Finally, the blue LEDs go through this sequence.

### 1.5.5 Normalizers

Normalizers serve as reference panels for adjustment of the instrument's optical detection system. They are used for adjustment of the LEDs (Red, Green and Blue) and fluorescence lamps.

For Red, Green and Blue correction, data from the normalizer panels are used to correct for variations in optical channel gain and to compensate for well-to-well parallax. Raw signals are source monitor corrected and are then ratioed to the value of the corresponding well of the normalizer panel. This ratio is multiplied by a correction factor, which is the expected transmittance level of the normalizer, to scale the resultant values. The fluorescence (UV) signal from the Normalizer is used to ensure that the UV intensity reaching the panel is within the acceptable range for proper interrogation of the fluorescent ID substrates on the BD Phoenix panel. If the UV level is either too high or too low at the Normalizer, a UV lamp adjust will be performed at the next time period when there are no ongoing panels. Extreme deviations from the normal UV signal will cause a system alert, resulting in the aborting of panels in the offending tier(s). This is followed by an attempt to perform a UV lamp adjustment.

A system alert will occur before expiration to allow for replacement scheduling. When the number of days before normalizers are set to expire are less than 60 and more than 30, the alert appears once every week. When only 30 days are left for the normalizers to expire, the message appears every day.

The normalizer panels are always located in station number 0 of each tier. When the door is opened, routine carousel access does not present the normalizer panel. The normalizer panel is constrained in its carrier to prevent inadvertent removal.

#### **Automatic Adjustment of Light Sources**

Based on the results of the system's Built-In-Test (BIT), as well as time and power cycling factors, the system may detect that readings from the ultraviolet (UV) and visible light sources (testing lamps) are out of tolerance. There are two main levels to this condition:

- 1. The deviation is great enough that panel results are invalidated (panel testing for the tier is aborted); the tier's stations are blocked; an automatic light source adjustment is performed as soon as all panels in the instrument complete testing.
- 2. The deviation is within limits that do not affect panel results; however available stations are blocked; as soon as all panels on the tier complete testing or are removed, an automatic light source adjustment is performed.

"E" type error codes and subcodes provide information on both of these conditions, for each of the tiers.

Automatic light source adjustment attempts to bring readings within acceptable ranges. It is performed when the following conditions are met: the instrument is warmed up, idle, and there are no ongoing panels. UV adjustment prohibits access to the instrument for entering panels into unaffected tiers, removing panels, performing maintenance checks, etc.

### 1.6 Use of this Manual

This user's manual is designed as an integral part of system operation for technologists, supervisors, and other personnel who operate and maintain the BD Phoenix instrument on a regular basis. Every attempt has been made to include all information which would be required during normal use and maintenance of the system. Should a question arise which is not answered in this manual, please contact the following parties (USA):

For assistance with mechanical, electrical, or software performance problems, in North America:

Field Service 1-800-544-7434

For procedural, panel, or software operation questions, in North America:

Technical Services 1-800-638-8663

International contacts are listed in Section 13, or contact a local BD representative.

Comments or recommendations on this user's manual may be expressed by emailing LabellingDD@bd.com.

Other documentation required for proper system operation includes:

Panel Package Inserts – These documents contain important information on panel use, performance, quality control, and limitations of procedures. A package insert is included with each box of panels, and is available upon request from BD.

## 1.7 Conventions

### 1.7.1 Keys

The six hard keys that have fixed functions are the UP ARROW (Increase) key, the DOWN ARROW (Decrease) key, the SILENCE ALARM key, the TAB key, the LOAD PANELS key, and the UNLOAD PANELS key. These keys are marked with symbols representing their functions, and operate identically regardless of the active display or operation. Eight other keys, the software (soft) keys are teal in color, and have functions that vary depending on the active display. Each display shows icons representing the current soft key assignments at the bottom of the screen. To perform the function represented by the icon, press the corresponding soft key, located just below the icon defining it. You can also press the corresponding function key on the keyboard to perform the function (e.g., 1 corresponds to Soft Key number 1, the leftmost soft key).

The six fixed function keys are always identified in your BD Phoenix manual by CAPITAL LETTERS (e.g., SILENCE ALARM key). The software keys are always identified by lowercase letters in quotes, and the words *soft key* (e.g., "panel results" soft key). Field names are shown in **bolded** text.

## 1.7.2 Symbols Used on the Equipment

Meaning	Symbol
•••	Manufacture
REF	Catalog Number
<u> </u>	Consult Information for Use
EC REP	Authorized Representative in the European Community
IVD	In Vitro Diagnostic Medical Device
SN	Serial Number
	Disposal of Electronic Products
C€	CE Mark
<u></u>	Biological Risks
<sub>M</sub>	Date of Manufacture

### Symbols used on BD Phoenix instrument

Meaning	Symbol
	1. Biohazard 2. Electrical Recycling required 3. On/Off

## 1.7.3 Notes, Cautions, and Warnings

Throughout this manual, important information is presented in boxes offset from the regular text, and is labeled as either a NOTE, CAUTION, or WARNING. These messages are formatted as shown below and bear the following significance:

#### NOTE

Important information about system use worthy of special attention is presented as a NOTE.

#### **CAUTION**

Information on an activity which potentially could cause damage to the instrument or system is presented as a CAUTION.

#### **WARNING**

INFORMATION ON AN ACTIVITY WHICH POTENTIALLY COULD CAUSE INJURY TO THE USER IS PRESENTED AS A WARNING.

## 1.8 Summary of Cautions and Warnings

- Protection provided by this equipment may be impaired if the equipment is used in a manner not consistent with the instructions in this manual.
- The intake filter on the top of the BD Phoenix instrument must remain unobstructed at all times. Restricted air flow may cause excessive temperatures in the instrument, which can affect test results and possibly cause hardware malfunctions.
- Due to the size and weight of the BD Phoenix instrument, never attempt to lift the instrument without the aid of mechanical lifting devices. Serious injury can result from attempting to lift the instrument.
- All system users should become thoroughly familiar with all controls and indicators before attempting to operate the instrument.
- Observe established precautions against microbiological hazards throughout all procedures. All specimens should be handled according to CDC-NIH recommendations, CLSI guidelines, or local institution guidelines for any potentially infectious human serum, blood, or other body fluids. Prior to discarding, sterilize specimen containers and other contaminated materials by autoclaving.
- In addition to wearing gloves, the use of disposable lab coats or gowns and protective glasses
  or goggles is recommended when working around the instrument.

- The instrument door is electromechanically latched and is controlled by the instrument software. Never attempt to defeat the door latching mechanism, or to open the door when the "unlocked" icon is not displayed. Serious injury can be caused by the rotating carousel. If the carousel is not completely stopped when the door is opened, immediately contact BD for service. Never attempt to rotate the carousel manually or serious injury may result.
- When the system displays alerts and errors, immediately respond to the condition.
- All maintenance and repair other than the procedures described in Section 6.2 Routine Maintenance and Section 6.3 – Module Replacement, must be performed by qualified service personnel. Non-compliance with this warning may result in personal injury or instrument malfunction.
- If the existing filter is reused, ensure that the filter is placed in the same orientation in which it was removed (i.e., with arrow stamped on the side of the filter pointing in the same direction).
- All portions of the body that could possibly come into contact with the affected instrument surfaces must be completely covered before beginning the decontamination process.
- If any error sub-codes other than those listed here appear, note the sub-code and contact BD for assistance.
- If the recommended corrective actions do not solve the problem, contact BD.

# 2 - Installation

## 2.1 General

This section provides specifications for installation and setup of the BD Phoenix system. The following major topics are included:

- Instrument specifications
- Software setup
- Software installation

#### **WARNING**

PROTECTION PROVIDED BY THIS EQUIPMENT
MAYBE IMPAIRED IN THE EQUIPMENT IS USED IN A
MANNER NOT CONSISTENT WITH THE
INSTRUCITONS IN THIS MANUAL.

#### **CAUTION**

The intake filter on the top of the BD Phoenix instrument must remain unobstructed at all times. Restricted air flow may cause excessive temperatures in the instrument, which can affect test results and possibly cause hardware malfunctions.

### 2.1.1 Installation

The BD Phoenix instrument is to be installed only by BD representatives.

#### WARNING

DUE TO THE SIZE AND WEIGHT OF THE BD PHOENIX INSTRUMENT, NEVER ATTEMPT TO LIFT THE INSTRUMENT WITHOUT THE AID OF MECHANICAL LIFTING DEVICES. SERIOUS INJURY CAN RESULT FROM ATTEMPTING TO LIFT THE INSTRUMENT.

The BD Phoenix instrument should be installed in an area that is free from undue vibration, direct sunlight, high humidity, dust, temperature extremes, and corrosive or explosive vapors or gases. The system will operate within specifications in room temperatures between 18–30 °C (64.4–86 °F). Relative humidity should be between 20% and 90% (non-condensing). The left, rear, and right sides of the instrument should be placed at least four inches from any wall. Environments which exceed these limits could adversely affect the performance of the system components.

The carousel should maintain its temperature to within plus or minus 1.5 °C of the temperature controller's setting (35 °C). This accuracy can be assured only if the room temperature meets the requirements given above.

Use of earthquake anchoring is strongly recommended in areas susceptible to earthquake activity.

## 2.2 Instrument Specifications

Physical Dimensions		
Height	41.7 in (105.9 cm)	
Width	44.3 in (112.5 cm)	
Depth	29.5 in (74.9 cm)	
Clearance - Right, Left, Rear	4 in (10.2 cm)	
Clearance – Front	18 in (45.7 cm)	
Weight – Empty	333 lb (151.4 kg)	
Weight – Full	351 lb (159.6 kg)	
Counter must be capable of supporting 500 lb (227.3 kg)		

Table 2-1 – Physical Dimensions

Environmental Requirements			
Non-Operating Usage			
Temperature	-17.8 °C->65.0 °C (0->149 °F)		
Humidity	10%–90% RH, non-condensing		
Operating Conditions			
Temperature	18–30 °C (64.4–86 °F)		
Humidity	20%–90% RH, non-condensing		
Locations	Level Surface, No direct sunlight, No direct heat		
Use of earthquake anchoring is strongly recommended for the BD Phoenix instrument in locations susceptible to earthquake activity.			
Installation Category II and Pollution Degree 2 as per IEC 664.			

**Table 2-2 – Environmental Requirements** 

Electrical Requirements				
Input Voltage	100-117 VAC or 220-240 VAC ±10%			
Input Current	8 Amp			
Input Line Frequency	47–53 Hz or 57–63 Hz			
Operating Conditions				
Temperature	1.03 Kwatts			
Humidity	3,515 Btu/hr.			

Table 2-3 – Electrical Requirements

Optical Specifications		
Peak Wavelengths		
428–623 nm, visible spectrum		
367 nm, UV Excitation		
410–640 nm Bandpass, UV Emission		

**Table 2-4 – Optical Specifications** 

## 2.3 Software Setup

The system ships with all setup parameters preset to factory default values. However, before using the instrument for panel testing, review the setup parameters to see if they are suitable for the laboratory. These parameters are grouped in the following categories:

- Instrument Configuration (Section 2.3.1)
- Communications Configuration (Section 2.3.2)
- Custom Interpretation Rule Set (Section 2.3.3)
- BDXpert Rule Configuration (Section 2.3.4
- Rapid Reporting Configuration (Section 2.3.5)
- Panel Lot Definition (Section 2.3.6)

Instrument setup parameters are explained in the paragraphs below. The Main Status screen, which is active immediately after instrument startup, is shown in Figure 2-1.

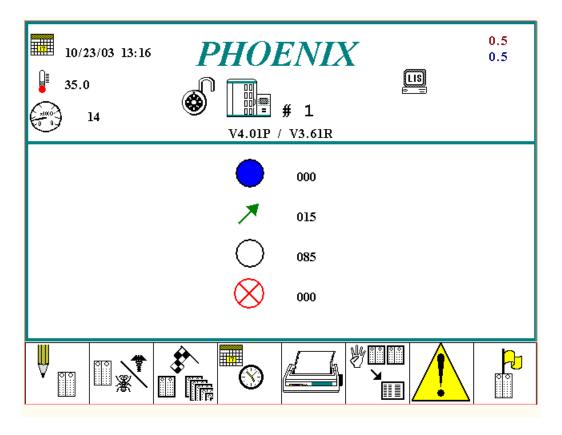


Figure 2-1 - Main Status Screen

To access the Configuration Menu, press the soft key corresponding to the icon shown below (the "configuration" soft key).



When the "configuration" soft key is pressed, the password window appears. To access configuration functions, enter the appropriate password then press the "perform action" soft key. All users with valid passwords have access to general instrument configuration parameters. Only administrators have access to password administration functions.



The configuration menu selections are presented as a new series of soft keys (Figure 2–2). Press the soft key corresponding to the type of configuration function you want to perform. The soft keys are as follows:

<b>S</b>	"instrument configuration"
J-C	"maintenance"
	"communications configuration"
*** *** ≥	"custom interpretation rule set configuration*"
<b>⊕</b>	"BDXpert rule configuration*"
= *	"rapid reporting configuration"

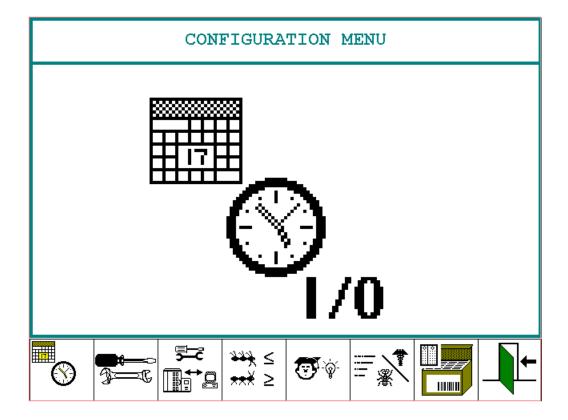


Figure 2-2 – Configuration Menu

Maintenance functions, accessed through the second soft key, are described in other sections of this manual where appropriate.

	"panel lot definition"
<b>—</b>	"exit"

Any changes to configuration parameters are in effect from the time of the change forward.

<sup>\*</sup> Note that the "custom interpretation rule set configuration" and "BDXpert rule configuration" icons do not appear if the BD Phoenix instrument is connected to and communicating with a BD EpiCenter system.

### 2.3.1 Instrument Configuration

To access general instrument configuration functions, press the "instrument configuration" soft key.



The Instrument Configuration display then appears (Figure 2-3).

When the desired configuration parameters have been entered or modified, press the "save" soft key to save the information.



### 2.3.1.1 General Instrument Configuration

The following parameters can be set in Instrument Configuration:

#### **GENERAL Window**

The GENERAL window is located at the top left of the display.

#### **Instrument Number**

Select the instrument identification number. The default setting is 1. To increase or decrease the instrument number, use the UP ARROW or DOWN ARROW key. Choose a number from 1 to 99. If there is only one instrument, leave this value set at 1.

#### Language

Select the language for screen displays and instrument reports. The default setting is English. To scroll through the available selections, use the UP ARROW or DOWN ARROW key. Choose from the following language selections (shown in the specified language):

English (English)	Espanol (Spanish)	
Francais (French)	Portugues (Portuguese)	
Deutsch (German)	日本語 (Japanese)	
Italiano (Italian)		

#### **Rule Set**

Select the rule set that the interpretation engine is to use. Only one rule set can be used. Choose from the following selections:

Custom (defined in Custom Interpretation Rule Set, Section 2.3.3)

EUCAST (European Committee on Antimicrobial Susceptibility Testing)

CLSI (Clinical and Laboratory Standards Institute)

SFM (Société Française de Microbiologie)

#### **Rule Version**

This read-only field shows the current version of the rule set selected in the previous field.

#### (Audible) Alarm Volume

Select the volume of the instrument's audible alarm. The default setting is 5, which is at the middle of the volume range. To increase or decrease the volume, use the UP ARROW or DOWN ARROW key (a sample volume tone sounds when the setting is adjusted). Select from 0 (audible alarm off) to 10 (loudest). Only the volume of "Alert" and "Activity" alarms (see 3.8 Audible Tones and Alarms) is affected by this setting.

#### Resistance/Critical Checkbox

This checkbox appears *only* when the BD Phoenix instrument is connected to a BD EpiCenter system but is *not* communicating with it. Check this box to enable the BD Phoenix instrument to operate in a standalone mode when communications with BD EpiCenter is interrupted. When this box is checked, the **BDXpert System Active** checkbox appears.

#### **BDXpert System Active Checkbox**

Press the s or "select" soft key to check this box. Checking the box activates the entire BDXpert System rules, which comprises CLSI, EUCAST, SFM, or Custom Interpretation Rules.

This field does not appear if the BD EpiCenter system is attached and communicating. However, if communication with the BD EpiCenter system is lost, the checkbox reappears. This enables the activation of BDXpert rules interpretations in the standalone BD Phoenix system. When communications with the BD EpiCenter system is restored, BDXpert rules interpretations are once again performed at the BD EpiCenter system, and this checkbox is removed from the display.

#### NOTE

Disabling all BDXpert rules also disables detection of Resistance Markers (e.g., ESBL), except those triggered by 1500-series rules.

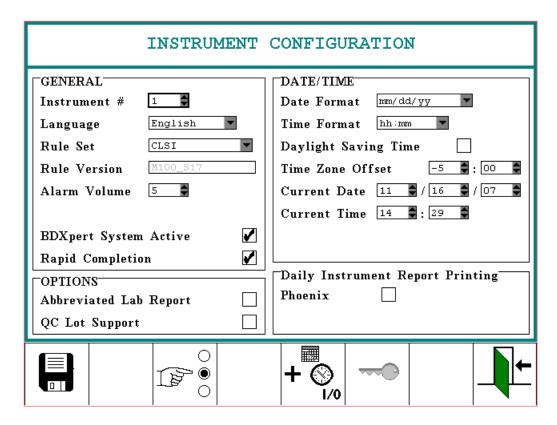


Figure 2-3 – Instrument Configuration Display

#### **Rapid Completion Checkbox**

Press the s or "select" soft key to check this box. Checking the box enables the instrument to provide BDXpert AST results (SIR) before determining actual MIC values. The instrument MIC values are provided as soon as they can be accurately determined. Within a test panel, some MIC values may be available earlier than others. The rapid completion feature can be used to predict resistance for uncompleted antibiotics using the ID alone (intrinsic resistance), or ID with completed MICs of related antibiotics, or resistance marker tests (BL, ESBL). The BDXpert system is used to make these predictions. This can be useful in situations where, for example, the results for drugs that have not yet received MICs would be of no clinical value based on the other results that are already available. Antimicrobials with Rapid Complete BDXpert interpretations are indicated by a "C" in the MIC column on Results screens and Lab reports. Uncheck the checkbox to disable rapid completion.

If Rapid Completion is enabled at the BD EpiCenter system, then it must also be enabled (checked) at the BD Phoenix instrument.

#### **OPTIONS Window**

The OPTIONS window is located at the bottom left of the display.

#### Abbreviated Lab Report

Press the s or "select" soft key to check this box. Checking the box causes the system to print a shortened version of the Lab Report. The shortened version does not contain results for the biochemical (ID) reactions. Uncheck the box to print the standard full-length Lab Report. The default is unchecked (full length). Note that QC Reports always print standard full-length Lab Reports.

#### **QC Lot Support**

Press the s or "select" soft key to check this box. Checking the box enables the QC Lot feature, which can be used to facilitate panel lot QC testing and tracking. When enabled, a new soft key ("panel lot definition") appears on the Configuration Menu. Refer to 2.3.6 Panel Lot Definition for more information.

#### **DATE/TIME Window**

The DATE/TIME window is located at the top right of the display.

#### **Date Format**

To adjust the date format, press the DOWN ARROW key to drop down a listing of all the available date formats. The default format is MM/DD/YY. Use the UP ARROW or DOWN ARROW to highlight the desired selection. Select from the following:

Slash	MM/DD/YY or	DD/MM/YY or	YY/MM/DD or
separators ( / )	MM/DD/YYYY	DD/MM/YYYY	YYYY/MM/DD
Hyphen	MM-DD-YY or	DD-MM-YY or	YY-MM-DD or
separators ( – )	MM-DD-YYYY	DD-MM-YYYY	YYYY-MM-DD
Period	MM.DD.YY or	DD.MM.YY or	YY.MM.DD or
separators ( . )	MM.DD.YYYY	DD.MM.YYYY	YYYY.MM.DD

Table 2-5 - Date Formats

Press the s or "select" soft key to select the highlighted entry.

#### **Time Format**

To adjust the time format, press the DOWN ARROW key to drop down a listing of all the available time formats. The default format is hh:mm. Use the UP ARROW or DOWN ARROW to highlight the desired selection. Select from the following: hh.mm OR hh:mm OR hh;mm.

Press the s or "select" soft key to select the highlighted entry.

#### **Daylight Saving Time Checkbox**

Press the s or "select" soft key to check this box. Checking the box adjusts the instrument time for daylight saving time. Uncheck the box to return to standard time. This field does not appear if the BD EpiCenter system is attached and communicating.

#### **Time Zone Offset**

Use the UP ARROW or DOWN ARROW to set your time zone difference from GMT (Greenwich Mean Time). Select negative integers if you are west of the Prime Meridian and east of the International Date Line. Select positive integers if you are east of the Prime Meridian and west of the International Date Line. This field does not appear if the BD EpiCenter system is attached and communicating.

#### **Current Date**

The current date is displayed in the format selected in the Date Format field.

To adjust the month, day, or year, press the "tab" key (or T key) to highlight the appropriate value according to your date format. Press the UP ARROW or DOWN ARROW key to increase or decrease the displayed value. This field does not appear if the BD EpiCenter system is attached and communicating.

#### **Current Time**

When this display is first accessed, the hours value is highlighted. To adjust the hours, use the UP ARROW or DOWN ARROW key to increase or decrease the displayed value.

To adjust the minutes value, press the "tab" key to highlight the minutes field. Use the UP ARROW or DOWN ARROW key to increase or decrease the displayed value. This field does not appear if the BD EpiCenter system is attached and communicating.

The time cannot be changed while panels are in protocol.

## **Daily Instrument Report Printing Window**

The Daily Instrument Report Printing window is located at the bottom right of the display.

#### **BD Phoenix Checkbox**

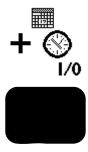
Press the s or "select" soft key to check this box. Checking the box causes the Auto Time field to appear, and tells the instrument to print a Daily Instrument Report automatically at the time specified in the **Auto Time** field. Uncheck the box to disable automatic printing. (If automatic printing is disabled, the report can still be printed at any time from the Reports Menu.)

### **Auto Time**

In the first Auto Time field, press UP ARROW or DOWN ARROW to enter the hour at which the Daily Instrument Report should print automatically. Time is calculated in 24-hour international (military) format. Press T to advance to the next time field and press UP ARROW or DOWN ARROW to enter the minutes.

## 2.3.1.2 More Configuration Options

A display with additional configuration options is accessible by pressing the "more configuration" soft key from the Instrument Configuration display. See Figure 2-4 – More Configuration Options Display.



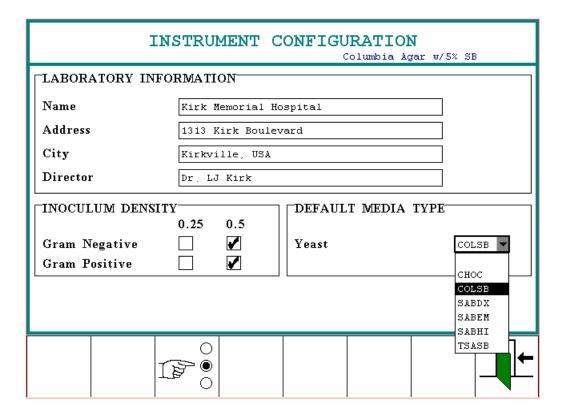


Figure 2-4 – More Configuration Options Display

## **Laboratory Information**

Information entered in the Laboratory Information window prints in the header of system reports.

#### Name

Enter the laboratory name, up to 40 characters.

## **Address**

Enter the address, up to 40 characters.

## City

Enter the city (as well as state and zip code, if desired), up to 40 characters.

## **Director**

Enter the name of the laboratory director, up to 40 characters.

## **Inoculum Density**

The Inoculum Density window enables the default McFarland concentration for inoculum to be set. Select 0.25 (acceptable density of 0.20–0.30) or 0.5 (acceptable density of 0.50–0.60) for Gram Positive and Gram Negative panels (Strep panels use only 0.5). The default density is 0.5 for Gram Negative and Gram Positive panel types. The density for Yeast ID panels is fixed at 2.0 McFarland (acceptable density of 2.00–2.40). Inoculum density is applicable only to panels that have an ID side. To select a different density, tab to the desired density and press the "select" soft key. A check appears in the selected density checkbox.

## **Default Media Type**

Yeast – This field enables the selection of a default media type that appears during Panel Login when a Yeast ID panel sequence number is scanned or typed in. Press ▼ to drop down a box listing all media types (abbreviations), sorted alphabetically. (When the media type is highlighted, the full name appears at the top right of the display.) Use ▼ or ▲ to highlight the desired media. Press the "select" soft key or J to select that media. A default media type does not have to be specified, but a media type must be selected when logging in Yeast ID panels.

### 2.3.1.3 Password Administration

The Password Administration display enables the user to set passwords for the three security levels of access. Only users with Administrator level passwords can access the Password Administration display. See Figure 2-5 – Password Administration Display.

The following security levels for passwords exist:

Administrator – Highest access level: access to all user functions and displays

**Supervisor** – Intermediate access level: cannot access password administration display; access to all other functions and displays

**General** – lowest access level: cannot access password administration display; cannot access event log display; access to all other functions and displays

Note that the passwords entered for each level must be unique.

### To access Password Administration:

<b>S</b>	From the Main Status screen, press the "configuration" soft key
1	The password window appears. To access configuration functions, enter the appropriate password then press the "perform action" soft key.
	From the Configuration Menu, press the "instrument configuration" soft key
****	From the Instrument Configuration display, press the "password administration" soft key

## Password Administration soft keys:





"exit"



PASSWORD ADMINISTRATION					
Administrator Password CAPTKIRK  New Password					
Supervisor Password ENTERPRISE  New Password					
General Password BEAMMEUP  New Password					

Figure 2-5 – Password Administration Display

## To assign a new password:

- The Administrator Password shows the current administrator level password (ADMIN by default). To change this password, type the new password in the New Password field, from 5 to 20 alphanumeric characters. The password is **not** case sensitive. Press the "save" soft key to save the changes. The new password immediately appears in the Administrator Password field.
- 2. The Supervisor Password shows the current supervisor level password (LISVIEW by default). To change this password, type the new password in the New Password field, from 5 to 20 alphanumeric characters. The password is **not** case sensitive. Press the "save" soft key to save the changes. The new password immediately appears in the Supervisor Password field.
- 3. The General Password shows the current general level password (ECOLI by default). To change this password, type the new password in the New Password field, from 5 to 20 alphanumeric characters. The password is **not** case sensitive. Press the "save" soft key to save the changes. The new password immediately appears in the General Password field.

## 2.3.2 Communications Configuration

The Communications Configuration display enables/disables communications from the BD Phoenix instrument to a compatible LIS (Laboratory Information System), and to adjust communications parameters for this type of connection. (It also enables BD representatives to enable/disable/adjust communications with the BD EpiCenter advanced data management system.) Only LIS *or* BD EpiCenter communications can be enabled. If there is a BD EpiCenter system and also a LIS system, BD EpiCenter can be configured to communicate with the LIS.

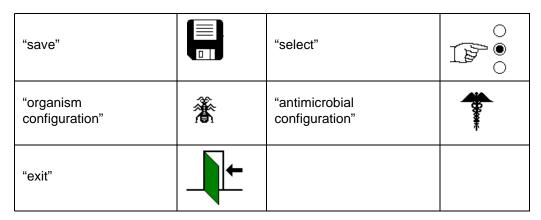
When the LIS communications state is changed (from disabled to enabled), the BD Phoenix instrument must be rebooted for the changes to take effect. In addition, changes to any of the LIS communications setup parameters require an instrument reboot to take effect.

LIS operations are discussed in 4.15 LIS Operations. This section explains configuring LIS communications only. See Figure 2-6 – Communications Configuration Display.

## To access Communications Configuration:

	From the Main Status screen, press the "configuration" soft key
<b>1</b>	The password window appears. To access configuration functions, enter the appropriate password then press the "perform action" soft key.
	From the Configuration Menu, press the "communications configuration" soft key

## **Communications Configuration soft keys:**



The following parameters can be set in Communications Configuration:

## **Communications Configuration window**

## LIS Enabled checkbox

Press the "select" soft key or s or J to check the box and enable LIS communications. If LIS communications is enabled, press the "select" soft key or s or J to uncheck the box.

## **Options window**

## Send Interpretation Results checkbox

This checkbox causes the final SIR values for antimicrobials to be included in the Results record uploaded to the LIS. Its default value is checked (enabled). To disable it, press the "select" soft key or s or J.

### **Unsolicited Queries checkbox**

This checkbox enables the BD Phoenix instrument to request panel information from the LIS if the panel is placed into the instrument *lacking* an organism ID for AST panels or Combination panels with only the AST portion of the panel enabled.

This field's default value is unchecked (disabled), which means the BD Phoenix instrument will NOT request missing information from the LIS. To enable it, press the "select" soft key or  $\rm s$  or  $\rm J$ .

#### Send When Placed in Instrument checkbox

This checkbox causes the BD Phoenix instrument to send a Results upload to the LIS when the panel is placed into the instrument.

This field's default value is checked (enabled). To disable it, press the "select" soft key or s or J.

## **ASTM Byte Mode Comments checkbox**

This checkbox only appears when Japanese is selected for the language.

This checkbox causes the ASTM standard to be followed (when enabled/checked) or not followed (when disabled/unchecked). When the ASTM standard is not followed, escape sequence characters that are usually rejected are instead accepted.

This field's default value is checked (enabled). To disable it, press the "select" soft key or s or J.

### **Results Upload Options window**

Results upload records consist of the following information:

- Header record (Delimiter fields, sender name, version number, message date/time)
- Order record (Accession number, Isolate number, Organism, Test ID, Sequence number, Priority, Report type)
- Comment record (contains Special Messages and/or BDXpert Rules)
- Results record
  - Panel sequence number
  - Instrument number
  - Instrument type
  - Instrument location (Station)
  - Time to identification (if applicable)
  - Test start time
  - Test end time
  - Test status

Pending - Panel has been logged in but has not been detected by instrument inventory.

**Ongoing** – Panel has been logged in and has been detected by instrument inventory, but no results are available.

**Partial complete** – One or more results (MIC or ID) have been generated but not all tests on the panel. BDXpert rules may be pending and the panel could have a Needs Attention condition.

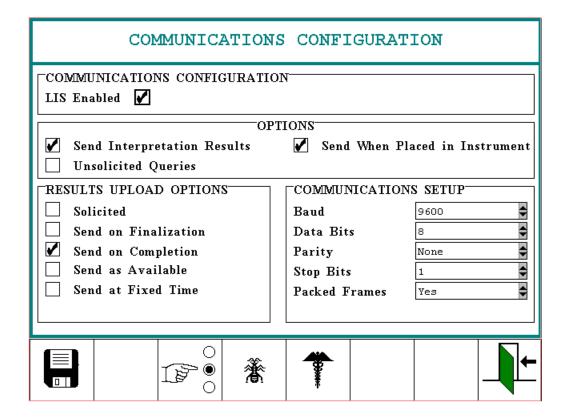


Figure 2-6 – Communications Configuration Display

**Complete** – The instrument has completed its readings and all panel test results have been determined, or cannot be interpreted. BDXpert rules may be pending and the panel could have a Needs Attention condition.

Rapid complete – The panel has not yet completed testing but the system has determined results for all drugs

**Complete with unignored Needs Attention condition** – Panel has completed testing and has active needs attention conditions associated. The panel cannot be finalized until the Needs Attention conditions are resolved or ignored.

**Complete with all ignored Needs Attention conditions** – Panel has completed testing and has Needs Attention conditions that were ignored by the user. By ignoring the Needs Attention condition, the user can finalize the panel.

**Complete QC Pass** – Panel was logged in as a QC panel, has completed testing, and has passed the QC criteria.

Complete QC Fail - Panel was logged in as a QC panel, has completed testing, and has failed the QC criteria.

- · Result type
- Antimicrobial code
- MIC value
- S / I / R / No Interp / Error value
- Resistance marker
- ID or Final ID
- Results status (finalized or unfinalized)

Only **ONE** of the Results Upload Options can be checked (enabled).

## Solicited checkbox

This checkbox causes the BD Phoenix instrument to upload Results records ONLY when the LIS requests the information. Its default value is unchecked (disabled). To enable it, press the "select" soft key or s or J.

QC panels and orphan panels are uploaded only when solicited by the LIS.

#### Send on Finalization checkbox

This checkbox causes the BD Phoenix instrument to upload Results records ONLY when the panel is finalized. Its default value is unchecked (disabled). To enable it, press the "select" soft key or s or J.

## Send on Completion checkbox

This checkbox causes the BD Phoenix instrument to upload Results records ONLY when the panel status becomes complete OR when a change is made to a complete panel. Its default value is checked (enabled). To disable it, tab to another Results Upload option and enable that option.

## Send as Available checkbox

This checkbox causes the BD Phoenix instrument to upload Results records at the following times: when an ID is determined; when an AST result is determined; when there is a change to a panel record that already has at least partial results. Its default value is unchecked (disabled). To enable it, press the "select" soft key or s or J.

#### Send at Fixed Time checkbox

This checkbox causes the BD Phoenix instrument to upload Results records for a panel with partial results at a fixed time that is specified. Its default value is unchecked (disabled). To enable it, press the "select" soft key or s or J.

When the box is checked, two additional fields appear that allow the specification of the time for sending Results records. In the first time field, press  $\blacktriangle$  or  $\blacktriangledown$  to enter the hour at which the results are to be sent. Time is calculated in 24-hour international (military) format. Press T to advance to the next time field and press  $\blacktriangle$  or  $\blacktriangledown$  to enter the minutes.

#### NOTE

Send as Available and Send at Fixed Time results should be considered PRELIMINARY until the panel is complete.

## **Communications Setup window**

#### Baud

Press the ▲ or ▼ to select the baud rate for serial communications with the LIS system. Available choices are: 2400, 4800, 9600 (default), 14400, 19200, 38400.

#### **Data Bits**

Press the ▲ or ▼ to select the number of data bits for serial communications with the LIS system. Available choices are: 7, 8 (default).

### **Parity**

Press the ▲ or ▼ to select the parity for serial communications with the LIS system. Available choices are: None (default), odd, even.

## **Stop Bits**

Press the  $\triangle$  or  $\nabla$  to select the stop bits for serial communications with the LIS system. Available choices are: 1 (default), 2.

### **Packed Frames**

Press the ▲ or ▼ to select whether packed frames can be used for serial communications with the LIS system. Available choices are: Yes (default), No. Packed frames (Yes) enable the BD Phoenix system to send multiple records per frame. No indicates that one record per frame is uploaded to the LIS.

## 2.3.2.1 Organism Configuration

The Organism Configuration display allows the LIS codes for the organisms in the BD Phoenix instrument database to be edited. LIS codes for organisms must be unique.

The main Organism Configuration display enables the selection of the organism (or Test Strain for QC organisms) to be edited. Perform the actual edits in the second display. Organisms are presented alphabetically by organism short name (refer to Section 16.2 Organism Names and Abbreviations for a short name/full name list); QC organisms are presented alphanumerically with the ATCC strain number appearing first.

### To access Organism Configuration:

	From the Main Status screen, press the "configuration" soft key
<b>(1)</b>	The password window appears. To access configuration functions, enter the appropriate password then press the "perform action" soft key.
	From the Configuration Menu, press the "communications configuration" soft key



## **Organism Configuration soft keys:**



## To edit an organism LIS code:

In the Organism Configuration display (Figure 2-7), press  $\blacktriangle$  or  $\blacktriangledown$  to highlight the name in the list and press the "select" soft key, s or J. Toggle from the organism box to the QC organism box by pressing the T key.

In the Organism Edit display (Figure 2-8), type the desired LIS code, up to 20 alphanumeric characters. Press the "okay" soft key to save the changes.

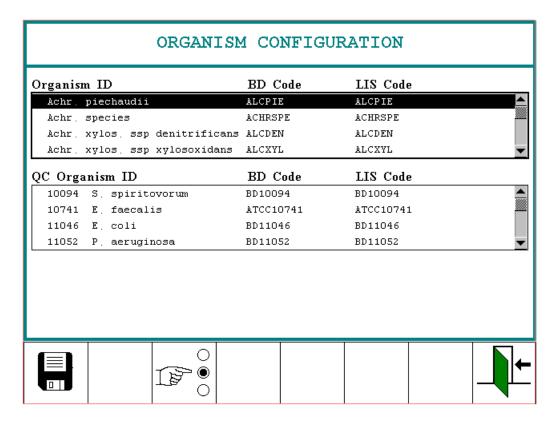


Figure 2-7 - Organism Configuration Display

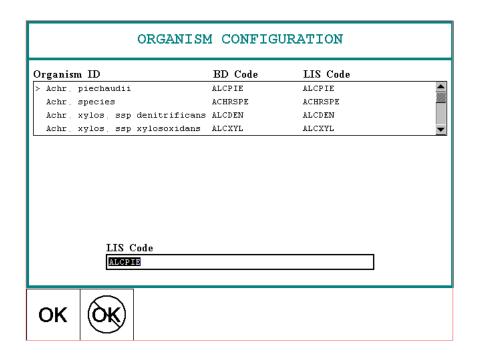


Figure 2-8 – Organism Edit Display

## 2.3.2.2 Antimicrobial Configuration

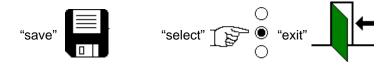
The Antimicrobial Configuration display allows the LIS codes for the antimicrobials in the BD Phoenix instrument database to be edited. LIS codes for antimicrobials must be unique.

The main Antimicrobial Configuration display enables you to select the antimicrobial to be edited. A second display is where you perform the actual edits. Antimicrobials are presented alphabetically by antimicrobial name.

## **To access Antimicrobial Configuration:**

	From the Main Status screen, press the "configuration" soft key
<b>1</b>	The password window appears. To access configuration functions, enter the appropriate password then press the "perform action" soft key.
	From the Configuration Menu, press the "communications configuration" soft key
****	From the Communications Configuration display, press the "antimicrobial configuration" soft key

## **Antimicrobial Configuration soft keys:**



#### To edit an antimicrobial LIS code:

In the Antimicrobial Configuration display (Figure 2-9), press  $\blacktriangle$  or  $\blacktriangledown$  to highlight the name in the list and press the "select" soft key, s or J.

In the Antimicrobial Edit display (Figure 2-10), type the desired LIS code, up to 20 alphanumeric characters. Press the "okay" soft key to save the changes.

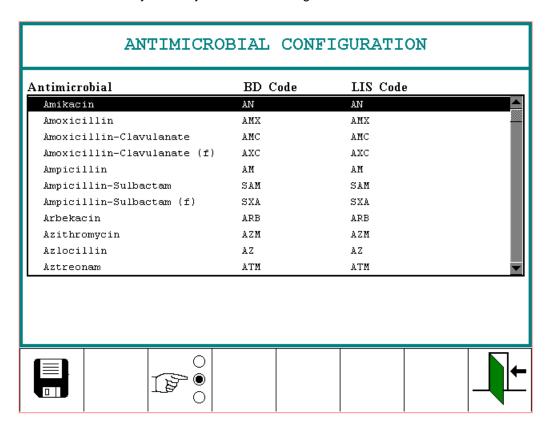


Figure 2-9 – Antimicrobial Configuration Display

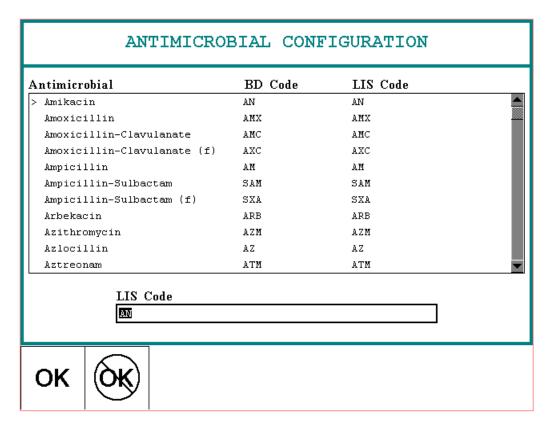


Figure 2-10 – Antimicrobial Edit Display

## 2.3.3 Custom Interpretation Rule Set

Custom Interpretation Rule Set Configuration enables interpretation rules to be tailored to the specific needs or requirements of your laboratory. The current rule set (whether default or already customized) is used as the basis for custom rules. Print the current custom rule set (if it is selected in Instrument Configuration) by selecting "Interpretation Rule Set Report" from the Reports menu (see 5.8.8 Interpretation Rule Set Report). Note that this configuration function is not available if the BD Phoenix instrument is connected to and communicating with a BD EpiCenter system.

Periodically, a software update or BD Phoenix Update Disk (PUD) operation may install new breakpoints. When custom breakpoints are changed, an icon appears on the Custom Interpretation Rule Set display provides the ability to print a Custom Breakpoint Difference Report. This report provides the following information:

Header: Report Title, Laboratory Information (if configured), and Date and Time Printed

**Body of Report:** Rule Set, Previous Version, Current Version, and columns for Antimicrobial (sort order), Organism Group, Organism Name, Rule Set, Previous and Current Standard and Custom: S(usceptible) value, R(esistant) value, and DTG. Breakpoints are listed in rows of the report.

See Figure 2-13 – Custom Breakpoint Difference Report.

#### Rules (Standards) Updates

The chart below depicts the logic of updates to Rules Sets. The top of the chart shows the effect of rules changes when you have customized a rule set. The bottom of the chart shows the rest of the cases for rules updates.

In the chart, the letters A, B, and C represent the entirety of a rule set (standard). For example, CLSI Rule Version M100\_S25 might be indicated by value "A". An update, delivered via the PUD, might install CLSI Rule Version M100\_S26, which might be indicated by the value "B." The customization of "A" might be represented by "C.". Therefore, if you follow Table 2-6 — Rules Updates, the effect of the update is that value "C" (the customized rules based on Version M100\_S25) would be retained.

## **NOTE**

An interpretation rule is considered custom if any of the following are modified: Susceptible Breakpoint, Resistant Breakpoint, or DTG.

	Old Standard	New Standard	Old Custom	Result after PUD (New Custom)
	А	А	В	В
If you have	А	В	С	С
custom	-	-	А	А
Tules	-	А	А	А
	-	А	В	А
	А	-	В	В
	Α	А	А	А
	А	В	А	В
No custom	-	А	-	А
rules	А	А	-	А
	А	В	-	В
	А	-	А	-

Table 2-6 - Rules Updates

## To print a Custom Breakpoint Difference Report:

	From the Custom Interpretation Rule Set configuration screen, press the "print" soft key
--	--

## To access Custom Interpretation Rule Set configuration:

<b>S</b>	From the Main Status screen, press the "configuration" soft key
<b>1</b>	The password window appears. To access configuration functions, enter the appropriate password then press the "perform action" soft key.
<del>223},</del> ≤	From the Configuration Menu, press the "custom interpretation rule set configuration" soft key

The Custom Interpretation Rule Set display then appears (Figure 2-11).

When the desired configuration parameters have been entered or modified, press the "save" soft key to save the information.

To use the custom rule set for interpretation, go to the Instrument Configuration display (2.3.1 Instrument Configuration), and advance to the **Rule Set** field. Highlight CUSTOM in the drop down box by pressing the DOWN ARROW, then press J or the "select" soft key to select it.

## **Custom Interpretation Rule Set soft keys:**

"save"		"select"	° • • • • • • • • • • • • • • • • • • •
"mark for deletion"	×	"delete marked items"	×××
"print report"		"exit"	

## **Custom Interpretation Rule Set fields:**

### **Based On**

Select the standard rule set upon which the custom rules are to be based. The standard rule sets are: CLSI, EUCAST, and SFM. Press DOWN ARROW to drop-down a box in which the desired rule set can be highlighted. Press s or the "select" soft key to select the highlighted set.

#### **NOTE**

If a rule set other than the current rule set is selected, the currently defined custom interpretation rules are deleted.

### **Rules Window**

The window in the middle of the screen shows the current rules in the rule set. This list is read-only and can be navigated with UP ARROW and DOWN ARROW. The following values are shown from left to right (items are explained below under **To modify a rule**):

Marked for Deletion Indicator ("x" indicates the rule marked for deletion)

#### **Antimicrobial**

**DTG** (Drug Test Group – see Step 4 below)

Org (anism) Group

## **Organism**

S (usceptible Value): <=

R (esistant Value): >=

## To add a rule:

- 4. Press the "tab" key to highlight the Rules Window.
- 5. Press the End key (keyboard) to move to the very bottom of the window. A blank line is highlighted.
- 6. Press the "select" soft key. The screen shown in Figure 2-12 appears.
- 7. Select the **Antimicrobial**, DTG, Org. Group, Organism, Susceptible, and Resistant values by pressing the DOWN ARROW to drop down a box listing all available values for the field. Use the UP ARROW or DOWN ARROW to highlight the desired value in the list, then press the "select" soft key or J key.

When all the desired values are selected, press the "ok" soft key to accept the new rule and return to the Rules Window.

8. Press the "save" soft key to save the new rule.

## To modify a rule:

- 1. Use the UP ARROW or DOWN ARROW to highlight the desired rule in the Rules Window. The antimicrobial name appears in the display title area, on the left.
- 2. Press the "select" soft key. The screen shown in Figure 2-12 appears.
- 3. To change the **Antimicrobial**, press the DOWN ARROW to drop down a box listing all available antimicrobials. Use the UP ARROW or DOWN ARROW to highlight the desired drug in the list, then press the "select" soft key or J key.

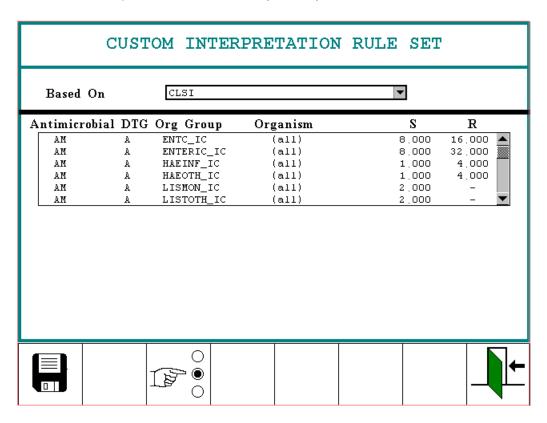


Figure 2-11 - Custom Interpretation Rule Set - Screen A

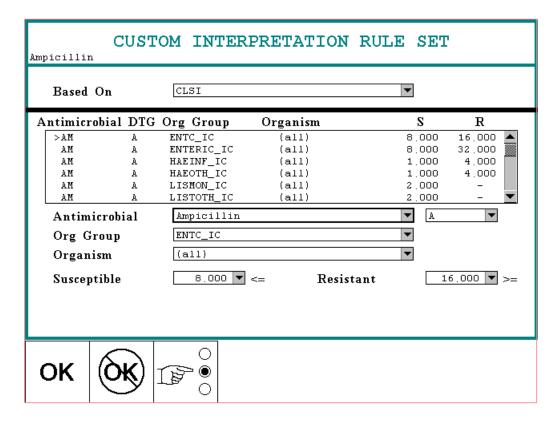


Figure 2-12 - Custom Interpretation Rule Set - Screen B

4. To change the **DTG**, press the DOWN ARROW to drop down a box listing all available DTGs. Use the UP ARROW or DOWN ARROW to highlight the desired DTG in the list, then press the "select" soft key or J key.

DTGs are derived from the AST Standards and are used to categorize antibiotics into distinct groups. For each drug, the groups are specific to the organism group and the recommended utilization for that drug. DTGs have no significance in BD Phoenix alone. They are used in conjunction with the BDXpert rules and are necessary for interface with the BD EpiCenter system. Generally, these are divided into seven groups shown below. Only the A, B, C and U codes may be reported on the Lab report(s). B and C groups are only reported when they are promoted to A by the BDXpert system.

- A Always tested and always reported.
- **B** Usually tested, but not always reported.
- **C** Sometimes tested and not always reported.
- **U** Urinary tract specific drug. Tested and reported for source urinary tract.
- O Other drugs that may be tested. Will not be reported unless changed by user.
- I Investigational drugs. Drugs not approved for clinical use are never reported.
- N Not grouped by standard. Will not be reported unless changed by user.

These drug testing codes are used for two purposes in the BD Phoenix system. First, the drug testing codes can be altered to more closely match the antibiotic formulary and drug utilization guidelines within an institution. The initial codes will be determined by the AST interpretive standard that have been selected. Allowable changes are shown below.

Starting Code	Allowable (Recommended) Changes
Α	B, C, U, O
В	A, C, U, O
С	A, B, U, O
U	A, B, C, O
0	A, B, C, U
I	None
N	A, B, C, U

The second application of the drug testing codes is for the promotion or suppression of drug results for the chartable report. This application is driven by the rules in the BDXpert system. If the rules alter the drug testing codes, these will be reflected on the Lab Report generated by the BD Phoenix system. The promotion and suppression actions are shown below. At the BD EpiCenter level, the drug testing codes will be used to determine which drug results actually appear on the chartable report.

Starting Code	Promotion	Suppression
Α	Not applicable	С
В	A	С
С	A	Not applicable
U	Not applicable	С
0	Not allowed	Not allowed
I	Not allowed	Not allowed

Custom Breakpoint Difference Report									
	03/05/05 09:11							:11	
Rule Set CLSI Previous Version M100_S12 Current Version M100_S13									
			<b>7.</b> 1. 6.		revious			urren	
Antimicrobial	Organism Group	Organism Name	Rule Set	<u>S</u>	<u>R</u> <u>I</u>	<u>OTG</u>	<u>S</u>	<u>R</u> ]	DTG
AM	ENTERIC_IC	(all)	CLSI Custom	8.000 4.000	32.000 32.000	A A		4.000 32.000	В ) А
AM	STRPNE_IC	(all)	CLSI Custom	2.000	-	Ā	2.000 2.000		A A
AN	ACIN_IC	(all)	CLSI Custom		64.000 64.000	B B		4.000 4.000	A A
			•		•				
	•	•	•	•	•	•	٠	•	•
•	•	End of R	eport	•	•	•	•	•	•

Figure 2-13 – Custom Breakpoint Difference Report

- 5. To change the **Org**(anism) **Group**, press the DOWN ARROW to drop down a box listing all available groups. "(All)" indicates that all the organism groups are considered in the rule. Use the UP ARROW or DOWN ARROW to highlight the desired group (or "All organisms") in the list, then press the "select" soft key or J key. (A list of organism groups is provided in Section 5.8.8 Interpretation Rule Set Report.)
- 6. To change or select a specific **Organism**, press the DOWN ARROW to drop down a box listing all available organisms. "(All)" indicates that all the organisms in the specified group are considered in the rule. Use the UP ARROW or DOWN ARROW to highlight the desired organism in the list, then press the "select" soft key or J key. (Note that if an organism group is selected, the organism list displays only organisms within the selected group.)
- 7. To change the **S** (usceptible Value) (i.e., the concentration at or below which the MIC value for the organism or group will return an interpretation of Susceptible), press the DOWN ARROW to drop down a box listing all available concentrations. Use the UP ARROW or DOWN ARROW to highlight the desired value in the list, then press the "select" soft key or J key.
- 8. To change the **R** (esistant Value) (i.e., the concentration at or above which the MIC value for the organism or group will return an interpretation of Resistant), press the DOWN ARROW to drop down a box listing all available concentrations. Use the UP ARROW or DOWN ARROW to highlight the desired value in the list, then press the "select" soft key or J key.
- 9. When the desired values for the current rule have been modified, press the "confirm" soft key to return to the Rules Window to select another rule to modify.





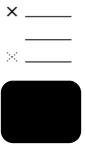
10. When the desired rules have been modified, press the "save" soft key to save your modifications to the rule set.



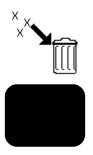


## To delete a rule:

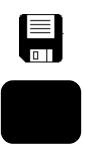
- 1. Use the UP ARROW or DOWN ARROW to highlight the desired rule in the Rules Window. The antimicrobial name appears in the display title area, on the left.
- 2. Press the "mark for deletion" soft key. This places an "X" to the right of the antimicrobial abbreviation.



- 3. Mark any additional rules you want to delete as described in Step 2.
- 4. To delete all the marked rules, press the "delete marked items" soft key.



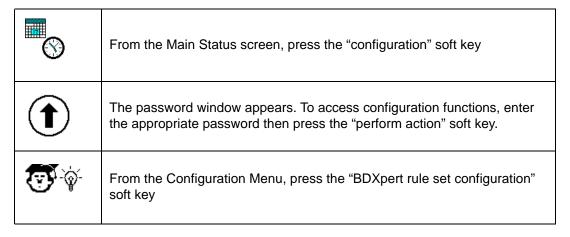
5. Save the deletions by pressing the "save" soft key.



## 2.3.4 BDXpert Rule Configuration

BDXpert Rule Configuration allows individual BDXpert rules to be enabled or disabled, or to be triggered automatically or manually, according to the specific needs or requirements of the laboratory. The existing BDXpert rule set can be printed by selecting "BDXpert Rule Set Database Report" from the Reports menu (see 5.8.9 BDXpert Rule Set Database Report). Note that this configuration function is not available if the BD Phoenix instrument is connected to and communicating with a BD EpiCenter system.

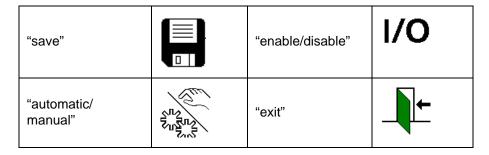
## To access BDXpert Rule configuration:



The BDXpert Rule Set Configuration display then appears (Figure 2-15).

When the desired configuration parameters have been entered or modified, press the "save" soft key to save the information.

## **BDXpert Rule Set soft keys:**



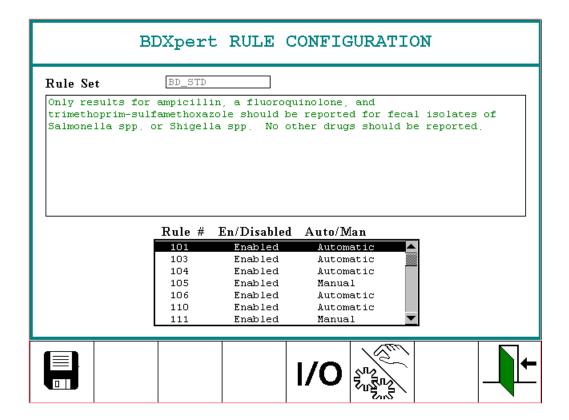


Figure 2-14 - BDXpert Rule Set Configuration

Note that the "auto/manual" soft key does not appear if the rule is disabled. Based On field appears only if Rule Set is "Custom."

## **BDXpert Rule Set fields:**

## **Rule Set**

The rule set currently being displayed is shown in this field. Values are CLSI, SFM, EUCAST, or Custom. Only rules in the selected set appear in the Rule Selection Window.

#### **Based On**

If the rule set is Custom, the rule set on which custom values are based is shown in this field.

## **Rule Window**

The rule window, located at the top of the display, shows the text of the rule selected in the rule selection window at the bottom of the display. GREEN text indicates a rule is enabled and automatic. RED text indicates a rule is disabled (auto/manual status is not applicable). BLUE text indicates a rule is enabled and manual.

## **Rule Selection Window**

The rule selection window, located at the bottom of the display, presents a summary of the status of each of the BDXpert rules and enables rules to be selected for modification.

To select a rule for modification, use the UP ARROW or DOWN ARROW to highlight the desired rule in the list.

To enable or disable the rule, press the "enable/disable" soft key to toggle the status. When disabled, a rule is not available for use in the system.

To set the rule to automatic or manual trigger, press the "auto/manual" soft key to toggle the status. When set to "auto," a rule will be triggered automatically by the system. When set to "manual," the rule must be accepted by the user before it is applied to results.

While 1500-series rules can be selected for viewing, they are fixed as enabled and automatic. These settings cannot be changed.

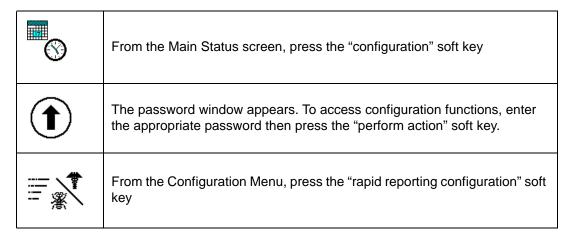
For more information on BDXpert Rules, refer to the BDXpert<sup>™</sup> System User's Manual. bd.com/e-labeling; Key-code: 441352.

## 2.3.5 Rapid Reporting Configuration

Rapid Reporting Configuration specifies the criteria for notification of critical panels and resistance markers. For Critical Panels, notification can originate by an automatic Lab Report printing, by an audible alarm, and/or by an upload to the LIS when certain types of results are obtained in non-QC panels. The types of results, which can be selected, are ID only, partial results, and complete results. For Resistance Markers, designate the type of notification desired when resistance markers (that are enabled) are triggered. For both, the disabling of both printing and audible alarms can be chosen. In this case, the only notification is that the panel is shown in red text on the Panel Inventory display.

Rapid reporting alarms exist in two states: unacknowledged and acknowledged. Unacknowledged alarm panels continue to display in red on the Panel Inventory display. Acknowledgment is achieved when an automatic Lab Report for the panel prints or when the panel is viewed in Panel Results. Audible alarms continue to sound for unacknowledged alarms until the SILENCE ALARM key is pressed.

## To access Rapid Reporting configuration:



The Rapid Reporting Configuration display then appears (Figure 2-15).

When the desired configuration parameters have been entered or modified, press the "save" soft key to save the information.

## Rapid Reporting soft keys:

"save"	"enable/disable"	1/0
"select"	"exit"	-

## **Rapid Reporting fields:**

### **Critical Panel Notification Window**

The Critical Panel Notification window allows parameters to be set for notification on critical panels. Critical panels are any panels for which special notification occurs when results become available. Notification can be audible and/or by immediate printing of a Lab Report (or neither). Panels can be marked as critical when you log them in via Panel Login, or subsequently on the Panel Results display.

#### **Auto Print**

Press the "select" soft key to check (enable) this field. When enabled, the system prints a Lab Report whenever the selected results parameters occur (ID Only, Partial, or Complete – see below). This field is disabled by default (auto print off). Both Auto Print AND Audible Alarm may be enabled simultaneously.

## **Upload to LIS**

This checkbox appears only if LIS Communications is enabled.

Press the "select" soft key to check (enable) this field. The default value is unchecked (disabled). When enabled, the system uploads results records whenever the selected results parameters occur (ID Only, Partial, or Complete – see below).

This field overrides the results upload values set in 2.3.2 Communications Configuration.

## **Audible Alarm**

Press the "select" soft key to check (enable) this field. When enabled, the system sounds an audible alarm whenever the selected results parameters occur (ID Only, Partial, or Complete – see below). This field is enabled by default (audible alarm on). Both Auto Print AND Audible Alarm may be enabled simultaneously.

## **Tone Select**

This field allows the selection of the tones sounded by the critical panel audible alarm. It appears only if Audible Alarm is checked (enabled). This field is set to Tone 1 by default. Press the ▲ or ▼ key to change from Tone 1 to Tone 2 to Tone 3. The system sounds a sample tone each time the field is selected or its contents are changed.

RAPID	REPORTING CONFIGUR	ATION			
CRITICAL PANEL NOTIFICATION  Auto Print  Upload to LIS  Audible Alarm Tone Select  Donly  Partial Results Complete					
RESISTANCE MARKER NOTIFICATION  Auto Print  Upload to LIS  All Panels  Critical Panels Only					
Resistance Marker  BLACT Beta-lactamase ESBL Extended Spectrum Beta-lactamase HLGR High Level Gentamicin Resistant HLKR High Level Kanamycin Resistant HLMUP High Level Mupiricin Resistant Staphylococcus HLPRSP High Level Penicillin Resistant S, pneumoniae HLSR High Level Streptomycin Resistant		En/Disable  Enabled Enabled Enabled Enabled Enabled Enabled Enabled			
	F • I/O				

Figure 2-15 – Rapid Reporting Configuration Display

## **NOTE**

Check (enable) one of the following three fields in order to receive any critical panel notifications.

#### **ID Only**

Press the "select" soft key to check (enable) this field. When enabled, critical panel notification is performed only when an organism ID is detected on a panel. This field is set to disabled by default (alarm/report on partial results). If this field is enabled, **Partial Results** and **Complete** cannot be enabled.

### **Partial Results**

Press the "select" soft key to check (enable) this field. When enabled, critical panel notification is performed when partial panel results are obtained. This field is set to enabled by default (alarm/report on partial results). If this field is enabled, **ID Only** and **Complete** cannot be enabled.

### Complete

Press the "select" soft key to check (enable) this field. When enabled, critical panel notification is performed only when complete panel results are obtained. This field is set to disabled by default (alarm/report on partial results). If this field is enabled, **ID Only** and **Partial Results** cannot be enabled.

#### **Resistance Marker Notification Window**

This window does not appear if the BD EpiCenter system is connected.

#### **Auto Print**

Press the "select" soft key to check (enable) this field. When enabled, the system prints a Lab Report whenever a resistance marker is triggered. This field is set to disabled by default.

## **Upload to LIS**

This checkbox appears only if LIS Communications is enabled.

Press the "select" soft key to check (enable) this field. The default value is unchecked (disabled). When enabled, the system uploads results records whenever the selected results parameters occur (ID Only, Partial, or Complete – see below).

This field overrides the results upload values set in **2.3.2 Communications Configuration**.

#### **Audible Alarm**

Press the "select" soft key to check (enable) this field. When enabled, the system sounds an audible alarm whenever a resistance marker is triggered. This field is enabled by default (audible alarm on).

#### **Tone Select**

This field enables you to select the tones sounded by the resistance marker audible alarm. This field appears only if Audible Alarm is checked (enabled). This field is set to Tone 1 by default. Press the ▲ or ▼ key to change from Tone 1 to Tone 2 to Tone 3. The system sounds a sample tone each time the field is selected its contents are changed.

#### **NOTE**

Check (enable) one of the following two fields in order to receive any resistance marker notifications.

#### **All Panels**

Press the "select" soft key to check (enable) this field. When enabled, resistance marker alarms are generated for all panels in which markers occur. This field is disabled by default. If this field is enabled, **Critical Panels Only** cannot be enabled.

## **Critical Panels Only**

Press the "select" soft key to check (enable) this field. When enabled, resistance marker alarms are generated only for critical panels in which markers occur. This field is enabled by default. If this field is enabled, **All Panels** cannot be enabled.

## Resistance Marker

The Resistance Marker window, located at the bottom of the display, enables and disables notification of individual resistance markers. The window shows the abbreviation and text of the Marker, as well as whether it is currently enabled or disabled. By default, all resistance markers are enabled. Resistance marker alarm notification occurs **only** for enabled markers.

To disable notification of a resistance marker, highlight the desired marker and press the

"enable/disable" soft key. The En/Disable field changes from Enabled to Disabled.

## 2.3.6 Panel Lot Definition

The Panel Lot Definition Display enables the definition of panel lots to facilitate QC testing and tracking. Panel lot definition saves the lot number, beginning and ending panel sequence numbers, definition date, and first and last used dates for a lot. Current and historical QC results can be viewed and printed. Note that this configuration function is not available if the BD Phoenix instrument is connected to and communicating with a BD EpiCenter system.

The display activities are:

- Define new panel lots
- · Recall existing panel lots
- Review current and historical QC results for panel lots
- Extend expiration dates for panel lots
- Print Panel Lot (current, historical) reports

Users with General and Supervisor level passwords may define new panel lots and recall existing panel lots. Users with Administrator passwords may do these things and may extend the expiration date of existing panel lots.

When a panel lot definition is saved, any Test Strain recommendations that exist are displayed in the Current QC Results window. The "toggle display" soft key provides the ability to toggle between Current and Historical QC Results windows. Current results show a summary of the most recent test for each strain for all instruments, up to 20 entries. Historical results show all tests for a strain for the current instrument only, up to 200 entries. In order to display results from other instruments, Panel Lots must be saved at those instruments and restored to the current instrument (see Section 6.2.4.5 Save Panel Lot Definitions and Section 6.2.4.6 Restore Panel Lot Definitions).

Field contents of these windows are explained below.

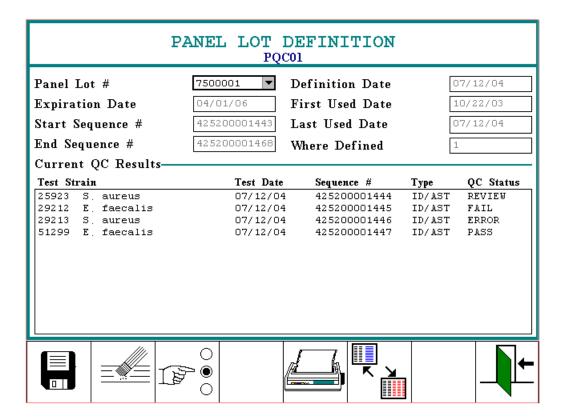
#### To access Panel Lot Definition:

<b>S</b>	From the Main Status screen, press the "configuration" soft key
<b>1</b>	The password window appears. To access configuration functions, enter the appropriate password then press the "perform action" soft key.
	From the Configuration Menu, press the "panel lot definition" soft key

The Panel Lot Definition display then appears (Figure 2-16 – Panel Lot Definition Display).

When the desired configuration parameters have been entered or modified, press the "save" soft key to save the information.

## **Panel Lot Definition soft keys:**



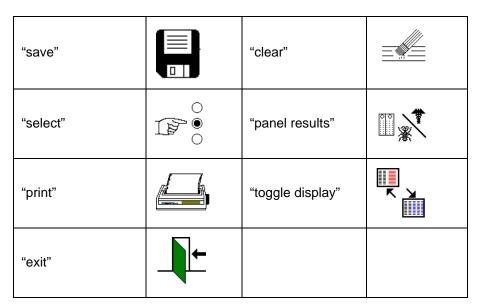


Figure 2-16 – Panel Lot Definition Display

#### Panel Lot fields:

### Panel Lot #

This field shows the lot number for the panel. To enter a new panel lot number, you *must* scan the lot number barcode (next to the L symbol) on the box. The panel lot number is encoded in the barcode. The lot number cannot be typed in this field when defining new panel lots.

**To recall a panel lot definition**, press the DOWN ARROW to drop down the list of all panels, or type the first few numbers of the panel lot number to jump to that portion of the list, or scan the panel lot barcode.

## **Expiration Date**

This field shows the lot's expiration date. This information is encoded in the panel lot barcode and is filled in automatically when the panel lot barcode is scanned. The expiration date cannot be typed in when defining new panel lots. This date can only be changed by scanning a new panel lot barcode provided by the BD Quality department (only if an Administrator is logged in).

## Start Sequence #

This field shows the starting barcode sequence number for the panel lot. To enter a new Start Sequence number, scan the lowest sequence number in the lot (next to the symbol on the box). This field can only be completed by scanning the panel sequence barcode; the sequence number cannot be typed in this field.

## **End Sequence #**

This field shows the ending barcode sequence number for the panel lot. To enter a new End Sequence number, scan the highest sequence number in the lot (next to the symbol on the box). This field can only be completed by scanning the panel sequence barcode; the sequence number cannot be typed in this field.

#### **Definition Date**

This field shows the date on which the panel lot was defined. It is completed automatically when the panel lot definition is saved. This is a read-only field that cannot be changed by the user.

#### **First Used Date**

This field shows the first date on which a panel from this lot was used. It is completed automatically when the panel is placed in the instrument. This is a read-only field that cannot be changed by the user.

## **Last Used Date**

This field shows the last date on which a panel from this lot was used. It is completed automatically when the panel is placed in the instrument. This is a read-only field that cannot be changed by the user.

## Where Defined

This field appears only if the panel lot was defined at a different number instrument than the current one. It shows the instrument number where the panel lot was defined. Panel lot definitions can be saved at one instrument and restored to another instrument through the **Save/Restore Panel Lot Definitions** functions in the **Maintenance Menu** (6.2.4.5 Save Panel Lot Definitions and 6.2.4.6 Restore Panel Lot Definitions).

## **Current QC Results Window**

This window appears only after a panel lot is saved. When a panel lot definition is saved, any QC Test Strain recommendations that exist are displayed in the Current QC Results window. Only the most recent QC test is shown for each test strain, up to a maximum of 20 tests. Results for other instruments can be shown in this window by saving those results at that instrument and restoring them at the current one (6.2.4.5 Save Panel Lot Definitions and 6.2.4.6 Restore Panel Lot Definitions).

The following read-only fields are shown in the Current Results window: Test Strain (sort order by name); Test Date; Sequence Number; (Test) Type (ID, AST, or ID/AST); QC Status (None for uncompleted test; Pass, Fail, Review, or Error for completed tests).

Results can be reviewed when the panel is in the instrument database as follows: press the TAB key to move to the Current Results window. Use UP/DOWN ARROW to highlight the desired strain, and press the "panel results" soft key when the desired strain is highlighted.

To print the Current QC Panel Lot Report, press the "print" soft key (with the Current QC Results Window showing). In addition to the fields listed above, the report includes standard report header information (Report Title, Laboratory Information (if configured), Date and Time Printed, and Instrument number where the report was printed); Panel Lot number; Panel Type; Expiration Date; Instrument number for each strain tested (blank if instrument is the same); and Tech ID. A sample Current QC Panel Lot Report is shown in Figure 2-17.

You can toggle between Current and Historical QC Results windows with the "toggle display" soft key.

		07/15/04 09:11 Instrument #1				
Panel Lot # Panel Type Expiration Date	7500001 PQC01 04/01/06					
Test Strain	Test Date	Sequence #	Type	QC Status	Instrument #	Tech ID
25923 S. aureus 29212 E. faecalis 29213 S. aureus 51299. E. faecalis	07/12/04 07/12/04 07/12/04 07/12/04	425200001444 425200001445 425200001446 425200001447	ID/AST ID/AST ID/AST ID/AST	REVIEW FAIL ERROR PASS .		ljk bee me up
		Enc	d of Repor	t		

Figure 2-17 – Sample Current QC Panel Lot Report

#### **Historical QC Results Window**

This window appears only after a panel lot is saved. Historical results show all tests for a strain for the current instrument only, up to 200 entries. To select a Test Strain, press the TAB key to advance to the Test Strain field, the press DOWN ARROW to drop down the list of strains. Use UP/DOWN ARROW to highlight the desired strain, then press the "select" soft key. When the desired panel is highlighted, you can jump to the QC Panel Results display, or print a Historical QC Panel Lot Report.

The following read-only fields are shown in the Historical Results window: Test Strain (drop down selection box); Test Date (sort order); Sequence #; (Test) Type (ID, AST, or ID/AST); QC Status (None, Pass, Fail, Review, Error); Tech ID.To print the Historical QC Panel Lot Report, press the "print" soft key (with the Historical QC Results Window showing). In addition to the fields listed above, the report includes standard report header information (Report Title, Laboratory Information (if configured), Date and Time Printed, and Instrument number where the report was printed); Panel Lot number; Panel Type; and Expiration Date. A sample Historical QC Panel Lot Report is shown in Figure 2-18.

