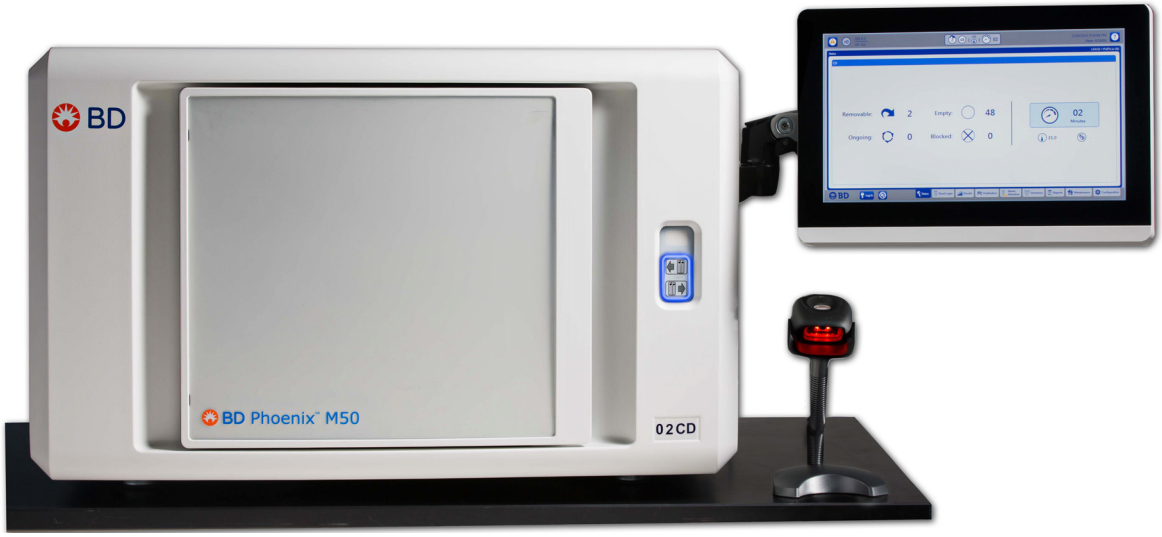
BD Phoenix™ M50

Automated Microbiology System
User's Manual



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Change History

Revision	Pages/Sections	Reason
01	All	New product release
02	2.4, 3.3.2, 3.4, 3.7, 3.8, 9, 5.2.5, 13, 14, 15, 16	Minor typographical errors; Formatting changes; Password management; Update glossary; Added monitor cleaning procedures; Added sections on lab procedures.

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1 – Introduction

1.1 Intended Use

The BD Phoenix™ 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. 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.[10, 11, 26-28]

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.[12] 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).

The introduction in 1956 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.[13] 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.[14]

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 Principles of the Procedure

A maximum of 50 identification and antimicrobial susceptibility tests can be performed in the BD Phoenix M50 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 BD BBL AST broth is cation-adjusted (e.g., Ca^{++} and Mg^{++}) to optimize susceptibility testing performance.

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 two 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 Emerge, ID only, AST only, or ID/AST combination. Unused wells are reserved for future use. BD Phoenix panels are inoculated with a standardized inoculum. Organism suspensions must be prepared only with the BD BBL™ 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 M50 instrument. BD Phoenix panels cannot be read manually.

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 8.3. 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 8.

Antimicrobial Susceptibility Testing

The BD Phoenix AST method 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.[15] 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 8. The list of antimicrobial agents and concentrations available for susceptibility testing in the BD Phoenix system is provided in Section 8.2.

The components required for testing include:

1 BD Phoenix panels with panel closures

2 BD Phoenix ID Broth

3 BD Phoenix AST Broth

4 BD Phoenix AST Indicator Solution

5 BD Phoenix AST-S Broth (for use with BD Phoenix Strep panels only)

6 BD Phoenix AST-S Indicator Solution (for use with BD Phoenix Strep panels only)

7 BD Phoenix Inoculation Station

8 BD Phoenix Panel Caddy

9 BD BBL CrystalSpec Nephelometer, the BD PhoenixSpec Nephelometer, or the BD Phoenix AP instrument

10 25 µL pipettor and sterile tips

11 Miscellaneous lab supplies (listed under **Materials Required but Not Provided:** in Section 4.3).

The BD Phoenix panel is for use with the BD Phoenix M50 instrument for either organism identification (ID) or antimicrobial susceptibility testing (AST), or for the combination of both. The panel is inclined with the inoculation ports at the top for filling. Separate inocula are added manually to the ID and AST ports. The inocula flow down the panel in serpentine fashion, filling the panel wells as the liquid front progresses toward the pad. The pad absorbs excess inoculum. Closures are manually inserted in the fill ports. An air admittance port is located in the divider area of the panel lid to ensure adequate oxygen tension in the panel for the duration of the test.

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 *Enterobacteriaceae*; 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 *mec*A-mediated Resistance with *S. aureus* (*mec*A); 8) detection of Vancomycin Resistant *Staphylococcus aureus* (VRSA); 9) detection of BD Phoenix Inducible Macrolide Resistance (IMLS) in *Staphylococcus* spp. For further information, consult the BDXpert manual.

BD Phoenix Extended Spectrum β-Lactamase (ESBL) Test[16]

The BD Phoenix ESBL test evolved from published data of known ESBL antibiogram patterns in the current literature.[18-21] Selected strains of various species with known β-lactamase genotype/phenotypes in the family *Enterobacteriaceae*, 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.[22] The BD Phoenix ESBL test is applied to *E. coli, K. pneumoniae* and *K. oxytoca*. Additionally, at the customer's discretion, it can be applied to other enteric species where production of ESBL has been reported in literature. 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** with BDXpert rule 1529. Customers can enable specific rules to reported as tested.[22]

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.[22, 23] 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.[22]

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.[22]

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. BD Phoenix cefoxitin MIC result is used to predict *mec*A-mediated resistance in *Staphylococcus aureus.* 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 *mec*A in staphylococci. The breakpoint selected in the instrument configuration is used for the categorical interpretation.

BD Phoenix Gram-Positive β-lactamase (BL) Test[16]

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 Phoenix panels will be changed to resistant.[22]

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 *mec*A-mediated Resistance Marker for *Staphylococcus aureus* (mecA)

The BD Phoenix *mec*A test is used to predict *mec*A-mediated resistance in *Staphylococcus aureu*s. The principle is similar to the CLSI-recommended Disk Diffusion test, which uses a cefoxitin (FOX) disk to predict *mec*A-mediated resistance in *S. aureu*s. The performance of the test was established against multiplex PCR methods[25] as well as the Disk Diffusion test. With the BD Phoenix *mec*A test, the *mec*A-specific FOX MICs used for detection of the resistance marker will be configured in the instrument. When the *mec*A resistance marker is detected, the interpretations for all beta-lactam drugs on the same BD Phoenix panel are changed to resistant,[22] and the BD Phoenix *mec*A 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 aureu*s. 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-S25 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 (IMLS) Test in *Staphylococcus* species

The BD Phoenix Inducible Macrolide Resistance (IMLS) Test is used to detect inducible macrolide lincosamide-streptogramin B (MLSb) resistance in *Staphylococcus* species. MLSb 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 MLSb resistance to distinguish them from isolates that are resistant to macrolides alone by efflux mechanism.

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,* 5th Edition, 2009, as well as other recommended literature.

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

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 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 two tiers, each of which functions as an 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 two 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. Fluorescent UV (ultraviolet) LEDs provide UV illumination.

1.5.1.2 Carousel Assembly

The Carousel Assembly is a cage-like structure comprised of aluminum rings and vertical ribs bolted together to form a right circular cylinder. The carousel holds 52 panel holders in two tiers. Each tier holds one normalizer panel and 25 sample panels.

During normal operation, the carousel is driven at either 1.0 RPM or 2.0 RPM, depending on the current operation. During panel location, the carousel can rotate at up to 10.0 RPM. The carousel rotates counterclockwise. A single rotation of the carousel is used to perform an inventory scan to identify panels within the instrument following a door closure. A complete test cycle requires seven minutes.

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. There is a single filter to remove dust from the electronics bay. 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 red, green, and amber LEDs mounted on a panel behind the carousel that shine through the light pipes and panels. Two columns of the carousel are exposed when the instrument door is open.

Two 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 External Barcode Scanner

The external barcode scanner 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.

1.5.2 Software and Operation Overview

Figure 1-1 – BD Phoenix M50 Instrument

The All-In-one (AIO) PC 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 AIO PC controls up to two BD Phoenix M50 instruments (see Figure 1-3. The AIO PC provides connectivity to the hand-held barcode scanner and printer. The Interface to a BD Data Management system or LIS is optionally supported by the AIO PC.

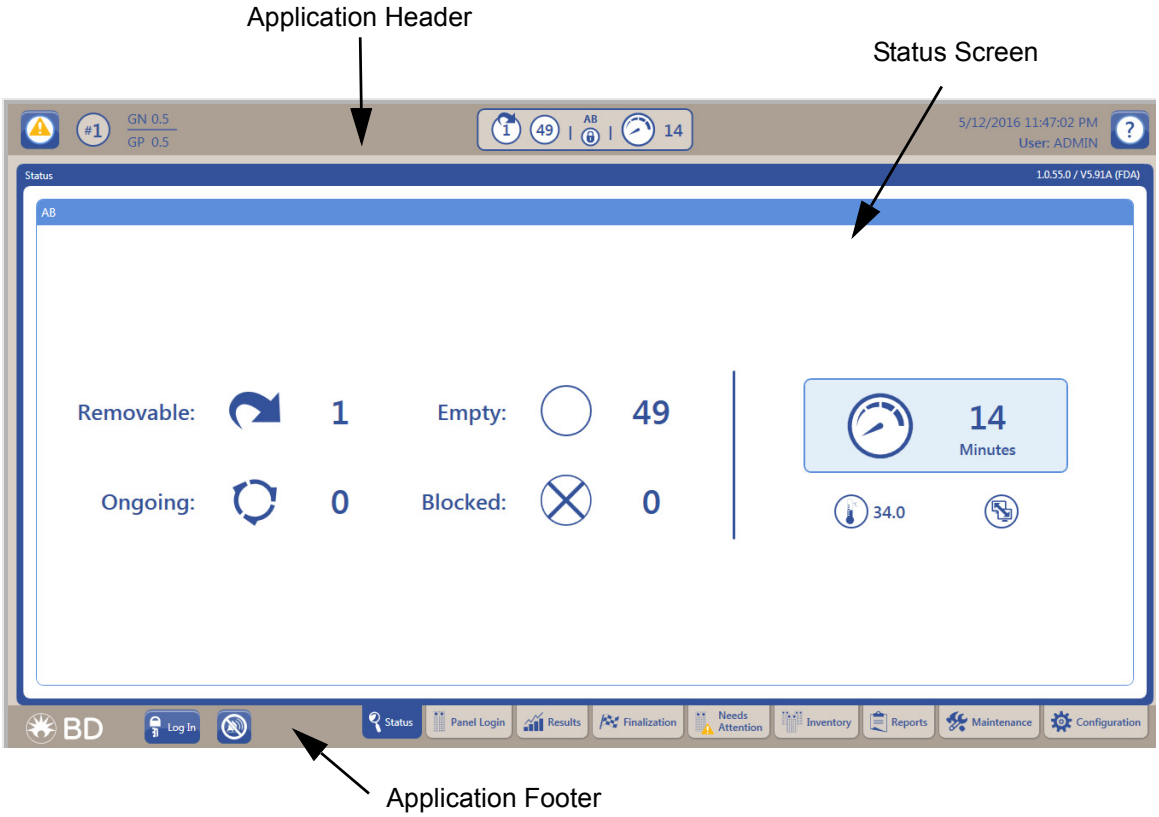

Figure 1-2 – BD Phoenix M50 User Interface for One Instrument

The User Interface on the AIO PC is divided into three regions (see Figure 1-2). The application header and footer appear on all screens of the BD Phoenix M50 instrument user interface. The middle region corresponds to the selected tab in the footer; in the figure above the status tab has been selected. The Application Header contains status information for the BD Phoenix M50 instrument. Either one or two instrument summary groups are displayed in the center of the header (See Figure 1-3). The application footer contains the tabs to navigate between different screens.

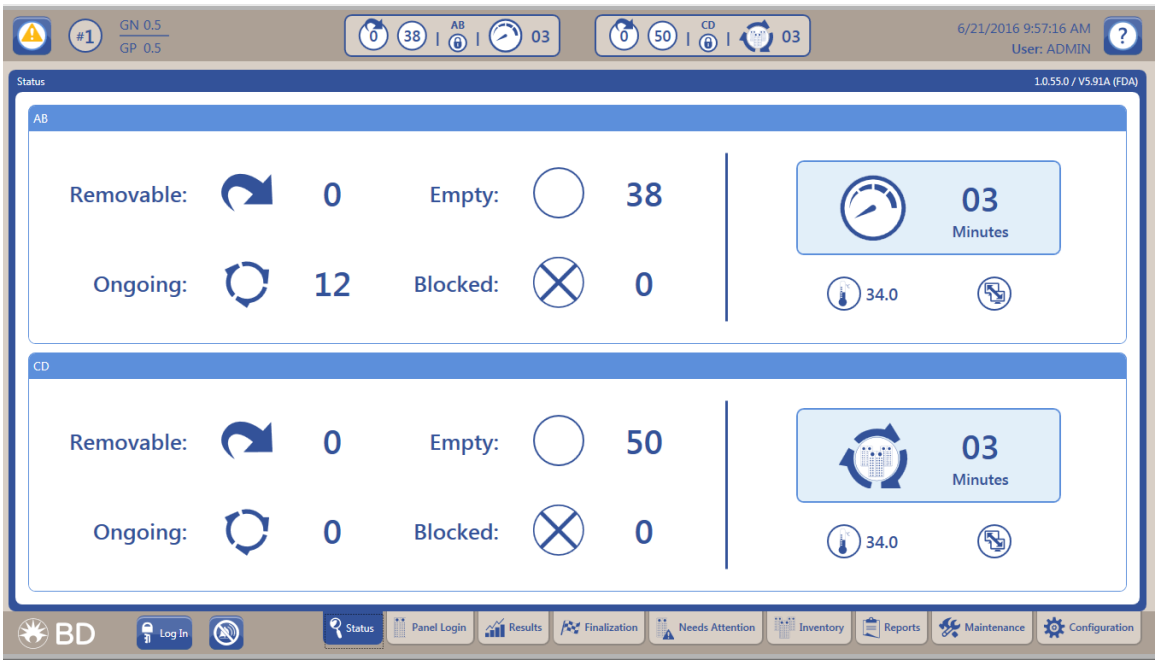

Figure 1-3 – BD Phoenix M50 User Interface for Two Instruments

1.5.3 Panel Overview

The BD Phoenix panel is available in three formats: 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 µL of inoculum in an environment that prevents significant evaporation during the course of incubation.

Figure 1-4 – Panel Inoculation Station

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.

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 M50 instrument. The caddy capacity is 20 panels. See Figure 1-5.

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 and the current time is read. Tiers perform dark readings, then the UV LEDs are turned on and allowed to warm up. UV readings are then taken for one revolution. The UV LEDs are 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.

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 (for example: Load Panels, Unload Panels) 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 Panel In/Out indicator is off (see Figure 2-7) and the **cannot get into instrument** tone sounds when a panel operation is requested.

After each test:

- The summary counters on the Status screen are adjusted to indicate current statuses
- Panels/records that require user action have a Needs Attention set
- System alerts are reported in the System Alerts list
- Auto Association occurs

The screen displays the icon below when a panel test is taking place. The number next to the icon indicates the number of minutes remaining in the test cycle.

1.5.5 Normalizers

Normalizers serve as reference panels for adjustment of the instrument's optical detection system and they are used for adjustment of the LEDs (red, green, blue and UV). For red, green, blue, and UV correction, data from the normalizer panels is 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.

Normalizers expire two years after installation. A system alert will occur before expiration to allow for scheduling replacement.

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

Automatic light source adjustment attempts to bring normalizer 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 activities such as entering panels into unaffected tiers, removing panels, and performing maintenance checks.

Based on the results of the system's Built-In-Test (BIT), as well as time and power cycling factors, the system detects that readings from the ultraviolet (UV) and visible light sources (testing LEDs) 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.

If any of the above conditions occur, E type error codes, and sub-codes will provide information for each of the tiers.

1.6 Limited Warranty

This warranty details specific legal rights. Additionally, there may be other rights that vary from region to region.

The BD Phoenix M50 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 re-manufactured 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 M50 System User's Manual.

Any damage to a BD Phoenix M50 instrument 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.

1.7 Conventions

1.7.1 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.

1.7.2 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.
- Due to the size and weight of the BD Phoenix M50 instrument, two people are required to lift the instrument in the absence of mechanical lifting devices.
- 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 electromagnetically 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 manually. 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 5.2 must be performed by qualified service personnel. Non-compliance with this warning may result in personal injury or instrument malfunction.
- 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.

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2 – Controls, Icons, Indicators, and Installation

2.1 General

This section describes instrument specification, installation, software icons, controls and indicators, and user configuration of the BD Phoenix M50 instrument.

WARNING

PROTECTION PROVIDED BY THIS EQUIPMENT MAY BE IMPAIRED IF THE EQUIPMENT IS USED IN A MANNER NOT CONSISTENT WITH THE INSTRUCTIONS IN THIS MANUAL.

CAUTION

The intake filter at the lower front right corner of the BD Phoenix M50 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.

2.2 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 warmup period (indicated by the Instrument is warming up icon). 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.

2.2.1 Instrument Installation

The BD Phoenix M50 Instrument is to be installed only by BD representatives.

CAUTION

Due to the size and weight of the BD Phoenix M50 instrument, at least two people are required to lift the instrument in the absence of a mechanical lifting device.

Language

The language setting is performed at installation by a BD representative. Supported languages include:

- English
- Spanish
- French
- Portuguese
- German
- Japanese
- Italian

The BD Phoenix M50 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 80% (non-condensing). The left, rear, and right sides of the instrument should be placed at least three inches from any wall. Environments which exceed these limits could adversely effect 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.

A stacking kit is required when stacking two instruments on top of one another.

Installation Category II and Pollution Degree 2 as per IEC 664.

2.3 Instrument Specifications

2.3.1 Specification Chart

Physical Dimensions	
Height	21 in (535 mm)
Width	32 in (815 mm)
Depth	30 in (765 mm)
Clearance–Right	21.5 in (546 mm)
Clearance–Left, Rear	3 in (76mm)
Clearance–Front	18 in (457 mm)
Weight–Empty	118 lb (53.5 kg)
Weight–Full	127 lb (57.6 kg)

Environmental Requirements	
Non-Operating Storage	
Temperature	-17.8–65 °C (0–149 °F)
Humidity	20–80% RH, non-condensing
Operating Conditions	
Temperature	18–30 °C (64.4–86 °F)
Humidity	20–80% RH, non-condensing
Locations	Level surface, No direct sunlight, No direct heat
Altitude	2,000 meters
Noise	at 1 m ≤ 55 dBA using ANSI Type 2 sound meter

Electrical Requirements	
Input Voltage	100–240 VAC
Input Current	6 Amp
Input Line Frequency	50/60 Hz

Instrument Heat Output at Input Voltage = 120 VAC	
Ambient Temperature	**BTU/hr**
18 °C	648
24 °C	464
30 °C	287

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

2.3.2 Controls and Indicators

2.3.2.1 Power Switch and Inputs / Outputs

Disconnecting power from the instrument:

1. Place power switch in the **OFF** position by pressing switch on the O side.
2. Unplug power cord from the instrument.

Figure 2-1 – Power off and disconnected

2.3.2.2 Connector Plate

Figure 2-2 – BD Phoenix M50 Connector Plate

USB Connector	**Serial (LIS) Connector**
USB Connector	**Remote Alarm Connector**
USB Host Connector (to All-in-one Computer)	**Network Connector**

2.3.2.3 All-in-one (AIO) PC controls

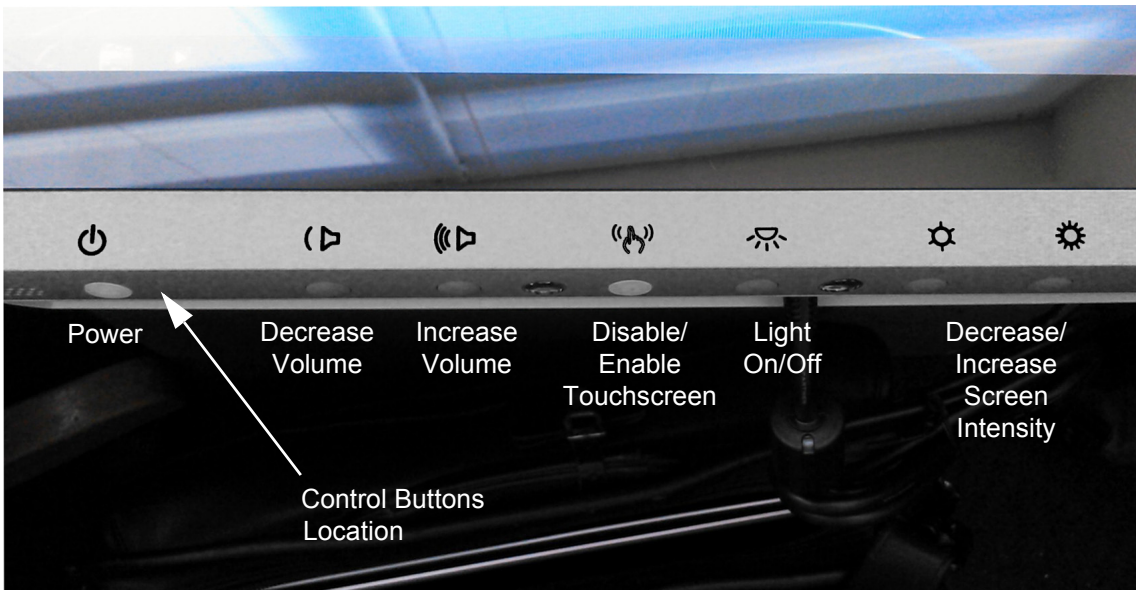


Figure 2-3 – All-in-one Controls

The AIO icons are located on the lower front portion of the PC. The control buttons can be found directly under each icon on the bottom portion of the standing PC.

2.3.2.4 Power Controls

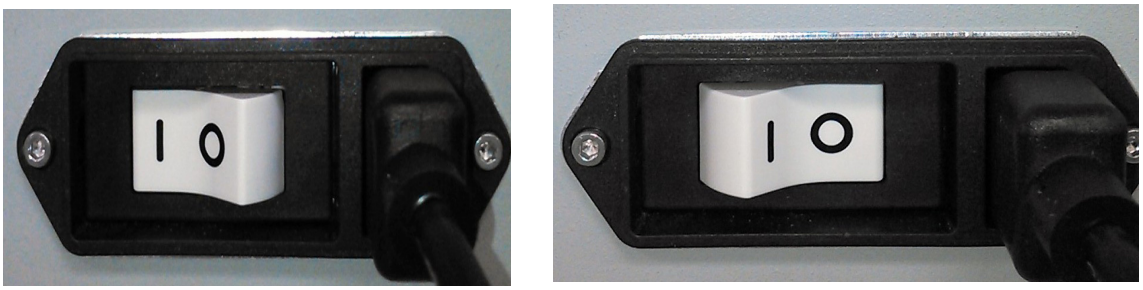


Figure 2-4 – Power On and Power Off

2.3.2.5 Other Indicators

Figure 2-5 – Symbols on Body of BD Phoenix M50 Instrument

From left to right:

- Biohazard
- Electrical Recycling required
- On/Off

2.3.2.6 Instrument Alert Indicator

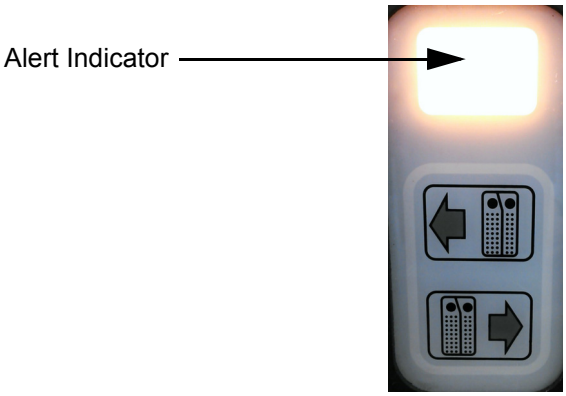


Figure 2-6 – Instrument Alert indicator

The instrument alert indicator represents the current alert status. See the information below for status details:

Instrument Alert Indicator		
LED Appearance	**State**	**Meaning**
Off	No Alerts / Instrument Communicating	The instrument does not have any outstanding alerts at this time and is connected to the AIO PC.
Blinking	Instrument not connected	The instrument is not connected or it is not communicating with the AIO PC showing the instrument to be in Isolation Mode.

Instrument Alert Indicator		
Solid On	Instrument Alert	The instrument has outstanding alerts. Details are available via the alert screen. The instrument is connected to the AIO PC.

2.3.2.7 System Alerts

As activities are performed on the BD Phoenix M50 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 (see Sections 6.2 and 6.3, audible tones (see Section 2.3.2.8), the system Alert icon appearing on the LCD screen, or the instrument's System Alert indicator flashing. A System Alert icon (see Section 2.5) in the upper left corner of the screen indicates the presence of a system alert. Touch the icon to display the System Alerts screen. The System Alerts screen enables the review any existing system alerts that may have occurred or that may still exist in the instrument.

Touching the >> icon expands the alert message providing more detailed information. All the **E** type errors are listed in Section 6.1. Not all error sub-codes can be addressed by the user.

CAUTION

Immediately respond when the system displays alert and error notifications.

2.3.2.8 Audible Tones and Alarms

As discussed above, audible tones and alarms sound to inform the user of various operational states of the instrument. Refer to the chart below for a detailed description of such tones and alarms.

Type	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

Type	Example	Sound
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, long beep
Carousel jammed	Carousel motion is impeded	High pitched trill

2.3.2.9 Instrument Door/Panel Button Status

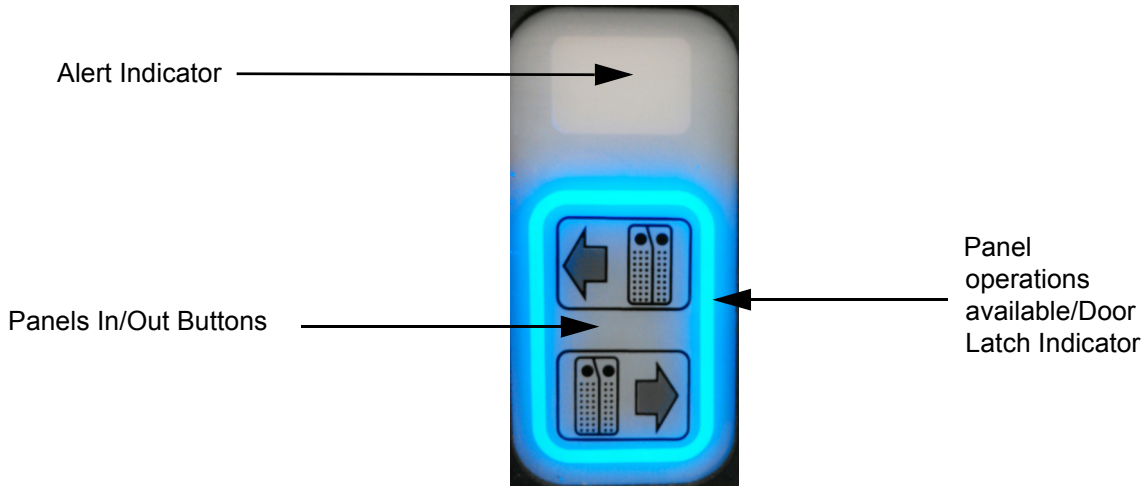


Figure 2-7 – Panel In/Out Indicator

The instrument has an indicator that provides the current panel button and door status to the user. The chart below explains the status details (refer to Section 3.3.2).

Panel In/Out Indicator		
LED Appearance	**State**	**Meaning**
Off	Panels In/Panels Out not available	If the instrument is powered: Panels In/ Panels Out are not available at this time. The door is locked and may not be opened by the user. The indicator is off when the instrument is performing an operation that may not be interrupted by a Panels In or Panels Out operation.
Blinking	The door on the instrument is unlocked	The door is unlocked and the user may open the door to access the panels.
Solid On	Panels In/Panels Out active	The Door is locked and may not be opened by the user. The user may press either the Panels In or Panels Out button.

2.3.2.10 Station Indicators

Each accessible station has a set of LED indicators providing the station or panel's status. The station indicators are located in the center of the station (see Figure 2-8). The appearance of green, amber, or red indicate the conditions shown in the table below for a given station.

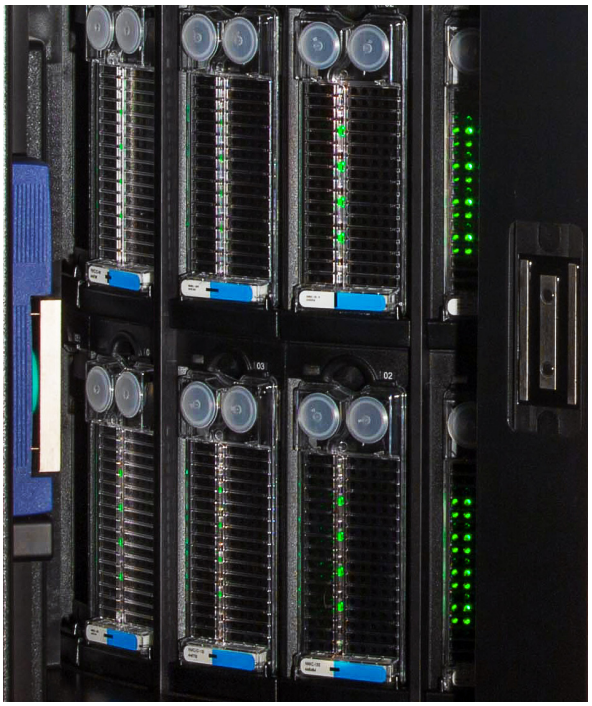


Figure 2-8 – Station Indicators

Station Status Indicators	
LED Appearance	**Meaning**
Off	Ongoing Panel (if panel is in station) or Available Station (if station is empty)
Green	Removable Panel
Amber	Panel found using locate panel function
Red	Blocked Station (also Temperature Standard Panel)

2.3.3 Printer

For an explanation of controls and indicators on the printer, refer to the manufacturer's operating instructions which is furnished separately. Note that a local printer should be connected to one of the instrument's USB ports. One printer can serve two BD Phoenix M50 instruments connected via one AIO PC.

2.3.4 Barcode Scanners

A hand-operated scanner is provided with the system to facilitate scanning panel barcodes. To scan a barcode press the trigger on the bottom side of the scanner. A single beep indicates a successful scan. Press the trigger to scan each additional barcode.

2.3.5 Touchscreen Keyboard

A touchscreen keyboard is available on the AIO PC for typing data directly into screen fields. To access the touchscreen keyboard touch the field where data is to be entered. Then touch the keyboard icon that appears to expose a full size touchscreen keyboard. When all data is entered via the touchscreen, touch the return key to close the touchscreen keyboard.

2.3.5.1 Enabling/Disabling Touchscreen Fields

The touchscreen user interface requires certain fields to be selected in order for them to be enabled or disabled. To enable or disable a field, simply touch a box and/or circle to make your selection. When the field is represented by a box, touching this box will insert a check indicating that the feature has been enabled. Touching this field again will remove the check; therefore indicating that the feature is disabled.

2.4 User Access and Management Summary

User Access

User login is accessed by touching **Log In** on the Status screen of the BD Phoenix M50 instrument application. When a user is logged in, the text changes to Log Out. The current user name is displayed in the upper right corner of application header region.

Logging In

Select **Log In** to access the user log in screen. The user name is the full user name. The tech ID will not be accepted as the user name for logging in. If improper credentials are submitted, the system will initiate an alert and prompt for retry. After 5 unsuccessful login attempts, the user account will be locked. If the user landed at this screen inadvertently or wishes to exit without logging in, select **Cancel** from the main screen.

> NOTE
>
> If the user has logged in, but the screen is idle for 15 minutes, the user will be logged out and any unsaved data will be lost.

Logging out

To access the log out screen, select **Log Out** from the Status screen and a confirmation will appear verifying that the user wishes to log out. To remain logged in, select **Cancel** to navigate back to the main application screen.

User Role Summaries

- Administrator — Lab administrator for lab location. All system functionality is accessible including system configuration. Administrators can create and delete other lab administrators and general lab users.
- General User — All system functionality is accessible except system configuration, which is read only. Users can reset their own password.

User Management

Access the user management features by navigating to the Configuration tab. The Users tab is first in the Configuration screen tab list.

Lab Administrator Users

Users that are at the Lab Administrator level will be able to access the full set of user management features.

A list of both active and inactive users of the system is displayed for Lab Administrators. User Details show the User ID Role, and Tech ID for the selected user.

Administrators can select a user from the list and perform one of the following actions:

- Reset a user's password.
- Deactivate/disable a user account. Deactivated User accounts still appear in the list.
- Add new users to the system.

General Lab Users

The only management feature available to General Lab users is the ability to change their passwords. All users will be required to change their passwords at certain intervals. To change passwords enter the new password and enter it again in the **confirm** field. Then select **Update Password**.

Password Management Criteria

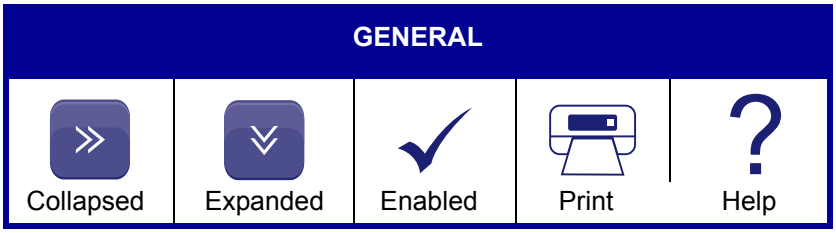
The password that the user creates must have:

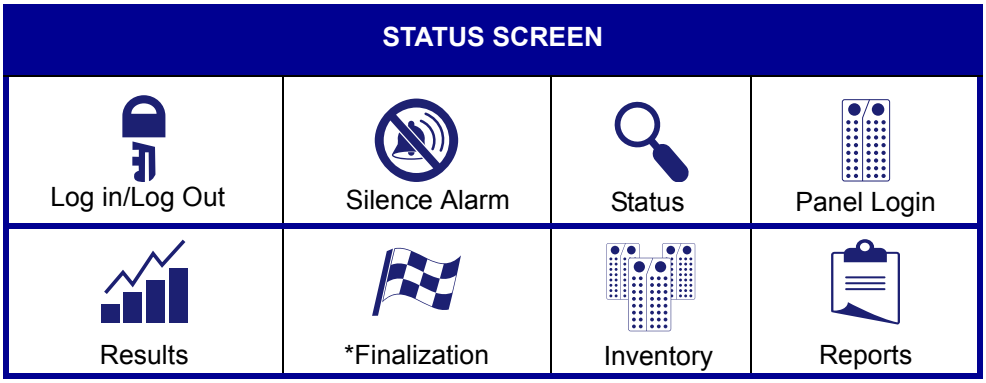
- a minimum of 8 characters appropriate for the selected language,
- at least 1 lower case and 1 upper case alphabet,
- at least 1 number and,
- at least 1 special character.

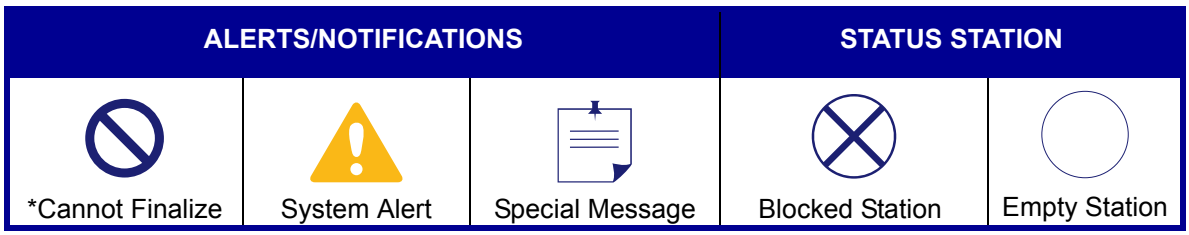
The user will not be allowed to reuse the 10 most recent passwords. Every 120 days, the password must be changed and the user will receive a notification for the same, each day, for 15 days prior to the due date. In case the password has been created by the system administrator, the user must change the password after the first login.

2.5 Software Icons

* Icon does not appear when connected to BD EpiCenter™.
** Icon does not appear when in standalone mode







2.6 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:

- User Management (Section 2.4)
- Instrument Configuration (Section 3.10.10)
- Communications Configuration (Section 3.10.3)
- Custom Interpretation Rule Set (Section 3.10.6)
- BDXpert Rule Configuration (Section 3.10.7)
- Rapid Reporting Configuration (Section 3.10.8)
- Panel Lot Definition (Section 3.10.9)

Instrument setup parameters are explained below. The Status screen, which is active immediately after instrument startup, is shown in Figure 1-2. The Status screen is the default when no activity has been initiated. This screen's tabs are covered in detail in Section 3.

Software updates are user installable. Insert the BD provided USB key in the USB connector on the AIO PC. On the Maintenance tab select Task Category: Software, Task: Upgrade Execute. The software update will be recorded on the Daily Instrument Report for reference. See Section 3.9.1 for step by step instructions.

NOTE
Custom Breakpoints
If any of the standard interpretation rule sets have changed when the software is updated or when a new BD Phoenix Update Data (PUD) is installed, then 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 3.10.6) after each system update or PUD install.

2.7 Isolation Mode

Isolation Mode is the condition that exists when communication between the BD Phoenix M50 instrument and the AIO PC is lost. Isolation Mode is designed to allow the ID/AST system to avoid test cycle gaps when the AIO PC is temporarily disconnected from the instrument. During Isolation Mode, the instrument continues to collect panel test cycle data and incubate the panels. However, Isolation Mode is not intended to enable routine workflows such as Panel Login or Removing Completed Panels. Since panel result analysis occurs at the AIO PC, no panel results are available for completed panels while the system is in Isolation Mode.

Please note the following conditions about Isolation Mode related to system operation:

- The yellow instrument alert indicator will blink when the instrument is in Isolation Mode.
- The AIO PC displays errors when communication is lost with the instrument. On the status screen, Instrument status is not available. (see Figure 2-9 below).

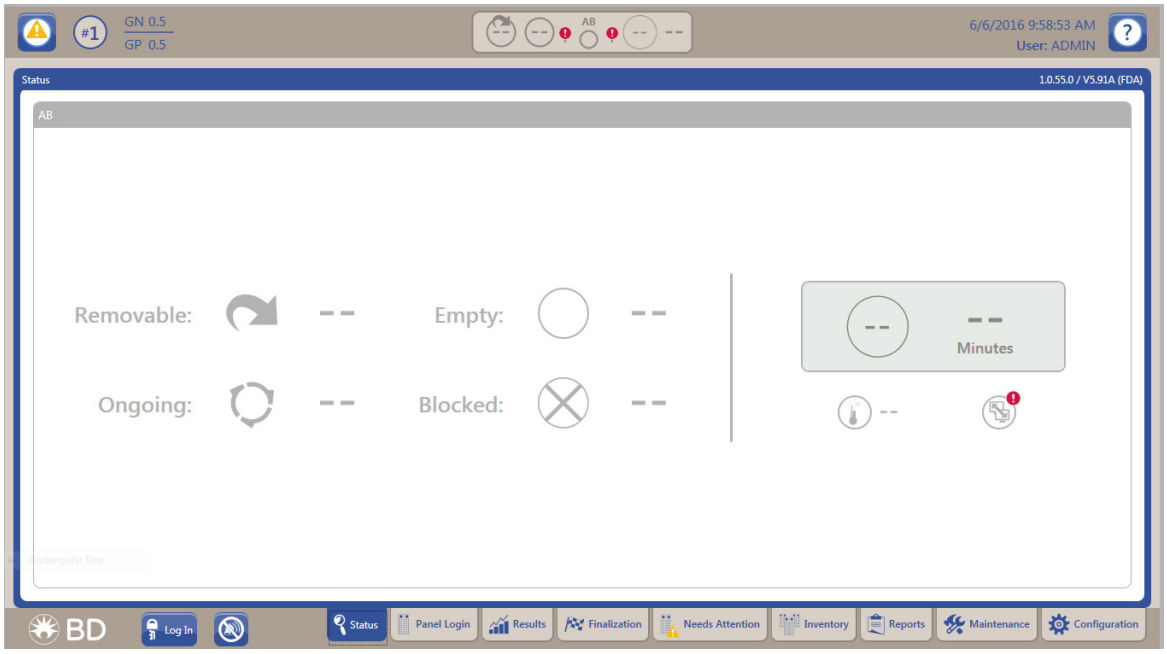


Figure 2-9 – Isolation Mode

- For a stack of BD Phoenix M50 instruments connected to the same AIO PC, each instrument can be in Isolation Mode independent of the other instrument (see Figure 2-10).

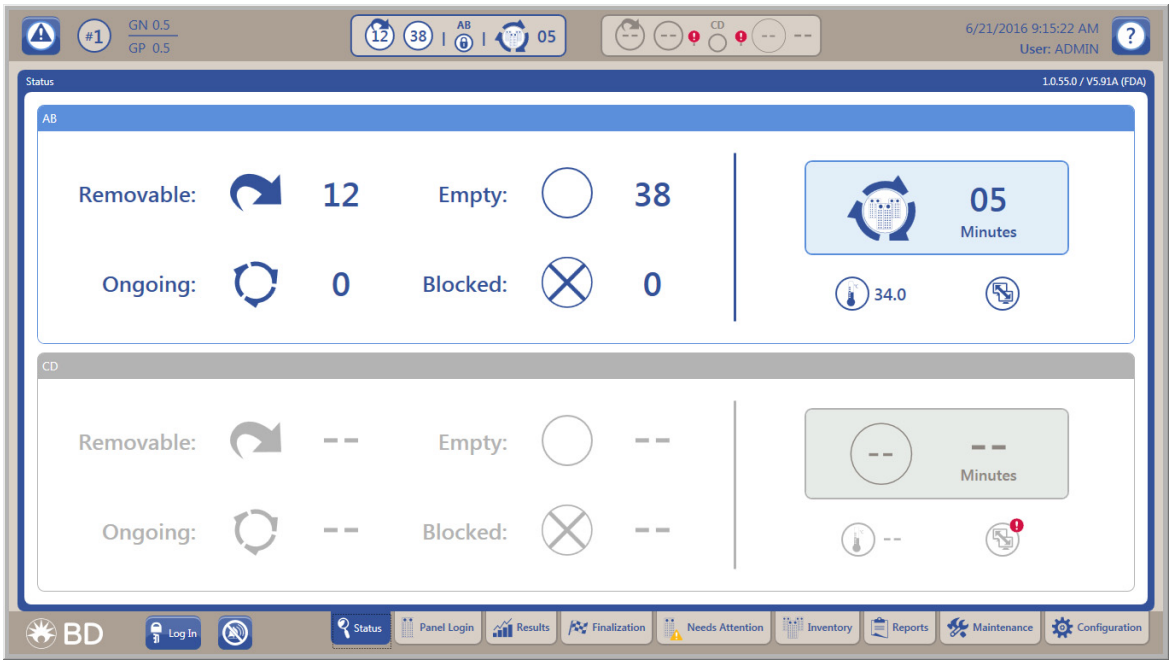


Figure 2-10 – Isolation Mode for One Instrument

- The AIO PC handles the transition of each instrument into and out of Isolation Mode independently.
- In Isolation Mode, when you open the instrument door, no station status indicators are lit. Routine workflow is not supported in Isolation Mode.
- The instrument and AIO PC both return to normal operations when communication between the two is reestablished. During the transition, test cycle data collected by the instrument while in Isolation Mode is transferred to the AIO PC and processed. Panel results are evaluated at this time for all panels that are still in the instrument when recovering from Isolation Mode.