The "toggle display" soft key provides the ability to toggle between Current and Historical QC Results windows with the "toggle display" soft key.

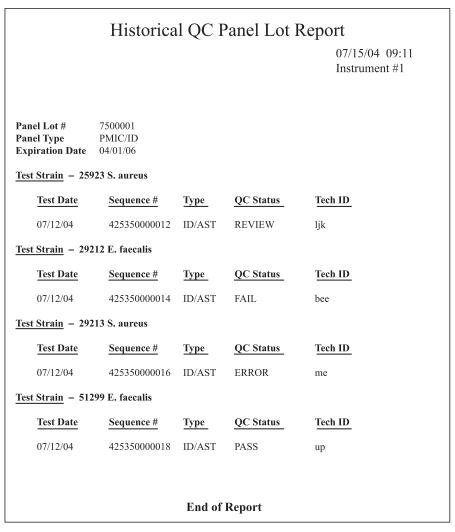


Figure 2-18 – Sample Historical QC Panel Lot Report

# 2.4 System Startup

Whenever power is applied to the system, it is initialized, performs self-diagnostics, and reports any problems to the user through alerts. If any files are missing or corrupted which would prevent proper operation of the system, the startup process is aborted. If not, the computer loads the operating system and user interface, and begins the warm-up period (indicated by the "Instrument is warming up" icon shown below). Afterwards, the system awaits the initiation of panel testing.



The temperature standard panel should be left in the instrument at least 45 minutes before reading it when the instrument is first powered up.

## 2.5 Software Installation

Software updates are to be performed by BD representatives.

#### **NOTE**

## **Custom Breakpoints**

When the software is updated, or when the PUD operation is performed, if any of the standard interpretation rule sets have changed, new rule sets are installed into the system database. Since custom rule sets are based on standard rule sets, a custom interpretation rule set will be merged with new standard rules. If custom breakpoints are used, be sure to print out the Custom Breakpoint Difference Report (Section 2.3.3) after each system update or PUD installation.

# 3 – Controls and Indicators

# 3.1 General

This section describes the meaning and use of the controls and indicators of the BD Phoenix instrument. The overall layout of the instrument is shown in Figure 3-1. Individual components are illustrated in figures accompanying the related text.

## **WARNING**

ALL SYSTEM USERS SHOULD BECOME THOROUGHLY FAMILIAR WITH ALL CONTROLS AND INDICATORS BEFORE ATTEMPTING TO OPERATE THE INSTRUMENT.

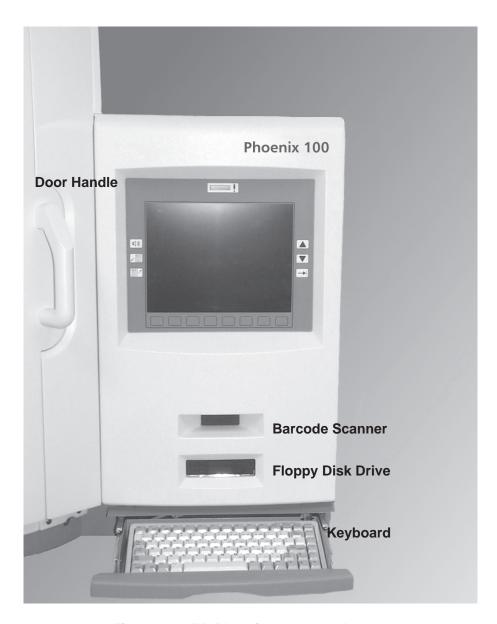


Figure 3-1 – BD Phoenix Instrument Layout

## 3.2 Power Switch

The system power (On/Off) rocker switch is on the right side of the instrument at the bottom (see Figure 3-2). When in the "O" (Off) position, power is removed from the instrument. When in the "|" (On) position, the switch illuminates green and power is applied to the instrument. Power must be turned On for the incubation and testing modules to work. For normal operation, the power should remain On at all times (except during some maintenance procedures).



Figure 3-2 – On/Off Switch

## 3.3 Keypad and LCD Display

The keypad and LCD display are located on the front of the instrument, at the top right. The keypad is used to issue commands to the instrument. The LCD display presents setup and status information, as well as the keypad definitions that allow routine operations to be performed. See Figure 3-3.

The controls and indicators of the keypad and LCD display are presented in clockwise order from the top right of the module.

## 3.3.1 DOWN /UP ARROW Keys

The DOWN and UP ARROW keys are located on the right side of the Keypad/LCD Display. The DOWN ARROW key, represented by a down arrowhead, is used to decrease a displayed value, or to scroll downward in a list. The UP ARROW key, represented by an up arrowhead, is used to increase a displayed value, or to scroll upward in a list.



Figure 3-3 – Keypad and LCD Display

## 3.3.2 TAB Key

The TAB Key is located below the DOWN and UP ARROW keys. It functions like the T key on the keyboard. When pressed, it advances the cursor to the next field on the display.

### 3.3.3 Soft Keys

The eight software (soft) keys are located near the bottom of the Keypad/LCD Display, at the center. These keys are teal colored. None of the keys has a fixed function – the functions of the keys vary depending on the current active display. Each display shows icons representing the current soft key assignments at the bottom of the screen. To perform the function represented by the icon, press the corresponding soft key. The soft keys available on each display are explained in Section 5 – Reference.

### 3.3.4 UNLOAD PANELS Key

The UNLOAD PANELS Key is used to unload any panels from the instrument that are ready to be removed. When pressed, the instrument rotates the carousel to make the first set of Removable panels (indicated by green LED) accessible when the door is opened. It then unlocks the door so that the panels can be removed. If there are additional panels to be removed, close the door and allow the instrument to reposition the carousel to provide access to additional panels.

### 3.3.5 LOAD PANELS Key

The LOAD PANELS Key is used to load panels into the instrument for testing. When pressed, the instrument rotates the carousel to make the first set of available stations accessible when the door is opened. It then unlocks the door so that the panels can be inserted. If there are additional panels to be inserted, close the door and allow the instrument to reposition the carousel to provide access to additional stations. Panels can be placed in any station that is unoccupied and has no indicator LEDs lit.

### 3.3.6 SILENCE ALARM Key

The SILENCE ALARM key is located on the left of the Keypad/LCD Display module. When pressed, it turns off the audible alarm for the current "alert" alarm. It does not silence "door open" type audible alarms, and it does not "clear" the error condition. (See 3.8 Audible Tones and Alarms, for an explanation of alarm types and tones.)

## 3.3.7 System Alert/Door Unlocked Indicator

The Alarm Indicator is located at the top of the Keypad/LCD Display, above the display area. This light illuminates or flashes yellow to indicate certain instrument conditions.

- When the indicator is FLASHING, an alert condition exists. The indicator continues flashing until the error condition is corrected.
- When the indicator is ON, no alert exists and you can open the instrument door.
- When the indicator is OFF, no alert condition exists but you cannot open the instrument door.

When an alarm occurs, an icon (resembling the one on the Alarm Indicator) appears in the soft key assignments area of the Main Status Screen. Press the soft key corresponding to the System Alert icon. The first error code is shown on the display. Correct any error conditions as soon as possible by following the directions in Section 7 – Troubleshooting. Scroll through the error log with the UP and DOWN ARROW keys.

If there is an audible alarm sounding, press the SILENCE ALARM key to silence it.

### 3.3.8 Display Area

The Display area is located at the center of the Keypad/LCD Display. It is used to present information to you, and to show the Soft Key definitions that allow you to perform routine operations. When the instrument starts up, the Main Status Screen is displayed. Other displays appear as various operations are performed. The LCD Display is programmed to automatically dim after 10 minutes of inactivity. To return the brightness to normal, press any keyboard or soft key. More information on displays is presented in Section 5 – Reference.

### 3.4 Barcode Scanners

The built-in barcode scanner is located below the Keypad/LCD Display module. The scanner remains on at all times ready to read a barcode. See Figure 3-1. To scan a barcode, place the panel in the recessed area below the scanner. If necessary, slowly tilt the panel until the acknowledgment beep sounds (indicating that the barcode was scanned successfully).

A hand-operated scanner is also provided with the system to facilitate certain scanning scenarios, such as scanning numerous panels. To scan a barcode with the handheld scanner, press the trigger button on the bottom side of the scanner. A single beep indicates a successful scan. The button must be pressed for each panel or barcode that needs to be scanned.

## 3.5 Floppy Disk Drive

The floppy disk drive is located on the front of the instrument, below the built-in barcode scanner. Its primary purposes are to enable data to be saved to a floppy disk, and to perform software updates when they are released. See Figure 3-4.

## 3.5.1 Floppy Disk Indicator

The Floppy Disk Drive Indicator light is on the left side of the drive below the insertion slot. When off it indicates that no activity is occurring in the drive. When on or flashing, it indicates that the disk drive is accessing a floppy disk. **Do not attempt to eject a floppy disk while this indicator is lit.** 

## 3.5.2 Floppy Disk Eject Button

The floppy disk drive eject button is located to the lower right of the insertion slot. When a floppy disk is inserted fully into the slot, this button extends itself. To remove a disk, fully depress the eject button. **Do not attempt to eject a floppy disk while the floppy disk indicator is lit.** 

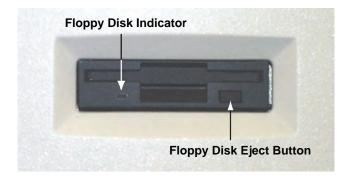


Figure 3-4 – Floppy Disk Drive Controls and Indicators

## 3.6 USB Functionality

Floppy disks will be referenced throughout the manual; however, some instruments now have USB functionality which allows data to be saved with a USB key.

## 3.7 Station Indicators

Each accessible station has a set of LED indicators that provides the station or panel status. The status indicators are located at the upper left of the station. See Figure 3-5. The color (red, green, or amber) and state (on or off) indicate the conditions shown in the table below for a given station.

Color	State	Meaning
Amber	ON	Panel found using "locate panel" soft key
Red	ON	Blocked Station (also Temperature Standard Panel)
Green	ON	Removable Panel
All colors	OFF	Ongoing Panel (if panel is in station) OR Available Station (if station is empty)

Table 3-1 - Station Indicators



Figure 3-5 – Station Status Indicators

## 3.8 Audible Tones and Alarms

Numerous different sounds are generated by the BD Phoenix instrument as you perform operations. Each of the sounds is unique. These tones are designed to provide information about various operational states of the instrument.

Туре	Example	Sound			
Informational					
Acknowledge	Scanning a barcode	Single short high beep			
Sample audible alert	In Configuration mode, the audible alert volume was adjusted	Three tones progressing from high to low ("Figaro")			
Carousel halted	The carousel has stopped, the door can be opened	Three tones progressing from low to high			
Door closed	The door has been completely closed and latched	Two short high beeps			
Activity completed	An operation has been completed	Three short high beeps			
Swap floppy	Current floppy disk is full, insert another with free space	Long medium beep			
Alarm					
Activity error (volume configurable)	Incorrect barcode scanned	Short high beep then short low beep – sequence repeated four times			
System alert (volume configurable)	Optical failure	Single medium beep –one second on, three seconds off, repeating			
Error tone	The attempted action cannot be performed	Short high beep then short low beep			
Door open alarm	Door has remained open longer than 5 minutes	Continuous shrill trill			
Cannot get into instrument	A higher priority activity prevents user access to the instrument	Single low beep			
Critical Panel/ Resistance Marker notification	Critical Panel: partial results, panel completes, or ID is determined; Resistance Marker: marker has been triggered	Tone 1 (Medium frequency): Long beep, short beep, long beep, short beep; Tones 2 (low frequency) and 3 (very high frequency): Long beep, short beep, long beep			
Carousel jammed	Carousel motion is impeded	High pitched trill			

Table 3-2 - Audible Tones/Alarms

## 3.9 Keyboard

The keyboard provides the ability to enter panel demographic information (e.g., accession numbers), and to perform all the soft key and keypad functions. In addition to the standard alphanumeric key functions, the following key functions exist:

- T Moves cursor to next field; equivalent to TAB (screened) key
- S-T Moves cursor to previous field
- u Moves up one "page" in a drop-down list field
- d Moves down one "page" in a drop-down list field
- s Toggles the check on/off in a checkbox; inserts a space character in a text field
- J Selects an item in a drop-down box
- t Moves up in a drop-down list field; displays previous selection in some fields with predefined values (e.g., instrument number); equivalent to UP ARROW screened key
- b Moves down in a drop-down list field; displays next selection in some fields with predefined values (e.g., instrument number); equivalent to DOWN ARROW screened key
- 1 8 Corresponds to the eight teal soft keys from left to right
- 9 Corresponds to LOAD PANELS key
- 0 Corresponds to UNLOAD PANELS key
- ! Corresponds to SILENCE ALARM key

## 3.10 Printer

For an explanation of controls and indicators on the printer, refer to the manufacturer's operating instructions furnished separately.

# 4 – Operation

## 4.1 General

This section describes the routine operation of the BD Phoenix 100 instrument. The following major topics are discussed:

- System Maintenance
- Storage and Handling
- Preparing Panels
- Logging in Panels
- Inserting Panels in the Instrument
- Panel Testing
- Responding to Needs Attention Panels
- Automatic Association of Panels
- Obtaining Results
- Panel Finalization
- Responding to Alarms and Errors
- Printing Reports
- Unloading and Discarding Panels
- Installing New Panel Formats
- BD Phoenix Update Disk (PUD)
- LIS Operations

## 4.2 Daily System Maintenance

Each day the following maintenance procedures should be performed. The best time to perform maintenance is first thing in the morning, but it may be done any time that is convenient. The following items should be checked:

- 1. Check the printer's paper supply. If the paper supply is low or exhausted, replace the paper as explained in the manufacturer's operating instructions.
- Record the temperature readout shown on the LCD display and that of the temperature standard panel. Note that the temperature panel can be brought into view by selecting one of the instrument LED check functions on the Maintenance menu (see 6.2.2 Weekly Maintenance). This temperature should be 35 °C ±1.5 °C.

## 4.3 Storage and Handling

**BD Phoenix Panels:** Panels are individually pouched and packaged in a box of 25. Panels must be stored unopened at room temperature (15–25 °C). Do not refrigerate or freeze. Visually inspect the packaging for holes or cracks in the foil package. Do not use if the packaging appears to be damaged. Do not use the panel if there is no desiccant or if the desiccant pouch is torn. If stored as recommended, the panels will retain expected reactivity until the date of expiration.

**BD Phoenix ID Broth:** Tubes are packaged as 100 tube packs. Visually inspect the tubes for cracks, leaks, etc. Do not use if there appears to be a leak, tube or cap damage or visual evidence of contamination (i.e., haziness, turbidity). Store BD Phoenix ID Broth tubes at 2–25 °C. Expiration dating is shown on the tube label.

**BD Phoenix AST Broth and BD Phoenix AST-S Broth:** Tubes are packaged as 100 tube packs. Visually inspect the tubes for cracks, leaks, etc. Do not use if there appears to be a leak, tube or cap damage or visual evidence of contamination (i.e., haziness, turbidity). Store BD Phoenix AST Broth tubes at 2–25 °C. Expiration dating is shown on the tube label.

**BD Phoenix AST Indicator Solution and BD Phoenix AST-S Indicator Solution:** The indicator solution is individually pouched and packaged as a package of 10 dropper bottles. Visually inspect the bottle for cracks, leaks, etc. Do not use if there appears to be a leak, bottle or cap damage, or any change from a dark blue color. **Store the BD Phoenix AST Indicator Solution at 2–8 °C.** Each bottle contains enough solution to test up to 100 panels. Expiration dating is shown on the box, pouch, and bottle label and is for unopened bottles. An opened bottle will be stable for up to 14 days if stored at 2–8 °C. **Be sure the bottle is held vertically when dispensing the AST Indicator Solution.** 

## 4.4 Preparing Panels

The BD Phoenix system is not used directly with clinical specimens. Only pure culture isolates of aerobic and/or facultatively anaerobic gram-negative, gram-positive, and yeast organisms are acceptable for testing. Make sure the test isolate is a pure culture. Cultures must be 18–24 hours old for gram-negative and gram-positive organisms and 18 to 48 hours old for yeast organisms.

For AST testing in the BD Phoenix System, isolates must be recovered from non-selective media. Media containing antibiotics should not be used for organisms to be tested in the BD Phoenix System except those specifically claimed in the table below. Selective media may inhibit some strains of bacteria and yeast, therefore use caution when selecting isolated colonies from these media. Use isolates from a blood agar plate such as BD Trypticase Soy Agar with 5% Sheep Blood. The Media selected during login of Yeast ID panels refers to the media on which the organism was grown.

Other recommended media are included in the table below:

Recommended Media		Approved Use		
	ID	AST	Strep	Yeast ID
BD BBL™ CHROMagar™ Orientation	Yes	Yes <sup>1</sup>	Х	Х
Bromthymol Blue (BTB) Lactose Agar	Yes <sup>4</sup>	Yes	Х	Х
Chocolate Agar	Yes	Yes	Yes <sup>2</sup>	Yes
Columbia Agar with 5% Horse Blood	Yes	Yes	Yes <sup>3</sup>	Х
Columbia Agar with 5% Sheep Blood	Yes	Yes	Yes	Yes
Columbia CNA Agar with 5% Sheep Blood (Gram Positives)	Yes	Х	Yes	Х
Cystine-Lactose-Electrolyte-Deficient (CLED) Agar	Yes <sup>5</sup>	Yes	Х	Х
Dey/Engley (D/E) Neutralizing Agar (Gram Negatives)	Yes	Х	Х	Х
Eosin Methylene Blue (Gram Negatives)	Yes	Yes	Х	Х
Hektoen Enteric Agar (Gram Negatives)	Yes	Х	Х	Х
MacConkey Agar (Gram Negatives)	Yes	Yes	Х	Х
Phenylethyl Alcohol Agar (Gram Positives)	Yes	Х	Yes	Х
Sabouraud Brain Heart Infusion Agar - SAB HI (Yeast)	Х	Х	Х	Yes
Sabouraud Dextrose Agar (Yeast)	Х	Х	Х	Yes
Sabouraud Dextrose Agar-Emmons (Yeast)	Х	Х	Х	Yes
BD Trypticase Soy Agar with 5% Sheep Blood	Yes	Yes	Yes	Yes
BD Trypticase Soy Agar with Lecithin and Tween 80	Yes	Х	Х	Х
BD Trypticase Soy Agar without Blood	Yes	Х	Х	Х
Xylose Lysine Desoxycholate Agar (Gram Negatives)	Yes	Х	Х	Х

<sup>&</sup>lt;sup>1</sup> The use of CHROMagar Orientation may produce false susceptibility results when testing erythromycin with Gram positive organisms. Antimicrobial susceptibility test results should be confirmed using BD Trypticase Soy Agar with 5% Sheep Blood.

Table 4-1 - Recommended Media

<sup>&</sup>lt;sup>2</sup> This media type should *not* be used for Streptococcal identification with SMIC/ID panels. Chocolate Agar may be used for Streptococcal susceptibility testing only.

<sup>&</sup>lt;sup>3</sup> The use of Columbia Agar with 5% Horse Blood may produce significantly higher MIC for SXT with *Streptococcus* species, which may result in false resistance. Antimicrobial susceptibility test results should be confirmed using BD Trypticase Soy Agar with 5% Sheep Blood.

 $<sup>^{\</sup>scriptscriptstyle d}$  The use of Bromthymol Blue Lactose Agar with Gram Positive organisms should be restricted to Staphylococci for both the 0.5 and 0.25 GP systems.

<sup>&</sup>lt;sup>5</sup> The use of Cystine-Lactose-Electrolyte-Deficient Agar with Gram Positive organisms should be restricted to Staphylococci for the 0.25 GP system.

The applicator swabs should be sterile cotton swabs; polyester swabs are not recommended. The quality of applicator swabs may vary from vendor to vendor and on occasion, loose fibers may dislodge from the swab affecting McFarland readings.



Figure 4-1 - Cotton Swabs

The usefulness of the BD Phoenix System or any other diagnostic procedure performed on clinical specimens is directly influenced by the quality of the specimens themselves. It is strongly recommended that laboratories employ methods discussed in the *Manual of Clinical Microbiology*<sup>17</sup> for specimen collection, transport, and placement on primary isolation media.

Due to variations in inoculum concentrations prepared with McFarland standards, use the BD BBL CrystalSpec Nephelometer, the BD PhoenixSpec Nephelometer, or the BD Phoenix AP instrument for adjusting the test inoculum prior to using them in the BD Phoenix System.

Instructions for an optional purity check are provided at the end of this subsection.

#### **WARNING**

- OBSERVE ESTABLISHED PRECAUTIONS AGAINST MICROBIOLOGICAL HAZARDS THROUGHOUT ALL PROCEDURES.
- ALL SPECIMENS SHOULD BE HANDLED ACCORDING TO CDC-NIH RECOMMENDATIONS, CLSI GUIDELINES, OR LOCAL INSTITUTION GUIDELINES FOR ANY POTENTIALLY INFECTIOUS HUMAN SERUM, BLOOD, OR OTHER BODY FLUIDS.
- PRIOR TO DISCARDING, STERILIZE SPECIMEN CONTAINERS AND OTHER CONTAMINATED MATERIALS BY AUTOCLAVING.
- IN ADDITION TO WEARING GLOVES, THE USE OF DISPOSABLE LAB COATS OR GOWNS AND PROTECTIVE GLASSES OR GOGGLES IS RECOMMENDED WHEN WORKING AROUND THE INSTRUMENT.

#### Materials Required that are Provided

- BD Phoenix Panels
- BD Phoenix ID Broth or BD Phoenix Inoculum Broth
- BD Phoenix AST and/or BD Phoenix AST-S Broth
- BD Phoenix AST Indicator Solution and/or BD Phoenix AST-S Indicator Solution
- BD Phoenix Panel closures
- BD Phoenix Inoculation Station
- BD Phoenix Transport Caddy
- BD BBL CrystalSpec Nephelometer, the BD PhoenixSpec Nephelometer, or the BD Phoenix AP instrument
- 25 μL pipettor and tips
- 50 μL pipettor and tips

#### **Materials Required but Not Provided**

- · Gram Stain Reagents
- Sterile Cotton Swabs, Inoculation Loops or Needles
- Nonselective Culture Plated Media (see 4.4 Preparing Panels)
- Incubators
- Biohazard Disposable Container
- Markers, etc.
- Vortex mixer

#### **NOTE**

- Exercise care in handling BD Phoenix panels. Handle panels by the sides only to avoid marking, smudging, or obscuring the bottom or top of the panel in any way.
- Accession bar code labels affixed to a BD Phoenix panel must not be
  of fluorescent material, should not cover any BD Phoenix panel
  reaction wells, should not cover the BD Phoenix sequence number
  (panel) barcode.
- The procedure that follows describes all the steps in preparing a
  combination panel for both identification and susceptibility testing. If a
  combination panel is being used for only ID or only AST testing, note
  that certain steps are not applicable in the procedure.

### 4.4.1 General Panel Preparation

If the BD Phoenix AP instrument is being used, refer to the BD Phoenix AP Instrument User's Manual for panel preparation.

BD Phoenix Strep panels, BD Phoenix Yeast ID panels, BD Phoenix Emerge panels, BD Phoenix Inoculum Broth, and BD Phoenix MIC panels have separate instructions that appear after these General Panel Preparation instructions.

#### NOTE

Before proceeding with the inoculum preparation for use in the BD Phoenix instrument, confirm the Gram stain reaction of the isolate.

- 1. Once the Gram stain reaction is confirmed, select the appropriate BD Phoenix panel for inoculation. Do not use the panel if the pouch is punctured or opened.
- 2. Remove the panel from the pouch. Discard the desiccant. Do not use the panel if there is no desiccant or if the desiccant pouch is torn. Use panel within 2 hours of removal from the pouch.

#### NOTE

Panels must be inoculated within 2 hours of being removed from the pouch.

- 3. Place the panel on the Inoculation Station with the inoculation ports on top and the pad on the bottom.
- 4. Label a BD Phoenix ID broth tube with the patient's specimen number.
- 5. Using aseptic technique, pick colonies of the same morphology with the tip of a sterile cotton swab (do not use a polyester swab) or a wooden applicator stick from one of the recommended media.
- 6. Suspend the colonies in the BD Phoenix ID broth (4.5 mL).
- 7. Cap the tube and vortex for five seconds.
- 8. Allow approximately ten seconds for air bubbles to surface. You can tap the tube gently to aid in eliminating bubbles.
- 9. Insert the tube into the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer. Make sure the tube is inserted as far as it will go. (Refer to the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer product insert for correct usage instructions.)
- 10. If the inoculum density is set to 0.5 McFarland for the panel type being run, then a range of 0.50–0.60 is acceptable. If the inoculum density is set to 0.25 McFarland for the panel type being run, then a range of 0.20–0.30 is acceptable. If the density of organisms is low, colonies can be added from the isolate. Re-vortex the sample and reread to confirm that the correct McFarland has been achieved. If the density of organisms exceeds 0.6 McFarland, follow the steps below to dilute the broth. It is very important to accurately indicate the level of the liquid in the tube since this volume is needed to adequately fill the wells in the panel.

- a. Using a marker, mark the broth level in the over-inoculated BD Phoenix ID Broth tube.
- b. Using a sterile pipette, aseptically add fresh BD Phoenix ID Broth to the inoculum. Only BD Phoenix ID Broth may be used to dilute the inoculum.
- Vortex the tube and allow to sit for 10 seconds.
- d. Place the tube in the Nephelometer and remeasure the turbidity of the suspension.
  - If the reading is greater than 0.6, repeat Steps b-d.
  - If the reading is 0.5–0.6, go to Step e.
- e. Using a sterile pipette, aseptically remove excess broth to the original level indicated by the mark on the tube created in Step a.
  - Remove excess broth to avoid overfilling the panel. Also, do not remove too much broth, as there may be insufficient broth to adequately fill the panel.
- f. Broth may now be used to inoculate the BD Phoenix AST Broth and/or the BD Phoenix Panel.

#### NOTE

- Yeast ID panels must be inoculated using a 2.00–2.40 McFarland inoculum density.
- Confirm current instrument settings for inoculum density before inoculating panels.
- See instructions below, ID Inoculum Density Flexibility, for information on using alternate densities.
- Only the BD PhoenixSpec Nephelometer and BD Phoenix AP instrument can be used to make inoculum densities of 0.25 McFarland
- Standardized bacterial suspension in ID Broth or Inoculum Broth must be used within 60 minutes of preparation.
- 11. If only identification is being performed, proceed to Step 16 and continue the procedure with the exception of Step 17 (which pertains to AST panels). If a BD Phoenix Emerge Panel is being inoculated, refer to Section 4.4.5 Preparing BD Phoenix Emerge Panels.
- 12. Label a BD Phoenix AST broth tube (8.0 mL) with the patient's specimen number. Add one free-falling drop of AST Indicator solution to the AST broth tube. Invert to mix. DO NOT VORTEX.

#### NOTE

- Allow AST Indicator Solution to warm to room temperature before dispensing into AST broth.
- Return the unused portion of the indicator to 2–8 °C as soon as possible. Do not store at room temperature for more than 2 hours.
   Opened bottles should be discarded after 14 days from initial opening.
- If volume other than one drop is added inadvertently, discard the tube and use a fresh tube of AST broth.
- After adding the indicator to AST broth, store the mixed solution in the dark, at room temperature, for as long as 8 hours.
- After adding AST Indicator Solution, if it is exposed to light, use the tubes within 2 hours.
- 13. If an inoculum density of 0.50–0.60 was used, transfer 25  $\mu$ L of the bacterial suspension from the ID tube into the AST broth tube. If an inoculum density of 0.20–0.30 was used, transfer 50  $\mu$ L (use 2 shots if utilizing a 25  $\mu$ L pipettor) of the bacterial suspension from the ID tube into the AST broth tube.

#### NOTE

Panels must be inoculated within 30 minutes of the time that the AST broth inoculum is prepared.

- 14. Cap the AST tube and invert several times to mix.
- 15. Wait a few seconds for air bubbles to surface. Tap the tube gently to aid in eliminating bubbles.
- 16. Pour the ID tube inoculum into the fill port on ID side of the panel (51-well side). Allow the fluid to traverse down the tracks before moving the panel. If using an AST (only) panel, DO NOT inoculate the ID side of the panel. Retain the ID tube for purity check (see below).
- 17. Pour the AST broth inoculum into the fill port on AST side of the panel (85-well side). Allow the fluid to traverse down the tracks before moving the panel.
- 18. Before placing panel closures check for residual droplets of inoculum on the edge of the fill ports. If a droplet is present remove the droplet with absorbent material. The used absorbent material must be decontaminated before discarding.
- 19. Snap on the panel closures. Make sure that the closures are fully seated. Use two closures regardless of panel type.
- 20. Visually inspect panels to be sure each of the wells is full. Look at both sides of the panel. Make certain that the wells are not overfilled. If any of the wells are unfilled or overfilled, inoculate a new panel.

#### NOTE (see NOTE above)

- Panels must be loaded into the instrument within 30 minutes of inoculation.
- Panels must be kept in the inoculation station after inoculation until the excess fluid has been completely absorbed by the pad.
- Panels should stay vertical in the caddy until loaded.
- Inoculated panels should be handled with care. Avoid knocking or jarring the panel.

#### NOTE

#### OPTIONAL PURITY CHECK

It is highly recommended that the purity of both ID and AST inocula be checked by preparing a purity plate.

To perform a purity check, using a sterile loop, recover a small drop from the inoculum fluid tube either before or after inoculating the panel and inoculate an agar plate (any appropriate medium) for purity check. Discard inoculum fluid tube and cap in a biohazard disposal container. Incubate the plate for 24–48 h at 35 °C under appropriate conditions.

## 4.4.2 ID Inoculum Density Flexibility

An ID portion of a panel may be run in the opposite mode from what is configured by darkening well A-17 on the back of a panel before placing the panel in the instrument. This allows a panel to be run at an inoculum density of 0.20–0.30 even if a density of 0.5 is configured for that particular panel type. Likewise, a panel can be run at an inoculum density of 0.50–0.60 if a density of 0.25 is configured.

There is no way to alter the density setting during Panel Login. To use a panel in the opposite density mode, using a black permanent marker, blacken the entire A-17 well as shown in the figure below.

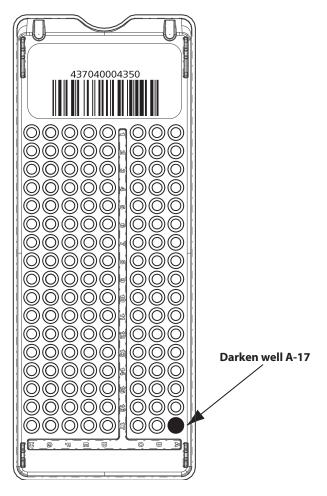


Figure 4-2 - Panel wells

Inoculum densities sent from the BD Phoenix AP instrument (via the BD EpiCenter System) cannot be changed by darkening well A-17. Inoculum densities sent from the BD Phoenix AP instrument are invalid if they are received after the completion of the first test cycle, or if the ID portion of the panel is disabled, or if the panel type does not support the inoculum density. If the instrument receives an invalid inoculum density for an ID panel that differs from the panel's determined inoculum density, the ID side of the panel fails, a Needs Attention code is triggered (Cannot Determine Organism ID), and a Special Message is triggered.

The following table outlines how to run the opposite mode from the density for which the instrument is configured.

Current Instrument Inoculum Density Configuration	Inoculum Concentration Desired for Test Panel	Amount of ID Inoculum to Add to AST Broth**	Well A-17
0.50	0.25	50 μL	Blackened
0.25	0.50	25 μL	Blackened
** If also running AST			

### 4.4.3 Preparing BD Phoenix Strep Panels

BD Phoenix Strep panels are for the identification and antimicrobial susceptibility testing of most *Streptococcus* species. Although *Streptococcus* species may be identified in the gram-positive panels, antimicrobial susceptibility cannot be reported when using these panels. The BD Phoenix Strep panels, which must be used with BD Phoenix AST-S Broth and BD Phoenix AST-S Indicator Solution, provide the conditions required for rapid AST testing of most *Streptococcus* species.

- 1. Follow Steps 1–10 (**General Panel Preparation**) to prepare the suspension of bacteria using a 0.5 McFarland inoculum density.
- 2. Label a BD Phoenix AST-S broth tube (8.0 mL) with the patient's specimen number. Add one drop of the BD Phoenix AST-S Indicator to the AST-S broth tube. Invert to mix. DO NOT VORTEX.

#### **NOTE**

- AST-S Broth and AST-S Indicator Solution are for use with the BD Phoenix Strep panels (SMIC/ID, SMIC) only. These reagents are not interchangeable with the AST Broth and AST Indicator Solution used with BD Phoenix Gram positive and Gram negative panels.
- Allow AST-S Indicator Solution to warm to room temperature before dispensing into AST-S broth.
- Make sure the unused portion of the indicator should be returned to 2–8 °C as soon as possible. Do not store at room temperature for more than two hours. After 14 days from opening, discard the bottles.
- If volume other than one drop is added inadvertently, discard the tube and use a fresh tube of AST-S broth.
- After adding the indicator to AST broth, store the mixed solution in the dark, at room temperature, for as long as 8 hours.
- After the addition of AST-S Indicator Solution, if the tubes are exposed to light, they must be used within two hours.
- 3. Using a pipettor, transfer 25  $\mu$ L of the standardized bacterial suspension from the ID tube into the AST-S broth tube.

#### NOTE

Panels must be inoculated within 30 minutes of the time that the AST-S broth inoculum is prepared.

- 4. Cap the AST-S tube and invert several times to mix.
- 5. Wait a few seconds for air bubbles to surface. You can tap the tube gently to aid in eliminating bubbles.
- 6. Pour the ID tube inoculum into the fill port on ID side of the panel (51-well side). Allow the fluid to traverse down the tracks before moving the panel. If you are using a BD Phoenix Strep MIC only panel, DO NOT inoculate the ID side of the panel. Retain the ID tube for an optional purity check (see below).

- 7. Pour the AST-S broth inoculum into the fill port on AST side of the panel (85-well side). Allow the fluid to traverse down the tracks before moving the panel.
- 8. Before placing panel closures, check for residual droplets of inoculum on the edge of the fill ports. If a droplet is present, remove the droplet with absorbent material. The used absorbent material must be discarded with biohazard waste.
- 9. Snap on the panel closures. Make sure that the closures are fully seated.
- 10. Visually inspect panels to be sure each of the wells is full. Look at both sides of the panel. Make certain that the wells are not overfilled. If any of the wells are unfilled or overfilled, inoculate a new panel.

#### NOTE

- Panels must be loaded into the instrument within 30 minutes of inoculation.
- Panels must be kept in the inoculation station after inoculation until the excess fluid has been completely absorbed by the pad.
- Panels should stay vertical in the caddy until loaded.
- Inoculated panels should be handled with care. Avoid knocking or jarring the panel.

#### **NOTE**

#### OPTIONAL PURITY CHECK

It is highly recommended that the purity of both ID and AST-S inocula be checked by preparing a purity plate.

To perform a purity check, using a sterile loop, recover a small drop from the inoculum fluid tube either before or after inoculating the panel and inoculate an agar plate (any appropriate medium) for purity check. Discard inoculum fluid tube and cap in a biohazard disposal container. Incubate the plate for 24–48 h at 35 °C under appropriate conditions.

## 4.4.4 Preparing BD Phoenix Yeast ID Panels

BD Phoenix Yeast ID panels are for the identification of most clinically relevant yeast and yeast-like species.

- 1. Follow Steps 1–9 (General Panel Preparation) to prepare the suspension of yeast.
- 2. The inoculum density is set to 2.0 McFarland for Yeast ID panels, with a range of 2.00–2.40 as acceptable. If the density of organism is low or the density of organisms exceeds 2.40 McFarland, follow the steps discussed in Step 10 (**General Panel Preparation**) to obtain the correct McFarland density and then proceed to the steps below.
- 3. Pour the ID tube inoculum into the fill port on the ID side of the panel (51-well side). Allow the fluid to traverse down the tracks before moving the panel.

- 4. Before placing panel closures, check for residual droplets of inoculum on the edge of the fill ports. If a droplet is present remove the droplet with absorbent material. The used absorbent material must be discarded with biohazard waste.
- 5. Snap on the panel closures. Make sure that the closures are fully seated. Use two closures regardless of panel type.
- 6. Visually inspect panels to be sure each of the wells is full. If any of the wells are unfilled or overfilled, inoculate a new panel.

#### NOTE

Yeast ID panels must be inoculated using a 2.00–2.40 McFarland inoculum density.

Standardized bacterial suspension in ID Broth or Inoculum Broth must be used within 60 minutes of preparation.

#### **NOTE**

Load panels into the instrument within 30 minutes of inoculation.

Keep panels in the inoculation station after inoculation until the excess fluid has been completely absorbed by the pad.

Panels should stay vertical in the caddy until loaded.

Handle inoculated panels with care. Avoid knocking or jarring the panel.

#### NOTE

#### OPTIONAL PURITY CHECK

It is highly recommended that the purity of ID inoculum be checked by preparing a purity plate.

To perform a purity check, using a sterile loop, recover a small drop from the inoculum fluid tube either before or after inoculating the panel and inoculate an agar plate (any appropriate medium) for purity check. Discard inoculum fluid tube and cap in a biohazard disposal container. Incubate the plate for 24–48 h at 35 °C under appropriate conditions.

### 4.4.5 Preparing BD Phoenix Emerge Panels

BD Phoenix Emerge panels are designed to perform susceptibility testing on an expanded number of antimicrobial agents. To accomplish these susceptibilities, antimicrobial agents are present on both sides of the BD Phoenix panel. These panels do not have the ability to perform bacterial identification. Because of the design, the inoculation technique is unique and is outlined below.

#### **OPTION 1: Two tubes of AST broth will be required.**

- 1. Follow Steps 1–10 (**General Panel Preparation**) to prepare the suspension of bacteria.
- 2. Label two BD Phoenix AST broth tubes (8.0 mL) with the patient's specimen number. Add one drop of the BD Phoenix AST Indicator to each AST broth tube. Invert to mix. DO NOT VORTEX.

#### **NOTE**

- Allow AST Indicator Solution to warm to room temperature before dispensing into AST broth.
- Return the unused portion of the indicator to 2–8 °C as soon as possible. Do not store at room temperature for more than 2 hours. Opened bottles should be discarded after 14 days from initial opening.
- If volume other than one drop is added inadvertently, discard the tube and use a fresh tube of AST broth.
- After adding the indicator to AST broth, store the mixed solution in the dark, at room temperature, for as long as 8 hours.
- After adding AST Indicator Solution, if it is exposed to light, use the tubes within 2 hours.
- 3. Transfer 25 µL (50 µL if low inoculum option is used) of the bacterial suspension from the ID tube to two BD Phoenix AST broth tubes. Cap and gently invert. Wait a few seconds for air bubbles to surface. Tap the tube gently to aid in eliminating bubbles.

#### **NOTE**

Inoculate panels within 30 minutes of the time that the AST broth inoculum is prepared.

- 4. Using sterile technique, remove 3.5 mL of broth from one of the inoculated BD Phoenix AST broth tubes and discard in an appropriate container.
- 5. Pour the remaining 4.5 mL into the left side of the BD Phoenix Emerge panel. Allow the fluid to traverse down the tracks before moving the panel. Pour the other BD Phoenix AST broth tube into the right side of the BD Phoenix Emerge panel. Allow the fluid to traverse down the tracks before moving the panel.
- 6. Follow steps 18–20 in **General Panel Preparation**. Follow the normal panel login procedure.

## OPTION 2: BD Phoenix Emerge AST Broth (12.5 mL) and BD Phoenix Emerge AST Indicator are required.

1. Follow Steps 1–10 (**General Panel Preparation**) to prepare the suspension of bacteria.

#### **NOTE**

For MIC only and Emerge panel set up, Inoculum broth (2.2 mL) can be utilized in place of ID Broth (4.5 mL) in Steps 4, 5, and 9 (see Section 4.4.6 Using BD Phoenix Inoculum Broth)

2. Label a BD Phoenix Emerge AST Broth tube (12.5 mL) with the patient's specimen number. Add one free-falling drop of BD Phoenix Emerge AST indicator into the Emerge AST Broth (12.5 mL). Cap the Emerge AST broth tube and invert to mix. DO NOT VORTEX.

#### **NOTE**

- Allow AST Indicator Solution to warm to room temperature before dispensing into AST broth.
- Return the unused portion of the indicator to 2–8 °C as soon as possible. Do not store at room temperature for more than 2 hours. Opened bottles should be discarded after 14 days from initial opening.
- If volume other than one drop is added inadvertently, discard the tube and use a fresh tube of AST broth.
- After adding the indicator to AST broth, store the mixed solution in the dark, at room temperature, for as long as 8 hours.
- After adding AST Indicator Solution, if it is exposed to light, use the tubes within 2 hours.
- 3. Pipette 39.1  $\mu$ L of the prepared 0.5–0.6 bacterial suspension from the ID tube using an adjustable pipettor and sterile tip, to the BD Phoenix Emerge AST broth with indicator.

#### **NOTE**

Inoculate panels within 30 minutes of the time that the AST broth inoculum is prepared.

- 4. Cap the Emerge AST broth tube and invert several times to mix. DO NOT VORTEX. Wait a few seconds for air bubbles to surface. Tap the tube gently to aid in eliminating bubbles.
- 5. Pipette 4.5 mL of inoculated AST broth using an appropriate pipettor and sterile tip and insert into the 51-well side (left hand side) of the BD Phoenix Emerge panel. Allow the fluid to traverse down the tracks before moving the panel.
- 6. Aseptically pour the remaining inoculated Emerge AST broth into the 85-well side (right hand side) of the BD Phoenix Emerge panel. Allow the fluid to traverse down the tracks before moving the panel.
- 7. Follow steps 18–20 in **General Panel Preparation**. Follow the normal panel login procedure.

### 4.4.6 Using BD Phoenix Inoculum Broth

BD Phoenix Inoculum Broth can be used to make the initial McFarland suspension of microorganisms when utilizing BD Phoenix MIC only panels (PMIC, NMIC, SMIC). The BD Phoenix Inoculum Broth is filled with 2.2 mL of BD Phoenix ID Broth and will reach the correct inoculum density by using fewer bacterial colonies.

- 1. Follow Steps 1–10 (described in **General Panel Preparation**) to prepare the suspension of bacteria using the BD Phoenix Inoculum Broth rather than the BD Phoenix ID Broth.
- 2. Label a BD Phoenix AST broth tube (8.0 mL) with the patient's specimen number.
- 3. For NMIC and PMIC panels, add one drop of the BD Phoenix AST Indicator to the BD Phoenix AST broth tube.
- 4. For SMIC panels, add one drop of the BD Phoenix AST-S Indicator to the BD Phoenix AST-S broth tube.
- 5. Invert to mix. DO NOT VORTEX.
- 6. Transfer 25  $\mu$ L (50  $\mu$ L if low inoculum option is used) of the BD Phoenix Inoculum Broth suspension to the BD Phoenix AST or AST-S tube(s).
- 7. Follow Steps 14–20 (described in **General Panel Preparation**). Follow the normal panel login procedure.

### 4.4.7 Quality Control

Refer to the panel package insert for information on ID/AST Quality Control. Note that QC panels cannot be marked as critical. Refer to Figure 4-3.

Quality Control testing is recommended for each lot of panels. The QC Lot Support feature can facilitate QC panel tracking and testing. If the QC Lot Support feature is enabled, then the panel lot number must be defined prior to logging in QC panels.

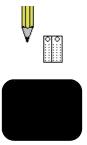
 Inoculate a panel with one of the organisms listed in the package insert. All microbial cultures, including QC organisms, are potentially infectious and should be treated with universal precautions. QC organisms are prepared for panel inoculation as specified in Section 4.4 Preparing Panels, immediately preceding this section.

#### NOTE

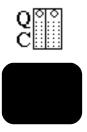
For most reliable results, it is recommended that the QC organisms be subcultured at least twice on two consecutive days onto TSA with 5% Sheep Blood agar before use in the BD Phoenix system. Use only well-isolated colonies.

For Yeast ID QC, the use of Sabouraud Dextrose Agar as the subculture media is also acceptable.

- 2. Log the panel in as a QC panel as follows:
  - a. Press the "panel login" soft key.



b. Press the "QC panel" soft key.



- c. In the **Sequence #** field, type in or scan the panel's sequence number.
- d. If desired, in the **Accession #** field, type in or scan an accession number. Press T to advance to the next field.
- e. If a combination panel is being used, both the ID and AST checkboxes are automatically checked (enabled).

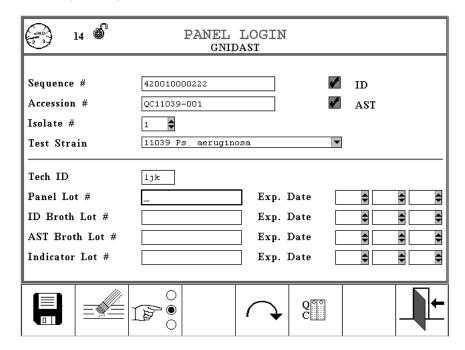


Figure 4-3 – QC Panel Login Display

For Yeast ID panels, the Media field appears to the right of the Isolate # field.

- f. The **Isolate** # field defaults to isolate number 1. Type in the isolate number, or press UP ARROW or DOWN ARROW to increase or decrease the number. Valid isolate numbers are 1 to 20. Press T to advance to the next field.
- g. For Yeast ID panels, a media type must be specified in the **Media** field. If a media type is not specified, a workflow error will be generated when an attempt is made to save the panel. If a Yeast ID panel is not logged in before placing it in the instrument for testing, the panel aborts after the first reading because no media has been specified.
  - A default media type can be configured (see 2.3.1.2 More Configuration Options), which appears when a Yeast ID panel sequence number is scanned during login.
  - To select a different media, press DOWN ARROW to drop down a box listing all media types (abbreviations), sorted alphabetically. (When the media type is highlighted, the full name appears at the top right of the display.) Use UP ARROW or DOWN ARROW to highlight the desired media. Press the "select" soft key or J to select that media.
- h. In the **Test Strain** field, press DOWN ARROW to drop down the QC organism selection box. (Only the predefined, required test strains appear [if available], otherwise all of the test strains appear. If a Sequence number has not been entered, "No Data Available" is displayed.) Use UP ARROW or DOWN ARROW to highlight the desired QC organism. Press J to select the organism. Press T to advance to the next field.
- i. In the **Tech ID** field, enter the identification for the technologist performing the QC test. Up to 3 alphanumeric characters are accepted. Press T to advance to the next field.

#### The following two fields do not appear when BD EpiCenter communications is enabled.

- j. In the **Panel Lot #** field, type in or scan the panel's lot number. Lot numbers must be 7 numeric digits. Press T to advance to the next field. (If the QC Lot Support feature is enabled, this field is completed automatically when the Sequence # barcode is scanned.)
- k. In the first Panel Lot # Exp(iration) Date field, press UP ARROW or DOWN ARROW to enter the expiration day, month, or year (depending on the configuration). Press T to advance to the next date field and press UP ARROW or DOWN ARROW to enter the expiration day, month, or year. Press T to advance to the next date field, and press UP ARROW or DOWN ARROW to enter the final portion of the date. (If the QC Lot Support feature is enabled, this field is completed automatically when the Sequence # barcode is scanned.)
- I. If desired, in the **ID Broth Lot #** field, type in or scan the broth lot number. Lot numbers must be 7 numeric digits. Press T to advance to the next field.
- m. If desired, in the first **ID Broth Lot # Exp**(iration) **Date** field, press UP ARROW or DOWN ARROW to enter the expiration day, month, or year (depending on the configuration). Press T to advance to the next date field and press UP ARROW or DOWN ARROW to enter the expiration day, month, or year. Press T to advance to the next date field, and press UP ARROW or DOWN ARROW to enter the final portion of the date.
- n. If desired, in the **AST Broth Lot #** field, type in or scan the broth lot number. Lot numbers must be 7 numeric digits. Press T to advance to the next field.
- o. If desired, in the first **AST Broth Lot # Exp**(iration) **Date** field, press UP ARROW or DOWN ARROW to enter the expiration day, month, or year (depending on the configuration). Press T to advance to the next date field and press UP ARROW or DOWN ARROW to enter the expiration day, month, or year. Press T to advance to the next date field, and press UP ARROW or DOWN ARROW to enter the final portion of the date.
- p. If desired, in the **Indicator Lot #** field, type in or scan the broth lot number. Lot numbers must be 7 numeric digits. Press T to advance to the next field.

- q. If desired, in the first Indicator Lot # Exp(iration) Date field, press UP ARROW or DOWN ARROW to enter the expiration day, month, or year (depending on the configuration). Press T to advance to the next date field and press UP ARROW or DOWN ARROW to enter the expiration day, month, or year. Press T to advance to the next date field, and press UP ARROW or DOWN ARROW to enter the final portion of the date.
- r. Press the "save" soft key to save the information.



- 3. Place the panel in the instrument (refer to 4.6 Inserting Panels in the Instrument.
- 4. When panel testing is complete, review the results for accuracy in the panel results display (see Section 4.10 Obtaining Results).

## 4.5 Panel Login

### 4.5.1 Using the Instrument Interface

The Liquid Crystal Display (LCD) presents all the information needed to monitor instrument status, to enter and remove panels, set up the instrument, print reports, and perform routine instrument maintenance. The information is presented in the form of screens and icons that graphically represent the information (e.g., a thermometer indicates the current temperature). The top region of the main status display presents instrument status information that is updated every few seconds. The middle region of the display initially presents station status information. As different screens and functions are accessed, they appear in place of the top and middle status windows. At the bottom of the displays, a series of icons shows the current software (soft) key definitions. Display regions are discussed in greater detail in Section 5 – Reference.

Most of the operations that are performed at the instrument are initiated by pressing soft keys. Soft key definitions change as their related functions are selected and different displays and operations are accessed.

The keyboard can be used instead of the soft keys. The soft keys, from left to right, correspond to the keyboard function keys 1-8. The UP ARROW, DOWN ARROW, and TAB keys correspond to the same keys on the keyboard.

In addition to the soft keys, six hard keys, which are marked with screened icons, perform fixed functions regardless of the current display or operation. The LOAD PANELS key is used to prepare the instrument for loading panels for testing; UNLOAD PANELS key is used to remove panels from the instrument; SILENCE ALARM key quiets any audible alerts; the UP and DOWN ARROW keys are used to scroll through lists or to increase or decrease values; and the TAB key is used to move the cursor to the next field on a display. Pressing the SILENCE ALARM + UP ARROW keys together prints the current display.

### 4.5.2 Logging in Panels

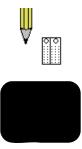
Depending on the type of panel selected, different fields appear on the Panel Login display. (For information on logging in QC panels, refer to 4.4.7 Quality Control.)

The inoculum density of the panel is set in Configuration. There is no way during Panel Login to change the density setting. The only way to use a different inoculum density is by blackening well A-17 as described in 4.4 Preparing Panels.

For Yeast ID panels (only), in order to insure optimal system performance, the correct media type must be provided via a drop-down box or by using the default media setting. The media type selection only applies to Yeast ID panels and is not displayed for other panel types.

Log the panel into the instrument as follows:

1. Press the "panel login" soft key.



- 2. In the **Sequence** # field, type in or scan the panel's sequence number.
- 3. In the **Accession #** field, type in or scan an accession number. Press T to advance to the next field (not required if barcode is scanned).
- 4. The **Isolate** # field defaults to isolate number 1. Type in the isolate number, or press UP ARROW or DOWN ARROW to increase or decrease the number. Valid isolate numbers are 1 to 20. Press T to advance to the next field. (An isolate number if must be entered if an accession number is entered.)
- 5. For Yeast ID panels, a media type must be specified in the **Media** field. If a media type is not specified, a workflow error is generated when an attempt is made to save the panel. If a Yeast ID panel is not logged in before placing it in the instrument for testing, the panel aborts after the first reading because no media has been specified.

A default media type can be configured (see 2.3.2.1 Organism Configuration), which appears when a Yeast ID panel sequence number is scanned during login.

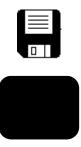
To select a different media, press  $\blacktriangledown$  to drop down a box listing all media types (abbreviations), sorted alphabetically. (When the media type is highlighted, the full name appears at the top right of the display.) Use  $\blacktriangledown$  or  $\blacktriangle$  to highlight the desired media. Press the "select" soft key or J to select that media.

- 6. To receive special notification (audible alarm and/or automatic printing of a Lab Report) when panel results are obtained (ID only, partial, or complete), press the "select" soft key to check the **Critical** checkbox. More information about critical panels is provided in Section 2.3.5.
- 7. If either the ID or AST portion of a combination panel only is being used, press the "tab" key to advance the cursor to the ID or AST checkbox. Press the "select" soft key to UN-check the part of the panel that is not being used.

8. If the **ID** checkbox is unchecked, or if you are using an AST-only or BD Phoenix Emerge panel, the **Organism ID** field appears. If the system is not performing the organism identification, you must provide the organism ID for SIR interpretation. (If an AST panel is being tested and you do not enter an organism ID, the panel will go to "Needs Attention" when the instrument completes reading. An organism ID must be provided in order for the BDXpert system to interpret MIC results.)

Press DOWN ARROW to select the desired organism from the drop-down box. Organisms are listed in alphabetical order. Enter the first few characters of the organism name to jump to that portion of the list quickly. Use UP ARROW or DOWN ARROW to highlight the desired organism. Press the "select" soft key or J to select the organism. The desired organism can also be scanned from the barcode list of organisms found in the Quick Reference Guide.

9. Press the "save" soft key to save the information.



10. Place the panel in the instrument (refer to 4.6 Inserting Panels in the Instrument).

The following soft key functions can be performed from Panel Login:



"save" - saves the information displayed



"clear" - clears the record currently displayed from the screen



"select" – checks/unchecks a checkbox field or selects highlighted item in drop-down list box



"QC panel" - brings up fields needed to login a QC panel



"repeat data" – enters the last accession number and media type for panels, or media type and lot information for QC panels as follows: if QC Lot Support is disabled (Panel Lot plus Expiration, ID Broth Lot plus Expiration, AST Broth Lot plus Expiration, Indicator Lot plus Expiration), if QC Lot Support is enabled (ID Broth Lot plus Expiration, AST Broth Lot plus Expiration, Indicator Lot plus Expiration)



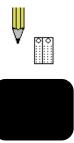
"LIS Orders" – brings up a window showing any order records that have been received from the LIS system (see Section 4.5.3 for more information)

### 4.5.3 Associating and Removing LIS Orders

The BD Phoenix instrument can save up to 200 Order records sent from an attached LIS system. These Order records can be accessed through a Panel Login – LIS Orders display. The LIS Orders display is accessible from the main Panel Login display via a soft key.

#### To access the LIS Orders display:

1. From the Main Status screen, press the "panel login" soft key.



- 2. Type in or scan the panel sequence number. (When a sequence number is entered, the system displays only LIS orders containing that panel type.)
- 3. Uncheck the ID or AST checkbox to disable that portion of a Combination panel, if desired.
- 4. From the Panel Login screen, press the "LIS Orders" soft key.



- 5. The LIS Orders display appears (Figure 4–3).
- 6. In the LIS Orders field, press ▼ to drop down a box listing LIS order records for that panel type, sorted alphabetically by accession number. The box lists the following information: accession number, isolate number, and organism or test strain (if available). Note that critical panels are shown in red text in the dropdown box.
- 7. Use ▼ or ▲ to highlight the Order record to be associated to the panel. Press the "select" soft key or J to select that Order.
- 8. Press the "save" soft key to save the association. The LIS order is then removed from the LIS Order list.

#### **Removing LIS Orders**

To remove one or more LIS Order records from the LIS Order list, you can access the Remove LIS Orders window. This window lists all the LIS Orders by panel type. Order records are first marked, then deleted via soft key functions.

To remove LIS order records:

**+** [LIS

From the LIS Orders window, press the "more LIS functions" soft key

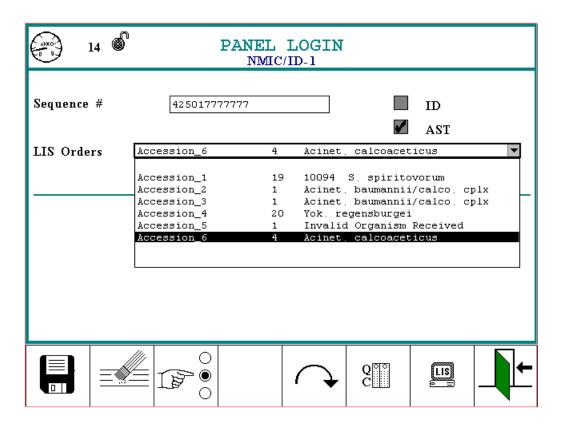


Figure 4-4 - Panel Login - LIS Orders Display

The Remove LIS Orders window appears

Use UP ARROW and DOWN ARROW to highlight individual order records to delete, then press the "mark for deletion" soft key

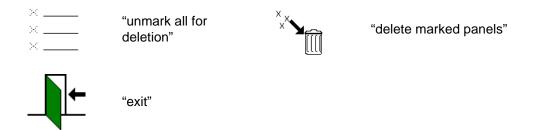
To mark all records, press the "mark all for deletion" soft key

Press the "delete marked panels" soft key to delete the orders

Press the "exit" soft key to exit the window

Remove LIS Orders soft keys:

×		×	
	"mark for deletion"	×	"mark all for deletion"
×		X	



## 4.6 Inserting Panels in the Instrument

Panels are inserted with the reaction (and panel sequence barcode label) side facing the interior of the instrument. Refer to Figure 4-5 – Inserting Panels.

#### **WARNING**

- THE INSTRUMENT DOOR IS ELECTROMECHANICALLY LATCHED AND IS CONTROLLED BY THE INSTRUMENT SOFTWARE.
- NEVER ATTEMPT TO DEFEAT THE DOOR LATCHING MECHANISM, OR TO OPEN THE DOOR WHEN THE DOOR LOCKED ICON IS DISPLAYED.
- IF THE CAROUSEL IS NOT COMPLETELY STOPPED WHEN THE DOOR IS OPENED, IMMEDIATELY CONTACT BD FOR SERVICE. NEVER ATTEMPT TO ROTATE THE CAROUSEL MANUALLY OR SERIOUS INJURY MAY RESULT.
- 1. Press the LOAD PANELS key.



2. When the audible signal sounds (and "door unlocked" icon appears), open the instrument door.



- 3. Select a panel holder where there is no panel in place and no LEDs are illuminated. Place the bottom part of the panel in the panel holder.
- 4. Press downward.

5. Pivot the top of the panel back into the panel holder.

#### **NOTE**

Do not snap the panel back into the holder. This may result in splashing of the inoculum, which may cause inaccurate results.

- 6. Allow the panel to move upward into place.
- 7. Close the instrument door. If more panels need to be inserted than there are available holders in the current section, wait for a moment for the carousel to rotate to provide additional available holders, and repeat Steps 2 through 7.
- 8. The system performs an inventory scan to locate any newly inserted panels and reads the barcodes of these panels.

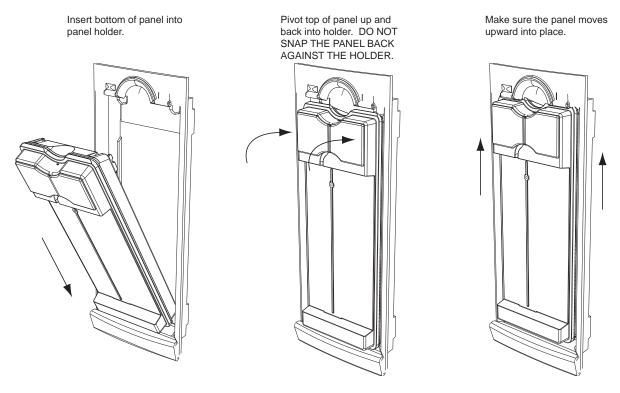


Figure 4-5 - Inserting Panels

#### **NOTE**

Check to see if panel closure fits properly before closing the door, as this may lead to jamming of the carousel.

## 4.7 Panel Testing

Panels placed in the instrument are continuously incubated at 35 °C. The instrument tests panels every 20 minutes: on the hour, at 20 minutes past the hour, and again at 40 minutes past the hour.

Before each test cycle the current time is read. If the test cycle completes successfully the time is saved. A successful test cycle occurs when there are no carousel errors and the user does not preempt the test by initiating a Load Panels, Unload Panels, or Locate Panel operation. When the user initiates these operations, the current time is compared to the last test cycle's start time. If more than 30 minutes have NOT elapsed, the requested operation (Load Panels, Unload Panels, etc.) is performed. If more than 30 minutes HAVE elapsed since the last test cycle's start time, a test cycle must successfully complete before the user is permitted to perform a Load Panels, Unload Panels, or Locate Panel operation. The system alert/door unlocked LED is also off (if a system alert is not active) and the "cannot get into instrument" tone sounds when more than 30 minutes has elapsed since the last test cycle when a panel operation is requested.

#### After each test:

- The summary counters on the Main Status Screen are adjusted to indicate current statuses
- Panels/records that require user action have a Needs Attention flag set
- System alerts are reported in the System Alerts list
- Auto Association occurs (see 4.9 Automatic Association of Panels).

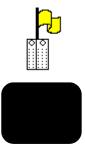
The LCD screen displays an icon to indicate when a panel test is taking place.



The number next to the icon indicates the number of minutes remaining in the test cycle.

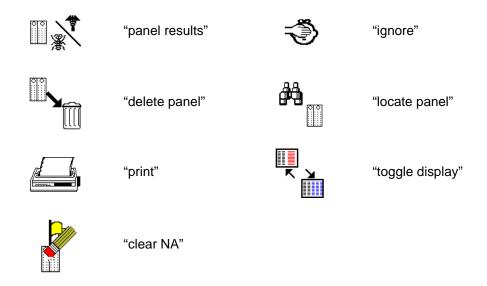
## 4.8 Responding to Needs Attention Panel

As system operation progresses, some panels may enter a state where they are flagged as needing attention. Usually, some action can be performed to correct the situation. In some cases, the condition warrants careful review of the panel's results. A listing of "Needs Attention" panels can be accessed by pressing the "needs attention" soft key on the Main Status Screen.



The Needs Attention display lists the first 30 panels with a Needs Attention flag, sorted by reason code (in the same order as the list above) and then by accession number within each reason code. Panels without an accession number are listed first within each Needs Attention reason code. Note that even after panels have been removed from the Needs Attention list, the highest priority reason code in the Panel Results display can still be viewed.

Depending on the Needs Attention reason, the following soft keys (and associated keyboard key) can be used in some cases to resolve the condition.



These soft keys are designed to enable (whenever possible) correction of the condition causing the panel to need attention. Where it is not possible, other resolutions are provided via soft keys.

"Panel Results" displays the Panel Results screen, where the Needs Attention code may be able to be corrected by adding information to the panel record.

"Ignore" does not correct the Needs Attention reason code, but it informs the system that the problem has been acknowledged by the user.

"Delete panel" displays Panel Results screen where the panel can be deleted.

"Locate panel" causes the carousel to rotate to the panels location and lights the station where the panel resides.

"Print" enables a Needs Attention List report to be printed. The report is filtered if that view is selected, or unfiltered if that view is selected.

"Toggle display" switches the display between filtered on highest priority reason (the default view) and unfiltered display (showing all needs attention reasons listed separately). When the list is filtered, only the highest priority needs attention condition is shown in the list. Panels are shown in blue if additional needs attention conditions exist for that panel.

"Clear NA" clears the Needs Attention condition

#### To resolve panels that need attention:

- 1. Access the Needs Attention display.
- 2. Refer to 5.11 Needs Attention and the chart below for detailed information on the particular needs attention reason.
- 3. Press the appropriate soft key to access Panel Results (to add or modify information), delete the panel, ignore or clear the reason, or to find the panel in the instrument.

Condition	Meaning	Possible Cause(s)	Resolution(s)	Action
Test aborted	A condition occurred which caused the panel to be invalid	Ongoing panel not tested for more than 1 hour     Instrument turned off for more than 1 hour     Instrument door open more than 1 hour     Panel moved to a different tier/instrument     Incubator temperature too high or too low     System software did not execute testing algorithms for more than 1 hour     Media type not specified for Yeast ID panel	Delete the panel     Repeat testing	Active soft keys: "ignore" "locate panel" "delete panel"
Cannot identify barcode	Internal barcode scanner could not read a panel barcode in a station where the instrument could determine that a panel was present	Barcode label obscured or missing     Unknown panel type was placed into the instrument	Locate the panel in the instrument and examine the barcode  If the barcode is obscured, the panel must be discarded and another inoculated  If the barcode appears to be intact, replace the panel and close the door. After the next inventory, check the Panel Needs Attention screen. If the panel does not appear, the internal scanner can now read the panel	Active soft keys: "ignore" "locate panel"
Cannot read panel wells	Internal barcode scanner has read a sequence number in a station but the instrument does not detect that a panel is present in that station	Panel not seated properly	Locate panel, remove it and replace it, as above	Active soft keys: "locate panel" "delete panel"
Panel lot expired	A panel was logged in (or has a test start date) with a panel lot number that has already expired	Panel being logged in or placed in the instrument is from an expired lot	Discard panel, reinoculate isolate using unexpired panel lot	Active soft keys: "ignore" "clear NA"
Invalid AST results	At least one MIC cannot be interpreted. (Excludes QC panels.)	Refer to Table 5–1	Repeat testing of the antibiotic that cannot be interpreted	Active soft keys: "ignore"
Panel missing	Internal barcode scanner read a sequence number on an Ongoing panel, but the panel is missing	Panel removed before the test was completed     Internal scanner failure and the sequence number can no longer be read	If the panel is replaced on the same tier within 1 hour after removal, testing will resume. If the panel is not replaced, testing will abort	Active soft keys: "ignore" "delete panel"
No growth on panel	No growth in growth control well. (Excludes ID only and QC panels.)	Instrument did not detect growth in the growth control well of the panel	Subculture the organism (to insure that it is viable) and inoculate a new panel. Panel has been aborted     From the Needs Attention screen delete or ignore the panel	Active soft keys: "ignore" "locate panel" "delete panel"
Panel Lot Undefined	A panel has been entered whose lot number is undefined (non QC panel)	Panel is from an undefined lot	Define panel lot or ignore	Active soft keys: none to address condition
Review QC results	Status of a completed QC panel is "Review"	QC panel which yielded an incorrect ID or incorrect AST result for at least one antibiotic, or has no growth in growth control well	Repeat QC organisms. Check: culture purity, inoculum density	Active soft keys: "panel results" "ignore" "locate panel" "delete panel"

Condition	Meaning	Possible Cause(s)	Possible Cause(s) Resolution(s)	
Missing accession number	Panel is missing accession or isolate information. (Orphan panel.)			Active soft keys: "panel results" "locate panel"
Missing organism ID	Panel has no organism ID. (ID required to determine SIR results. Excludes QC panels.)	For AST only panel, no ID has been entered     The panel has an unresolved tie or triplet instrument ID and has no related panel with an ID	Key in the organism ID (cursor will be at the ID field and the field will be highlighted). OR open the drop down box by pushing the DOWN ARROW key and keying in the first letters of the organism name. The list scrolls to those letters in the organism list. Press the "select" soft key to select the highlighted organism. Any BDXpert rules triggered by the given ID will automatically be presented at this point. Select or ignore the rules. When completed, push the "exit" key to see complete test results.	Active soft keys: "panel results"
Cannot determine organism ID	Panel has an Instrument ID of "No identification" or has a related panel with "No identification" as a final ID	Panel has been in test for 12 hours and the instrument cannot determine the identification	and the instrument cannot  • Inoculum density • Correct panel used?	
Invalid organism ID	Organism ID is not in BD Phoenix database	Panel received download information of an organism ID that is not in the BD Phoenix database		Active soft keys: "panel results" "ignore"
Organism ID conflict	Panel completes testing and has at least one related un- finalized panel that contains a different Final ID. Excludes QC panels.	Completed panel has at least one related panel that contains a different ID.	Select "Panel Results" soft key and choose an organism. Selecting the organism may trigger BDXpert rules. If the rules are configured as manual, the "BDXpert" soft key appears.	Active soft keys: "panel results"
BDXpert Rule flagged	Panel triggered at least one BDXpert rule and the rule is manually enabled in Configuration.	A BDXpert rule needs to be invoked in order to determine AST results. A panel is flagged if BDXpert rules are configured as enabled/manual. (Rules that are configured as enabled/automatic will automatically "trigger" and the panel will not be displayed in Needs Attention.	Each Expert rule is displayed individually, in sequence. To accept the rule, press the "OK" soft key; to reject the rule press the "reject" soft key.  Use the "Refresh" soft key to delete BDXpert system "decisions" and start over.  When all rules have been displayed and dispositioned, complete AST results show.  After all rules have been invoked, press "Special Messages" soft key (if present) to view Special messages about characteristics of the organism.	Active soft keys: "panel results"
Pending too long	Panel has not been scanned (during an inventory count) within 30 minutes of logging in Panel Login.	Panel was logged into the instrument but was not placed in the instrument within 2 reading cycles (approximately 30 minutes).	Repeat testing.  Delete the panel.	Active soft keys: "ignore"

**Table 4-2 – Needs Attention Resolution** 

## 4.9 Automatic Association of Panels

#### 4.9.1 Overview

The purpose of Automatic Association of Panels is to associate ID results from one panel (an ID or Combination panel) to the AST panels that are related to it and that lack an ID. Panels are related by virtue of having the same accession and isolate number. Thus panels with the same accession number and different isolate numbers are NOT related, and Auto Association does not occur between such panels.

Auto Association often involves the initial stage of Organism ID Conflict Checking. Conflict Checking is the process where the system verifies that the panel which has triggered the process does not have a related panel with a Final ID that is different from its own. If there is a conflict, Auto Association does not occur between related panels. The circumstances where Conflict Checking occurs are described below.

Auto Association can help eliminate unnecessary work such as the need to manually enter an organism ID for related panels. In addition, the Conflict Checking function helps to ensure that the same organism ID is made for all the panels related to a patient specimen. Auto Association does not set the critical panel attribute for related panels.

## 4.9.2 Panel Types

The panel types whose ID information is associated to related panels are:

- ID panels
- Combination panels (with both ID and AST sides enabled)
- Combination panels with only the ID side enabled

Auto Association uses the Final ID.

The related panels whose IDs are set by Auto Association are:

- AST panels
- Combination panels with only the AST side enabled

#### 4.9.3 When Auto Association Is Not Performed

Auto Association is NOT performed in the following circumstances:

- When an organism ID conflict exists within an accession/isolate
- To a related AST panel that has been finalized or deleted, or that already has a Final ID
- Between related ID-type panels
- Between related AST-type panels
- Between related QC panels

If the Instrument ID field contains a Tie/Triplet, this information is not associated to any related AST panels, however the Final ID information IS auto associated

## 4.9.4 Organism ID Conflict Checking

Organism ID Conflict checking is performed using the Final ID for panels within the same accession/ isolate (i.e., related panels) that are not finalized (and are not QC panels). If both panels have a Final ID (both are not blank) and they do not match exactly, an Organism ID Conflict is considered to exist. When an Organism ID Conflict exists, no Auto Association is performed. All the panels involved in the conflict have a Needs Attention flag set indicating that there is an organism conflict. Once the conflict is resolved (and provided that all other conditions for Auto Association are met), then Auto Association does occur.

Note that Organism ID Conflict checking is not performed on QC panels.