Instrument Alert Indicator during Isolation Mode		
LED Appearance	**State**	**Meaning**
Blinking	Instrument not connected	The instrument is not connected or it is not communicating with the AIO PC

Isolation Mode Operation

- Routine workflow is not supported in Isolation Mode

Isolation Mode Troubleshooting

Isolation Mode can be caused by the following conditions:

- AIO PC malfunction
- AIO PC power or communication (USB) cable disconnected
- BD Phoenix M50 instrument application on the AIO PC has stopped working

To return to normal operating mode, check USB and power cables and reconnect if needed. Rebooting the AIO PC and/or instrument may also be necessary. If these actions do not correct the problem, contact your local BD representative.

2.8 LIS Operations

2.8.1 General

The LIS communications feature enables the BD Phoenix M50 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 M50 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 be configured to be uploaded to the LIS system also.

2.8.2 Results Upload Records

Results records are uploaded from the BD Phoenix M50 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)

2.8.3 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 your 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 M50 instrument is connected to a LIS, it cannot be connected to the BD EpiCenter system. However, if the BD Phoenix M50 instrument is connected to BD EpiCenter, then a LIS connection can be established via BD EpiCenter.

2.8.4 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 log in 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 screen. 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 3.3.2.

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 **Options** in Section 3.10.2 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.)

2.8.5 Routine System Operation

Operation of the BD Phoenix M50 instrument with an 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 M50 instrument. Consult your LIS manufacturer's operation manual for complete instructions on data entry and downloading records.

LIS systems operate either in real-time 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 by the user. After patient records are logged in, download them to the BD Phoenix M50 instrument. Any data sent to the 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. For example, the user can continue to perform tasks such as: loading the instrument, printing reports, monitoring the system for complete panels, and performing maintenance; however, it is recommended that the user be especially alert and quickly respond to any system or activity alerts that occur.

3 – User Interface Operations

3.1 Using the Instrument Interface

The touchscreen presents all of the information needed to monitor instrument status, log in panels, set up the instrument, print reports, and perform routine instrument maintenance. For more information on how to use the touchscreen refer to Section 2.3.5. Operations are presented in the form of tabs which, when selected, produce functional, interactive screens, as well as icons that graphically represent the information (e.g., a thermometer indicates the current temperature). The screen's application header presents instrument status information that is updated every few seconds. The middle region of the screen initially presents station status information. Display regions are discussed in greater detail in Section 2.

The information below details the tab functions (left to right) which appear on the Status screen's application footer.

3.2 Status Tab

The Status tab will show one or two instrument status' that report the following information:

- Removable: number of panels ready for removal
- Ongoing: number of panels in testing progress
- Empty: number of empty panels
- Blocked: available stations that cannot be used due to an error in the system.
- Time: time remaining for test cycle
- Temperature
- Connection status

3.3 Panel Login Tab

Panel Login enables the log in of panel demographic information to be tested. Depending on the type of panel being used, not all fields listed below may appear on the screen. For information on logging in QC panels, refer to Section 4.3.1. More than one of the same panel type may be logged in for an accession number, but the system displays a notification for duplication with an activity error message.

Panel Login Fields:

Accession Number

Type in or scan an accession number, up to 20 alphanumeric characters. If the accession barcode was 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: * ? [ ] ! # |.

Sequence Number

Type in or scan the panel's sequence number. (If the Sequence Number was 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. Enter a panel sequence number to save a record. If an existing sequence number is entered, the system displays the Panel Results screen.

Isolate Number

Defaults to isolate number 1. Valid isolate numbers are 1 to 20. If an accession number has been entered, an isolate number must also be entered. If the isolate number is changed from 1 to another value, an accession number must be entered.

Critical Check Box

Defaults to disabled. The system can be configured (Section 3.10.8) to provide a notification 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 Check Box

Defaults to enabled if a combination panel sequence number is scanned. This field appears only when a combination panel is used. This field is automatically checked (enabled) when a QC panel is logged in.

AST Check Box

Defaults to checked if a combination panel sequence number is scanned. This check box appears only when a combination panel is used. This field is automatically enabled when a QC panel is logged in.

Organism ID/Test Strain

Use the drop down list to select the organism ID. Organisms are listed in alphabetical order. Enter the first few characters of the organism name to jump to that portion of the list quickly.

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 Number

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 number barcode is scanned.)

Expiration Date (Panel Lot)

This field appears for QC panels. 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 number barcode is scanned.)

ID Broth Lot Number

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

Expiration Date (ID Broth)

This field appears for QC panels. An expiration date must be entered to save a QC panel.

AST Broth Lot Number

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

Expiration Date (AST Broth)

This field appears for QC panels.An expiration date must be entered to save a QC panel.

Indicator Lot Number

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

Expiration Date (Indicator Lot)

This field appears for QC panels. An expiration date must be entered to save a QC panel.

3.3.1 Logging in Panels

The inoculum density of the panel is set in Configuration. The density setting cannot be changed during Panel Login. The only way to use a different inoculum density is by blackening well A-17 as described in Section 4.3.

In order to insure optimal system performance for Yeast ID panels only, 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. Select the **Panel Login** tab.
2. Select **Clinical**.
3. If the receipt of a special notification is desired (audible alarm and/or automatic printing of a Lab Report) when panel results are obtained (ID only, partial, or complete), select Critical. More information about critical panels is provided in Section 3.10.8.
4. In the Accession Number field, type in or scan an accession number.
5. In the Sequence Number field, type in or scan the panel's sequence number.
6. The Isolate Number field defaults to isolate number 1. Type in the isolate number, or touch the **+/–** to increase/decrease the number. Valid isolate numbers are 1 to 20. Enter an isolate number if an accession number has been entered.

7 For Yeast ID panels, a media type must be specified in the Media field. If a media type has not been specified, a workflow error is generated when the panel is attempted to be saved. 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 OPTIONS in Section 2) which appears when a Yeast ID panel sequence number is scanned during login.To select a different media, use the drop down box listing all media types (abbreviations), sorted alphabetically. (When the media type is selected, the full name appears at the top right of the screen.) Select the media type.

8 If either the ID or AST portion of a combination panel is only being used, disable the part of the panel you are not using.

9 If you disable ID on a combination panel, or if an AST-only or BD Phoenix™ Emerge panel is not being used, the Organism ID field appears. If the system is not performing the organism identification, an organism ID for SIR interpretation must be provided. (If an AST panel is being tested and an organism ID is not entered, the panel will go to **Needs Attention** when the instrument completes reading. An organism ID will have to be provided in order for the BDXpert system to interpret MIC results.) Highlight the desired organism from the drop-down box. Organisms are listed in alphabetical order. Enter the first few characters of the organism name to move up to that portion of the list quickly. Select the desired organism. The desired organism can also be scanned from the barcode list of organisms found in the Quick Reference Guide.

10 Select **Save** to save the information.

11 Place the panel in the instrument (refer to Section 3.3.2). The following functions can be performed from Panel Login:

Save – saves the information displayed

Repeat Data – enters the last accession number and media types 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)

Cancel – clears the displayed record from the screen

3.3.2 Inserting Panels in the Instrument

Panels are inserted with the reaction (and panel sequence barcode label) sides facing the interior of the instrument.

1 Select Panel In (see Figure 3-1)

2 When the blue light is blinking, open the instrument door. An audible tone will sound and the unlock icon will be visible.

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.**

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.

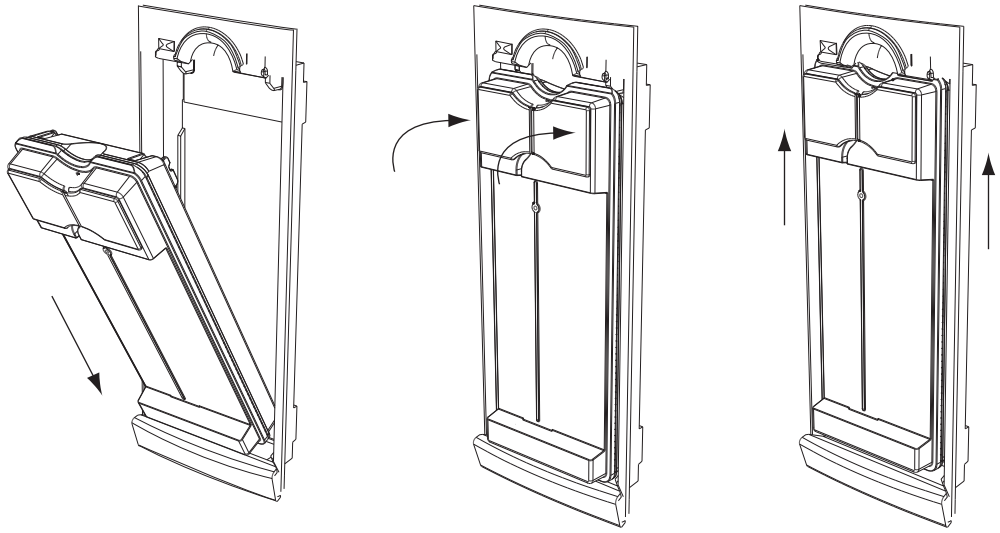
6 Allow the panel to move upward into place.

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.

NOTE

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



Insert bottom of panel into panel holder.

Pivot top of panel up and back into the holder. DO NOT SNAP THE PANEL BACK AGAINST THE HOLDER.

Make sure the panel moves upward into place.

Figure 3-1 – Inserting Panels

3.3.3 Unloading and Discarding Panels

When panel testing is completed, panels should 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. Select **PANELS OUT**.
2. When the blue Panel In/Out indicator blinks, 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. Open the door and continue removing completed panels.
6. Discard the panels in a biohazard container.

3.4 Results Tab

Results enables the review and modification of panel test results. Results 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

Results can be accessed in several ways:

- scanning a known panel sequence number or accession number with the external scanner while the Status screen is displayed
- selecting **Results** from the Status screen (see Figure 3-2)
- scanning or entering a known panel sequence number while the Panel Login screen is displayed
- selecting **Delete** or **AST Results** for a panel in the Needs Attention tab when the Delete option is active
- selecting **AST Results** from the Batch Finalization screen
- selecting **Results** from Inventory (Section Figure 3.7) or Panel Lot Definition (Section Section 3.10.9).

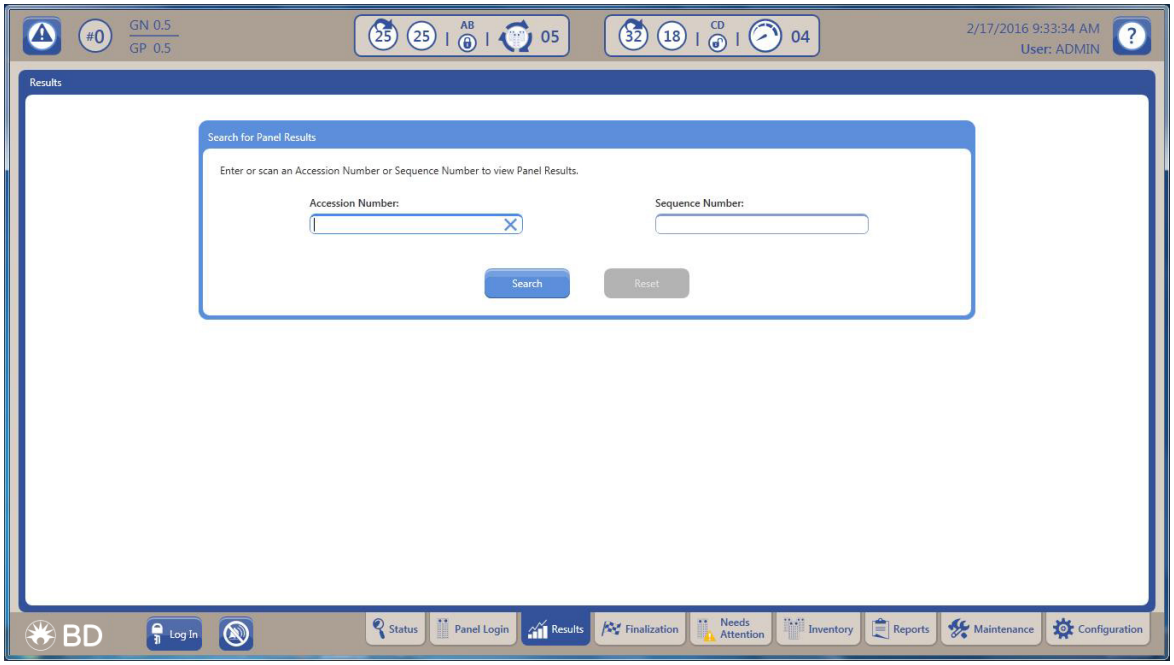


Figure 3-2 – Results Screen

Typical Panel Results are shown in the figure below. (Figure 3-3)

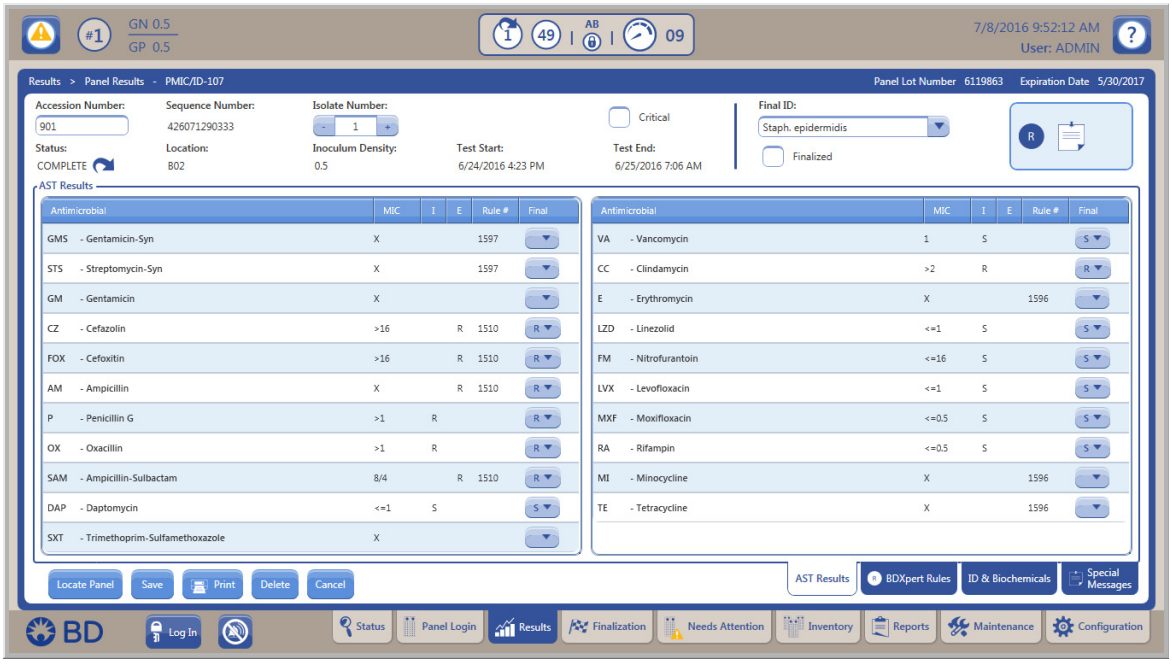


Figure 3-3 – Panel Results Screen

Actions available from all screens are:

- **Locate Panel** – causes the instrument to locate and indicate the current panel and unlock the door
- **Save** – saves any changes
- **Print** – prints a copy of the Lab Report for the current panel
- **Delete** – deletes the panel results
- **Cancel** – returns user to initial Search for Panel Results screen

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 six months.

The type of panel is shown in the title area of the screen. The inoculum density used for the identification (if applicable) is shown in the results header area after the first test cycle completes.

AST Results Sub-Tab

The read-only field displays the abbreviation and name for the antimicrobial and sometimes even describes the Minimum Inhibitory Concentration value determined by the instrument.

BDXpert Rules Sub-Tab

When BDXpert Rule is selected, the following are displayed (note that all fields may not be displayed depending on the type of panel and whether or not the instrument is connected to a BD EpiCenter system):

- Rule Number
- Status
- Resistance Marker
- Name
- Rule Description

ID and Biochemicals Sub Tab

When ID and Biochemicals is selected, the following appears:

- Instrument Organism ID which may consist of Instrument Organism ID, Confidence Value, and Up to 5 Supplemental Tests if the panel was set up using low inoculum
- Biochemical Results which consist of: Biochemical Abbreviation, Actual Result (+, -,?, or X) or Expected Result (+, -, V, or blank) shown in Figure 3-4
- Special Messages (icon represented in Figure 3-4)
- Needs Attention (icon represented in Figure 3-4)

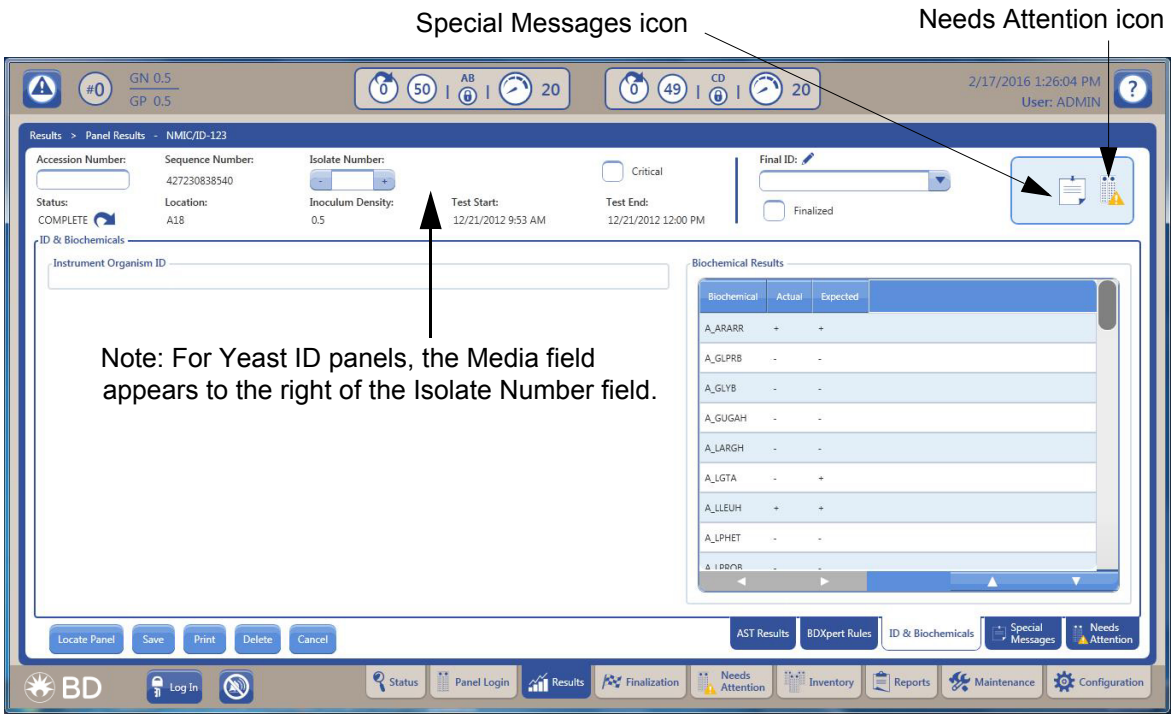


Figure 3-4 – ID and Biochemical Results

If a Needs Attention (see Section 3.6 Needs Attention Tab) exists for the panel, it appears in the results header area. If a special message (see Section 3.4.8) exists for the panel, an icon is shown in the results header area. If a Resistance Marker has triggered for the panel, the Resistance Marker icon (see Section 2.5) is shown in the results header area.

If a panel is recalled by accession number only, and there is more than one panel attached to the accession, the Results List screen appears. From this screen, select the specific panel to review/modify.

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

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 an 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.

Different results appear depending on which tab is selected. The header information remains the same no matter which tab is selected:

Panel Results Fields:

> NOTE
>
> Modifying the Accession Number or Isolate Number may invoke Auto Association which can change results.

Accession Number

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 Results List screen appears.

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 Number

This field cannot be edited.

Isolate 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 (BD 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)

Critical

Enable this field to mark the panel as critical. An audible alarm and/or an automatically printed Lab Report (or neither) notification can be configured (Rapid Reporting configuration (Section 3.10.8) for critical panel results (ID results have been obtained, partial panel results, or complete panel results).

Previously marked critical panels can be disabled.

This field does not appear for QC panels.

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.

Location

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

Inoculum Density

This field cannot be edited.

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.

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) organism ID cannot be manually selected if there is no instrument-based ID listed.

Note that if the **Modify Related Panels** check box 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 4.4).

Organisms are listed in alphabetical order. Enter the first few characters of the organism name to find that portion of the list quickly.

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.

Finalized

Check the box to 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, MIC results processing 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.).

Special Messages icon

Needs Attention icon

Panel Lot Number

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

Expiration 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 Final ID of Related Panels Check Box

This field appears when the Final ID field is modified. Defaults to be 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, disable this field as it has no affect on related QC panels. This field does not appear if the EpiCenter system is attached and communicating.

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.

3.4.1 Adding/Modifying ID Results

The system allows an organism ID to be entered manually, or the organism identified by the instrument can 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 screen (accessible via **Special Messages**), or through other tests performed. To add/modify the Final ID:

1. Select Final ID field in the Results header.
2. Highlight the desired organism.
3. Press the Save button to save.

The following icon appears:

3.4.2 Modifying AST Results

There may be times when the Final SIR results for a panel need modification. Note that 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, the SIR results can be modified manually if desired.

To modify the Final SIR results:

1. Select **AST Results** from Results
2. Select the **FINAL SIR** field for the desired antimicrobial. The following selections are available:

   S(usceptible)

   I(ntermediate)

   R(esistant)

   X = Invalid, cannot interpret
   (see Table 3-1 in Section 2)

   N(not Susceptible)*

   Blank (indicates ID is required)

* 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.

3.4.3 Modify Panel Usage Sub-Tab

Results will display Modify Panel Usage when the currently recalled panel:

- is an ID/AST Combination panel type and both sides of the panel are enabled
- status is not complete
- has no instrument organisms determined for the panel
- does not have any AST Complete set on its AST side

The user can disable the ID or the AST side of the panel when no other changes have been made to the panel on the Results screen. When the user disables the ID or AST side of the panel, no other tab will be accessible. If the user attempts to leave the tab, a message will be displayed instructing the user to save or cancel the panel usage change.