#### 4.9.5 Auto Association and Related Actions

The trigger events that invoke Auto Association include: an ID or Combination panel status transitioning to Removable or accession/isolate information being modified. If there are no unresolved tie/triplet conditions and no Organism ID Conflicts exist:

- 1. The instrument searches for the first *unfinalized* related ID or Combination panel with a Final ID. If a panel with these criteria is found, the instrument performs Auto Association.
- If a panel with the above criteria is not found, the instrument then searches for the first finalized related ID or Combination panel. If a finalized panel is found, the instrument performs Auto Association.
- If there are related ID panels with no Final ID when an AST panel invokes Auto Association (and no Organism ID Conflict condition exists), the instrument sets a Missing Organism ID Needs Attention reason for the AST panel if its status is Removable.
- 4. Auto Association is performed for any related AST panels that do not have information in their Final ID fields if the AST panel's status is either ongoing or Removable (Auto Association is not performed on AST panels with a status of Pending).
- 5. Auto Association is the action of modifying an AST panel's Final ID field (when this field is blank) to contain the same information as a related ID panel's information.
- 6. The instrument ID information is only associated provided it is a single Organism ID and not a Tie/Triplet condition.
- A Combination panel with both sides enabled uses its ID result to perform interpretations on the AST side of the panel.
- 8. When Auto Association is performed successfully, any existing Missing Organism ID Needs Attention reasons are automatically cleared from the AST panels.

## 4.9.6 Typical Auto Association Examples

#### **Instrument ID Is Associated**

ID and AST panels are logged with the same Accession/Isolate number. (The AST panel is not logged in with an Organism ID.) They are both placed into the instrument at the same time. The ID panel finishes testing. The panels look like the following:

Panel	Instrument ID	Final ID
ID	Org A	Org A
AST	_	_

When the ID panel has completed testing, it looks for related panels. It sees the AST panel with no Final ID. The ID panel checks for Organism ID Conflicts. There is no Organism ID Conflict condition, so the ID panel associates its Instrument ID to the AST panel record's Instrument ID field (regardless of the AST panel's status). The panels look like the following:

Panel	Instrument ID	Final ID
ID	Org A	Org A
AST	Org A	Org A

#### Instrument ID and Final ID Are Associated

The ID panel is logged in with an Accession/Isolate number. It is placed into the instrument to test. It completes testing and looks like the following:

Panel	Instrument ID	Final ID	
ID	Org A	Org A	

The user changes the Final ID for this panel. It now looks like the following:

Panel	Instrument ID	Final ID
ID	Org A	Org B

The user then logs in an AST panel with the same Accession/Isolate number as the ID panel. (The AST panel is not logged in with an Organism ID.) The AST panel completes testing and looks for related panels. It sees the ID panel and checks to make sure that there is no Organism ID Conflict within the Isolate. There is no Organism ID Conflict, so the AST panel associates the ID panel's ID to itself. The panels now look like the following:

Panel	Instrument ID	Final ID	
ID	Org A	Org B	
AST	Org A	Org B	

#### Final ID Is Associated

An ID panel is logged in with an Accession/Isolate number. The panel is placed in the instrument to test. The ID panel finishes testing first with a Tie /Triplet condition. When this situation occurs, the panel looks like the following:

Panel	Instrument ID	Final ID
ID	Org A	_
_	Org B	_
_	Org C	_

When the Tie/Triplet is resolved (by the user selecting one of the organisms listed or another organism), the ID panel will look like the following:

Panel	Instrument ID	Final ID
ID	Org A	_
-	Org B	_
-	Org C	Org A

The user then logs in an AST panel with the same Accession/Isolate number as the ID panel. (The AST panel is not logged in with an Organism ID.) The AST panel completes testing and looks for related panels. It sees the ID panel and checks to make sure that there is no Organism ID Conflict within the Isolate. There is no Organism ID Conflict, so the AST panel associates the ID panel's Final ID to itself. The panels now look like the following:

Panel	Instrument ID	Final ID
ID	Org A	_
-	Org B	_
-	Org C	Org A
AST	_	Org A

# 4.10 Obtaining Results

The primary means of viewing results of panel testing is the Panel Results display. Panel Results enables the following functions:

- display a panel whose data is stored in the BD Phoenix database
- · modify the information for a panel that is resident in the database
- mark a panel as critical
- print a Lab report on any panel that can be recalled or displayed on the screen
- locate a panel resident in the same instrument where the panel data is recalled
- delete panel information from the BD Phoenix database
- answer or display any triggered BDXpert Rules
- display any special messages
- · finalize a panel

The Panel Results display can be accessed in several different ways:

- scanning a known panel sequence number or accession number with the external scanner while the Main screen is displayed
- selecting the "panel results" soft key (or its keyboard equivalent) from the Main Status Screen



- scanning or entering a known panel sequence number while the Panel Login screen is displayed
- selecting the "delete panel" soft key (or its keyboard equivalent) or the "panel results" soft key (or its keyboard equivalent) for a panel in the Needs Attention screen when the Delete option is active
- selecting the "panel results" soft key (or its keyboard equivalent) from the Batch Finalization screen
- selecting the "panel results" soft key (or its keyboard equivalent) from the Panel Inventory or Panel Lot Definition displays

Typical Panel Results displays are shown in Figure 4-6 and Figure 4-7.

When a panel is recalled in the Panel Results screen, the following fields are displayed (note that all fields may not be displayed depending on the type of panel and whether the instrument is connected to a BD EpiCenter system):

- Accession Number
- Sequence Number
- Isolate Number
- Media
- Status
- Final ID (Test Strain for QC Panel)
- Panel Lot # (if QC Lot Support feature is enabled)
- (Panel Lot) Expiration Date (if QC Panel, and QC Lot Support feature is enabled)
- Test Start
- Test End
- Location
- Finalized Status (QC Status for QC Panel)
- Critical Status
- Needs attention flag
- Resistance marker flag
- Instrument Organism ID which may consist of:
  - Instrument Organism ID
  - Confidence Value
  - Up to 5 Supplemental Tests
- Biochemical Results (Figure 4–5) which consist of:
  - Biochemical Abbreviation
  - Actual Result (+, -, ?, or X)
  - Expected Result (+, -, V, or blank)
- AST Results (Figure 4–6) which consist of:
  - Antimicr(obial)
  - Minimum Inhibitory Concentration (MIC)
  - Instrument SIR (I)
  - BDXpert SIR (E)
  - Final SIR Result (F)

#### And for QC panels:

- Tech ID
- Panel Lot # and Exp. Date
- ID Broth Lot # and Exp. Date
- AST Broth Lot # and Exp. Date
- Indicator Lot # and Exp. Date

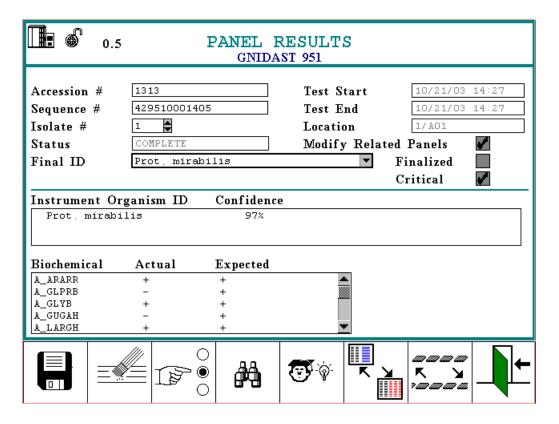


Figure 4-6 - Panel Results Display - ID Results

For Yeast ID panels, the Media field appears to the right of the Isolate # field.

The following icons signify the conditions noted:



A Needs Attention reason exists



A Resistance Marker has triggered

The following soft key functions can be performed from Panel Results:



"save" - saves the information displayed



"clear" - clears the record currently displayed from the screen



"select" – checks/unchecks a checkbox field or selects highlighted item in drop-down list box

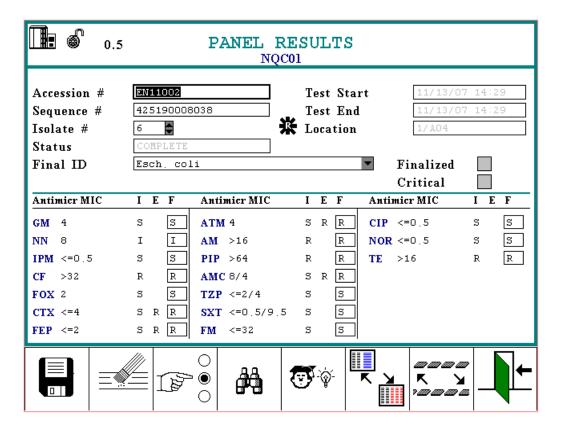


Figure 4-7 - Panel Results Display - AST Results



"find" – recalls the data for the accession # entered (or the panel results list display if there is more than one panel for the accession)



"toggle display" – switches between ID results, AST results, and Resistance Marker displays (if applicable) for combination panels



"toggle soft keys" – switches between the currently displayed set of soft keys and additional ones



"print Lab Report" – prints a copy of the Lab Report for the current panel



"locate panel" – causes the instrument to locate and indicate the current panel and unlock the door



"delete panel" - removes the current panel from the database



"go to BDXpert Rules" – accesses the BDXpert Rules Triggered display



"more antimicrobials" – displays additional antimicrobials if there are more than can be displayed on one screen



"special messages" - accesses special messages display



"exit" - exits the current display

# 4.10.1 Adding/Modifying ID Results

The system enables an organism ID to be entered manually, or the organism identified by the instrument to be overridden. In addition, in some cases, the system will not be able to make a single identification determination based on panel results. In these cases, two or three organisms may appear in the Instrument ID field. When more than one organism appears as the Instrument ID, the system does NOT automatically enter an identification in the Final ID field. The user must select the desired organism. The actual organism may be determined either through supplemental tests, which are recommended in the Instrument ID window and/or the Special Messages display (accessible via the "special messages" soft key, shown above), or through other tests performed.

#### To add/modify the Final ID:

- 1. From the Panel Results display, press the "tab" soft key to advance to the Final ID field.
- 2. Press the DOWN ARROW key to drop down the listing of organisms.
- 3. Type the first few letters of the organism name to jump to that alphabetical part of the organism listing.
- 4. Use the UP ARROW or DOWN ARROW to highlight the desired organism.
- 5. Press the J or s key, or the "select" soft key to select the highlighted organism.

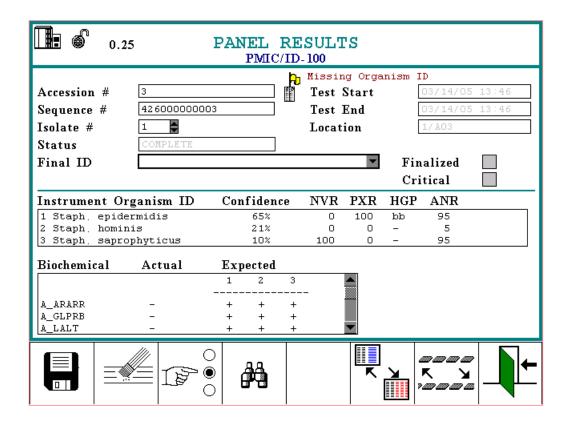


Figure 4-8 - Panel Results Display - ID Results Showing Triplets

# 4.10.2 Modifying AST Results

There may be times when the Final SIR results for a panel need modification. Note that any Final SIR results cannot be modified if there are manual BDXpert rules pending. The pending rules must first be accepted or rejected, which allows the system to perform its final results processing. After the final processing is complete, SIR results can be modified manually if desired.

#### To modify the Final SIR results:

- 1. From the Panel Results display, press the "tab" soft key to advance to the **Final SIR** field for the desired antimicrobial.
- 2. Press the DOWN ARROW to toggle the field entry among the following results:

S(usceptible)

I(ntermediate)

R(esistant)

X = Invalid, cannot interpret (see Table 5-1 – MIC/SIR Values and Causes)

N(ot Susceptible)\*

Blank (indicates ID is required)

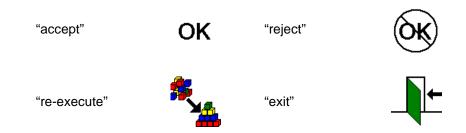
<sup>\*</sup> N indicates that the antimicrobial/organism does not have an upper breakpoint. When there is no upper breakpoint there are no criteria for calling an organism intermediate or resistant. This often occurs when there are no known resistant strains of an organism. In this case, if the MIC is below the lower breakpoint the SIR results can be reported as susceptible but if the MIC is above the lower breakpoint the only result that can be reported is N or not susceptible.

## 4.10.3 BDXpert Triggered Rules Display

By default, the BDXpert Rules are enabled and set to trigger automatically when test results are processed. However, there is an option in the BDXpert Rule Configuration to disable some rules (which means they would not be applied to results) or to set BDXpert rules to trigger manually. Any rules set to trigger manually must be accepted or rejected by the user before any additional rule processing or Final SIR determination occurs.

#### To access BDXpert Triggered Rules:

- 1. From the Panel Results display, press the "go to BDXpert rules" soft key to access the BDXpert Triggered Rules display.
- 2. The first pending rule is highlighted in the Rules (bottom left) window.
- 3. The effect of the rule on Final SIR values can be viewed in the AST Results (bottom right) window.
- 4. Press: the "accept" soft key to accept the pending rule; "cancel" to reject the rule; "re-execute" to cause all interpretation rules to be reapplied to the raw data; or "exit" to return to the Panel Results display.



# 4.10.4 Resistance Marker Display

If Resistance Markers have triggered on a particular panel, the "toggle display" soft key cycles from the AST results display to the Resistance Marker review display (Figure 4-9) to the ID results display.

The Resistance Marker review display shows the same information in the top window as the other two displays (ID and AST results). In the bottom window, the following information is shown:

- The BDXpert rule number that triggered the Resistance Marker
- The Resistance Marker code (abbreviation)
- The Resistance Marker Name
- The BDXpert rule Description

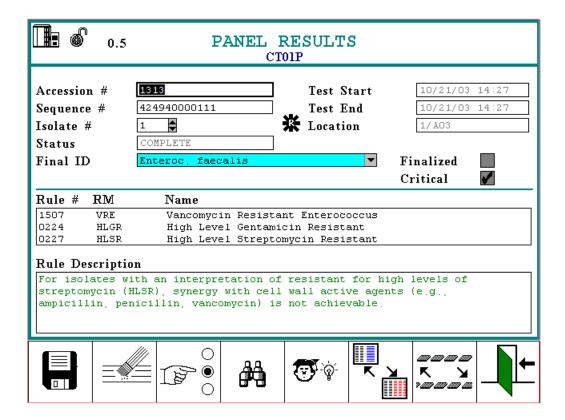


Figure 4-9 – Resistance Marker Review Display

# 4.11 Panel Finalization

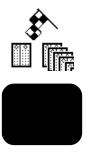
The panel finalization function enables finalization of panel test results in a single, or in a batch mode. Panel results can be finalized for all panels that are ready for finalization or for individual panels. Individual panel results can be reviewed prior to finalization.

All fields on the Finalization display are read-only. To *modify* information for a panel, press the "panel results" soft key.

When the instrument is connected to the BD EpiCenter Data Management System, the Finalization display is not available.

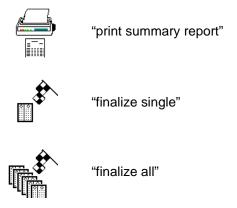
#### To finalize/batch finalize panels:

1. From the Main Status screen, press the "finalization" soft key. The Finalization display (Figure 4-10) appears.



if there are no panels to be finalized, only the "exit" soft key is available.

If there ARE panels to finalize, the following soft keys appear:



- 2. To finalize ALL eligible panels, press the "finalize all" soft key.
- 3. To finalize panels one at a time, press the "finalize single" soft key.

The first panel eligible for finalization is shown in the main body of the display. Press one of the following keys:

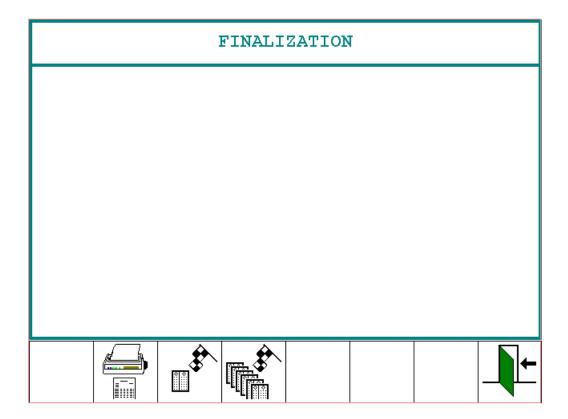
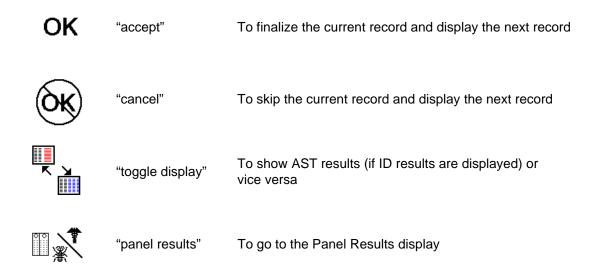


Figure 4-10 – Finalization Display



4. To print a summary report of all panels eligible for finalization, press the "finalization summary report" soft key. A sample is shown in Figure 4-11. This report shows the Accession # (primary sort), Isolate # (secondary sort), Test End date and time, Sequence #, Instr #/Station, and Finalized status (\* if finalized, blank if not).

Finalization Summary Report						
				08/15/	08/15/01 09:11	
Accession #	Isolate #	Test End	Sequence #	Instr # / Station	<u>Finalized</u>	
1313	1	08/15/01 13:13	420011234567	1/A02	*	
1344	1	08/15/01 13:13	420027654321	1/B03	*	
1489	1	08/15/01 13:13	420031234123	1/C04	*	
1566	1	08/15/01 13:13	420047654765	1/D05		
End of Report						
End of Report						

Figure 4-11 - Finalization Summary Report

- 5. If the Panel Results display is accessed to add or modify information before finalizing a panel, be sure to save the modifications. Press the "exit" soft key (from Panel Results) to return to the Finalize Single display.
- 6. Once an individual (or batch of) panel(s) has been finalized, the "print Lab Report" soft key appears on the Finalization display. This key enables you to print Lab Reports for all panels that have been finalized during this session (up to 200 maximum).



7. Continue to review panel records and finalize until no additional panel records are displayed.

# 4.12 Responding to Alarms and Errors

As activities are performed at the BD Phoenix instrument, and as testing progresses, system alerts and errors may occur. Different types of alerts and errors are flagged by one or more of the following: "E" and "W" error codes, audible tones, the System Alert icon appearing on the LCD display, or the instrument's System Alert indicator flashing. Generally, the more serious the condition, the more ways the system provides notification of the problem.

#### **CAUTION**

Immediately respond to the condition when the system displays alert and error notifications.

System alerts, which comprise all "E" type error codes, are reported in the system alert list. These errors cause: the system alert icon to appear on the Main Status screen; the System Alert indicator to flash; and the audible alarm to sound. They can be reviewed by pressing the "system alert" soft key (see below) and scrolling through the listing with the UP/DOWN ARROW keys. The errors must be reviewed to clear the system alert condition.



Activity errors comprise all "W" type error codes. These errors (such as attempting to enter an invalid Sequence # in the Panel Login screen) cause the activity error icon to appear on the currently displayed screen. They do not put the system into an alert condition. These errors can frequently be cleared by simply performing the activity correctly (such as entering a valid Sequence #).



All the "E" and "W" error codes are discussed in detail in Section 7.2 Error/Alert Messages. The audible tones are discussed in 3.8 Audible Tones and Alarms. The audible alarm can be silenced by pressing the SILENCE ALARM key, if the alarm is a "system alert" type of alarm.

# 4.13 Printing Reports

If a compatible printer is connected to the instrument, the following reports can be selected for printing (see Figure 4-12):

- Completed Lab Report contains information for all panels whose status became "Complete" during the selected time period (up to the past 48 hours).
- Accession Lab Report provides information for a specified accession number.
- Needs Attention List Report lists all panels in the instrument's database that have a Needs Attention flag set that have not been ignored.
- Resident Panel Report lists the panels contained in stations 1–25 for each tier.
- QC Lab Report lists all Test Strain Organisms that have completed testing and all biochemical and/or antimicrobial MIC results (for a specified Panel Lot #) that exist in the BD Phoenix databases when the report is requested.\*
- Cumulative QC Report provides information on quality control testing of all panel types. \*
- Daily Instrument Report lists the status of the instrument at the time the report is generated, along with a maintenance checklist.
- Interpretation Rule Set Report lists the antimicrobial breakpoints of the Interpretation Rule Set defined as the default Rule Set in the Instrument Configuration screen.
- BDXpert Rule Set Database Report lists each BDXpert rule number and the text describing
  the rule, whether each rule is enabled/disabled and whether each rule is set to trigger
  automatically or manually in the system.
- Organism ID Code List Report displays all Organism Names, abbreviations for all Organism Names that exist in the BD Phoenix database.
- Antimicrobial Code Report displays all antimicrobials, abbreviations for all antimicrobials, and the LIS codes that exist in the BD Phoenix database from all panel configurations
- Lab Report contains all information for a panel sequence number that exists in the BD Phoenix database, including all information in the Panel Results screen, any special messages, BDXpert Rules that triggered, or Needs Attention Reasons if they exist. This report can only be printed from the Panel Results display or Finalization display.
- Finalization Summary Report contains all the panels eligible for finalization at the time the report was requested, as well as finalization status. This report can only be printed from the Finalization display.
- Panel Inventory Lab Report prints a Lab Report for all panels in the instrument. This report can only be printed from the Panel Inventory display.
- Custom Breakpoint Difference Report prints a listing of differences between old breakpoints and new ones after a BD Phoenix Update Disk or Install/Upgrade operation. This report can only be printed from the Custom Interpretation Rule Set (Configuration) display.
- Current QC Panel Lot Report contains information on the most recent QC test for each of the required strains for a panel lot, up to a maximum of 20 strains. This report can only be printed from the Panel Lot Definition display.
- Historical QC Panel Lot Report contains information on all tests for a strain for the current instrument, up to 200 tests. This report can only be printed from the Panel Lot Definition display.
- Panel Lot Report lists all the panel records for any panel lot number in the current instrument.
- Panel Lot Database Report lists all the defined panel lots in the current instrument, and provides statistical and reference information on those lots.

<sup>\*</sup>Report does not appear when BD EpiCenter communications is enabled.

More information on these reports and samples are provided in Section 5 – Reference.

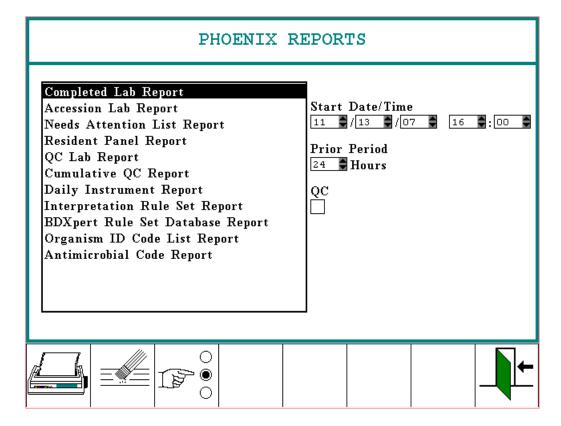


Figure 4-12 - Reports Menu

#### To print a report:

1. From the Main Status Screen, press the "print reports" soft key.



- 2. The report menu appears.
- 3. Use the UP ARROW or DOWN ARROW to highlight the desired report.
- 4. Complete any additional fields (such as an accession number for the Accession Lab Report) and press the "print reports" soft key to print the report. (See Section 5 Reference for additional field requirements.)

Several reports can also be printed from the displays that relate to them (e.g., Needs Attention List Report).

# 4.14 Unloading and Discarding Panels

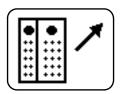
When panel testing is completed, panels may be removed from the instrument and discarded.

#### **WARNING**

- THE INSTRUMENT DOOR IS ELECTROMECHANICALLY LATCHED AND IS CONTROLLED BY THE INSTRUMENT SOFTWARE.
- NEVER ATTEMPT TO DEFEAT THE DOOR LATCHING MECHANISM, OR TO OPEN THE DOOR WHEN THE UNLOCKED ICON IS NOT DISPLAYED. SERIOUS INJURY CAN BE CAUSED BY THE ROTATING CAROUSEL.
- IF THE CAROUSEL IS NOT COMPLETELY STOPPED WHEN THE DOOR IS OPENED, IMMEDIATELY CONTACT BD FOR SERVICE. NEVER ATTEMPT TO ROTATE THE CAROUSEL MANUALLY OR SERIOUS INJURY MAY RESULT.

#### To remove panels:

1. Press the UNLOAD PANELS key.



2. When the "door unlocked" icon appears, open the instrument door.



- 3. All panels that are ready to be removed are indicated by a SOLID GREEN LED indicator.
- 4. Remove the panels by pushing the panel down, pivoting the top of the panel outward, and pulling the panel out of the panel holder.
- 5. If there are completed panels that are not in the accessible stations, close the door and allow the instrument to reposition the carousel to provide access to those panels. When the "door unlocked" icon appears (the carousel halted tone also sounds), open the door and continue removing completed panels.
- 6. Discard the panels in a biohazard container.

# 4.15 LIS Operations

#### **4.15.1 General**

The Laboratory Information System (LIS) communications feature enables the BD Phoenix instrument to exchange information with a compatible Laboratory Information System (LIS). LIS communications can be configured to exchange Order records and Results records at a variety of times.

Order records can be downloaded from the LIS system to the BD Phoenix instrument. These Order records can include the information listed in the second bullet below. If all this information is sent from the LIS system, then the panel is automatically logged in just as if the login were done at the instrument. If the panel sequence number is omitted, the Order record can be associated to a specific panel manually in Panel Login. Order records can also be configured to be uploaded to the LIS.

Results records are uploaded from the BD Phoenix instrument to the LIS system. These records consist of:

- Header record (Delimiter fields, sender name, version number, message date/time)
- Order record (Accession number, Isolate number, Organism, Test ID, Sequence number, Priority, Report type)

#### **NOTE**

If an Organism code is included in the order record, for either a new or existing panel, the ID side of the panel is disabled.

- Comment record (contains Special Messages and/or BDXpert Rules)
- Results record
- Panel sequence number
- Instrument number
- Instrument type
- Instrument location (Station)
- Time to result for identification or MIC produced
- Test start time
- Test end time
- Test status (ongoing, complete, partial complete, complete with needs attention reason, complete with all ignored needs attention reasons, complete QC Pass, complete QC Review, pending, or rapid complete)
- Result type
- Antimicrobial code
- MIC value
- S/I/R/No Interp/Error value
- Resistance marker
- ID or Final ID
- Results status (finalized or unfinalized)

The LIS Communications function is based on the American Society of Testing and Materials (ASTM) LIS Communications Standards (1381 and 1394), and is compatible with a number of popular LIS systems. For specific information on which LIS systems are compatible, contact a local BD representative. The LIS Vendor Interface Specification (available upon request) provides complete details on the BD Phoenix implementation of LIS Communications.

#### NOTE

If the BD Phoenix instrument is connected to a LIS, it cannot be connected to the BD EpiCenter™ system. However, if the BD Phoenix instrument is connected to BD EpiCenter, then a LIS connection can be established via BD EpiCenter.

## 4.15.2 Important Concepts

There are several concepts with which the user should be familiar in order to understand the information presented here, and to ensure that the LIS communications feature is set up properly for your laboratory. These concepts are discussed below.

LIS communication is able to send Results records from the instrument to the LIS (*upload*), Order records when panels are placed into the instrument, and queries to (and from) the LIS for Order records. Results upload can be configured to include or exclude Interpretation (SIR) results. The instrument can be set up to upload Results records only when the LIS requests them (*solicited upload*); or at one of the following *unsolicited upload* times: when panels are finalized; when panels complete testing or when complete panel records change; when ID or AST results are determined; or at a fixed time. QC panels and orphan panels are uploaded only when solicited by the LIS. If the instrument is configured for unsolicited upload, it still responds to requests from the LIS for results (solicitations or queries). If the instrument is configured for unsolicited uploads, the LIS must always be ready to receive data from the instrument.

By downloading barcode (panel) sequence numbers, the instrument can automatically login panels when records are received. If panel sequence numbers are omitted from the Order record, the panel can still be associated to the Order record in the Panel Login display.

If the panel sequence numbers are not included in downloaded records, the records that are downloaded are stored (up to 200 Order records) for manual association to panels. This process is described in Section 4.5.3.

Organism Configuration and Antimicrobial Configuration enable the user to enter the specific codes required by your LIS system for the organisms and antimicrobials uploaded in Results records. Refer to Sections 2.3.2.1 and 2.3.2.2 for additional information.

LIS configuration settings are independent of critical panel configuration settings. (E.g., if LIS configuration is set to send results only when the panel is complete, the results are **not** uploaded if the panel is critical and rapid reporting configuration is set for notification on ID results or partial results.)

# 4.15.3 Processing Panel Orders

Refer to Section 4.5.3 Associating and Removing LIS Orders, for step-by-step instructions.

## 4.15.4 Routine System Operation

Operation of the BD Phoenix instrument with a LIS interface differs very little from routine operation of the system. The major difference is the ability to enter panel/accession data via the LIS into the system.

With LIS communications, patient information can be logged in at the LIS and transferred to the BD Phoenix instrument. (Consult your LIS manufacturer's operation manual for complete instructions on data entry and downloading records.)

LIS systems operate either in realtime mode, where the system automatically downloads each Order as it is logged in, or in batch mode where multiple Orders in a group are logged in and downloaded. After patient records are logged in, download them to the BD Phoenix instrument.

Any data sent to the BD Phoenix instrument that does not directly correlate to one of the fields defined as the "Order record" is ignored by the system. Any information sent from the LIS for a Finalized panel is rejected.

After the Order records have been downloaded, and the panels have been attached to those records (if necessary), routine system operation does not differ in any way. Continue to load the instrument, print reports, monitor the system for complete panels, perform maintenance, etc. However, it is recommended that the user be especially alert to and respond to any system or activity alerts that occur.

# 5 - Reference

# 5.1 General

This section presents reference material on the BD Phoenix instrument user interface. All the screens, icons, reports, and functions in the user interface are described in the order in which they are accessed through the Main Status screen. The following information is presented:

- Main Status screen
- Panel Login
- Panel Results
- Finalization
- Configuration/Maintenance
- Reports
- Panel Inventory
- System Alerts
- Needs Attention

## 5.2 Software Tree

The following is a hierarchical list of all displays/functions in the system. The sections where these activities are discussed in detail are noted in parentheses.

```
Main Status screen (Section 5.3)
        Panel Login (Section 5.4)
        Panel Results (Section 5.5)
               BDXpert Rules Triggered (Section 5.5.1)
               Resistance Markers (Section 5.5.2)
               Special Messages (Section 5.5.3)
               Lab Report (Section 5.5.4)
        Finalization (Section 5.6)
        Finalization Summary Report (Section 5.6)
        Configuration/Maintenance (Section 5.7)
               Instrument Configuration (Section 2.3.1)
                        General Instrument Configuration (Section 2.3.1.1)
                        Laboratory Information (Section 2.3.1.2)
                        Password Administration (Section 2.3.1.3)
               Maintenance (Section 4.2, 2.5, 7.3, 6.2.2, 6.2.4)
               Communications Configuration (Section 2.3.2)
                       Organism Configuration (Section 2.3.2.1)
                       Antimicrobial Configuration (Section 2.3.2.2)
               Custom Interpretation Rule Set (Breakpoint) Configuration (Section 2.3.3)
               BDXpert Rule Configuration (Section 2.3.4)
               Rapid Reporting Configuration (Section 2.3.5)
               Panel Lot Definition (Section 2.3.6)
        Reports (Section 5.8)
               Completed Lab Report (Section 5.8.1)
               Accession Lab Report (Section 5.8.2)
               Needs Attention List Report (Section 5.8.3)
               Resident Panel Report (Section 5.8.4)
               QC Lab Report (Section 5.8.5)
               Cumulative QC Report (Section 5.8.6)
               Daily Instrument Report (Section 5.8.7)
               Interpretation Rule Set Report (Section 5.8.8)
               BDXpert Rule Set Database Report (Section 5.8.9)
               Organism ID Code List Report (Section 5.8.10)
               Antimicrobial Code Report (Section 5.8.11)
               Lab Report/QC Lab Report (Section 5.8.12)
               Finalization Summary Report (Section 5.8.13)
               Custom Breakpoint Difference Report (Section 5.8.14)
               Panel Lot Report (Section 5.8.17)
               Panel Lot Database Report (Section 5.8.18)
        Panel Inventory (Section 5.9)
        System Alerts (Section 5.10)
        Needs Attention (Section 5.11)
```

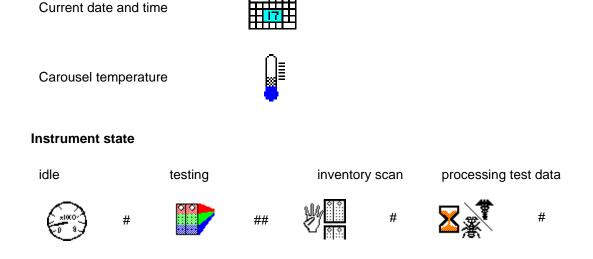
# 5.3 Main Status Screen

The Main Status screen (Figure 5-1) is the default screen that is displayed when no activity has been initiated. This screen presents up to eight icons representing soft key definitions that allow the user to perform activities. These icons are as follows:

- The "panel login" icon, which allows login of new panels.
- The "panel results" icon, which allows viewing and modification of the panel ID or AST results
  or deletion of them.
- The "finalization" icon, which allows finalization of panels that have completed testing. (Not available when instrument is connected to the BD EpiCenter Data Management System.)
- The "configuration" icon, which allows setting up of the instrument, laboratory-specific rules, and communications parameters, and performance of instrument maintenance checks.
- The "print reports" icon. This icon appears only if a printer is attached, turned on, and online.
- The "panel inventory" icon, which allows the review of a list of all panels in the instrument and
  the ability to sort the list by various criteria (such as by panel sequence number, accession
  number, result, etc.)
- The "system alert" icon, which allows the review of any system alerts that may have occurred or that may still exist. (Icon appears only if system alert is present.)
- The "needs attention" icon, which allows the user to respond to panels that have been flagged as needing attention. Usually, some action to correct the situation can be performed. (Icon appears only if there are panels that need attention.)

The Main Status screen has three areas: the top region presents system status information; the middle region presents station status information; and the bottom region displays the current soft key definitions.

The system status information presented at the top of the screen includes the following:

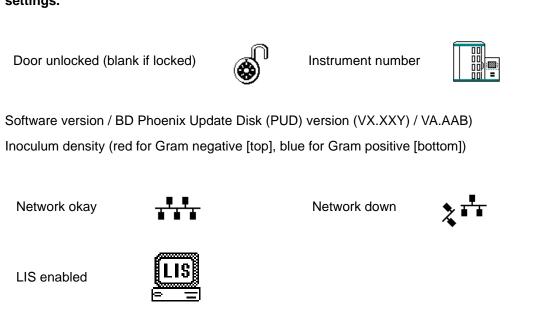


# = number of minutes until next test
## = number of minutes left in current test for testing state

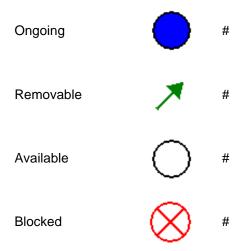


\* = number of minutes adjustment has been in progress

When the "processing test data" icon is displayed, do not change any configuration settings.

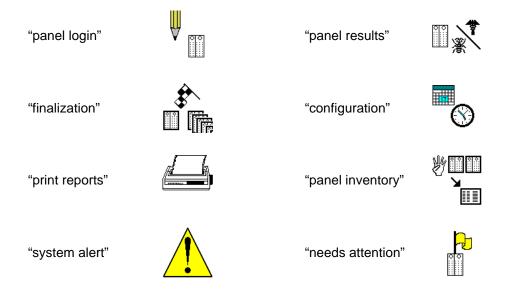


Station statuses presented in the middle area of the display include the following:



The numbers (#) to the right of the icons represent the number of stations/panels that exist for a status.

The soft key assignment area (very bottom of the screen) shows the current soft key definitions. These definitions change as different functions and screens are accessed. The Main Status screen icons include:



Note that the "finalization" icon does not appear when the BD Phoenix instrument is attached and communicating with a BD EpiCenter system.

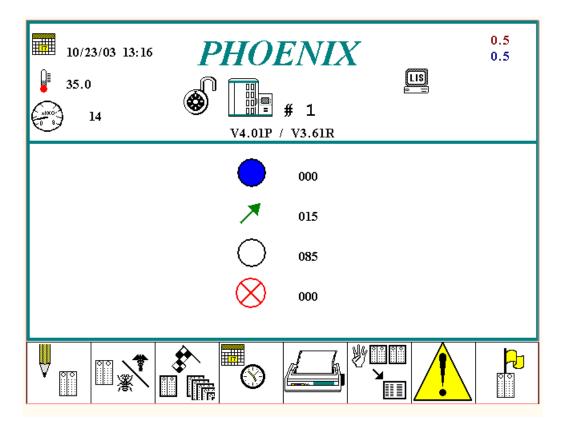


Figure 5-1 - Main Status Screen (with optional LIS indicator)

# 5.4 Panel Login

The Panel Login display enables demographic information to be logged in for panels to be tested. Depending on the type of panel being used, not all fields listed below may appear on the display. More than one of the same panel type may be logged in for an accession number, but the system notifies the user of the duplication with an activity error message.

The inoculum density of the panel is set in Configuration. There is no way during Panel Login to change the density setting. The only way to use a different inoculum density is by blackening well A-17 as described in 4.4 Preparing Panels.

See Figure 5-2 – Panel Login Display.

#### To access Panel Login:

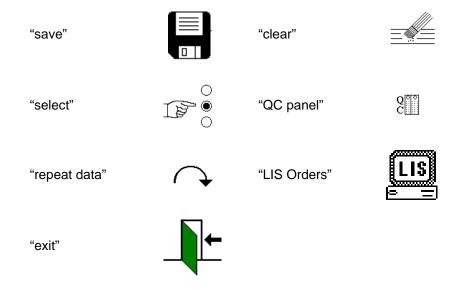


Press the "panel login" soft key from the Main Status screen

or

Scan a *new* Accession with the handheld barcode scanner or scan a new panel barcode with either scanner from the Main Status screen

#### Panel Login soft keys:



#### **Panel Login fields:**

### Sequence #

Type in or scan the panel's sequence number. (If the Sequence # is scanned to access Panel Login, this field is completed automatically.) The sequence number contains digits that identify the panel type. Valid sequence numbers are 12 digits long and must conform to BD panel sequence number specifications. A panel sequence number must be entered to save a record. If an existing sequence number is entered, the system takes the user to the Panel Results display.

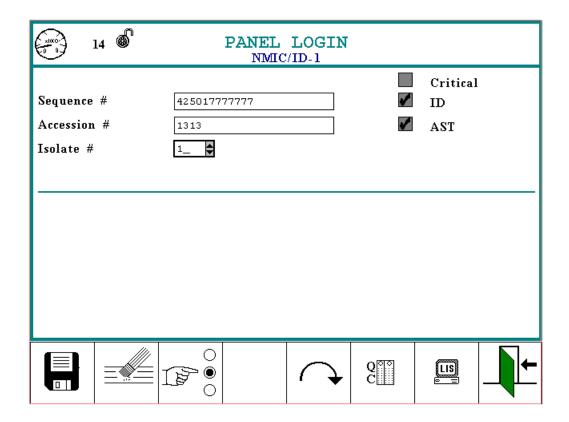


Figure 5-2 - Panel Login Display

For Yeast ID panels, the Media field appears to the right of the Isolate # field.

#### Accession #

Type in or scan an accession number, up to 20 alphanumeric characters. (If the accession barcode is scanned to access Panel Login, the Accession # is completed automatically.) Spaces at the beginning or end of the number are ignored, but spaces within the number are valid. The following characters CANNOT be used in accession numbers: \* ? [ ] ! # |

#### Isolate #

Defaults to isolate number 1. Type in the isolate number, or press UP ARROW or DOWN ARROW to increase or decrease the number. Valid isolate numbers are 1 to 20. If an accession number has been entered, you must also enter an isolate number. If the isolate # is changed from "1" to another value, an accession number must be entered.

#### Media

This field appears only if a Yeast ID panel sequence number is scanned or typed in.

Defaults to media type specified in Configuration (optional). To select a different media for the isolate, press ▼ to drop down a box listing all media types (abbreviations), sorted alphabetically. (When you highlight the media type, the full name appears at the top right of the display.) Use ▼ or ▲ to highlight the desired media. Press the "select" soft key or J to select that media. A media type can be selected or changed until the first panel test. The panel test is aborted if a media type is not specified before the first test cycle.

A media type must be selected to save the panel information.

#### Critical Checkbox

Defaults to unchecked. Press the "select" soft key to check the box and mark the panel as critical. The system can be configured (Rapid Reporting configuration, Section 2.3.5) to notify the user of critical panel results (ID results obtained, partial panel results, or complete panel results) by sounding an audible alarm and/or printing a Lab Report automatically (or neither).

#### **ID** Checkbox

Defaults to checked if a combination panel sequence number is scanned. If only the AST portion of a combination panel is used, press the "select" soft key to UN-check the box. This checkbox appears only when a combination panel is used. This field is automatically checked (enabled) when a QC panel is logged in.

#### **AST** Checkbox

Defaults to checked if a combination panel sequence number is scanned. If only the ID portion of a combination panel is used, press the "select" soft key to UN-check the box. This checkbox appears only when a combination panel is used. This field is automatically checked (enabled) when a QC panel is logged in.

#### Organism ID/Test Strain

Press DOWN ARROW to drop down the organism selection box. Organisms are listed in alphabetical order. Enter the first few characters of the organism name to navigate to that portion of the list quickly. Use UP ARROW or DOWN ARROW to highlight the desired organism. Press J to select the organism.

This field appears only for AST-only panels or when using the AST side of a Combination panel.

For QC panels, this field is named Test Strain, and lists only the strains of organisms predefined in the database, sorted by strain number (alphanumerically). A test strain must be entered to save a QC panel.

#### **Tech ID**

This field appears for QC panels. Enter the identification for the technologist performing the QC test. Up to 3 alphanumeric characters are accepted. A tech ID must be entered to save a QC panel.

#### Panel Lot #

This field appears for QC panels. Type in or scan the panel's lot number. Lot numbers must be 7 digits. A lot number must be entered to save a QC panel. (When the QC Lot Support feature is enabled, this field is completed automatically when the Sequence # barcode is scanned.)

#### (Panel Lot #) Exp. Date

This field appears for QC panels. In the first Panel Lot # Exp(iration) Date field, press UP ARROW or DOWN ARROW to enter the expiration day, month, or year (depending on the configuration). Press T to advance to the next date field and press UP ARROW or DOWN ARROW to enter the expiration day, month, or year. Press T to advance to the next date field, and press UP ARROW or DOWN ARROW to enter the final portion of the date. An expiration date must be entered to save a QC panel. (When the QC Lot Support feature is enabled, this field is completed automatically when the Sequence # barcode is scanned.)

#### ID Broth Lot #

This field appears for QC panels. Type in or scan the broth lot number. Lot numbers can be up to 7 characters.

#### (ID Broth Lot #) Exp. Date

This field appears for QC panels. In the first ID Broth Lot # Exp(iration) Date field, press UP ARROW or DOWN ARROW to enter the expiration day, month, or year (depending on the configuration). Press T to advance to the next date field and press UP ARROW or DOWN ARROW to enter the expiration day, month, or year. Press T to advance to the next date field, and press UP ARROW or DOWN ARROW to enter the final portion of the date.

#### AST Broth Lot #

This field appears for QC panels. Type in or scan the broth lot number. Lot numbers can be up to 7 characters.

#### (AST Broth Lot #) Exp. Date

This field appears for QC panels. In the first AST Broth Lot # Exp(iration) Date field, press UP ARROW or DOWN ARROW to enter the expiration day, month, or year (depending on the configuration). Press T to advance to the next date field and press UP ARROW or DOWN ARROW to enter the expiration day, month, or year. Press T to advance to the next date field, and press UP ARROW or DOWN ARROW to enter the final portion of the date.

#### Indicator Lot #

This field appears for QC panels. Type in or scan the indicator lot number. Lot numbers can be up to 7 characters.

#### (Indicator Lot #) Exp. Date

This field appears for QC panels. In the first Indicator Lot # Exp(iration) Date field, press UP ARROW or DOWN ARROW to enter the expiration day, month, or year (depending on the configuration). Press T to advance to the next date field and press UP ARROW or DOWN ARROW to enter the expiration day, month, or year. Press T to advance to the next date field, and press UP ARROW or DOWN ARROW to enter the final portion of the date.

#### **LIS Orders**

This field appears when the "LIS Orders" soft key is pressed. Entering a Sequence number and pressing the DOWN ARROW opens a drop-down box listing up to 200 Order records received from the LIS. The list contains only those LIS order records for the same panel type as the Sequence number entered. The list is sorted alphabetically by accession number. It lists the following information: accession number, isolate number, and organism or test strain (if available). Any critical Order records are shown in red text in the box. Use the UP ARROW or DOWN ARROW to highlight the desired Order record and press the "select" soft key to associate that Order to the Sequence # entered.

## 5.5 Panel Results

The Panel Results display enables the review and modification of panel test results. The Panel Results display can be used for the following functions:

- display a panel whose data is stored in the BD Phoenix database
- modify the information for a panel in the BD Phoenix database
- mark a panel as critical
- print a Lab report on any panel that can be recalled or displayed on the screen
- locate a panel resident in the instrument
- delete panel information from the BD Phoenix database
- · answer or display any triggered BDXpert Rules
- · display any special messages
- finalize a panel

Panel Results (clinical panels) are retained for 31 days (possibly longer depending on number of QC panels tested). QC panel results are retained for at least 6 months.

Additional information about the panel is displayed in the display title area. The type of panel is shown below the title. Also, the inoculum density used for the identification (if applicable) is shown near the top left after the first test cycle completes.

If there is a Needs Attention flag for the panel, it appears above the **Test Start** field. If multiple Needs Attention reasons exist, only the highest priority reason is shown. If a Resistance Marker has triggered for the panel, an icon is shown just to the left of the **Location** field.

If a panel is recalled by accession number only, and there is more than one panel attached to the accession, the Panel Results List display appears. From this display, the specific panel can be selected to review/modify. See Figure 5-3 for the Panel Results List display. See Figure 5-4 for a sample ID Panel Results display, and Figure 5-5 for a sample AST Panel Results display.

Note that depending on the type of panel being used, as well as other circumstances, not all fields listed below may appear on the display.

AST or Combination panel types (with at least the AST side enabled) each contain a set of antimicrobials. The instrument reports a result for each antimicrobial on the panel. Each antimicrobial reports an individual MIC value. Once an antimicrobial has a MIC value, the instrument calculates an Instrument susceptibility (SIR) value for each MIC value that has been determined. (The instrument requires the panel to have an Organism ID defined to interpret MIC values into Instrument SIR values. Also note that SIR values are not calculated by the instrument if it is attached to a BD EpiCenter Data Management System.)

If Rapid Completion is enabled, the instrument is able to provide BDXpert AST results (SIR) before determining actual MIC values. The instrument MIC values are provided as soon as they can be accurately determined. Within a test panel, some MIC values may be available earlier than others. The rapid completion feature can be used to predict resistance for uncompleted antibiotics using the ID alone (intrinsic resistance), or ID with completed MICs of related antibiotics, or resistance marker tests (BL, ESBL). The BDXpert system is used to make these predictions. This can be useful in situations where, for example, the results for drugs that have not yet received MICs would be of no clinical value based on the other results that are already available. Antimicrobials with Rapid Complete BDXpert interpretations are indicated by a "C" in the MIC column on Results screens and Lab reports.

When both a MIC value and Instrument SIR value have been determined for an antimicrobial, the instrument executes the BDXpert Rules (providing the BDXpert System is enabled). The instrument reports a value in the BDXpert SIR field if an enabled BDXpert Rule triggered and the reported BDXpert SIR value is different from the value in the Instrument SIR field.

#### To access Panel Results:

Press the "panel results" soft key from the Main Status screen



or Scan an existing Accession with the handheld barcode scanner from the Main Status screen; or scan an existing panel barcode with either scanner from the Panel Login or Main Status screen

Panel Results can also be accessed in certain conditions from the Needs Attention and Batch Finalization displays.

#### Panel Results soft keys:



<sup>\*</sup> Note that this icon does not appear if the BD EpiCenter system is attached and communicating.

#### Panel Results fields:

#### **NOTE**

Modifying the Accession # or Isolate # may invoke Auto Association, which can change results.

#### Accession #

Type in or scan the accession number to recall. If only an accession number is entered, and there is more than one panel attached to the accession, the Panel Results List display appears (Figure 5–3).

This field can be modified for unfinalized panels. Enter up to 20 alphanumeric characters for the accession, excluding \*? []!#|. Modifying an accession number does not affect the accession number of any related panels.

#### Sequence #

Type in or scan the panel's sequence number to recall. This field cannot be edited.

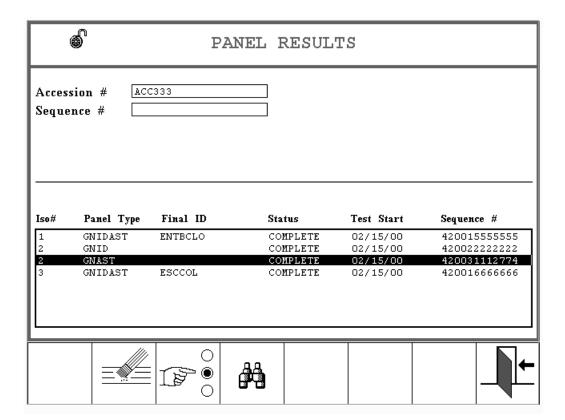


Figure 5-3 - Panel Results List Display

A maximum of 30 panels can be displayed in the list. To select a panel, use the UP ARROW or DOWN ARROW to highlight the panel and press the "select" soft key.

#### Isolate #

Press UP ARROW or DOWN ARROW to increase or decrease the number. Valid isolate numbers are 1 to 20. This field can be modified for unfinalized panels, however an existing isolate number cannot be changed to a blank number.

#### Media

This field is editable only before the first test cycle completes.

Shows the media type selected during Panel Login for Yeast ID panels only. The following values can appear in this field: blank for Unspecified Media Type; INVLD (Invalid Media Type); SABDX (Sabouraud Dextrose Agar); TSASB (Trypticase Soy Agar w/5% SB); COLSB (Columbia Agar w/5% SB); CHOC (Chocolate II Agar); SABEM (Sabouraud Dextrose Emmons); SABHI (Sab Brain Heart Inf Ag Deep)

#### Status

Read-only field shows the panel's testing status: Pending, Ongoing, Complete, or Rapid Complete (if enabled). Rapid Complete panels have not finished testing and show BDXpert results. If a Rapid Complete panel is removed from the instrument, it then becomes Complete. If it is left in the instrument, Rapid Complete MICs are replaced by actual MIC results as they are determined.

#### Final ID

**Final ID** can be completed automatically by the system from a single instrument-based ID or by the user selecting among tie instrument-based IDs. For ID panels (or ID-only portions of Combination panels) an organism ID cannot be manually selected if there is no instrument-based ID listed.

Note that if the **Modify Related Panels** checkbox is checked, the ID in the database of all related panels (panels with the same accession and isolate number) is set with the same organism ID through the Auto Association function (see Section 4.9).

Press DOWN ARROW to drop down the organism selection box. Organisms are listed in alphabetical order. Enter the first few characters of the organism name to jump to that portion of the list quickly. Use UP ARROW or DOWN ARROW to highlight the desired organism. Press J to select the organism.

When this field is modified by the user, the instrument changes the background color of the field to cyan. In addition, if the **Modify Related Panels** checkbox was checked at the time the **Final ID** was modified, all modified panels' **Final ID** fields are also displayed with a cyan background. When the field is modified, the system re-evaluates each antimicrobial's instrument SIR value, as well as re-evaluating BDXpert information.

The field cannot be modified if the panel is finalized.

For QC panels, this field is named **Test Strain**, and lists only the ATCC strains of organisms predefined in the database, sorted by strain number.

#### Panel Lot #

Read-only field shows the panel lot number. This field shows only when the QC Lot Support feature is enabled.

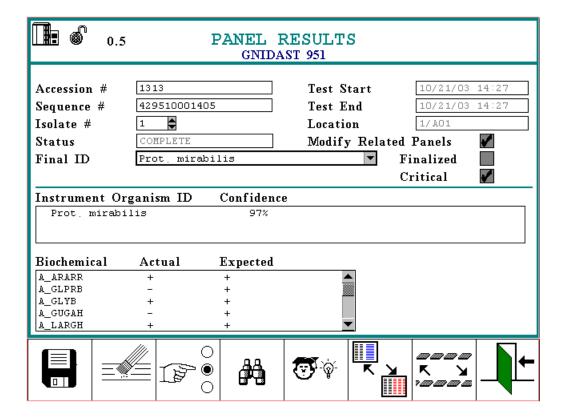


Figure 5-4 - Panel Results Display - ID

For Yeast ID panels, the Media field appears to the right of the Isolate # field.

#### Exp. Date

Read-only field shows the date and time that the panel lot expires. This field shows only for QC panels and only when the QC Lot Support feature is enabled.

#### Modify Related Panels Checkbox

This field appears when the Final ID field is modified. Defaults to checked when the Final ID is modified. If the ID for unfinalized related panels is NOT to be modified when the currently displayed panel is modified, press the "select" soft key to UN-check the box. This checkbox has no effect on related QC panels. This checkbox does not appear if the BD EpiCenter system is attached and communicating.

#### **Test Start**

Read-only field shows the date and time that panel testing was started.

#### **Test End**

Read-only field shows the date and time that panel testing was completed.

#### Location

Read-only field shows the location of the panel, in the form I/Tst, where I is the Instrument number, T is the Tier, and st is the station number.

#### **QC Status**

This field shows the status of a QC panel. The field is blank until the panel status becomes Complete. Statuses are initially PASS or REVIEW. Review indicates that the panel has not passed. Check any panels with Review status and determine why the panel did not pass.

The status is REVIEW if any of the following conditions occur:

- · QC strain was identified incorrectly
- The test on a QC panel is aborted
- At least one of the antimicrobial results fail

From a status of REVIEW, the final status may be set to REPEAT if it is determined that the panel failed due to error in preparation or handling of the panel. If it is not determined that a panel preparation/handling error was made, the final status should be set to FAIL. Selecting REPEAT or FAIL clears the "Review QC Results" Needs Attention condition.

#### **Finalized**

Press the "select" soft key or s to check the box and finalize the panel. The **Finalized** field is displayed as a read-only field when the BD Phoenix system is connected and communicating with the BD EpiCenter Data Management Center. In this case, all Finalization is done at the BD EpiCenter system. **Finalized** is not displayed for QC panels.

If a panel with Rapid Complete status is finalized, processing of MIC results stops, and the panel status becomes Complete. Any drugs that did not complete testing maintain their current MIC value (e.g., C in MIC column remains C, X remains X, etc.).

#### Critical

Press the "select" soft key or s to check the box and mark the panel as critical. The system can be configured (Rapid Reporting configuration, Section 2.3.5) to notify the user of critical panel results (ID results obtained, partial panel results, or complete panel results) by sounding an audible alarm and/or printing a Lab Report automatically (or neither).

Previously marked critical panels can be unmarked by unchecking the checkbox.

This field does not appear for QC panels.

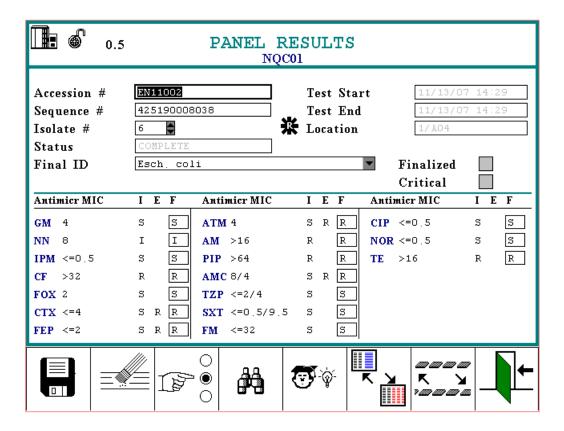


Figure 5-5 - Panel Results Display - AST

### Antimicr(obial)

Read-only field showing the abbreviation for the antimicrobial.

#### MIC

The Minimum Inhibitory Concentration value determined by the instrument. The following values may also appear in this field:

- > growth occurred for all concentrations of the antimicrobial
- so of the antimicrobial
- ? MIC determination is pending (SIR values remain blank)
- X MIC value cannot be produced; or Final ID is not claimed in the Taxa listing (Section 9.3) for AST testing; or the panel's drug dilution series does not cover the BD Phoenix reportable MIC range, or for additional causes, see Table 5–1. Check Special Messages display (Section 5.5.3) for an explanation.
- C Rapid Complete (MIC is pending, BDXpert SIR is based on ID and completed drug and/or resistance marker results). These values are replaced by actual MIC values as they are determined.

For QC Panels, the following values may appear in this field:

Actual MIC value (number, ?, or X for error)

Expected MIC range (if defined)

QC Result

P the actual MIC value is within the expected MIC range

F the actual MIC value is not within the expected MIC range

R Repeat: the actual MIC value is "X"

blank no range is defined for the antimicrobial/organism combination

I (Instrument SIR)

This field is the instrument interpretation for the MIC based on the breakpoints currently running in the system (selected in Instrument Configuration).

The SIR value is blank for antimicrobials that require an ID to perform the SIR interpretation. In this case, the **BDXpert SIR** field (if present) and the **Final SIR** field are also blank.

The following represent the interpretation values:

S Susceptible
I Intermediate
R Resistant

N Not Susceptible\*

X Cannot produce interpretation

Blank No SIR (missing or invalid Final ID; MIC = ?, C, or X; unclaimed organism for Final ID)

(Instrument SIR) does not appear if the BD EpiCenter system is attached and communicating. If communications with the BD EpiCenter system is lost, the field automatically appears.

### (BD)E(Xpert SIR)

Possible field values are: Blank, S, I, R, N, and X. These values have the same meanings as I(nstrument SIR) above.

The BDXpert SIR field is not shown when the BDXpert System is disabled. It is also not shown for QC, ID, or ID/AST panels with AST disabled. This field contains the results calculated by the BDXpert System based on the execution of all enabled BDXpert Rules. Values appear in this field only if a BDXpert rule triggered and caused the BDXpert SIR value to differ from the instrument interpretation.

<sup>\*</sup> N indicates that the antimicrobial/organism does not have an upper breakpoint. When there is no upper breakpoint there are no criteria for calling an organism intermediate or resistant. This often occurs when there is an absence or rare occurrence of resistant strains of an organism. In this case, if the MIC is below the lower breakpoint the SIR results can be reported as susceptible but if the MIC is above the lower breakpoint the only result that can be reported is N or not susceptible.

### F(inal SIR)

Field values are the same as I(nstrument SIR) above. The Final SIR can be one of the following (from highest to lowest priority): a user-entered SIR value; the BDXpert SIR value; the instrument SIR value; or blank.

Final SIR values are produced when a MIC value or error is determined, AND there are no pending manual BDXpert rules (if the BDXpert System is enabled).

When the BD EpiCenter System is not connected and the BDXpert System is disabled, the Final SIR field is not displayed for an antimicrobial until the MIC value is something other than "?."

The chart below provides explanations of different combinations of blank and "X" results. Detailed explanations for actual results are provided as Special Messages (see 5.5.3 Special Messages Display).

Antimicrobial	MIC	Instrument SIR	Expert SIR	Final SIR	Example for Possible Causes
Any Drug	?	[Blank]	[Blank]	[Blank]	Results pending.
Any Drug	BD Phoenix MIC Result	S, I, R	[Blank]	S, I, R	Instrument SIR = Final SIR (No BDXpert rule SIR).
Any Drug	BD Phoenix MIC Result	S or I	R	R	Final SIR = BDXpert SIR if rule accepted.
Any Drug	BD Phoenix MIC Result	[Blank]	[Blank]	[Blank]	No breakpoints for this drug/organism combination within the chosen standard (CLSI, SFM, EUCAST,Custom).
Any Drug	BD Phoenix MIC Result	Х	[Blank]	Х	MIC value is outside the breakpoints for the selected standard. Example: Panel drug range = 1–16 μg/mL, susceptible breakpoint = 0.5 μg/mL
Any Drug	BD Phoenix MIC Result	Х	[Blank]	Х	SIR is suppressed by a BDXpert rule. User must provide Final SIR based on manual interpretation or additional testing.
Any Drug	Х	[Blank]	[Blank]	[Blank]	The MIC for this drug and organism combination is not reported by the BD Phoenix system. An alternative method should be used.
					This species is not included in the BD Phoenix AST taxonomy; perform an alternative method.
All Drugs	X	[Blank]	[Blank]	[Blank]	An excessive amount of indicator was detected in the panel. The AST portion of the panel has been terminated and the isolate should be retested.
Any Drug	Х	[Blank]	[Blank] or R	[Blank] or R	The MIC for this antibiotic is not reported (see Special Message). Interpretation based on BDXpert Rule.
Any Drug	С	[Blank]	R	R	Rapid Completion SIR (BDXpert SIR based on ID and/or another completed drug and/or resistance marker result).

Table 5-1 - MIC/SIR Values and Causes

#### **Instrument Organism ID**

Read-only field showing the organism identified by the instrument based on biochemical results in an ID or ID/AST panel. Organism IDs listed for a Tie (two possible organisms meet the results) are listed in the Instrument Organism ID field as "organism 1 / organism 2."

#### Confidence

The Confidence value computed by the system is based on the actual biochemical results versus the expected results. The Confidence value is a percentage from 0 to 99.

#### **Supplemental Tests**

Supplemental Tests are displayed in the Instrument Organism ID field and/or in the Special Messages display if there is more than one Organism listed there. Once these tests have been performed, the results of the tests will help to distinguish which organism ID to associate to the AST results. At this point, a single organism ID can be selected from the Final ID field.

#### **Biochemical**

Read-only field showing the abbreviation for the biochemical used to determine the ID.

#### **Actual**

Read-only field showing the observed biochemical result at the time when the organism ID was determined: + for positive or – for negative. A ? indicates that the biochemical result is pending or that the test was aborted prior to ID results being determined. X indicates an Error.

#### **Expected**

Read-only field showing the expected biochemical result according to the Instrument Organism ID: + or – for the organism. A V indicates that the result can be variable. This field is blank when the actual results are "?" (for non-QC panels), or until an Organism ID has been determined, or when more than one organism is listed in the Instrument Organism ID field.

# 5.5.1 BDXpert Triggered Rules Display

The BDXpert Triggered Rules display provides a view of the BDXpert system rules that have been triggered for a panel (the panel currently selected in Panel Results). A listing of rules that have been triggered, the text of those rules, and the effect that the rules have on Final SIR values can be viewed, and pending (manual) rules can be accepted or rejected. All rules can also be re-run. See Figure 5-6 – BDXpert Rules Triggered Display.

After all rules have been reviewed and Accepted/Rejected, any changes must be saved in the Panel Results display via the "save" soft key.

The BDXpert Triggered Rules icon does not appear, and the display is not available if the BD EpiCenter system is attached and communicating with the BD Phoenix instrument. However, if communications with the BD EpiCenter system is lost, and the BDXpert system is reactivated in Instrument Configuration (Section 2.3.1), the icon reappears and the display can be accessed. When communications with the BD EpiCenter system is restored, BDXpert rules interpretations are once again performed at the BD EpiCenter system, and the "go to BDXpert Rules" icon no longer appears on the Panel Results display.

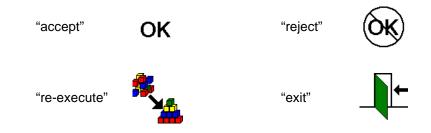
### To access BDXpert Triggered Rules:



Press the "go to BDXpert Rules" soft key from the Panel Results screen

The display appears automatically if a change is made to the Final ID field (in Panel Results) that causes a manual BDXpert Rule to be triggered

### **BDXpert Triggered Rules soft keys:**



#### **BDXpert Triggered Rules fields:**

#### Accession #

Read-only field that shows the current panel's accession number.

#### Sequence #

Read-only field that shows the current panel's barcode sequence number.

#### Isolate #

Read-only field that shows the current panel's isolate number.

#### Final ID

Read-only field shows the panel's final organism identification.

#### **Rule Description Window**

Read-only field that shows the text of the current rule. (The current rule is highlighted in the lower left window (Rules Window) of the display.) The color of the text of the rule indicates the following statuses:

GREEN	Automatic Rule
BLUE	Pending Manual Rule; execution of additional rules is suspended until this rule is either Accepted or Rejected
GREEN	Manual Rule that has been Accepted
RED	Manual Rule that has been Rejected

#### **Rules Window**

#### Rule #

Read-only field that shows the numeric designation of the highlighted rule. A maximum of 25 rules can be displayed in this window.

#### **Status**

Shows the status of the highlighted rule. The initial status of Automatic (a rule that executes automatically without user intervention) or Manual (a rule that must be manually Accepted or Rejected by the user) is set in the BDXpert Rule Configuration display (Section 2.3.3). Statuses shown in this window are:

Automatic - rule is enabled and set to Automatic

Pending – rule is enabled and set to Manual; Manual rules must be Accepted or Rejected; only the first Manual rule shows as Pending

Accepted - rule is enabled and set to Manual and has been Accepted by the user

Rejected - rule is enabled and set to Manual and has been Rejected by the user

Pending rules can be accepted or rejected via the "accept" or "cancel" key. Once a rule is accepted or rejected, the status can only be changed by re-executing the rules.

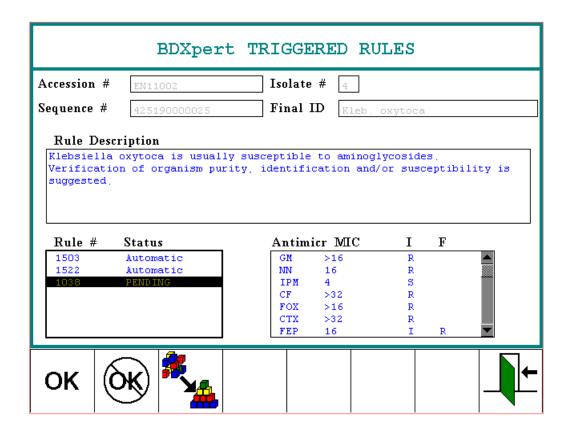


Figure 5-6 – BDXpert Rules Triggered Display

Display reflects rules that had been triggered up to the time when the display was accessed. Display is not updated dynamically with new triggered rules.

#### **AST Results Window**

#### Antimicr(obial)

Read-only field that shows the abbreviation for the antimicrobial.

#### MIC

Read-only field that shows the MIC for that panel.

I(nstrument SIR)

Read-only field that shows the Instrument interpretation for that drug/MIC.

F(inal SIR)

Read-only field that shows the Final interpretation after any rules have been applied to the results.

# 5.5.2 Resistance Marker Display

The Resistance Marker display provides a view of any resistance markers that have triggered for a given panel. It is accessed through a soft key on the Panel Results display. See Figure 5-7.

The Resistance Marker review display shows the same information in the top window as ID and AST Panel Results displays. In the bottom window, the following information is shown:

- The BDXpert rule number that triggered the Resistance Marker
- The Resistance Marker code (abbreviation)
- The Resistance Marker Name
- The BDXpert rule Description (green if the rule is automatic or accepted manual; blue if the rule is pending manual)

The resistance markers are shown in the order in which they trigger.

### To access the Resistance Marker display:



Press the "toggle display" soft key from the Panel Results screen

The soft keys on the Resistance Marker display are the same as the Panel Results display.

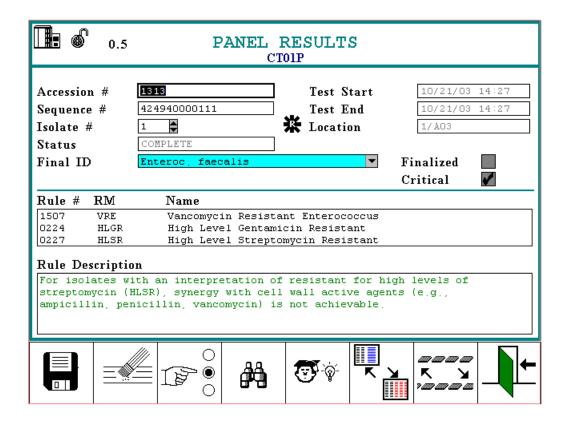


Figure 5-7 – Resistance Marker Review Display

# **5.5.3 Special Messages Display**

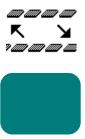
The Special Messages display provides access to information about certain panel ID and AST results, as well as some panel readings. These special messages are triggered and are available for viewing regardless of whether the BDXpert System is enabled or disabled. If a recalled panel has an associated Special Message, the "special messages" soft key is displayed on the Panel Results display. See Figure 5-7.

Special Messages on a recalled panel are shown according to hierarchy on the Special Messages display, up to a maximum of 1000 characters. (Only complete special messages are shown.) If a message exceeds the 1000 character limit, it does not appear on the display. To view all messages in their entirety, print a Lab Report.

The Special Messages screen reflects messages that exist *at the time* the display is accessed: it is not updated dynamically with messages that are triggered after the display has been accessed. To view newly triggered messages, return to the Panel Results display, recall the panel again, and re-enter the Special Messages display again.

## To access the Special Messages display:

1 From the Panel Results display, press the "more soft keys" soft key to view additional soft key definitions.



2 When the new soft keys appear, press the "special messages" soft key.



3 To return to Panel Results, press the "exit" soft key.



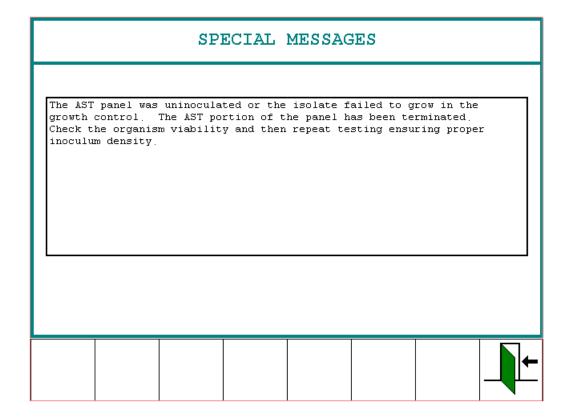


Figure 5-8 - Special Messages Display

# 5.5.4 Lab Report

The Lab Report contains all information for a panel sequence number that exists in the BD Phoenix database, including all information in the Panel Results screen, any special messages, BDXpert Rules that triggered, or Needs Attention Reasons if they exist. The Lab Report is not accessible from the Reports menu. It can only be printed from the Panel Results or Finalization displays.

The QC Lab Report is also accessible from the Panel Results display. It provides similar information to the Lab Report, but prints when a QC panel is being displayed and a report is requested.