To modify panel usage:

1. Select **Results**.
2. Enter or scan the panel barcode sequence number of the panel whose usage you wish to modify. The system automatically completes the Accession # and Isolate # fields, which are read-only.
3. Select **Modify Panel Usage**.
4. The following screen appears:

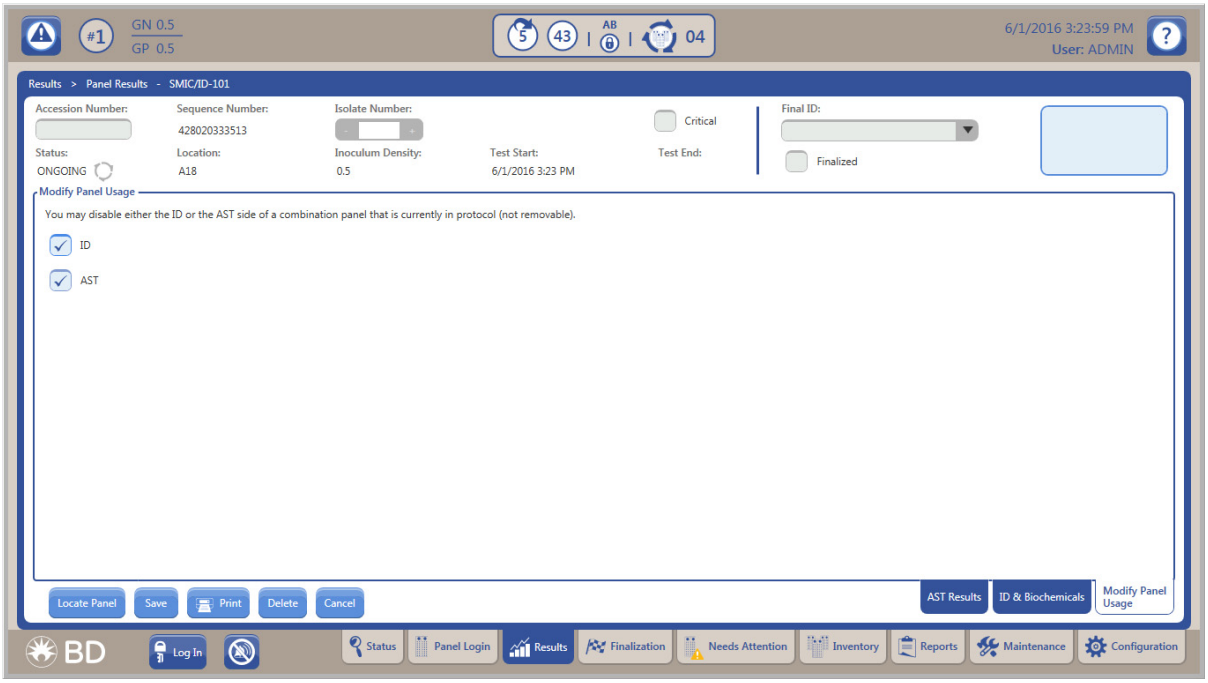


Figure 3-5 – Modify Panel Usage Screen

5 Select **ID or AST** for the side of the panel to be disabled. If both are selected then workflow alert code W305 will be displayed. The screen data will be maintained and the save attempt will be stopped.

6 Select **Save** to save the panel modification.

Note the following conditions for panel usage modification:

- No information for related panels is modified when panel usage is changed.
- 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.
- 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.

3.4.4 AST Results Sub-Tab

Antimicrobial

Read-only field showing the abbreviation and name 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
≤	**no** growth occurred in all of the concentrations 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 (see Section 8.3) 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 3-1 – MIC/ SIR Values and Causes). Check the Special Messages displayed on the screen (Section 3.4.8 Special Messages Sub-Tab) 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)

Status

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(nstrument SIR)

This field is the instrument interpretation for the MIC based on the breakpoints currently running in the system (selected in Section 3.10.10 Instrument Sub-Tab).

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)

* 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.

I(nstrument 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.

Rule #

Read-only field that shows the numeric designation of the highlighted rule.

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 following table provides explanations of different combinations of blank and X results. Detailed explanations for actual results are provided as Special Messages (Section Section 3.4.8).

Antimicrobial	MIC	Instrument SIR	BDXpert SIR	Final SIR	Possible Cause Examples
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	X	[Blank]	X	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	X	[Blank]	X	SIR is suppressed by a BDXpert rule. User must provide Final SIR based on manual interpretation or additional testing.

Antimicrobial	MIC	Instrument SIR	BDXpert SIR	Final SIR	Possible Cause Examples
Any Drug	X	[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.
All Drugs	X	[Blank]	[Blank]	[Blank]	This species is not included in the BD Phoenix AST taxonomy; perform an alternative method. 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	X	[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	C	[Blank]	R	R	Rapid Completion SIR (BDXpert SIR based on ID and/or another completed drug and/or resistance marker result).

Table 3-1 – MIC/SIR Values and Causes

3.4.5 BDXpert Rules Sub-Tab

The BDXpert Triggered Rules screen provides a view of the BDXpert system rules that have been triggered for a panel (the panel currently selected in the Results tab). Other views available are: a listing of rules that have been triggered, the text of those rules, the effect that the rules have on Final SIR values, and the ability to accept or reject pending (manual) rules. Additionally, all rules can be re-run.

After all rules have been reviewed and Accepted/Rejected, any changes must be saved.

The BDXpert Rules tab does not appear, and the screen is not available if the BD EpiCenter system is attached and communicating with the BD Phoenix M50 instrument. However, if communications with the BD EpiCenter system is lost, and the BDXpert system is reactivated in Instrument Configuration (Section 3.10.10), the tab reappears and the screen can be accessed. When communications with the BD EpiCenter system is restored, BDXpert rules interpretations are once again performed at the BD EpiCenter system.

Rules Field

Rule

Read-only field that shows the numeric designation of the highlighted rule.

Status

Shows the status of the 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) is set in the BDXpert Rule Configuration screen (Section 3.10.7). Statuses 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 **Accept** or **Cancel**. Once a rule is accepted or rejected, the status can only be changed by re-running the rules.

3.4.6 Lot Information Sub-Tab

This sub-tab provides a listing of disposables used in the setup of panels. To access this sub-tab, follow the steps below:

1. Enable QC Lot Support (see Section 3.10.2) in System Configuration.
2. Go to Panel Lot Definition (see Section 3.10.9) and scan in the barcodes.
3. Go to Results and enter an Accession Number.
4. Select Search.
5. Lot Information Sub-tab appears (see Figure 3-6).

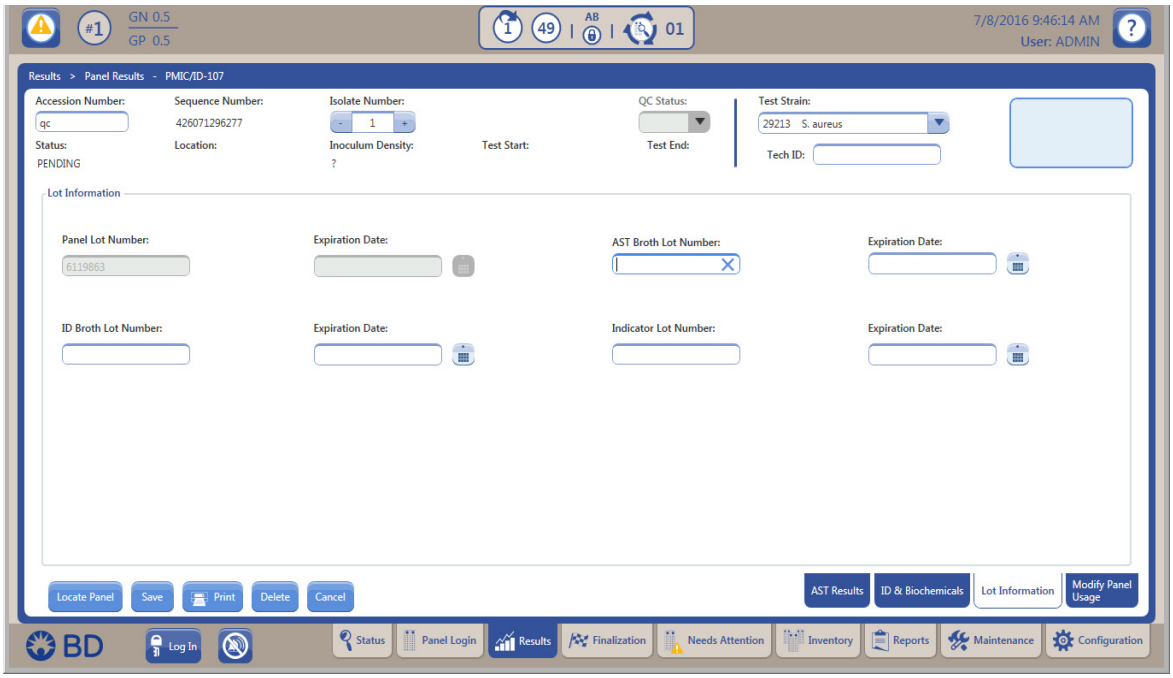


Figure 3-6 – Lot Information Sub-Tab Screen

3.4.7 Instrument Organism ID Sub-Tab

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.** 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 this field. The user must select the desired organism to enter into the Final ID field.

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 on the Special Messages screen 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. The letter **X** indicates an error.

Expected

Read-only field showing the expected biochemical result according to the Instrument Organism ID: **+** or **–** for the organism. The letter **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.

Resistance Marker Field

Resistance markers are shown in the order in which they trigger. The following information is shown when a Resistance Marker is detected and is displayed on the BDXpert Rules tab:

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

3.4.8 Special Messages Sub-Tab

Special Messages allows information to be accessed 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**, an icon is displayed in the header area of the results screen.

Special Messages on a recalled panel are shown according to hierarchy on the Special Messages window.

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

3.4.9 Needs Attention Sub-Tab

Needs Attention provides a list of all needs attention reasons, listed in priority order as shown in Table 3-2. When any of these conditions occur, the panel will have a Needs Attention reason code set and the Panel with a Needs Attention reason will be displayed on the Needs Attention screen. To ignore a Needs Attention reason, select the corresponding field next to the condition. For additional information on Needs Attention see Section 3.6.

3.4.10 Lab Report

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

The QC Lab Report is accessible from the Reports menu and Results screen. 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/PUD version.

Body of Report: Top Region: Accession Number, Isolate Number, Sequence Number, 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, 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 (Section 3.10.10) to print an abbreviated lab report. The abbreviated report does not contain the individual biochemical results for ID or ID/AST panels.

3.5 Finalization Tab

Finalization enables the review and finalization of panel test results in a batch mode or individually. Panel results can be finalized 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 screen are read-only. To modify information for a panel, select **Results**. When the instrument is connected to the BD EpiCenter Data Management System, the Finalization screen 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 reasons. Eligible panels are sorted first by accession number and then by isolate number.

When **Batch Finalize** is selected, the hourglass icon indicates that the finalization operation is in progress. A maximum of 200 panels may be finalized in a given finalization session.

To finalize/batch finalize panels:

1. If there are no panels to be finalized, no data appears on the Finalization screen. If there ARE panels to finalize, the following options appear:
2. To finalize ALL eligible panels, select **Finalize**.
3. To finalize panels one at a time, check the box next to the panel, then select **Finalize**.
4. To print a summary report of all panels eligible for finalization, select **Finalized**. This report shows the Accession Number (primary sort), Isolate Number (secondary sort), Test End date and time, Sequence Number, Instrument Number/Station, and Finalized status (* if finalized, blank if not). Select the panel row to go to the **Results** tab.
5. If **Results** is accessed to add or modify information before finalizing a panel, be sure to save the modifications, and return to the **Finalization** screen.
6. Once an individual (or batch of) panel(s) has been finalized, the **Finalized** button appears on the Finalization screen. This action enables the printing of 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.

Two types of reports, standard Lab Report(s) and the 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.

Finalization fields:

Sequence Number

Read-only field showing the panel's sequence number.

Accession Number

Read-only field showing the panel's accession number.

Isolate Number

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.

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, select **Results**.

3.6 Needs Attention Tab

Needs Attention displays 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.

When viewing the Needs Attention panel list, 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 screen.

The Needs Attention screen lists the highest priority reason (see Table 3-2 below). Selecting a panel opens the results screen in the Needs Attention tab, listing additional reasons if they exist. Two reports are available for printing: all Needs Attention reasons, and highest priority Needs Attention reasons.

Condition	Active Operations
Test Aborted	• ignore • locate panel • delete panel
Can Not Identify Barcode	• ignore • locate panel
Can Not Read Panel Wells	• locate panel • delete panel
Panel Lot Expired	• ignore • clear NA
Invalid AST Results	• ignore
Panel Missing	• ignore • delete panel
No Growth on Panel	• ignore • locate panel • delete panel
Panel Lot Undefined	none to address condition
Review QC results	• ignore • locate panel • delete panel • panel results
Missing Accession Number	• locate panel • panel results
Missing Organism ID	• panel results
Can Not Determine Organism ID	• ignore • panel results
Invalid Organism ID	• ignore • panel results
Organism ID Conflict	• panel results
BDXpert Rule Flagged (if enabled and manual)	• panel results
Pending Too Long	• ignore

Table 3-2 – Needs Attention Resolutions

The Needs Attention screen lists the first 100 panels with a Needs Attention, 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 screen can still be viewed.

Needs Attention resolution options

Ignore Check Box – check to ignore the Needs Attention condition. Ignore does not correct the Needs Attention reason code, but it informs the system that the problem has been acknowledged by the user.

Reason – lists the reason for the Needs Attention.

Locate panel – causes the carousel to rotate to the panel's location and lights the station where the panel resides.

Save – saves any selections that are made.

Print – enables the printing of a Needs Attention List report.

Delete – delete all panel results.

Cancel – removes any selections that have been made.

These options are designed to enable the correction of (whenever possible) the condition causing the panel to need attention. Where it is not possible, other resolutions are provided. **AST Results** displays the Panel Results screen, where the Needs Attention condition may be able to be corrected by adding information to the panel record.

To resolve panels that need attention:

1. Access the Needs Attention screen.
2. Refer to the chart below for detailed information on the particular Needs Attention reason.
3. Press the AST Results tab to access Results (to add or modify information), the Delete button to delete the panel, check Ignore or Locate Panel to find the panel in the instrument.

Condition	Meaning	Possible Cause(s)	Resolution(s)
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
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
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

Condition	Meaning	Possible Cause(s)	Resolution(s)
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
Invalid AST results	At least one MIC cannot be interpreted. (Excludes QC panels.)	Refer to Table 3-1	Repeat testing of the antibiotic that cannot be interpreted
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
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
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
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
Missing accession number	Panel is missing accession or isolate information. (Orphan panel.)	Failure to enter accession or isolate information	Press the "panel results" key. Add the accession number using the barcode reader or by typing it in
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	Select the organism ID. Any BDXpert rules triggered by the given ID will automatically be presented at this point. Select or ignore the rules and save. When completed, exit to see complete test 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	Repeat testing. Check the following: • Culture purity • Inoculum density • Correct panel used? • Organism may not be in the BD Phoenix database
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	Use alternate method
Organism ID conflict	Panel completes testing and has at least one related unfinalized panel that contains a different Final ID. Excludes QC panels.	Completed panel has at least one related panel that contains a different ID	Select Results and choose an organism. Selecting the organism may trigger BDXpert rules. If the rules are configured as manual, BDXpert appears
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, select Accept. To reject the rule, select Reject. Use ReRun 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, select Special Messages (if present) to view Special messages about characteristics of the organism.
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

3.7 Inventory Tab

Inventory provides a listing of all panels in the instrument (except temperature reference panels). This listing can be sorted in ascending or descending order by the following fields: sequence number, accession 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 screen configuration (primary/secondary) used. If there are no panels in the instrument **No Data Available** appears on the screen.

The top of the Panel Inventory screen 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.

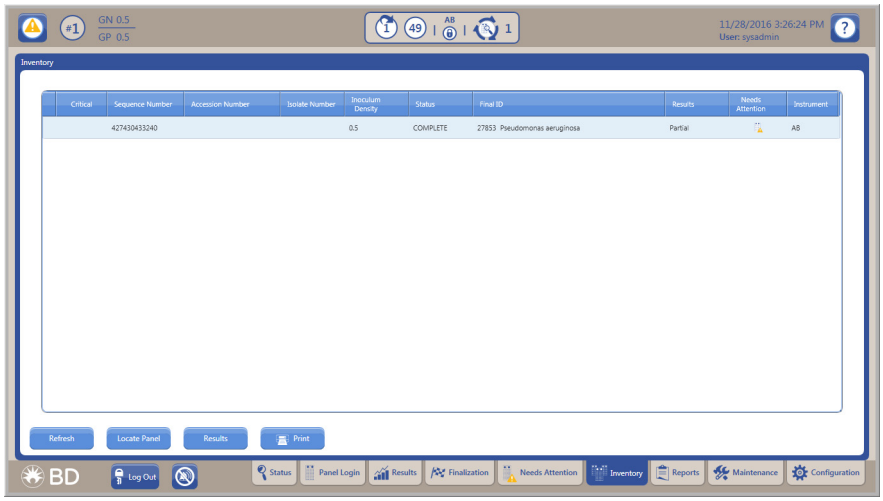


Figure 3-7 – Inventory Tab Screen

The following fields are shown on the Panel Inventory screen (if the information is known):

- A **!** (exclamation mark) at the beginning of the row indicates that a critical panel or a panel with a resistance marker has not been acknowledged.
- Critical - checked if panel has been marked as Critical at login.
- Sequence Number (of the panel).
- Accession Number (panels without accession numbers are listed first.)
- Isolate Number.
- 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).
- Final (Organism) ID.
- 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.
- Needs Attention - the active Needs Attention icon appears if an unignored Needs Attention reason exists; **blank** when no Needs Attention reasons exist or they have all been ignored).
- Instrument - in which instrument the panel is located.

After the list appears, highlight a panel and access the Results screen to view or edit panel information, perform an instrument locate panel operation, or to print a Lab Report for panels with final or partial results.

3.8 Reports Tab

Numerous instrument reports are available for printing. Click each report to learn more.

- Accession Lab Report: For more information, see Section 3.8.3.
- Antimicrobial Code Report: For more information, see Section 3.8.12.
- BDXpert Rule Set Database Report: For more information, see Section 3.8.10.
- Completed Lab Report: For more information, see Section 3.8.2.
- Cumulative QC Report: For more information, see Section 3.8.7.
- Daily Instrument Report: For more information, see Section 3.8.8.
- Interpretation Rule Set Report: For more information, see Section 3.8.9.
- Needs Attention List Report: For more information, see Section 3.8.4.
- Organism ID Code List Report: For more information, see Section 3.8.11.
- Panel Lot Report: For more information, see Section 3.8.18.
- Panel Lot Database Report: For more information, see Section 3.8.19.
- QC Lab Report: For more information, see Section 3.8.6.
- Resident Panel Report: For more information, see Section 3.8.5.
- Lab Report/QC Lab Report: For more information, see Section 3.8.13.
- Finalization Summary Report: For more information, see Section 3.8.14.
- Panel Inventory Lab Report: For more information, see Section 3.8.20.
- Custom Breakpoint Difference Report: For more information, see Section 3.8.15.
- Current QC Panel Lot Report: For more information, see Section 3.8.16.
- Historical QC Panel Lot Report: For more information, see Section 3.8.17.

3.8.1 How to Print Reports

To print a report:

1. Select the **Reports** tab.
2. Highlight the desired report.
3. Complete any additional fields (such as an Accession Number for the Accession Lab Report) and select **Print Reports**. (See Section 3.8 for additional requirements.)

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

Each of the reports is discussed in greater detail in the sections that follow.

3.8.2 Completed Lab Report

This report contains information for **all panels** whose status became **Complete** during the time selected 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 / PUD version.

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, 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.

3.8.3 Accession Lab Report

This 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 / PUD version.

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, 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.

3.8.4 Needs Attention List Report

This report lists all the panels in the instrument's database that have an unignored Needs Attention. This report can also be printed from the Needs Attention screen. The user is able to filter the reports on the highest priority reason by selecting the Filtered checkbox. If the checkbox is not selected, the report shows all reasons. 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 (Figure 3-8), and by Accession within each Reason type.

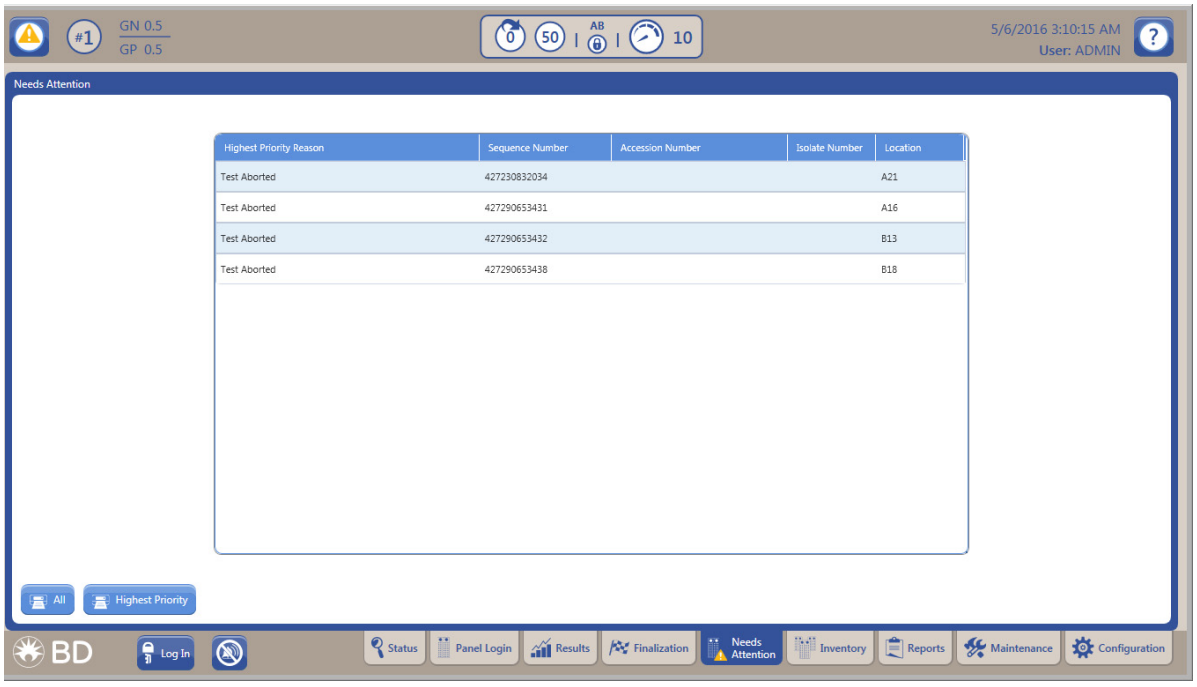


Figure 3-8 – Needs Attention List Report

3.8.5 Resident Panel Report

This 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.