The report provides the following information:

**Header:** Report Title, Preliminary indication (if Status is Ongoing, Pending, or Partial Complete; and/or if there are unignored Needs Attention conditions or a Needs Attention condition of Cannot Identify Barcode; and/or if the panel is not eligible for finalization), Laboratory Information (if configured), and Date and Time Printed, Software version (X.XXY) / BD Phoenix Update Disk (PUD) version (A.AAB)

**Body of Report:** Top Region: Accession #, Isolate #, Sequence #, Panel Type, Status (Ongoing, Complete), CRITICAL panel indication, Test Start with time, Test End with time, Instr #/Station (location), Finalized status, Panel Lot # (if QC Lot Support is enabled), and Inoculum Density. The Lab Report is sorted by Accession # then by Isolate # within accessions.

Below this information the organism Final ID is listed. An asterisk next to the Final ID indicates that the ID was changed by the user. Below this, the Media Type (for Yeast ID panels only) appears.

Next any instrument ID results are listed, along with the Confidence Value for the result. In the lower region of the report, for ID tests, the Biochemical, Instr(ument) Result, and Expected Result are provided. For AST tests, the Antimicrobial, Instr(ument) MIC, Instr(ument) SIR, BDXpert SIR, Final SIR, and Rule # are printed. If any panels have Resistance Markers, BDXpert Rules, Needs Attention flags, or Special Messages, these are printed at the bottom of the report.

ID and AST sections of combination panels print on separate pages of the report.

For QC panels, in addition to the information listed above, the following information is included: Panel Lot # and Expiration Date, Tech ID, ID Broth Lot # and Expiration Date, AST Broth Lot # and Expiration Date, Indicator Lot # and Expiration Date, and Test Strain. The QC Status of PASS, REVIEW, ERROR, or FAIL is indicated.

The system can be configured (see 2.3.1.1 General Instrument Configuration) to print an "abbreviated" lab report. The abbreviated report does not contain the individual biochemical results for ID or ID/AST panels.

See Figure 5-9.

#### To print a Lab Report:



From the Panel Results display, press the "print" soft key.

# Lab Report

03/30/03 09:11 VX.XXY / VA.AAB

Accession #	1313	<b>Test Start</b>	03/28/03 18:16
Isolate #	1	Test End	03/29/03 22:07
C	420011224567	T 4	1/401

Sequence #420011234567Instru # / Station1/A01Panel TypeGPIDASTFinalizedNo

**Status** COMPLETE

Final ID Staphylococcus haemolyticus Inoculum Density 0.5

**Instrument ID(s)**Staph. haemolyticus

Confidence Value
99%

Biochemical	Instr Result	Expected Result	Biochemical		Expected Result	Biochemical		Expected Result
A_ARARR A_LARGH	-	-		-	-	A_LALT A_LISO	-	-
A_LLEUH	-	-	A_LPHET	-	-	A_LPROB	-	-
•								
•			•			•		

[second page, header identical]

Antimicrobial	Instr <u>MIC</u>	Instr SIR	BDXpert SIR	Final SIR	Rule #
Ampicillin	>32	R		R	
Azithromycin	>8	R		R	
Ceftazidime	>64	R		R	
Clindamycin	0.25	S		S	
•					
	•				
	•				

#### **RESISTANCE MARKERS**

abcd - ABRV Text of triggered resistance markers appears here.

## **BDXpert TRIGGERED RULES**

1234 - AUTO Text of BDXpert triggered rule appears here.

## **End of Report**

Figure 5-9 - Sample Lab Report

# 5.6 Finalization

The Finalization display enables the review and finalization of panel test results in a batch mode or individually. The user can finalize panel results for one or all panels meeting the specified conditions, skip to a new panel, or modify and finalize panel results for a single panel. All fields on the Finalization display are read-only. To modify information for a panel, press the "panel results" soft key. When the instrument is connected to the BD EpiCenter Data Management System, the Finalization display is not available.

When Finalization is selected, the instrument finds the records that are eligible for finalization. To be eligible, a panel must have a status of Removable, not be a QC panel, and have no unignored Needs Attention flags. Eligible panels are sorted first by accession number and then by isolate number.

When the "batch finalize" soft key is pressed, the hourglass icon indicates that the finalization operation is in progress. A maximum of 200 panels may be finalized in a given finalization session.

Two types of reports, standard Lab Report(s) and a finalization Summary Report, may be printed. The Lab Report can only be printed after one or more panels have been finalized. The Summary report may be printed any time.

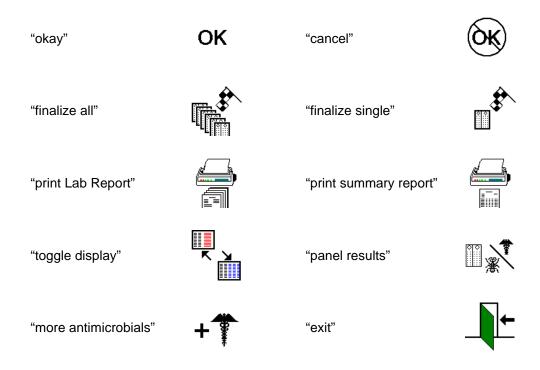
See Figure 5-10.

#### To access Finalization:



Press the "finalization" soft key from the Main Status screen

#### Finalization soft keys:



#### Finalization fields:

#### Accession #

Read-only field showing the panel's accession number.

### Sequence #

Read-only field showing the panel's sequence number.

#### Isolate #

Read-only field showing the panel's isolate number.

#### Media

Read-only field showing the media type selected during Panel Login for Yeast ID panels.

#### **Status**

Read-only field showing the panel's status.

#### Final ID

Read-only field showing the panel's final organism ID.

#### **Test Start**

Read-only field showing the panel's start of testing date and time.

#### **Test End**

Read-only field showing the panel's end of testing date and time.

#### Location

Read-only field showing the panel's location.

#### **Finalized**

Read-only field showing the panel's finalized status.

#### **Instrument Organism ID**

Read-only field showing the instrument identification of the organism.

#### Confidence

Read-only field showing the confidence value for the Instrument Organism ID.

#### **Biochemical**

Read-only field showing the biochemical abbreviation.

#### Actual

Read-only field showing the actual biochemical result.

#### **Expected**

Read-only field showing the expected biochemical result.

#### Antimicr(obial)

Read-only field showing the drug name.

#### MIC

Read-only field showing the Minimum Inhibitory Concentration value.

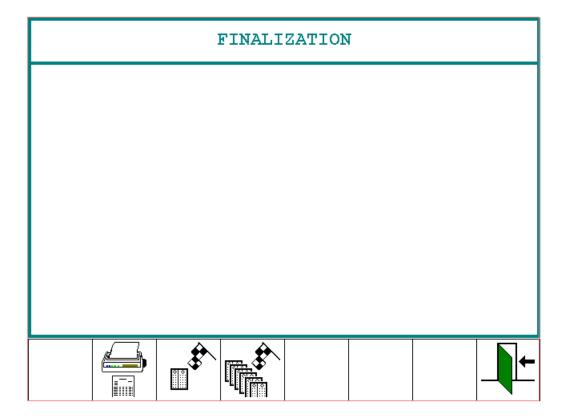


Figure 5-10 - Finalization Display

#### Interpretation

Read-only field showing the Susceptibility interpretation.

### **BDXpert SIR**

Read-only field showing the final results calculated by the BDXpert System based on the execution of all enabled BDXpert Rules as if they had been executed automatically.

#### **Final SIR**

Read-only field showing the Final Susceptibility interpretation. To modify a Final SIR value, press the "panel results" soft key to go to the Panel Results display.

# 5.7 Configuration/Maintenance

Refer to Section 2.3 for complete information on system Configuration. Refer to 4.2 Daily System Maintenance and 6 – Maintenance for information on system maintenance.

# 5.8 Reports

Numerous instrument reports are available for printing. The reports are as follows:

- Completed Lab Report contains information for all panels for which status became "Complete" during the selected time period (up to the past 48 hours).
- Accession Lab Report provides information for a specified accession number.
- Needs Attention List Report lists all panels in the instrument's database that have a Needs Attention flag set that have not been ignored.
- Resident Panel Report lists the panels contained in stations 1–25 for each tier.
- QC Lab Report lists all Test Strain Organisms that have completed testing and all biochemical and/or antimicrobial MIC results (for a specified Panel Lot #) that exist in the BD Phoenix databases when the report is requested.
- Cumulative QC Report provides information on quality control testing of all panel types.
- Daily Instrument Report lists the status of the instrument at the time the report is generated, along with a maintenance checklist.
- Interpretation Rule Set Report lists the antimicrobial breakpoints of the Interpretation Rule Set defined as the default Rule Set in the Instrument Configuration screen.
- BDXpert Rule Set Database Report lists each BDXpert rule number and the text describing
  the rule, whether each rule is enabled/disabled and whether each rule shall trigger
  automatically/manually in the system.
- Organism ID Code List Report displays all Organism Names, BD and LIS codes for all Organism Names that exist in the BD Phoenix database.
- Antimicrobial Code Report displays all antimicrobials, BD and LIS codes for all antimicrobials, that exist in the BD Phoenix database from all panel configurations.
- Lab Report contains all information for a panel sequence number that exists in the BD Phoenix database, including all information in the Panel Results screen, any special messages, BDXpert Rules that triggered, or Needs Attention Reasons if they exist. This report can only be printed from the Panel Results display or Finalization display.
- Finalization Summary Report contains all the panels eligible for finalization at the time the
  report was requested, as well as finalization status. This report can only be printed from the
  Finalization display.
- Panel Inventory Lab Report prints a Lab Report for all panels in the instrument. This report
  can only be printed from the Panel Inventory display.
- Custom Breakpoint Difference Report prints a listing of differences between old breakpoints and new ones after a BD Phoenix Update Disk or Install/Upgrade operation. This report can only be printed from the Custom Interpretation Rule Set (Configuration) display.
- Current QC Panel Lot Report contains information on the most recent QC test for each of the
  required strains for a panel lot, up to a maximum of 20 strains. This report can only be printed
  from the Panel Lot Definition display.
- Historical QC Panel Lot Report contains information on all tests for a strain for the current instrument, up to 200 tests. This report can only be printed from the Panel Lot Definition display.
- Panel Lot Report lists all the panel records for any panel lot number in the current instrument.
- Panel Lot Database Report lists all the defined panel lots in the current instrument, and provides statistical and reference information on those lots.

Each of the reports is discussed in greater detail in the sections that follow.

# 5.8.1 Completed Lab Report

The Completed Lab Report contains information for *all panels* for which status became "Complete" during the selected time period (up to the past 48 hours). The report provides the following information:

**Header:** Report Title, Preliminary indication (if Status is Ongoing, Pending, or Partial Complete; and/or if there are unignored Needs Attention conditions or a Needs Attention condition of Cannot Identify Barcode; and/or if the panel is not eligible for finalization), Laboratory Information (if configured), and Date and Time Printed, Software version (X.XXY) / BD Phoenix Update Disk (PUD) version (A.AAB).

**Body of Report:** Top Region: Accession #, Isolate #, Sequence #, Panel Type, Status (Ongoing, Complete), CRITICAL panel indication, Test Start with time, Test End with time, Instr #/Station (location), Finalized status, Panel Lot # (if QC Lot Support is enabled), and Inoculum Density. The Completed Lab Report is sorted by Accession # then by Isolate # within accessions.

For QC panels, in addition to the information listed above, the following information is included: Panel Lot # and Expiration Date, Tech ID, ID Broth Lot # and Expiration Date, AST Broth Lot # and Expiration Date, Indicator Lot # and Expiration Date, and Test Strain. The QC Status of PASS, REVIEW, ERROR, or FAIL is indicated.

Below this information the organism Final ID is listed. An asterisk next to the Final ID indicates that the ID was changed by the user. Below this, the Media Type (for Yeast ID panels only) appears.

Next any Instrument ID results are listed, along with the Confidence Value for the result. In the lower region of the report, for ID tests, the Biochemical, Instr(ument) Result, and Expected Result are provided. For AST tests, the Antimicrobial, Instr(ument) MIC, Instr(ument) SIR, BDXpert SIR, Final SIR, and Rule # are printed. If any panels have Resistance Markers, BDXpert Rules, Needs Attention flags, or Special Messages, these are printed at the bottom of the report. Any SIR values and Rule # are not reported for QC panels.

ID and AST sections of combination panels print on separate pages of the report.

See Figure 5-11 – Sample Completed Lab Report.

#### To print a Completed Lab Report:



From the Main Status screen, press the "print" soft key to access the Reports menu.



Use the UP ARROW or DOWN ARROW to highlight Completed Lab Report.

Start Date/Time

**Prior Period** 

This field defaults to the current date and time. This is the end time of the Completed Lab Report print period. The beginning time is the hour offset specified in Prior Period (below). Press the ▲ or ▼ key to increase or decrease the displayed value (Month, Day, Year, Hour, or Minute) to the

desired end date/time.

This field represents the number of hours back to print the report. That is, if "2" is selected for this field, the system prints Lab Reports for all panels that have completed testing from the time specified in Start Date/Time back 2 **hours**. This field defaults to 24 hours. Press the ▲ or ▼ key to increase or

decrease the displayed value anywhere from 1 to 48 hours ago.

QC Checkbox Press "select" to print a Completed QC Lab Report (disabled by default).

Press the "print" soft key again to print the report.

# Completed Lab Report

03/30/03 09:11 VX.XXY / VA.AAB

 Accession #
 1313
 Test Start
 03/28/03 18:16

 Isolate #
 1
 Test End
 03/29/03 22:07

 Source at #
 420011324567
 Instant # / Station
 1/401

Sequence #420011234567Instru # / Station1/A01Panel TypeGPIDASTFinalizedNo

**Status** COMPLETE

Final ID Staphylococcus haemolyticus Inoculum Density 0.5

Instrument ID(s) Confidence Value Supplemental Test(s)

Staph. haemolyticus 99%

Instr **Expected** Instr **Expected** Instr Expected Result Biochemical Result Result Biochemical Result Result Biochemical Result A\_GLPRB -A\_LALT A\_ARARR A\_LARGH A\_LHIST A\_LISO A LLEUH A LPHET A LPROB

[second page, header identical]

<u>Antimicrobial</u>	Instr MIC	Instr SIR	BDXpert SIR	Final SIR	Rule #
Ampicillin	>32	R		R	
Azithromycin	>8	R		R	
Ceftazidime	>64	R		R	
Clindamycin	0.25	S		S	
•		•			

#### RESISTANCE MARKERS

abcd - ABRV Text of triggered resistance markers appears here.

### **BDXpert TRIGGERED RULES**

1234 - AUTO Text of BDXpert triggered rule appears here.

**End of Report** 

Figure 5-11 - Sample Completed Lab Report

# 5.8.2 Accession Lab Report

The Accession Lab Report is basically a collection of lab reports for a specified accession number. It provides information for a specified accession number. Such information includes, as applicable: organism ID results, including specific biochemical reactions; AST results including SIR interpretation and MIC; QC pass/fail results; and any BDXpert Rules that were triggered. The report provides the following information:

**Header:** Report Title, Preliminary indication (if Status is Ongoing, Pending, or Partial Complete; and/or if there are unignored Needs Attention conditions or a Needs Attention condition of Cannot Identify Barcode; and/or if the panel is not eligible for finalization), Laboratory Information (if configured), Date and Time Printed, Software version (X.XXY) / BD Phoenix Update Disk (PUD) version (A.AAB).

**Body of Report:** Top Region: Accession #, Isolate #, Sequence #, Panel Type, Status (Ongoing, Complete), CRITICAL panel indication, Test Start with time, Test End with time, Instr #/Station (location), Finalized status, Panel Lot # (if QC Lot Support is enabled), and Inoculum Density. The Completed Lab Report is sorted by Accession # then by Isolate # within accessions.

Below this information the organism Final ID is listed. An asterisk next to the Final ID indicates that the ID was changed by the user. Below this, the Media Type (for Yeast ID panels only) appears.

Next any Instrument ID results are listed, along with the Confidence Value for the result. In the lower region of the report, for ID tests, the Biochemical, Instr(ument) Result, and Expected Result are provided. For AST tests, the Antimicrobial, Instr(ument) MIC, Instr(ument) SIR, BDXpert SIR, Final SIR, and Rule # are printed. If any panels have Resistance Markers, BDXpert Rules, Needs Attention flags, or Special Messages, these are printed at the bottom of the report. Any SIR values and Rule # are not reported for QC panels.

ID and AST sections of combination panels print on separate pages of the report.

For QC panels, in addition to the information listed above, the following information is included: Panel Lot # and Expiration Date, Tech ID, ID Broth Lot # and Expiration Date, AST Broth Lot # and Expiration Date, Indicator Lot # and Expiration Date, and Test Strain. The QC Status of PASS, REVIEW, ERROR, or FAIL is indicated.

See Figure 5-12 - Sample Accession Lab Report.

#### To print an Accession Lab Report:



From the Main Status screen, press the "print" soft key to access the Reports menu.



Use the UP ARROW or DOWN ARROW to highlight Accession Lab Report.



Type in or scan the desired Accession number. If an incorrect number is selected, press the "clear" soft key to clear the field and reenter the correct number.



Press the "print" soft key again to print the report.

# Accession Lab Report

03/30/03 09:11 VX.XXY / VA.AAB

Accession #	1313	Test Start	03/28/03 18:16
Isolate #	1	Test End	03/29/03 22:07
Sequence #	420011234567	Instru # / Station	1/A01
Panel Type	GPIDAST	Finalized	No

**Status** COMPLETE

Final ID Staphylococcus haemolyticus Inoculum Density 0.5

Instrument ID(s) Confidence Value Staph. haemolyticus 99%

Biochemical	Instr Result	Expected Result	Biochemical		Expected Result	Biochemical		Expected Result
A_ARARR	_	_	A_GLPRB	_	_	A_LALT	_	_
A_LARGH	_	_	A_LHIST	_	_	A_LISO	-	_
A_LLEUH	-	-	A_LPHET	-	-	A_LPROB	-	-
•			•					
			•					

[second page, header identical]

	<del>-</del>		_		
Antimicrobial	Instr MIC	Instr SIR	BDXpert SIR	Final SIR	Rule #
Ampicillin	>32	R		R	
Azithromycin	>8	R		R	
Ceftazidime	>64	R		R	
Clindamycin	0.25	S		S	
		·			
•					

#### RESISTANCE MARKERS

abcd - ABRV Text of triggered resistance markers appears here.

### **BDXpert TRIGGERED RULES**

1234 - AUTO Text of BDXpert triggered rule appears here.

**End of Report** 

Figure 5-12 - Sample Accession Lab Report

# 5.8.3 Needs Attention List Report

The Needs Attention List Report lists all the panels in the instrument's database that have a Needs Attention flag set that have not been ignored. This report can also be printed from the Needs Attention display. The report provides the following information:

**Header:** Report Title, Filtered report notification (if selected), Laboratory Information (if configured), and Date and Time Printed.

**Body of Report:** Needs Attention Reason, Sequence #, Accession #, Isolate #, Instr #/Station (location), and Status (Ongoing, Complete). If the report is filtered (default selection), an asterisk appears to the left of the Reason for panels with multiple Needs Attention conditions. The report is sorted by the priority of the Needs Attention Reasons (see 5.11 Needs Attention), and by Accession within each Reason type.

See Figure 5-13 – Sample Needs Attention List Report.

#### To print a Needs Attention List Report:



From the Main Status screen, press the "print" soft key to access the Reports menu.



Use the UP ARROW or DOWN ARROW to highlight Needs Attention List Report.

т

To print an unfiltered report, press T to advance to the Filtered checkbox. Press s or the "select" soft key to clear the check in the box.



Press the "print" soft key again to print the report.

# Needs Attention List Report

Filtered on highest priority reason

10/27/03 09:11

Reason	Sequence #	Accession #	Isolate #	Instr # / Station	<u>Status</u>
No Growth On Panel	420011234567	1313	1	1/A02	COMPLETE
Review QC Results	420027654321	1344	1	1/B03	COMPLETE
Can Not Determine Organism ID	420031234123	1489	1	1/C04	ONGOING
Can Not Identify Barcode	420047654765	1566	1	1/D05	COMPLETE

**End of Report** 

Figure 5-13 – Sample Needs Attention List Report

# 5.8.4 Resident Panel Report

The Resident Panel Report lists the panels contained in stations 1 - 25 for each tier detected during the last inventory scan. The report provides the following information:

**Header:** Report Title, Laboratory Information (if configured), Date and Time Printed, and Instrument #.

**Body of Report:** Accession #, Isolate #, Sequence #, QC (if panel is QC), Test Start with time, Inoculum Density, Panel Type, Status (Ongoing, Complete), and the highest priority Needs Attention Reason if one exists. The report is sorted by Accession # and then by Isolate # within each Accession.

See Figure 5-14 - Sample Resident Panel Report.

#### To print a Resident Panel Report:



From the Main Status screen, press the "print" soft key to access the Reports menu.



Use the UP ARROW or DOWN ARROW to highlight Resident Panel Report.



Press the "print" soft key again to print the report.

# Resident Panel Report

07/30/99 09:11 Instrument #1

Accession #	Isolate #	Sequence #	QC Test Start	Inoculum Density	n <u>Panel Type</u>	Status	Needs Attention
1654	1	420011234567	07/28/99 14:52	0.5	GNIDAST	COMPLETE	Missing Accession Number
1876	1	420011234568	07/28/99 15:33	0.5	GNIDAST	COMPLETE	•
11899	1	420011234569	07/28/99 15:36	0.5	GNIDAST	COMPLETE	
1945	1	420011234560	07/28/99 15:45	0.5	GNIDAST	COMPLETE	
•		•	•				•
•	•	•	•		•	•	•
•	•	•	•	•	•	•	•

**End of Report** 

Figure 5-14 - Sample Resident Panel Report

# 5.8.5 QC Lab Report

The QC Lab Report lists all QC panels from the Test Start date field entry to the current date. It lists all Test Strain Organisms that have completed testing and all biochemical and/or antimicrobial MIC results (for a specified panel lot number) that exist in the BD Phoenix database. The report provides the following information:

**Header:** Report Title, Laboratory Information (if configured), and Date and Time Printed, Software version (X.XXY) / BD Phoenix Update Disk (PUD) version (A.AAB).

**Body of Report:** Panel Lot # and Expiration Date, Test Start and time, Test End and time, Panel Type, Instr #/Station (location), Status (Ongoing, Complete), Tech ID, ID Broth Lot # and Expiration Date, AST Broth Lot # and Expiration Date, Indicator Lot # and Expiration Date, Sequence #, Accession #, Isolate #, Test Strain, Inoculum Density, Media Type (Yeast ID panels only), Instrument ID(s), and QC Status of PASS/FAIL/REPEAT/REVIEW. At the bottom of the report, any Needs Attention reasons or Special Messages are printed. Each Biochemical, along with Instr(ument) Result, and Expected Result are provided, as well as Antimicrobials, Instr(ument) MICs, Expected MICs, and Pass/Fail status.

This report is only available when BD EpiCenter is disabled.

See Figure 5-15 – Sample QC Lab Report.

#### To print a QC Lab Report:



From the Main Status screen, press the "print" soft key to access the Reports menu.





Use the UP ARROW or DOWN ARROW to highlight QC Lab Report.

#### Panel Lot #

Scan or type in the Panel Lot #; if QC Lot Support is enabled, press TAB to advance to the Panel Lot # field, then press DOWN ARROW to drop down the list of all defined lot numbers, and highlight the desired lot number then press the "select" soft key to select the lot.

In the first Test Start date field, press UP ARROW or DOWN ARROW to enter the desired day, month, or year (depending on the configuration). Press T to advance to the next date field and press UP ARROW or DOWN ARROW to enter the desired day, month, or year. Press T to advance to the next date field, and press UP ARROW or DOWN ARROW to enter the final portion of the date. If an incorrect number is entered, press the "clear" soft key to clear all the fields and reenter the correct number.

#### **Test Start**

If a Test Start date is not entered, the instrument prints all data from the database for the Panel Lot # entered.



Press the "print" soft key again to print the report.

# QC Lab Report

10/30/03 09:11 VX.XXY / VA.AAB

Panel Lot #	7777777	<b>Expiration Date Test End</b>	10/07/05
Test Start	10/28/03 10:02		10/29/03 22:07
Panel Type	GPIDAST	Instru # / Station	1/A01
Status	COMPLETE	Tech ID	ljk
ID Broth Lot #	6666666	Expiration Date	07/07/05
AST Broth Lot #	5555555	Expiration Date	08/08/05
Indicator Lot #	44444444	Expiration Date	09/09/05
Sequence # Accession # Isolate #	420012222222 9911 1		
Test Strain 292	213 Staphylococcus aureus	Inoculum Density	0.5

#### Instrument ID(s)

Staph. aureus

QC Status PASS

Biochemical	Instr Result	Expected Result	Biochemical		Expected Result	Biochemical		Expected Result
A_ARARR	_	-	A_GLPRB	-	-	A_LALT	-	-
A_LARGH	-	V	A_LHIST	-	-	A_LISO	-	-
A_LLEUH	-	-	A_LPHET	-	-	A_LPROB	-	-

[second page, header identical]

Antimicrobial	Instr MIC	Expected MIC	Pass/Fail
Amikacin	2	1.00-4.00	Pass
Chloramphenicol	4	2.00-8.00	Pass
Ciprofloxacin	0.25	0.13-0.50	Pass
Cephalexin	4	2.00-8.00	Pass
•		•	

#### **Needs Attention Reasons**

Text of Needs Attention Reasons goes here

### SPECIAL MESSAGES

The beta-lactamase test (nitrocefin based) passed QC.

**End of Report** 

Figure 5-15 - Sample QC Lab Report

# 5.8.6 Cumulative QC Report

The Cumulative QC Report provides information on completed quality control testing of all panel types. The report provides the following information:

**Header:** Report Title, Laboratory Information (if configured), Date and Time Printed, and Instrument #.

Body of Report: Selection Criteria: Panel Lot #, Panel Type, and Test Strains selected.

Below this, the panel Sequence # (sort order), QC Status (PASS, FAIL, REVIEW, ERROR), Test Strain, Test Start and time, Panel Lot #, ID Broth Lot #, AST Broth Lot #, Indicator Lot #, and Tech ID are listed for each panel.

This report is only available when BD EpiCenter is disabled.

See Figure 5-16 – Sample Cumulative QC Report.

#### To print a Cumulative QC Report:



From the Main Status screen, press the "print" soft key to access the Reports menu.



Use the UP ARROW or DOWN ARROW to highlight Cumulative QC Report.

#### If QC Lot Support is disabled:

Panel Lot #

Type in or scan the desired panel lot number. If an incorrect number is entered, press the "clear" soft key to clear all the fields and reenter the correct number.

All Checkbox

Initially, this box is checked, indicating that all completed QC data will be printed. Press the "move to next field" soft key to advance the cursor to this checkbox and press the "select" soft key to UN-check the box to specify panel types or test strains on which to report. The All checkbox supersedes any entry in the Panel Lot # field.

**Panel Type** 

Press UP ARROW or DOWN ARROW to highlight the desired panel type, or select "(all)" for all types. Only completed panel types appear in the list.

**Test Strain** 

Press UP ARROW or DOWN ARROW to highlight the desired test strain, or select "(all)" for all strains.

### If QC Lot Support is enabled:

Panel Lot #

To select results to print by lot number, use this field. Select "(all)" to print all panel lot numbers. To specify a specific lot #, press DOWN ARROW to drop down the list of defined lot numbers, highlight the desired lot number then press the "select" soft key to select the lot. The panel type field is completed automatically.

**Panel Type** 

To select results to print by panel type, use this field. Press DOWN ARROW to select a specific panel type to print, or select "(all)" for all types.

## **Test Strain**

To select results to print by test strain, use this field. Press DOWN ARROW to highlight the desired test strain, or select "(all)" for all strains. The "(all)" selection prints all strains when a panel lot number is specified (even strains not required for a panel type).



Press the "print" soft key again to print the report.

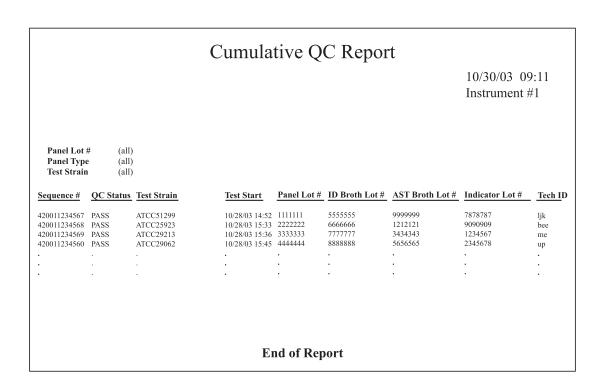


Figure 5-16 – Sample Cumulative QC Report

# 5.8.7 Daily Instrument Report

The Daily Instrument Report lists the status of the instrument at the time the report is generated, and provides areas to record maintenance activities. The Daily Instrument Report can be set to print automatically at a specified time. Refer to Section 2.3.1.

The report provides the following information:

**Header:** Report Title, Laboratory Information (if configured), Date and Time Printed, and Software version (X.XXY) / BD Phoenix Update Disk (PUD) version (A.AAB).

**Body of Report:** Instrument #, Serial #, Instrument Temperature Pass/Fail status, Carousel Rotational Test Pass/Fail status, Power Supply Check Pass/Fail status, Normalizer Panels Sequence #, Pass/Fail status, and Expiration Status (date if expiration is more than 60 days; "expires on date" if expiration is between 60 and 0 days; and "EXPIRED" if the panel is expired) for each tier, and blanks to record the reading, Pass/Fail status, and Tech ID for each of the following maintenance checks: Daily: Instrument Temperature (Main Status screen), Standard Panel Temperature, Printer Paper Supply: Weekly: Internal Green LEDs, Internal Red LEDs, Internal Amber LEDs, System Alert Indicator, and Instrument Audible Alarm. An area is provided for comments at the bottom.

The instrument temperature is considered to have passed when there are no outstanding E01 temperature alerts.

See Figure 5-17 – Sample Daily Instrument Report.

## To print a Daily Instrument Report:



From the Main Status screen, press the "print" soft key to access the Reports menu.



Use the UP ARROW or DOWN ARROW to highlight Daily Instrument Report.



Press the "print" soft key again to print the report.

#### Daily Instrument Report 11/30/07 09:11 VX.XXY / VA.AAB **Instrument** # Serial # 12345 Instrument Temperature Pass Carousel Rotational Test Pass Power Supply Check Pass **Normalizer Panels** Status **Expiration Status** Tier Sequence # 429990000001 Pass 10/21/08 Α 429990000002 10/21/08 В Pass $\mathbf{C}$ 429990000003 Pass 10/21/08 D 429990000004 10/21/08 Pass **Daily Pass Fail** Tech ID Record Instrument Temperature From Main Screen Range: (33.5 - 36.5) Record Standard Panel Temperature Range: (33.5 - 36.5) Check Printer Paper Supply Weekly Instrument Internal Green LEDs Instrument Internal Red LEDs Instrument Internal Amber LEDs Instrument System Alert Indicator Instrument Audible Alarm Comments

Figure 5-17 - Sample Daily Instrument Report

**End of Report** 

# 5.8.8 Interpretation Rule Set Report

The Interpretation Rule Set Report lists the antimicrobial breakpoints of the currently selected Interpretation Rule Set (defined as the default Rule Set in the Instrument Configuration screen). The report provides the following information:

Header: Report Title, Laboratory Information (if configured), and Date and Time Printed.

**Body of Report:** Rule Set, Rule Version, and columns for Antimicrobial (sort order), Test Group, Organism Group, Organism Name, S(usceptible) value, and R(esistance) value. Each antimicrobial breakpoint is listed in a separate row of the report.

The Interpretation Rule Set is a large report. Spooling and printing the report can consume system resources such that other reports cannot be printed until the current one completes.

To print reports of ALL the rule sets in the instrument, first select a rule set in Instrument Configuration (Section 2.3.1), then access the Reports menu and select Interpretation Rule Set Report. The currently selected rule set prints. When printing is complete, return to Instrument Configuration, and select the next rule set. Then access the Reports menu again and print the current Interpretation Rule Set. Continue selecting rule sets and printing until all rule set selections are printed. Remember to return to Instrument Configuration and select the desired rule set to use for interpretations when all printing is complete.

#### **NOTE**

Modification of the Interpretation Rule Set should not be performed while there are ongoing panels. This could lead to inaccurate interpretations.

See Figure 5-18 – Sample Interpretation Rule Set Report (sample data only).

#### To print an Interpretation Rule Set Report:



From the Main Status screen, press the "print" soft key to access the Reports menu.



Use the UP ARROW or DOWN ARROW to highlight Interpretation Rule Set Report.



Press the "print" soft key again.



A message informs the user about the report size. Press the "okay" soft key to print the report, or press the "cancel" soft key to cancel printing.

#### Interpretation Rule Set Report 03/30/05 09:11 **Rule Set** CLSI **Rule Version** M100-S13 Test Antimicrobial Organism Name Group Organism Group <u>S</u> <u>R</u> Ampicillin ENTC\_IC (all) <=8.00 >=16.00 Α Ampicillin A ENTERIC\_IC (all) <=8.00 >=32.00 Ampicillin HAEINF\_IC >=4.00 A (all) <=1.00 Ampicillin HAEIOTHF\_IC (all) <=1.00 >=4.00 A Ampicillin LISMON\_IC <=2.00 Α (all) Ampicillin O STAAUE\_IC (all) <=0.25 >=0.50 STAOTH\_IC Ampicillin Ο (all) <=0.25 >=0.50Ampicillin STRBET\_IC <=0.25 (all) Α **End of Report**

Figure 5-18 – Sample Interpretation Rule Set Report (sample data only)

# Organism (Interpretation) Group Codes: CLSI, SFM, or EUCAST

Interpretation Code	Interpretation Name	
ACIN_IC	Acinetobacter spp.	
AERM_IC	Aeromonas spp.	
AERMHC_IC	Aeromonas hydrophila complex	
BACI_IC	Bacillus spp.	
BURCEP_IC	Burkholderia cepacia	
CARHOM_IC	Cardiobacterium hominis	
CORY_IC	Corynebacterium spp.	
EIKCOR_IC	Eikenella corrodens	
ENTC_IC	Enterococcus spp.	
ENTERIC_IC	Enterobacterales	
ERYRHU_IC	Erysipelothrix rhusiopathiae	

Interpretation Code	Interpretation Name		
GNCBOTH_IC	Gram-negative coccobacilli, including Moraxella spp. other than MORBCAT_IC		
GNROTH_IC	Gram-negative rod, other than ACIN_IC, BURCEP_IC, ENTERIC, NFGNROTH_IC, PSEAER_IC, STEMAL_IC, PAST_IC		
GPCOTH_IC	Gram-positive, other than, <i>Staphylococcus</i> spp., <i>Streptococcus</i> spp., ENTC_IC, LEUC_IC, PEDI_IC		
GPROTH_IC	Gram-positive rod, other than BACI_IC, CORY_IC, ERYRHU_IC		
KIN_IC	Kingella spp.		
LEUC_IC	Leuconostoc spp.		
LISMON_IC	Listeria monocytogenes		
LISTOTH_IC	Listeria spp., other than LISMON_IC		
MORBCAT_IC	Moraxella (Branhamella) catarrhalis		
NFGNROTH_IC	Nonfermentative GNR, other than ACIN_IC, BURCEP_IC, PSEAER_IC, STEMAL_IC, ACTBACT_IC, CARHOM_IC, EIKCOR_IC		
NO_INTERP_IC	No Interpretation		
PAST_IC	Pasteurella spp.		
PEDI_IC	Pediococcus spp.		
PLESI_IC	Plesiomonas shigelloides		
PSEAER_IC	Pseudomonas aeruginosa		
STAAUE_IC	Staphylococcus aureus		
STAOTH_IC	Staphylococcus spp., other than STAAUE_IC		
STEMAL_IC	Stenotrophomonas maltophilia		
STRBET_IC	Streptococcus beta-hemolytic		
STROTH_IC	Streptococcus spp., other than STRBET_IC, STRPNE_IC, STRVIR_IC		
STRPNE_IC	Streptococcus pneumoniae		
STRVIR_IC	Streptococcus viridans group		
VIBCHO_IC	Vibrio cholerae		
VIBROTH_IC	Vibrio spp., other than VIBCHO_IC		

**Table 5-2 – Organism Group Codes** 

# 5.8.9 BDXpert Rule Set Database Report

The BDXpert Rule Set Database Report lists each BDXpert rule number and the text describing the rule, whether each rule is enabled/disabled and whether each rule shall trigger automatically/manually in the system. The report provides the following information:

**Header:** Report Title, Laboratory Information (if configured), Date and Time Printed, Rule Set (CLSI, SFM, EUCAST, or Custom), and Based On (CLSI, SFM, or EUCAST if Rule Set is Custom).

Body of Report: Rule #, text of the rule, Enabled/Disabled status, and Automatic/Manual status.

The BDXpert Rule Set Database is a large report. Spooling and printing the report can consume system resources such that other reports cannot be printed until the current one completes.

See Figure 5-19 – Sample BDXpert Rule Set Database Report.

#### To print a BDXpert Rule Set Database Report:



From the Main Status screen, press the "print" soft key to access the Reports menu.



Use the UP ARROW or DOWN ARROW to highlight BDXpert Rule Set Database Report.



Press the "print" soft key again.

**OK** 

A message informs the user about the report size. Press the "okay" soft key to print the report, or press the "cancel" soft key to cancel printing.

# BDXpert Rule Set Database Report

03/17/05 09:11

		03/1//	05 09:11
Rule Based			
Rule	<u>#</u>		
101	Only results for ampicillin, a fluoroquinolone, and trimethoprim-sulfamethoxazole should be reported for fecal isolates of Salmonella spp. or Shigella spp. No other drugs should be reported.	Enabled	Automatic
103	Results for chloramphenicol and a third generation cephalosporin should be reported for Salmonella spp. from extraintestinal sites.	Enabled	Automatic
104	Salmonella spp. and Shigella spp. should not be reported as susceptible or intermediate to first and second generation cephalosporins even if they appear to be susceptible in vitro because they are not effective clinically.	Enabled	Automatic
105	Ampicillin is the class representative for amoxicillin.	Enabled	Automatic
106			
•			

Figure 5-19 – Sample BDXpert Rule Set Database Report

**End of Report** 

# 5.8.10 Organism ID Code List Report

The Organism ID Code List Report prints all Organism Names and Abbreviations for all Organism Names that exist in the BD Phoenix database. The report provides the following information:

Header: Report Title, Laboratory Information (if configured), and Date and Time Printed.

Body of Report: Organism name (sort order), BD Code (abbreviation), and LIS Code (if enabled).

The Organism ID Code List is a large report. Spooling and printing the report can consume system resources such that other reports cannot be printed until the current one completes.

See Figure 5-20 – Sample Organism ID Code List Report.

## To print an Organism ID Code List Report:



From the Main Status screen, press the "print" soft key to access the Reports menu.



Use the UP ARROW or DOWN ARROW to highlight Organism ID Code List Report.



Press the "print" soft key again.

**OK** 

A message informs the user about the report size. Press the "okay" soft key to print the report, or press the "cancel" soft key to cancel printing.

# Organism ID Code List Report

07/30/99 09:11

Organism	BD Code	LIS Code
Achr. species	ACHRSPE	
Acinet. baumannii	ACINBAU	
Acinet. baumannii/calco. cplx	ACINBCX	
Acinet. calcoaceticus	ACINCAL	
•	•	
•	•	
•	•	
	<b>End of Report</b>	

Figure 5-20 - Sample Organism ID Code List Report

# 5.8.11 Antimicrobial Code Report

The Antimicrobial Code Report prints all antimicrobials and abbreviations for all antimicrobials that exist in the BD Phoenix database from all panel configurations. The report provides the following information:

Header: Report Title, Laboratory Information (if configured), and Date and Time Printed.

**Body of Report:** Antimicrobial name (sort order), BD Code (abbreviation), and LIS Code (if enabled).

The Antimicrobial Code is a large report. Spooling and printing the report can consume system resources such that other reports cannot be printed until the current one completes.

See Figure 5-21 – Sample Antimicrobial Code Report.

## To print an Antimicrobial Code Report:



From the Main Status screen, press the "print" soft key to access the Reports menu.



Use the UP ARROW or DOWN ARROW to highlight Antimicrobial Code Report.



Press the "print" soft key again.

OK

A message informs the user about the report size. Press the "okay" soft key to print the report, or press the "cancel" soft key to cancel printing.

# Antimicrobial Code Report

03/30/05 09:11

Antimicrobial	BD Code	LIS Code
Amikacin	AN	AN
Amoxicillin	AMX	AMX
Amoxicillin/Clavulanate	AMC	AMC
	•	•
	•	•
	•	•
	End of Report	

Figure 5-21 - Sample Antimicrobial Code Report

# 5.8.12 Lab Report/QC Lab Report

The Lab Report (Section 5.5.4) contains all information for a panel sequence number that exists in the BD Phoenix database, including all information in the Panel Results screen, any special messages, BDXpert Rules that triggered, or Needs Attention Reasons if they exist. The Lab Report is not accessible from the Reports menu. It can only be printed from the Panel Results or Finalization displays. A Panel Inventory Lab Report prints the same information for all panels listed in the Panel Inventory display (i.e., resident in the instrument and with final or partial results). Refer to 5.5.4 Lab Report for additional information.

The QC Lab Report (5.8.5) is also accessible from the Panel Results display. It provides similar information to the Lab Report, but for QC panels.

# 5.8.13 Finalization Summary Report

The Finalization Summary Report contains a listing of all the panels eligible for finalization at the time the report was requested, as well as finalization status. The Finalization Summary Report is not accessible from the reports menu. It can only be printed from the Finalization display. Refer to 5.6 Finalization for additional information.

# 5.8.14 Custom Breakpoint Difference Report

The Custom Breakpoint Difference Report contains a listing of differences between old breakpoints and new ones after a BD Phoenix Update Disk or install/upgrade operation. The Custom Breakpoint Difference Report is not accessible from the Reports menu. It can only be printed from the Custom Interpretation Rule Set (Configuration) display. Refer to 2.3.3 Custom Interpretation Rule Set for additional information.

# 5.8.15 Current QC Panel Lot Report

The Current QC Panel Lot Report contains information on the most recent QC test for each of the required strains for a panel lot, up to a maximum of 20 strains. The report includes information for any instruments whose data has been restored to the current instrument. The Current QC Panel Lot Report cannot be printed from the Reports menu. It can only be printed from the Panel Lot Definition display. Refer to 2.3.6 Panel Lot Definition.

# 5.8.16 Historical QC Panel Lot Report

The Historical QC Panel Lot Report contains information on all tests for a strain for the current instrument (only), up to 200 tests. The Historical QC Panel Lot Report cannot be printed from the Reports menu. It can only be printed from the Panel Lot Definition display. Refer to 2.3.6 Panel Lot Definition.

# 5.8.17 Panel Lot Report

The Panel Lot Report lists all the panel records for any panel lot number in the current instrument. The report first lists clinical panels, then QC panels. Within each of those groups, the report is sorted by Accession # then Isolate #.

The report provides the following information:

**Header:** Report Title, Laboratory Information (if configured), Date and Time Printed, Instrument where printed.

**Body of Report:** Panel Lot # and Panel Type; Accession #, Isolate #, Sequence #, QC (if panel is QC), Test Date, and Status (Pending, Ongoing, Complete) for each panel tested that belongs to the lot.

This report is only available when BD EpiCenter is disabled and QC Lot Support is enabled.

See Figure 5-21 – Sample Antimicrobial Code Report.

## To print a Panel Lot Report:



From the Main Status screen, press the "print" soft key to access the Reports menu.



Use the UP ARROW or DOWN ARROW to highlight Panel Lot Report.



Press the TAB key to move to the Panel Lot field.



Press DOWN ARROW to drop down the list of Panel lots; then highlight the desired lot and press the "select" soft key to select the highlighted lot.



Press the "print" soft key again.

Panel Lot Report  07/15/04 09:11 Instrument #1						
Panel Lot # Panel Type	7500001 PMIC/ID					
Accession #	Isolate #	Sequence #	<u>QC</u>	Test Date	Status	
QCA25923 QCA29212 QCA29213 1313.	2 1 1 2	425350001444 425350001445 425350001446 425350001447	QC QC QC	07/12/04 07/12/04 07/12/04 07/12/04	COMPLETE COMPLETE COMPLETE COMPLETE	
		:				
		End of R	eport			

Figure 5-22 – Sample Panel Lot Report

# 5.8.18 Panel Lot Database Report

The Panel Lot Database Report lists all the defined panel lots in the current instrument, and provides statistical and reference information on those lots.

The report provides the following information:

**Header:** Report Title, Laboratory Information (if configured), Date and Time Printed, Instrument where printed.

**Body of Report:** Panel Lot # (sort order, descending); Panel Type; Expiration Date; Extension Date (if Expiration date was extended); Start and End Sequence #s (Range); Definition Date; First and Last Date Used; and number of Panels Used.

This report is only available when BD EpiCenter is disabled and QC Lot Support is enabled.

See Figure 5-23 – Sample Panel Lot Database Report.

#### To print a Panel Lot Database Report:



From the Main Status screen, press the "print" soft key to access the Reports menu.



Use the UP ARROW or DOWN ARROW to highlight Panel Lot Database Report.



Press the "print" soft key again.

Panel Lot Database Report  07/15/04 09:11 Instrument #1									
Panel Lot #	Panel Type	Expiration Date	Extension Date	Sequence N	umber Range End	Definition Date	First Used Date	Last Used Date	Panels Used
9856543 7600001 7500001 7400001	NMIC/ID-1 SMIC/ID-2 PMIC/ID-17 NMIC	08/14/05 04/01/06 04/01/05 10/06/08		425010000001 428510004200 425350000101 422509999990	425010000099 428510004210 425350000200 422509999999	06/12/04 06/12/04 06/12/04 06/12/04	06/22/04 06/22/04 06/23/04 06/23/04	07/14/04 07/14/04 07/14/04 07/14/04	5 2 5 3
	End of Report								

Figure 5-23 - Sample Panel Lot Database Report

# 5.9 Panel Inventory

The Panel Inventory display provides a listing of all panels in the instrument (except temperature reference panels). This listing can be sorted in ascending (0–9, A–Z) or descending (9–0, Z–A) order by the following fields: panel sequence number, accession/isolate number, results, or needs attention reason. The initial default sort order is by accession/isolate number in ascending order. Subsequently, the list defaults to the last sort criteria and display configuration (primary/secondary) that was used. If there are no panels in the instrument, the display shows the message, "No Data Available."

The top of the Panel Inventory display shows the number of panels in the list (if there is more than one panel), the sort field, and whether the sort field is ascending or descending. See Figure 5-24.

The following fields are shown on the Panel Inventory display (if the information is known):

- ①② Sequence # of the panel
- Accession # (panels without accession numbers are listed first)
- ①② Iso(late number)
- ① (Inoculum) Density (blank for AST panels; "?" for ID panels until first test completes)
- Status (ongoing; complete; rapid if Rapid Completion is enabled and has been triggered for a panel)
- Results (final if panel is complete and there are no active Needs Attention conditions [all MIC results are determined for an AST panel, or all MIC values and the organism ID are determined for a Combination panel, or the organism ID is determined for an ID panel]; partial if a panel is ongoing or complete but has an active (unignored) Needs Attention condition [at least one MIC value is determined for an AST or Combination panel, or the organism ID is determined for a Combination panel]; none if no MIC values or organism ID is determined for any type of panel; a + preceding the result indicates that a Resistance Marker has triggered for that panel)
- N(eeds) A(ttention)/C(ritical Panel) ( "\*" if a Needs Attention reason that has not been ignored exists; blank when no Needs Attention reasons exist or they have all been ignored;
   if a critical panel event is triggered)
- ② Final (Organism) ID

Fields listed above with a "one" (①) appear on the primary Panel Inventory display. Fields listed above with a "two" (②) appear on the secondary display (Figure 5-25), which is accessed from the primary display via a soft key.

After the list is displayed, use the ▲ or ▼ key to highlight a panel and access the Panel Results display to view or edit panel information, to perform an instrument "locate panel" operation, or to print a Lab Report for panels with final or partial results. These functions are performed by the soft keys described below. Panels shown in red are critical panels that have not been acknowledged.

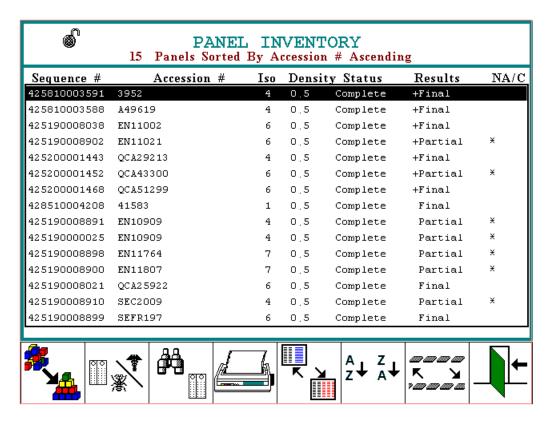


Figure 5-24 - Panel Inventory Display (primary)

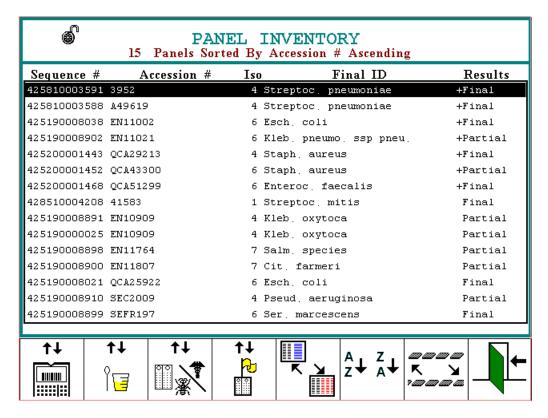


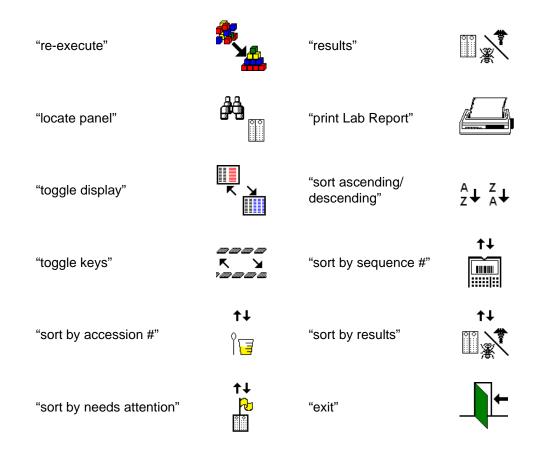
Figure 5-25 – Panel Inventory Display (secondary)

#### To access Panel Inventory:



Press the "panel inventory" soft key from the Main Status screen

#### Panel Inventory soft keys:



# 5.10 System Alerts

The System Alerts display provides a review of any existing system alerts that may have occurred or that may still exist in the instrument.

When the System Alerts display is accessed, the first alert in the list is shown in the middle of the screen. This alert is represented by an "E" code (such as E12). Below the "Enn" (where nn is a two-digit number) code one or more subcodes appear which are 8 digits. The subcode represents the specific condition of the alert. For example, E07 is a power supply alert, and subcode 00000002 specifies a problem in the 5 Volt power supply.

To view additional alerts that exist, press the UP ARROW or DOWN ARROW. All the "E" type errors are listed in **7 – Troubleshooting**. Not all error sub-codes can be addressed by the user.

# **System Alert Icons:**

Power was removed at indicated time

Power was restored at indicated time



More information on system alerts is provided in Section 4.12. A complete listing of system (E) and activity (W) alerts is provided in **7 – Troubleshooting**.

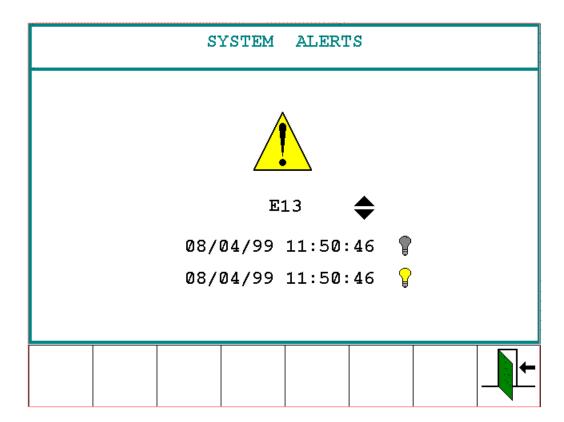


Figure 5-26 – System Alerts Display

# 5.11 Needs Attention

The Needs Attention display provides a list of panels in the instrument's database that have encountered a condition that requires operator attention. These conditions generally represent problems with the panels themselves, or with the information related to the panels. In many cases, the conditions can be corrected by operator action. See Figure 5-27 – Needs Attention Display.

When the Needs Attention panel list is viewed, the system provides the opportunity to resolve or ignore the condition that caused the panel to be placed in the list. If the panel was placed in the list due to missing or unresolved information (e.g., a Tie), the instrument provides the ability to add or edit the information to resolve the condition. If the panel was placed in the list due to a software, panel, or hardware error, the instrument provides the ability to delete the panel to resolve the error condition. Deleting a panel that is still testing causes that panel's protocol to be aborted. Only panels whose Needs Attention reason has not been ignored are shown in the display.

The Needs Attention display can be filtered to show one line per panel (filtered) or one line for each needs attention reason (unfiltered). A "toggle display" soft key provides the ability to switch the display between filtered (the default view) and unfiltered. When the display is filtered, only the highest priority reason is listed. Panels are shown in blue if additional needs attention conditions exist for that panel. When the display is unfiltered, each needs attention condition is listed separately. If a report is printed, it prints either filtered or unfiltered, depending on the current view.

When the unfiltered display to the filtered display is toggled, the highest priority Needs Attention reason code for the selected panel is highlighted. When the user toggles back to the unfiltered display, the same reason code is highlighted if it still appears in the list (see below).

The Needs Attention display lists the first 30 panels with a Needs Attention flag, sorted by reason code (in the same order as the list below) and then by accession number. Panels without an accession number are listed first within each Needs Attention reason code. If more than 30 panels need attention, only the 30 panels with the highest priority are shown until some of the panels are resolved.

When a Needs Attention reason code is cleared or ignored, the next highest priority reason code for that panel is highlighted. If there are no more reason codes for that panel, then the item at the top of the list is highlighted.

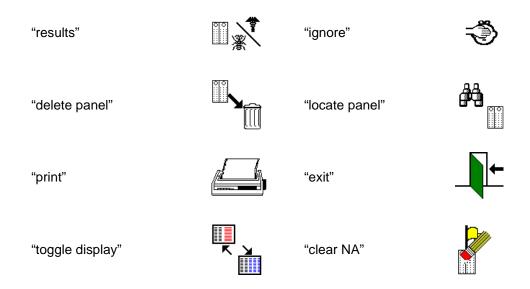
A Needs Attention reason code will remain highlighted if the screen is first toggled to the Panel Results display, and then is toggled back to the Needs Attention. If that reason is resolved, then the next highest priority reason code for that panel is highlighted. If there are no more reason codes for that panel, then the item at the top of the list is highlighted.

#### To access Needs Attention:



Press the "needs attention" soft key from the Main Status screen

## **Needs Attention soft keys:**



A panel may possess multiple Needs Attention reasons. If this is the case, the reasons are given in a prioritized list. The Needs Attention reasons are (in order of priority):

- Test Aborted one of several incubator System Alerts occurred; or an ongoing panel that
  was in the instrument has not tested for more than one hour; or the instrument was turned off
  for more than one hour; or the instrument door has been opened for more than one hour; or
  system software did not execute testing algorithms for more than one hour; or a panel was
  moved to a different tier/instrument; or a media type was not specified for a Yeast ID panel
- Cannot Identify Barcode internal barcode scanner could not read a panel sequence number in the same station where the instrument could determine a panel present condition (possible scratched or missing label); or invalid panel sequence number was scanned; or an unknown panel type was scanned
- Cannot Read Panel Wells internal barcode scanner has read a sequence number in a station but the instrument cannot determine that a panel is present in that same station
- Panel Lot Expired panel was logged in (or has a test start date) with a panel lot number that has already expired
- Invalid AST Results at least one MIC field contains a value of "X"; excludes QC panels
- Panel Missing internal barcode scanner reads a sequence number on a panel with an
  ongoing status during an inventory scan, but either the panel was removed before it completed
  its test protocol and hasn't obtained a result, or an internal scanner failure occurred and the
  sequence number can no longer be read
- **No Growth on Panel** instrument did not detect growth in Growth Control well of panel; excludes QC panels and ID panels
- Panel Lot Undefined Panel being logged in or placed in the instrument is from an undefined lot
- Review QC Results the status of a completed QC panel is "REVIEW." Panel results should be reviewed to determine if an error occurred during panel preparation/handling (select status of REPEAT) or if QC test actually failed (select status of FAIL)
- Missing Accession Number panel does not have any accession/isolate information; excludes QC panels

- **Missing Organism ID** panel has no organism ID, or has unresolved tie IDs, and has no related panel with an organism ID (which includes related panels that have unresolved tie IDs or organism conflicts); excludes QC panels
- Cannot Determine Organism ID panel has an Instrument Organism ID (or user-selected ID) of "No Identification" or it has no ID and its related panel has "No Identification" for its final ID, or ID panel concludes testing protocol without obtaining ID result; excludes QC panels
- Invalid Organism ID panel has no defined organism ID and its related panels have a defined Organism ID of "Invalid Organism Received" (conferred to the panel via Auto Association); or panel receives download of an organism ID not in the BD Phoenix database; or panel is logged in or modified to "Invalid Organism Received" in the Organism ID field
- Organism ID Conflict panel completes testing and has at least one related un-finalized panel
  that contains a different Final ID; excludes QC panels. Note that this code can be erroneously set
  as a result of conflicting system activities, such as when a panel completes testing and begins
  auto associating ID results as the system is modifying all the related panels with a user selected
  ID. If this occurs prior to the completion of the manually triggered modifications, the system can
  set this Needs Attention reason because IDs were in conflict due to two independent processes
  occurring. Determine this by reviewing all panel ID results.
- BDXpert Rule Flagged panel triggered one of the BDXpert rules defined, and the BDXpert
  rule is manually enabled in the Configuration menu, and the BDXpert rule triggered is pending;
  excludes QC panels, ID panels, and Combination panels with only the ID side enabled
- **Pending Too Long** panel has not been scanned internally by an instrument (during an inventory scan) within 30 minutes of being entered in Panel Login

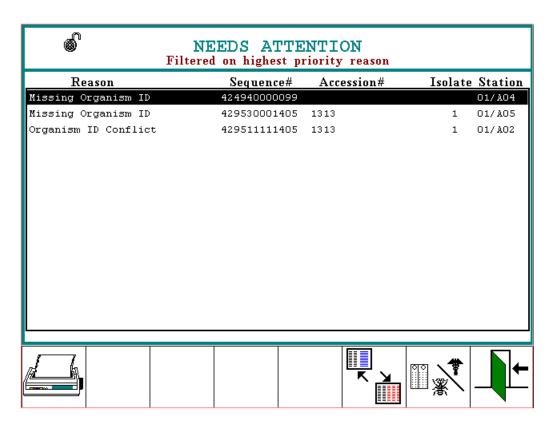


Figure 5-27 - Needs Attention Display

The following chart shows which soft keys are active for each reason code.

	"panel results"	"ignore"	"locate panel"	"delete panel"	"clear NA"
Test Aborted		*	*	*	
Cannot Identify Barcode		*	*		
Cannot Read Panel Wells			*	*	
Panel Lot Expired		*			*
Invalid AST Results		*			
Panel Missing		*		*	
No Growth on Panel		*	*	*	
Review QC Results	*	*	*	*	
Panel Lot Undefined					
Missing Accession Number	*		*		
Missing Organism ID	*				
Cannot Determine Organism ID	*	*			
Invalid Organism ID	*	*			
Organism ID Conflict	*				
BDXpert Rule Flagged	*				
Pending Too Long		*			

Table 5-3 – Needs Attention: Active Soft Keys

#### **Needs Attention fields:**

Note that some fields may be blank because panels are often placed in the Needs Attention list due to missing information.

# Reason

Read-only field showing the Needs Attention reason (full list above)

# Sequence #

Read-only field showing the panel barcode sequence number.

## Accession #

Read-only field showing the accession number.

# Isolate

Read-only field showing the isolate number.

# **Station**

Read-only field showing the last known location of the panel, in the form II/Tst (where II is the instrument number, T is the Tier, and st is the station number).

BD Phoenix Automated Microbiology System User's Manual							

# 6 - Maintenance

# 6.1 General

The BD Phoenix system requires little maintenance from the user to provide reliable performance. Daily activities include checking the instrument temperature and printer paper supply. Weekly, check the operation of the station status indicators (LEDs), the audible alarm, and the system alert indicator. Routine preventive maintenance consists of a monthly check of the recirculating air filters. All other procedures are on an "as needed" basis. Any maintenance or repair not described in this section should be performed by BD personnel only.

No preventive maintenance is required to be performed by BD authorized service personnel.

## **WARNING**

ALL MAINTENANCE AND REPAIR OTHER THAN THE PROCEDURES DESCRIBED IN SECTION 6.2 AND SECTION 6.3, MUST BE PERFORMED BY QUALIFIED SERVICE PERSONNEL. NON-COMPLIANCE WITH THIS WARNING MAY RESULT IN PERSONAL INJURY OR INSTRUMENT MALFUNCTION.

# 6.2 Routine Maintenance

# 6.2.1 Daily Maintenance

Each day the following maintenance procedures should be performed. The best time to perform maintenance is first thing in the morning, but it may be done any time that is convenient. The following items should be checked:

- 1. Check the printer's paper supply. If the paper supply is low or exhausted, replace the paper as explained in the manufacturer's operating instructions.
- Record the temperature readout on the LCD display and on the temperature standard panel. Note that the temperature panel can be brought into view by selecting one of the instrument LED check functions on the Maintenance menu (see 6.2.2). This temperature should be 35 °C ±1.5 °C.

# 6.2.2 Weekly Maintenance

Each week, verify the operation of the instrument indicator lamps and audible alarm. (These items appear on the Daily Instrument Report and may be performed daily if desired.)

1. To perform lamp verification, access the Main Status screen (Figure 6-1):

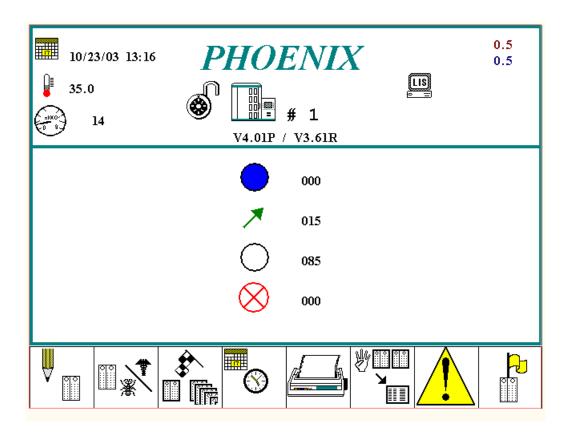
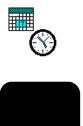


Figure 6-1 - Main Status Screen

2. Press the "configuration" soft key:



3. The password window appears. Enter the appropriate password and press the "perform action" soft key.



4. From the main Configuration display, press the "maintenance" soft key.



5. Perform tests on the internal and external LEDs and audible alarm (see list below). To select an item, use the UP ARROW or DOWN ARROW key to highlight the item. Then press the "perform action" soft key (below). For the internal LED tests, after a moment, the "door unlocked" icon appears, and the corresponding tone sounds. Open the door (only required for the first item being checked the door may remain open after that until maintenance is complete) and verify the item being checked.



Each of the following items that appear in the maintenance menu should be checked:

Test internal green LEDs (causes green LEDs at the 20 accessible stations to illuminate)

Test internal red LEDs (causes red LEDs at the 20 accessible stations to illuminate)

Test internal amber LEDs (causes amber LEDs at the 20 accessible stations to illuminate)

Test System Alert Indicator – (causes system alert indicator to blink for five repetitions at one second on followed by one second off)

Test Alarm – (causes sample audible alarm tone to sound at the default alarm volume of 5)

If any item that is being verified (LEDs, audible alarm) fails to operate, contact a BD representative to schedule repair.

# 6.2.3 Periodic Maintenance

# 6.2.3.1 Air Filter Replacement

There are three air filters on the BD Phoenix instrument. The Electronics Bay Filter is located on the right side of the instrument above the I/O ports. The Source Bay Filter is located on the left side of the instrument just below the center. The Incubator Air filter is located on the right side of the center bay of the instrument, near the top.

Check and if necessary change these air filters every six months. If the instrument's environment is especially dusty, check the filters more frequently. These filters must remain clean and unobstructed; restricted air flow may cause the instrument interior to reach excessive temperatures, which can affect results and possibly cause hardware malfunctions or failures. It is particularly important to keep the incubator air filter clean.

#### **Required Material**

New air filters (see Section 11 – Replacement Parts for catalog numbers)

Medium Phillips screwdriver (No. 2)

#### To Replace the Electronics Bay Air Filter (Figure 6-2)

- 1. The Electronics Bay Filter is located on the right side of the instrument above the I/O ports. The air filter is located behind a cover held in place by two Phillips screws.
- 2. To remove the filter, use a No. 2 Phillips screwdriver to loosen the two screws holding the filter cover in place. The screws are captive and require only one-quarter turn. They cannot be removed completely.
- 3. Flip the filter out and examine it for excessive dust and debris. Either replace the filter with a new one or return the existing filter back in the instrument.
- 4. Place the filter cover back in place. Tighten the two captive screws.

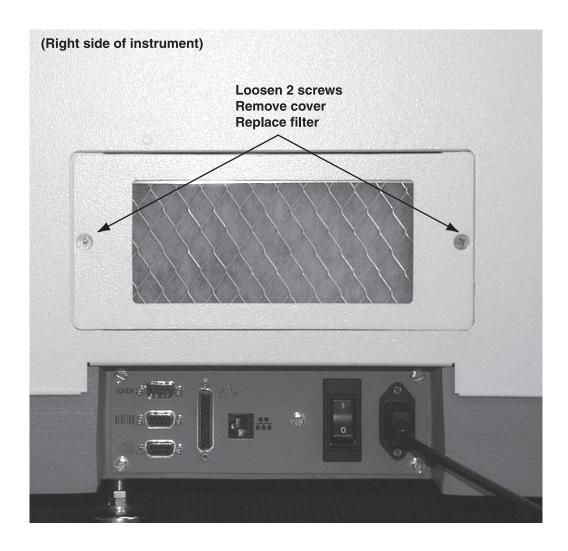


Figure 6-2 – Electronics Bay Filter Replacement

# To Replace the Source Bay Air Filter (Figure 6–3)

- 1. The Source Bay Filter is located on the left side of the instrument just below the center. The air filter is located behind a cover held in place by two Phillips screws.
- 2. To remove the filter, use a No. 2 Phillips screwdriver to loosen the two screws holding the filter cover in place. The screws are captive and require only one-quarter turn. They cannot be removed completely.
- 3. Flip the filter out and examine it for excessive dust and debris. Either replace the filter with a new one or return the existing filter back in the instrument.
- 4. Place the filter cover back in place. Tighten the two captive screws.

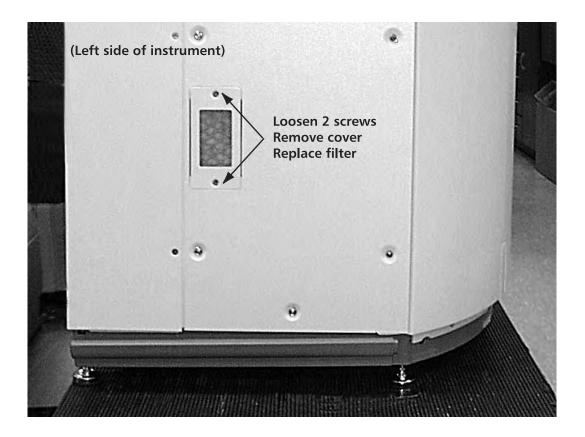


Figure 6-3 – Source Bay Filter Replacement

#### To Replace the Incubator Air Filter (Figure 6–4)

- 1. The Incubator Air filter is located on the right side of the center bay of the instrument, near the top. The air filter is located behind a cover held in place by two Phillips screws.
- 2. To remove the filter, use a No. 2 Phillips screwdriver to loosen the two screws holding the filter cover in place. The screws are captive and require only one-quarter turn. They cannot be removed completely.
- 3. Flip the filter out and examine it for excessive dust and debris. Either replace the filter with a new one or return the existing filter back in the instrument.

#### **CAUTION**

If the existing filter is reused, insure that it is replaced in the same orientation that it was removed (i.e., with arrow stamped on the side of the filter pointing in the same direction).

4. Place the filter cover back in place. Tighten the two captive screws.

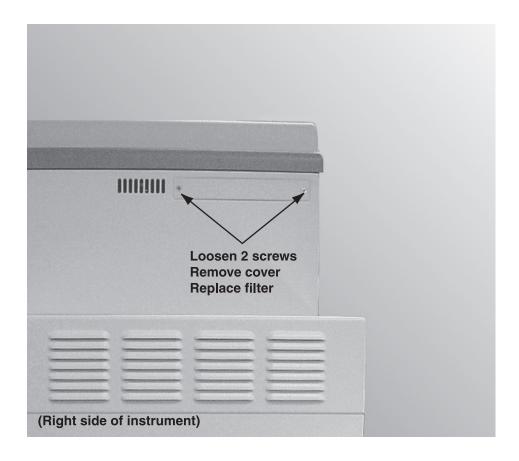


Figure 6-4 – Incubator Filter Replacement

# 6.2.3.2 Cleaning the Barcode Scanner Window

There are no user-serviceable parts in the barcode scanners. After a period of use, a barcode scanner may not seem to scan barcode labels as easily as before. If this happens, try to solve the problem by cleaning the scanner's window. To clean the window, use a lint-free, nonabrasive cloth dampened with distilled water. Dry the window with a dry lint-free nonabrasive cloth.

# 6.2.3.3 Cleaning/Decontamination

A situation requiring biological decontamination of one or more panel locations can occur if a panel should leak while in the instrument. The priority in this situation is to first limit the extent of the contamination and then to decontaminate the panel location(s) and other accessible instrument areas receiving the spill. If the spill extends into regions of the carousel not accessible for topical decontamination, contact BD Technical Service (USA) for further instructions (800–638–8663).

#### To Decontaminate Carousel Panel Locations

The solution recommended to clean the affected surfaces should be at least a 10% household bleach solution. All surfaces must be thoroughly washed with the freshly prepared bleach solution, so that the surfaces are "glistening wet." If the extent of the contamination is unknown, thoroughly wash the exposed portions of the carousel and cabinet with the freshly prepared bleach solution.

#### **WARNING**

# INFORMATION ON AN ACTIVITY WHICH POTENTIALLY COULD CAUSE INJURY TO THE USER IS PRESENTED AS A WARNING.

- 1. Wear gloves and a gown, completely covering any body surfaces that could possibly come into contact with the affected instrument surfaces.
- 2. Turn off power to the instrument. Unplug the instrument power cord before proceeding.
- 3. Completely absorb the contaminated spill (gauze pads are most effective).
- 4. Apply the bleach solution to the affected surfaces, so that the surfaces are "glistening wet." Let stand for approximately 15 minutes.
- 5. Absorb the applied solution with gauze pads or paper towels.
- 6. Dampen a clean cloth with water. Wipe down the decontaminated surfaces.
- 7. Thoroughly dry all wet surfaces.
- 8. Discard all cleanup materials as biohazardous waste.

# 6.2.4 Maintenance Menu

The Maintenance menu, accessible from the Configuration menu, provides several functions for performing instrument maintenance. A number of these functions, noted below, are for BD use only. Others are for user weekly and "as needed" maintenance. The following functions appear under the Maintenance menu:

Test Internal Green LEDs (Section 6.2.2

Test Internal Red LEDs (Section 6.2.2)

Test Internal Amber LEDs (Section 6.2.2)

Test System Alert Indicator (Section 6.2.2)

Test Alarm (Section 6.2.2)

Install/Upgrade (Section 2.5)

Save System Data to Disk/USB (Section 7.3)

Save Syslog to Disk/USB (Section 7.4)

Access Normalizer Panel (for BD use only)

Save User Data to Disk/USB (Section 6.2.4.1)

Restore User Data from Disk/USB (Section 6.2.4.2)

Save LIS Codes to Disk/USB (Section 6.2.4.3)

Restore LIS Codes from Disk/USB (Section 6.2.4.4)

Save Panel Lot Definitions (Section 6.2.4.5)

Restore Panel Lot Definitions (Section 6.2.4.6)

Save Panel Configuration (Section 6.2.4.7)

Install Panel Configuration (Section 6.2.4.8)

BD Phoenix Update Disk/USB (Section 6.2.4.9)

Modify Panel Usage (Section 6.2.4.10)

Write Lightsrc to Disk/USB (Section 6.2.4.11)

Read Lightsrc from Disk/USB (Section 6.2.4.12)

View Syslog (Section 6.2.4.13)

Save Syslog to Network (Section 6.2.4.14)

Display UV and RGB Status (Section 6.2.4.15)

Force Front UV Bulb Adjustment (Section 6.2.4.16)

Force Rear UV Bulb Adjustment (Section 6.2.4.17)

Force RGB LED Adjustment (Section 6.2.4.18)

Front Panel Reader Setup (Section 6.2.4.19)

#### 6.2.4.1 Save User Data to Disk or USB

Save User Data provides the ability to backup the configuration parameters that have been set. This data includes: Custom Interpretation Rule Set Configuration, and BDXpert Rules Configuration. The information saved is for the current instrument only. However, information saved at one instrument can be restored at another instrument. This provides consistent configurations among all the instruments. To save data, follow the steps below:

1. Press the "configuration" soft key.



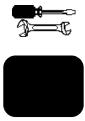


2. The password window appears. Enter the appropriate password and press the "perform action" soft key.





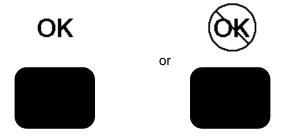
3. From the main Configuration display, press the "maintenance" soft key.



- 4. Press the UP ARROW or DOWN ARROW to highlight the selection, "SAVE USER DATA TO DISK."
- 5. Insert a USB key or a blank, formatted, write-enabled floppy disk in the disk drive.
- 6. Press the "perform action" soft key.



7. The system asks you to confirm that you wish to save the data to diskette. Press the "confirm" soft key to proceed with the save or "cancel" to cancel the operation.



8. An hourglass icon appears while the information is being written to the disk.



- 9. When the activity is complete, the "activity completed" tone sounds and the hourglass icon disappear. Make sure the disk indicator is off, then remove the floppy disk by pressing the disk eject button.
- 10. Write protect the disk.

## 6.2.4.2 Restore User Data from Disk

Restore User Data from Disk provides restoration of the configuration parameters have been copied to floppy disk back to the instrument. This data includes: Custom Interpretation Rule Set Configuration, and BDXpert Rules Configuration. To restore, the instrument door must be closed. To restore data from disk, follow the steps below:

#### NOTE

This operation should not be performed while there are ongoing panels.

1. Press the "configuration" soft key.





2. The password window appears. Enter the appropriate password and press the "perform action" soft key.



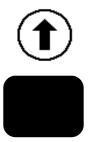
3. From the main Configuration display, press the "maintenance" soft key.



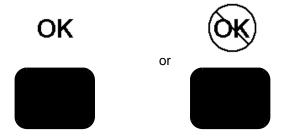


- 4. Press the UP ARROW or DOWN ARROW to highlight the selection, "RESTORE USER DATA FROM DISK."
- 5. Insert the saved user data floppy disk in the disk drive.

6. Press the "perform action" soft key.



7. Confirm that restoration of the data from diskette is desired, and advises that the instrument will reboot when the restore is complete. Press the "confirm" soft key to proceed with the restore or "cancel" to cancel the operation.



- 8. The system verifies the dates of the backed up files on the floppy disk. If any files are older than the ones currently on the instrument, confirm that the more current files on the instrument should be replaced with the older files on the floppy disk. None, one, several, or all of the newer files can be replaced.
- 9. An hourglass icon appears while the information is being copied from the disk, as well as the message, "Restoring Data."



- 10. When the activity is complete, the "activity completed" tone sounds and the hourglass icon disappear. The instrument then automatically reboots.
- 11. Make sure the disk indicator is off, then remove the floppy disk by pressing the disk eject button. Note that the new files may take at least 15 minutes to load into instrument memory.

#### 6.2.4.3 Save LIS Codes to Disk

Saving LIS Codes to Disk provides the ability to save all the Organism and Antimicrobial LIS codes defined to floppy disk. This produces a text file that can be edited on a PC, which might be quicker for some users who have many edits to perform. Then, the edited codes can be restored (see 6.2.4.4 Restore LIS Codes from Disk) back to the BD Phoenix instrument. The function also provides the ability to copy codes from one instrument to another. Save LIS Codes to Disk appears on the Maintenance menu only if LIS Communications is enabled.

Entries in the text field consist of:

Identifier (ORG, QC\_ORG, DRUG) | BD Code | Short Name/Drug | LIS Code

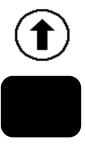
Codes cannot be added or deleted, and **only** the LIS Code portion can be modified. If another field is changed, the instrument will not restore the codes.

# To save codes to disk, follow the steps below:

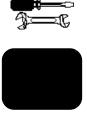
1. Press the "configuration" soft key.



2. The password window appears. Enter the appropriate password and press the "perform action" soft key.



3. From the main Configuration display, press the "maintenance" soft key.

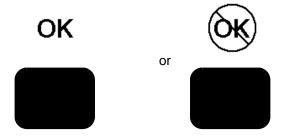


- Press the UP ARROW or DOWN ARROW to highlight the selection, "SAVE LIS CODES TO DISK."
- 5. Insert a blank, formatted, write-enabled floppy disk in the disk drive.

6. Press the "perform action" soft key.



7. The system asks you to confirm that you wish to save the data to diskette. Press the "confirm" soft key to proceed with the save or "cancel" to cancel the operation.



8. An hourglass icon appears while the information is being written to the disk.



9. When the activity is complete, the "activity completed" tone sounds and the hourglass icon disappears. Make sure the disk indicator is off, then remove the floppy disk by pressing the disk eject button.

### 6.2.4.4 Restore LIS Codes from Disk

Restoring LIS Codes from Disk provides the ability to restore the Organism and/or Antimicrobial codes that have been previously copied to floppy disk back to the instrument. The restore operation completely overwrites the existing Organism/Antimicrobial LIS Code database. Codes will not be restored if any field other than LIS Code was modified, or if LIS Code was entered in an incorrect format. If this happens, an error log is written on the floppy disk, and you can review this file to see what caused the error. Restore LIS Codes from Disk appears on the Maintenance menu only if LIS Communications is enabled.

# To restore codes from disk, follow the steps below:

1. Press the "configuration" soft key.

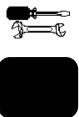




2. The password window appears. Enter the appropriate password and press the "perform action" soft key.



3. From the main Configuration display, press the "maintenance" soft key.

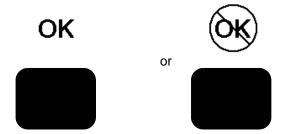


- 4. Press the UP ARROW or DOWN ARROW to highlight the selection, "RESTORE LIS CODES FROM DISK."
- 5. Insert the saved LIS codes floppy disk in the disk drive.
- 6. Press the "perform action" soft key.





7. Press the "confirm" soft key to proceed with the restore from the diskette or "cancel" to cancel the operation.



8. An hourglass icon appears while the information is being copied from the disk, as well as the message "Restoring Data."



- 9. When the activity is complete, the message, "Complete" flashes on the screen, the "activity completed" tone sounds, and the hourglass icon disappears.
- 10. Make sure the disk indicator is off, then remove the floppy disk by pressing the disk eject button.

#### 6.2.4.5 Save Panel Lot Definitions

Save Panel Lot Definitions provides the ability to save the panel lots present in the instrument to a floppy disk. This enables the transfer of these lot definitions (and QC panel results) to other instruments so that the records can be viewed/used there. **Save Panel Lot Definitions** saves the defined panel lots and related data (Sequence #s, Expirations Dates, etc.), and QC results for any strains tested in those lots. Save Panel Lot Definitions appears on the Maintenance menu only if QC Lot Support is enabled.

#### To save panel lot definitions to disk, follow the steps below:

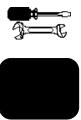
1. Press the "configuration" soft key.



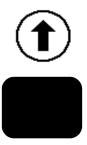
2. The password window appears. Enter the appropriate password and press the "perform action" soft key.



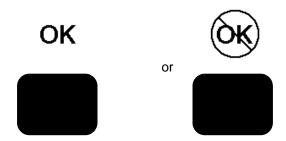
3. From the main Configuration display, press the "maintenance" soft key.



- 4. Press the UP ARROW or DOWN ARROW to highlight the selection, "SAVE PANEL LOT DEFINITIONS."
- 5. Insert a blank, formatted, write-enabled floppy disk in the disk drive.
- 6. Press the "perform action" soft key.



7. Press the "confirm" soft key to save or "cancel" to cancel the operation.



8. An hourglass icon appears while the information is being written to the disk.



When the activity is complete, the "activity completed" tone sounds and the hourglass icon disappears. Make sure the disk indicator is off, then remove the floppy disk by pressing the disk eject button.

#### 6.2.4.6 Restore Panel Lot Definitions

Restore Panel Lot Definitions provides the ability to restore Panel Lot Definitions saved at one instrument to another. This makes Panel Lot definitions and QC panel results transferrable in labs that use multiple instruments, so that a lot needs to be defined only once using the box (carton) label. Restore Panel Lot Definitions appears on the Maintenance menu only if QC Lot Support is enabled.

#### To restore panel lot definitions from disk, follow the steps below:

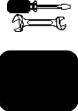
1. Press the "configuration" soft key.



2. The password window appears. Enter the appropriate password and press the "perform action" soft key.



3. From the main Configuration display, press the "maintenance" soft key.

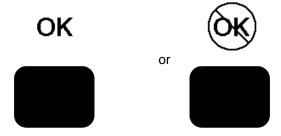


4. Press the UP ARROW or DOWN ARROW to highlight the selection, "RESTORE PANEL LOT DEFINITIONS."

- 5. Insert the saved definitions floppy disk in the disk drive.
- 6. Press the "perform action" soft key.



7. Press the "confirm" soft key to proceed with the restore or "cancel" to cancel the operation.



8. An hourglass icon appears while the information is being copied from the disk, as well as the message "Restoring Data."



- 9. If a message appears about a conflict between the restore disk and the instrument's panel lot information, contact BD for assistance.
  - Otherwise, when the activity is complete, the message, "Complete" flashes on the screen, the "activity completed" tone sounds, and the hourglass icon disappears.
- 10. Make sure the disk indicator is off, then remove the floppy disk by pressing the disk eject button.

# 6.2.4.7 Save Panel Configuration

Save Panel Configuration provides the ability to backup the instrument's panel configurations to floppy disk. The information saved is for the current instrument only. However, information saved at one instrument can be installed at another instrument. This provides consistent panel configurations among all the instruments. To save panel configurations to disk, follow the steps below:

1. Press the "configuration" soft key.



2. The password window appears. Enter the appropriate password and press the "perform action" soft key.



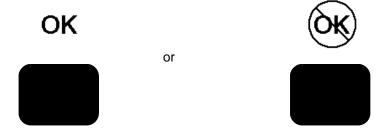
3. From the main Configuration display, press the "maintenance" soft key.



- 4. Press the UP ARROW or DOWN ARROW to highlight the selection, "SAVE PANEL CONFIGURATION."
- 5. Insert a blank, formatted, write-enabled floppy disk in the disk drive.
- 6. Press the "perform action" soft key.



7. Press the "confirm" soft key to proceed with the save or "cancel" to cancel the operation.



8. An hourglass icon appears while the information is being written to the disk.



- 9. When the activity is complete, the "activity completed" tone sounds and the hourglass icon disappears. Make sure the disk drive indicator is off, then remove the floppy disk by pressing the disk eject button.
- 10. Write protect the disk.

# 6.2.4.8 Install Panel Configuration

Install Panel Configuration provides the ability to update the instrument's panel configurations. To perform this operation, the instrument door must be closed.

To install panel configurations, follow the steps below:

#### **NOTE**

This operation should not be performed while there are ongoing panels.

1. Press the "configuration" soft key.





2. The password window appears. Enter the appropriate password and press the "perform action" soft key.





3. From the main Configuration display, press the "maintenance" soft key.



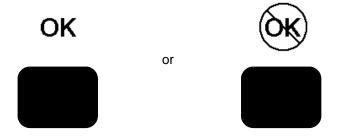


- 4. Press the UP ARROW or DOWN ARROW to highlight the selection, "INSTALL PANEL CONFIGURATION."
- 5. Insert the (first, if there is more than one) panel configuration floppy disk in the disk drive.

6. Press the "perform action" soft key.



7. Confirm the wish to install the data from diskette. The instrument will reboot when the installation is complete. Press the "confirm" soft key to proceed with the installation or "cancel" to cancel the operation.



8. An hourglass icon appears while the information is being copied from the disk.



- 9. When the activity is complete, the "activity completed" tone sounds and the hourglass icon disappears. The instrument then automatically reboots.
- 10. Make sure the disk indicator is off, then remove the floppy disk by pressing the disk eject button.

# 6.2.4.9 BD Phoenix Update Disk

BD Phoenix Update Disk (PUD) provides the ability to update numerous data files in the instrument, such as antimicrobial breakpoints and rules, QC data, drugs, organisms, etc. To install the BD Phoenix Update Disk, follow the steps below:

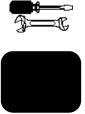
1. Press the "configuration" soft key.



2. The password window appears. Enter the appropriate password and press the "perform action" soft key.



3. From the main Configuration display, press the "maintenance" soft key.



- 4. Press the UP ARROW or DOWN ARROW to highlight the selection, "PHOENIX UPDATE DISK."
- 5. Insert the (first, if there is more than one) update disk in the disk drive.
- 6. Press the "perform action" soft key.



7. Confirm the wish to install the data from diskette. The instrument will reboot when the installation is complete. Press the "confirm" soft key to proceed with the installation or "cancel" to cancel the operation.



- 8. The system verifies the version and configuration of the files on the floppy disk. If any files are older than the ones currently on the instrument, the instrument issues an alert (E34) and does not perform the update.
- 9. An hourglass icon appears while the information is being copied from the disk.



10. If additional disks are required, the system displays the following message: "Please insert disk # n of BD Phoenix update set, then press OK to continue."

Remove the disk and insert BD Phoenix update floppy disk # n in the disk drive.

- 11. When the activity is complete, the "activity completed" tone sounds and the hourglass icon disappears. The instrument then automatically reboots.
- 12. Make sure the disk indicator is off, then remove the floppy disk by pressing the disk eject button.

# 6.2.4.10 Modify Panel Usage

The Modify Panel Usage operation provides the ability to disable either the ID or the AST side of a combination panel that is not Removable (provided both sides are currently enabled). To modify panel usage:

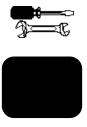
1. Press the "configuration" soft key.



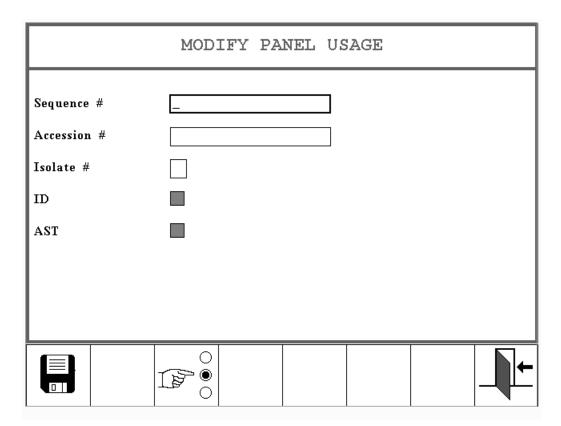
2. The password window appears. Enter the appropriate password and press the "perform action" soft key.



3. From the main Configuration display, press the "maintenance" soft key.



- 4. Press the UP ARROW or DOWN ARROW to highlight the selection, "MODIFY PANEL USAGE."
- 5. The following display appears:



- Enter or scan the panel barcode sequence number of the panel whose usage to be modified.
   The system automatically completes the Accession # and Isolate # fields, which are read-only.
- 7. Use the "tab" key to advance to either the **ID** or **AST** Checkbox (depending on which side of the panel is to be disabled). Press the "select" soft key or s to "un-check" the checkbox.
- 8. Press the "save" soft key to save the panel modification.

Note the following conditions for panel usage modification:

- H No information for related panels is modified when panel usage is changed.
- H If there is no user-entered Final ID and the ID side is disabled, the Instrument ID, Biochemical Results, Confidence Values, SIR Values, and ID Special Messages are removed from the record.
- H If there IS a user-entered Final ID and the ID side is disabled, this ID is retained, as are SIR Values. However, Instrument ID, Biochemical Results, Confidence Values, and ID Special Messages are removed from the record.

# 6.2.4.11 Write Light Source to Disk

The Write Light Source to Disk operation provides the ability to create a floppy disk containing the current values needed by the instrument to establish setpoints for source LEDs. **The operation should only be performed when advised by the local BD representative.** 

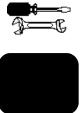
1. From the Main Status Screen, press the "configuration" soft key. The main configuration screen appears.



2. The password window appears. Enter the appropriate password and press the "perform action" soft key.

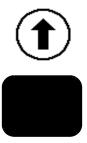


3. From the main Configuration display, press the "maintenance" soft key.

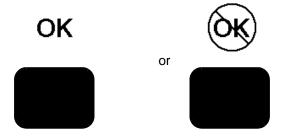


4. Insert a blank, formatted, write-enabled floppy disk in the disk drive. Be sure the disk is labeled "Light Source Disk" and includes the instrument serial number.

- 5. Use the UP ARROW or DOWN ARROW to highlight the selection, "WRITE LIGHTSRC TO DISKETTE." The instrument verifies that a proper disk is in the drive.
- 6. Press the "perform action" soft key.



7. Press the "confirm" soft key to save the data to the diskette or "cancel" to cancel the operation.



8. An hourglass icon appears while the Light Source information is being written to the disk.



- 9. When the activity is complete, the "activity completed" tone sounds and the hourglass icon disappears. Make sure the disk drive indicator is off, then remove the floppy disk by pressing the disk eject button.
- 10. Write protect the disk.

# 6.2.4.12 Read Light Source from Diskette

Read Light Source from Disk provides the ability to install new light source files that have been saved on floppy disk (either the one provided with the system at installation or one suggested by BD to create). The operation can be performed only when the instrument is idle, there are no ongoing panels, and the instrument has completed an inventory scan. The same normalizer panels must be present in the instrument as when the light source disk was made.

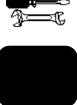
1. Press the "configuration" soft key.



2. The password window appears. Enter the appropriate password and press the "perform action" soft key.



3. From the main Configuration display, press the "maintenance" soft key.

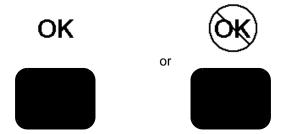


- 4. Press the UP ARROW or DOWN ARROW to highlight the selection, "READ LIGHTSRC FROM DISKETTE."
- 5. Insert the light source floppy disk in the disk drive.
- 6. Press the "perform action" soft key.





7. Press the "confirm" soft key to proceed with the installation of the data from the diskette to NVRAM or "cancel" to cancel the operation.



- 8. The system verifies the dates of the files on the floppy disk. If any files are older than the ones currently on the instrument, confirm the replacement of the more current files on the instrument with the older files on the floppy disk. Choose to replace none, one, several, or all of the newer files.
- 9. An hourglass icon appears while the information is being copied from the disk.



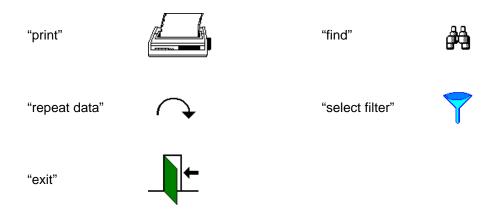
- 10. When the activity is complete, the "activity completed" tone sounds and the hourglass icon disappears.
- 11. Make sure the disk indicator is off, then remove the floppy disk by pressing the disk eject

# 6.2.4.13 View Syslog

View Syslog provides the ability to view a list of messages that the LIS communications function has generated. Note that the display will contain no messages if the BD EpiCenter system is connected. The messages represent status messages that have occurred during communications, such as query messages, log entries, interface messages, etc. This list can be filtered by date, printed (a potentially large report that prints in landscape orientation), and can be searched to find particular words or phrases (with repeat find of the term).

Refer to Section 15 – Event Log Messages for a complete listing of messages and corrective actions.

# View Syslog soft keys:



#### To view the system log:

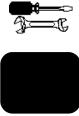
1. Press the "configuration" soft key.



2. The password window appears. Enter the appropriate password and press the "perform action" soft key.



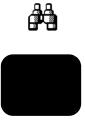
3. From the main Configuration display, press the "maintenance" soft key.



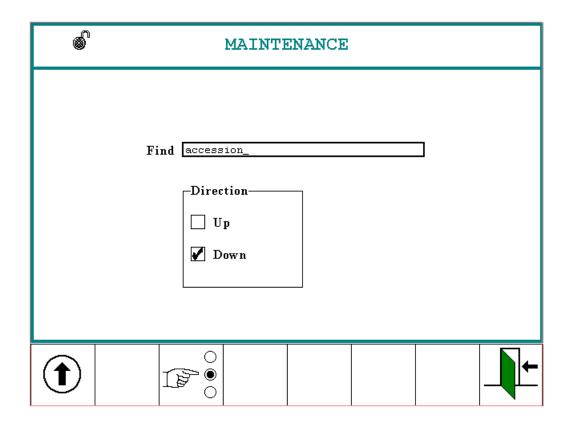
- 4. Press the UP ARROW or DOWN ARROW to highlight the selection, "VIEW SYSLOG" and press the "perform action" soft key. The system log then appears.
- 5. All available LIS messages appear in the window, with the oldest messages at the top. If more messages exist than can fit in the window, use the DOWN ARROW to view messages below those displayed. If the message is wider than the window size, press r on the keyboard to see the rest of the message. Press I to return the display to the original position.

#### To search the system log:

1. Press the "find" soft key.

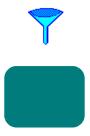


- 2. The Find display appears.
- 3. In the Find field, up to 37 characters (not case sensitive) can be entered for the system to search.
- 4. Specify whether the search should proceed upward or downward (the default) by using the Direction checkboxes. Press the "select" soft key to check or uncheck the desired direction. Only one direction can be selected.
- 5. Press the "perform action" soft key to begin the search. The display returns to the system log, with the first message containing the term at the top of the window and highlighted. If the term is not found, no messages are highlighted.
- 6. To find the next occurrence of the term, press the "repeat data" key. If the term appears again, it is highlighted in the system log. If the term does not appear again, the same message remains highlighted and the "repeat data" key disappears.



# To filter the system log:

1. Press the "select filter" soft key.



2. Enter a Start Date/Time, an End Date/Time, both, or neither.

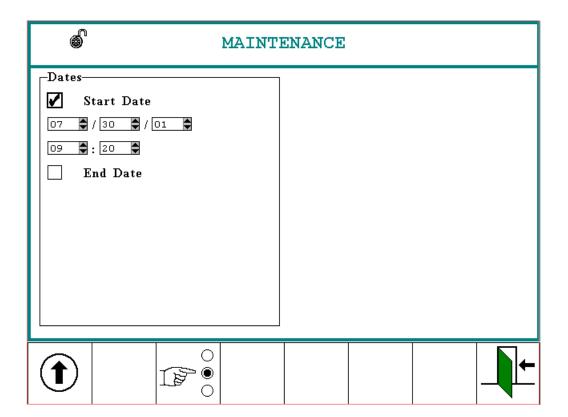
If only a start date is entered, the filter returns all messages from that date forward to the current time.

If only an end date is entered, the filter returns all messages from that date back to the oldest message in the log.

If both dates are entered, the filter returns all messages between the two dates.

If neither date is entered, all messages in the log are displayed (same as when the log is first accessed).

3. The Filter Selection display appears.



- 4. To enter a Start Date/Time or End Date/Time, highlight the desired checkbox and press the "select" soft key. Date and time fields appear when the box is checked. Move the cursor to the day, month, year, hour, or minute field, and press the UP ARROW or DOWN ARROW to increase or decrease the displayed value.
- 5. When the desired dates and times are entered, press the "perform action" soft key to execute the filter.

# 6.2.4.14 Save Syslog to Network

Save Syslog to Network should only be used when advised by a local BD representative.

The Save Syslog to Network option appears only when the instrument is connected to a BD EpiCenter system. This option provides the ability to save the event log to a BD EpiCenter system.

Under certain circumstances, a BD representative may advise saving (writing) the syslog to the BD EpiCenter system. These circumstances include some error conditions and system malfunctions. The Save Syslog function copies the system event log, which contains logged system messages about various system, instrument, and communications events. The instrument door must be closed, and the instrument must be idle to save the syslog.

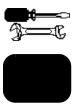
1. Press the "configuration" soft key.



2. The password window appears. To access configuration functions, enter the appropriate password then press the "perform action" soft key.



3. From the main Configuration display, press the "maintenance" soft key.



- 4. Press the UP ARROW or DOWN ARROW to highlight the selection, "SAVE SYSLOG TO NETWORK."
- 5. Insure that the data collection application is launched on the BD EpiCenter computer.

6. Press the "perform action" soft key.



7. An hourglass icon appears while the information is being sent.



8. When the activity is complete, the "activity completed" tone sounds and the hourglass icon disappears, and the event log file is saved to the directory in which the data collection application resides on the BD EpiCenter computer.

# 6.2.4.15 Display UV and RGB Status

The Display UV and RGB Status operation provides the ability to view information about the UV and RGB source bulbs. The operation should only be performed when advised by the local BD representative.

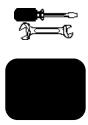
1. From the Main Status Screen, press the "configuration" soft key. The main configuration screen appears.



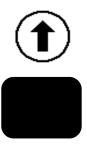
2. The password window appears. Enter the appropriate password and press the "perform action" soft key.



3. From the main Configuration display, press the "maintenance" soft key.



- Use the UP ARROW or DOWN ARROW to highlight the selection, "DISPLAY UV AND RGB STATUS."
- 5. Press the "perform action" soft key.



6. The instrument displays the following information on the left side of the screen:

For Front and Rear UV Bulbs:

In Service (YES/NO)

Telsum (value)

Cycles (value)

Time (Min) (value)

Available (YES/NO)

Intensity (%)

Adjustment (----/PEND)

For RGB Source LEDs:

Adjustment (----/PEND)

7. Press the "exit" soft key to return to the Maintenance menu.

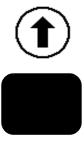
# 6.2.4.16 Force Front UV Bulb Adjustment

The Force Front UV Bulb Adjustment orders the instrument to adjust the front UV bulb. **The operation should only be performed when advised by a local BD representative.** If the front UV bulb is currently in use, a message appears stating that the adjustment will not occur until there are no ongoing panels in the instrument. If the rear UV bulb is currently in use, the front UV bulb will become the "in service" bulb and the adjustment will not occur until there are no ongoing panels in the instrument.

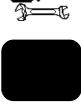
1. From the Main Status Screen, press the "configuration" soft key. The main configuration screen appears.



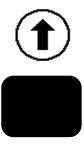
2. The password window appears. Enter the appropriate password and press the "perform action" soft key.



3. From the main Configuration display, press the "maintenance" soft key.



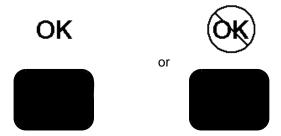
- 4. Use the UP ARROW or DOWN ARROW to highlight the selection, "FORCE FRONT UV BULB ADJUSTMENT."
- 5. Press the "perform action" soft key.



6. If the front UV bulb is currently in service, a message appears stating that the adjustment remains pending until there are no ongoing panels in the instrument.

If the rear UV bulb is currently in service, a message appears stating that the front UV bulb will become the "in service" bulb. The adjustment remains pending until there are no ongoing panels in the instrument.

To continue the UV adjustment process, press the "confirm" soft key. To cancel the process, press the "cancel" soft key.



- 7. The system waits until there are no ongoing panels and then performs the UV bulb adjustment.
- 8. An hourglass icon appears while the adjustment is being performed.



- 9. When the activity is complete, the "activity completed" tone sounds and the hourglass icon disappears.
- 10. Press the "exit" soft key to return to the Maintenance menu.

# 6.2.4.17 Force Rear UV Bulb Adjustment

The Force Rear UV Bulb Adjustment orders the instrument to adjust the rear UV bulb. **The operation should only be performed when advised by a local BD representative.** If the rear UV bulb is currently in use, a message appears stating that the adjustment will not occur until there are no ongoing panels in the instrument. If the front UV bulb is currently in use, the rear UV bulb will become the "in service" bulb and the adjustment will not occur until there are no ongoing panels in the instrument.

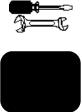
1. From the Main Status Screen, press the "configuration" soft key. The main configuration screen appears.



2. The password window appears. Enter the appropriate password and press the "perform action" soft key.



3. From the main Configuration display, press the "maintenance" soft key.



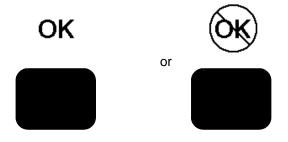
- 4. Use the UP ARROW or DOWN ARROW to highlight the selection, "FORCE REAR UV BULB ADJUSTMENT."
- 5. Press the "perform action" soft key.



6. If the rear UV bulb is currently in service, a message appears stating that the adjustment remains pending until there are no ongoing panels in the instrument.

If the front UV bulb is currently in service, a message appears stating that the rear UV bulb will become the "in service" bulb. The adjustment remains pending until there are no ongoing panels in the instrument.

To continue the UV adjustment process, press the "confirm" soft key. To cancel the process, press the "cancel" soft key.



- 7. The system waits until there are no ongoing panels and then performs the UV bulb adjustment.
- 8. An hourglass icon appears while the adjustment is being performed.



- 9. When the activity is complete, the "activity completed" tone sounds and the hourglass icon disappears.
- 10. Press the "exit" soft key to return to the Maintenance menu.

# 6.2.4.18 Force RGB LED Adjustment

The Force RGB LED Adjustment orders the instrument to adjust the Red, Green, and Blue source LEDs. The operation should only be performed when advised by a local BD representative. When the operation is selected, a message appears stating that the adjustment will not occur until there are no ongoing panels in the instrument.

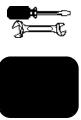
1. From the Main Status Screen, press the "configuration" soft key. The main configuration screen appears.



2. The password window appears. Enter the appropriate password and press the "perform action" soft key.

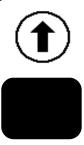


3. From the main Configuration display, press the "maintenance" soft key.

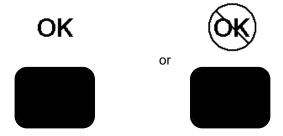


4. Use the UP ARROW or DOWN ARROW to highlight the selection, "FORCE RGB LED ADJUSTMENT."

5. Press the "perform action" soft key.



6. A message appears stating that the adjustment remains pending until there are no ongoing panels in the instrument. To continue the adjustment process, press the "confirm" soft key. To cancel the process, press the "cancel" soft key.



- 7. The system waits until there are no ongoing panels and then performs the RGB LED adjustment.
- 8. An hourglass icon appears while the adjustment is being performed.



- 9. When the activity is complete, the "activity completed" tone sounds and the hourglass icon disappears.
- 10. Press the "exit" soft key to return to the Maintenance menu.

# 6.2.4.19 Front Panel Reader Setup

The Front Panel Reader Setup provides the ability to view and/or change how the instrument's built-in barcode scanner is treated when the instrument reboots. **The operation should only be performed when advised by a local BD representative.** The 2 choices offered are to 1) reset the scanner to factory default settings, or 2) retain the current settings when the instrument reboots.

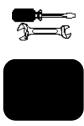
1. From the Main Status Screen, press the "configuration" soft key. The main configuration screen appears.



2. The password window appears. Enter the appropriate password and press the "perform action" soft key.



3. From the main Configuration display, press the "maintenance" soft key.



- 4. Use the UP ARROW or DOWN ARROW to highlight the selection, "FRONT PANEL READER SETUP."
- 5. Press the "perform action" soft key.



- 6. The current Startup Status is shown at the left of the display.
- 7. Press the "perform action" soft key to change the displayed setting. Set the Startup Status value to "Initialize" to reset the scanner to factory default settings when the BD Phoenix instrument reboots. Set the Startup Status value to "Retain" to allow the scanner to retain its current settings when the instrument reboots.
- 8. Press the "exit" soft key to return to the Configuration menu.

# 6.3 Module Replacement

# 6.3.1 General

The BD Phoenix instrument has been designed and tested for a trouble-free performance. In the event of malfunction, you should contact BD for service under the terms of your existing service contract or warranty. Only the external barcode scanner is user-replaceable.

Replacement modules may be swapped for failed modules which are then returned to BD. Credit is then applied towards the replacement module. Only replacement parts supplied by BD should be used in the procedures described in this section.

# 6.3.2 Barcode Scanner Replacement

The barcode scanner is connected to the instrument at the I/O panel on the right side of the instrument. Refer to Figure 6–5.

# **Required Materials**

1/8 in. flat screwdriver

#### To Replace the Barcode Scanner

- On the I/O panel on the right side of the instrument, locate the cable connection for the barcode scanner. This cable is held in place by two small screws. Unscrew the screws and unplug the cable.
- 2. Note that the cable connector is roughly D-shaped, with the top of the connector being wider than the bottom part. Plug in the new scanner cable, being sure to align the cable connector to the plug in the correct orientation. Tighten the screws.
- 3. To verify proper operation of the new scanner, go to the Panel Login screen, advance the cursor to the **Sequence** # field, and scan a panel number barcode. Verify that the correct number is entered in the field. Press the "exit" soft key to exit the display without saving the entry.



Figure 6-5 - Barcode Scanner Replacement

# 6.3.3 Thermometer Removal

If the fluid in the thermometer of the temperature standard panel has separated, follow the procedure below to remove the thermometer and replace it.

#### To Remove/Replace the Thermometer

- 1. Remove the temperature standard panel from the BD Phoenix instrument.
- 2. Using the small access hole at the bottom of the panel, gently push the thermometer upward through the large slotted opening at the top of the temperature panel.
- 3. Using your fingers pull the thermometer completely out of the panel through the slotted opening at the top of the temperature panel.
- 4. Reunite the separated fluid column per the instructions below.
- 5. Install the thermometer in the reverse order described above.

# 6.3.4 Reuniting Separated Liquid in the Thermometer

If the fluid in the thermometer of the temperature standard panel has separated, follow the procedure below to reunite the liquid.

#### To Reunite Separated Liquid

- 1. Should there be a separation in the capillary or in the expansion chamber at the top of the thermometer, heat the bulb of the thermometer in a hot liquid which exceeds the range of the thermometer until the separation and main liquid column enter the expansion chamber and unite with each other.
- 2. Quickly remove the thermometer from the liquid, so that the liquid does not completely fill the expansion chamber which could possibly harm the thermometer.
- 3. Check the thermometer against a certified, traceable thermometer or an ice bath to assure the thermometer is reading correctly.

# 7 – Troubleshooting

# 7.1 General

# 7.1.1 Instrument Service

If the BD Phoenix 100 instrument malfunctions or operates unusually in any way, initially attempt to solve the problem by following the recommendations in this section. All other servicing attempts will terminate the responsibility of the manufacturer under the terms of the warranty.

If a system malfunction cannot be repaired, contact a local BD representative (contact numbers are listed in Section 13).

This section discusses error messages, which appear when the system has encountered a known problem. These messages are listed in numerical order, along with possible causes of the message and corrective actions.

# 7.2 Error/Alert Messages

#### **CAUTION**

When the system generates alerts and errors, immediately respond to the condition.

When the system encounters an alert or error condition, the error code (EXX or WXXX, where XX or XXX is a number) is either displayed on the screen or written into the system alert list. The error code is an abbreviation for the conditions described in the listing below.

Different types of alerts and errors behave in different ways. There are three basic types of alert condition:

- ? Self-Clearing these alerts are removed from the System Alert Screen after they have been displayed and the screen has been exited. No other intervention is required.
- , Persistent these alerts remain in the System Alert Screen (even after displaying the alert code) until the instrument determines that the error causing the alert has been corrected. Correction can be accomplished with or without user intervention, depending on the alert.
- f Auto Clear these alerts are removed from the System Alert Screen as soon as the condition causing the error has been cleared. There is no requirement to display the alert code on the System Alerts List Screen. If the alert is still present when reviewing the Alert list, it will be displayed.

"W" error codes are displayed on the screen when they occur. (They also cause the Activity Error tone to sound [sequence of short high beep and short low beep repeated four times].) These are activity (or "workflow") types of errors. In most cases, this means that some action that was performed was not what the system expected, but the correct action can usually be performed, as recommended below, without exiting the current operation. These activity errors are flagged by the Activity Error icon:



"W" error codes are grouped as follows:

- W1XX Problem with the Sequence Number
- W2XX Problem with the Accession, Isolate Number, or Media type
- W3XX Problem with a QC panel only
- W4XX Action to get into the instrument is not allowed
- W5XX Configuration/Maintenance screen activity not allowed (as long as it is not an instrument action)
- W6XX Screen activity is not allowed
- W7XX LIS errors
- W8XX QC Lot Support errors

System alerts, which comprise all "E" type error codes, are reported in the system alert list. These errors cause the Alert tone (medium beep on for one second, off for 3 seconds, repeating) to sound (if it is enabled). Also the System Alert icon appears on the Main Status screen and the System Alert indicator flashes. The errors must be reviewed to clear the system alert condition. The system alert list can be viewed from the Main Status screen by pressing the "system alert" soft key:



The error codes are listed in numerical order. Error sub-codes are 8-digit numeric codes that appear below the EXX readout in the system alert list. The sub-codes indicate specific conditions detected. Many sub-codes are listed in the "Possible Causes" and "Corrective Actions" sections below.

#### CAUTION

If any error sub-codes other than those listed here appear, note the sub-code and contact BD for assistance.

If the recommended corrective actions do not solve the problem, contact BD.

#### E01Incubator temperature alert

Temperature readings are taken every 5 seconds for 10 minutes and these readings are averaged.

ALERT TYPE – Persistent – Cleared when a.) the instrument considers the sub-code reported cleared, and, b.) the alert code has been displayed on the System Alerts screen.

#### POSSIBLE CAUSE(S)

00000001 – Average temperature too high (> 36.5 °C)

00000002 – Average temperature too low (< 33 °C)

00000010 - Average temperature too high for more than one hour (> 36.5 °C)

00000020 - Average temperature too low for more than one hour (< 33 °C)

00000040 – Absolute high temperature (> 38.5 °C)

Note that if the instrument temperature reaches 39 °C ± 0.5 °C, the instrument disables the heater.

For all sub-codes, causes include: room temperature is not within recommended range, or other environmental specification is not being met (such as instrument sitting in direct sunlight or too close to HVAC air register). Air filters are dirty, restricting fresh air intake.

#### **CORRECTIVE ACTION(S)**

- Make sure environmental specifications are met (see Section 2 Installation).
- Replace air filters.

# E02 Lightbay temperature alert

The instrument has detected either that the temperature is too high or too low on any of the tiers, or communications with the lightbay sensor is terminated. The instrument continues testing on schedule.

ALERT TYPE – Persistent – Cleared when a.) the instrument considers the sub-code reported cleared, and, b.) the alert code has been displayed on the System Alerts screen.

Temperature too High (Light Source: Tier A (Applicable subcodes: 00000001, 00000008)
 50 °C; Tier Micro: > 60 °C)
 Tier A (Applicable subcodes: 000000040, 00000200)

Tier C (Applicable subcodes: 00001000, 00008000) Tier D (Applicable subcodes: 00040000, 00200000)

Temperature too Low (< 18 °C):</li>
 Tier A (Applicable subcodes: 00000002, 00000010)

Tier B (Applicable subcodes: 00000080, 00000400) Tier C (Applicable subcodes: 00002000, 00010000) Tier D (Applicable subcodes: 00080000, 00400000)

 Causes include: room temperature is not within recommended range, or other environmental specification is not being met (such as instrument sitting in direct sunlight or too close to HVAC air register). Air filter is dirty, restricting fresh air intake.

#### **CORRECTIVE ACTION(S)**

- Make sure environmental specifications are met (see Section 2 Installation).
- · Replace air filters.

#### E03 Ambient temperature alert

Communication with the ambient sensor is terminated. The instrument continues testing on schedule.

ALERT TYPE – Persistent – Cleared when a.) the instrument considers the sub-code reported cleared, and, b.) the alert code has been displayed on the System Alerts screen.

# POSSIBLE CAUSE(S)

Failure of ambient temperature sensor

#### **CORRECTIVE ACTION(S)**

Contact a local BD representative.

#### E05 Carousel alert

The instrument reports this alert if one of the following occurs: the reported RPM is below spec, certain flag readings are incorrect, or the carousel is jammed or stalled. It is detected during any carousel rotation. Any inventory scan or panel test in progress is aborted and the instrument ignores any data received from the test or scan.

ALERT TYPE – Persistent – Cleared when a.) the instrument considers the sub-code reported cleared, and, b.) the alert code has been displayed on the System Alerts screen.

#### **POSSIBLE CAUSE(S)**

- 00000001 RPM is below spec
- 00000040 Carousel is stalled
- 00000080 Carousel is jammed

Listed codes: something is impeding the motion of the carousel.

#### **CORRECTIVE ACTION(S)**

 Open the door, look for and remove any obstructions such as a panel that is ajar or a panel closure that is not seated. Do not manually rotate the carousel. Close the door. If message recurs, contact a local BD representative.

# E06 Tier alert

This is the general alert condition for problems related to specific tiers. Such problems include: flag readings are incorrect, optical errors, timeout conditions, and normalizer problems. The alert is reported in the following format (typical sub-codes are shown):

E06 00000001 00000000 00000100 00000280

The first line of the error represents Tier A, the second line represents Tier B, the third line represents Tier C, and the fourth line represents Tier D. A code of 00000000 indicates that there is no error condition for that tier.

Tier alerts are detected during a test cycle or inventory scan. The instrument ignores any data received from the test or scan for the tier that has sustained the error. Data received from good tiers is retained. All stations in the bad tier are automatically blocked.

ALERT TYPE – Persistent – Cleared when a.) the instrument considers the sub-code reported cleared, and, b.) the alert code has been displayed on the System Alerts screen.

#### POSSIBLE CAUSE(S)

- 00000020 Rotor timeout
- 00002000 Tier out of service the instrument cannot communicate with the tier

#### CORRECTIVE ACTION(S)

- 00000020 Check for/remove object impeding motion of carousel
- 00002000 Reboot instrument (turn power off, wait 10 seconds, turn power back on)

#### E07 Power supply alert

One of the power supplies was out of specification. The instrument ignores any data received from the test.

ALERT TYPE – Persistent – Cleared when a.) the instrument considers the sub-code reported cleared, and, b.) the alert code has been displayed on the System Alerts screen.

#### POSSIBLE CAUSE(S)

Temporary electrical anomaly.

#### **CORRECTIVE ACTION(S)**

Contact a local BD representative.

#### E08 Tier power supply alert

One of the tier power supplies was out of specification. The instrument ignores any data received from the test for panels in that tier. The alert is reported in the following format (typical sub-codes are shown):

E17 00000001 00000002 00000004 0000000A The first line of the error represents Tier A, the second line represents Tier B, the third line represents Tier C, and the fourth line represents Tier D. A code of 00000000 indicates that there is no error condition for that tier.

Tier alerts are detected during a test cycle. The instrument ignores any data received from the test for the tier that has sustained the error. Data received from good tiers is retained. All stations in the bad tier are automatically blocked.

ALERT TYPE – Persistent – Cleared when a.) the instrument considers the sub-code reported cleared, and, b.) the alert code has been displayed on the System Alerts screen.

#### **POSSIBLE CAUSE(S)**

Temporary electrical anomaly.

#### **CORRECTIVE ACTION(S)**

Contact a local BD representative.

### E09 Test aborted

Panel testing has not occurred for more than one hour.

ALERT TYPE – Self-Clearing – cleared when the alert code has been displayed on the System Alerts screen

### POSSIBLE CAUSE(S)

 20000000 – Causes include: instrument was off or door was open for more than an hour, system clock was set ahead one hour or more, test cycle has not occurred in more than an hour, etc.

# **CORRECTIVE ACTION(S)**

 All ongoing panels are set to Needs Attention, and their status is set to Removable. Some results may be incomplete, and all affected panel results should be reviewed.

#### E10 System database corruption

ALERT TYPE – Self-Clearing – cleared when the alert code has been displayed on the System Alerts screen

#### POSSIBLE CAUSE(S)

• 00000002, 00000008, 00000020, 00000040, 00000100, 00000200, 00000400 – Database checksum test failed or data in one of the databases (see below) was corrupted and replaced by a default database.

#### **CORRECTIVE ACTION(S)**

- Write data to disk (see 7.3 Save System Data to Disk Function) and call BD.
- 00000002 Check the settings in the Configuration screens and reset them to the preferred setting (see 2.3.1 Instrument Configuration).
- 00000008 Check the settings in BDXpert Rule Configuration and reset them to the preferred setting (see 2.3.4 BDXpert Rule Configuration).
- 00000020 Check the breakpoint settings in Custom Interpretation Rule Set Configuration and reset them to the preferred setting (see 2.3.3 Custom Interpretation Rule Set).
- 00000040 Check the settings in Organism and Antimicrobial Configuration and reset them to the preferred setting (see 2.3.2.1 Organism Configuration and 2.3.2.2 Antimicrobial Configuration).

- 00000100 Perform a Read Light Source from Diskette operation as described in 6.2.4.12 Read Light Source from Diskette.
- 00000200 Perform a Read Light Source from Diskette operation as described in 6.2.4.12 Read Light Source from Diskette.
- 00000400 Informational message indicating that LIS orders have been deleted from the
  database. This can occur when there is a checksum error in the LIS orders area of the
  database, or the internal data structures have been changed during a software update.
  Resend any orders that were deleted as a result of this alert.

#### E11 Printer error

# ALERT TYPE – Self-Clearing – cleared when the alert code has been displayed on the System Alerts screen

#### **POSSIBLE CAUSE(S)**

#### 20000000

- Printer paper is jammed or exhausted.
- Printer cable is disconnected during printing.
- Printer power is turned off during printing.
- Printer was taken offline during printing.

#### **CORRECTIVE ACTION(S)**

- · Check paper and clear jam or add paper if necessary.
- Check printer cables (power and communications), reattach if necessary.
- Turn printer power on.
- Place printer online.
- Report will resume printing automatically when error condition is corrected.

#### E12 Source monitor error

This is the alert condition for problems related to testing LEDs in the tiers. The alert is reported in the following format (typical sub-codes are shown):

E12 00000100 00000000 00000000 00000000

The first line of the error represents stations with errors in Tier A, the second line represents stations with errors in Tier B, the third line represents stations with errors in Tier C, and the fourth line represents stations with errors in Tier D. A code of 00000000 indicates that there is no error condition for that tier.

Source monitor errors are detected during a test cycle. The instrument ignores any data received from the test for the panel/station that has sustained the error. Data received from good panels is retained, unless the station sustaining the error was the normalizer station. All error stations are automatically blocked. If the normalizer has this error, the whole tier is blocked.

ALERT TYPE – Persistent – Cleared when a.) the instrument considers the sub-code reported cleared, and, b.) the alert code has been displayed on the System Alerts screen.

Optical problem with source LEDs.

#### **CORRECTIVE ACTION(S)**

Contact a local BD representative.

#### E13 Power failure

ALERT TYPE – Self-Clearing – cleared when the alert code has been displayed on the System Alerts screen

#### POSSIBLE CAUSE(S)

• 20000000 – Power was removed from instrument.

#### **CORRECTIVE ACTION(S)**

 Message is informational. If multiple power failures have occurred, only the latest one is reported in the alert list. Note the power failure and restore times in the instrument log. Note that power fail events are not recognized until the instrument user interface has successfully loaded.

# E14 CCD underrun

Scanning of a panel stopped prematurely. The alert is reported in the following format:

E14 00000000

00000100

00000000

00000000

The first line of the error represents stations with errors in Tier A, the second line represents stations with errors in Tier B, the third line represents stations with errors in Tier C, and the fourth line represents stations with errors in Tier D. A code of 00000000 indicates that there is no error condition for that tier.

CCD underrun errors are detected during a test cycle. The instrument ignores any data received from the test for the panel/station that has sustained the error. Data received from good panels is retained, unless the station sustaining the error was the normalizer station. All error stations are automatically blocked. If the normalizer has this error, the whole tier is blocked.

ALERT TYPE – Persistent – Cleared when a.) the instrument considers the sub-code reported cleared, and, b.) the alert code has been displayed on the System Alerts screen.

#### POSSIBLE CAUSE(S)

Problem in the tier.

#### **CORRECTIVE ACTION(S)**

Contact a local BD representative.

# E15 UV bulb switched

ALERT TYPE – Self-Clearing – cleared when the alert code has been displayed on the System Alerts screen

#### Either:

- 00000001 The rear ultraviolet bulb
- 00000002 The front ultraviolet bulb

was switched.

#### **CORRECTIVE ACTION(S)**

 Message is informational. The switch happened as a result of an automatic light source adjustment.

#### E16 485 master communication

There was a communications error relating to testing. The alert is reported in the following format:

E16 00000001 00000000 00000000 00000000

The first line of the error represents Tier A, the second line represents Tier B, the third line represents Tier C, and the fourth line represents Tier D. A code of 00000000 indicates that there is no error condition for that tier.

The instrument ignores any data received from a test or scan for the tier that has sustained the error. Data received from good tiers is retained. All stations in the bad tier are automatically blocked.

ALERT TYPE – Persistent – Cleared when a.) the instrument considers the sub-code reported cleared, and, b.) the alert code has been displayed on the System Alerts screen.

# POSSIBLE CAUSE(S)

Communications problems in instrument.

#### **CORRECTIVE ACTION(S)**

Contact a local BD representative.

#### E18 Normalizer alert – row averages

There is a problem with normalizer panel data. The alert is reported in the following format:

E18 00000001 00000000 00000000 00000000

The first line of the error represents Tier A, the second line represents Tier B, the third line represents Tier C, and the fourth line represents Tier D. A code of 00000000 indicates that there is no error condition for that tier.

Normalizer errors are detected during a test cycle. Test data received may be discarded or retained, depending on the error subcode (below). All available stations in the bad tier are automatically blocked; ongoing stations become blocked as testing completes or panels are removed.

ALERT TYPE – Persistent – Cleared when a.) the instrument considers the sub-code reported cleared, and, b.) the alert code has been displayed on the System Alerts screen.

- 00000001, 00000002, 00000004, 00000008 Light source adjustment will be performed when there are no ongoing panels
- 00000010, 00000020, 00000040, 00000080 All tests are aborted in the affected tier; light source adjustment will be performed when all panels complete or are removed

#### **CORRECTIVE ACTION(S)**

Automatic light source adjustment will be performed when there are no ongoing panels in the
instrument. Do not enter any new panels or move any ongoing panels into any tier reporting
this error (i.e., with a subcode other than 00000000). The instrument may be able to correct
this error via the light source adjustment process.

#### E19 Passed read position

One of the tiers passed the position where data scanning must occur. The alert is reported in the following format:

E19 00000000 00000000 00000100 00000000

The first line of the error represents stations with errors in Tier A, the second line represents stations with errors in Tier B, the third line represents stations with errors in Tier C, and the fourth line represents stations with errors in Tier D. A code of 00000000 indicates that there is no error condition for that tier.

The instrument ignores any data received from the test for the panel/station that has sustained the error. Data received from good panels is retained, unless the station sustaining the error was the normalizer station. All error stations are automatically blocked. If the normalizer has this error, the whole tier is blocked.

ALERT TYPE – Persistent – Cleared when a.) the instrument considers the sub-code reported cleared, and, b.) the alert code has been displayed on the System Alerts screen.

#### **POSSIBLE CAUSE(S)**

Optical or mechanical problem with instrument.

#### **CORRECTIVE ACTION(S)**

Contact a local BD representative.

#### E20 Barcode scanner not communicating

# ALERT TYPE – Self-Clearing – cleared when the alert code has been displayed on the System Alerts screen

#### POSSIBLE CAUSE(S)

- Instrument cannot communicate properly with a barcode scanner.
- 00000001 Tier A scanner
- 00000002 Tier B scanner
- 00000004 Tier C scanner
- 00000008 Tier D scanner

00000010 – External scanner

#### **CORRECTIVE ACTION(S)**

 No testing occurs on the tier experiencing this error, and all the tier stations are automatically blocked. Instrument must be rebooted before the alert can be cleared.

#### E21 Level 2 rotor step warning

The instrument has sensed that rotor rotation was not ideal but still acceptable. The alert is reported in the following format:

E21 00000000 00000100 00000000 00000000

The first line of the error represents stations with errors in Tier A, the second line represents stations with errors in Tier B, the third line represents stations with errors in Tier C, and the fourth line represents stations with errors in Tier D. A code of 00000000 indicates that there is no error condition for that tier.

ALERT TYPE – Persistent – Cleared when a.) the instrument considers the sub-code reported cleared, and, b.) the alert code has been displayed on the System Alerts screen.

#### **POSSIBLE CAUSE(S)**

 Likely impediment to or problem with rotor rotation mechanism. Check for a panel protruding from its carrier, an improperly seated closure, or user-applied label peeling off.

### CORRECTIVE ACTION(S)

If no obvious visible cause for the error exists, contact a local BD representative.

#### E22 Level 3 rotor step error

The instrument has sensed that rotor rotation was out of specification. The alert is reported in the following format:

E22 00000100 00000000 00000000 00000000

The first line of the error represents stations with errors in Tier A, the second line represents stations with errors in Tier B, the third line represents stations with errors in Tier C, and the fourth line represents stations with errors in Tier D. A code of 00000000 indicates that there is no error condition for that tier.

The instrument ignores any data received from the test for the panel/station that has sustained the error. Data received from good panels is retained, unless the station sustaining the error was the normalizer station. All error stations are automatically blocked. If the normalizer has this error, the whole tier is blocked.

ALERT TYPE – Persistent – Cleared when a.) the instrument considers the sub-code reported cleared, and, b.) the alert code has been displayed on the System Alerts screen.

• Likely impediment to or problem with rotor rotation mechanism. Check for a panel or panel closure protruding from the carrier or from the panel itself, or for a detached label.

#### **CORRECTIVE ACTION(S)**

• If no obvious visible cause for the error exists, contact a local BD representative.

#### E23 Normalizer alert – highest/lowest well reading

There is a problem with normalizer panel data. The alert is reported in the following format:

E23	00000001
	00000000
	00000000
	00000000

The first line of the error represents Tier A, the second line represents Tier B, the third line represents Tier C, and the fourth line represents Tier D. A code of 00000000 indicates that there is no error condition for that tier.

Normalizer errors are detected during a test cycle. The instrument ignores any data received from the test for the tier that has sustained the error. Data received from good tiers is retained. All stations in the bad tier are automatically blocked.

ALERT TYPE – Persistent – Cleared when a.) the instrument considers the sub-code reported cleared, and, b.) the alert code has been displayed on the System Alerts screen.

#### POSSIBLE CAUSE(S)

Problem with normalizer panel data.

#### **CORRECTIVE ACTION(S)**

Contact a local BD representative.

#### E25 UV bulb error

ALERT TYPE – Self-Clearing – cleared when the alert code has been displayed on the System Alerts screen

#### POSSIBLE CAUSE(S)

#### Either:

- 00000001 The rear ultraviolet bulb
- 00000002 The front ultraviolet bulb

has burned out and the system cannot switch operation to alternate bulb. The system tried to switch bulbs as a result of an automatic light source adjustment.

#### **CORRECTIVE ACTION(S)**

Contact a local BD representative for replacement of the UV bulb(s).

#### E30 Normalizer Expiration Alert

The instrument issues a weekly alert beginning when Normalizer panel expiration is 60 days away, which progresses to a daily alert when expiration is 30 days away. The alert is reported in the following format:

E30 00000001 00000001 00000001 00000001

The first line of the error represents Normalizers in Tier A, the second line represents Normalizers in Tier B, the third line represents Normalizers in Tier C, and the fourth line represents Normalizers in Tier D. A code of 00000000 indicates that there is no error condition for that tier.

# ALERT TYPE – Self-Clearing – cleared when the alert code has been displayed on the System Alerts screen

#### POSSIBLE CAUSE(S)

0000001

Normalizer panel expiration date is between 60 and 30 days away.

00000002

Normalizer panel expiration date is less than 30 days away (but has not expired).

#### **CORRECTIVE ACTION(S)**

00000001, 00000002

 Schedule Normalizer panel replacement for the affected tiers before they expire (expiration date is shown on Daily Instrument report).

#### E31 Normalizer Expired

Normalizer panel expiration date has passed. Stations in all affected tiers are blocked. Ongoing panel testing is aborted. The alert is reported in the following format:

E31 00000001 00000001 00000001 00000001

The first line of the error represents Normalizers in Tier A, the second line represents Normalizers in Tier B, the third line represents Normalizers in Tier C, and the fourth line represents Normalizers in Tier D. A code of 00000000 indicates that there is no error condition for that tier.

ALERT TYPE - Persistent - Cleared when a.) the instrument considers the sub-code reported cleared, and, b.) the alert code has been displayed on the System Alerts screen.

#### POSSIBLE CAUSE(S)

0000001

Normalizer panel expiration date has passed.

#### **CORRECTIVE ACTION(S)**

0000001

Schedule Normalizer panel replacement immediately.

#### E34 Update error

# ALERT TYPE – Self-Clearing – cleared when the alert code has been displayed on the System Alerts screen

#### POSSIBLE CAUSE(S)

#### 00000001

During a "Restore User Data" operation, an error occurred.

#### 00000002

• During an "Install Panel Configuration" operation, an error occurred.

#### 0000004

 During a BD Phoenix Update Disk" installation, the number of breakpoints or breakpoint differences exceeded 1200.

#### 80000008

During a "BD Phoenix Update Disk" installation, an error occurred.

#### 00000010

During a "Restore Panel Lot Definition" operation, an error occurred.

#### **CORRECTIVE ACTION(S)**

0000001, 00000002, 00000008, 00000010

Return to the operation specified above and repeat the process.

#### 0000004

 Check the breakpoints in the Custom Interpretation Rule Set display. If the number of breakpoints exceeded 1200, breakpoints beyond 1200 were removed. These breakpoints would have appeared at the bottom of the list.

#### E40 IP Address Network error

The instrument was unable to obtain necessary network information.

ALERT TYPE – 00000001 – Self-Clearing – cleared when the alert code has been displayed on the System Alerts screen 00000010 – Persistent – Cleared when a.) the instrument considers the sub-code reported cleared, and, b.) the alert code has been displayed on the System Alerts screen.

#### **POSSIBLE CAUSE(S)**

- 00000001 Attempt to connect too many instruments.
- 00000010 BD EpiCenter system is not running, or hardware problem between systems, such as disconnected cable between instrument and BD EpiCenter workstation, bad NIC (Network Interface Card) in workstation or instrument, etc.

#### **CORRECTIVE ACTION(S)**

- 00000001 Do not attempt to connect more than 28 of the same instrument.
- 00000010 Start BD EpiCenter system. Look for obvious source of problem such as disconnected cable. If no obvious source exists, contact a local BD representative.

#### E44 LIS communications error

The instrument was unable to communicate with the attached LIS system.

ALERT TYPE – Persistent – Cleared when a.) the instrument considers the sub-code reported cleared, and, b.) the alert code has been displayed on the System Alerts screen.

#### POSSIBLE CAUSE(S)

- 00000001 LIS system is not running, or hardware problem between systems, such as disconnected cable between instrument and LIS, etc.
- 00000004 LIS queue is full.

#### **CORRECTIVE ACTION(S)**

- 00000001 Start LIS system. Look for obvious source of problem such as disconnected cable.
   If no obvious source exists, contact a local BD representative.
- 00000004 Wait until LIS processes some of the pending transmissions from the BD Phoenix system before attempting to transfer additional ones.

#### E50 Internal software error

ALERT TYPE – Self-Clearing – cleared when the alert code has been displayed on the System Alerts screen

#### POSSIBLE CAUSE(S)

System encountered a software error.

#### **CORRECTIVE ACTION(S)**

 Write data to disk (see Section 7.3 Save System Data to Disk Function) and call a local BD representative.

#### E99 Memory Error

ALERT TYPE – Self-Clearing – cleared when the alert code has been displayed on the System Alerts screen

#### POSSIBLE CAUSE(S)

The instrument software encountered a lack of memory.

#### **CORRECTIVE ACTION(S)**

Contact a local BD representative.

#### W100 Invalid Panel Sequence Number

#### POSSIBLE CAUSE(S)

• The panel sequence number typed or scanned does not meet the required number format.

#### CORRECTIVE ACTION(S)

 Panel sequence number barcode is located at the top of the reaction side of the panel. Scan or type in the correct panel sequence number. Check panel carton for panel update barcodes; if they are present, refer to 6. Discard the panels in a biohazard container., for information on how to proceed.

#### W101 Missing Panel Sequence Number

#### **POSSIBLE CAUSE(S)**

 An operation (find, delete, print, etc.) was attempted and the value in the panel Sequence # field was blank.

#### **CORRECTIVE ACTION(S)**

Type in or scan the correct panel sequence number before attempting the operation again.

#### W102 Unknown Panel Sequence Number

#### **POSSIBLE CAUSE(S)**

 An attempt was made to save or select a panel sequence number that is not in the BD Phoenix database.

#### **CORRECTIVE ACTION(S)**

 Verify that the correct panel sequence number was entered. If error recurs, the panel may need to be logged in if it is a new panel. Older, completed, finalized panels eventually age out of the database.

#### W200 Invalid Accession Number

#### **POSSIBLE CAUSE(S)**

An attempt was made to save, find, or print information for an invalid accession number.

#### **CORRECTIVE ACTION(S)**

Enter a valid accession number, up to 20 characters excluding: \* ? []!#|

#### W201 Missing Accession Number

#### POSSIBLE CAUSE(S)

An operation (find, save, print, etc.) was attempted and the value in the Accession # field was invalid or blank. This can include: a record with a valid panel Sequence # and an Isolate # greater than 1 with no Accession #; an orphan panel with just an Isolate #; trying to change a saved record to a blank Accession #; etc.

#### **CORRECTIVE ACTION(S)**

Type in or scan the correct accession number before attempting the operation again.

#### W202 Unknown Accession Number

#### **POSSIBLE CAUSE(S)**

 At attempt was made to find data or print a report for an accession number that is not located in the BD Phoenix database.

#### **CORRECTIVE ACTION(S)**

 Verify that the correct accession number was entered. If error recurs, the record may need to be logged in if it is new. Older, completed, finalized records eventually age out of the database.

#### W203 Missing Isolate Number

#### POSSIBLE CAUSE(S)

 An attempt was made to save a record when an accession number is present without an isolate number.

#### **CORRECTIVE ACTION(S)**

• To save a record, if an accession number is entered, an isolate number must also be entered.

#### W204 Missing Media Type

#### POSSIBLE CAUSE(S)

An attempt was made to save a Yeast ID panel during Panel Login and no Media is specified.

#### **CORRECTIVE ACTION(S)**

 To save a record, if a Yeast ID panel sequence number is entered, a media type must be selected.

#### W300 Missing Test Strain for a QC Panel

#### POSSIBLE CAUSE(S)

An attempt was made to save a QC panel without an organism ID (Test Strain).

#### **CORRECTIVE ACTION(S)**

An organism (Test Strain) must be selected to save a QC panel. Advance to the Test Strain
field with the "tab" soft key and press DOWN ARROW to drop down a box listing the available
test strains. Use UP ARROW or DOWN ARROW to highlight the desired organism. Press the
"select" soft key to select the highlighted organism.

#### W301 Missing Tech ID for a QC Panel

#### POSSIBLE CAUSE(S)

An attempt was made to save a QC panel without a Tech ID.

#### **CORRECTIVE ACTION(S)**

• A Tech ID must be entered to save a QC panel. Advance to the **Tech ID** field with the "tab" soft key and enter a Tech ID, up to 3 alphanumeric characters excluding: \* ? [ ] ! # |

#### W302 Invalid Tech ID

#### POSSIBLE CAUSE(S)

• An attempt was made to save a QC panel with an invalid Tech ID.

#### **CORRECTIVE ACTION(S)**

• Enter up to 3 alphanumeric characters excluding: \* ? [ ] ! # | for the Tech ID.

#### W303 Invalid Lot Number

#### **POSSIBLE CAUSE(S)**

 An attempt was made to save a record or print a report for an invalid panel lot number, ID broth lot number, AST broth lot number, or indicator lot number.

#### **CORRECTIVE ACTION(S)**

 Enter the correct lot number. Lot numbers can be up to 7 characters. The lot number is shown on the item carton.

#### W304 Missing Lot Number

#### POSSIBLE CAUSE(S)

An attempt was made to save or print a report for a QC panel without a panel lot number, or an
expiration date has been entered for one of the optional lot number fields (ID Broth, AST
Broth, Indicator) with no corresponding lot number.

#### **CORRECTIVE ACTION(S)**

- A panel lot number must be entered to save a QC panel. Advance to the Panel Lot # field with the "tab" soft key and enter a lot number, up to 7 digits. The lot number is shown on the panel carton.
- If an expiration date is entered for one of the optional lot number fields, the corresponding lot number must also be entered.

#### W305 ID or AST Must be Enabled

#### **POSSIBLE CAUSE(S)**

 An attempt was made to save a panel or QC panel, and both the ID and AST checkboxes are unchecked.

#### **CORRECTIVE ACTION(S)**

 The ID/AST checkboxes are set to checked or unchecked based on the type of panel, according to the panel sequence number. Unchecking either checkbox disables that type of testing. At least one checkbox must be checked for the panel record to be saved and for testing to occur.

#### W401 Cannot Perform Panel Locate

#### POSSIBLE CAUSE(S)

• The panel is not located in the instrument, or cannot be accessed on the instrument using the Normalizer Panel Replacement function (e.g., because there are ongoing panels).

#### **CORRECTIVE ACTION(S)**

 Verify that the correct panel sequence number is entered or that the instrument can be accessed (for Normalizer Panel Replacement activity, ongoing panels render the instrument inaccessible for this activity).

#### W500 Upgrade Error

#### POSSIBLE CAUSE(S)

The floppy disk in the disk drive does not contain a readable, same, or newer version of
instrument software. Causes include: older version of instrument software on floppy disk;
floppy disk was removed before the update completed; floppy disk contains a corrupted or
missing file, etc.

#### **CORRECTIVE ACTION(S)**

 Verify that the correct version (current or later) is printed on the floppy disk label. Attempt the update operation again. If error recurs, contact a local BD representative.

#### W501 Duplicate Instrument Number

#### POSSIBLE CAUSE(S)

An attempt was made to modify the instrument number to be the same as another instrument.
 (Occurs only when the BD EpiCenter system is attached.)

#### **CORRECTIVE ACTION(S)**

Instrument numbers must be unique. Enter a unique instrument number.

#### W502 Diskette Error

#### POSSIBLE CAUSE(S)

 The floppy disk drive cannot read a disk. Causes include: no floppy disk in the drive; unformatted disk in the drive; floppy disk has been improperly inserted in the disk drive; floppy disk is or becomes full; floppy disk is write-protected; floppy disk was removed before the operation completed; defective floppy disk drive.

#### **CORRECTIVE ACTION(S)**

 Insert floppy disk with the shutter first and the label facing upward. For save operations, the floppy disk must be formatted, not write-protected, contain sufficient free space for the information being saved, and be left in the drive until the operation completes.

#### W503 Duplicate Rule

#### POSSIBLE CAUSE(S)

 In defining custom rules, the data contained in the Antimicrobial, Org(anism) Group, and Organism fields is the same for the rule being saved as a different rule already defined in the Rule Set.

#### **CORRECTIVE ACTION(S)**

 One of the parameters (Antimicrobial, Organism Group, or Organism) must be unique for the record to be saved.

#### W504 Cannot Change Parameter / Ongoing Panels

#### **POSSIBLE CAUSE(S)**

 An attempt was made to save changes to the Current Date or Current Time field in Instrument Configuration and Ongoing panels exist in the instrument.

#### **CORRECTIVE ACTION(S)**

Wait until all panels in the instrument are complete before attempting to perform the operation.

#### W505 Ineligible For Usage Modification

#### **POSSIBLE CAUSE(S)**

 At attempt was made in Maintenance to Modify Panel Usage and the panel is ineligible for modification. Only combination panels with both ID and AST enabled, that are NOT complete, are eligible for modification.

#### **CORRECTIVE ACTION(S)**

 If incorrect panel Sequence number was entered, enter correct number. Otherwise, panel usage cannot be modified.

#### W506 Instrument Not Idle

#### **POSSIBLE CAUSE(S)**

An attempt was made to read light source files or save the syslog from/to floppy disk or to the
network and the instrument was not in an idle state (i.e., it was testing, was in the first
30 seconds of an inventory, warming up, etc.), or the carousel was jammed.

#### **CORRECTIVE ACTION(S)**

Wait until instrument is idle (or correct carousel jam) before performing this activity.

#### W507 Invalid Password

#### **POSSIBLE CAUSE(S)**

An invalid (or no) password was entered to access a Configuration display.

#### **CORRECTIVE ACTION(S)**

Enter the correct password (ECOLI) and press the "perform action" soft key.

#### W510 Invalid Time Zone

#### POSSIBLE CAUSE(S)

• In Instrument Configuration, an attempt was made to save a Time Zone Offset greater than +12 hours or less than -12 hours.

#### **CORRECTIVE ACTION(S)**

Valid Time Zone Offsets are between –12:00 and +12:00 hours.

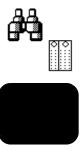
#### W600 Panel Cannot be Deleted

#### **POSSIBLE CAUSE(S)**

 An attempt was made to delete a panel that is still physically in the instrument or a non-pending QC panel that is not physically in the instrument (if QC Lot Support is enabled).

#### **CORRECTIVE ACTION(S)**

• Remove the panel from the instrument before attempting to delete it. Use the "find panel" soft key (below) to make the carousel present the panel when the door is opened.



• If the panel has already been removed, then close the instrument door and allow the instrument to complete an inventory scan before attempting to delete the panel.

#### W601 Cannot Finalize

#### POSSIBLE CAUSE(S)

 An attempt was made to finalize a panel either whose status is not Removable or that has an "unignored" Needs Attention flag set.