3.8.6 QC Lab Report

This 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 / PUD version.

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.

3.8.7 Cumulative QC Report

This 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.

3.8.8 Daily Instrument Report

This 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.

The report provides the following information:

Header: Report Title, Laboratory Information (if configured), Date and Time Printed, and Software version/PUD version.

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 (Status screen), Standard Panel Temperature, Printer Paper Supply: Weekly: Internal Green LEDs, Internal Red LEDs, Internal Amber LEDs, 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.

3.8.9 Interpretation Rule Set Report

This 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 System Configuration (Section 3.10.2), then access **Reports** and select Interpretation Rule Set Report. The currently selected rule set prints. When printing is complete, return to **System Configuration**, and select the next rule set. Then access **Reports** 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 System 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.

Interpretation Codes:

CLSI or EUCAST

Interpretation Code	Interpretation Name
ACIN_IC	*Acinetobacter* spp.
AERM_IC	*Aeromonas* spp.
BURCEP_IC	*Burkholderia cepacia* complex
ENTC_IC	*Enterococcus* spp.
ENTERIC_IC	*Enterobacteriaceae*
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

3.8.10 BDXpert Rule Set Database Report

This 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.

3.8.11 Organism ID Code List Report

This 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.

3.8.12 Antimicrobial Code Report

This 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.

3.8.13 Lab Report/QC Lab Report

This report (Section 3.4.9 Needs Attention Sub-Tab) 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 Reports. It can only be printed from Results or Finalization. A Panel Inventory Lab Report prints the same information for all panels listed in the Panel Inventory screen (i.e., resident in the instrument and with final or partial results). Refer to Section 3.4.9 for additional information.

The QC Lab Report (Section 3.8.6) is also accessible from Results. It provides similar information to the Lab Report, but for QC panels.

3.8.14 Finalization Summary Report

This 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 Reports; it can only be printed from Finalization.

3.8.15 Custom Breakpoint Difference Report

This report contains a listing of differences between old breakpoints and new ones after a BD Phoenix Update Data or install/upgrade operation. The Custom Breakpoint Difference Report is not accessible from Reports. It can only be printed from the Custom Interpretation Rule Set (Configuration) tab by selecting the Difference Report button located at the bottom of the screen. Breakpoints that have been customized will not be overwritten with updates from the PUD. The Custom Breakpoint Difference Report will provide the appropriate data to determine if customized breakpoints need to be manually updated to reflect the currently installed PUD. Refer to Table 3-3 for details on how breakpoints are updated.

3.8.16 Current QC Panel Lot Report

This 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 Reports. It can only be printed from Panel Lot Definition. Refer to Section 3.10.9.

3.8.17 Historical QC Panel Lot Report

This 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 Reports. It can only be printed from Panel Lot Definition. Refer to Section 3.10.9.

3.8.18 Panel Lot Report

This 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.

3.8.19 Panel Lot Database Report

This 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.

3.8.20 Panel Inventory Lab Report

This report prints the same information for all panels listed in the Panel Inventory screen (i.e., resident in the instrument and with final or partial results). Refer to Section 3.4.9 Needs Attention Sub-Tab for additional information prints a Lab Report for all panels in the instrument. This report can only be printed from the Inventory tab.

3.9 Maintenance Tab

Maintenance (see Figure 3-9) provides several tasks for performing instrument maintenance. There are user tasks for weekly and as needed maintenance. There are other tasks for BD use only.

Under Task Category, select the category of maintenance to be performed:

- Hardware
- Software
- LIS
- Panel
- Field Service
- Internal BD Use

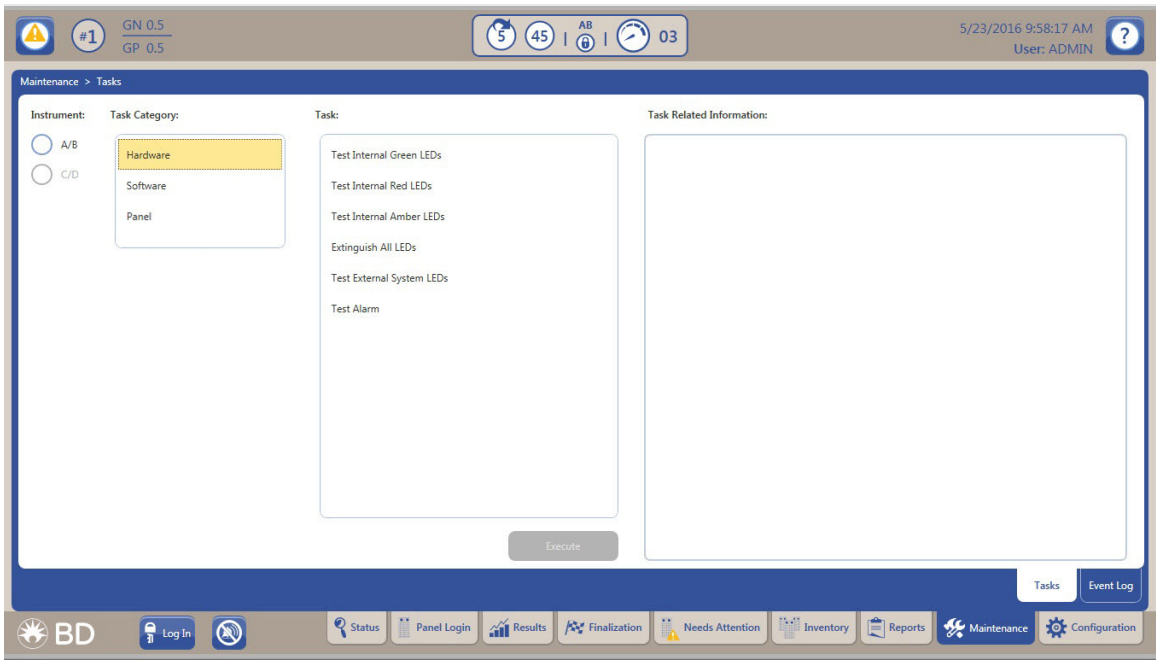


Figure 3-9 – Maintenance Screen

3.9.1 Maintenance Hardware Functions

For detailed information, refer to Section 5.2.

- Test system indicators
- Test Alarm

3.9.2 Maintenance Software Functions

Each of the software functions are described in detail below. Unless otherwise specified, perform the following steps to save data after accessing each software function via the Maintenance tab.

1. Insert the USB key, BD part number 443866, into the AIO PC.
2. Select the Maintenance screen tab.
3. On the Maintenance screen select Software under the Task Category.
4. From the Task list select the function to be performed.
5. Select Execute; the **Are You Sure?** message is displayed.
6. Select OK.

Save System Data Task

Under certain circumstances, BD may advise that system data be saved to a USB key. 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.

Save Event Log Task

Save Event Log to Network should only be used when advised by your local BD representative. The Save Event Log to Network option appears only when the instrument is connected to a BD EpiCenter system. This option enables the event log to be saved to a BD EpiCenter system.

Under certain circumstances, a BD representative may advise that the Event Log be saved to the BD EpiCenter system or to a USB key. These circumstances include some error conditions and system malfunctions. The Save Event Log 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 Event Log.

Upgrade Task

Upgrade enables instrument and AIO PC updates to be performed. To perform this operation, the instrument door must be closed. The software update will be recorded on the Daily Instrument Report for reference. To upgrade, follow the step by step instructions in Section 3.9.1. After OK is Selected, the following window appears:

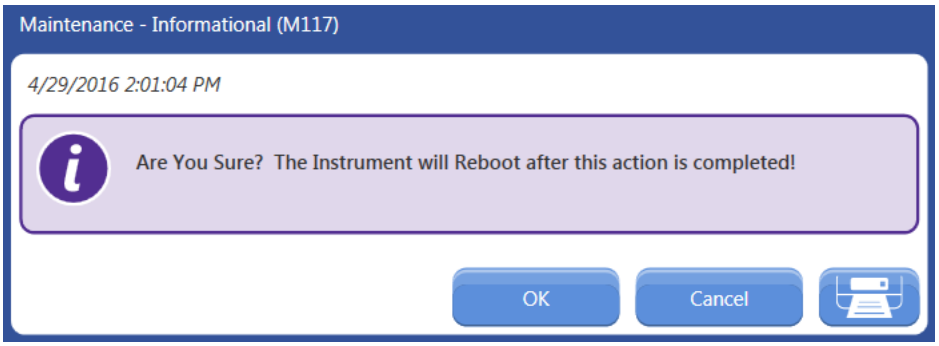


Figure 3-10 – Instrument Reboot Message

After the upgrade, files on the USB key are validated. The system will copy the upgrade files and reboot.

After the AIO PC finishes rebooting, the following message will be displayed:

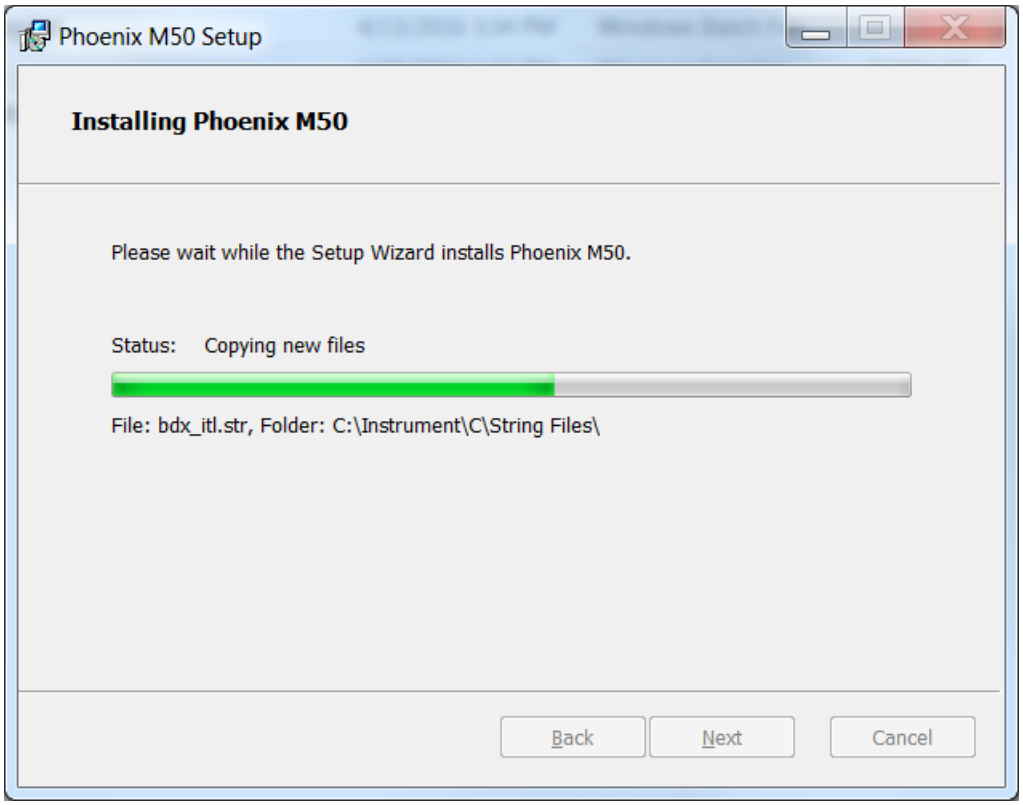


Figure 3-11 – Installation Message

The message above will show the status of each step of the upgrade process. The user will not be able to cancel this process once it has started.

When the upgrade completes successfully, the following message is displayed:

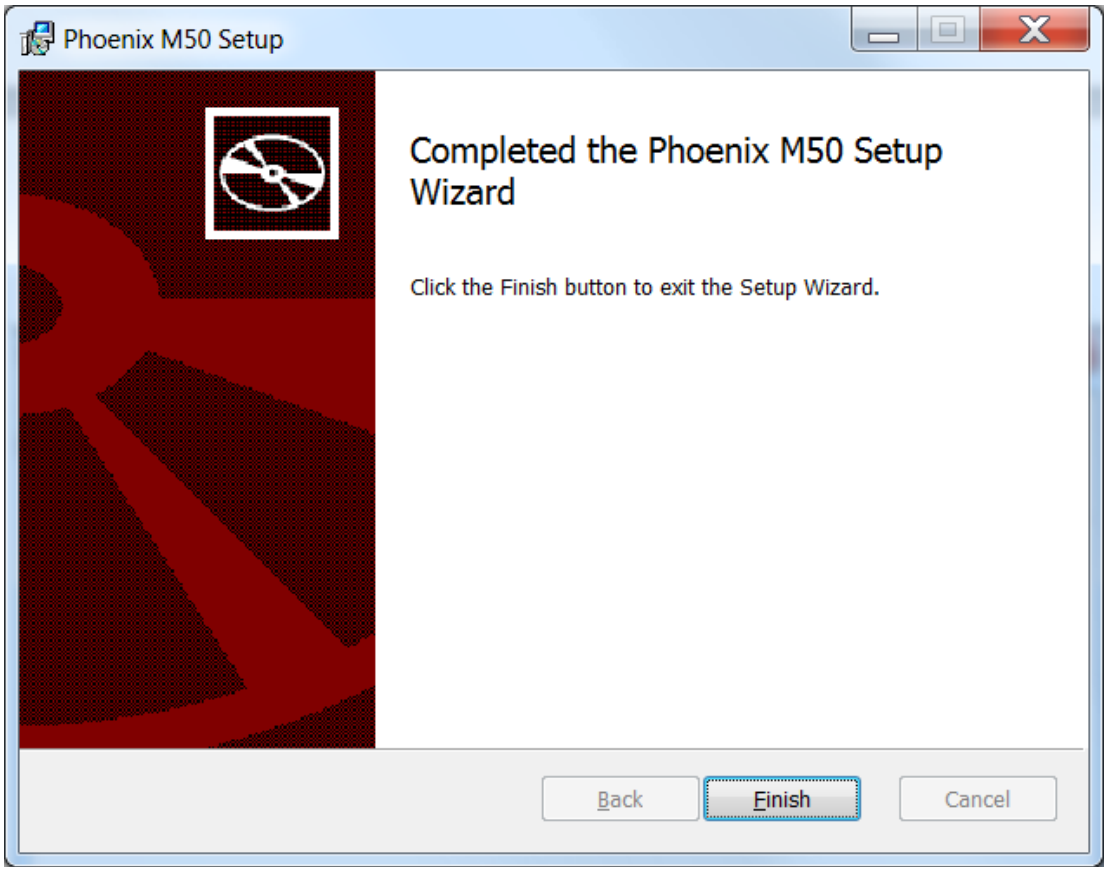


Figure 3-12 – Setup Wizard Message

When Finish is selected, the system will reboot and the newly installed version of the application on the AIO PC will synchronize with the instrument. If the upgrade includes new software for internal components of the instrument, these updates will take place immediately and the use of the application will be temporarily blocked. Once the instrument software has been successfully updated, the application will be available for use.

If custom breakpoints are in place, print the Custom Breakpoint Difference Report (See Section 3.10.6)

NOTE

When the software is updated, or when the PUD install 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 3.10.6) after each system update or PUD install.

Save User Data Task

Save User Data allows the back up of Configuration parameters to a USB key. This includes Custom Interpretation Rule Set Configuration and BDXpert Rules Configuration. The information that is saved is for the current instrument only. However, information saved at one instrument can be restored on another instrument. It is recommended that Configuration parameters be stored on a USB key in the event of a system failure.

Restore User Data Task

Restore User Data enables the restoration of the saved configuration parameters. This data includes: Custom Interpretation Rule Set Configuration, and BDXpert Rules Configuration. To restore, the instrument door must be closed.

BD Phoenix Update Data (PUD)

A BD Phoenix Update Data may be provided from time to time to update BD Phoenix M50 instrument databases and support files. These updates do not affect or change the basic instrument application software. For this reason, the Status screen shows both the software version and the PUD version near the top of the screen.

BD Phoenix Update Data (PUD) enables the update of numerous data files in the instrument, such as antimicrobial breakpoints and rules, QC data, drugs, organisms, etc.

> NOTE
>
> After a PUD upgrade, a Custom Breakpoint Difference Report should be printed and reviewed to determine if manual updates are required for custom breakpoints. Refer to Section 3.8.15 for additional information on this report. Refer to Section 3.10.6 for additional information on how custom interpretation rules are updated with a PUD upgrade.

Backup SQL Database Task

This feature provides data to BD Service for instrument troubleshooting purposes.

3.9.3 Maintenance LIS Functions

Each of these functions is described in detail below. Unless otherwise specified, perform the following steps to save data after accessing each software function via the Maintenance tab.

1. Insert the USB key, BD catalog number 443866 into the AIO PC.
2. Select the Maintenance screen tab.
3. On the Maintenance screen select LIS under the Task Category.
4. From the Task list select the function to be performed.
5. Select Execute; the **Are You Sure?** message is displayed.
6. Select OK.

Save LIS Codes Task

Save LIS Codes enables all the Organism and Antimicrobial LIS codes you have defined to be saved. 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 back to the BD Phoenix M50 instrument. The function also enables codes to be copied from one instrument to another. Save LIS Codes appears on the Maintenance tab 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.

Restore LIS Codes Task

Restore LIS Codes enables the restoration of the Organism and/or Antimicrobial codes that were previously saved. 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, and the file can be reviewed to see what caused the error. Restore LIS Codes appears on the Maintenance menu only if LIS Communications is enabled.

3.9.4 Maintenance Panel Functions

Each of these functions is described in detail below. Unless otherwise specified, perform the following steps to save data after accessing each software function via the Maintenance tab.

1. Insert the USB key, BD catalog number 443866 into the AIO PC.
2. Select the Maintenance screen tab.
3. On the Maintenance screen select Panel under the Task Category.
4. From the Task list select the function to be performed.
5. Select Execute; the **Are You Sure?** message is displayed.
6. Select OK.

Save Panel Lot Definitions Task

This enables the transfer of 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 and related data (Sequence #s, Expiration Dates, etc.), and QC results for any strains tested in those. Save Panel Lot Definitions only applies when QC Lot Support is enabled.

Restore Panel Lot Definitions Task

This makes Panel Lot definitions and QC panel results transferable in labs that use multiple instruments, so that a lot only has to be defined once using the box (carton) label. Restore Panel Lot Definitions only applies when QC Lot Support is enabled.

Save Panel Configuration Task

Save Panel Configuration enables the backup of the instrument's panel configuration. The information saved is for the current instrument only. However, information saved at one instrument can be installed at another instrument. This enables the presence of consistent panel configurations among all the instruments.

Install Panel Configuration Task

Install Panel Configuration enables the update of the instrument's panel configurations. To perform this operation, the instrument door must be closed.

> NOTE
>
> This operation should not be performed while there are ongoing panels.

3.9.5 Maintenance Field Service Functions

For Field Service use only.

3.9.6 Maintenance Internal BD Use Functions

For internal BD use only.

3.9.7 Maintenance Event Log Tab

The Event Log provides a list of messages generated by LIS communications. Note that the screen (see Figure 3-13) will not contain messages if the BD EpiCenter system is connected. The messages represent status messages that have occurred during LIS communications such as: query messages, log entries, and interface messages.

The Event Log list of LIS messages may be filtered based on date range. There is also a Find function to search for specific message content.

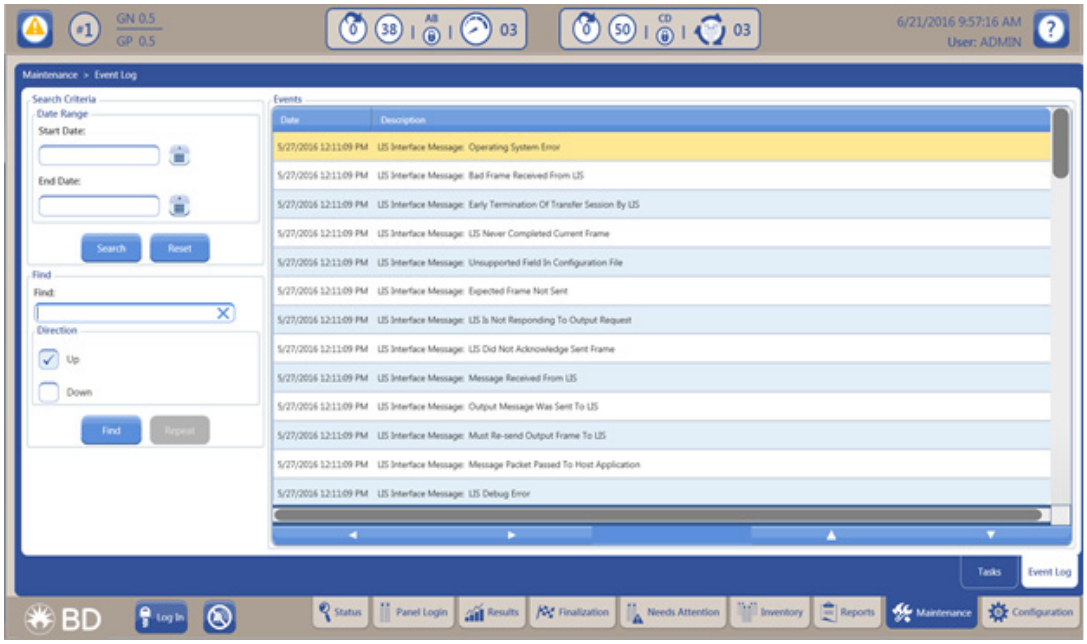


Figure 3-13 – Event Log Screen

3.10 Configuration Tab

To access the configuration functions, select the **Configuration** tab. The configuration screen then appears with sub-tabs for each specific configuration: Users, System, Communications, Custom Interpretation Rule Set, BDXpert Rules, Rapid Reporting, and Instrument. When the desired configuration parameters have been entered or modified, select **Save** to make the changes permanent.