#### **CORRECTIVE ACTION(S)**

• If panel is Ongoing, wait until it becomes Removable before attempting to finalize it. If panel has a Needs Attention flag set, resolve the reason before attempting to finalize the panel.

#### W602 Invalid Date

#### POSSIBLE CAUSE(S)

 An attempt was made to save a record containing, or to print a report specifying, an invalid date. Or, a panel lot barcode containing an invalid expiration date was scanned.

#### **CORRECTIVE ACTION(S)**

Refer to Section 5 – Reference for information on proper date entry.

#### W603 Database Underwrite

#### POSSIBLE CAUSE(S)

 An attempt was made to save displayed information, but the database was modified by another activity, such as an inventory scan, download from the BD EpiCenter or LIS system, etc.

#### CORRECTIVE ACTION(S)

Recall the information, make the desired changes again, and save the information.

#### W604 Panel Still Testing

#### POSSIBLE CAUSE(S)

- An attempt was made to save a Final ID to an ID or Combination panel that has not reported an Instrument organism ID.
- An attempt was made to perform a Read Light Source from Disk maintenance operation.

#### **CORRECTIVE ACTION(S)**

- A Final ID cannot be selected and saved until the instrument ID results are obtained. Wait until the instrument calculates an ID before attempting to select a Final ID.
- Wait until all panels in the instrument are complete before attempting to perform the operation.

#### W605 Invalid Date Range

#### POSSIBLE CAUSE(S)

• In Reports, a date greater than the current system date was specified, or a date range exceeding 30 days was entered.

#### **CORRECTIVE ACTION(S)**

- Specify only dates UP TO the current system date.
- Do not exceed 30 days in date range entries.

#### W606 Cannot Modify Data for a Finalized Panel

#### POSSIBLE CAUSE(S)

• Information for a panel that has been finalized has been recalled and modified. Changes to finalized panels cannot be saved.

#### **CORRECTIVE ACTION(S)**

• If information for a finalized panel must be modified, recall the panel and "un-finalize" it by unchecking the Finalize checkbox. Make the required changes and save the information.

#### W607 Missing Date

#### POSSIBLE CAUSE(S)

 An attempt was made to save a panel without a panel lot number expiration date or without expiration dates for other lot number fields IF panel lot numbers have been entered.

#### **CORRECTIVE ACTION(S)**

• A valid panel lot number expiration date must be entered for panels. If other lot number fields are completed, their corresponding expiration dates must be entered.

#### W608 Improper Barcode Scan

#### POSSIBLE CAUSE(S)

The barcode number scanned is too long for the current active field, or is not the correct type
of barcode for the field (e.g., scanning a lot number in a non-lot number field).

#### CORRECTIVE ACTION(S)

 Verify which field is currently active and check what type of barcode is to be scanned. Refer to Section 5 – Reference for information on field lengths.

#### W609 Database Full

#### POSSIBLE CAUSE(S)

• An attempt was made to log in a new panel and 100 panels exist in the instrument database with a pending record status, with no panels eligible for deletion.

#### **CORRECTIVE ACTION(S)**

 Pending panels should be placed in the instrument and allowed to complete an inventory scan before attempting to log in any new panels.

#### W700 Invalid LIS Code

#### **POSSIBLE CAUSE(S)**

 An invalid LIS code was entered in the Organism Configuration or Antimicrobial Configuration display.

#### **CORRECTIVE ACTION(S)**

LIS Codes can be up to 20 alphanumeric characters.

#### W701 Duplicate LIS Code

#### **POSSIBLE CAUSE(S)**

• A duplicate LIS code was entered in the Organism Configuration or Antimicrobial Configuration display.

#### **CORRECTIVE ACTION(S)**

LIS Codes must be unique in the system.

#### W702 Invalid LIS Association

#### POSSIBLE CAUSE(S)

 During Panel Login, when associating downloaded LIS Order records, an attempt was made to associate an Order record containing an organism ID to an ID or Combination panel, or to associate an Order record containing an organism ID to a QC panel, or to associate an Order record containing a Test Strain to a non-QC panel.

#### **CORRECTIVE ACTION(S)**

 An organism ID cannot be associated to a BD Phoenix ID or Combination panel, nor to a QC panel; and a Test Strain cannot be associated to a non-QC panel.

#### W800 Panel Lot Undefined

#### POSSIBLE CAUSE(S)

 An attempt was made to log in a QC panel but the panel sequence number is not within the range of a defined/saved Panel Lot.

#### **CORRECTIVE ACTION(S)**

 When QC Lot Support is enabled in Configuration, all QC panels must belong to a defined/ saved panel lot. Clinical panels may be from an undefined panel lot and still be logged in, though such panels generate a Panel Lot Undefined Needs Attention condition.

#### W801 Panel Lot Range Incomplete

#### **POSSIBLE CAUSE(S)**

• During Panel Lot Definition, an attempt was made to save a panel lot but one or both panel sequence number fields were blank.

#### **CORRECTIVE ACTION(S)**

 Both a starting sequence number (lowest) and ending sequence number (highest) must be scanned for any panel lot to be saved. The sequence numbers can be scanned in any order, but both must be scanned. A sequence number cannot be typed in on the Panel Lot Definition display.

#### W802 Panel Lot Range Invalid

#### POSSIBLE CAUSE(S)

 During Panel Lot Definition, an attempt was made to save a panel lot but the two panels scanned were different panel types.

#### **CORRECTIVE ACTION(S)**

• Both panels must be the same type for any panel lot to be saved.

#### W803 Panel Lot Range Conflict

#### **POSSIBLE CAUSE(S)**

• During Panel Lot Definition, an attempt was made to save a panel lot but one or both panel sequence numbers conflicted with an existing panel lot definition.

#### **CORRECTIVE ACTION(S)**

 A panel sequence number can only belong to one defined/saved panel lot. Contact a local BD representative.

# 7.3 Save System Data to Disk Function

Under certain circumstances, BD may advise the user to save (write) system data to a floppy disk. These circumstances include some error conditions and system malfunctions. The Save System Data function is NOT a backup and cannot be restored by the user. To save data to disk, follow the steps below:

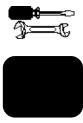
Press the "configuration" soft key.



The password window appears. To access configuration functions, enter the appropriate password then press the "perform action" soft key.



From the main Configuration display, press the "maintenance" soft key.



- Press the UP ARROW or DOWN ARROW to highlight the selection, "SAVE SYSTEM DATA TO DISK."
- 5 Insert a blank, formatted, write-enabled floppy disk in the disk drive.

6 Press the "perform action" soft key.



7 An hourglass icon appears while the information is being written to the disk.



8 If additional disks are required, the system displays the following icon:



Remove the disk and insert another blank, formatted, write-enabled floppy disk in the disk drive.

**9** When the activity is complete, the "activity completed" tone sounds and the hourglass icon disappears. Make sure the disk indicator is off, then remove the floppy disk by pressing the disk eject button. If there are multiple disks, be sure to number them sequentially and include the date and the facility name on the label.

# 7.4 Save Syslog to Disk Function

Under certain circumstances, BD may advise you to save (write) the syslog to a floppy disk. These circumstances include some error conditions and system malfunctions. The Save Syslog function copies the system event log, which contains logged system messages about various system, instrument, and communications events. The instrument door must be closed, and the instrument must be idle to save the syslog.

1 Press the "configuration" soft key.



2 The password window appears. To access configuration functions, enter the appropriate password then press the "perform action" soft key.



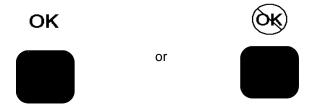
**3** From the main Configuration display, press the "maintenance" soft key.



- 4 Press the UP ARROW or DOWN ARROW to highlight the selection, "SAVE SYSLOG TO DISK."
- 5 Insert a blank, formatted, write-enabled floppy disk in the disk drive.
- 6 Press the "perform action" soft key.



**7** The system asks if you are sure you want to save the syslog. Press the "confirm" soft key to proceed or "cancel" to cancel the operation.



8 An hourglass icon appears while the information is being written to the disk, as well as the message "Saving Data."



9 When the activity is complete, the "activity completed" tone sounds and the hourglass icon disappears. Make sure the disk indicator is off, then remove the floppy disk by pressing the disk eject button.

BD Phoenix Automated Microbiology System User's Manual					

# 8 – Performance and Limitations

This section describes the following:

- 8.1 Performance Characteristics
- 8.2 Limitations of the Procedure
- 8.3 Limitations of the BD Phoenix CPO detect test

### 8.1 Performance Characteristics

#### **Definitions:**

Essential Agreement (EA): Essential agreement occurs when the MIC of the BD Phoenix System and the CLSI Reference Broth Microdilution are identical or within ± 1 dilution of each other.

Category Agreement (CA): Category agreement occurs when the BD Phoenix System results are within  $\pm$  1 dilution from the CLSI Reference Broth Microdilution with respect to the CLSI categorical interpretative criteria.

### 8.1.1 Gram Negative Performance

#### **Gram Negative Identification**

In two internal studies, the performance of the BD Phoenix Gram Negative Identification was evaluated. The 0.5 inoculum density configuration and the 0.25 inoculum density configuration were tested with 721 strains (0.5) and 784 strains (0.25) respectively. Enteric and non-enteric isolate results were evaluated against commercial and non-commercial methods.

The BD Phoenix Gram Negative Identification performance is outlined below:

	Inoculum Density (McFarland)	Agreement	No Agreement	No ID
Genus Level	0.5	97.2%	1.9%	0.8%
Genus Level	0.25	98.5%	1.0%	0.5%
Species Level	0.5	95.6%	3.6%	0.8%
Species Level	0.25	98.1%	1.4%	0.5%

#### **Gram Negative Susceptibility**

The performance of the BD Phoenix Gram Negative AST System was evaluated at multiple trial sites. Comparisons were made to AST results generated from reference testing according to CLSI standard guidelines. Discrepant results were arbitrated by duplicate repeat testing in both test and reference methods.

#### **BD Phoenix™ Confirmatory ESBL Test**

To determine the accuracy of the BD Phoenix Confirmatory ESBL test, accuracy testing was performed at multiple sites using Clinical and Challenge isolates. The results from the ESBL test resident on the BD Phoenix panels were compared to the results obtained from the reference confirmatory ESBL test. For Challenge organisms this result is an expected result and for Clinical isolates, this result was obtained from concurrent testing in the CLSI reference broth microdilution method.

#### Positive/Negative Detection:

Positive Percent Agreement = 340/360 = 94.4% Negative Percent Agreement = 847/882 = 96.0% Overall Percent Agreement = 1,187/1,242 = 95.6%

#### **BD Phoenix<sup>™</sup> Confirmatory CPO detect Test**

The BD Phoenix CPO detect test uses the principles of Ambler-class specific beta-lactamase inhibition and Ambler-class specific antibiotic resistance to detect the presence of a carbapenemase and to derive the Ambler class of the carbapenemase. In some isolates, the presence of multiple resistance mechanisms, including more than one carbapenemase, may result in a "CPO Positive" test result with no Ambler classification (i.e., "unclassified"). The frequency of these isolates may vary regionally.

To determine the accuracy of the CPO detect test with *Enterobacterales, P. aeruginosa*, and *A. baumannii*, testing was performed at multiple sites using Clinical and Challenge isolates. For clinical isolates a composite reference method was used, which included, but was not limited to, the modified Carbapenem Inactivation Method (mCIM), MIC Screen (utilizing carbapenem threshold values) and multiplex PCR testing. Multiplex PCR testing for *Enterobacterales* included *bla*KPC, *bla*NDM, *bla*IMP, *bla*VIM, and OXA-48-like genes. Multiplex PCR testing for *P. aeruginosa* and *A. baumannii* included *bla*KPC, *bla*NDM, *bla*IMP, *bla*VIM, OXA-23-like, OXA-24-like, OXA-48-like, and OXA-58-like genes. Challenge isolates were compared to previously established results.

#### **Positive/Negative Detection:**

Positive Percent Agreement = 465/473 = 98.3% Negative Percent Agreement = 538/562 = 95.7% Overall Percent Agreement = 1,003/1,035 = 96.9%

#### Ambler Classification (A,B,D):

Overall Accuracy = 914/944 = 96.8%

Of the 473 isolates identified as carbapenemase-producers during the clinical trial by the composite reference method, the BD Phoenix CPO detect test did not assign an Ambler classification to 69 isolates.

ANTIMICROBIAL	CODE	EA N	EA %	CA N	CA %
Amikacin	AN	974	94.3	974	99.2
Amoxicillin	AMX	725	95.9	839	96.9
Amoxicillin-Clavulanate	AMC	636	97.8	749	97.1
Amoxicillin-Clavulanate (f)	AXC	364	96.4	411	97.6
Ampicillin	AM	639	97.5	753	98.0
Ampicillin-Sulbactam	SAM	848	96.8	962	96.9
Ampicillin-Sulbactam (f)	SXA	1,682	92.3	1,682	94.5
Arbekacin	ARB	2,083	94.1	2,083	99.2
Aztreonam	ATM	1,488	97.8	1,431	98.5
Cefazolin	CZ	634	97.0	752	97.1
Cefdinir	CDR	633	92.7	747	94.5
Cefditoren	CDN	1,270	97.2	1,270	98.4
Cefepime	FEP	1,463	97.8	1,463	98.6
Cefetamet	CAT	629	96.0	746	97.7
Cefixime	CFM	1,454	96.7	1,454	98.1
Cefmetazole	CMZ	608	94.7	718	96.4
Cefoperazone	CFP	854	95.1	972	97.7
Cefoperazone-Sulbactam	SCP	1,921	93.1	1,921	96.0
Cefotaxime	CTX	849	96.9	970	97.2
Cefotetan	CTT	627	96.2	748	96.4
Cefotiam	CFT	1,428	94.9	1,428	97.6

ANTIMICROBIAL	CODE	EA N	EA %	CA N	CA %
Cefoxitin	FOX	628	96.7	748	97.6
Cefpirome	СРО	846	96.2	964	97.0
Cefpodoxime	CPD	616	94.5	737	97.0
Cefsulodin	CFS	55	98.2	56	98.2
Ceftaroline	CPT	1,343	93.9	1,078	95.9
Ceftazidime	CAZ	2,388	96.6	2,388	94.7
Ceftazidime-Avibactam	CZA	1,528	96.8	1,413	99.2
Ceftibuten	СТВ	590	90.5	708	95.9
Ceftizoxime	ZOX	854	97.3	971	97.2
Ceftolozane-Tazobactam	СТ	1,446	94.8	1,310	96.9
Ceftriaxone	CRO	2,416	96.1	2,416	91.6
Cefuroxime	CXM	623	97.0	744	98.5
Cephalexin	CN	319	97.8	366	96.5
Cephalothin	CF	613	98.0	731	98.5
Chloramphenicol	С	978	97.7	978	98.7
Ciprofloxacin	CIP	977	99.4	977	99.7
Colistin	CL	467	97.9	467	98.7
Ertapenem*	ETP	1,625	97.8	1,264	99.4
Fosfomycin	FF	446	93.0	446	96.9
Garenoxacin	GRN	1,977	98.1	1,977	99.4
Gatifloxacin	GAT	752	99.5	752	99.6
Gemifloxacin	GEM	2,096	98.6	2,096	99.0
Gentamicin	GM	973	95.8	973	99.8
Imipenem	IPM	1,527	94.8	1,465	99.0
Isepamicin	ISP	468	93.8	468	99.4
Kanamycin	К	735	95.8	735	99.9
Levofloxacin	LVX	972	99.6	972	100.0

ANTIMICROBIAL	CODE	EA N	EA %	CA N	CA %
Lomefloxacin	LOM	976	99.1	976	99.6
Mecillinam	MEC	345	95.7	345	94.8
Meropenem	MEM	1,449	97.0	1,393	98.3
Meropenem-Vaborbactam	MEV	1,530	96.8	1,247	99.8
Minocycline	МІ	2,094	93.8	2,094	98.3
Moxalactam	MOX	2,063	96.9	2,063	98.3
Moxifloxacin	MXF	746	98.5	747	99.7
Nalidixic Acid	NA	750	94.0	750	99.1
Netilmicin	NET	974	96.7	974	99.3
Nitrofurantoin	FM	744	98.4	744	98.8
Norfloxacin	NOR	976	98.9	976	99.6
Ofloxacin	OFX	971	99.3	971	99.7
Pefloxacin	PEF	469	98.5	469	99.4
Piperacillin	PIP	860	94.7	973	97.1
Piperacillin-Tazobactam	TZP	856	92.9	970	96.2
Temocillin	TEM	1,410	96.1	1,410	98.9
Tetracycline	TE	975	95.6	975	98.5
Ticarcillin	TIC	859	94.8	973	97.8
Ticarcillin-Clavulanate	TIM	534	92.7	589	94.6
Tigecycline	TGC	1,428	97.1	1,110	96.7
Tobramycin	NN	977	94.2	977	99.4
Trimeth-Sulfa (DIN)	STG	463	97.8	463	97.8
Trimethoprim	TMP	752	96.0	752	99.6
Trimethoprim-Sulfamethoxazole	SXT	976	95.5	976	97.3

<sup>\*</sup> Ability to Detect Resistance Unknown

#### 8.1.2 Gram Positive Performance

#### **Gram Positive Identification**

In two internal studies, the performance of the BD Phoenix Gram Positive Identification was evaluated. The 0.5 inoculum density configuration and the 0.25 inoculum density configuration were tested with 696 strains (0.5) and 755 strains (0.25) respectively. Results were evaluated against commercial and non-commercial methods.

The BD Phoenix Gram Positive Identification performance is outlined below:

	Inoculum Density (McFarland)	Agreement	No Agreement	No ID
Genus Level	0.5	99.0%	0.3%	0.7%
Genus Level	0.25	99.6%	0.0%	0.4%
Species Level	0.5	95.4%	3.9%	0.7%
Species Level	0.25	98.0%	1.6%	0.4%

#### **Gram Positive Susceptibility**

The performance of the BD Phoenix Gram Positive AST System was evaluated at multiple trial sites. Comparisons were made to AST results generated from reference testing according to CLSI standard guidelines. Discrepant results were arbitrated by duplicate repeat testing in both test and reference methods.

ANTIMICROBIAL	CODE	EA N	EA %	CA N	CA %
Amikacin	AN	487	95.7	487	95.7
Amoxicillin	AMX	395	90.6	659	97.1
Amoxicillin-Clavulanate	AMC	180	97.8	446	97.5
Amoxicillin-Clavulanate (f)	AXC	397	96.7	664	97.6
Ampicillin	AM	402	94.0	667	98.7
Ampicillin-Sulbactam	SAM	179	96.7	445	97.1
Ampicillin-Sulbactam (f)	SXA	1,449	94.6	1,449	95.2
Arbekacin*	ARB	973	96.2	973	99.9
Azithromycin	AZM	702	95.7	702	97.7
Cefaclor	CEC	182	91.8	449	95.6
Cefazolin	CZ	180	97.2	441	97.5
Cefdinir	CDR	182	94.5	434	96.8

ANTIMICROBIAL	CODE	EA N	EA %	CA N	CA %
Cefditoren	CDN	944	96.2	944	97.8
Cefepime	FEP	181	97.2	446	97.5
Cefmetazole	CMZ	174	96.6	430	97.2
Cefoperazone	CFP	184	95.7	447	97.8
Cefotaxime	СТХ	185	96.2	446	97.8
Cefotetan	СТТ	183	94.5	439	96.6
Cefotiam	CFT	965	91.5	965	94.0
Cefoxitin	FOX	184	96.2	445	97.5
Cefozopran	CFZ	1,130	89.8	1,130	89.6
Cefpirome	СРО	183	100.0	446	97.5
Cefpodoxime	CPD	185	91.4	451	95.6
Ceftaroline*	CPT	1,313	94.5	866	99.7
Ceftazidime	CAZ	183	95.1	448	97.1
Ceftizoxime	ZOX	184	93.5	447	96.2
Ceftriaxone	CRO	184	95.1	447	97.3
Cefuroxime	CXM	184	94.6	447	98.2
Cephalexin	CN	185	90.3	452	97.4
Cephalothin	CF	182	97.8	441	97.3
Chloramphenicol	С	705	92.8	705	95.3
Ciprofloxacin	CIP	686	96.4	686	97.4
Clarithromycin	CLR	485	96.3	485	98.1
Clindamycin	СС	703	98.2	703	98.3
Daptomycin*	DAP	1,361	97.6	1,361	99.8
Doxycycline	D	1,211	96.5	1,211	99.8
Ertapenem	ETP	670	91.6	670	95.4
Erythromycin	Е	474	95.4	474	95.8
Fosfomycin	FF	472	97.0	472	98.3

ANTIMICROBIAL	CODE	EA N	EA %	CA N	CA %
Fusidic Acid	FA	477	96.7	477	99.0
Garenoxacin	GRN	1,212	97.1	1,212	99.0
Gatifloxacin	GAT	481	98.8	481	100.0
Gemifloxacin	GEM	1,400	96.2	1,400	97.4
Gentamicin	GM	487	98.4	487	99.2
Gentamicin-Syn	GMS	NA	NA	198	97.5
Gentamicin-Syn (SFM)	GMF	NA	NA	87	100.0
Imipenem	IPM	185	100.0	448	97.5
Inducible Macrolide Resistance (iMLSB) Test	ECC	NA	NA	295	97.6
Kanamycin	К	463	92.2	464	97.4
Kanamycin Synergy	KS	501	100.0	501	96.6
Levofloxacin	LVX	698	96.9	698	98.6
Lincomycin	L	696	98.3	696	98.7
Linezolid	LZD	474	99.4	474	100
Lomefloxacin	LOM	486	97.7	486	99.2
Meropenem	MEM	185	98.4	447	97.5
Minocycline	MI	1,448	98.5	1,448	99.2
Moxalactam	MOX	935	95.9	935	96.0
Moxifloxacin	MXF	486	99.0	486	99.6
Mupirocin	MUP	938	96.6	938	99.7
Mupirocin High Level	MUH	968	100.0	968	99.9
Netilmicin	NET	488	93.9	488	96.3
Nitrofurantoin	FM	707	98.3	707	98.3
Norfloxacin	NOR	674	96.0	674	97.8
Ofloxacin	OFX	487	99.2	488	99.8
Oxacillin	ОХ	449	95.8	449	97.8
Pefloxacin	PEF	706	97.9	706	98.0

ANTIMICROBIAL	CODE	EA N	EA %	CA N	CA %
Penicillin	Р	401	96.0	662	98.0
Piperacillin	PIP	382	81.7	639	98.0
Piperacillin-Tazobactam	TZP	386	100.0	649	98.3
Pristinamycin	PR	695	93.2	695	95.5
Quinupristin-Dalfopristin	SYN	704	97.2	704	97.6
Rifampin	RA	700	84.0	700	88.3
Streptomycin-Syn	STS	NA	NA	198	99.0
Streptomycin-Syn (SFM)	STF	NA	NA	87	98.8
Teicoplanin	TEC	671	97.6	671	99.4
Tetracycline	TE	707	96.3	707	98.6
Ticarcillin	TIC	395	95.4	659	98.2
Ticarcillin-Clavulanate	TIM	396	97.5	656	97.9
Tigecycline*	TGC	1,356	96.8	1,044	100.0
Tobramycin	NN	473	97.0	473	97.3
Trimeth-Sulfa (DIN)	STG	645	91.0	646	92.7
Trimethoprim	TMP	479	95.4	479	97.9
Trimethoprim-Sulfamethoxazole	SXT	654	89.5	654	93.0
Vancomycin	VA	702	99.3	702	99.9

<sup>\*</sup> Ability to Detect Resistance Unknown

# 8.1.3 Streptococci Performance (with the BD Phoenix SMIC/ID, SMIC Panels)

#### Streptococci Identification (SMIC/ID only)

In an internal study, the performance of the BD Phoenix Streptococci Identification was evaluated. Results from 655 isolates were evaluated against commercial and non-commercial methods.

The BD Phoenix Streptococci Identification performance is outlined below:

	Agreement	No Agreement	No ID
Species Level	96.3%	2.4%	1.2%

#### Streptococci Susceptibility

The performance of the BD Phoenix Streptococci AST System was evaluated at four clinical trial sites using clinical isolates. Comparisons were made to AST results generated from reference broth microdilution panels prepared according to CLSI standard guidelines. Discrepant results were arbitrated by duplicate repeat testing in both systems.

ANTIMICROBIAL	CODE	EA N	EA %	CA N	CA %
Amoxicillin	AMX	1,576	99.2	1,576	99.7
Amoxicillin-clavulanate	AMC	1,564	97.9	1,564	99.3
Ampicillin	AM	1,569	98.0	1,569	99.4
Cefepime	FEP	1,571	97.6	1,571	99.7
Cefotaxime	СТХ	1,578	98.5	1,578	99.6
Ceftriaxone	CRO	1,579	98.5	1,579	99.8
Cefuroxime	CXM	1,581	97.7	1,581	98.8
Chloramphenicol	С	1,587	97.4	1,587	99.6
Clindamycin	СС	1,591	94.0	1,591	97.4
Daptomycin	DAP	1,566	93.1	1,566	99.9
Ertapenem	ETP	1,585	97.9	1,585	99.6
Erythromycin	E	1,577	93.2	1,577	98.2
Garenoxacin*	GRN	1,515	95.5	1,515	99.7
Gatifloxacin	GAT	1,587	95.1	1,587	99.5
Gemifloxacin*	GEM	1,592	98.9	1,592	99.7
Gentamicin-Syn	GMS	1,032	99.6	1,032	99.6

ANTIMICROBIAL	CODE	EA N	EA %	CA N	CA %
Imipenem	IPM	1,581	98.0	1,581	99.6
Kanamycin-Syn	KS	1,032	99.6	1,032	99.6
Levofloxacin	LVX	1,595	97.4	1,595	99.8
Linezolid	LZD	1,586	97.1	1,586	99.4
Meropenem	MEM	1,579	97.4	1,579	99.7
Moxifloxacin*	MXF	1,590	95.8	1,590	99.6
Ofloxacin	OFX	1,594	98.2	1,594	98.7
Penicillin	Р	1,585	93.9	1,585	98.5
Pristinamycin*	PR	1,583	94.8	1,583	99.8
Quinupristin-dalfopristin*	SYN	1,581	97.3	1,581	99.7
Streptomycin-Syn	STS	1,031	99.9	1,031	99.9
Teicoplanin*	TEC	1,593	99.8	1,593	99.9
Tetracycline	TE	1,589	93.3	1,589	97.6
Trimethoprim-Sulfamethoxazole	SXT	1,008	93.8	1,008	98.3
Vancomycin*	VA	1,588	98.2	1,588	99.9

<sup>\*</sup> Ability to Detect Resistance Unknown

#### 8.1.4 Yeast Performance

The performance of the BD Phoenix Yeast identification was evaluated across multiple sites using pure colonies isolated from Sabouraud Dextrose Agar (SAB) and BD Trypticase Soy Agar with 5% Sheep Blood (TSA). Results from 507 (SAB) and 505 (TSA) clinical and challenge isolates were evaluated against conventional and molecular methods.

The BD Phoenix Yeast identification performance is outlined below:

	Source Media	Agreement	No Agreement	No ID
Genus/Species Level	SAB	95.3%	3.8%	0.9%
Gentas, openes Level	TSA	96.6%	2.7%	0.8%

Additionally, testing was performed at multiple sites to demonstrate reproducibility. The identification results obtained using the BD Phoenix system were compared with expected results. This performance testing demonstrated inter-site reproducibility of ≥95%.

### 8.2 Limitations of the Procedure

See the panel package insert for specific organism/antimicrobial limitations.

#### General

A Gram stain test is required for the selection of the appropriate BD Phoenix panel types. Accurate identification and/or AST results may not be made without this test.

Use only well-isolated bacterial or yeast colonies from one of the recommended primary isolation media. Use of mixed colonies could result in inaccurate identification and/or AST interpretations.

If the instrument inoculum density (for the panel type being used) is configured to 0.5, an inoculum density of 0.50–0.60 McFarland must be met. Only the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer can be used to measure the inoculum density.

If the instrument inoculum density (for the panel type being used) is configured to 0.25, an inoculum density of 0.20–0.30 McFarland must be met. Only the BD PhoenixSpec Nephelometer can be used to measure the inoculum density for this range.

For identification of yeast, a suspension equivalent of 2.00–2.40 McFarland standard must be met and prepared only with the BD PhoenixSpec Nephelometer. Use of alternate methods for suspension preparation may cause erroneous identification results.

BD Phoenix panels can be read only by the BD Phoenix instrument. Visual interpretation of the BD Phoenix panels is not possible. Any attempt to manually interpret results from the panel may lead to misidentification and/or inaccurate AST interpretations.

Panels must be placed into the BD Phoenix instrument within 30 minutes of inoculation.

For the most reliable results, it is recommended that the QC organisms be subcultured at least twice on two consecutive days onto TSA with 5% Sheep Blood before use in the BD Phoenix System.

#### Identification

The unique panel environment combined with the shortened incubation time may result in BD Phoenix panel reactions varying from those obtained using conventional biochemical media.

#### **Antimicrobial Susceptibility Testing**

AST Indicator solution may be added to the AST broth tubes and stored in the dark for up to 8 hours prior to use. Use only one free-falling drop of the AST Indicator solution from the dropper bottle. If more than one drop is added inadvertently, discard the tube and use a fresh tube of AST broth.

After the addition of BD Phoenix AST Indicator Solution to the AST broth tubes, mix by inversion. DO NOT VORTEX. Vortexing may cause air bubbles to form in the AST broth, which can result in inappropriate filling of the BD Phoenix panel during inoculation.

Because of the low probability of occurrence some organisms included in the ID taxa are not included in the AST database. These organisms will display the message "Organism not included in the AST database, perform alternate method."

For some organism/antimicrobial combinations, the absence of resistant strains precludes defining any result categories other than "susceptible." For strains yielding results suggestive of a "nonsusceptible" category, organism identification and antimicrobial susceptibility test results should be confirmed. Subsequently, the isolates should be saved and submitted to a reference laboratory that will confirm the result using the CLSI reference microbroth dilution method.

The use of CHROMagar Orientation may produce false susceptibility results when testing erythromycin with gram-positive organisms. Antimicrobial susceptibility results should be confirmed using BD Trypticase Soy Agar with 5% Sheep Blood.

This media type [Chocolate Agar] should *not* be used for Streptococcal identification with SMIC/ID panels. Chocolate Agar may be used for Streptococcal susceptibility testing only.

The use of Columbia Agar with 5% Horse Blood may produce significantly higher MIC for SXT with *Streptococcus* species, which may result in false resistance. Antimicrobial susceptibility test results should be confirmed using BD Trypticase Soy Agar with 5% Sheep Blood.

#### **NOTE**

MIC results for isolates without a genus and species identified in the BD Phoenix results Final ID field may not be valid.

When changing the BD Phoenix Final ID from an organism not claimed in the AST Taxa list to an organism that is claimed in the AST Taxa, the MIC and Interpretation results will be based on the Final ID that is claimed in the AST Taxa.

## 8.3 Limitations of the BD Phoenix CPO detect test

Due to the small number of tested isolates identified as harboring carbapenemases from multiple Ambler classes there is limited information on the performance of the BD Phoenix CPO detect with organisms co-producing different classes of carbapenemases.

Carbapenemase positive isolates that are carbapenem susceptible (*Enterobacterales*, *Pseudomonas aeruginosa*, or *Acinetobacter baumannii*) are rare, as encountered in the clinical study. Please conduct additional confirmatory testing before reporting carbapenemase activity in a susceptible isolate.

Certain bacterial species have been shown to exhibit resistance to carbapenems by resistance mechanisms other than carbapenemase production.

In silico analysis of carbapenemase gene variants was assessed in the validation of the PCR multiplex method for the reference method. Performance of isolates harboring specific carbapenemase gene variants expressing enzymes from various Ambler classes by BD Phoenix CPO detect was not determined.

The specificity of the BD Phoenix CPO detect when testing isolates with known carbapenem non-susceptibility by cephalosporinase or ESBL coupled with decreased permeability through porin mutations among *Enterobacterales*, *Pseudomonas aeruginosa*, and *Acinetobacter baumannii* has not been fully evaluated.

BD Phoenix Automated Microbiology System User's Manual				

# 9 - Panel Information

The topics discussed in this section are:

- 9.1 List of Antimicrobial Agents in BD Phoenix Panels
- 9.2 List of Reagents and Principles Employed in the BD Phoenix System
- 9.3 Taxa for ID/AST Determination

# 9.1 List of Antimicrobial Agents in BD Phoenix Panels

Antimicrobic		Available Con	centrations		
		Gram Negative	Gram Positive	Strep	
Class	Drug Name	Drug Code	Range	Range	Range
Aminoglycoside	Amikacin	AN	0.5-64	0.5-64	N/A
Beta-lactam	Amoxicillin	AMX	0.5-32	0.25-32	0.125-32
Beta-lactam	Amoxicillin- Clavulanate (f)	AXC	0.5/2- 32/2	0.25/2- 32/2	N/A
Beta-lactam	Amoxicillin- Clavulanate	AMC	0.5/0.25-32/ 16	0.25/ 0.125- 32/16	0.125/ 0.06- 32/16
Beta-lactam	Ampicillin	AM	0.5-32	0.0625-32	0.0625-32
Beta-lactam	Ampicillin- Sulbactam (f)	SXA	0.5/8- 32/8	0.5/8- 32/8	N/A

Antimicrobic		Available Co	ncentrations		
			Gram Negative	Gram Positive	Strep
Class	Drug Name	Drug Code	Range	Range	Range
Beta-lactam	Ampicillin- Sulbactam	SAM	1/0.5- 32/16	0.5/0.25- 32/16	N/A
Aminoglycoside	Arbekacin	ARB	0.25-16	0.25-16	N/A
Macrolides Lincosmides Streptogramins	Azithromycin	AZM	N/A	0.06-8	N/A
Beta-lactam	Aztreonam	ATM	0.25-64	N/A	N/A
Beta-lactam	Cefaclor	CEC	N/A	0.5-32	N/A
Beta-lactam	Cefazolin	CZ	0.5-32	0.5-32	N/A
Beta-lactam	Cefdinir	CDR	0.125-4	0.125-4	N/A
Beta-lactam	Cefditoren	CDN	0.125-8	0.125-8	N/A
Beta-lactam	Cefepime	FEP	0.125-64	1-64	0.0625-4
Beta-lactam	Cefetamet- pivoxil	CAT	0.25-16	N/A	N/A
Beta-lactam	Cefixime	CFM	0.125-8	N/A	N/A
Beta-lactam	Cefmetazole	CMZ	2-64	1-64	N/A
Beta-lactam	Cefoperazone	CFP	0.5-64	1-64	N/A
Beta-lactam	Cefoperazone- Sulbactam	SCP	0.5/8- 64/8	N/A	N/A
Beta-lactam	Cefotaxime	СТХ	0.5-64	1-64	0.0625-4
Beta-lactam	Cefotetan	СТТ	2-64	1-64	N/A
Beta-lactam	Cefotiam	CFT	0.5-64	0.5-64	N/A
Beta-lactam	Cefoxitin	FOX	0.5-64	1-64	N/A
Beta-lactam	Cefozopran	CFZ	N/A	1-64	N/A
Beta-lactam	Cefpirome	СРО	0.5-64	0.5-64	N/A
Beta-lactam	Cefpodoxime	CPD	0.125-8	0.5-8	N/A
Beta-lactam	Cefsulodin	CFS	1-64	N/A	N/A
Beta-lactam	Ceftaroline	CPT	0.015625-4	0.0625-4	N/A
Beta-lactam	Ceftazidime	CAZ	0.5-64	1-64	N/A
Beta-lactam	Ceftazidime- Avibactam	CZA	0.25–32	N/A	N/A

Antimicrobic			Available Con	centrations	
			Gram Negative	Gram Positive	Strep
Class	Drug Name	Drug Code	Range	Range	Range
Beta-lactam	Ceftibuten	СТВ	0.5-32	N/A	N/A
Beta-lactam	Ceftizoxime	ZOX	0.5-64	1-64	N/A
Beta-lactam	Ceftolozane- Tazobactam	СТ	0.25–32	N/A	N/A
Beta-lactam	Ceftriaxone	CRO	0.5-64	1-64	0.0625-4
Beta-lactam	Cefuroxime	CXM	1-64	1-64	0.125-4
Beta-lactam	Cephalexin	CN	1-64	0.5-64	N/A
Beta-lactam	Cephalothin	CF	1-64	0.5-64	N/A
Phenicol	Chloramphenicol	С	1-32	1-32	1-32
Quinolone	Ciprofloxacin	CIP	0.125-4 For organisms except Salmonella spp. and Acinetobacter spp.	0.405.4	N/A
Quinolone	Ciprofloxacin	CIP	0.015–4 For Salmonella spp. and Acinetobacter spp.	0.125-4	N/A
Macrolides Lincosamides Streptogramins	Clarithromycin	CLR	N/A	0.06-8	N/A
Macrolide Lincosamide	Clindamycin	CC	N/A	0.12-8	0.03-4
Cyclic peptide	Colistin	CL	0.5-4	N/A	N/A
Cyclic lipopeptide	Daptomycin	DAP	N/A	0.125-32	0.03-16
Tetracycline	Doxycycline	D	N/A	0.25-16	N/A
Beta-lactam	Ertapenem	ETP	0.0625-4	0.25-32	0.0625-4
Macrolide Lincosamide	Erythromycin	Е	N/A	0.125-8	0.015-4
Fosfomycin	Fosfomycin	FF	16-256	8-256	N/A
Fusidane	Fusidic Acid	FA	N/A	0.5-32	N/A
Quinolone	Garenoxacin	GRN	0.125-16	0.25-8	0.03125-4
Quinolone	Gatifloxacin	GAT	0.25-8	0.25-8	0.0625-8
Quinolone	Gemifloxacin	GEM	0.125-8	0.125-2	0.0625-8
Aminoglycoside	Gentamicin	GM	0.5-16	0.5-16	N/A
Aminoglycoside	Gentamicin-Syn	GMS	N/A	500	250-1000

Antimicrobic		Available Co	ncentrations		
			Gram Negative	Gram Positive	Strep
Class	Drug Name	Drug Code	Range	Range	Range
Aminoglycoside	Gentamicin-Syn (SFM)	GMF	N/A	250	N/A
Beta-lactam	Imipenem	IPM	0.0625-16	0.5-16	0.015-4
Aminoglycoside	Isepamycin	ISP	0.5-32	N/A	N/A
Aminoglycoside	Kanamycin	K	0.5-64	0.5-64	N/A
Aminoglycoside	Kanamycin-Syn	KS	N/A	250	250-1000
Quinolone	Levofloxacin	LVX	0.25-8	0.25-8	0.25-16
Macrolides Lincosamides Streptogramin	Lincomycin	L	N/A	0.5-16	N/A
Oxazolidinone	Linezolid	LZD	N/A	0.25-32	0.25-16
Quinolone	Lomefloxacin	LOM	0.25-8	0.25-8	N/A
Beta-lactam	Mecillinam	MEC	0.5-32	N/A	N/A
Beta-lactam	Meropenem	MEM	0.125-32	0.5-16	0.03125-2
Beta-lactam	Meropenem- Vaborbactam	MEV	0.125-32	N/A	N/A
Tetracycline	Minocycline	MI	0.5-16	1-32	N/A
Beta-lactam	Moxalactam	MOX	1-64	1-64	N/A
Quinolone	Moxifloxacin	MXF	0.125-8	0.25-8	0.0625-8
Pseudomonic acid	Mupirocin	MUP	N/A	0.0625-8	N/A
Pseudomonic acid	Mupirocin High level	MUH	N/A	256	N/A
Quinolone	Nalidixic Acid	NA	1-32	N/A	N/A
Aminoglycoside	Netilmicin	NET	0.5-32	0.5-32	N/A
Nitrofuran	Nitrofurantoin	FM	8-512	16-512	N/A
Quinolone	Norfloxacin	NOR	0.25-16	0.25-16	N/A
Quinolone	Ofloxacin	OFX	0.25-8	0.25-8	0.5-16
Beta-lactam	Oxacillin	ОХ	N/A	0.06-4	N/A
Quinolone	Pefloxacin	PEF	0.25-8	0.25-8	N/A
Beta-lactam	Penicillin G	Р	N/A	0.0625-32	0.03125-8
Beta-lactam	Piperacillin	PIP	0.5-128	1-128	N/A

Antimicrobic		Available Con	centrations		
		Gram Negative	Gram Positive	Strep	
Class	Drug Name	Drug Code	Range	Range	Range
Beta-lactam	Piperacillin- Tazobactam	TZP	0.5/4- 128/4	1/4-128/4	N/A
Macrolides Lincosamides Streptogramin	Pristinamycin	PR	N/A	0.25-4	0.0625-4
Macrolides Lincosamides Streptogramin	Quinupristin- Dalfopristin	SYN	N/A	0.5-4	0.125-8
Rifamycin	Rifampin	RA	N/A	0.25-32	N/A
Aminoglycoside	Streptomycin- Syn	STS	N/A	1000	250-1000
Aminoglycoside	Streptomycin- Syn (SFM)	STF	N/A	250	N/A
Glycopeptide	Teicoplanin	TEC	N/A	0.5-32	1-32
Beta-lactam	Temocillin	TEM	2 – 32	N/A	N/A
Tetracyclinee	Tetracycline	TE	0.5-16	0.5-16	0.0625-16
Beta-lactam	Ticarcillin	TIC	1-128	1-128	N/A
Beta-lactam	Ticarcillin- Clavulanate	TIM	1/2-128/2	1/2-128/2	N/A
Glycylcycline	Tigecycline	TGC	0.25-16	0.03125-4	N/A
Aminoglycoside	Tobramycin	NN	0.12-16	1 -16	N/A
Folate Antagonist	Trimeth- Sulfa (DIN)	STG	0.4/7.6-12.8/ 243.2	0.4/7.6- 12.8/243.2	N/A
Folate Antagonist	Trimethoprim	TMP	0.5-16	0.5-16	N/A
Folate Antagonist	Trimethoprim- Sulfamethoxazol e	SXT	0.5/9.5- 16/304	0.5/9.5-16/ 304	0.06/1.19- 16/304
Glycopeptide	Vancomycin	VA	N/A	0.5-32	0.0625-32

Bold = Different Range for Gram Negative and Gram Positive

#### NOTE

MIC dilutions appearing in this manual are actual serial 2-fold dilution concentrations. MIC values appearing on reports may be rounded.

In general, the BD Phoenix System provides a MIC for all organisms at any of the concentrations defined on a specific panel. For certain drug and organism combinations in the following tables, a specific minimum/maximum MIC is reported even if there is a lower/higher concentration on the panel.

Antimicrobial	Organism	Min MIC	Max MIC
		(µg/mL)	(µg/mL)
Gram Negative			
Amikacin	Morganella morganii	2	_
Amoxicillin-Clavulanic Acid (fixed clav. acid conc.)	Proteus mirabilis	1/2	_
Amoxicillin-Clavulanic Acid (variable clav. acid conc.)	Proteus mirabilis	2/1	-
	Klebsiella aerogenes	1	-
Arbekacin	Morganella morganii	1	-
	Providencia spp.	1	-
Cefdinir	Proteus mirabilis	0.25	-
Cefixime	Proteus mirabilis	0.5	-
Cenxime	Providencia spp.	0.5	-
	Citrobacter freundii	2	_
Cefotiam	Proteus mirabilis	4	_
	Providencia spp.	4	_
Ceftaroline	Aeromonas spp.	0.0625	4
	Acinetobacter spp.	0.25	8
Ceftazidime-Avibactam	Hafnia alvei	1	32
	Pantoea spp.	2	32
	Aeromonas spp.	0.5	32
Coftolozopo Tozobootom	Proteus spp. except P. mirabilis	1	32
Ceftolozane-Tazobactam	Providencia stuartii	0.5	32
	Yersinia spp.	0.5	32
Ciprofloxacin	For organisms except Salmonella spp. and Acinetobacter spp.	0.125	4
Fosfomycin w/G6P	Pseudomonas aeruginosa	16	64
Fosfomycin w/G6P	Serratia spp.	32	256
Imipenem	Achromobacter spp.	2	_
Garenoxacin	Stenotrophomonas maltophilia	1	_

Antimicrobial	Organism	Min MIC	Max MIC
		(µg/mL)	(µg/mL)
Kanamycin	Proteus mirabilis	4	_
	Aeromonas spp.	0.25	_
Meropenem	Burkholderia spp.	0.5	_
	Proteus mirabilis	0.5	_
	Aeromonas spp.	0.5	32
Meropenem-Vaborbactam	Proteus mirabilis	0.5	32
	Providencia spp.	2	32
Ticarcillin	Proteus mirabilis	4	_
Gram Positive			
Amikacin	Staphylococcus epidermidis	8	_
Allikacili	Staphylococcus other*	8	_
Amoxicillin	Staphylococcus aureus	2	_
ATTOXICIIIIT	Staphylococcus epidermidis	2	_
Ampioillin	Staphylococcus aureus	_	1
Ampicillin	Enterococcus other**	1	_
Ampicillin-Sulbactam (f) (SXA)	Staphylococcus epidermidis	1	_
Ampicillin-Sulbactam (SAM)	Enterococcus other**	2	_
Cefotetan	Staphylococcus epidermidis	8	_
Ceftriaxone	Staphylococcus aureus	2	_
Cephalexin	Staphylococcus epidermidis	1	_
Daptomycin	Enterococcus casseliflavus/ gallinarum	2	-
Lincomycin	Enterococcus other**	1	8
Minocycline	Enterococcus spp.	1	32
Williocycline	Staphylococcus spp.	1	32
Netilmicin	Staphylococcus epidermidis	2	_
Norfloxacin	Enterococcus other**	2	_
	Staphylococcus aureus	_	1
Penicillin	Staphylococcus epidermidis	_	1
	Enterococcus other**	2	_
Piperacillin	Staphylococcus epidermidis	2	_

Antimicrobial	Organism	Min MIC	Max MIC
		(µg/mL)	(µg/mL)
Teicoplanin	Staphylococcus epidermidis	2	_
Ticarcillin	Staphylococcus epidermidis	4	_
Ticarciiiii	Staphylococcus other*	4	_
Ticarcillin/Clavulanate	Staphylococcus aureus	4/2	_
Trovafloxacin	Enterococcus faecium	1	_
Streptococci			
Daptomycin	Viridans group	0.25	_

<sup>\*</sup> Coagulase negative Staphylococcus other than S. epidermidis

# 9.2 List of Reagents and Principles Employed in the BD Phoenix System

# 9.2.1 Gram Negative

SUBSTRATE NAME	CODE	PRINCIPLE
L-PHENYLALANINE-AMC	A_LPHET	
4MU-N-ACETYL-BD- GLUCOSAMINIDE	M_NAG	
L-GLUTAMIC ACID-AMC	A_LGTA	
L-TRYPTOPHAN-AMC	A_LTRY	
L-PYROGLUTAMIC ACID-AMC	A_LPYR	
L-PROLINE-AMC	A_LPROB	Enzymatic hydrolysis of the amide or glycosidic bond results in the release of a
L-ARGININE-AMC	A_LARGH	fluorescent coumarin or
ARGININE-ARGININE-AMC	A_ARARR	4-methylumbelliferone derivative.
GLYCINE-AMC	A_GLYB	
L-LEUCINE-AMC	A_LLEUH	
LYSINE-ALANINE-AMC	A_LYALD	
GLUTARYL-GLYCINE-ARGININE-AMC	A_GUGAH	
GLYCINE-PROLINE-AMC	A_GLPRB	

<sup>\*\*</sup> Enterococcus sp. other than E. faecalis and E. faecium

SUBSTRATE NAME	CODE	PRINCIPLE	
COLISTIN	C_CLST	Resistance to the antimicrobial agent	
POLYMYXIN B	C_PXB	results in a reduction of the resazurin based indicator.	
D-MANNITOL	C_DMNT		
CITRATE	C_CIT		
ACETATE	C_ACT		
ADONITOL	C_ADO	Utilization of a carbon source results in a reduction of the resazurin based indicator.	
MALONATE	C_MLO		
ALPHA-KETOGLUTARIC ACID	C_KGA		
TIGLIC ACID	C_TIG		
FLUORESCENT POSITIVE CONTROL	FLR_CTL	Control to standardize fluorescent substrate results.	
L-PROLINE-NA	N_LPROT	Enzymatic hydrolysis of the colorless amide	
GAMMA-L-GLUTAMYL-NA	N_LGGH	substrate releases yellow p-nitroaniline.	
BIS (PNP) PHOSPHATE	P_BPHO	Enzymatic hydrolysis of the colorless aryl	
PNP-BD-GLUCOSIDE	P_BDGLU	substituted glycoside releases yellow p- nitrophenol.	
BETA-ALLOSE	R_BALL		
N-ACETYL-GALACTOSAMINE	R_NGA		
N-ACETYL-GLUCOSAMINE	R_NGU		
SORBITOL	R_DSBT		
SUCROSE	R_DSUC		
GALACTURONIC ACID	R_GRA		
MALTULOSE	R_MTU		
L-RHAMNOSE	R_LRHA	Utilization of carbohydrate results in lower	
BETA-GENTIOBIOSE	R_BGEN	pH and change in indicator (phenol red).	
DEXTROSE	R_DEX		
D-GALACTOSE	R_DGAL		
D-FRUCTOSE	R_DFRU		
D-GLUCONIC ACID	R_DGUA		
D-MELIBIOSE	R_DMLB		
L-ARABINOSE	R_LARA		
METHYL-B-GLUCOSIDE	R_MBGU		

SUBSTRATE NAME	CODE	PRINCIPLE
ORNITHINE	S_ORN	Utilization of ornithine results in pH rise and change in fluorescent indicator.
UREA	S_URE	Hydrolysis of urea and the resulting ammonia change results in pH rise and change in fluorescent indicator.
ESCULIN	T_ESC	Hydrolysis of esculin results in a black precipitate in the presence of ferric ion.

#### 9.2.2 Gram Positive

SUBSTRATE NAME	CODE	PRINCIPLE
4MU-BD-CELLOBIOSIDE	M_BDCEL	
L-ALANINE-AMC	A_LALT	
4MU-BD-GLUCOSIDE	M_BDGLU	
L-PROLINE-AMC	A_LPROB	
L-PYROGLUTAMIC ACID-AMC	A_LPYR	
L-PHENYLALANINE-AMC	A_LPHET	
L-TRYPTOPHAN-AMC	A_LTRY	
4MU-PHOSPHATE	M_PHOS	
METHIONINE-AMC	A_META	
4MU-AD-GLUCOSIDE	M_ADGLU	Enzymatic hydrolysis of the amide or glycosidic bond results in the release of a
ARGININE-ARGININE-AMC	A_ARARR	fluorescent coumarin or
GLYCINE-PROLINE-AMC	A_GLPRB	4-methylumbelliferone derivative.
4MU-BD-GLUCURONIDE	M_BDGLC	
L-LEUCINE-AMC	A_LLEUH	
4MU-N-ACETYL-BD- GLUCOSAMINIDE	M_NAG	
L-ARGININE-AMC	A_LARGH	
4MU-PHOSPHATE (with Trehalose)	M_PHOT	
L-HISTIDINE-AMC	A_LHIST	
L-ISOLEUCINE-AMC	A_LISO	
4MU-BD-GALACTOSIDE	M_BDGAL	

SUBSTRATE NAME	CODE	PRINCIPLE
COLISTIN	C_CLST	Resistance to the antimicrobial agent results
POLYMYXIN B	C_PXB	in a reduction of the resazurin based indicator.
D-GLUCONIC ACID	C_DGUA	
3-METHYL GLUTARIC ACID	C_3MGA	
D-FRUCTOSE	C_DFRU	
IMINODIACETIC ACID	C_IMN	Utilization of a carbon source results in a
ALPHA-KETOGLUTARIC ACID	C_KGA	reduction of the resazurin based indicator.
D-MANNITOL	C_DMNT	
3-METHYLADIPIC ACID	C_MAA	
THYMIDINE	C_THY	
FLUORESCENT POSITIVE CONTROL	FLR_CTL	Control to standardize fluorescent substrate results.
ALANINE-ALANINE-PNA	N_ALALH	
L-PROLINE-PNA	N_LPROT	Enzymatic hydrolysis of the colorless amide substrate releases yellow <i>p</i> -nitroaniline.
VALINE-ALANINE-PNA	N_VAALA	,,
PNP-AD-GLUCOSIDE	P_ADGLU	Enzymatic hydrolysis of the colorless aryl
PNP-PHOSPHATE	P_PHOL	substituted glycoside releases yellow p-nitrophenol.
BETA-GENTIOBIOSE	R_BGEN	
D-SUCROSE	R_DSUC	
MALTOTRIOSE	R_MTT	
N-ACETYL-GLUCOSAMINE	R_NGU	
D-TREHALOSE	R_DTRE	Utilization of carbohydrate results in lower pH and change in indicator (phenol red).
D-TAGATOSE	R_DTAG	,
MALTOSE	R_MAL	
DEXTROSE	R_DEX	
METHYL-α-D-GLUCOSIDE	R_MGP	
UREA	S_URE	Hydrolysis of urea and the resulting ammonia change results in pH rise and change in fluorescent indicator.
ESCULIN	T_ESC	Hydrolysis of esculin results in a black precipitate in the presence of ferric ion.

SUBSTRATE NAME	CODE	PRINCIPLE
NITROCEFIN	L_NCF	Enzymatic hydrolysis of the ß-Lactam ring results in a color change.

# 9.2.3 Streptococci

SUBSTRATE NAME	CODE	PRINCIPLE
AMYGDALIN	R_AMY	
D-GALACTOSE	R_DGAL	
D-MANNITOL	R_DMTL	
D-RAFFINOSE	R_DRAF	
D-SORBITOL	R_DSBT	Utilization of carbohydrate results in lower
D-TREHALOSE	R_DTRE	pH and change in indicator (Phenol red).
DEXTRIN	R_DXN	
N-ACETYL-GLUCOSAMINE	R_NGU	
PHENYL GLUCOSIDE	R_PHG	
SALICIN	R_SAL	
ONP-BD-GLUCOSIDE	O_BOGLU	
PNP-AD-GALACTOSIDE	P_ADGAL	
PNP-BD-CELLOBIOSIDE	P_CELB	Enzymatic hydrolysis of the colorless aryl substituted glycoside releases yellow
PNP-BD-GALACTOSIDE	P_GALB	p-nitrophenol.
PNP-AD-GLUCOSIDE	P_PAGLU	
PNP-PHOSPHATE	P_PHOL	
ALANINE-ALANINE-PNA	N_ALALH	
VALINE-ALANINE-PNA	N_VAALA	Enzymatic hydrolysis of the colorless amide substrate releases yellow p-nitroanilide.
L-LYSINE-PNA	N_LLYSB	, ,
FLUORESCENT POSITIVE CONTROL	FLR_CTL	Control to standardize fluorescent substrate results.
THYMIDINE	C_THY	
PULLULAN	C_PUL	Utilization of a carbon source resulting in a reduction of the indicator (Resazurin
D-TREHALOSE	C_TRL	based).
D-LACTOSE	C_DLAC	

SUBSTRATE NAME	CODE	PRINCIPLE
LYSINE-AMC	A_LYSA	
SERINE-TYROSINE-AMC	A_SETY	
L-CITRULLINE-AMC	A_LCTU	
L-PYROGLUTAMIC ACID-AMC	A_LPYR	
ISOLEUCINE-AMC	A_LISO	
L-TRYPTOPHAN-AMC	A_LTRY	
L-VALINE-AMC	A_LVAL	
ARGININE-ARGININE-AMC	A_ARARR	
LYSINE-ALANINE-AMC	A_LYALD	
ASPARAGINE-AMC	A_APGT	Enzymatic hydrolysis of the amide or
L-ARGININE-AMC	A_LARGH	glycosidic bond results in the release of a fluorescent coumarin or
L-HISTIDINE-AMC	A_LHIST	4-methylumbelliferone derivative.
ALANINE-AFC	Z_ALFT	
4MU-BD-CELLOBIOSIDE	M_BDCEL	
4MU-BD-GLUCOSIDE	M_BDGLU	
4MU-PHOSPHATE	M_PHOS	
4MU-AD-GLUCOSIDE	M_ADGLU	
4MU-BD-GLUCURONIDE	M_BDGLC	
4MU-N-ACETYL-BD-GLUCOSAMINE	M_NAG	
4MU-PHOSPHATE (with trehalose)	M_PHOT	
4MU-BD-GALACTOSIDE	M_BDGAL	
ESCULIN	T_ESC	Hydrolysis of esculin results in a black precipitate in the presence of ferric ion.

#### 9.2.4 Yeast

SUBSTRATE NAME	CODE	PRINCIPLE	
PNP-BD-GLUCOSIDE	P_BDGLU	Enzymatic hydrolysis of the colorless aryl	
PNP-AD-GLUCOSIDE	P_PAGLU	substituted glycoside releases yellow	
ONP-BD-GLUCOSIDE	O_BOGLU	<i>p</i> -nitrophenol.	
L-SORBOSE	C_LSBO		
DEXTROSE	C_DEX		
D-MANNITOL	C_DMNT	Utilization of a carbon source results in a	
D-SUCROSE	C_DSUC	reduction of the resazurin based indicator.	
METHYL-AD-GLUCOPYRANOSIDE	C_MGP		
N-ACETYL-BD-GLUCOSAMINIDE	C_NAG		
DEXTROSE	R_DEX		
D-FRUCTOSE	R_DFRU		
D-GALACTOSE	R_DGAL	Utilization of carbohydrate results in lower	
SUCROSE	R_DSUC	pH and change in indicator (phenol red).	
D-TREHALOSE	R_DTRE		
MALTOTRIOSE	R_MTT		
ESCULIN	T_ESC	Hydrolysis of esculin results in a black precipitate in the presence of ferric ion.	
FLUORESCENT POSITIVE CONTROL	FLR_CTL	Control to standardize fluorescent substrate results.	
GAMMA-L-GLUTAMYL-NA	N_LGGH	Enzymatic hydrolysis of the colorless amide	
L-PROLINE-PNA	N_LPROT	substrate releases yellow p-nitroaniline.	

SUBSTRATE NAME	CODE	PRINCIPLE
ASPARAGINE-AMC	A_APGT	
L-ARGININE-AMC	A_LARGH	
L-GLUTAMINE-AMC	A_LGLNB	
L-TYROSINE-AMC	A_LTYO	
L-HISTIDINE-AMC	A_LHIST	
ORNITHINE-AMC	A_ORN	
THREONINE-AMC	A_THR	
HYDROXY PROLINE-AMC	A_LHYP	
4MU-N-ACETYL-BD-GLUCOSAMINE	M_NAG	
4MU-AD-GLUCOSIDE	M_ADGLU	
4MU-PHOSPHATE	M_PHOS	
LYSINE-ALANINE-AMC	A_LYALD	
GLYCINE-ARGININE-AMC	A_GLARH	Enzymatic hydrolysis of the amide or
ALANINE-AFC	Z_ALFT	glycosidic bond results in the release of a fluorescent coumarin or
GLYCINE-AMC	A_GLYB	4-methylumbelliferone derivative.
L-CITRULLINE-AMC	A_LCTU	
L-GLUTAMIC ACID-AMC	A_LGTA	
L-VALINE-AMC	A_LVAL	
L-ALANINE-AMC	A_LALT	
L-PROLINE-AMC	A_LPROB	
L-TRYPTOPHAN-AMC	A_LTRY	
H-B-ALANINE-AMC	A_HBALT	
4MU-BD-CELLOBIOSIDE	M_BDCEL	
4MU-BD-GLUCOSIDE	M_BDGLU	
GLYCINE-PROLINE-AMC	A_GLPRB	
LYSINE-PROLINE-AMC	A_LYPRA	
BENZYL-L-CYSTEINE-AMC	A_BZLCY	
AMINO ACID	S_GTN	Utilization of the amino acid results in a change in fluorescence.
UREA	S_URE	Hydrolysis of urea and the resulting ammonia change results in pH rise and change in fluorescent indicator.

# 9.3 Taxa for ID/AST Determination

# 9.3.1 Gram Negative (0.5 McFarland)

GRAM NEGATIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Achromobacter denitrificans	AST
Achromobacter insolitus	AST
Achromobacter mucicolens	AST
Achromobacter piechaudii	AST
Achromobacter ruhlandii	AST
Achromobacter spanius	AST
Achromobacter species	ID/AST
Achromobacter xylosoxidans	AST
Acinetobacter baumannii	ID/AST
Acinetobacter baumannii/calcoaceticus complex <sup>2</sup>	ID/AST
Acinetobacter baumannii/haemolyticus	AST
Acinetobacter bereziniae	AST
Acinetobacter calcoaceticus	AST
Acinetobacter guillouiae	AST
Acinetobacter haemolyticus	ID/AST
Acinetobacter johnsonii	AST
Acinetobacter junii	AST
Acinetobacter Iwoffii	ID/AST
Acinetobacter lwoffii/haemolyticus	ID/AST
Acinetobacter nosocomialis	AST
Acinetobacter parvus	AST
Acinetobacter pittii	AST
Acinetobacter radioresistens	AST
Acinetobacter schindleri	AST
Acinetobacter seifertii	AST
Acinetobacter species	ID/AST
Acinetobacter ursingii	AST

GRAM NEGATIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Actinobacillus lignieresii	ID
Actinobacillus suis	ID
Actinobacillus ureae	ID
Aeromonas allosaccharophila	AST
Aeromonas caviae	ID/AST
Aeromonas eucrenophila	AST
Aeromonas hydrophila	ID/AST
Aeromonas hydrophila group	AST
Aeromonas jandaei	AST
Aeromonas media	AST
Aeromonas salmonicida	AST
Aeromonas salmonicida ssp. achromogenes	AST
Aeromonas salmonicida ssp. masoucida	ID/AST
Aeromonas salmonicida ssp. pectinolytica	AST
Aeromonas salmonicida ssp. salmonicida	ID/AST
Aeromonas salmonicida ssp. smithia	ID/AST
Aeromonas schubertii	ID/AST
Aeromonas species	AST
Aeromonas trota	AST
Aeromonas veronii bv sobria	ID/AST
Aeromonas veronii bv veronii	ID/AST
Alcaligenes faecalis	ID/AST
Alcaligenes faecalis ssp. faecalis	AST
Alcaligenes species	AST
Bergeyella zoohelcum	ID
Bordetella bronchiseptica	ID
Brevundimonas diminuta	ID/AST
Brevundimonas species	AST
Brevundimonas vesicularis	ID/AST
Burkholderia caryophylli	AST

GRAM NEGATIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Burkholderia cepacia complex	ID/AST
Burkholderia cepacia/Ralstonia pickettii	ID/AST
Burkholderia diffusa	AST
Burkholderia gladioli	ID/AST
Burkholderia glathei	AST
Burkholderia graminis	AST
Burkholderia latens	AST
Burkholderia metallica	AST
Burkholderia multivorans	AST
Burkholderia phenazinium	AST
Burkholderia pyrrocinia	AST
Burkholderia seminalis	AST
Burkholderia species	AST
Burkholderia species/Ralstonia species	ID/AST
Cardiobacterium hominis	ID
CDC group Vb-3	ID
Cedecea davisae	ID/AST
Cedecea lapagei	ID/AST
Cedecea neteri	ID/AST
Cedecea species	AST
Cedecea species 3	AST
Cedecea species 5	AST
Chromobacterium violaceum	ID
Chryseobacterium gleum	ID/AST
Chryseobacterium indologenes	ID/AST
Chryseobacterium scophthalmum	AST
Chryseobacterium species	AST
Citrobacter amalonaticus	ID/AST
Citrobacter braakii	ID/AST

GRAM NEGATIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Citrobacter farmeri	ID/AST
Citrobacter freundii	ID/AST
Citrobacter gillenii	AST
Citrobacter koseri	ID/AST
Citrobacter murliniae	AST
Citrobacter rodentium	AST
Citrobacter sedlakii	ID/AST
Citrobacter species	AST
Citrobacter werkmanii	ID/AST
Citrobacter youngae	ID/AST
Comamonas terrigena	ID
Comamonas testosteroni	ID
Cronobacter sakazakii complex	ID/AST
Cupriavidus gilardii	AST
Cupriavidus pauculus	ID/AST
Delftia acidovorans	ID/AST
Edwardsiella hoshinae	ID/AST
Edwardsiella ictaluri	ID/AST
Edwardsiella species	AST
Edwardsiella tarda	ID/AST
Edwardsiella tarda biogroup 1	AST
Eikenella corrodens	ID
Elizabethkingia anophelis	AST
Elizabethkingia meningoseptica	ID/AST
Elizabethkingia miricola	AST
Empedobacter brevis	ID
Enterobacter asburiae	ID/AST
Enterobacter bugandensis	AST
Enterobacter cancerogenus	ID/AST

GRAM NEGATIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Enterobacter cloacae <sup>2</sup>	ID/AST
Enterobacter cloacae ssp. dissolvens	AST
Enterobacter hormaechei	ID/AST
Enterobacter kobei	AST
Enterobacter ludwigii	AST
Enterobacter nimipressuralis	AST
Enterobacter species	AST
Escherichia albertii	AST
Escherichia coli <sup>2</sup>	ID/AST
Escherichia coli serotype O111	AST
Escherichia coli serotype O157	AST
Escherichia fergusonii	ID/AST
Escherichia hermannii	ID/AST
Escherichia species	AST
Ewingella americana	ID
Gram-negative rod unidentified enteric	AST
Gram-negative rod unidentified nonfermenter	AST
Grimontia hollisae	ID
Hafnia alvei	ID/AST
Hafnia alvei group 1	AST
Kingella denitrificans	ID
Kingella kingae	ID
Klebsiella aerogenes <sup>2</sup>	ID/AST
Klebsiella granulomatis	AST
Klebsiella oxytoca <sup>2</sup>	ID/AST
Klebsiella ozaenae	ID/AST
Klebsiella pneumoniae <sup>2</sup>	ID/AST
Klebsiella rhinoscleromatis	ID/AST
Klebsiella species	AST

GRAM NEGATIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Klebsiella variicola	AST
Kluyvera ascorbata	ID/AST
Kluyvera cryocrescens	ID/AST
Kluyvera georgiana	AST
Kluyvera intermedia	ID/AST
Kluyvera species	AST
Leclercia adecarboxylata	ID/AST
Lelliottia amnigena biogroup 1	ID/AST
Lelliottia amnigena biogroup 2	ID/AST
Leminorella grimontii	ID
Leminorella richardii	ID
Mannheimia haemolytica	ID
Methylobacterium extorquens	ID
Moellerella wisconsensis	ID/AST
Moraxella (Branhamella) catarrhalis	ID
Moraxella species	ID
Morganella morganii <sup>2</sup>	ID/AST
Morganella morganii ssp. morganii	AST
Morganella morganii ssp. morganii biogroup 1	AST
Morganella morganii ssp. sibonii	AST
Morganella species	AST
Myroides injenensis	AST
Myroides odoratimimus	AST
Myroides odoratus	AST
Myroides odoratus/odoratimimus	ID/AST
Myroides species	AST
Neisseria animaloris	ID
Neisseria zoodegmatis	ID
Ochrobactrum anthropi	ID/AST

GRAM NEGATIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Oligella ureolytica	ID
Oligella urethralis	ID
Pantoea agglomerans	ID/AST
Pantoea ananatis	AST
Pantoea calida	AST
Pantoea dispersa	AST
Pantoea gaviniae	AST
Pantoea septica	AST
Pantoea species	AST
Pantoea stewartii	AST
Pantoea stewartii ssp. indologenes	AST
Pantoea stewartii ssp. stewartii	AST
Paracoccus yeei	ID
Pasteurella aerogenes	ID
Pasteurella multocida	ID
Photobacterium damselae	ID
Plesiomonas shigelloides	ID
Pluralibacter gergoviae	ID/AST
Pragia fontium	ID
Proteus hauseri	AST
Proteus mirabilis <sup>2</sup>	ID/AST
Proteus penneri	ID/AST
Proteus species	AST
Proteus vulgaris	ID/AST
Proteus vulgaris/penneri	ID/AST
Providencia alcalifaciens	ID/AST
Providencia heimbachae	AST
Providencia rettgeri	ID/AST
Providencia rustigianii	ID/AST

GRAM NEGATIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Providencia species	AST
Providencia stuartii	ID/AST
Pseudescherichia vulneris	ID/AST
Pseudomonas aeruginosa²	ID/AST
Pseudomonas alcaligenes	AST
Pseudomonas fluorescens	ID/AST
Pseudomonas fluorescens/putida	AST
Pseudomonas luteola	ID/AST
Pseudomonas mendocina	ID/AST
Pseudomonas monteilii	AST
Pseudomonas oryzihabitans	ID/AST
Pseudomonas pertucinogena	AST
Pseudomonas pseudoalcaligenes	ID/AST
Pseudomonas pseudoalcaligenes ssp. pseudoalcaligenes	AST
Pseudomonas putida	ID/AST
Pseudomonas species	ID/AST
Pseudomonas stutzeri	ID/AST
Pseudomonas veronii	AST
Rahnella aquatilis	ID
Ralstonia insidiosa	AST
Ralstonia pickettii	ID/AST
Ralstonia solanacearum	AST
Ralstonia species	AST
Raoultella ornithinolytica	ID/AST
Raoultella planticola	AST
Raoultella species	AST
Raoultella terrigena	AST
Rhizobium radiobacter	ID
Rodentibacter pneumotropicus	ID

GRAM NEGATIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Salmonella enterica ssp. arizonae	ID/AST
Salmonella enterica ssp. diarizonae	AST
Salmonella enterica ssp. enterica serovar Choleraesuis	ID/AST
Salmonella enterica ssp. enterica sv Gallinarum bv Gallinarum	ID/AST
Salmonella enterica ssp. enterica sv Gallinarum bv Pullorum	ID/AST
Salmonella enterica ssp. enterica sv Paratyphi A	ID/AST
Salmonella enterica ssp. enterica sv Typhi	ID/AST
Salmonella enterica ssp. houtenae	AST
Salmonella enterica ssp. indica	AST
Salmonella enterica ssp. salamae	AST
Salmonella species	ID/AST
Serratia entomophila	AST
Serratia ficaria	ID/AST
Serratia fonticola	ID/AST
Serratia grimesii	AST
Serratia liquefaciens	ID/AST
Serratia marcescens <sup>2</sup>	ID/AST
Serratia odorifera	AST
Serratia odorifera 1	ID/AST
Serratia odorifera 2	ID/AST
Serratia plymuthica	ID/AST
Serratia proteamaculans ssp. proteamaculans	AST
Serratia proteamaculans ssp. quinovora	AST
Serratia rubidaea	ID/AST
Serratia species	AST
Shewanella algae	AST
Shewanella putrefaciens	ID/AST
Shewanella species	AST

GRAM NEGATIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Shigella boydii	ID/AST
Shigella dysenteriae	ID/AST
Shigella flexneri	ID/AST
Shigella sonnei	ID/AST
Shigella species	ID/AST
Sphingobacterium multivorum	ID/AST
Sphingobacterium multivorum/thalpophilum	ID/AST
Sphingobacterium species	AST
Sphingobacterium spiritivorum	ID/AST
Sphingobacterium thalpophilum	ID/AST
Sphingomonas paucimobilis	ID/AST
Sphingomonas paucimobilis group	AST
Sphingomonas sanguinis	AST
Stenotrophomonas maltophilia <sup>2</sup>	ID/AST
Suttonella indologenes	ID
Tatumella ptyseos	ID
Vibrio alginolyticus	ID
Vibrio cholerae	ID
Vibrio fluvialis	ID
Vibrio metschnikovii	ID
Vibrio mimicus	ID
Vibrio parahaemolyticus	ID
Vibrio vulnificus	ID
Weeksella virosa	ID
Yersinia aldovae	AST
Yersinia bercovieri	AST
Yersinia enterocolitica	ID/AST
Yersinia enterocolitica group	AST
Yersinia frederiksenii	ID/AST

GRAM NEGATIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Yersinia intermedia	ID/AST
Yersinia kristensenii	ID/AST
Yersinia mollaretii	AST
Yersinia pseudotuberculosis	ID/AST
Yersinia rohdei	AST
Yersinia ruckeri	ID/AST
Yersinia species	AST
Yokenella regensburgei	ID

<sup>\*</sup>Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (see Section 2.3.3 Custom Interpretation Rule Set).