* Note that the Custom Interpretation Rule Set and BDXpert Rules Configuration tabs do not appear if the BD Phoenix M50 instrument is connected to and communicating with a BD EpiCenter system.

3.10.1 Users Sub-Tab

Refer to Section 2.4.

3.10.2 System Configuration Sub-Tab

The following parameters can be set in System Configuration (see Figure 3-14):

GENERAL System Settings

System Number

Select the system identification number. The default setting is 0. Choose a number from 1 to 99. If there is only one instrument, leave this value set at 1.

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:

CLSI (Clinical and Laboratory Standards Institute)

EUCAST (European Committee on Antimicrobial Susceptibility Testing)

SFM (Société Française de Microbiologie)

Custom (defined in Section 3.10.6)

Rule Version

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

Alarm (audible) Volume

Select the volume of the instrument's audible alarm. The default setting is 5. Select from 0 (audible alarm off) to 10 (loudest). Only the volume of Alert and Activity alarms (see Section 2.3.2.8) is affected by this setting.

Resistance Marker Notification

This field appears only when the BD Phoenix M50 instrument is connected to a BD EpiCenter system but is not communicating with it. Enable the instrument to operate in a standalone mode when communications with BD EpiCenter is interrupted. When this field is enabled, the BDXpert System Active field appears.

BDXpert System Active

This field activates the entire BDXpert System rules which includes 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 field reappears. This enables the activitation of BDXpert rules interpretations in the standalone BD Phoenix M50 instrument. When communications with the BD EpiCenter system is restored, BDXpert rules interpretations are once again performed at the BD EpiCenter system, and this field is removed from the screen.

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

Rapid Completion

This field 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.

If Rapid Completion is selected at the BD Phoenix M50 instrument and the instrument is connected to BD EpiCenter, then it must also be enabled (checked) at the BD EpiCenter.

OPTIONS

Abbreviated Lab Report

Enabling this field causes the system to print a shortened version of the Lab Report. The shortened version does not contain results for the biochemical (ID) reactions. Disable this field to print the standard full-length Lab Report. The default is disabled (full length). Note that QC Reports always print standard full-length Lab Reports.

QC Lot Support

This field enables the QC Lot feature, which can be used to facilitate panel lot QC testing and tracking (see Section 3.4.6).

Daily Instrument Report Printing

System Check Box

Enabling this field causes the Daily Print Hour and Daily Print Minute fields to appear, and tells the instrument to print a Daily Instrument Report automatically at the time specified in these fields. If automatic printing is disabled, the report can still be printed at any time from Reports.)

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

Inoculum Density 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.

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. From the drop down box, highlight the desired media and select save to store the configuration setting. A default media type does not have to be specified, but a media type must be selected when logging in Yeast ID panels.

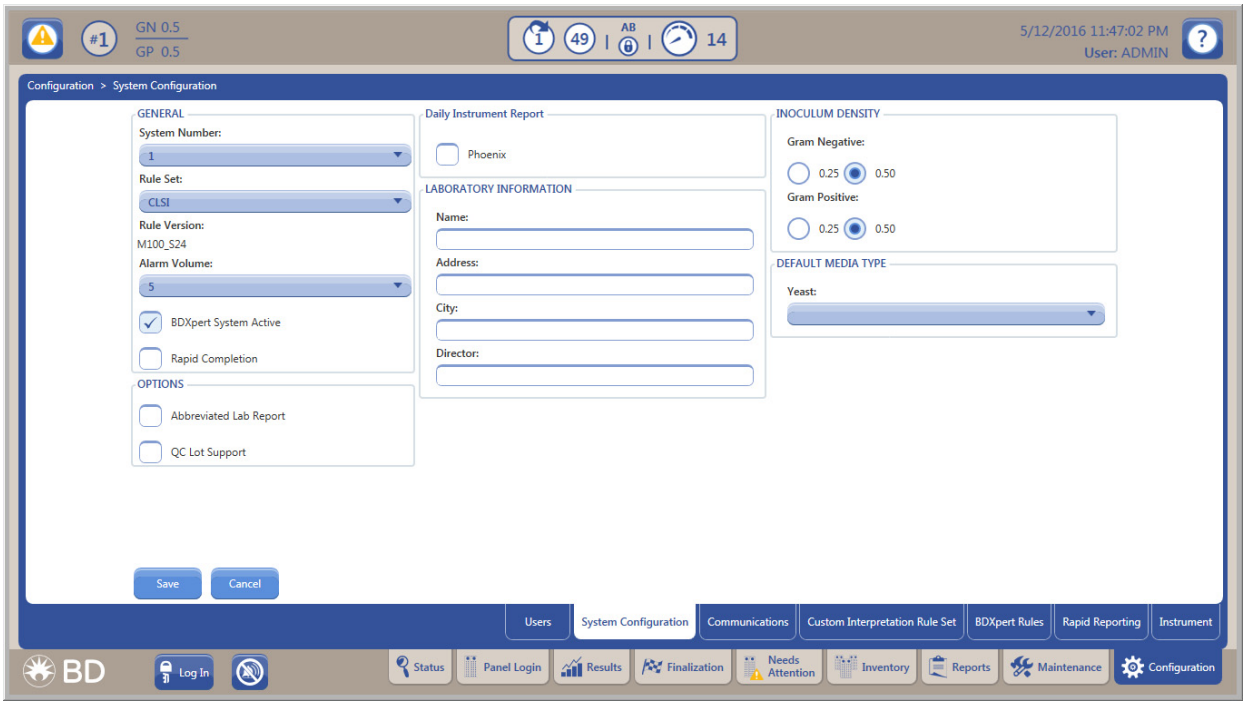


Figure 3-14 – Systems Configuration Screen

3.10.3 Communications Sub-Tab

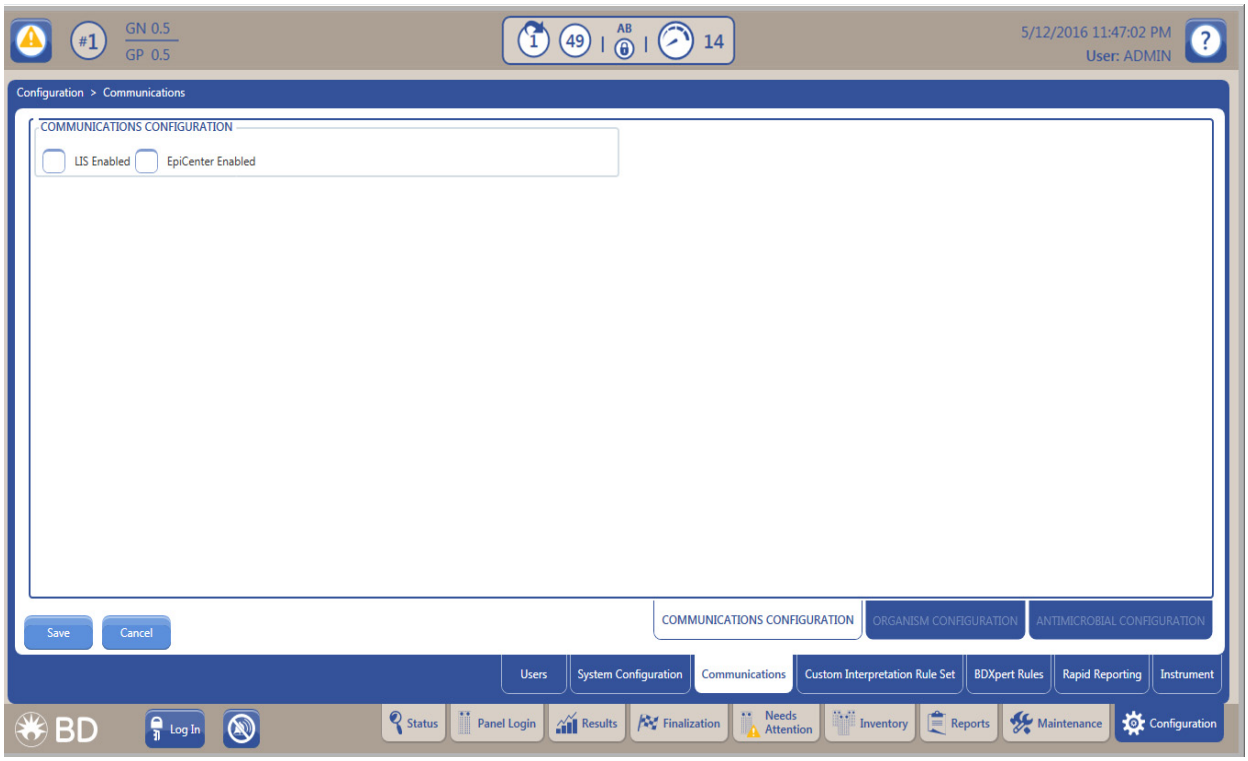


Figure 3-15 – Communications Configuration Screen

The Communications Configuration screen (Figure 3-15) enables/disables and configures communications for the BD Phoenix M50 instrument with a compatible LIS (Laboratory Information System). 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 connected and communications with a LIS system is required, BD EpiCenter can be configured to communicate with the LIS.

LIS operations are discussed in Section 2.8. The AIO PC displays the LIS connection status icon the upper left side of status screen.

LIS Enabled

Touch the **LIS Enabled** field to establish a connection. When LIS Enabled is checked, the following fields appear: Network Configuration, Options, and Results Upload Options.

Network Configuration

Baud

Available choices are: 2400, 4800, 9600 (default), 14400, 19200, 38400.

Data Bits

Available choices are: 7, 8 (default).

Parity

Available choices are: None (default), odd, even.

Stop Bits

Available choices are: 1 (default), 2.

Packed Frames

Select whether packed frames can be used for serial communications with the LIS system. Enable this field to allow the BD Phoenix M50 instrument to send multiple records per frame. A disabled field indicates that one record per frame is uploaded to the LIS.

Options

Send Interpretation Results

Enabling this option causes the final SIR values for antimicrobials to be included in the Results record uploaded to the LIS. Its default value is enabled.

Unsolicited Queries

Enabling this option causes the BD Phoenix M50 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 disabled, which means the BD Phoenix M50 instrument will NOT request missing information from the LIS.

Send When Placed in Instrument

Enabling this option causes the BD Phoenix M50 instrument to send a Results upload to the LIS when the panel is placed into the instrument. This field's default value is enabled.

ASTM Byte Mode Comments

This field only appears when Japanese is selected for the language and causes the ASTM standard to be followed (when enabled) or not followed (when disabled). When the ASTM standard is not followed, escape sequence characters that are usually rejected are instead accepted.

This field's default value is enabled.

Results Upload Options

Only one option from the list below can be selected.

Solicited

Enabling this option causes the BD Phoenix M50 instrument to upload Results records only when the LIS requests the information. Its default value is disabled.

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

Send on Finalization

Enabling this option causes the BD Phoenix M50 instrument to upload Results records only when the panel is finalized. Its default value is disabled.

Send on Completion

Enabling this option causes the BD Phoenix M50 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 enabled.

Send as Available

Enabling this option causes the BD Phoenix M50 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 disabled.

Send at Fixed Time

Enabling this option causes the BD Phoenix M50 instrument to upload Results records for a panel with partial results at a fixed, specified time. The default value is disabled.

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

Results records are uploaded from the BD Phoenix M50 instrument to the LIS system. These records are covered in detail in Section 2.8.2.

3.10.4 Organism Configuration Sub-Tab

The Organism Configuration screen allows the LIS codes for the organisms in the BD Phoenix M50 instrument database to be edited. LIS codes for organisms must be unique.

The Organism Configuration screen enables the selection of the organism (or Test Strain for QC organisms) to be edited.

To edit an organism LIS code:

In the Organism Configuration screen, select the name in the list and type in the new LIS Code in the Modify Organism ID LIS Code area at the bottom of the screen. Select Save LIS Code to save the changes. When all modifications to the LIS codes have been completed, save and exit the Communications Configuration screen.

3.10.5 Antimicrobial Configuration Sub-Tab

The Antimicrobial Configuration screen allows the LIS codes for the antimicrobials in the BD Phoenix M50 instrument database to be edited. LIS codes for antimicrobials must be unique.

This screen also enables the selection of the antimicrobial to be edited. Antimicrobials are presented alphabetically by antimicrobial name.

To edit an antimicrobial LIS code:

In the Antimicrobial Configuration screen, select the antimicrobial and type in the new LIS code in the Modify LIS Code window at the bottom of the list. Select Save LIS Code to save the modifications. When all modifications to the LIS codes are complete, save and exit the Communications Configuration screen.

3.10.6 Custom Interpretation Rule Set Sub-Tab

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. The current interpretation rule set from Reports can be printed (see Section 3.8). Note that this configuration function is not available if the BD Phoenix M50 instrument is connected to and communicating with a BD EpiCenter system.

Periodically, a software update or BD Phoenix Update Data (PUD) operation may install new breakpoints. When a software or PUD update has been performed, print a Custom Breakpoint Difference Report by selecting the Difference Report button at the bottom of the screen. Breakpoints that have been customized will not be overwritten with updates from the PUD. The Custom Breakpoint Difference Report will provide the appropriate data to determine if customized breakpoints need to be manually updated to reflect the currently installed PUD. Refer to Table 3-1 for details on how breakpoints are updated. Refer to Section 3.8.15 for additional details on this report.

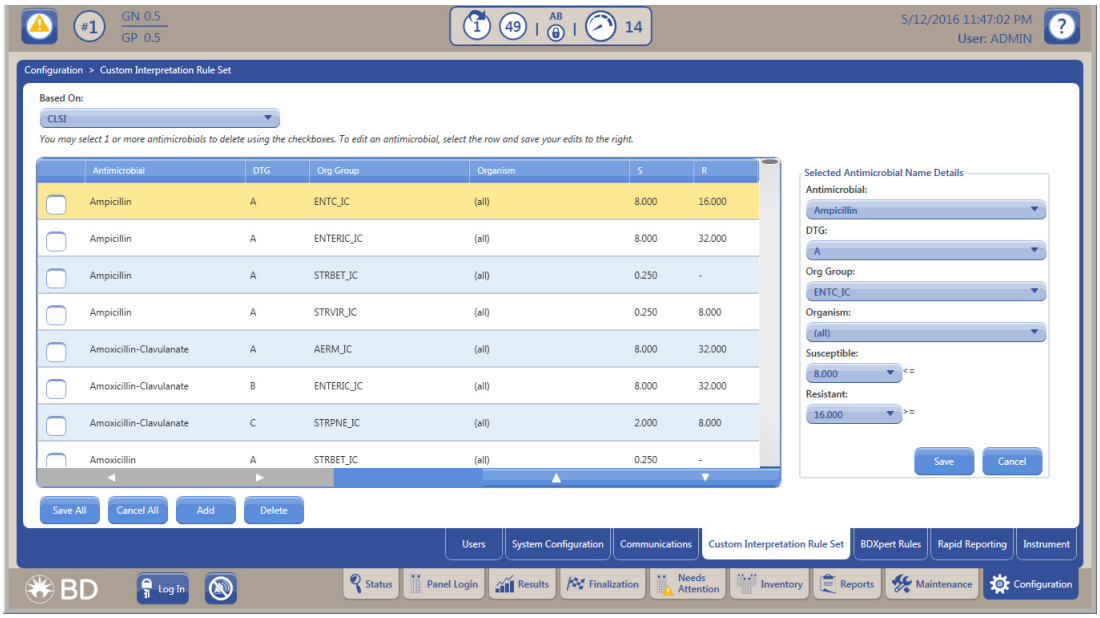


Figure 3-16 – Custom Interpretation Rule Set Screen

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 a customized rule set is present. 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 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, by following the chart below, the effect of the update is that value C (the customized rules based on Version M100_S25) would be retained.

	Old Standard	New Standard	Old Custom		Result after PUD (New Custom)
Custom rules are present	A	A	B		B
	A	B	C		C
	–	–	A		A
	–	A	A		A
	–	A	B		A
	A	–	B		B
No custom rules	A	A	A		A
	A	B	A		B
	–	A	–		A
	A	A	–		A
	A	B	–		B
	A	–	A		–

Table 3-3 – Rules Updates

NOTE

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

To use the custom rule set for interpretation, go to the **System Configuration** tab and select **custom** from the Rule Set drop down menu.

Custom Interpretation Rule Set – Based On:

The Based On drop down list selects the standard rule upon which the custom rules are to be based. The standard rule sets are: CLSI, EUCAST, and SFM.

NOTE

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

Custom Rule Set Table

The main window on this screen shows the current rules in the rule set. The following values are shown from left to right (items are explained below under To modify a rule):

Check box next to a rule (indicates the rule is marked for deletion)

Antimicrobial

DTG (Drug Test Group - see information below)

Org (anism) Group

Organism

S (usceptible Value)

R (esistant Value)

To add a rule:

1. Select **Add**. A new rule is added to the end of the list and selected for modification.
2. Modify the rule attributes in the Selected Antimicrobial Name Details window and then save.
3. Once all new rules have been added select **Save All** to save the new rules and exit the custom interpretation rule set configuration screen.

To modify a rule:

1. Select the row containing the rule to be modified. The row will be highlighted and the rule attributes will be populated in Selected Antimicrobial Name Details. Note - Do not check the field next to the rule. This is used to delete rules.
2. Modify the rules attributes and Save when all modifications are complete.

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 the BD Phoenix system 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 M50 instrument. First, 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
A	B, C, U, O
B	A, C, U, O
C	A, B, U, O
U	A, B, C, O
O	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 M50 instrument. 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
A	Not applicable	C
B	A	C
C	A	Not applicable
U	Not applicable	C
O	Not allowed	Not allowed
I	Not allowed	Not allowed

When the desired rules have been modified, select **Save All** to save modifications to the rule set and exit Custom Interpretation Rule Set Configuration.

To delete a rule:

1. Check the field next to the rule to be deleted.
2. Select **Delete**.
3. Select **OK** in the Are you sure message box.
4. **Save All** to save the modifications and exit the Custom interpretation rule set screen.

3.10.7 BDXpert Rules Sub-Tab

BDXpert Rule Configuration allows individual BDXpert rules to be enabled or disabled, or triggered automatically or manually according to the specific needs or requirements of each laboratory. The existing BDXpert rule set can be printed by selecting BDXpert Rule Set Database Report from Section 3.8 Reports Tab. Note that this configuration function is not available if the BD Phoenix M50 Instrument is connected to, and communicating with an BD EpiCenter system. See Figure 3-17.

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 Set field.

Based On

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

Rule Description

The Rule Description field shows the text of the rule selected.

Figure 3-17 – BDXpert Rule Configuration Screen

Rule Set

This screen presents a summary of the status of each of the BDXpert rules and enables rules to be selected for modification.

To enable or disable a rule, Select **Enable/Disable** 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, select Automatic/Manual to toggle the status. When set to Automatic, 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. When all parameters have been modified, select **Save**.

3.10.8 Rapid Reporting Sub-Tab

Rapid Reporting Configuration specifies the criteria for notification of critical panels and resistance markers. Notifications for critical panels can originate from an automatic Lab Report printing, 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 are 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, disabling 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 screen.

Rapid reporting alarms exist in two states: unacknowledged and acknowledged. Unacknowledged alarm panels continue to display a red **!** (exclamation mark) on the Inventory screen. Acknowledgment is achieved when an automatic Lab Report for the panel prints or when the panel is viewed in Results. Audible alarms continue to sound for unacknowledged alarms until the Silence Alarm button is pressed.

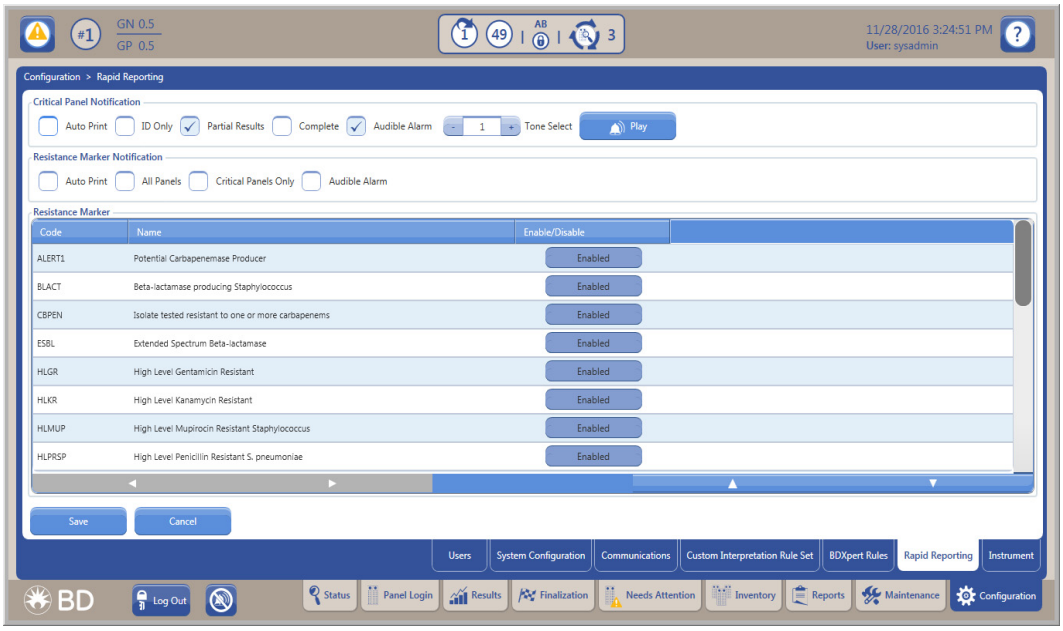


Figure 3-18 – Rapid Reporting Configuration Screen

Critical Panel Notification

The Critical Panel Notification field allows parameters to be set for notification on critical panels. Critical panels are any panels where 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 they are logged in via Panel Login, or subsequently on the Results screen.

Auto Print

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 only appears if LIS Communications is enabled. The default value is 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 Communications Configuration.

Audible Alarm

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. The system sounds a sample tone each time the field is selected or its contents are changed.

> NOTE
>
> Enable one of the following three fields in order to receive any critical panel notifications.