#### 9.3.2 Gram Negative (0.25 McFarland)

GRAM NEGATIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Achromobacter species	ID/AST
Acinetobacter baumannii/calcoaceticus complex	ID/AST
Acinetobacter haemolyticus	ID/AST
Acinetobacter Iwoffii	ID/AST
Actinobacillus lignieresii	ID
Actinobacillus suis	ID
Actinobacillus ureae	ID
Aeromonas caviae	ID/AST
Aeromonas hydrophila	ID/AST
Aeromonas salmonicida ssp. masoucida	ID/AST
Aeromonas salmonicida ssp. salmonicida	ID/AST
Aeromonas salmonicida ssp. smithia	ID/AST
Aeromonas schubertii	ID/AST
Aeromonas veronii bv sobria	ID/AST

<sup>&</sup>lt;sup>1</sup>Not all species encountered during clinical performance evaluations.

<sup>&</sup>lt;sup>2</sup>Organism encountered in clinical trials and ≥20 strains available for antimicrobial/ organism performance analysis.

GRAM NEGATIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Aeromonas veronii bv veronii	ID/AST
Alcaligenes faecalis	ID/AST
Bergeyella zoohelcum	ID
Bordetella bronchiseptica	ID
Brevundimonas diminuta	ID/AST
Brevundimonas vesicularis	ID/AST
Burkholderia cepacia complex	ID/AST
Burkholderia gladioli	ID/AST
Cardiobacterium hominis	ID
CDC group Vb-3	ID
Cedecea davisae	ID/AST
Cedecea lapagei	ID/AST
Cedecea neteri	ID/AST
Chromobacterium violaceum	ID
Chryseobacterium gleum	ID/AST
Chryseobacterium indologenes	ID/AST
Citrobacter amalonaticus	ID/AST
Citrobacter braakii	ID/AST
Citrobacter farmeri	ID/AST
Citrobacter freundii	ID/AST
Citrobacter koseri	ID/AST
Citrobacter sedlakii	ID/AST
Citrobacter werkmanii	ID/AST
Citrobacter youngae	ID/AST
Comamonas terrigena	ID
Comamonas testosteroni	ID
Cronobacter sakazakii complex	ID/AST
Cupriavidus pauculus	ID/AST
Delftia acidovorans	ID/AST

GRAM NEGATIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Edwardsiella hoshinae	ID/AST
Edwardsiella ictaluri	ID/AST
Edwardsiella tarda	ID/AST
Eikenella corrodens	ID
Elizabethkingia meningoseptica	ID/AST
Empedobacter brevis	ID
Enterobacter asburiae	ID/AST
Enterobacter cancerogenus	ID/AST
Enterobacter cloacae	ID/AST
Enterobacter hormaechei	ID/AST
Escherichia coli	ID/AST
Escherichia fergusonii	ID/AST
Escherichia hermannii	ID/AST
Ewingella americana	ID
Grimontia hollisae	ID
Hafnia alvei	ID/AST
Klebsiella aerogenes	ID/AST
Klebsiella oxytoca	ID/AST
Klebsiella ozaenae	ID/AST
Klebsiella pneumoniae	ID/AST
Klebsiella rhinoscleromatis	ID/AST
Kluyvera ascorbata	ID/AST
Kluyvera cryocrescens	ID/AST
Kluyvera intermedia	ID/AST
Leclercia adecarboxylata	ID/AST
Lelliottia amnigena biogroup 1	ID/AST
Lelliottia amnigena biogroup 2	ID/AST
Leminorella grimontii	ID
Leminorella richardii	ID

GRAM NEGATIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Mannheimia haemolytica	ID
Moellerella wisconsensis	ID/AST
Morganella morganii	ID/AST
Myroides odoratus/odoratimimus	ID/AST
Neisseria animaloris	ID
Neisseria zoodegmatis	ID
Ochrobactrum anthropi	ID/AST
Oligella ureolytica	ID
Oligella urethralis	ID
Pantoea agglomerans	ID/AST
Paracoccus yeei	ID
Pasteurella aerogenes	ID
Pasteurella multocida	ID
Photobacterium damselae	ID
Plesiomonas shigelloides	ID
Pluralibacter gergoviae	ID/AST
Pragia fontium	ID
Proteus mirabilis	ID/AST
Proteus penneri	ID/AST
Proteus vulgaris	ID/AST
Proteus vulgaris/penneri	ID/AST
Providencia alcalifaciens	ID/AST
Providencia rettgeri	ID/AST
Providencia rustigianii	ID/AST
Providencia stuartii	ID/AST
Pseudescherichia vulneris	ID/AST
Pseudomonas aeruginosa	ID/AST
Pseudomonas fluorescens	ID/AST
Pseudomonas luteola	ID/AST

GRAM NEGATIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Pseudomonas mendocina	ID/AST
Pseudomonas oryzihabitans	ID/AST
Pseudomonas putida	ID/AST
Pseudomonas stutzeri	ID/AST
Rahnella aquatilis	ID
Ralstonia pickettii	ID/AST
Raoultella ornithinolytica	ID/AST
Rhizobium radiobacter	ID
Rodentibacter pneumotropicus	ID
Salmonella enterica ssp. arizonae	ID/AST
Salmonella enterica ssp. enterica serovar Choleraesuis	ID/AST
Salmonella enterica ssp. enterica sv Gallinarum bv Gallinarum	ID/AST
Salmonella enterica ssp. enterica sv Gallinarum bv Pullorum	ID/AST
Salmonella enterica ssp. enterica sv Paratyphi A	ID/AST
Salmonella enterica ssp. enterica sv Typhi	ID/AST
Salmonella species	ID/AST
Serratia ficaria	ID/AST
Serratia fonticola	ID/AST
Serratia liquefaciens	ID/AST
Serratia marcescens	ID/AST
Serratia odorifera 1	ID/AST
Serratia odorifera 2	ID/AST
Serratia plymuthica	ID/AST
Serratia rubidaea	ID/AST
Shewanella putrefaciens	ID/AST
Shigella boydii	ID/AST
Shigella dysenteriae	ID/AST
Shigella flexneri	ID/AST

GRAM NEGATIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Shigella sonnei	ID/AST
Sphingobacterium multivorum	ID/AST
Sphingobacterium spiritivorum	ID/AST
Sphingobacterium thalpophilum	ID/AST
Sphingomonas paucimobilis	ID/AST
Stenotrophomonas maltophilia	ID/AST
Suttonella indologenes	ID
Tatumella ptyseos	ID
Vibrio alginolyticus	ID
Vibrio cholerae	ID
Vibrio fluvialis	ID
Vibrio metschnikovii	ID
Vibrio mimicus	ID
Vibrio parahaemolyticus	ID
Vibrio vulnificus	ID
Weeksella virosa	ID
Yersinia enterocolitica	ID/AST
Yersinia frederiksenii	ID/AST
Yersinia intermedia	ID/AST
Yersinia kristensenii	ID/AST
Yersinia pseudotuberculosis	ID/AST
Yersinia ruckeri	ID/AST
Yokenella regensburgei	ID

<sup>\*</sup> Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (see Section 2.3.3 Custom Interpretation Rule Set). 

<sup>1</sup>Not all species encountered during clinical performance evaluations.

# 9.3.3 Gram Positive (0.5 McFarland)

GRAM POSITIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Aerococcus urinae	ID
Aerococcus viridans	ID
Alloiococcus otitis	ID
Arcanobacterium haemolyticum	ID
Bacillus cereus	ID
Bacillus circulans	ID
Bacillus coagulans	ID
Bacillus licheniformis	ID
Bacillus megaterium	ID
Bacillus pumilus	ID
Bacillus subtilis	ID
Bacillus thuringiensis	ID
Brevibacillus brevis	ID
Brevibacterium species	ID
Cellulomonas turbata	ID
Cellulosimicrobium cellulans	ID
Corynebacterium amycolatum	ID
Corynebacterium amycolatum/minutissimum	ID
Corynebacterium amycolatum/striatum	ID
Corynebacterium bovis	ID
Corynebacterium diphtheriae	ID
Corynebacterium jeikeium	ID
Corynebacterium kutscheri	ID
Corynebacterium matruchotii	ID
Corynebacterium minutissimum	ID
Corynebacterium propinquum	ID
Corynebacterium pseudodiphtheriticum	ID
Corynebacterium pseudotuberculosis	ID

GRAM POSITIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Corynebacterium renale	ID
Corynebacterium striatum	ID
Corynebacterium ulcerans	ID
Corynebacterium urealyticum	ID
Corynebacterium xerosis	ID
Dermabacter hominis	ID
Dermacoccus nishinomiyaensis	ID
Enterococcus asini	AST
Enterococcus avium	ID/AST
Enterococcus casseliflavus	ID/AST
Enterococcus casseliflavus/gallinarum	ID/AST
Enterococcus cecorum	AST
Enterococcus columbae	AST
Enterococcus dispar	AST
Enterococcus durans	ID/AST
Enterococcus durans/faecium	AST
Enterococcus faecalis	ID/AST
Enterococcus faecalis/faecium	AST
Enterococcus faecium	ID/AST
Enterococcus flavescens	AST
Enterococcus gallinarum	ID/AST
Enterococcus gilvus	AST
Enterococcus haemoperoxidus	AST
Enterococcus hirae	ID/AST
Enterococcus hirae/faecium	AST
Enterococcus malodoratus	AST
Enterococcus moraviensis	AST
Enterococcus mundtii	AST
Enterococcus pallens	AST

GRAM POSITIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Enterococcus pseudoavium	AST
Enterococcus raffinosus	ID/AST
Enterococcus raffinosus/avium	AST
Enterococcus ratti	AST
Enterococcus saccharolyticus	AST
Enterococcus species	AST
Enterococcus sulfureus	AST
Erysipelothrix rhusiopathiae	ID
Gardnerella vaginalis	ID
Gemella haemolysans	ID
Gemella morbillorum	ID
Globicatella sanguinis	ID
Helcococcus kunzii	ID
Kocuria kristinae	ID
Kocuria rosea	ID
Kocuria varians	ID
Kytococcus sedentarius	ID
Lactobacillus dextrinicus	ID
Lactococcus garvieae	ID
Lactococcus lactis ssp. cremoris	ID
Lactococcus lactis ssp. hordniae	ID
Lactococcus lactis ssp. lactis	ID
Lactococcus plantarum	ID
Lactococcus raffinolactis	ID
Leifsonia aquatica	ID
Leuconostoc citreum	ID
Leuconostoc lactis	ID
Leuconostoc mesenteroides ssp. cremoris	ID
Leuconostoc mesenteroides ssp. mesenteroides	ID

GRAM POSITIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Leuconostoc pseudomesenteroides	ID
Listeria grayi	ID
Listeria innocua	ID
Listeria ivanovii	ID
Listeria monocytogenes	ID
Listeria monocytogenes/innocua	ID
Listeria welshimeri	ID
Lysinibacillus sphaericus	ID
Macrococcus caseolyticus	ID
Micrococcus luteus	ID
Micrococcus lylae	ID
Paenibacillus alvei	ID
Paenibacillus macerans	ID
Pediococcus acidilactici	ID
Pediococcus damnosus	ID
Pediococcus parvulus	ID
Pediococcus pentosaceus	ID
Rhodococcus equi	ID
Rothia dentocariosa	ID
Rothia mucilaginosa	ID
Staphylococcus argenteus	AST
Staphylococcus arlettae	AST
Staphylococcus aureus	ID/AST
Staphylococcus aureus ssp. anaerobius	AST
Staphylococcus aureus ssp. aureus	AST
Staphylococcus auricularis	ID/AST
Staphylococcus capitis	ID/AST
Staphylococcus capitis ssp. capitis	ID/AST
Staphylococcus capitis ssp. urealyticus	ID/AST

GRAM POSITIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Staphylococcus caprae	ID/AST
Staphylococcus carnosus	ID/AST
Staphylococcus carnosus ssp. carnosus	AST
Staphylococcus carnosus ssp. utilis	AST
Staphylococcus chromogenes	ID/AST
Staphylococcus chromogenes/hyicus	ID/AST
Staphylococcus coagulase-negative	AST
Staphylococcus coagulase-positive	AST
Staphylococcus cohnii	ID/AST
Staphylococcus cohnii ssp. cohnii	ID/AST
Staphylococcus cohnii ssp. urealyticum	ID/AST
Staphylococcus condimenti	AST
Staphylococcus delphini	AST
Staphylococcus epidermidis	ID/AST
Staphylococcus equorum	ID/AST
Staphylococcus felis	ID/AST
Staphylococcus fleurettii	AST
Staphylococcus gallinarum	ID/AST
Staphylococcus haemolyticus	ID/AST
Staphylococcus haemolyticus/lugdunensis	ID
Staphylococcus hominis	ID/AST
Staphylococcus hominis ssp. hominis	AST
Staphylococcus hominis ssp. novobiosepticus	AST
Staphylococcus hyicus	ID/AST
Staphylococcus intermedius	ID/AST
Staphylococcus kloosii	ID/AST
Staphylococcus lentus	ID/AST
Staphylococcus lugdunensis	ID/AST
Staphylococcus lutrae	AST

GRAM POSITIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Staphylococcus muscae	AST
Staphylococcus pasteuri	ID/AST
Staphylococcus petrasii	AST
Staphylococcus pettenkoferi	ID/AST
Staphylococcus piscifermentans	AST
Staphylococcus pseudintermedius	AST
Staphylococcus pulvereri	AST
Staphylococcus saccharolyticus	AST
Staphylococcus saprophyticus	ID/AST
Staphylococcus saprophyticus ssp. bovis	AST
Staphylococcus saprophyticus ssp. saprophyticus	AST
Staphylococcus schleiferi	ID/AST
Staphylococcus schleiferi ssp. coagulans	ID/AST
Staphylococcus schleiferi ssp. schleiferi	ID/AST
Staphylococcus sciuri	ID/AST
Staphylococcus sciuri ssp. carnaticus	AST
Staphylococcus sciuri ssp. rodentium	AST
Staphylococcus sciuri ssp. sciuri	AST
Staphylococcus simulans	ID/AST
Staphylococcus species	AST
Staphylococcus succinus	AST
Staphylococcus succinus ssp. casei	AST
Staphylococcus succinus ssp. succinus	AST
Staphylococcus vitulinus	ID/AST
Staphylococcus warneri	ID/AST
Staphylococcus warneri/pasteuri	AST
Staphylococcus xylosus	ID/AST
Streptococcus acidominimus	ID
Streptococcus agalactiae (Strep. group B)	ID

GRAM POSITIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Streptococcus anginosus	ID
Streptococcus canis	ID
Streptococcus constellatus	ID
Streptococcus cristatus	ID
Streptococcus dysgalactiae ssp. dysgalactiae	ID
Streptococcus dysgalactiae ssp. equisimilis	ID
Streptococcus equi	ID
Streptococcus equi ssp. equi	ID
Streptococcus equi ssp. zooepidemicus	ID
Streptococcus equinus	ID
Streptococcus gallolyticus ssp. gallolyticus	ID
Streptococcus gallolyticus ssp. pasteurianus/ infantarius	ID
Streptococcus gallolyticus/infantarius	ID
Streptococcus gordonii	ID
Streptococcus group C/G (large colony)	ID
Streptococcus intermedius	ID
Streptococcus mitis	ID
Streptococcus mitis/pneumoniae	ID
Streptococcus mutans	ID
Streptococcus oralis	ID
Streptococcus parasanguinis	ID
Streptococcus pneumoniae	ID
Streptococcus porcinus	ID
Streptococcus pyogenes (Strep. group A)	ID
Streptococcus salivarius	ID
Streptococcus sanguinis	ID
Streptococcus sobrinus	ID
Streptococcus uberis	ID

GRAM POSITIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Streptococcus vestibularis	ID
Trueperella pyogenes	ID

Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (see Section 2.3.3 Custom Interpretation Rule Set).

<sup>1</sup>Not all species encountered during clinical performance evaluations.

### 9.3.4 Gram Positive (0.25 McFarland)

GRAM POSITIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Aerococcus urinae	ID
Aerococcus viridans	ID
Alloiococcus otitis	ID
Dermacoccus nishinomiyaensis	ID
Enterococcus avium	ID/AST
Enterococcus casseliflavus	ID/AST
Enterococcus durans	ID/AST
Enterococcus faecalis	ID/AST
Enterococcus faecium	ID/AST
Enterococcus gallinarum	ID/AST
Enterococcus hirae	ID/AST
Enterococcus raffinosus	ID/AST
Gemella haemolysans	ID
Gemella morbillorum	ID
Globicatella sanguinis	ID
Helcococcus kunzii	ID
Kocuria kristinae	ID
Kocuria rosea	ID
Kocuria varians	ID
Kytococcus sedentarius	ID
Lactobacillus dextrinicus	ID

GRAM POSITIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Lactococcus lactis ssp. cremoris	ID
Lactococcus lactis ssp. hordniae	ID
Lactococcus plantarum	ID
Leuconostoc citreum	ID
Leuconostoc lactis	ID
Leuconostoc mesenteroides ssp. mesenteroides	ID
Listeria innocua	ID
Listeria monocytogenes	ID
Macrococcus caseolyticus	ID
Micrococcus luteus	ID
Micrococcus lylae	ID
Pediococcus acidilactici	ID
Pediococcus damnosus	ID
Pediococcus parvulus	ID
Pediococcus pentosaceus	ID
Rothia mucilaginosa	ID
Staphylococcus aureus	ID/AST
Staphylococcus auricularis	ID/AST
Staphylococcus capitis	ID/AST
Staphylococcus caprae	ID/AST
Staphylococcus carnosus	ID/AST
Staphylococcus chromogenes	ID/AST
Staphylococcus cohnii ssp. cohnii	ID/AST
Staphylococcus cohnii ssp. urealyticum	ID/AST
Staphylococcus epidermidis	ID/AST
Staphylococcus equorum	ID/AST
Staphylococcus felis	ID/AST
Staphylococcus gallinarum	ID/AST
Staphylococcus haemolyticus	ID/AST

GRAM POSITIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Staphylococcus hominis	ID/AST
Staphylococcus hyicus	ID/AST
Staphylococcus intermedius	ID/AST
Staphylococcus kloosii	ID/AST
Staphylococcus lentus	ID/AST
Staphylococcus lugdunensis	ID/AST
Staphylococcus pasteuri	ID/AST
Staphylococcus saprophyticus	ID/AST
Staphylococcus schleiferi ssp. coagulans	ID/AST
Staphylococcus schleiferi ssp. schleiferi	ID/AST
Staphylococcus sciuri	ID/AST
Staphylococcus simulans	ID/AST
Staphylococcus vitulinus	ID/AST
Staphylococcus warneri	ID/AST
Staphylococcus xylosus	ID/AST
Streptococcus agalactiae (Strep. group B)	ID
Streptococcus anginosus	ID
Streptococcus constellatus	ID
Streptococcus cristatus	ID
Streptococcus equi	ID
Streptococcus gallolyticus ssp. gallolyticus	ID
Streptococcus gallolyticus ssp. pasteurianus/ infantarius	ID
Streptococcus gallolyticus/infantarius	ID
Streptococcus gordonii	ID
Streptococcus group C/G (large colony)	ID
Streptococcus intermedius	ID
Streptococcus mitis	ID
Streptococcus mutans	ID

GRAM POSITIVE TAXA <sup>1</sup>	ID, AST, ID/AST*
Streptococcus oralis	ID
Streptococcus parasanguinis	ID
Streptococcus pneumoniae	ID
Streptococcus porcinus	ID
Streptococcus pyogenes (Strep. group A)	ID
Streptococcus salivarius	ID
Streptococcus sanguinis	ID
Streptococcus sobrinus	ID
Streptococcus uberis	ID
Streptococcus vestibularis	ID

<sup>\*</sup>Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (see Section 2.3.3 Custom Interpretation Rule Set).

#### 9.3.5 Streptococci

STREPTOCOCCI TAXA <sup>1</sup>	ID, AST, ID/AST*
Streptococcus acidominimus	ID/AST
Streptococcus agalactiae (Strep. group B)	ID/AST
Streptococcus alactolyticus	AST
Streptococcus alpha-hemolytic	AST
Streptococcus anginosus	ID/AST
Streptococcus anginosus (previously milleri) group	ID/AST
Streptococcus australis	AST
Streptococcus beta-hemolytic ACG (large colony)	AST
Streptococcus canis	ID/AST
Streptococcus constellatus	ID/AST
Streptococcus constellatus ssp. constellatus	AST
Streptococcus constellatus ssp. pharyngis	AST
Streptococcus criceti	AST

<sup>&</sup>lt;sup>1</sup>Not all species encountered during clinical performance evaluations.

STREPTOCOCCI TAXA <sup>1</sup>	ID, AST, ID/AST*
Streptococcus cristatus	ID/AST
Streptococcus downei	AST
Streptococcus dysgalactiae	AST
Streptococcus dysgalactiae ssp. dysgalactiae	ID/AST
Streptococcus dysgalactiae ssp. equisimilis	ID/AST
Streptococcus dysgalactiae/canis	ID/AST
Streptococcus equi	ID/AST
Streptococcus equi ssp. equi	ID/AST
Streptococcus equi ssp. zooepidemicus	ID/AST
Streptococcus equinus	ID/AST
Streptococcus ferus	AST
Streptococcus gallolyticus	AST
Streptococcus gallolyticus ssp. gallolyticus	ID/AST
Streptococcus gallolyticus ssp. macedonicus	AST
Streptococcus gallolyticus ssp. pasteurianus	AST
Streptococcus gallolyticus ssp. pasteurianus/ infantarius	ID/AST
Streptococcus gallolyticus/infantarius	AST
Streptococcus gordonii	ID/AST
Streptococcus group A (small colony)	AST
Streptococcus group A (Strep. pyogenes)	AST
Streptococcus group B (Strep. agalactiae)	AST
Streptococcus group C (large colony)	AST
Streptococcus group C (small colony)	AST
Streptococcus group C/G (large colony)	ID/AST
Streptococcus group C/G (small colony)	AST
Streptococcus group CFG (small colony)	AST
Streptococcus group D (non-enterococcus)	AST
Streptococcus group E	AST

STREPTOCOCCI TAXA <sup>1</sup>	ID, AST, ID/AST*
Streptococcus group F	AST
Streptococcus group G (large colony)	AST
Streptococcus group G (small colony)	AST
Streptococcus group L	AST
Streptococcus hyointestinalis	AST
Streptococcus infantarius	AST
Streptococcus infantarius ssp. coli	AST
Streptococcus infantarius ssp. infantarius	AST
Streptococcus infantis	AST
Streptococcus iniae	AST
Streptococcus intermedius	ID/AST
Streptococcus lutetiensis	AST
Streptococcus massiliensis	AST
Streptococcus milleri group	AST
Streptococcus minor	AST
Streptococcus mitis	ID/AST
Streptococcus mitis group	ID/AST
Streptococcus mitis/oralis	AST
Streptococcus mitis/pneumoniae	ID/AST
Streptococcus mutans	ID/AST
Streptococcus mutans group	AST
Streptococcus oralis	ID/AST
Streptococcus parasanguinis	ID/AST
Streptococcus peroris	AST
Streptococcus pneumoniae	ID/AST
Streptococcus porcinus	ID/AST
Streptococcus pseudopneumoniae	AST
Streptococcus pseudoporcinus	AST
Streptococcus pyogenes (Strep. group A)	ID/AST

STREPTOCOCCI TAXA <sup>1</sup>	ID, AST, ID/AST*
Streptococcus ratti	AST
Streptococcus salivarius	ID/AST
Streptococcus salivarius group	AST
Streptococcus salivarius ssp. thermophilus	AST
Streptococcus sanguinis	ID/AST
Streptococcus sanguinis group	AST
Streptococcus sinensis	AST
Streptococcus sobrinus	ID/AST
Streptococcus species	AST
Streptococcus suis	AST
Streptococcus uberis	ID/AST
Streptococcus urinalis	AST
Streptococcus vestibularis	ID/AST
Streptococcus viridans beta-hemolytic (small colony)	AST
Streptococcus viridans group	AST

<sup>\*</sup> Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (see Section 2.3.3 Custom Interpretation Rule Set). 

1Not all species encountered during clinical performance evaluations.

### 9.3.6 Yeast

YEAST TAXA <sup>2</sup>	SABDX SABEM SABHI	CHOC COLSB TSASB
Candida albicans	<b>V</b>	√
Candida apicola	1	√
Candida boidinii	<b>√</b>	_
Candida bracarensis	V	_
Candida catenulata	$\checkmark$	$\checkmark$
Candida ciferrii	1	$\checkmark$
Candida dubliniensis	V	√
Candida firmetaria	V	$\checkmark$
Candida freyschussii	1	$\checkmark$
Candida glabrata	$\checkmark$	$\checkmark$
Candida guilliermondii	1	√
Candida guilliermondii var membranaefaciens	<b>√</b>	V
Candida haemulonii/auris	<b>√</b>	√
Candida inconspicua	1	√
Candida kefyr	1	√
Candida krusei	1	√
Candida lipolytica	1	√
Candida lusitaniae	1	√
Candida magnoliae	1	√
Candida melibiosica	1	√
Candida membranifaciens	1	√
Candida norvegensis	<b>√</b>	√
Candida parapsilosis complex	<b>√</b>	√
Candida pararugosa	<b>√</b>	√
Candida pelliculosa	<b>√</b>	√
Candida pulcherrima	<b>√</b>	√

YEAST TAXA <sup>2</sup>	SABDX SABEM SABHI	CHOC COLSB TSASB
Candida rugosa	√	√
Candida sake	√	√
Candida sphaerica	√	_
Candida tropicalis	√	√
Candida utilis	√	√
Candida viswanathii	√	√
Candida zeylanoides	√	√
Cryptococcus albidus	√	√
Cryptococcus humicola	√	√
Cryptococcus laurentii	√	_
Cryptococcus luteolus	√	√
Cryptococcus neoformans	√1	√
Cryptococcus terreus	√	_
Cryptococcus uniguttulatus	√	√
Exophiala dermatitidis	√	√
Exophiala species	√	√
Geotrichum species	√	√
Hortaea werneckii	√	√
Hyphopichia burtonii	√	√
Kloeckera species	√	_
Magnusiomyces capitatus	√	√
Malassezia furfur complex	√	_
Malassezia pachydermatis	√	_
Malassezia sympodialis	V	_
Millerozyma farinosa	√	√
Prototheca wickerhamii	V	V
Prototheca zopfii	V	√
Rhodotorula glutinis	√	√

YEAST TAXA <sup>2</sup>	SABDX SABEM SABHI	CHOC COLSB TSASB
Rhodotorula minuta	√	<b>√</b>
Rhodotorula mucilaginosa var mucilaginosa	√	√
Saccharomyces cerevisiae	√	√
Sporobolomyces salmonicolor	√	<b>√</b>
Trichosporon asahii	√	<b>√</b>
Trichosporon inkin	√	_
Trichosporon loubieri	√	_
Trichosporon mucoides	√	<b>√</b>
Trichosporon ovoides	√	_
Zygosaccharomyces bailii	√	_

<sup>1</sup>With an ID result of *Cryptococcus neoformans* and a substrate profile that may be indicative of *C. gattii*, the following message will print: The instrument produced an ID result of *Cryptococcus neoformans* with a profile that may be indicative of *C. gattii*. Recommend testing to rule out *C. gattii*.

<sup>2</sup>Not all species encountered during clinical performance evaluations.

## 10 – Limited Warranty

This warranty details specific legal rights. Additionally, there may be other rights that vary from region to region.

The BD Phoenix 100 Automated Microbiology System is warranted to the original purchaser to be free from defects in materials and workmanship for a period of one year following installation. BD's sole responsibility under this warranty shall be to repair or replace any instrument or its components (except for expendable supplies such as printer cartridges, paper, or filters) which under normal operating conditions, prove to be defective within one year of delivery.

BD will furnish new or remanufactured components upon its option. All replacements shall meet new part specifications and shall be warranted as above for the remainder of the one year period. Replaced components become the property of BD.

It is understood that the equipment covered by this Agreement has been installed in accordance with the recommendations and instructions in the *BD Phoenix System User's Manual*.

Any damage to a BD Phoenix system resulting from the insertion or removal of cables that connect this instrument to systems other than those approved or supplied by BD or the failure of the owner to maintain reasonable care and precautions in the operation and maintenance of the system will void this warranty and terminate the obligations of the manufacturer as stated herein.

This warranty is in lieu of all other warranties, whether express or implied, including but not limited to, warranties of merchantability, or fitness for a particular use. In no event will BD be liable for indirect, incidental, special or consequential damages regardless of whether BD has been advised of such.

BD Phoenix Automated Microbiology System User's Manual	

# 11 - Replacement Parts

The following items may be ordered by contacting a local BD representative at the numbers in Section 13 – International Contacts.

Catalog Number	Items
246001	BD Phoenix™ ID Broth
246003	BD Phoenix™ AST Broth
246004	BD Phoenix™ AST Indicator Solution
246005	BD Phoenix <sup>™</sup> Inoculum Broth
246007	BD Phoenix™ AST-S Broth
246009	BD Phoenix™ AST-S Indicator Solution
440503	Barcode Scanner (external)
445401	Cable, Printer
445847	Floppy Disks, High Density, Formatted (10)
445878	Uninterruptible Power Supply (UPS), Japan (1.3 kVA)
445879	Uninterruptible Power Supply (UPS), Europe (1.3 kVA)
445880	Uninterruptible Power Supply (UPS), North America (1.3 kVA)
445882	Printer, Laser
445884	Cable, Ethernet

Catalog Number	Items
445886	Cartridge, Laser Printer
447101	Filter, Air, Source Bay
447103	Filter, Air, Electronics Bay, Incubator
448021	BD Phoenix <sup>™</sup> System User's Manual (ea.)
448984	Temperature Standard Panel

# 12 – Software Update Log

Whenever you receive a software update, please take a moment to log it below. This can assist you and BD personnel in identifying software revision levels, potential software problems, etc.

Date Received	Software Version	Date Installed	Installed By	Notes

BD Phoenix Automated Microbiology Sys	stem User's Manual	

## 13 - International Contacts

BD

7 Loveton Circle

Sparks, Maryland 21152 USA

Voice: (410) 316-4000 • Fax: (410) 527-0244 Toll-Free: Technical Services: 1.800.638.8663

Customer Service: 1.800.675.0908

bd.com

2100 Derry Road West Suite 100

Mississauga, Ontario Canada L5N 0B3 Voice: 866-979-9408

Fax: 800-565-0897

Monte Pelvoux 111 • 9th Floor Col. Lomas de Chapultepec

11000 Mexico D.F.

Voice: 52 5 237 1200 • Fax: 52 5 237 1287

11 Rue Aristide Bergès BP4 38800 Le Pont de Claix France

Voice: 33 476 68 36 36 • Fax: 33 476 68 34 95

Akasaka DS Building 5-26 Akasaka 8-chome Minato-ku, Tokyo 107-0052

Voice: (81) 3 54138181 • Fax (81) 3 54138144

30 Tuas Avenue 2 Singapore 639461

Voice: (65) 8610633 • Fax: (65) 8601590

Rua Alexandre Dumas 1976 04717-004 Sao Paulo, S.P. Brazil

Voice: (55) 11 5459833 • Fax: (55) 11 2478644

Australian Sponsor: Becton Dickinson Pty Ltd. 66 Waterloo Road Macquarie Park NSW 2113 Australia

New Zealand Sponsor: **Becton Dickinson Limited** 14B George Bourke Drive Mt. Wellington Auckland 1060 New Zealand

Report any serious incident that has occurred in relation to the device to your BD Representative (or Manufacturer) and EU National Competent Authority. For incidents occurring outside of the EU, contact your BD Representative.

Ωi	bd.com/e-labeling	
	GR	00 800 161 220 577 99
	HR	+800 135 79 135
	IS	800 8996
	LT	880 030 728
	RO	0800 895 084
	SK	0800 606 287
	TR	00800 142 064 866
	LI	+31 20 796 5692
	MT	+31 20 796 5693
	Non-EU:	+31 20 794 7071
	CA	+1 855 805 8539
	AR, CO, UY, AU, NZ, RU	+800 135 79 135
	BR	0800 5911 055

# 14 – Bibliography

- 1. Bronfenbrenner, J., and M.J. Schlesginer. 1918. A rapid method for the identification of bacteria fermenting carbohydrates. *Am. J. Public. Health*. 8:922-923.
- 2. Arnold, W.M., Jr., and R.H. Weaver. 1948. Quick microtechniques for the identification of cultures. I. Indole production. *J. Lab. Clin. Med.* 33:195-195.
- Bachmann, B., and R.H. Weaver. 1951. Rapid microtechniques for identification of cultures. V. Reduction of nitrates. Am. J. Clin. Pathol. 21:195-196.
- 4. Hannan, J., and R.H. Weaver. 1949. Quick microtechniques for the identification of cultures II. Germentations. *J. Lab. Clin. Med.* 33:1338-1341.
- 5. Hartman, P.A. 1968. Miniaturized microbiological methods. Academic Press, New York.
- 6. Sanders, A.C., J.E. Faber, and T.M. Cook. 1957. A rapid method for the characterization of enteric pathogen using paper discs. *Appl. Microbiol.* 5:36-40.
- 7. Snyder, M.L. 1954. Paper discs containing entire culture medium for the differentiation of bacteria. *Pathol. Bacteriol.* 67:217-226.
- 8. Soto, O.B. 1949. Fermentation reactions with dried paper discs containing carbohydrate and indicator. *Puerto Rican J. Publ. Hlth. Trop. Med.* 25:96-100.
- 9. Weaver. R.H. 1954. Quicker bacteriological results. Am. J. Med. Technol. 20:14-26.
- 10. Kampfer, P., O. Rauhoff, And W. Dott. 1991. Glycosidase profiles of members of the family *Enterobacterales. J. Clin. Microbiol.* 29:2877-2879.
- 11. Manafi, M., W. Kneifel, and S. Bascomb. 1991. Fluorogenic and chromogenic substrates used in bacterial diagnostics. Microbiol. Rev. 55:335-348.
- 12. Rammelkamp, C.H., and T. Maxon. 1942. Resistance of *Staphylococcus aureus* to the action of penicillin. *Proc. Soc. Biol. And Med.* 51:386-389.
- 13. Marymont, J.H. and R.M. Wentz. 1966. Serial dilution antibiotic sensitivity testing with the microtitrator system. *Am. J. Clin. Pathol.* 45:548-551.
- 14. Gavan, R.L., and M.A. Town. 1970. A microdilution method for antibiotic susceptibility testing: an evaluation. *Am. J. Clin. Pathol.* 53:880-885.

- 15. Lancaster, M.V. and D. Rebecca. 1996. Antibiotic and cytotoxic drug susceptibility assays using resazurin and poising agents. US Patent #5,501,959.
- 16. Data on file at Becton, Dickinson and Company.
- 17. Jorgensen, James H., et al. ed., *Manual of Clinical Microbiology*, 11th Edition, ASM Press, Washington, D.C., 2015.
- 18. DM Livermore. 1995. Beta-Lactamases in laboratory and clinical resistance. Clin. Microbiol. Rev. 8: 557-584.
- 19. K Bush, GA Jacoby, and AA Medeiros. 1995. A functional classification scheme for beta-lactamases and its correlation with molecular structure. Antimicrob. Agents Chemother. 39: 1211-1233.
- 20. GA Jacoby and P Han. 1996. Detection of extended-spectrum beta-lactamases in clinical isolates of *Klebsiella pneumoniae* and *Escherichia coli*. J. Clin. Microbiol. 34: 908-911.
- 21. Kenneth S. Thomson, Christine C. Sanders, and Ellen Smith Moland. 1999. Use of Microdilution Panels with and without -Lactamase Inhibitors as a Phenotypic Test for-Lactamase Production among *Escherichia coli*, *Klebsiella* spp., *Enterobacter* spp., *Citrobacter freundii*, and *Serratia marcescens*. Antimicrob. Agents Chemother. 43: 1393-1400.
- 22. CLSI. M100-S26 Performance Standards for Antimicrobial Susceptibility Testing; Twenty-sixth Informational Supplement. January 2016.
- 23. CLSI. M07-A10 Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard Tenth Edition. January 2015.
- Livermore, D.M., T.G. Winstanley, and K.P. Shannon. 2001. Interpretative reading: recognizing the unusual and inferring resistance mechanisms from resistance phenotypes. J. Antimicrob. Chemother. 48, Suppl. S1, 87-102.
- Cauwelier, et al. "Evaluation of a disk diffusion method with cefoxitin (30 mcg) for detection of methicillin-resistant Staphylococcus aureus." Eur J. Clin. Microbiol Infect Dis. May 2004,23(5):389-392.
- 26. Barnett, J.A., Payne, R.W. and Yarrow, D., Yeasts: Characteristics and Identification, 3rd Edition, Cambridge University Press, Cambridge, U.K. 2000.
- 27. Larone, D. H., Medically Important Fungi, A Guide to Identification, 5th Edition, ASM Press, Washington, D.C. 2011.
- 28. de Hoog, G.S., Guarro, J., Gené, J. and Figueras, M.J., Atlas of Clinical Fungi, 4th Edition, Centraalbureau voor Schimmelcultures, Utrecht, the Netherlands/Universita Rovira I Virgili, Reus, Spain, 2014.
- 29. Djahmi, N., C. Dunyach-Remy, A. Pantel, M. Dekhil, A.Sotto, and J. Lavigne. 2014. Epidemology of Carbapenemase-Producing *Enterobacterales* and *Acinetobacter baumannii* in Mediterranean Countries. BioMed Research International. Article ID 305784, 11 pages.
- Liakopoulos, A., A. Mavroidi, E.A. Katsifas, A. Theodosiou, A.D. Karagouni, V. Miriagou and E. Petinaki. 2013. Carbapenemase-producing Pseudomonas aeruginosa from central Greece: molecular epidemiology and genetic analysis of class I integrons. BCM Infectious Diseases. 13: 505.
- 31. Maya, J.J., S.J. Ruiz, V.M. Blanco, E. Gotuzzo, M. Guzman-Blanco, J. Labarca, M. Salles, J.P. Quinn, and M.V. Villegas. 2013. Current Status of Carbapenemaseses in Latin America. Expert Rev Anti Infect Ther. 11(7): 657-667.
- 32. Naas, T., M. Levy, C. Hirschauer, H. Marchandin and P. Nordmann. 2005. Outbreak of Carbapenem-Resistant Acinetobacter baumannii Producing the carbapenemase OXA-23 in a Tertiary Care Hospital of Papeete, French Polynesia. Journal Clinical Microbiology. 43(9): 4826-4829.

## 15 – Event Log Messages

### 15.1 LIS Related Messages

The View Syslog function, accessible through the Maintenance Menu (see Section 6.2.4.13), enables you to see messages that the instrument writes to the Event Log. The messages are in the following format:

date time message type: message text

where date represents the day, month, and year in the format you have chosen

time represents the time in the format you have chosen

message type is one of the following:

LIS Interface Message

LIS Unsolicited Message

LIS Order Cancelled

LIS Query Assembly

LIS Receiving Query

LIS Configuration Change

message text is the actual text message that appears

Below is a list of the messages, along with a description of the message and any actions you may perform to correct the problem. These messages are grouped by the *message type* listed above.

#### LIS Interface Messages

LIS Interface Messages are library messages generated by the LIS manager. They are listed below in alphabetical order.

#### **Bad Frame Received From LIS**

- **DESCRIPTION** This error is generated when the LIS downloads a frame that has not been properly formatted. The error type is listed as LIS NON FATAL.
- **CORRECTIVE ACTION(S)** The solution to this problem is to review the information that is being sent to the instrument via a communications line monitor. Compare the information captured with the specifications found in the BD LIS Vendor Interface Document. Any discrepancies observed should be corrected and then the transmission should be attempted again.

#### **Detailed Download Message Attached To Notification**

- **DESCRIPTION** These notifications are generated whenever a complete message is sent or received across the port. The error types are LIS\_NOTIFY. The detailed description is not displayed.
- **CORRECTIVE ACTION(S)** Message is informational no action required.

#### **Detailed Upload Message Attached To Notification**

- **DESCRIPTION** These notifications are generated whenever a complete message is sent or received across the port. This provides the Host Application with the complete ASTM message string that was exchanged. The error types are LIS\_NOTIFY and the detailed descriptions contain the ASTM message string.
- **CORRECTIVE ACTION(S)** Message is informational no action required.

#### **Disallowed Characters Contained In Field**

- **DESCRIPTION** This error is generated when an upload field contains characters that are not allowed in an upload message. These characters differ based on logical protocol and will be stripped from the upload field. This error type is LIS\_NON\_FATAL. The detailed description is not displayed.
- **CORRECTIVE ACTION(S)** If this error is reported the problem should be reported to a local BD representative for further investigation.

#### **Download Field Was Concatenated**

- **DESCRIPTION** This notification is generated when a download field is larger than the maximum size set by the Host Application. The field will be concatenated to the maximum size. This error type is listed as LIS\_LOG. The detailed description is not displayed.
- **CORRECTIVE ACTION(S)** In this case the content that is being assembled needs to be reviewed. Review the BD Vendor Interface Specification for limitations on field lengths in the message. Then the LIS code should be updated so that the information sent to the instrument remains within the defined limits.

#### LIS Interface Messages (cont.)

#### Download Message Has A Bad Or Missing Header Record

- **DESCRIPTION** This error is generated when a download message does not have a properly formatted header record. The LIS IM cannot continue processing the message and it will be deleted. This error type is listed as LIS\_NON\_FATAL, and the detailed description holds the ASTM message received from the LIS.
- **CORRECTIVE ACTION(S)** Check the header line for errors. Correct the header error and resend the message.

#### **Download Physical Communication With LIS Has Begun**

**DESCRIPTION** – This notification is generated when the download thread in the physical layer is actively downloading a message.

**CORRECTIVE ACTION(S)** – Message is informational – no action required.

#### **Download Physical Communication With LIS Has Completed**

**DESCRIPTION** – This notification is generated when the download thread in the logical layer has completed processing a download message.

**CORRECTIVE ACTION(S)** – Message is informational – no action required.

#### **Download Record Is Out Of Sequence Or Has Bad Sequence Number**

- **DESCRIPTION** This error is generated when a download record contains records with a bad sequence number, or violates the record hierarchy for the logical level protocol. This will cause the message to be deleted from the download queue. This error type is listed as LIS NON FATAL.
- **CORRECTIVE ACTION(S)** Appropriate updates should be made to the application generating the logical message so the structure conforms to the ASTM specifications for the interface. Most questions concerning the message content can be addressed by referencing the BD Vendor Interface Specifications and the ASTM specifications for the interface.

#### **Early Termination Of Transfer Session By LIS**

- **DESCRIPTION** This error is generated when there is an error in LIS communication. The control character to end a transfer session was received before the appropriate number of characters for the frame were received.
- **CORRECTIVE ACTION(S)** Review the frames being exchanged between the instrument and the LIS to assure that the proper number of characters are contained within the packets that are being exchanged. If the correct number of characters is not in the packet, update the code so that the correct number of characters is included in each frame.

#### LIS Interface Messages (cont.)

#### **Expected Frame Not Sent**

- **DESCRIPTION** This error is generated when there is an error in LIS communication. The LIS initiated a transfer session but did not send any data before a time-out occurred. This error type is listed as LIS\_NON\_FATAL.
- CORRECTIVE ACTION(S) Connect a communications line monitor and restart the transmission. Observe the transmission to determine if the complete transmission occurs or if the transmission is interrupted early. If the transmission appears to be complete or the LIS appears to be attempting to send the transmission contact a local BD representative for assistance. If the transmission appears to be incomplete from the LIS side of the transmission then the LIS code should be investigated for problems that could terminate the transmission early.

#### **Internal Assert Condition Found In LIS Library**

- **DESCRIPTION** This message indicates that the Instrument has encountered an error that should not occur. This error will result in the instrument rebooting.
- **CORRECTIVE ACTION(S)** Contact a local BD representative. At the time the problem occurs the application writes data to the log file that indicates the nature of the Assert. The BD representative should instruct you on the appropriate procedure to collect the data for the condition.

#### LIS Debug Error

- **DESCRIPTION** This error is generated when there has been a problem internally to the instrument physical layer. This error may be triggered for an index out of bounds, or unsupported memory area IDs, etc. This error type is listed as LIS\_FATAL.
- **CORRECTIVE ACTION(S)** This error is a Fatal Error. If this error appears in the log file, contact a local BD representative. The sequence of events that produced this message should be documented so that BD representatives can reproduce the error and then provide an appropriate course of action to address the problem.

#### LIS Did Not Acknowledge Sent Frame

- **DESCRIPTION** This error is generated when the instrument has sent a frame to the LIS but has not received an acknowledgment before a time-out occurred. This error type is listed as LIS\_NON\_FATAL.
- **CORRECTIVE ACTION(S)** This message should not occur during normal operation of the instrument interface. If this error is being encountered during development of the interface then the LIS development group should connect a data communication monitor to the serial interface cable and review the information that is being exchanged between the two devices. It is likely that the LIS is not generating the appropriate response to the message that the instrument has sent.

#### **LIS Is Not Responding To Output Request**

- **DESCRIPTION** This error is generated when the instrument is trying to establish a transfer session but the LIS is not responding. When this error is sent, the instrument is assuming the LIS connection is broken or the LIS is down. This error type is listed as LIS\_NON\_FATAL.
- CORRECTIVE ACTION(S) Check to assure that the LIS interface is active and ready to receive messages from the instrument. If the LIS is operating correctly, connect a communications line monitor and review the information that has been captured. If the instrument is attempting to establish communications with the LIS, it would be appropriate to review the code that has been written to interface with the instrument and assure that the code is appropriate to receive the information sent by the instrument.

#### **LIS Never Completed Current Frame**

- **DESCRIPTION** This error is generated when there is an error in LIS communication. The control characters expected to end a transmitted frame were never received.
- **CORRECTIVE ACTION(S)** Review the frames being exchanged between the instrument and the LIS via line monitor. Be sure to review all frames included in the transmission. If any frames do not contain the appropriate termination characters make appropriate changes to the interface code to correct the problem.

### Logical Processing Of LIS Data Has Begun

**DESCRIPTION/CORRECTIVE ACTION(S)** – Message is informational – no action required.

## Logical Processing Of LIS Data Has Completed

**DESCRIPTION/CORRECTIVE ACTION(S)** – Message is informational – no action required.

#### Message Packet Passed To Host Application

- **DESCRIPTION** This notification is generated when the LIS IM has successfully passed a message on to the Host Application. This notification exists mostly as a debug message. This error type is listed as LIS\_LOG.
- **CORRECTIVE ACTION(S)** No action required by user. Information is included to help LIS manufacturers debug and implement their interface.

#### Message Received By LIS

- **DESCRIPTION** This notification is generated after the LIS has received and acknowledged a message from the instrument.
- **CORRECTIVE ACTION(S)** Message is informational no action required.

#### Message Received From LIS

**DESCRIPTION** – This notification is generated when a download message has been properly received by the Physical Interface from the LIS. This error type is listed as LIS\_LOG.

**CORRECTIVE ACTION(S)** – This message is an informational message and requires no action to be taken. The transmission was successful. This message will be generated even if the message contained content errors.

#### **Must Re-send Output Frame To LIS**

- **DESCRIPTION** This notification is generated when a frame sent by the LIS IM was not properly received by the LIS. The message frame will be resent, according to low level protocol specifications. This error type is listed as LIS\_LOG.
- **CORRECTIVE ACTION(S)** If this message appears infrequently and the messages that are being exchanged are completed correctly, it is likely that no action is required. If the message above is encountered frequently, there is likely a problem in the interface. The LIS manufacturer and BD representative should be contacted to diagnose the interface to assure that it is operating properly. When the link is operating optimally this message should not appear in the log.

#### **No Queue Memory For Download Messages**

**DESCRIPTION** – The BD Phoenix Instrument is designed to operate in a limited amount of memory (as defined in the configuration structure). When these memory resources are full with download or upload messages, this notification will be generated. The notification may be common if the LIS tries to download too much information at once. The BD Phoenix Instrument will NAK data for which it cannot allocate memory, and the LIS will have to resend the data.

CORRECTIVE ACTION(S) - Resend the messages that were rejected by the instrument.

#### **No Queue Memory For Upload Messages**

- **DESCRIPTION** The BD Phoenix Instrument is designed to operate in a limited amount of memory (as defined in the configuration structure). When these memory resources are full with download or upload messages, this notification will be generated. This message should not be encountered when using the instrument LIS interface.
- **CORRECTIVE ACTION(S)** If this message is encountered, the problem should be reported to the BD representative. It will be helpful if the process that generated the problem is documented.

#### LIS Interface Messages (cont.)

#### No Response Received From Previous LIS Request Message

- **DESCRIPTION** This notification is generated when the LIS IM has uploaded a query but no response is received. This notification indicates that the original query was cancelled. This notification should occur some time after the query, as determined by the value in the configuration structure. The error type is listed as LIS\_LOG. The detailed description is not displayed in the current version.
- **CORRECTIVE ACTION(S)** Validate that the LIS system is correctly connected to the instrument and that the LIS interface has been activated.

#### **Operating System Error**

- **DESCRIPTION** This error is generated when the operating system class encounters an error in one of its routines. This could be caused by a number of OS errors, including not properly initializing a port or not properly creating an event handle, and others. These errors should not occur under normal conditions and the LIS IM cannot recover from them. The error type is listed as LIS FATAL.
- **CORRECTIVE ACTION(S)** If this error is reported the problem should be reported to a local BD representative for further investigation.

#### **Output Message Was Sent To LIS**

- **DESCRIPTION** This notification is generated when an upload message has been successfully transmitted to the LIS. This error type is listed as LIS\_NOTIFY. Notification sent when the instrument begins sending a message to the LIS. Receiving this notification does not signify the message was accepted by the LIS.
- **CORRECTIVE ACTION(S)** Message is informational no action required.

#### **Queue Memory For Download Messages Free**

- **DESCRIPTION** This notification is used in pairs with the No Queue Memory For Download Messages above. When memory has previously been determined to be full, and now has been released, this notification will be generated.
- **CORRECTIVE ACTION(S)** This is an indication to a user of a batch-oriented interface that the instrument is capable of receiving the next group of messages.

#### **Queue Memory For Upload Messages Free**

- **DESCRIPTION** This notification is used in pairs with the No Queue Memory For Upload Messages above. When memory has previously been determined to be full, and now has been released, this notification will be generated.
- **CORRECTIVE ACTION(S)** This message should not appear in the log during operation of the interface. If this message appears in the log, contact a local BD representative.

#### LIS Interface Messages (cont.)

Response Message Received

**DESCRIPTION** – This notification is generated when the LIS has downloaded a response to a BD generated query. This is also an indication that the LIS IM can upload another query to the LIS. The error type is LIS\_NOTIFY. The detailed description is not displayed in the current version.

**CORRECTIVE ACTION(S)** – Message is informational – no action required.

#### **Unsupported Field In Configuration File**

**DESCRIPTION** – This error is generated during startup when a field in the configuration structure does not match one of the supported configurations of the LIS IM. This error type is listed as LIS FATAL.

**CORRECTIVE ACTION(S)** – If this error is reported the problem should be reported to a local BD representative for further investigation.

## **Upload Physical Communication With LIS Has Begun**

**DESCRIPTION** – This notification is generated when the upload thread in the physical layer is actively uploading a message.

**CORRECTIVE ACTION(S)** – Message is informational – no action required.

### Upload Physical Communication With LIS Has Completed

**DESCRIPTION** – This notification is generated when the upload thread in the physical layer has completed sending a message to the LIS.

**CORRECTIVE ACTION(S)** – Message is informational – no action required.

#### LIS Unsolicited Message

The following sections contain the possible messages associated with Event Log entries in response to unsolicited download requests. They are listed below in alphabetical order.

LIS Response Error

**DESCRIPTION** – This message is set after the LIS sends an incorrectly formatted query message to the instrument. We will respond by sending a response error message to the LIS.

**CORRECTIVE ACTION(S)** – If the interface is operating correctly, this message should not be present in the log. If this message is found in the log during validation or development of the interface, the code responsible for generating the queries should be reviewed and adjusted so that the query is assembled without the invalid field. The invalid field will be the last "LIS Query Assembly" message listed before this message in the log file.

### LIS Sent Query Before Previous Query Completed

**DESCRIPTION** – This message is set if the LIS initiates a query and while the instrument is busy with this query, the LIS cancels the first query and immediately starts another.

**CORRECTIVE ACTION(S)** – If the interface is operating correctly this message should not be present in the log. If this message is found in the log during validation or development of the interface, the code responsible for generating the queries should be reviewed and adjusted so that it will not send another query while it is waiting for an outstanding query to be canceled.

#### LIS Order Cancelled Messages

#### (Message consists of a field name shown below at \* and invalid field contents.)

**DESCRIPTION** – The validation for the noted field failed.

\*Invalid Sequence Number Field

Missing Accession Number Field

Invalid Accession Number Field [cannot be 12 digits and begin with 42 or 50 - 59; see Section 5 - Reference for other requirements]

Missing Isolate Field

Invalid Isolate Field

Invalid Panel Usage

Invalid Test ID Field

Invalid Test Strain for this QC Panel Type

Mismatch Sequence Number & Test ID

Missing Test ID Field

Invalid Organism ID Field

Invalid Priority Field

Problem Storing Record to Database

When an error is detected, the message for that error is logged and the remainder of the message checking is terminated. There could be other errors in the order that were not reported. The error checking priority depends upon whether the order contains a sequence number or not.

**CORRECTIVE ACTION(S)** – In an operational interface it is possible to encounter these errors if the LIS implementation allows entry of data into the fields that violate the Instrument field rules. In this case the user of the LIS should limit the characters entered into the fields sent to the instrument to those characters noted in the System User's Manual as valid for the field. Once the information has been updated to conform with the instrument's rules the order should be sent to the instrument again.

If the interface is under development the developer of the interface should limit the data being sent to the instrument to those characters that are appropriate for the fields.

#### LIS Query Assembly Messages

All of the following messages are written to the log file regardless of whether they are invalid or valid. They are placed in the log so that they can be used in conjunction with the messages that follow them. If an error is found in one of the fields, the contents of the field in error will be logged.

#### (Message consists of a field name shown below at \*\*.)

**DESCRIPTION** – The message is logged when the instrument uploads a query to the LIS.

\*\*Accession Number

Sequence Number

Test ID

**Test Status** 

**Result Qualifier** 

Time Qualifier

Start Date/Time

End Date/Time

**CORRECTIVE ACTION(S)** – If the query is valid, the message is informational – no action required. If the query is invalid, then review the field in error, correct, and resend the query.

#### (Message consists of a field name and value shown below at \*\*\*.)

**DESCRIPTION** – This message is logged when the instrument uploads a query to the LIS.

\*\*\*Sequence Number and the value

**CORRECTIVE ACTION(S)** – Message is informational – no action required.

#### LIS Configuration Change Messages

#### (Message consists of a configuration value shown below at \*\* with old and new values.)

**DESCRIPTION** – The message is logged when the LIS configuration is changed.

\*\*LIS Enabled Value Changed

Send Interpretation Results Option Changed

**Unsolicited Queries Option Changed** 

Send When Placed In Instrument Option Changed

Results Upload Options Changed

**Baud Value Changed** 

Data Bits Value Changed

Parity Value Changed

Stop Bits Value Changed

Packed Frames Value Changed

**CORRECTIVE ACTION(S)** – Message is informational – no action required.

# 16 - Glossary

The topics discussed in this section are:

- 16.1 Definitions
- 16.2 Organism Names and Abbreviations
- 16.3 Supplemental Id Test Abbreviations
- 16.4 Interpretation Codes

### **16.1 Definitions**

Term	Definition
absolute threshold	A positivity assessment made by determining if the normalized panel well reading is above (positive) or below (negative) a given fixed threshold.
AST	Antimicrobial Susceptibility Test(ing)
ATCC	American Type Culture Collection
barcode	Machine-readable marking as part of the panel label which uniquely identifies that panel. Contains the product coding and sequence number in Code-128 numeric format.
ВР	Blood plate
breakpoint	An interpretation of panel MIC data that which produces Susceptible, Intermediate, or Resistant result classifications. Breakpoints in the MIC data are established by the Clinical and Laboratory Standards Institute (CLSI) and other groups.
caddy	Accessory device used to transport inoculated panels to the instrument for loading.
carousel	The rotating drum which holds the 100 BD Phoenix panels and positions them for test readings, barcode readings, and loading or unloading.
CLSI	Clinical and Laboratory Standards Institute
CNA	Colistin Nalidixic Acid agar
Col (HRBC)	Columbia agar with Horse Blood
Col (SRBC)	Columbia agar with Sheep Blood
controller	An electronic module that includes a CPU, memory, and interface hardware to control the operation of the instrument.
database	The database is the repository of all information that the instrument collects for the panels that are tested by the instrument. The database is set up to maintain panel results information for the panels tested for 31 days (possibly longer depending on the number of QC panels tested). QC panel results are retained for at least 6 months. The database also maintains the user configurable information for the instrument.
demographic data	Accession information for a panel record
detector	The optical system that measures colorimetric and fluorometric intensities from the reagent reactions in the BD Phoenix panel wells.

Term	Definition
DIN	German Institute for Standardization
DTG	Drug Test Group
EMB	Eosin Methylene Blue agar
end-point results	Results based on well readings obtained after 16 hours of incubation. Microbiological events have reached terminal, or "end-point" values.
error station	Station that has sustained an optical or electro-mechanical error and has been blocked.
EUCAST	European Committee on Antimicrobial Susceptibility Testing
HE	Hektoen Enteric media agar
ID	Microbial Identification
ID/AST combination (combo) panel	The disposable device that contains all reagents needed for both ID and AST.
inoculation station	The inoculation station holds three BD Phoenix panels at the appropriate angle for optimal fill. The station also holds six broth tubes total, two per organism tested. One tube is for dilution of colony growth for Identification, the other for AST.
instrument test cycle	A complete test of all sample panels located in the carousel, resulting in color and/or fluorescence data values being recorded for each pertinent well of each panel.
MIC	Minimum Inhibitory Concentration; the lowest concentration of an antimicrobic which prohibits continued growth of the tested organism.
normalizer	A reference panel for use in the BD Phoenix instrument. The Normalizer panel contains a matrix of visible light absorber and fluorescent material in panel-well format, which is used to correct individual well signals for losses occurring in the optical system
orphan	A panel with a valid sequence number, but no associated accession number and isolate number.
panel carrier	The plastic carousel insert, which clips each BD Phoenix sample panel into place. The carousel contains 104 inserts, 26 in each of four tiers.
panel dataset	Each panel's set of color and fluorescence measurements, the panel's position identifier, test time stamps, and error flags are recorded for each test cycle throughout the test protocol. The test parameters determining each well's results are keyed by the individual barcode label signifying the panel type, and hence the type of test.

Term	Definition
PEA	Phenylethyl Alcohol agar
position	The station. The physical location of the BD Phoenix panel within the instrument. This identifier includes instrument number, carousel tier letter, and numeric position on that tier.
panel presence detection threshold	Each inventory scan or test cycle, the instrument "looks" for both the barcode label of a panel in each carousel position and panel well data, color or fluorescence. If either is detected the instrument declares a panel logically present in that location. A panel without a valid barcode to provide panel type information will not be processed, but will be flagged as a "Needs Attention" candidate.
BD Phoenix AST indicator	An oxidation-reduction indicator used to signify microbial metabolism in the BD Phoenix panels. The indicator changes from blue to pink as initial reduction occurs. Further reduction causes the indicator to change from pink to colorless.
"rapid" results	AST Result obtained within 16 hours of panel inoculation.
related panel	Panels with the same accession number and isolate number are related.
Resistance Marker	Condition that is triggered when specific results indicate antimicrobic resistance. The action of some BDXpert rules is to trigger Resistance Markers; other rules may be called as a result of a specific Resistance Marker being triggered.
RGB	Red, Green and Blue. A shorthand representation of the visible light sources / wavelength regions used to interrogate the BD Phoenix panel.
sample	A specimen contained in a BD Phoenix panel. In practice, this would be a processed and resuspended dilution of microbiological growth from primary isolation culture in either ID diluent or AST broth which is then poured into the test panel.
SFM	Société Française de Microbiologie
SIR	Susceptible, Intermediate, or Resistant; refers to breakpoint AST categories. See also Breakpoint.
standard panel	A special panel containing custom concentrations of various dyes and fluorogenic compounds or materials used to test instrument optical system performance, used internally for engineering, manufacturing and test purposes.