ID Only

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

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

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

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

Auto Print

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 appears only if LIS Communications is enabled. The default value is disabled. When enabled, the system uploads results records whenever the selected results parameters occur (ID Only, Partial, or Complete – see above).

This field overrides the results upload values set in Communications Configuration (Section 3.10.3).

> NOTE
>
> Enable one of the following two fields in order to receive any resistance marker notifications.

All Panels

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

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

This field enables or disables the notification of individual resistance markers. The field 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.

3.10.9 Panel Lot Definition Sub-Tab

Panel Lot Definition 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 M50 instrument is connected to and communicating with a BD EpiCenter system.

This tab's activities are:

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

When a panel lot definition is saved, any Test Strain recommendations that exist are displayed in the Current QC Results window. There is a toggle feature 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 Restore Panel Lot Definitions Task in Section 3.9.4).

Field contents of these windows are explained below.

Panel Lot Number

This field shows the lot number for the panel. To enter a new panel lot number, 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, select a panel lot from the drop down list, 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 Number

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 Number

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 found on the Maintenance Tab (see Section 3.9).

Current QC Results

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 (see Save Panel Configuration Task and Restore Panel Lot Definitions Task in Section 3.9).

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).

A Current QC Panel Lot Report is available by exiting the Panel Lot Definition tab and selecting the Reports tab. 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.

Historical QC Results

This 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. When the desired panel is highlighted, move to the QC Panel Results screen, 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.

A Historical QC Panel Lot Report is available by exiting the Panel Lot Definition tab and selecting the Reports tab. 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.

3.10.10 Instrument Sub-Tab

BD field service only.

4 – Routine Panel Operation

4.1 General

This section describes routine panel operations: preparation, quality control and automatic association.

4.2 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 and/or leaks. 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.

4.3 Preparing Panels

The BD Phoenix system is not for use 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. The test isolate must be a pure culture. It is recommended that cultures be 18–24 hours old for gram-negative and gram-positive organisms and 18–48 hours old for yeast organisms. For AST testing in the BD Phoenix system, isolates recovered from non-selective media are recommended. It is recommended that media containing antibiotics 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 caution must be used 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[1]	X	X
Bromthymol Blue (BTB) Lactose Agar	Yes[4]	Yes	X	X
Chocolate Agar	Yes	Yes	Yes[2]	Yes
Columbia Agar with 5% Horse Blood	Yes	Yes	Yes[3]	X
Columbia Agar with 5% Sheep Blood	Yes	Yes	Yes	Yes
Columbia CNA Agar with 5% Sheep Blood (Gram Positives)	Yes	X	Yes	X
Cystine-Lactose-Electrolyte-Deficient (CLED) Agar	Yes[5]	Yes	X	X
Dey/Engley (D/E) Neutralizing Agar (Gram Negatives)	Yes	X	X	X
Eosin Methylene Blue (Gram Negatives)	Yes	Yes	X	X
Hektoen Enteric Agar (Gram Negatives)	Yes	X	X	X
MacConkey Agar (Gram Negatives)	Yes	Yes	X	X
Phenylethyl Alcohol Agar (Gram Positives)	Yes	X	Yes	X
Sabouraud Brain Heart Infusion Agar - SAB HI (Yeast)	X	X	X	Yes
Sabouraud Dextrose Agar (Yeast)	X	X	X	Yes
Sabouraud Dextrose Agar-Emmons (Yeast)	X	X	X	Yes
BD Trypticase Soy Agar with 5% Sheep Blood	Yes	Yes	Yes	Yes
BD Trypticase Soy Agar with Lecithin and Tween 80	Yes	X	X	X
BD Trypticase Soy Agar without Blood	Yes	X	X	X
Xylose Lysine Desoxycholate Agar (Gram Negatives)	Yes	X	X	X

[1] 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.
[2] This media type should not be used for Streptococcal identification with SMIC/ID panels. Chocolate Agar may be used for Streptococcal susceptibility testing only.
[3] 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.
[4] 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.
[5] The use of Cystine-Lactose-Electrolyte-Deficient Agar with Gram Positive organisms should be restricted to *Staphylococci* for the 0.25 GP system.

Table 4-1 – Recommended Media

It is recommended that the applicator swabs are 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.

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[17] for specimen collection, transport, and placement on primary isolation media.

Due to variations in inoculum concentrations prepared with McFarland standards, use of the BD BBL CrystalSpec Nephelometer, the BD PhoenixSpec Nephelometer, or the BD Phoenix AP instrument is required for adjusting the test inoculum prior to use in the BD Phoenix system.

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

WARNINGS

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:

- 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 PhoenixAST-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

Materials Required but Not Provided:

- Gram Stain Reagents
- Sterile Cotton Swabs, Inoculation Loops or Needles
- Nonselective Culture Plated Media (see Section 4.3)
- Incubators
- Biohazard Disposable Container
- Markers, etc.
- Vortex mixer

NOTES

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.

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 Step 19 of these instructions.

1 Confirm the Gram stain reaction of the isolate before proceeding with the inoculum preparation for use in the BD Phoenix M50 instrument. Once the Gram stain reaction is confirmed, select the appropriate BD Phoenix panel for inoculation.

2 Examine the pouch, and do not use the panel if the pouch is punctured or opened. 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.

NOTE

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

3 Place the panel on the Inoculation Station; inoculation ports on top, and the pad on the bottom.

4 Label a BD Phoenix ID broth tube with the patient's specimen number. 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.

5 Suspend the colonies in the BD Phoenix ID broth (4.5 mL).

6 Cap the tube and vortex for five seconds.

7 Allow approximately ten seconds for air bubbles to surface. Tap the tube gently to aid in eliminating bubbles.

8 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.)

9 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.

c 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.

NOTES

- 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.

10 If identification only is being performed, proceed to Step 15 and continue the procedure. If a BD Phoenix Emerge Panel is being inoculated, refer to the section below, BD Phoenix Emerge Panels.

11 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.

NOTES

- Allow AST Indicator Solution to warm to room temperature before dispensing into AST broth.
- 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 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 the addition of the Indicator to AST broth, the mixed solution can be stored in the dark, at room temperature, for as long as 8 hours.
- Tubes must be used within 2 hours after the addition of AST Indicator Solution if exposed to light.

12 If an inoculum density of 0.50–0.60 was used, transfer 25 µL 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 µL (use 2 shots if utilizing a 25 µL 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.

13 Cap the AST tube and invert several times to mix.

14 Wait a few seconds for air bubbles to surface. Tap the tube gently to aid in eliminating bubbles.

15 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 an AST (only) panel is being used, DO NOT inoculate the ID side of the panel. Retain the ID tube for an optional purity check (see below).

16 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.

17 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.

18 Snap on the panel closures. Make sure that the closures are fully seated. Use 2 closures regardless of panel type.

19 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.

NOTES

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.

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 1–9** (General Panel Preparation) to prepare the suspension of bacteria.

2 Add one drop of the BD Phoenix AST-S Indicator to each AST-S broth tube. Invert to mix. DO NOT VORTEX.

NOTES (See note above)

- 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.
- 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. 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-S broth.
- After the addition of the Indicator to AST-S broth, the mixed solution can be stored in the dark, at room temperature, for as long as eight hours.
- Tubes must be used within two hours after the addition of AST-S Indicator Solution if exposed to light.

3 Using a pipettor, transfer 25 µL 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. 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 a BD Phoenix Strep MIC only panel is being used, 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.

NOTES

- 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

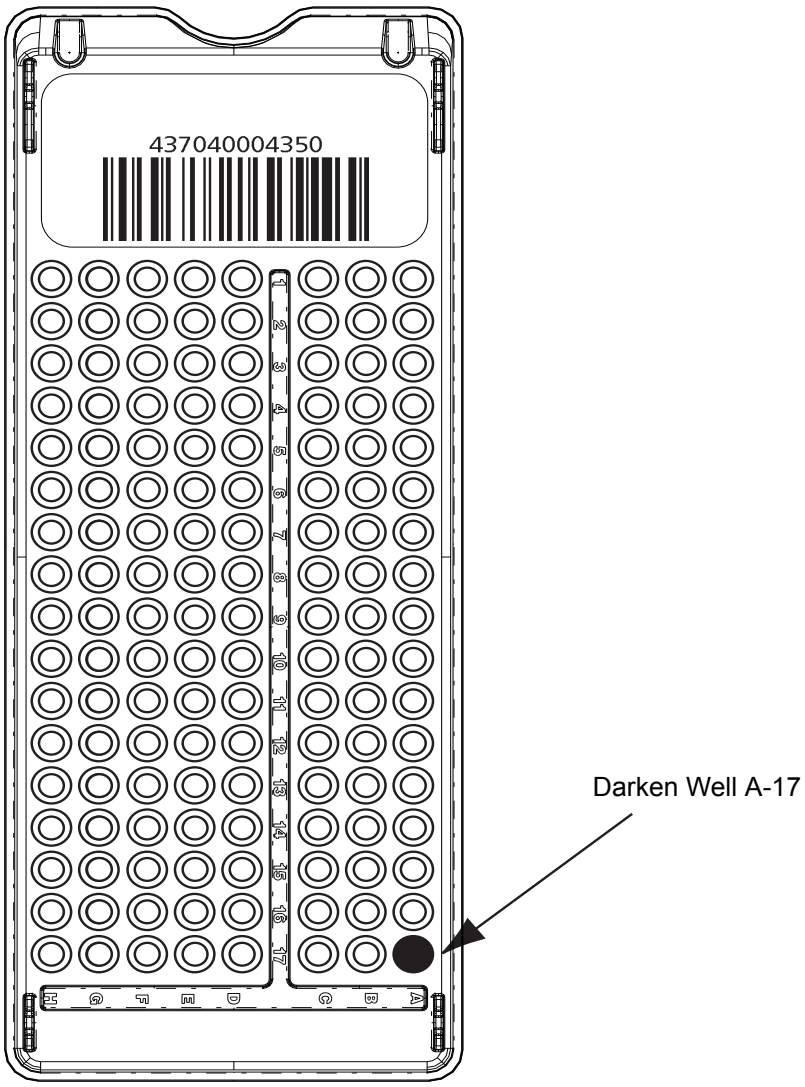
It is highly recommended that the purity of both ID and AST-S inocula be checked by preparing a purity plate.

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.

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.



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 (Can Not 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			

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 through 8** (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 9 (General Panel Preparation) to obtain the correct McFarland density.
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.

NOTES

See note above

- 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.

NOTES

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 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.

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. Two tubes of AST broth will be required.

1. Follow **Steps 1–9** (General Panel Preparation) to prepare the suspension of bacteria.
2. Add one drop of the BD Phoenix AST Indicator to each AST broth tube.
3. Transfer 25 µL (50 µL if low inoculum option is used) of the suspension to two BD Phoenix AST broth tubes. Cap and gently invert.
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. Pour the other BD Phoenix AST broth tube into the right side of the BD Phoenix Emerge panel.
6. Cap the panel and follow the normal panel login procedure.

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 through 9** (General Panel Preparation) to prepare the suspension of bacteria using the BD Phoenix Inoculum Broth rather than the BD Phoenix ID Broth.
2. For NMIC and PMIC panels, add one drop of the BD Phoenix AST Indicator to the BD Phoenix AST broth tube.
3. For SMIC panels, add on drop of the BD Phoenix AST-S Indicator to the BD Phoenix AST-S broth tube.
4. Transfer 25 µL (50 µL if low inoculum option is used) of the BD Phoenix Inoculum Broth suspension to the BD Phoenix AST or AST-S tube(s).
5. Follow **Steps 16 through 19** (General Panel Preparation). Follow the normal panel login procedure.

BD Phoenix MIC (NMIC, PMIC, SMIC) Panels

Inoculum can be prepared using either BD Phoenix ID Broth or BD Phoenix Inoculum (step 4, General Plan Preparation)

1. Follow **Steps 1–9** (General Panel Preparation) to prepare the suspension of bacteria.
2. For NMIC and PMIC panels, add one drop of the BD Phoenix AST Indicator to the BD Phoenix AST broth tube. For SMIC panels, add one drop of the BD Phoenix AST-S Indicator to the BD Phoenix AST-S broth tube.
3. Transfer 25 µL (50 µL if low inoculum option is used with NMIC or PMIC panels) of the BD Phoenix ID Broth to the BD Phoenix AST or AST-S tube. Cap and gently invert. Retain the ID tube or Inoculum tube for an optional purity check (see above).
4. Follow **Steps 16 through 19** (General Panel Preparation). Follow the normal panel login procedure.

4.3.1 Quality Control

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

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.

1. 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 4.3, immediately preceding this section.
2. Log the panel in as a QC panel as follows:

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 M50 instrument. Use only well-isolated colonies.

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

a Select **Panel Login.**

b Select **QC**.

c If desired, enter Tech ID.

d If desired, in the Accession Number field, type in or scan an accession number.

e In the Sequence Number field, type in or scan the panel's sequence number. If an invalid Sequence Number is entered, message W100 appears. Invalid Panel Sequence Number (see The field above does not display when BD EpiCenter communications is enabled.).

f The Isolate Number field defaults to isolate number 1. Type in the isolate number, or select the **+** or the **–** to increase or decrease the number. Valid isolate numbers are 1 to 20.

g For Yeast ID panels, the Media field appears to the right of the isolate number field. If a media type is not specified, a workflow error is generated when the panel is attempted to be saved. 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 3.10.2 in Section 3.10), which appears when a Yeast ID panel sequence number is scanned during login. To select a different media, select the down arrow to display a drop down box listing all media types (abbreviations), sorted alphabetically. (When the media type is selected, the full name appears at the top right of the screen.) Highlight the desired media. Select **Save**.

h In the Test Strain field, select the QC organism selection box from the drop down menu. 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. Highlight the desired QC organism. Select the organism.

i In the Panel Lot Number field, type in or scan the panel's lot number. Lot numbers must be seven numeric digits. Press tab to advance to the next field. (If the QC Lot Support feature is enabled, this field is completed automatically when the Sequence Number barcode is scanned.)

j In the Expiration Date field, select the calendar icon to enter the expiration month, day, or year. (If the QC Lot Support feature is enabled, this field is completed automatically when the Sequence Number barcode is scanned.)

k If desired, in the ID Broth Lot Number field, type in or scan the broth lot number. Lot numbers must be seven numeric digits.

l If desired, in the Expiration Date field, press the calendar icon to select the expiration month, day, or year

m If desired, in the AST Broth Lot Number field, type in or scan the broth lot number. Lot numbers must be seven numeric digits.

n If desired, in the Expiration Date field, press the calendar to select the expiration month, month, or year.

o If desired, in the Indicator Lot Number field, type in or scan the broth lot number. Lot numbers must be seven numeric digits.

p If desired, in the first Expiration Date field, press the calendar to select the expiration month, day, or year.

q Select **Save** to save the information.

Place the panel in the instrument (refer to Section 3.3.2 Inserting Panels in the Instrument).

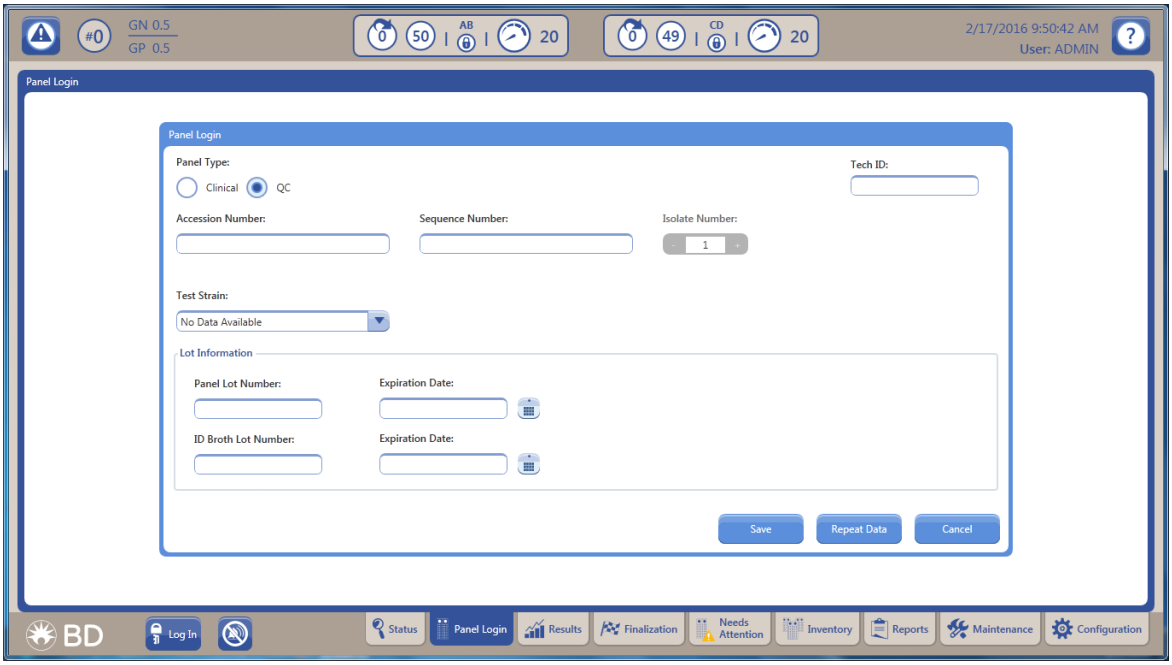


Figure 4-1 – QC Panel Login Screen

The field above does not display when BD EpiCenter communications is enabled.

4.4 Automatic Association of Panels

4.4.1 Overview

The purpose of Automatic Association 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. The circumstances where Conflict Checking occurs are described below. 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.

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 ensure that the same organism ID is made for all the panels related to a patient specimen.

Note that Auto Association does not set the critical panel attribute for related panels.

4.4.2 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), and 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, and Combination panels with only the AST side enabled.

4.4.3 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 QC and regular 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

4.4.4 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 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.

4.4.5 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.
2. 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.
3. 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.

7 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.

4.4.6 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

4.4.7 BDXpert Triggered Rules Screen

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. Select **BDXpert Rules** from the Results screen.
2. The first pending rule is highlighted.
3. The effect of the rule can be viewed on Final SIR values in the AST Results screen.
4. Select **Accept** to accept the pending rule, **Reject** to reject the rule, and **Re-Run** to cause all interpretation rules to be reapplied to the raw data.

4.4.8 Resistance Markers

If Resistance Markers have triggered on a particular panel, they are listed with the BDXpert rules.

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: Accept, Reject, Re-execute or Exit

5 – Maintenance

5.1 General

The BD Phoenix M50 instrument requires little maintenance from the user to provide reliable performance. Daily activities include checking the instrument temperature and printer paper supply. On a weekly basis check the operation of the station status indicators (LEDs), the audible alarm, and the alert indicator. Routine preventive maintenance consists of a monthly check of the ambient air filter. 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.

WARNING

ALL MAINTENANCE AND REPAIR OTHER THAN THE PROCEDURES DESCRIBED IN SECTION 5.2 AND SECTION 5.3, MUST BE PERFORMED BY QUALIFIED SERVICE PERSONNEL. NON-COMPLIANCE WITH THIS WARNING MAY RESULT IN PERSONAL INJURY OR INSTRUMENT MALFUNCTION.

No yearly preventative maintenance is required to be performed by BD authorized service personnel.

5.2 Routine Maintenance

Time Frame	Procedure
Daily **Record results on Daily Instrument Report**	• Check paper supply. • Record temperature on the Status screen. The temperature should be 35 °C ± 1.5 °C. • Record temperature standard panel. The temperature standard panel can be brought into view by selecting one of the instrument LED check functions on the Maintenance tab. • The temperature should be 35 °C ± 1.5 °C. • Perform Daily Verification on BD PhoenixSpec. • See Nephelometer Calibration in the BD PhoenixSpec package Insert.

Time Frame	Procedure
Weekly	• Test Internal Green LEDs • Test Internal Red LEDs • Test Internal Amber LEDs • Extinguish all LEDs • Test External System LED • Test Alarm Perform the tasks listed under the Maintenance Hardware category. See below for description of task.
Every 3 Months	Perform calibration of BD PhoenixSpec. • See Nephelometer Calibration in BD PhoenixSpec package Insert.
As Needed	Clean panel stations if they become contaminated by a leaking panel. 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. • The contamination procedure applies only to accessible areas. If the spill extends into regions of the carousel that are not accessible, contact your local BD service representative. • The solution recommended to clean the affected surfaces should be at least a 10% household bleach solution. • To clean monitors, the only solution recommended is 70% alcohol. 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 uncertain, thoroughly wash the exposed portions of the carousel and cabinet with the freshly prepared bleach solution. See Section 5.2.5 for a detailed cleaning procedure.

Time Frame	Procedure
	Replace the Barcode Scanner **1** Locate the cable connecting the barcode scanner to the instrument. **2** Unplug the cable. **3** Plug in the new scanner cable. **4** Verify the proper operation of the new scanner by scanning a panel sequence number at the Login screen. **5** View that the sequence number is correct. • Select **Cancel** to exit the screen without saving the panel.

5.2.1 Cleaning and Checking the Air Filter

The filter should be checked monthly and cleaned/replaced if needed (see below, Cleaning the Air Filter).

If the instrument's environment is especially dusty, the air intake filter should be checked more frequently and cleaned or replaced if needed. The filter must remain clean and unobstructed; restricted airflow from a dirty filter may cause the instrument interior to reach excessive temperatures, which can affect results and possibly cause hardware malfunctions or failures. The filter can be cleaned and reused.

The instrument’s filter is located inside the panel accesses area on the lower right. The filter can be removed without tools.