Term	Definition
station	The instrument carousel is divided vertically into four tiers (A, B, C, D), each of which holds 26 panels. With one location occupied by a Normalizer panel, 25 locations per tier can accommodate test panels. This means that test panels can populate 100 total locations. Each location is assigned a tier letter and a number to determine the location on the tier. Indicator LEDs located on each panel holder indicate station status (see Section 3 – Controls and Indicators).
sequence number	A count of the number of readings taken by the instrument for a given sample well in a particular test panel, initialized to zero at the time of panel entry.
TSA	BD Trypticase Soy Agar: USB Universal Serial Bus. A common interface that enables communication between devices.
USB	Universal Serial Bus: A common interface that enables communication between devices.
XLD	Xylose Lysine Deoxycholate agar

## **16.2 Organism Names and Abbreviations**

Long Name	Short Name	Abbreviation
Achromobacter denitrificans	Achr. denitrificans	ALCDEN
Achromobacter insolitus	Achr. insolitus	ACHRINS
Achromobacter mucicolens	Achr. mucicolens	ACHRMUC
Achromobacter piechaudii	Achr. piechaudii	ALCPIE
Achromobacter ruhlandii	Achr. ruhlandii	ACHRRUH
Achromobacter spanius	Achr. spanius	ACHRSPA
Achromobacter species	Achr. species	ACHRSPE
Achromobacter xylosoxidans	Achr. xylosoxidans	ALCXYL
Acinetobacter baumannii	Acinet. baumannii	ACINBAU
Acinetobacter baumannii/ calcoaceticus complex	Acinet. baumannii/calco. cplx	ACINBCX
Acinetobacter baumannii/ haemolyticus	Acinet. baumannii/ haemolyticus	ACINBAUHAE
Acinetobacter bereziniae	Acinet. bereziniae	ACINGSP10
Acinetobacter calcoaceticus	Acinet. calcoaceticus	ACINCAL
Acinetobacter guillouiae	Acinet. guillouiae	ACINGSP11
Acinetobacter haemolyticus	Acinet. haemolyticus	ACINHAE
Acinetobacter johnsonii	Acinet. johnsonii	ACINJOH
Acinetobacter junii	Acinet. junii	ACINJUN
Acinetobacter Iwoffii	Acinet. Iwoffii	ACINLWO
Acinetobacter Iwoffii/haemolyticus	Acinet. Iwoffii/haemol.	ACINLWOHAE
Acinetobacter nosocomialis	Acinet. nosocomialis	ACINNOS
Acinetobacter parvus	Acinet. parvus	ACINPAR
Acinetobacter pittii	Acinet. pittii	ACINPIT
Acinetobacter radioresistens	Acinet. radioresistens	ACINRAD
Acinetobacter schindleri	Acinet. schindleri	ACINSCH
Acinetobacter seifertii	Acinet. seifertii	ACINSEI
Acinetobacter species	Acinet. species	ACINSPE
Acinetobacter ursingii	Acinet. ursingii	ACINURS
Actinobacillus lignieresii	Actinob. lignieresii	ACTBLIG

Long Name	Short Name	Abbreviation
Actinobacillus suis	Actinob. suis	ACTBSUI
Actinobacillus ureae	Actinob. ureae	ACTBURE
Aerococcus species	Aeroc. species	AERCSPE
Aerococcus urinae	Aeroc. urinae	AERCURI
Aerococcus viridans	Aeroc. viridans	AERCVIR
Aeromonas allosaccharophila	Aerom. allosaccharophila	AERMALL
Aeromonas caviae	Aerom. caviae	AERMCAV
Aeromonas eucrenophila	Aerom. eucrenophila	AERMEUC
Aeromonas hydrophila	Aerom. hydrophila	AERMHYD
Aeromonas hydrophila group	Aerom. hydrophila gr.	AERMHYDGR
Aeromonas jandaei	Aerom. jandaei	AERMJAN
Aeromonas media	Aerom. media	AERMMED
Aeromonas salmonicida	Aerom. salmonicida	AERMSAL
Aeromonas salmonicida ssp. achromogenes	Aerom. salmonic. ssp. ach.	AERMSALA
Aeromonas salmonicida ssp. masoucida	Aerom. salmonic. ssp. mas.	AERMSALM
Aeromonas salmonicida ssp. pectinolytica	Aerom. salmonic. ssp. pec.	AERMSALPE
Aeromonas salmonicida ssp. salmonicida	Aerom. salmonic. ssp. sal.	AERMSALSA
Aeromonas salmonicida ssp. smithia	Aerom. salmonic. ssp. smit.	AERMSALSM
Aeromonas schubertii	Aerom. schubertii	AERMSCH
Aeromonas species	Aerom. species	AERMSPE
Aeromonas trota	Aerom. trota	AERMTRO
Aeromonas veronii bv sobria	Aerom. veronii bv sobria	AERMVERS
Aeromonas veronii bv veronii	Aerom. veronii bv veronii	AERMVERV
Alcaligenes faecalis	Alc. faecalis	ALCFAE
Alcaligenes faecalis ssp. faecalis	Alc. faecalis ssp. faecalis	ALCFAEF
Alcaligenes species	Alc. species	ALCSPE
Alloiococcus otitis	All. otitis	ALLOTI
Arcanobacterium haemolyticum	Arcan. haemolyticum	ARCAHAE

Long Name	Short Name	Abbreviation
Bacillus cereus	Baci. cereus	BACICER
Bacillus circulans	Baci. circulans	BACICIR
Bacillus coagulans	Baci. coagulans	BACICOA
Bacillus licheniformis	Baci. licheniformis	BACILIC
Bacillus megaterium	Baci. megaterium	BACIMEG
Bacillus pumilus	Baci. pumilus	BACIPUM
Bacillus subtilis	Baci. subtilis	BACISUB
Bacillus thuringiensis	Baci. thuringiensis	BACITHU
Bergeyella zoohelcum	Ber. zoohelcum	BERZOO
Bordetella bronchiseptica	Bord. bronchiseptica	BORBROS
Brevibacillus brevis	Brevs. brevis	BACIBRE
Brevibacterium species	Brevm. species	BREISPE
Brevundimonas diminuta	Brevu. diminuta	BREUDIM
Brevundimonas species	Brevu. species	BREUSPE
Brevundimonas vesicularis	Brevu. vesicularis	BREUVES
Burkholderia caryophylli	Burk. caryophylli	BURCAR
Burkholderia cepacia complex	Burk. cepacia complex	BURCEP
Burkholderia cepacia/Ralstonia pickettii	Burk. cepacia/Ral. pickettii	BURCEPRALPIC
Burkholderia diffusa	Burk. diffusa	BURDIF
Burkholderia gladioli	Burk. gladioli	BURGLA
Burkholderia glathei	Burk. glathei	BURGLT
Burkholderia graminis	Burk. graminis	BURGRA
Burkholderia latens	Burk. latens	BURLAT
Burkholderia metallica	Burk. metallica	BURMET
Burkholderia multivorans	Burk. multivorans	BURMUL
Burkholderia phenazinium	Burk. phenazinium	BURPHE
Burkholderia pyrrocinia	Burk. pyrrocinia	BURPYR
Burkholderia seminalis	Burk. seminalis	BURSEM
Burkholderia species	Burk. species	BURSPE
Burkholderia species/Ralstonia species	Burk. species/Ral. species	BURSPERALSPE

Long Name	Short Name	Abbreviation
Candida albicans	Can. albicans	CANALB
Candida apicola	Can. apicola	CANAPI
Candida boidinii	Can. boidinii	CANBOI
Candida bracarensis	Can. bracarensis	CANBRA
Candida catenulata	Can. catenulata	CANCAT
Candida ciferrii	Can. ciferrii	CANCIF
Candida dubliniensis	Can. dubliniensis	CANDUB
Candida firmetaria	Can. firmetaria	CANLAM
Candida freyschussii	Can. freyschussii	CANFRE
Candida glabrata	Can. glabrata	TORGLA
Candida guilliermondii	Can. guilliermondii	CANGUI
Candida guilliermondii var membranaefaciens	Can. guillier. var membranaef.	CANGUIM
Candida haemulonii/auris	Can. haemulonii/auris	CANHAEAUR
Candida inconspicua	Can. inconspicua	CANINC
Candida kefyr	Can. kefyr	CANKEF
Candida krusei	Can. krusei	CANKRU
Candida lipolytica	Can. lipolytica	CANLIP
Candida lusitaniae	Can. lusitaniae	CANLUS
Candida magnoliae	Can. magnoliae	CANMAG
Candida melibiosica	Can. melibiosica	CANMEL
Candida membranifaciens	Can. membranifaciens	CANMEM
Candida norvegensis	Can. norvegensis	CANNOR
Candida parapsilosis complex	Can. parapsilosis complex	CANPARPX
Candida pararugosa	Can. pararugosa	CANPARR
Candida pelliculosa	Can. pelliculosa	CANPEL
Candida pulcherrima	Can. pulcherrima	CANPUL
Candida rugosa	Can. rugosa	CANRUG
Candida sake	Can. sake	CANSAK
Candida sphaerica	Can. sphaerica	CANSPH
Candida tropicalis	Can. tropicalis	CANTRO

Long Name	Short Name	Abbreviation
Candida utilis	Can. utilis	CANUTI
Candida viswanathii	Can. viswanathii	CANVIS
Candida zeylanoides	Can. zeylanoides	CANZEY
Cardiobacterium hominis	Card. hominis	CARHOM
CDC group Vb-3	CDC Vb-3	CDCVb3
Cedecea davisae	Ced. davisae	CEDDAV
Cedecea lapagei	Ced. lapagei	CEDLAP
Cedecea neteri	Ced. neteri	CEDNET
Cedecea species	Ced. species	CEDSPE
Cedecea species 3	Ced. species 3	CEDSPE3
Cedecea species 5	Ced. species 5	CEDSPE5
Cellulomonas turbata	Cell. turbata	OERTUR
Cellulosimicrobium cellulans	Cellulo. cellulans	CLLCEL
Chromobacterium violaceum	Chrom. violaceum	CHROVIO
Chryseobacterium gleum	Chryseob. gleum	CHRBGLE
Chryseobacterium indologenes	Chryseob. indologenes	CHRBIND
Chryseobacterium scophthalmum	Chryseob. scophthalmum	CHRBSCO
Chryseobacterium species	Chryseob. species	CHRBSPE
Citrobacter amalonaticus	Cit. amalonaticus	CITAMA
Citrobacter braakii	Cit. braakii	CITBRA
Citrobacter farmeri	Cit. farmeri	CITFAR
Citrobacter freundii	Cit. freundii	CITFRE
Citrobacter gillenii	Cit. gillenii	CITSPE10
Citrobacter koseri	Cit. koseri	CITKOS
Citrobacter murliniae	Cit. murliniae	CITSPE11
Citrobacter rodentium	Cit. rodentium	CITSPE9
Citrobacter sedlakii	Cit. sedlakii	CITSED
Citrobacter species	Cit. species	CITSPE
Citrobacter werkmanii	Cit. werkmanii	CITWER
Citrobacter youngae	Cit. youngae	CITYOU
Comamonas terrigena	Coma. terrigena	COMTER

Long Name	Short Name	Abbreviation
Comamonas testosteroni	Coma. testosteroni	COMTES
Corynebacterium amycolatum	Cory. amycolatum	CORAMY
Corynebacterium amycolatum/ minutissimum	Cory. amycolatum/ minutissimum	CORAMYMIN
Corynebacterium amycolatum/ striatum	Cory. amycolatum/striatum	CORAMYSTR
Corynebacterium bovis	Cory. bovis	CORBOV
Corynebacterium diphtheriae	Cory. diphtheriae	CORDIP
Corynebacterium jeikeium	Cory. jeikeium	CORJEI
Corynebacterium kutscheri	Cory. kutscheri	CORKUT
Corynebacterium matruchotii	Cory. matruchotii	CORMAT
Corynebacterium minutissimum	Cory. minutissimum	CORMIN
Corynebacterium propinquum	Cory. propinquum	CORPRO
Corynebacterium pseudodiphtheriticum	Cory. pseudodiphth.	CORPSD
Corynebacterium pseudotuberculosis	Cory. pseudotuberc.	CORPST
Corynebacterium renale	Cory. renale	CORREN
Corynebacterium striatum	Cory. striatum	CORSTR
Corynebacterium ulcerans	Cory. ulcerans	CORULC
Corynebacterium urealyticum	Cory. urealyticum	CORURE
Corynebacterium xerosis	Cory. xerosis	CORXER
Cronobacter sakazakii complex	Cronob. sakazakii complex	ENTBSAK
Cryptococcus albidus	Cryp. albidus	CRYALB
Cryptococcus gattii	Cryp. gattii	CRYNEOG
Cryptococcus humicola	Cryp. humicola	CRYHUM
Cryptococcus laurentii	Cryp. laurentii	CRYLAU
Cryptococcus luteolus	Cryp. luteolus	CRYLUT
Cryptococcus neoformans	Cryp. neoformans	CRYNEO
Cryptococcus terreus	Cryp. terreus	CRYTER
Cryptococcus uniguttulatus	Cryp. uniguttulatus	CRYUNI
Cupriavidus gilardii	Cup. gilardii	RALGIL
Cupriavidus pauculus	Cup. pauculus	CDCIVC2

Long Name	Short Name	Abbreviation
Delftia acidovorans	Delf. acidovorans	COMACI
Dermabacter hominis	Dermab. hominis	DERBHOM
Dermacoccus nishinomiyaensis	Derm. nishinomiyaen.	MICNIS
Edwardsiella hoshinae	Ed. hoshinae	EDWHOS
Edwardsiella ictaluri	Ed. ictaluri	EDWICT
Edwardsiella species	Ed. species	EDWSPE
Edwardsiella tarda	Ed. tarda	EDWTAR
Edwardsiella tarda biogroup 1	Ed. tarda biogr. 1	EDWTAR1
Eikenella corrodens	Eik. corrodens	EIKCOR
Elizabethkingia anophelis	Eliz. anophelis	ELIANO
Elizabethkingia meningoseptica	Eliz. meningosept.	CHRBMEN
Elizabethkingia miricola	Eliz. miricola	ELIMIR
Empedobacter brevis	Emp. brevis	EMPBRE
Enterobacter asburiae	Enterob. asburiae	ENTBASB
Enterobacter bugandensis	Enterob. bugandensis	ENTBBUG
Enterobacter cancerogenus	Enterob. cancerogenus	ENTBCAN
Enterobacter cloacae	Enterob. cloacae	ENTBCLO
Enterobacter cloacae ssp. dissolvens	Enterob. cloacae ssp. dissolven	ENTBDIS
Enterobacter hormaechei	Enterob. hormaechei	ENTBHOR
Enterobacter kobei	Enterob. kobei	ENTBKOB
Enterobacter ludwigii	Enterob. ludwigii	ENTBLUD
Enterobacter nimipressuralis	Enterob. nimipressuralis	ENTBNIM
Enterobacter species	Enterob. species	ENTBSPE
Enterococcus asini	Enteroc. asini	ENTCASI
Enterococcus avium	Enteroc. avium	ENTCAVI
Enterococcus casseliflavus	Enteroc. casseliflavus	ENTCCAS
Enterococcus casseliflavus/ gallinarum	Enteroc. cassel./gallin.	ENTCCASGAL
Enterococcus cecorum	Enteroc. cecorum	ENTCCEC
Enterococcus columbae	Enteroc. columbae	ENTCCOL
Enterococcus dispar	Enteroc. dispar	ENTCDIS

Long Name	Short Name	Abbreviation
Enterococcus durans	Enteroc. durans	ENTCDUR
Enterococcus durans/faecium	Enteroc. durans/faecium	ENTCDURFAI
Enterococcus faecalis	Enteroc. faecalis	ENTCFAA
Enterococcus faecalis/faecium	Enteroc. faecalis/faecium	ENTCFAAFAI
Enterococcus faecium	Enteroc. faecium	ENTCFAI
Enterococcus flavescens	Enteroc. flavescens	ENTCFLA
Enterococcus gallinarum	Enteroc. gallinarum	ENTCGAL
Enterococcus gilvus	Enteroc. gilvus	ENTCGIL
Enterococcus haemoperoxidus	Enteroc. haemoperoxidus	ENTCHAE
Enterococcus hirae	Enteroc. hirae	ENTCHIR
Enterococcus hirae/faecium	Enteroc. hirae/faecium	ENTCHIRFAI
Enterococcus malodoratus	Enteroc. malodoratus	ENTCMAL
Enterococcus moraviensis	Enteroc. moraviensis	ENTCMOR
Enterococcus mundtii	Enteroc. mundtii	ENTCMUN
Enterococcus pallens	Enteroc. pallens	ENTCPAL
Enterococcus pseudoavium	Enteroc. pseudoavium	ENTCPSE
Enterococcus raffinosus	Enteroc. raffinosus	ENTCRAF
Enterococcus raffinosus/avium	Enteroc. raffinosus/avium	ENTCRAFAVI
Enterococcus ratti	Enteroc. ratti	ENTCRAT
Enterococcus saccharolyticus	Enteroc. saccharolyticus	ENTCSAC
Enterococcus species	Enteroc. species	ENTCSPE
Enterococcus sulfureus	Enteroc. sulfureus	ENTCSUL
Erysipelothrix rhusiopathiae	Ery. rhusiopathiae	ERYRHU
Escherichia albertii	Esch. albertii	ESCALB
Escherichia coli	Esch. coli	ESCCOL
Escherichia coli serotype O111	Esch. coli O111	ESCCOL0111
Escherichia coli serotype O157	Esch. coli O157	ESCCOL0157
Escherichia fergusonii	Esch. fergusonii	ESCFER
Escherichia hermannii	Esch. hermannii	ESCHER
Escherichia species	Esch. species	ESCSPE
Ewingella americana	Ew. americana	EWIAME

Long Name	Short Name	Abbreviation
Exophiala dermatitidis	Exo. dermatitidis	EXODER
Exophiala species	Exo. species	EXOSPE
Gardnerella vaginalis	Gard. vaginalis	GARVAG
Gemella haemolysans	Gem. haemolysans	GEMHAE
Gemella morbillorum	Gem. morbillorum	GEMMOR
Gemella species	Gem. species	GEMSPE
Geotrichum species	Geo. species	GEOSPE
Globicatella sanguinis	Glob. sanguinis	GLOSAN
Gram-negative rod unidentified enteric	GNR unident. enteric	GNRUNIE
Gram-negative rod unidentified nonfermenter	GNR unident. NF	GNRUNINF
Grimontia hollisae	Grim. hollisae	VIBHOL
Hafnia alvei	Haf. alvei	HAFALV
Hafnia alvei group 1	Haf. alvei gr. 1	HAFALV1
Helcococcus kunzii	Helco. kunzii	HELCKUN
Hortaea werneckii	Hor. werneckii	HORWER
Hyphopichia burtonii	Hyphop. burtonii	HYPBUR
Kingella denitrificans	King. denitrificans	KINDEN
Kingella kingae	King. kingae	KINKIN
Klebsiella aerogenes	Kleb. aerogenes	KLEAER
Klebsiella granulomatis	Kleb. granulomatis	CALYGRA
Klebsiella oxytoca	Kleb. oxytoca	KLEOXY
Klebsiella ozaenae	Kleb. ozaenae	KLEPNEO
Klebsiella pneumoniae	Kleb. pneumoniae	KLEPNEP
Klebsiella rhinoscleromatis	Kleb. rhinoscleromatis	KLEPNER
Klebsiella species	Kleb. species	KLESPE
Klebsiella variicola	Kleb. variicola	KLEVAR
Kloeckera species	Kloeck. species	KLOSPE
Kluyvera ascorbata	Kluyvera ascorbata	KLUASC
Kluyvera cryocrescens	Kluyvera cryocres.	KLUCRY
Kluyvera georgiana	Kluyvera georgiana	KLUGEO

Long Name	Short Name	Abbreviation
Kluyvera intermedia	Kluyvera intermedia	ENTBINT
Kluyvera species	Kluyvera species	KLUSPE
Kocuria kristinae	Koc. kristinae	MICKRI
Kocuria rosea	Koc. rosea	MICROS
Kocuria varians	Koc. varians	MICVAR
Kytococcus sedentarius	Kyto. sedentarius	MICSED
Lactobacillus dextrinicus	Lactob. dextrinicus	LACBDEX
Lactococcus garvieae	Lactoc. garvieae	LACCGAR
Lactococcus lactis ssp. cremoris	Lactoc. lactis ssp. crem.	LACCLACC
Lactococcus lactis ssp. hordniae	Lactoc. lactis ssp. hord.	LACCLACH
Lactococcus lactis ssp. lactis	Lactoc. lactis ssp. lactis	LACCLACL
Lactococcus plantarum	Lactoc. plantarum	LACCPLA
Lactococcus raffinolactis	Lactoc. raffinolactis	LACCRAF
Lactococcus species	Lactoc. species	LACCSPE
Leclercia adecarboxylata	Lec. adecarboxylata	LECADE
Leifsonia aquatica	Leif. aquatica	CORAQU
Lelliottia amnigena biogroup 1	Lell. amnigena biogr. 1	LELAMN1
Lelliottia amnigena biogroup 2	Lell. amnigena biogr. 2	LELAMN2
Leminorella grimontii	Lem. grimontii	LEMGRI
Leminorella richardii	Lem. richardii	LEMRIC
Leuconostoc citreum	Leu. citreum	LEUCIT
Leuconostoc lactis	Leu. lactis	LEULAC
Leuconostoc mesenteroides ssp. cremoris	Leu. mesenter. ssp. crem.	LEUMESC
Leuconostoc mesenteroides ssp. mesenteroides	Leu. mesenter. ssp. mes.	LEUMESM
Leuconostoc pseudomesenteroides	Leu. pseudomesenter.	LEUPSE
Leuconostoc species	Leu. species	LEUSPE
Listeria grayi	Lis. grayi	LISGRA
Listeria innocua	Lis. innocua	LISINN
Listeria ivanovii	Lis. ivanovii	LISIVA
Listeria monocytogenes	Lis. monocytogenes	LISMON

Long Name	Short Name	Abbreviation
Listeria monocytogenes/innocua	Lis. monocytogenes/innocua	LISMONINN
Listeria species	Lis. species	LISSPE
Listeria welshimeri	Lis. welshimeri	LISWEL
Lysinibacillus sphaericus	Lysini. sphaericus	BACISPH
Macrococcus caseolyticus	Macroc. caseolyticus	STACAS
Magnusiomyces capitatus	Magnus. capitatus	MAGCAP
Malassezia furfur complex	Mal. furfur complex	MALFURX
Malassezia pachydermatis	Mal. pachydermatis	MALPAC
Malassezia sympodialis	Mal. sympodialis	MALSYM
Mannheimia haemolytica	Mann. haemolytica	PASHAE
Methylobacterium extorquens	Methylob. extorquens	METEXT
Micrococcus luteus	Microc. luteus	MICLUT
Micrococcus lylae	Microc. lylae	MICLYL
Millerozyma farinosa	Mill. farinosa	MILFAR
Moellerella wisconsensis	Moel. wisconsensis	MOEWIS
Moraxella (Branhamella) catarrhalis	Morax. (Bran.) cat.	MORABRACAT
Moraxella species	Morax. species	MORASPE
Morganella morganii	Morg. morganii	MORGMOR
Morganella morganii ssp. morganii	Morg. morg. ssp. morg.	MORGMORM
Morganella morganii ssp. morganii biogroup 1	Morg. morg. ssp. morg. biog. 1	MORGMORM1
Morganella morganii ssp. sibonii	Morg. morg. ssp. sibonii	MORGMORS
Morganella species	Morg. species	MORGSPE
Myroides injenensis	Myr. injenensis	MYRINJ
Myroides odoratimimus	Myr. odoratimimus	MYRODI
Myroides odoratus	Myr. odoratus	MYRODA
Myroides odoratus/odoratimimus	Myr. odoratus/odoratimimus	MYRODAODI
Myroides species	Myr. species	MYRSPE
Neisseria animaloris	Nei. animaloris	NEIANI
Neisseria zoodegmatis	Nei. zoodegmatis	NEIZOO
Ochrobactrum anthropi	Och. anthropi	OCHANT

Long Name	Short Name	Abbreviation
Oligella ureolytica	Olig. ureolytica	OLIURO
Oligella urethralis	Olig. urethralis	OLIURT
Paenibacillus alvei	Paen. alvei	PAEALV
Paenibacillus macerans	Paen. macerans	PAEMAC
Pantoea agglomerans	Pan. agglomerans	PANAGG
Pantoea ananatis	Pan. ananatis	ERWANA
Pantoea calida	Pan. calida	PANCAL
Pantoea dispersa	Pan. dispersa	PANDIS
Pantoea gaviniae	Pan. gaviniae	PANGAV
Pantoea septica	Pan. septica	PANSEP
Pantoea species	Pan. species	PANSPE
Pantoea stewartii	Pan. stewartii	PANSTE
Pantoea stewartii ssp. indologenes	Pan. ste. ssp. indologenes	PANSTEI
Pantoea stewartii ssp. stewartii	Pan. ste. ssp. stewartii	PANSTES
Paracoccus yeei	Parac. yeei	PARCYEE
Pasteurella aerogenes	Past. aerogenes	PASAER
Pasteurella multocida	Past. multocida	PASMUL
Pediococcus acidilactici	Ped. acidilactici	PEDACI
Pediococcus damnosus	Ped. damnosus	PEDDAM
Pediococcus parvulus	Ped. parvulus	PEDPAR
Pediococcus pentosaceus	Ped. pentosaceus	PEDPEN
Pediococcus species	Ped. species	PEDSPE
Photobacterium damselae	Photob. damselae	PHOBDAM
Plesiomonas shigelloides	Ples. shigelloides	PLESHI
Pluralibacter gergoviae	Plural. gergoviae	PLUGER
Pragia fontium	Prag. fontium	PRAFON
Proteus hauseri	Prot. hauseri	PROTHAU
Proteus mirabilis	Prot. mirabilis	PROTMIR
Proteus penneri	Prot. penneri	PROTPEN
Proteus species	Prot. species	PROTSPE
Proteus vulgaris	Prot. vulgaris	PROTVUL

Proteus vulgaris/penneri         Prot. vulgaris/penneri         PROTVULPEN           Prototheca wickerhamii         Protot. wick.         PROHWIC           Prototheca zopfii         Protot. zopfii         PROHZOP           Providencia alcalifaciens         Prov. dealifaciens         PROVALC           Providencia heimbachae         Prov. heimbachae         PROVALC           Providencia heimbachae         Prov. studie         PROVSTU           Providencia heimbachae         Prov. studie         PROVSTU           Providencia studienia         Prov. studie         Prov. Pr	Long Name	Short Name	Abbreviation
Prototheca zopfii Protot. zopfii PROHZOP Providencia alcalifaciens Prov. alcalifaciens PROVALC Providencia heimbachae Prov. heimbachae PROVHEI Providencia rettgeri Prov. rettgeri PROVRET Providencia rustigianii Prov. rustigianii PROVRUS Providencia species Prov. species PROVSPE Providencia stuartii Prov. stuartii PROVSTU Pseudescherichia vulneris Pseudes. vulneris PSEEVUL Pseudomonas aeruginosa Pseud. aeruginosa PSEAER Pseudomonas fluorescens Pseud. fluorescens PSEFLU Pseudomonas fluorescens Pseud. fluorescens PSEFLU Pseudomonas fluorescens/putida Pseud. fluorescens/putida PSEFLUPUT Pseudomonas mendocina Pseud. mendocina PSEMEN Pseudomonas monteilii Pseud. monteilii PSEMON Pseudomonas pertucinogena Pseud. pertucinogena PSEPER Pseudomonas pseudoalcaligenes Pseud. pseudoalcaligenes PSEPSE Pseudomonas pseudoalcaligenes Pseud. pseudoalcaligenes PSEPSE Pseudomonas putida Pseud. species PSEPSE Pseudomonas species Pseud. species PSESE Pseudomonas stutzeri Pseud. stutzeri PSESTU Pseudomonas veronii Pseud. renoii PSEVER Rahnella aquatilis Ral. solanacearum BURSOL	Proteus vulgaris/penneri	Prot. vulgaris/penneri	PROTVULPEN
Providencia alcalifaciens Prov. alcalifaciens PROVALC Providencia heimbachae Prov. heimbachae PROVHEI Providencia rettgeri Prov. rettgeri PROVRET Providencia rustigianii Prov. rustigianii PROVRUS Providencia species Prov. species PROVSPE Providencia stuartii Prov. stuartii PROVSTU Pseudescherichia vulneris Pseudes. vulneris PSEEVUL Pseudomonas aeruginosa Pseud. aeruginosa PSEAER Pseudomonas fluorescens Pseud. fluorescens PSEFLU Pseudomonas fluorescens Pseud. fluorescens PSEFLU Pseudomonas fluorescens/putida Pseud. fluorescens/putida PSEMEN Pseudomonas Incescens/putida Pseud. mendocina PSEMEN Pseudomonas mendocina Pseud. mendocina PSEMEN Pseudomonas monteilii Pseud. monteilii PSEMON Pseudomonas pertucinogena Pseud. pertucinogena PSEPER Pseudomonas pseudoalcaligenes Pseud. pseudoalcaligenes PSEPSE Pseudomonas pseudoalcaligenes Pseud. pseudoal. ssp. pseud. PSEPSE Pseudomonas putida Pseud. stutzeri PSESTU Pseudomonas veronii Pseud. veronii PSEVER Rahnella aquatilis Rah. aquatilis Ral. solanacearum BURSOL	Prototheca wickerhamii	Protot. wick.	PROHWIC
Providencia heimbachae Prov. heimbachae PROVHEI Providencia rettgeri Prov. rettgeri PROVRET Providencia rustigianii Prov. rustigianii PROVRUS Providencia species Prov. species PROVSPE Providencia stuartii Prov. stuartii PROVSTU Pseudescherichia vulneris Pseudes. vulneris PSEEVUL Pseudomonas aeruginosa Pseud. alealigenes PSEAER Pseudomonas alealigenes Pseud. fluorescens PSEFLU Pseudomonas fluorescens/putida Pseud. fluorescens/putida PSEFLUPUT Pseudomonas luteola Pseud. mendocina PSEMEN Pseudomonas mendocina Pseud. mendocina PSEMEN Pseudomonas monteilii Pseud. monteilii PSEMON Pseudomonas pertucinogena Pseud. pertucinogena PSEPER Pseudomonas pseudoalcaligenes Pseud. pseudoalcaligenes PSEPSE Pseudomonas stutzeri Pseud. stutzeri PSESTU Pseudomonas veronii Pseud. veronii PSEVER Rahnella aquatilis Rah. aquatilis RAHAQU Ralstonia insidiosa Ral. insidiosa RALINS Ralstonia polanacearum BURSOL	Prototheca zopfii	Protot. zopfii	PROHZOP
Providencia rettgeri Prov. rettgeri PROVRET Providencia rustigianii Prov. rustigianii PROVRUS Providencia species Prov. species PROVSPE Providencia stuartii Prov. stuartii PROVSTU Pseudescherichia vulneris Pseudes. vulneris PSEEVUL Pseudomonas aeruginosa Pseud. aeruginosa PSEAER Pseudomonas alcaligenes Pseud. alcaligenes PSEALC Pseudomonas fluorescens Pseud. fluorescens PSEFLU Pseudomonas fluorescens/putida Pseud. fluorescens/putida PSEFLUPUT Pseudomonas Iuteola Pseud. nendocina PSEMEN Pseudomonas mendocina Pseud. mendocina PSEMEN Pseudomonas monteilii Pseud. monteilii PSEMON Pseudomonas oryzihabitans Pseud. oryzihabitans FLAIORY Pseudomonas pertucinogena Pseud. pseudoalcaligenes PSEPSE Pseudomonas pseudoalcaligenes Pseud. pseudoal. ssp. pseud. PSEPSE Pseudomonas petida Pseud. species PSEPSE Pseudomonas stutzeri Pseud. stutzeri PSESTU Pseudomonas veronii Pseud. Ral. insidiosa Ral. insidiosa Ral. insidiosa Ral. solanacearum BURSOL	Providencia alcalifaciens	Prov. alcalifaciens	PROVALC
Providencia rustigianii Prov. rustigianii PROVRUS Providencia species Prov. species PROVSPE Providencia species Prov. species PROVSPE Providencia stuartii Prov. stuartii PROVSTU Pseudescherichia vulneris Pseudes. vulneris PSEEVUL Pseudomonas aeruginosa Pseud. aeruginosa PSEAER Pseudomonas alcaligenes Pseud. alcaligenes PSEALC Pseudomonas fluorescens Pseud. fluorescens PSEFLU Pseudomonas fluorescens/putida Pseud. fluorescens/putida PSEFLUPUT Pseudomonas luteola Pseud. luteola CHRMLUT Pseudomonas mendocina Pseud. mendocina PSEMEN Pseudomonas monteilii Pseud. monteilii PSEMON Pseudomonas oryzihabitans Pseud. oryzihabitans FLAIORY Pseudomonas pertucinogena Pseud. pertucinogena PSEPER Pseudomonas pseudoalcaligenes Pseud. pseudoalcaligenes PSEPSE Pseudomonas pseudoalcaligenes Pseud. putida PSEPSE Pseudomonas pseudoalcaligenes Pseud. putida PSEPUT Pseudomonas stutzeri Pseud. stutzeri PSESTU Pseudomonas veronii Pseud. veronii PSEVER Rahnella aquatilis Rah. aquatilis RAHAQU Ralstonia insidiosa Ral. insidiosa RALINS Ralstonia solanacearum BURSOL	Providencia heimbachae	Prov. heimbachae	PROVHEI
Providencia species Prov. species PROVSPE Providencia stuartii Prov. stuartii PROVSTU Pseudescherichia vulneris Pseudes. vulneris PSEEVUL Pseudomonas aeruginosa Pseud. aeruginosa PSEAER Pseudomonas alcaligenes Pseud. alcaligenes PSEALC Pseudomonas fluorescens Pseud. fluorescens PSEFLU Pseudomonas fluorescens/putida Pseud. fluorescens/putida PSEFLUPUT Pseudomonas luteola Pseud. luteola CHRMLUT Pseudomonas mendocina Pseud. mendocina PSEMEN Pseudomonas monteilii Pseud. monteilii PSEMON Pseudomonas oryzihabitans Pseud. oryzihabitans FLAIORY Pseudomonas pertucinogena Pseud. pertucinogena PSEPER Pseudomonas pseudoalcaligenes Pseud. pseudoalcaligenes PSEPSE Pseudomonas pseudoalcaligenes Pseud. pseudoal. ssp. pseud. PSEPSE Pseudomonas pseudoalcaligenes Pseud. species PSESPE Pseudomonas species Pseud. species PSESTU Pseudomonas stutzeri Pseud. veronii PSESTU Pseudomonas veronii Pseud. insidiosa RALINS Ralstonia insidiosa Ral. insidiosa BURPIC Ralstonia solanacearum BURSOL	Providencia rettgeri	Prov. rettgeri	PROVRET
Providencia stuartii Prov. stuartii PROVSTU  Pseudescherichia vulneris Pseudes. vulneris PSEEVUL  Pseudomonas aeruginosa Pseud. aeruginosa PSEAER  Pseudomonas alcaligenes Pseud. alcaligenes PSEALC  Pseudomonas fluorescens Pseud. fluorescens PSEFLU  Pseudomonas fluorescens/putida Pseud. fluorescens/putida PSEFLUPUT  Pseudomonas luteola Pseud. luteola CHRMLUT  Pseudomonas mendocina Pseud. mendocina PSEMEN  Pseudomonas monteilii Pseud. monteilii PSEMON  Pseudomonas pertucinogena Pseud. pertucinogena PSEPER  Pseudomonas pseudoalcaligenes Pseud. pseudoalcaligenes PSEPSE  Pseudomonas pseudoalcaligenes Pseud. pseudoal. ssp. pseud.  PSEPSE Pseudomonas pseudoalcaligenes Pseud. pseudoalcaligenes PSEPSE  Pseudomonas pseudoalcaligenes Pseud. pseudoalcaligenes PSEPSE  Pseudomonas pseudoalcaligenes Pseud. pseudoal. ssp. pseud.  PSEPSE Pseudomonas psecies Pseud. pseudoalcaligenes PSEPSE  Pseudomonas putida Pseud. putida PSEPUT  Pseudomonas stutzeri Pseud. stutzeri PSESTU  Pseudomonas veronii Pseud. veronii PSEVER  Rahnella aquatilis Rah. aquatilis RAHAQU  Ralstonia insidiosa Ral. insidiosa RALINS  Ralstonia pickettii BURPIC  Ralstonia solanacearum BURSOL	Providencia rustigianii	Prov. rustigianii	PROVRUS
Pseudescherichia vulneris Pseudomonas aeruginosa Pseud. aeruginosa Pseud. aeruginosa Pseudomonas alcaligenes Pseudomonas fluorescens Pseud. fluorescens Pseudomonas fluorescens/putida Pseudomonas luteola Pseudomonas luteola Pseudomonas mendocina Pseud. mendocina Pseudomonas mendocina Pseudomonas monteilii Pseudomonas pertucinogena Pseud. pertucinogena Pseudomonas pertucinogena Pseudomonas pseudoalcaligenes Pseudomonas pseudoalcaligenes Pseudomonas pseudoalcaligenes Pseudomonas pertucinogena Pseud. pseudoal. ssp. pseud. PSEPSE Pseudomonas petida Pseud. pseudoal. ssp. pseud. PSEPSE Pseudomonas petida Pseud. pseudoalcaligenes Pseud. pseudoalcaligenes Pseudomonas pseudoalcaligenes Pseud. pseudoalcaligenes Pseudomonas pseudoalcaligenes Pseud. pseudoalcaligenes Pseudomonas pseudoalcaligenes Pseud. pseudoalcaligenes Pseudomonas pseudoalcaligenes Pseud. pseudoalcaligenes Pseud. pseudoalcaligenes Pseud. pseudoalcaligenes Pseudomonas putida Pseud. pseudoalcaligenes Pseudomonas putida Pseud. pseudoalcaligenes Pseudomonas pecies Pseudom	Providencia species	Prov. species	PROVSPE
Pseudomonas aeruginosa Pseud. aeruginosa PSEAER Pseudomonas alcaligenes Pseud. alcaligenes PSEALC Pseudomonas fluorescens Pseud. fluorescens PSEFLU Pseudomonas fluorescens/putida Pseud. fluorescens/putida PSEFLUPUT Pseudomonas luteola Pseud. luteola CHRMLUT Pseudomonas mendocina Pseud. mendocina PSEMEN Pseudomonas monteilii Pseud. monteilii PSEMON Pseudomonas oryzihabitans Pseud. oryzihabitans FLAIORY Pseudomonas pertucinogena Pseud. pertucinogena PSEPER Pseudomonas pseudoalcaligenes Pseud. pseudoalcaligenes PSEPSE Pseudomonas pseudoalcaligenes Pseud. pseudoal. ssp. pseud. PSEPSE Pseudomonas pseudoalcaligenes Pseud. pseudoal. ssp. pseud. PSEPSE Pseudomonas pseudoalcaligenes Pseud. pseudoal. ssp. pseud. PSEPSE Pseudomonas pseudoalcaligenes Pseud. putida PSEPUT Pseudomonas species Pseud. stutzeri PSESTU Pseudomonas veronii Pseud. veronii PSEVER Rahnella aquatilis Rah. aquatilis RAHAQU Ralstonia insidiosa Ral. insidiosa RALINS Ralstonia pickettii BURPIC Ralstonia solanacearum BURSOL	Providencia stuartii	Prov. stuartii	PROVSTU
Pseudomonas alcaligenes Pseud. alcaligenes PSEALC Pseudomonas fluorescens Pseud. fluorescens PSEFLU Pseudomonas fluorescens/putida Pseud. fluorescens/putida PSEFLUPUT Pseudomonas luteola Pseud. luteola CHRMLUT Pseudomonas mendocina Pseud. mendocina PSEMEN Pseudomonas monteilii Pseud. monteilii PSEMON Pseudomonas oryzihabitans Pseud. oryzihabitans FLAIORY Pseudomonas pertucinogena Pseud. pertucinogena PSEPER Pseudomonas pseudoalcaligenes Pseud. pseudoalcaligenes PSEPSE Pseudomonas pseudoalcaligenes Pseud. pseudoal. ssp. pseud. PSEPSEP Pseudomonas putida Pseud. species PSESPE Pseudomonas species Pseud. species PSESPE Pseudomonas stutzeri Pseud. stutzeri PSESTU Pseudomonas veronii Pseud. veronii PSEVER Rahnella aquatilis Rah. aquatilis RAHAQU Ralstonia insidiosa Ral. insidiosa RALINS Ralstonia pickettii BURPIC Ralstonia solanacearum BURSOL	Pseudescherichia vulneris	Pseudes. vulneris	PSEEVUL
Pseudomonas fluorescens Pseud. fluorescens Pseud. fluorescens/putida Pseudomonas fluorescens/putida Pseudomonas fluorescens/putida Pseudomonas luteola Pseudomonas mendocina Pseud. mendocina Pseudomonas mendocina Pseudomonas mendocina Pseudomonas monteilii Pseudomonas monteilii Pseudomonas oryzihabitans Pseud. oryzihabitans Pseudomonas pertucinogena Pseud. pertucinogena Pseper Pseudomonas pseudoalcaligenes Pseud. pseudoalcaligenes Pseudomonas putida Pseud. pseudoal. ssp. pseud. PSEPSE Pseudomonas species Pseudomonas species Pseudomonas stutzeri Pseudomonas stutzeri Pseudomonas veronii Pseud. stutzeri Pseudomonas veronii Pseudomonas veronii Pseudomonas veronii Rah. aquatilis Rah. aquatilis Rah. aquatilis Ral. insidiosa Ral. insidiosa Ral. insidiosa Ral. solanacearum BURSOL	Pseudomonas aeruginosa	Pseud. aeruginosa	PSEAER
Pseudomonas fluorescens/putida Pseud. fluorescens/putida PSEFLUPUT Pseudomonas luteola Pseud. luteola CHRMLUT Pseudomonas mendocina Pseud. mendocina PSEMEN Pseudomonas monteilii Pseud. monteilii PSEMON Pseudomonas oryzihabitans Pseud. oryzihabitans FLAIORY Pseudomonas pertucinogena Pseud. pertucinogena PSEPER Pseudomonas pseudoalcaligenes Pseud. pseudoalcaligenes PSEPSE Pseudomonas pseudoalcaligenes Pseud. pseudoal. ssp. pseud. Pseudomonas putida Pseud. putida PSEPUT Pseudomonas species Pseud. stutzeri PSESTU Pseudomonas stutzeri Pseud. stutzeri PSESTU Pseudomonas veronii Pseud. veronii PSEVER Rahnella aquatilis Rah. aquatilis RAHAQU Ralstonia insidiosa Ral. insidiosa RALINS Ralstonia pickettii BURPIC Ralstonia solanacearum BURSOL	Pseudomonas alcaligenes	Pseud. alcaligenes	PSEALC
Pseudomonas luteolaPseud. luteolaCHRMLUTPseudomonas mendocinaPseud. mendocinaPSEMENPseudomonas monteiliiPseud. monteiliiPSEMONPseudomonas oryzihabitansPseud. oryzihabitansFLAIORYPseudomonas pertucinogenaPseud. pertucinogenaPSEPERPseudomonas pseudoalcaligenesPseud. pseudoalcaligenesPSEPSEPseudomonas pseudoalcaligenesPseud. pseudoal. ssp. pseud.PSEPSEPSEPSEPSEPSEPSEPSEPSEPSEPSEPSEPSEP	Pseudomonas fluorescens	Pseud. fluorescens	PSEFLU
Pseudomonas mendocinaPseud. mendocinaPSEMENPseudomonas monteiliiPseud. monteiliiPSEMONPseudomonas oryzihabitansPseud. oryzihabitansFLAIORYPseudomonas pertucinogenaPseud. pertucinogenaPSEPERPseudomonas pseudoalcaligenesPseud. pseudoalcaligenesPSEPSEPseudomonas pseudoalcaligenesPseud. pseudoal. ssp. pseud.PSEPSEPPseudomonas putidaPseud. putidaPSEPUTPseudomonas speciesPseud. speciesPSESPEPseudomonas stutzeriPseud. stutzeriPSESTUPseudomonas veroniiPseud. veroniiPSEVERRahnella aquatilisRah. aquatilisRAHAQURalstonia insidiosaRal. insidiosaRALINSRalstonia pickettiiRal. pickettiiBURPICRalstonia solanacearumBURSOL	Pseudomonas fluorescens/putida	Pseud. fluorescens/putida	PSEFLUPUT
Pseudomonas monteiliiPseud. monteiliiPSEMONPseudomonas oryzihabitansPseud. oryzihabitansFLAIORYPseudomonas pertucinogenaPseud. pertucinogenaPSEPERPseudomonas pseudoalcaligenesPseud. pseudoalcaligenesPSEPSEPseudomonas pseudoalcaligenesPseud. pseudoal. ssp. pseud.PSEPSEPPseudomonas putidaPseud. putidaPSEPUTPseudomonas speciesPseud. speciesPSESPEPseudomonas stutzeriPseud. stutzeriPSESTUPseudomonas veroniiPseud. veroniiPSEVERRahnella aquatilisRah. aquatilisRAHAQURalstonia insidiosaRal. insidiosaRALINSRalstonia pickettiiRal. pickettiiBURPICRalstonia solanacearumRal. solanacearumBURSOL	Pseudomonas luteola	Pseud. luteola	CHRMLUT
Pseudomonas oryzihabitansPseud. oryzihabitansFLAIORYPseudomonas pertucinogenaPseud. pertucinogenaPSEPERPseudomonas pseudoalcaligenesPseud. pseudoalcaligenesPSEPSEPseudomonas pseudoalcaligenes ssp. pseudoalcaligenesPseud. pseudoal. ssp. pseud.PSEPSEPPseudomonas putidaPseud. putidaPSEPUTPseudomonas speciesPseud. speciesPSESPEPseudomonas stutzeriPseud. stutzeriPSESTUPseudomonas veroniiPseud. veroniiPSEVERRahnella aquatilisRah. aquatilisRAHAQURalstonia insidiosaRal. insidiosaRALINSRalstonia pickettiiRal. pickettiiBURPICRalstonia solanacearumRal. solanacearumBURSOL	Pseudomonas mendocina	Pseud. mendocina	PSEMEN
Pseudomonas pertucinogenaPseud. pertucinogenaPSEPERPseudomonas pseudoalcaligenesPseud. pseudoalcaligenesPSEPSEPseudomonas pseudoalcaligenesPseud. pseudoal. ssp. pseud.PSEPSEPPseudomonas putidaPseud. putidaPSEPUTPseudomonas speciesPseud. speciesPSESPEPseudomonas stutzeriPseud. stutzeriPSESTUPseudomonas veroniiPseud. veroniiPSEVERRahnella aquatilisRah. aquatilisRAHAQURalstonia insidiosaRal. insidiosaRALINSRalstonia pickettiiRal. pickettiiBURPICRalstonia solanacearumRal. solanacearumBURSOL	Pseudomonas monteilii	Pseud. monteilii	PSEMON
Pseudomonas pseudoalcaligenesPseud. pseudoalcaligenesPSEPSEPseudomonas pseudoalcaligenes ssp. pseudoalcaligenesPseud. pseudoal. ssp. pseud.PSEPSEPPseudomonas putidaPseud. putidaPSEPUTPseudomonas speciesPseud. speciesPSESPEPseudomonas stutzeriPseud. stutzeriPSESTUPseudomonas veroniiPseud. veroniiPSEVERRahnella aquatilisRah. aquatilisRAHAQURalstonia insidiosaRal. insidiosaRALINSRalstonia pickettiiRal. pickettiiBURPICRalstonia solanacearumRal. solanacearumBURSOL	Pseudomonas oryzihabitans	Pseud. oryzihabitans	FLAIORY
Pseudomonas pseudoalcaligenes ssp. pseudoalcaligenesPseud. pseudoal. ssp. pseud.PSEPSEPPseudomonas putidaPseud. putidaPSEPUTPseudomonas speciesPseud. speciesPSESPEPseudomonas stutzeriPseud. stutzeriPSESTUPseudomonas veroniiPseud. veroniiPSEVERRahnella aquatilisRah. aquatilisRAHAQURalstonia insidiosaRal. insidiosaRALINSRalstonia pickettiiRal. pickettiiBURPICRalstonia solanacearumRal. solanacearumBURSOL	Pseudomonas pertucinogena	Pseud. pertucinogena	PSEPER
Pseudomonas putida Pseudomonas putida Pseudomonas species Pseudomonas species Pseudomonas stutzeri Pseudomonas stutzeri Pseudomonas veronii	Pseudomonas pseudoalcaligenes	Pseud. pseudoalcaligenes	PSEPSE
Pseudomonas speciesPseud. speciesPSESPEPseudomonas stutzeriPseud. stutzeriPSESTUPseudomonas veroniiPseud. veroniiPSEVERRahnella aquatilisRah. aquatilisRAHAQURalstonia insidiosaRal. insidiosaRALINSRalstonia pickettiiRal. pickettiiBURPICRalstonia solanacearumRal. solanacearumBURSOL		Pseud. pseudoal. ssp. pseud.	PSEPSEP
Pseudomonas stutzeri Pseud. stutzeri PSESTU  Pseudomonas veronii Pseud. veronii PSEVER  Rahnella aquatilis Rah. aquatilis RAHAQU  Ralstonia insidiosa Ral. insidiosa RALINS  Ralstonia pickettii Ral. pickettii BURPIC  Ralstonia solanacearum BURSOL	Pseudomonas putida	Pseud. putida	PSEPUT
Pseudomonas veroniiPseud. veroniiPSEVERRahnella aquatilisRah. aquatilisRAHAQURalstonia insidiosaRal. insidiosaRALINSRalstonia pickettiiRal. pickettiiBURPICRalstonia solanacearumRal. solanacearumBURSOL	Pseudomonas species	Pseud. species	PSESPE
Rahnella aquatilisRah. aquatilisRAHAQURalstonia insidiosaRal. insidiosaRALINSRalstonia pickettiiRal. pickettiiBURPICRalstonia solanacearumRal. solanacearumBURSOL	Pseudomonas stutzeri	Pseud. stutzeri	PSESTU
Ralstonia insidiosaRal. insidiosaRALINSRalstonia pickettiiRal. pickettiiBURPICRalstonia solanacearumRal. solanacearumBURSOL	Pseudomonas veronii	Pseud. veronii	PSEVER
Ralstonia pickettii Ral. pickettii BURPIC Ralstonia solanacearum Ral. solanacearum BURSOL	Rahnella aquatilis	Rah. aquatilis	RAHAQU
Ralstonia solanacearum Ral. solanacearum BURSOL	Ralstonia insidiosa	Ral. insidiosa	RALINS
	Ralstonia pickettii	Ral. pickettii	BURPIC
Ralstonia species Ral. species RALSPE	Ralstonia solanacearum	Ral. solanacearum	BURSOL
	Ralstonia species	Ral. species	RALSPE

Long Name	Short Name	Abbreviation
Raoultella ornithinolytica	Rao. ornithinolytica	KLEORN
Raoultella planticola	Rao. planticola	KLEPLA
Raoultella species	Rao. species	RAOSPE
Raoultella terrigena	Rao. terrigena	KLETER
Rhizobium radiobacter	Rhizob. radiobacter	AGRRAD
Rhodococcus equi	Rhodoc. equi	RHOCEQU
Rhodotorula glutinis	Rhodot. glutinis	RHOTGLU
Rhodotorula minuta	Rhodot. minuta	RHOTMIN
Rhodotorula mucilaginosa var mucilaginosa	Rhodot. mucilag. var mucilag.	RHOTMUCM
Rodentibacter pneumotropicus	Rod. pneumotropicus	RODPNE
Rothia dentocariosa	Roth. dentocariosa	ROTDEN
Rothia mucilaginosa	Roth. mucilaginosa	STOMUC
Saccharomyces cerevisiae	Sac. cerevisiae	SACCER
Salmonella enterica ssp. arizonae	Salm. enterica ssp. arizonae	SALCHOA
Salmonella enterica ssp. diarizonae	Salm. enterica ssp. diarizonae	SALCHOD
Salmonella enterica ssp. enterica serovar Choleraesuis	Salm. enterica sv Choleraesuis	SALCHOC
Salmonella enterica ssp. enterica sv Gallinarum bv Gallinarum	Salm. Gallinarum	SALGAL
Salmonella enterica ssp. enterica sv Gallinarum bv Pullorum	Salm. Pullorum	SALPUL
Salmonella enterica ssp. enterica sv Paratyphi A	Salm. Paratyphi A	SALPARA
Salmonella enterica ssp. enterica sv Typhi	Salm. Typhi	SALTYP
Salmonella enterica ssp. houtenae	Salm. enterica ssp. houtenae	SALCHOH
Salmonella enterica ssp. indica	Salm. enterica ssp. indica	SALCHOI
Salmonella enterica ssp. salamae	Salm. enterica ssp. salamae	SALCHOS
Salmonella species	Salm. species	SALSPE
Serratia entomophila	Ser. entomophila	SERENT
Serratia ficaria	Ser. ficaria	SERFIC
Serratia fonticola	Ser. fonticola	SERFON

Long Name	Short Name	Abbreviation
Serratia grimesii	Ser. grimesii	SERGRI
Serratia liquefaciens	Ser. liquefaciens	SERLIQ
Serratia marcescens	Ser. marcescens	SERMAR
Serratia odorifera	Ser. odorifera	SERODO
Serratia odorifera 1	Ser. odorifera 1	SERODO1
Serratia odorifera 2	Ser. odorifera 2	SERODO2
Serratia plymuthica	Ser. plymuthica	SERPLY
Serratia proteamaculans ssp. proteamaculans	Ser. proteamac. ssp. proteam.	SERPROP
Serratia proteamaculans ssp. quinovora	Ser. proteamac. ssp. quino.	SERPROQ
Serratia rubidaea	Ser. rubidaea	SERRUB
Serratia species	Ser. species	SERSPE
Shewanella algae	Shew. algae	SHEALG
Shewanella putrefaciens	Shew. putrefaciens	SHEPUT
Shewanella species	Shew. species	SHESPE
Shigella boydii	Shig. boydii	SHIBOY
Shigella dysenteriae	Shig. dysenteriae	SHIDYS
Shigella flexneri	Shig. flexneri	SHIFLE
Shigella sonnei	Shig. sonnei	SHISON
Shigella species	Shig. species	SHISPE
Sphingobacterium multivorum	Sphingob. multivorum	SPHBMUL
Sphingobacterium multivorum/ thalpophilum	Sphb. multivorum/ thalpophilum	SPHBMULTHA
Sphingobacterium species	Sphingob. species	SPHBSPE
Sphingobacterium spiritivorum	Sphingob. spiritivorum	SPHBSPI
Sphingobacterium thalpophilum	Sphingob. thalpophilum	SPHBTHA
Sphingomonas paucimobilis	Sphingom. paucimobilis	SPHMPAU
Sphingomonas paucimobilis group	Sphingom. paucimobilis gr.	SPHMPAUGR
Sphingomonas sanguinis	Sphingom. sanguinis	SPHMSAN
Sporobolomyces salmonicolor	Sporobol. salmonicolor	SPOBSAL
Staphylococcus argenteus	Staph. argenteus	STAARG

Long Name	Short Name	Abbreviation
Staphylococcus arlettae	Staph. arlettae	STAARL
Staphylococcus aureus	Staph. aureus	STAAUE
Staphylococcus aureus ssp. anaerobius	Staph. aureus ssp. anaerob.	STAAUEAN
Staphylococcus aureus ssp. aureus	Staph. aureus ssp. aureus	STAAUEAU
Staphylococcus auricularis	Staph. auricularis	STAAUI
Staphylococcus capitis	Staph. capitis	STACAI
Staphylococcus capitis ssp. capitis	Staph. capitis ssp. capitis	STACAIC
Staphylococcus capitis ssp. urealyticus	Staph. capitis ssp. urealyt.	STACAIU
Staphylococcus caprae	Staph. caprae	STACAP
Staphylococcus carnosus	Staph. carnosus	STACAR
Staphylococcus carnosus ssp. carnosus	Staph. carn. ssp. carn.	STACARC
Staphylococcus carnosus ssp. utilis	Staph. carn. ssp. utilis	STACARU
Staphylococcus chromogenes	Staph. chromogenes	STACHR
Staphylococcu chromogenes/hyicus	Staph. chromogenes/hyicus	STACHRHYI
Staphylococcus coagulase-negative	Staph. coag. neg.	STACNEG
Staphylococcus coagulase-positive	Staph. coag. pos.	STACPOS
Staphylococcus cohnii	Staph. cohnii	STACOH
Staphylococcus cohnii ssp. cohnii	Staph. cohnii ssp. cohnii	STACOHC
Staphylococcus cohnii ssp. urealyticum	Staph. cohnii ssp. urealyt.	STACOHU
Staphylococcus condimenti	Staph. condimenti	STACON
Staphylococcus delphini	Staph. delphini	STADEL
Staphylococcus epidermidis	Staph. epidermidis	STAEPI
Staphylococcus equorum	Staph. equorum	STAEQU
Staphylococcus felis	Staph. felis	STAFEL
Staphylococcus fleurettii	Staph. fleurettii	STAFLE
Staphylococcus gallinarum	Staph. gallinarum	STAGAL
Staphylococcus haemolyticus	Staph. haemolyticus	STAHAE
Staphylococcus haemolyticus/ lugdunensis	Staph. haemol./lugdun.	STAHAELUG

Long Name	Short Name	Abbreviation
Staphylococcus hominis	Staph. hominis	STAHOM
Staphylococcus hominis ssp. hominis	Staph. hom. ssp. hom.	STAHOMH
Staphylococcus hominis ssp. novobiosepticus	Staph. hom. ssp. novo.	STAHOMN
Staphylococcus hyicus	Staph. hyicus	STAHYI
Staphylococcus intermedius	Staph. intermedius	STAINT
Staphylococcus kloosii	Staph. kloosii	STAKLO
Staphylococcus lentus	Staph. lentus	STALEN
Staphylococcus lugdunensis	Staph. lugdunensis	STALUG
Staphylococcus lutrae	Staph. lutrae	STALUT
Staphylococcus muscae	Staph. muscae	STAMUS
Staphylococcus pasteuri	Staph. pasteuri	STAPAS
Staphylococcus petrasii	Staph. petrasii	STAPER
Staphylococcus pettenkoferi	Staph. pettenkoferi	STAPET
Staphylococcus piscifermentans	Staph. piscifermentans	STAPIS
Staphylococcus pseudintermedius	Staph. pseudintermedius	STAPSI
Staphylococcus pulvereri	Staph. pulvereri	STAPUL
Staphylococcus saccharolyticus	Staph. saccharolyticus	STASAC
Staphylococcus saprophyticus	Staph. saprophyticus	STASAP
Staphylococcus saprophyticus ssp. bovis	Staph. sap. ssp. bovis	STASAPB
Staphylococcus saprophyticus ssp. saprophyticus	Staph. sap. ssp. saprophyticus	STASAPS
Staphylococcus schleiferi	Staph. schleiferi	STASCH
Staphylococcus schleiferi ssp. coagulans	Staph. schleiferi ssp. coagul.	STASCHC
Staphylococcus schleiferi ssp. schleiferi	Staph. schleiferi ssp. schleif.	STASCHS
Staphylococcus sciuri	Staph. sciuri	STASCI
Staphylococcus sciuri ssp. carnaticus	Staph. sciuri ssp. carnaticus	STASCIC
Staphylococcus sciuri ssp. rodentium	Staph. sciuri ssp. rodentium	STASCIR
Staphylococcus sciuri ssp. sciuri	Staph. sciuri ssp. sciuri	STASCIS
Staphylococcus simulans	Staph. simulans	STASIM

Long Name	Short Name	Abbreviation
Staphylococcus species	Staph. species	STASPE
Staphylococcus succinus	Staph. succinus	STASUC
Staphylococcus succinus ssp. casei	Staph. suc. ssp. casei	STASUCCA
Staphylococcus succinus ssp. succinus	Staph. suc. ssp. succinus	STASUCSU
Staphylococcus vitulinus	Staph. vitulinus	STAVIT
Staphylococcus warneri	Staph. warneri	STAWAR
Staphylococcus warneri/pasteuri	Staph. warneri/pasteuri	STAWARPAS
Staphylococcus xylosus	Staph. xylosus	STAXYL
Stenotrophomonas maltophilia	Sten. maltophilia	STEMAL
Streptococcus acidominimus	Strep. acidominimus	STRACI
Streptococcus agalactiae (Strep. group B)	Strep. agalactiae (Str. gr. B)	STRAGA
Streptococcus alactolyticus	Strep. alactolyticus	STRALA
Streptococcus alpha-hemolytic	Strep. alpha-hemolytic	STRAHE
Streptococcus anginosus	Strep. anginosus	STRANG
Streptococcus anginosus (previously milleri) group	Strep. anginosus (milleri) gr.	STRANGGR
Streptococcus australis	Strep. australis	STRAUS
Streptococcus beta-hemolytic ACG (large colony)	Strep. beta-hemo ACG (Ig col)	STRBHE
Streptococcus canis	Strep. canis	STRCAN
Streptococcus constellatus	Strep. constellatus	STRCON
Streptococcus constellatus ssp. constellatus	Strep. con ssp. constellatus	STRCONCO
Streptococcus constellatus ssp. pharyngis	Strep. con ssp. pharyngis	STRCONPH
Streptococcus criceti	Strep. criceti	STRCRC
Streptococcus cristatus	Strep. cristatus	STRCRS
Streptococcus downei	Strep. downei	STRDOW
Streptococcus dysgalactiae	Strep. dysgalactiae	STRDYS
Streptococcus dysgalactiae ssp. dysgalactiae	Strep. dysgal. ssp. dysgal.	STRDYSDY

Long Name	Short Name	Abbreviation
Streptococcus dysgalactiae ssp. equisimilis	Strep. dysgal. ssp. equis.	STRDYSEM
Streptococcus dysgalactiae/canis	Strep. dysgal./canis	STRDYSCAN
Streptococcus equi	Strep. equi	STREQU
Streptococcus equi ssp. equi	Strep. equi ssp. equi	STREQUE
Streptococcus equi ssp. zooepidemicus	Strep. equi ssp. zooepid.	STREQUZ
Streptococcus equinus	Strep. equinus	STREQN
Streptococcus ferus	Strep. ferus	STRFER
Streptococcus gallolyticus	Strep. gallolyticus	STRGAL
Streptococcus gallolyticus ssp. gallolyticus	Strep. galloly. ssp. galloly.	STRGALGAL
Streptococcus gallolyticus ssp. macedonicus	Strep. galloly. ssp. macedon.	STRGALMAC
Streptococcus gallolyticus ssp. pasteurianus	Strep. galloly. ssp. pasteur.	STRGALPAS
Streptococcus gallolyticus ssp. pasteurianus/infantarius	Strep. galloly. ssp. pas./infa.	STRGALPASINA
Streptococcus gallolyticus/infantarius	Strep. galloly./infa.	STRGALINA
Streptococcus gordonii	Strep. gordonii	STRGOR
Streptococcus group A (small colony)	Strep. group A (sm col)	STRGRAS
Streptococcus group A (Strep. pyogenes)	Strep. group A (Str. pyogenes)	STRGRA
Streptococcus group B (Strep. agalactiae)	Strep. group B (Str. agalact.)	STRGRB
Streptococcus group C (large colony)	Strep. group C (lg col)	STRGRC
Streptococcus group C (small colony)	Strep. group C (sm col)	STRGRCS
Streptococcus group C/G (large colony)	Strep. group C/G (lg col)	STRGRCG
Streptococcus group C/G (small colony)	Strep. group C/G (sm col)	STRGRCGS
Streptococcus group CFG (small colony)	Strep. group CFG (sm col)	STRGRCFG
Streptococcus group D (non- enterococcus)	Strep. group D (non-enteroc.)	STRGRDNE
Streptococcus group E	Strep. group E	STRGRE

Long Name	Short Name	Abbreviation
Streptococcus group F	Strep. group F	STRGRF
Streptococcus group G (large colony)	Strep. group G (lg col)	STRGRG
Streptococcus group G (small colony)	Strep. group G (sm col)	STRGRGS
Streptococcus group L	Strep. group L	STRGRL
Streptococcus hyointestinalis	Strep. hyointestinalis	STRHYO
Streptococcus infantarius	Strep. infantarius	STRINA
Streptococcus infantarius ssp. coli	Strep. infa ssp. coli	STRINACO
Streptococcus infantarius ssp. infantarius	Strep. infa ssp. infantarius	STRINAIN
Streptococcus infantis	Strep. infantis	STRINF
Streptococcus iniae	Strep. iniae	STRINI
Streptococcus intermedius	Strep. intermedius	STRINR
Streptococcus lutetiensis	Strep. lutetiensis	STRLUT
Streptococcus massiliensis	strep. massiliensis	STRMAS
Streptococcus milleri group	Strep. milleri gr.	STRMILGR
Streptococcus minor	Strep. minor	STRMIN
Streptococcus mitis	Strep. mitis	STRMIT
Streptococcus mitis group	Strep. mitis gr.	STRMITGR
Streptococcus mitis/oralis	Strep. mitis/oralis	STRMITORA
Streptococcus mitis/pneumoniae	Strep. mitis/pneum.	STRMITPNE
Streptococcus mutans	Strep. mutans	STRMUT
Streptococcus mutans group	Strep. mutans gr.	STRMUTGR
Streptococcus oralis	Strep. oralis	STRORA
Streptococcus parasanguinis	Strep. parasanguinis	STRPAR
Streptococcus peroris	Strep. peroris	STRPER
Streptococcus pneumoniae	Strep. pneumoniae	STRPNE
Streptococcus porcinus	Strep. porcinus	STRPOR
Streptococcus pseudopneumoniae	Strep. pseudopneumoniae	STRPSE
Streptococcus pseudoporcinus	Strep. pseudoporcinus	STRPPO
Streptococcus pyogenes (Strep. group A)	Strep. pyogenes (Str. gr. A)	STRPYO
Streptococcus ratti	Strep. ratti	STRRAT

Long Name	Short Name	Abbreviation
Streptococcus salivarius	Strep. salivarius	STRSAL
Streptococcus salivarius group	Strep. salivarius gr.	STRSALGR
Streptococcus salivarius ssp. thermophilus	Strep. salivar. ssp. thermoph.	STRTHE
Streptococcus sanguinis	Strep. sanguinis	STRSAN
Streptococcus sanguinis group	Strep. sanguinis gr.	STRSANGR
Streptococcus sinensis	Strep. sinensis	STRSIN
Streptococcus sobrinus	Strep. sobrinus	STRSOB
Streptococcus species	Strep. species	STRSPE
Streptococcus suis	Strep. suis	STRSUI
Streptococcus uberis	Strep. uberis	STRUBE
Streptococcus urinalis	Strep. urinalis	STRURI
Streptococcus vestibularis	Strep. vestibularis	STRVES
Streptococcus viridans beta- hemolytic (small colony)	Strep. vir. beta-hemo (sm col)	STRBHES
Streptococcus viridans group	Strep. viridans gr.	STRVIRGR
Suttonella indologenes	Sutto. indologenes	SUTIND
Tatumella ptyseos	Tat. ptyseos	TATPTY
Trichosporon asahii	Tric. asahii	TRIASA
Trichosporon inkin	Tric. inkin	TRIINK
Trichosporon loubieri	Tric. loubieri	TRILOU
Trichosporon mucoides	Tric. mucoides	TRIMUC
Trichosporon ovoides	Tric. ovoides	TRIOVO
Trueperella pyogenes	True. pyogenes	ACTMPYO
Vibrio alginolyticus	Vib. alginolyticus	VIBALG
Vibrio cholerae	Vib. cholerae	VIBCHO
Vibrio fluvialis	Vib. fluvialis	VIBFLU
Vibrio metschnikovii	Vib. metschnikovii	VIBMET
Vibrio mimicus	Vib. mimicus	VIBMIM
Vibrio parahaemolyticus	Vib. parahaemolyticus	VIBPAR
Vibrio vulnificus	Vib. vulnificus	VIBVUL
Weeksella virosa	Week. virosa	WEEVIR

Long Name	Short Name	Abbreviation
Yersinia aldovae	Yer. aldovae	YERALD
Yersinia bercovieri	Yer. bercovieri	YERBER
Yersinia enterocolitica	Yer. enterocolitica	YERENT
Yersinia enterocolitica group	Yer. enterocolitica gr.	YERENTGR
Yersinia frederiksenii	Yer. frederiksenii	YERFRE
Yersinia intermedia	Yer. intermedia	YERINT
Yersinia kristensenii	Yer. kristensenii	YERKRI
Yersinia mollaretii	Yer. mollaretii	YERMOL
Yersinia pseudotuberculosis	Yer. pseudotuberculosis	YERPSE
Yersinia rohdei	Yer. rohdei	YERROH
Yersinia ruckeri	Yer. ruckeri	YERRUC
Yersinia species	Yer. species	YERSPE
Yokenella regensburgei	Yok. regensburgei	YOKREG
Zygosaccharomyces bailii	Zyg. bailii	ZYGBAI

## **16.3 Supplemental ID Test Abbreviations**

Test	Description	Test	Description
10C	Growth at 10 °C	CAT	Catalase
42C	Growth at 42 °C	CEL	Cellobiose
45C	Growth at 45 °C	CIT	Citrate
50C	Growth at 50 °C	COA	Coagulase
ACE	MBM + Acetate	DNA	Dnase
ALC	a-Lactose	ESC	Esculin
ANR	Anaerobic growth	FRU	Fructose
ARA	Arabinose	GAS	Gas from Glucose
ARG	Arginine	GEL	Gelatin
BE	Bile esculin	GLC	Beta glucuronidase
BSO	Bile solubility	GLU	Glucose
CAM	CAMP with Staphylococcusaureus	H <sup>2</sup> S	Hydrogen Sulfide
HGN	Hemolysis - Gram Negative	OPS	Optochin susceptibility
HGP	Hemolysis - Gram Positive	ORN	Ornithine
HIP	Hippurate	ОХ	Oxidase
IND	Indole	PXR	Polymyxin Resistance
KCN	Growth in KCN	PXS	Polymyxin Susceptibility
LAC	Lactose	PYR	Pyrrolidonyl arylamidase
LYS	Lysine	RAF	Raffinose
MAC	Growth in MacConkey	SBT	Sorbitol
MAL	Maltose	SLT	Growth in 6.5% NaCl
MEL	Melibiose	SOR	Sorbose
MNS	Mannose	SUC	Sucrose
MNT	Mannitol	TRE	Trehalose
MOR	Morphology	URE	Urea
МОТ	Motility	VAN	Vancomycin
MR	Methyl Red	VP	Voges Proskauer
NIT	Nitrate	XYL	Xylose
NVR	Novobiocin Resistance	YEL	Yellow/orange pigment

## **16.4 Interpretation Codes**

Interpretation Code	Interpretation Name
ACIN_IC	Acinetobacter spp.
AERM_IC	Aeromonas spp.
BURCEP_IC	Burkholderia cepacia complex
ENTC_IC	Enterococcus spp.
ENTERIC_IC	Enterobacterales
NFGNROTH_IC	Nonfermentative GNR, other than ACIN_IC, BURCEP_IC, PSEAER_IC, STEMAL_IC, ACTBACT_IC, CARHOM_IC, EIKCOR_IC
PSEAER_IC	Pseudomonas aeruginosa
STAAUE_IC	Staphylococcus aureus
STAOTH_IC	Staphylococcus spp., other than STAAUE_IC
STEMAL_IC	Stenotrophomonas maltophilia
STRBET_IC	Streptococcus beta-hemolytic
STROTH_IC	Streptococcus spp., other than STRBET_IC, STRPNE_IC, STRVIR_IC
STRPNE_IC	Streptococcus pneumoniae
STRVIR_IC	Streptococcus viridans group

BD Phoenix Automated Microbiology System User's Manual

## **17 – Index**

A	panel overview 1–9 panel testing 4–26
access levels 2–14, 2–15 alarms 4–45 antimicrobial used in Phoenix panels 15–1, 15–4, 15–5, 15– 6 AST Broth (also AST-S Broth) storage and handling 4–2 use of 4–8, 4–9, 4–14, 4–15 AST Indicator Solution (also AST-S Indicator Solution) storage and handling 4–2 use of 4–8, 4–10, 4–14, 4–15 AST results 4–35, 4–39, 5–17, 5–18, 5–19 Resistance Markers 2–39, 2–40, 3–8, 4–40 audible alarms meaning 3–8 setting the volume 2–9 verification 6–4	precautions 1–5 principles of the procedure 1–2, 1–3, 1–4, 1–5 quality control 4–15, 4–16, 4–17, 4–18 replacement parts 11–1 service 7–1 software installation 2–46 software overview 1–8 software setup 2–4, 2–6, 2–7, 2–8, 2–9, 2–10, 2–11, 2–12, 2–13, 2–14, 2–15 software update log 12–1 specifications 2–3, 2–4 startup process 2–46 system alerts 5–61 testing overview 1–10 warnings 1–14, 1–15 weekly maintenance 6–4 BDXpert system viewing triggered rules 4–40
В	_
barcode scanners 3–5 cleaning 6–7 replacement 6–43	cautions 1–15 critical panels 2–37, 2–39, 3–8, 4–20, 4–22, 4–34
BD Phoenix system alarms and errors 4–45 cautions 1–14, 1–15 daily maintenance 6–2 decontamination 6–7 explanation of the test 1–2 installation 2–2 instrument layout 3–2 instrument overview 1–6, 1–7, 1–8 intended use 1–1	date setting 2–12 setting format 2–11 decontamination 6–7 door unlocked indicator 3–5

E	inoculate panels 4–8, 4–11
	insert panels in the instrument 4–24
	log in panels 4–19
E01 7–3	log in panels downloaded from a LIS system 4-
E02 7–4	22
E03 7-4	obtain service 7–1
E05 7-5	prepare panels 4–5, 4–6, 4–9, 4–11, 4–13, 4–
E06 7-5	
E07 7–6	14
E08 7–6	print reports 4–47
	resolve panels needing attention 4–28
E09 7–6	scan a barcode 3–5
E10 7–7	select rule set 2–9
E11 7–7, 7–8	set audible alarm volume 2-9
E12 7–8	set date format 2-11
E13 7–8	set inoculum density 2–13, 2–14
E14 7-9	set instrument number 2–8
E15 7–9	
E16 7–10	set language 2–8
E18 7–10	set LIS codes for antimicrobials 2–24
E19 7–11	set LIS codes for organisms 2–21
	set LIS communications parameters 2–16
E20 7–11	set the date 2–12
E21 7–12	set the time 2–12
E22 7–12	set time format 2–12
E23 7–13	setup the software 2-4, 2-6, 2-7, 2-8, 2-11,
E25 7–13	2–12
E30 7-14	test a QC panel 4–15, 4–18
E31 7–14	update panel database 6–23, 6–24
E34 7–15	· · · · · · · · · · · · · · · · · · ·
E40 7–15	use the instrument interface 4–19
E44 7–16	view panel inventory 5–58
E50 7–16	view panel results 4-35, 4-37, 4-38
	•
errors 4–45	
<b>E</b>	
F	icons 2-34, 2-36, 2-41
floppy disk	BDXpert Triggered Rules screen 4–40, 5–21
eject button 3–6	configuration 2–6, 2–7, 2–25, 2–46
indicator 3–6	Finalization screen 5–29
	Main Status screen 5–4
Function	Needs Attention screen 5–60, 5–63
USB 3–6	Panel Inventory screen 5–61
11	Panel Login screen 5-6
Н	Panel Results screen 5–11
	System Alerts screen 5-61
how to	ID Broth
adjust for daylight savings time 2–11	storage and handling 4–2
configure custom rules 2–28, 2–30, 2–31, 2–	
	use of 4–6
32, 7–7	ID results 4–33, 5–20
copy configuration from one instrument to	adding 4–38
another 6–12	modifying 4–38
disable ID or AST test on a panel 4-20, 6-26	inoculum density 2-13, 2-14, 4-7, 4-8, 4-12
enable/disable BDXpert rules 2-36	instrument
enable/disable LIS communications 2–16	automatic light source adjustment 1-10
enter hospital/laboratory name/address 2-13	barcode scanners 1–7
	· *** ** * * ***** * * * * * * * * * *

carousel 1–6 control electronics 1–8 drive mechanism 1–6 incubation 1–7 normalizers 1–10 optical system 1–6 panel status indicators 1–7 symbols appearing on 1–13 interpretation rules activating/deactivating BDXpert system 2–9 configuring custom rules 2–28, 2–30, 2–31, 2– 32, 7–7 enabling/disabling BDXpert rules 2–36 how to select rule set 2–9 viewing rule set version 2–9 viewing triggered BDXpert rules 4–38	Save Panel Configuration 6–19 Save Panel Lot Definitions 6–16 software maintenance menu 6–8 View Syslog 6–30 weekly 6–4 Write Light Source to Disk 6–27 manual conventions 1–12 notes, cautions, and warnings 1–14 structure 1–11 summary of cautions and warnings 1–15 use of 1–11  O  On/Off switch 3–2
K	Р
keyboard key functions 3–9 location 3–2 keys  DOWN/UP ARROW 3–3 LOAD PANELS 3–5 SILENCE ALARM 3–5 soft(ware) 3–4 TAB 3–4 UNLOAD PANELS 3–4  L  LCD display automatic dimming 3–5 LIS communications	panels antimicrobials 15–1, 15–5, 15–6 automatic association of ID results 4–33 batch finalization 4–42, 4–44 critical 2–37, 2–39, 3–8, 4–20, 4–22, 4–34 disabling ID or AST test on panel 6–26 disposal 4–48 finalizing 5–16 handling recommendations 4–5, 4–9, 4–11 how to log in 4–19 how to place in instrument 4–24 how to test 4–26 ID results 4–33 inoculating 4–8, 4–11 inoculation station (photo) 1–9 inspection after inoculation 4–9, 4–11, 4–13
operation 4–50, 4–52 setup 2–16 viewing Syslog 6–30, 6–31, 6–32, 6–33	isolates 4–2 labels (applying) 4–6 materials required for preparation 4–4, 4–5 media to avoid 4–4
M	microbiological hazards 4–4 modifying panel usage 6–24 Needs Attention 4–28
maintenance air filter replacement 6–4, 6–5, 6–6 daily 4–2 decontamination 6–7 Install Panel Configuration 6–21 Modify Panel Usage 6–24 Phoenix Update Disk 6–23 Read Light Source from Diskette 6–28 Restore LIS Codes from Disk 6–14 Restore Panel Lot Definitions 6–18 Restore User Data from Disk 6–11 Save LIS Codes to Disk 6–12	overview 1–9 Phoenix Update Disk 6–23 preparing 4–5, 4–8, 4–9, 4–11, 4–13, 4–14 reagents 15–9 storage and handling 4–2 taxa for ID/AST determination 15–15 timing requirements 4–6, 4–8, 4–9, 4–10, 4–11 4–14 transportation caddy (photo) 1–9 unloading 4–48 updating panel database 4–49, 6–24

viewing results 4–35, 4–37, 4–38 password administration 2–14, 2–15 power switch 3–2  Q quality control 4–18	system alerts  "E" codes 7–1  "W" codes 7–2  indicator 3–5  reviewing 7–2  sub-codes 7–3  types 7–2  verification 6–4
rapid reporting of results 2–36, 2–37, 2–39, 2–40	-
reagents	time
used in Phoenix panels 15–9	setting 2–12
replacement parts 11–1	setting daylight savings time 2–11
reports 4–47	setting format 2–12 time zone offset 2–11
abbreviated Lab Report 2–10	time zone onset z=11
Accession Lab 5–36	U
Antimicrobial Code 5–53	•
BDXpert Rule Set Database 5–51 Completed Lab 5–33	USB
Cumulative QC 5–43	Definition 9–4
Custom Breakpoint Difference 2–27	Disk Function 7–26, 7–27
Daily Instrument 5–44	Function 3–6
enabling/disabling auto printing 2-12	LIS Code 6–12
entering hospital/laboratory name/address 2-	Restore Data 6–11
13	Restore LIS Code 6–14
Finalization Summary 4–43, 4–44	Save User Data to Disk 6–9
Interpretation Rule Set 5–47	<b>\</b> \/
Lab Report 5–26	W
Needs Attention List 5–38 Organism ID Code List 5–51	
Panel Lot 5–55	W100 7–16
Panel Lot Database 5–57	W101 7–17
QC Lot Number 5–40	W102 7–17 W200 7–17
Resident Panel 5–39	W200 7-17 W201 7-17
Resistance Markers 2-40, 3-8, 4-35	W202 7–17
setting auto report time 2–12	W203 7–18
Resistance Markers 2–39, 2–40, 3–8, 4–36, 4–40	W300 7-18
C	W301 7–18
S	W302 7–18
	W303 7–19
soft keys	W304 7–19
location 3–4	W305 7–19
software	W401 7–19
how to use 4–19	W500 7–20
installation 2–46 menu tree 5–1	W501 7–20 W502 7–20
overview 1–8	W503 7–20
setup 2–4, 2–6, 2–7, 2–8, 2–11, 2–12	W504 7–21
update log 12–1	W505 7–21
stations	W506 7–21
status indicators 3–7	W507 7–21
verifying LEDs 6–4	W510 7–21

W601 7-22

W602 7-22

W603 7-22

W604 7-23

W605 7-23

W606 7-23

W607 7-23

W608 7-24

W609 7-24

W700 7-24

W701 7-24

W702 7-24

W800 7-25

W801 7-25

W802 7-25

W803 7-25

warnings 1–15

warranty 10-1

BD Phoenix Automated Microbiology System User's Manual