5.2.2 Removing the Air Filter

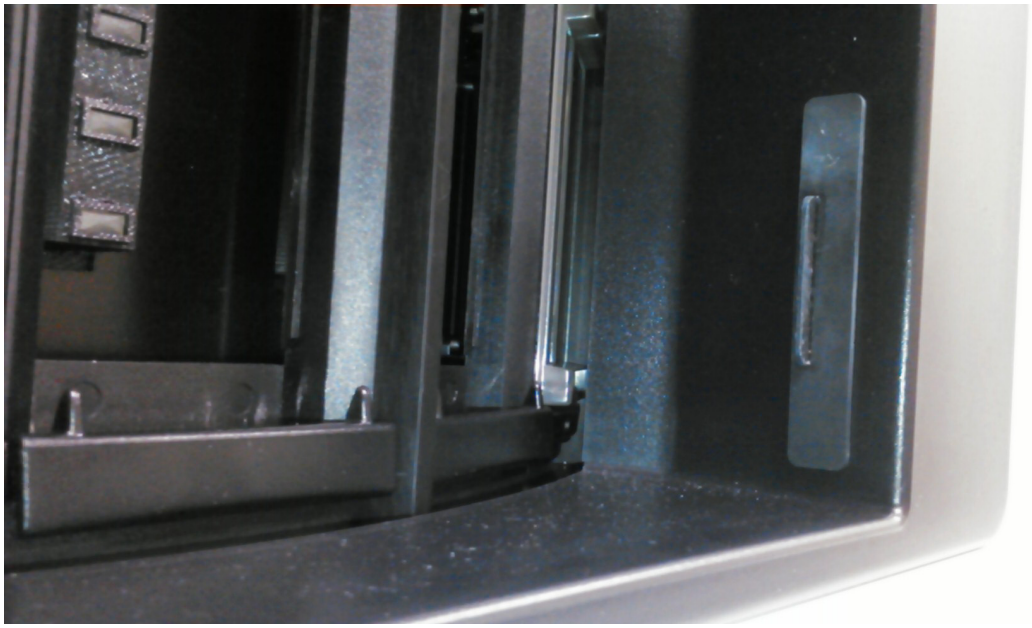


Figure 5-1 – Air Filter Location

1 Press Panels in or Panels out button to access panel entry area.

2 The filter is located on the lower right side of the opening.

3 To remove the filter, grasp black tab and slide towards the left side of the panel access area.

4 Remove the old filter and clean and dry it before replacing in the instrument, or place a new filter in the housing while the old one is cleaned and dried.

5 To insert a clean filter, grasp the black tab on the side of the filter and slide to the right until filter flange is flush with right side of instrument access area.

6 Close the instrument door.

5.2.3 Cleaning the Air Filter

1 Wash the dirty filter in a bactericidal disinfectant.

2 Place the filter on a paper towel and dry it thoroughly (if it is going to be reused immediately).

3 To save time, replace the dirty filter with a spare clean filter. Wash, dry, and set aside the removed dirty filter for the next filter replacement.

Figure 5-2 – Air Filter

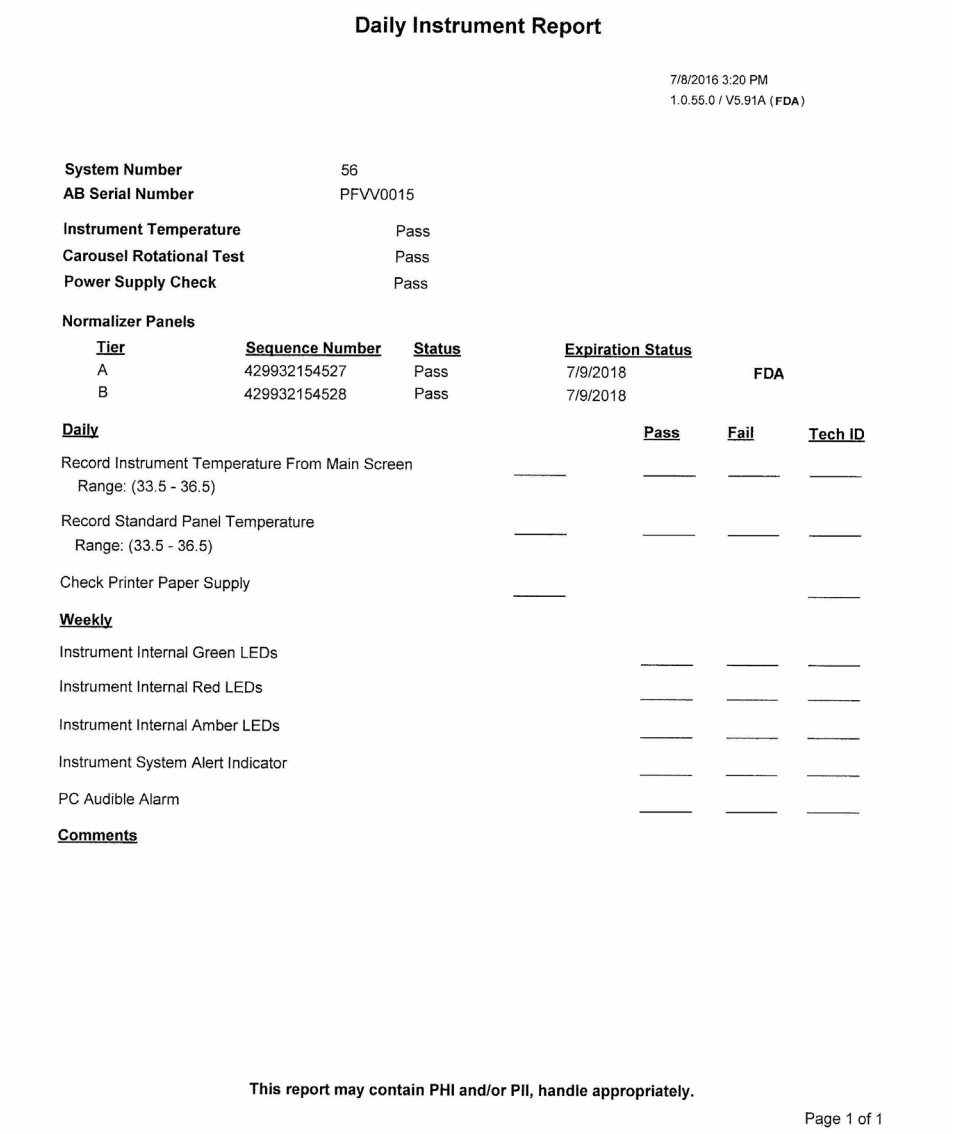
5.2.4 Daily Instrument Report

The Daily Instrument Report can automatically print at a user defined time or it can be printed upon request. (see Figure 5-3).

For instructions on configuring the report to automatically print at a certain time, see the Instrument Configuration section of this manual.

The Daily Instrument Report has three sections:

Section	Description
Top	Lists information that was configured when the system was set-up: • Facility name and address • Date and Time the report was printed • Instrument Number • Serial Number
Middle	Lists information about the internal operation of the BD Phoenix as well as the Normalizer Panels. • This section should be reviewed on a daily basis to make sure that these operations have passed testing.
Bottom	Lists the maintenance items that need to be checked and recorded on a Daily and Weekly basis.



Daily Instrument Report

7/8/2016 3:20 PM
1.0.55.0 / V5.91A (FDA)

System Number	56
AB Serial Number	PFVV0015
Instrument Temperature	Pass
Carousel Rotational Test	Pass
Power Supply Check	Pass

Normalizer Panels

Tier	Sequence Number	Status	Expiration Status	
A	429932154527	Pass	7/9/2018	FDA
B	429932154528	Pass	7/9/2018	

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	_____	_____	_____
PC Audible Alarm	_____	_____	_____

Comments

This report may contain PHI and/or PII, handle appropriately.

Page 1 of 1

Figure 5-3 – Daily Instrument Report

5.2.5 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 your local BD representative for further instructions.

To Decontaminate Carousel Panel Locations

The solution recommended to clean the affected surfaces should be at least a 10 percent 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 uncertain, thoroughly wash the exposed portions of the carousel and cabinet with the freshly prepared bleach solution.

Required Materials:

- 10% bleach solution
- Personal protection equipment, including gloves, gown, eye protection (e.g., face shield, goggles, etc.)
- Gauze pads or paper towels
- Tap water

Cleaning Procedures:

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.

WARNING

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.

To Clean Monitors

During normal use, a POC (Point-of-Care) terminal may become dirty and should be cleaned regularly. The solution recommended for cleaning the monitor is 70% alcohol.

Required Materials:

- 70% alcohol

Cleaning Procedures:

1. Prepare a cleaning agent per manufacturer's instruction or hospital protocol.
2. Prepare a clean cloth that has been moistened in a cleaning solution.
3. Wipe the POC thoroughly with a clean wipe.

CAUTION

Do not:

- **immerse or rinse a POC terminal or its peripherals**
- **spray cleaning agents on the chassis**
- **use disinfectants containing phenol**

5.3 Module Replacement

5.3.1 General

The BD Phoenix M50 instrument has been designed and tested for trouble-free performance. In the event of malfunction, contact BD for service under existing contract terms or warranty. Only the external barcode scanner is user-replaceable.

Replacement modules may be exchanged. Only replacement parts supplied by BD should be used in the procedures described in this section.

5.3.2 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 M50 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. Manually pull the thermometer completely out of the temperature standard 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.

5.3.3 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.

6 – System Alert Messages

6.1 Error / Alert Messages

CAUTION

When the system displays 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 conditions:

- 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.
- 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.

Each error code called out in this chapter will contain one of these three types of alerts and errors.

W error codes are displayed on the screen when they occur. (They also cause the Workflow 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 a Workflow Error (see Figure 6-1).

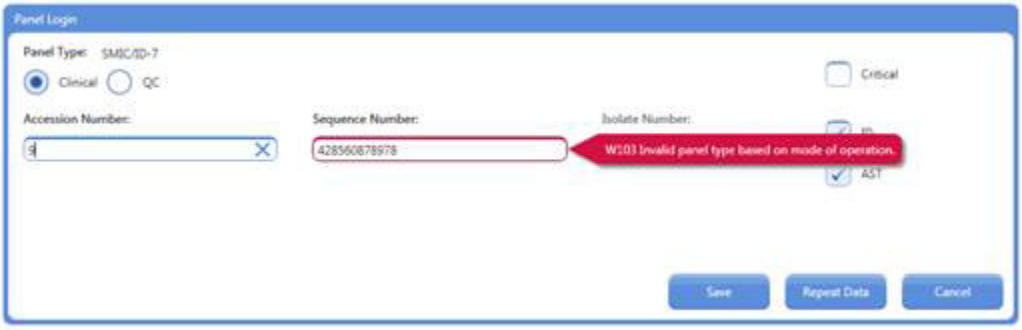


Figure 6-1 – Workflow Error

W error codes are grouped as follows and full descriptions can be found in Section 6.3:

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

6.2 System Alerts (E error codes)

System alerts (each shown in separate tables below), comprise of all **E** type error codes and 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 Status screen and the Alert indicator is illuminated. The errors must be reviewed to clear the system alert condition. The system alert list can be viewed from the Status screen by touching the alert icon on the upper left corner of the display.

The **E** 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 and many are listed in the associated alert tables 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.

E01 Incubator Temperature			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001	Persistent	Average temperature too high (> 36.5 °C)	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). Make sure environmental specifications are met (see Environmental Requirements in Section 2.3) Clean and/or repair air filters to permit fresh air intake.
00000002		Average temperature too low (< 33.5 °C)	
00000004		Communication with the incubator temperature sensor is lost	
00000010		Average temperature too high for more than one hour (> 36.5 °C)	
00000020		Average temperature too low for more than one hour (< 33.5 °C)	
00000040		Absolute high temperature (> 38.5 °C)	
00000080		Control and QC temperatures disagree	
00000100		QC temperature is out of range	

Temperature readings are taken every five seconds for 10 minutes and these readings are averaged. Note that if the instrument temperature reaches 38.5 °C, the instrument disables the heater.

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E05 Carousel Alert			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001 00000080	Persistent	Carousel RPM is below specification. Carousel is jammed (no panel flags detected, drum not moving)	The instrument reports these alerts if something is impeding the motion of the carousel. This can be attributed to one of the following: 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. 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 reoccurs, contact your local BD representative.

E06 Tier Alert*			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001 00000002 00000004 00000008 00000010 00000040 00000080 00000100 00000200 00000400 00004000 00020000 00040000 00080000 00100000 00200000 00400000	Persistent	This is the general alert condition for problems related to specific tiers including: incorrect flag readings, optical errors, timeout conditions, and normalizer problems.	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 locations in the bad tier are automatically blocked. Some conditions reported for the E05 alert are also detected by the tier micro and reported with the E06 alert. They include missing/extra panel flags, home flag, etc. Follow screen instructions to correct the alert.

* 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.

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E09 Test Aborted Sub-code			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
20000000	Self-clearing	Panel testing has not occurred for more than one hour because the instrument was off, the door was open for more than an hour, the system clock was set ahead one hour or more or the test cycle had not occurred in more than an hour.	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			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000002	Self-clearing	System Parameters Database Corrupted	Check your settings in the Configuration screens (see Section 3.10.2) and reset them to your preferences. Save data to a USB key and contact your local BD representative.
00000008		BDXpert Rules Database Corrupted	Check your settings for BDXpert Rule Configuration (see Section 3.4.5) and reset them to your preferences. Save data to a USB key and contact your local BD representative.
00000020		Custom Breakpoint Database Corrupted	Check your breakpoint settings for Custom Interpretation Rule Set Configuration (see Section 3.10.6) and reset them to your preferences. Save data to a USB key and contact your local BD representative.
00000040		User Codes Database Corrupted	Check your settings in the Organism and Antimicrobial Configuration screens see Sections 3.10.4 and 3.10.5) and reset them to your preferences. Save data to a USB key and contact your local BD representative.
00000001 00000010 00000080 00001000 00002000 00004000 00008000 00010000 00020000 00040000 00080000 00100000 00200000 00400000		Database corruption: Panel, Panel Lot, Alert / Eventlog. Corruption of instrument configuration record, instrument history, system parameters, light source, etc.	Save data to a USB key and contact your local BD representative.

E11 Printer Error			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
20000000	Self-clearing	Paper jam or power condition	Check printer paper (jammed our out), cable connection, power on, and/or online indicator.

E13 Power Failure			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
0x20000000	Self-clearing	Power removed from instrument	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 your instrument log. Note that power fail events are not recognized until the instrument user interface has successfully loaded.

E14 CCD Underrun*			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000000	Persistent	Scanning of a panel stopped prematurely 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. To clear, re-boot the instrument.

*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.

E18 Normalizer Row Averages*			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001 00000002 00000004 00000008 00000010 00000020 00000040 00000080	Self-clearing	The tier had a problem with normalizer panel data averages	A source adjustment can only be performed when all panels in an instrument are no longer ongoing. Normalizer errors are detected during a test cycle. Test data received may be discarded or retained depending on the error sub-code. All available stations in the bad tier are automatically blocked; ongoing stations become blocked as testing completes or panels are removed. Do not enter any new panels or move an ongoing panels into any tier reporting this error. The instrument may be able to correct this error via the light source adjustment process.

* 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.

E20 Barcode Scanner Not Communicating			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001 00000002 00000004 00000008 00000010	Self-clearing	Tier barcode scanner (or handheld scanner) is not communicating and all the tier stations are automatically blocked	Reboot the instrument.

E21 Level 2 Rotor Step Warning*			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000000	Persistent	The instrument has sensed that rotor rotation was not ideal but still acceptable	Check for a panel protruding from its carrier, an improperly seated closure, or user applied label peeling off. If no obvious visible cause for the error exists, contact your local BD representative.

* 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.

E22 Level 3 Rotor Step Error*			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000000	Persistent	The instrument has sensed that rotor rotation was out of specification	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. Check for a panel protruding from its carrier, an improperly seated closure, or user applied label peeling off. If no obvious visible cause for the error exists, contact your local BD representative.

* 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.

E30 Normalizer Expiration Alert*			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001	Self-clearing	The tier's normalizer panel expiration date is between 60 and 30 days away	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. Schedule Normalizer panel replacement for the affected tiers before they expire (expiration date is shown on Daily Instrument report.) Contact your local BD representative.
00000002		The tier's normalizer panel expiration date is less than 30 days away but has not expired	

*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.

E31 Normalizer Expired*			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001	Persistent	Normalizer panel expiration date has passed. Stations in all affected tiers are blocked	Schedule normalizer replacement immediately to resume testing.

* 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.

E44 LIS Fatal Operating System Error			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001	Persistent	The instrument is not able to send data to the LIS due to a fatal software exception that occurs within the LIS library at the instrument	Start LIS system. Look for obvious source of problem such as disconnected cable. If no obvious source exists, contact your local BD representative.
00000008		A fatal operating error was detected by the LIS_IM	Contact your local BD representative.

E50 Internal Software Error			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001	Self-clearing	System encountered a software general protection error.	Save data to USB key (see Section 3.9.1 Maintenance Hardware Functions) and contact your local BD representative.
00000002		Internal software error	

E51 Duplicate Panel Barcode Detected			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000000	Self-clearing	Duplicate barcodes have been detected.	Carefully examine the reported stations for duplicate barcodes. All panels with duplicate barcodes have been aborted. If duplicates are found, then remove the panels from your system and contact your local BD representative immediately. If no duplicates are found, then the alert may be a result of moving an existing panel between instruments. Avoid moving panels across instruments as they will be aborted. If the alert reoccurs, contact your local BD representative.

E52 Instrument Communications Application Layer (ICAL) Alert			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001	Self-clearing	Instrument is not registered	Configure the instrument in the system.
00000002		Instrument history purged because instrument was in isolation mode too long.	Reconnect the instrument and Tablet PC or contact your local BD representative.
00000004		Extra Device Alert: three or more instruments are plugged into the application.	Remove the instrument(s) that are not configured in the system.

E98 PC Alert			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001	Persistent	The IDS layer timed out	If the condition reoccurs, contact your local BD representative.
00000002		The IDS system received an invalid parameter	Contact your local BD representative.
00000004		The IDS system rejected a message	
00000008		An invalid alert sub-code was detected	

6.3 Workflow Alerts (W error codes)

Field level alerts are displayed when data, entered into a specific field, is invalid. These errors (such as attempting to enter an invalid Sequence Number in the Panel Login screen) cause workflow error messages to appear on the 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 Number). When the error is corrected, the field level alert is removed from the display. All other workflow alerts are displayed in a dialog with two or more buttons.

W100 Invalid Panel Sequence Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	The panel sequence number typed or scanned does not meet the required number format.	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.

W101 Missing Panel Sequence Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	Panel sequence number field empty when save is pressed.	Type in or scan the correct panel sequence number before attempting the operation again.

W102 Unknown Panel Sequence Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to save or select a panel sequence number that is not in the BD Phoenix database.	Verify that the correct panel sequence number was entered. If error reoccurs, the panel may need to be logged in if it is a new panel. Older, completed, finalized panels eventually age out of the database.

W103 Invalid Panel Type for Region		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to log in a panel barcode that is not valid for the region.	Verify that the correct panel barcode was entered.

W200 Invalid Accession Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made save, find, or print information for an invalid accession number.	Enter a valid accession number, up to 20 characters excluding : * ? [ ] ! #

W201 Missing Accession Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An operation (find, save, print) was attempted and the value in the Accession Number field was invalid or blank. This can include: a record with a valid panel Sequence Number and an Isolate Number greater than 1 with no Accession Number; an orphan panel with just an Isolate Number, or trying to change a saved record to a blank Accession Number.	Type in or scan the correct accession number before attempting the operation again.

W202 Unknown Accession Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	At attempt was made to find data or print a report for an accession number that is not located in the BD Phoenix database.	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		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to save a record when an accession number is present without an isolate number.	To save a record, if you enter an accession number, you must also enter an isolate number

W204 Missing Media Type		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to save a Yeast ID panel during Panel Login and no Media is specified.	To save a record, if you enter a Yeast ID panel sequence number, you must select a media type.

W205 Panel Not Found		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	An attempt was made to find a Sequence and Accession combination that is not in the BD Phoenix database.	The Sequence and Accession combination does not exist in the database.

W300 Missing Test Strain for a QC Panel		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	An attempt was made to save a QC panel without an organism ID (Test Strain).	You must select an organism (Test Strain) to save a QC panel. Advance to the Test Strain field to drop down a box listing the available test strains. Highlight the desired organism. **Select** the highlighted organism.

W301 Missing Tech ID for a QC Panel		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to save a QC panel without a Tech ID.	You must enter a Tech ID to save a QC panel. Advance to the Tech ID field and enter a Tech ID, up to 3 alphanumeric characters excluding: * ? [ ] ! # |.

W302 Invalid Tech ID for a QC Panel		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to save a QC panel with an invalid Tech ID.	Enter up to 3 alphanumeric characters excluding: * ? [ ] ! # | for the Tech ID.

W303 Invalid Lot Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	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.	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		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	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.	You must enter a panel lot number to save a QC panel. Advance to the Panel Lot # field and enter a lot number, up to 7 digits. The lot number is shown on the panel carton.

W305 ID or AST Must be Enabled		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	An attempt was made to save a panel or QC panel, and both the ID and AST fields are unabled.	The ID/AST fields are enabled or disabled based on the type of panel, according to the panel sequence number. At least one field must be enabled for the panel record to be saved and for testing to occur.

W400 Door Already Open		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	A request was made to perform a task that requires the door to be opened when the door is already open.	Select OK.

W401 Can Not Perform Panel Locate		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	The panel you are trying to locate is not in the instrument, or you cannot access the instrument using the Normalizer Panel Replacement function (e.g., because there are ongoing panels).	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		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	The USB key does not contain a readable, same, or newer version of instrument software. Causes include: older version of instrument software; USB key was removed before the update completed, or the USB key contains a corrupted or missing file.	Attempt the update operation again. If error reoccurs, contact your local BD representative.

W502 Removable Media Error		
Message Type	**Alert Cause**	**Alert Corrective Action**
Retry Cancel Print Screen	The USB key is not in the drive, full, write protected or it was removed before completion of the task.	Attempt the update operation again. If error reoccurs, contact your local BD representative.

W503 Duplicate Rule		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	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.	One of the parameters (Antimicrobial, Organism Group, or Organism) must be unique for the record to be saved.

W506 Instrument Not Idle		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	An attempt to execute an upgrade failed because the instrument was not idle.	Wait until instrument is idle (or correct carousel jam) before performing this activity.

W507 Invalid Password		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	An invalid (or no) password was entered to access a Configuration screen.	Enter the correct password and perform the action again.

W511 Battery Mode		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	An attempt to install or restore data while the tablet is unplugged and working in battery mode.	Retry the install or restore data when battery mode is not in progress.

W600 Panel Can Not Be Deleted		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	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).	Remove the panel from the instrument.You can use the find panel tab to make the carousel present the panel when the door is opened. If you know you have already removed the panel, then close the instrument door and allow the instrument to complete an inventory scan before attempting to delete the panel.

W601 Can Not Finalize		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to finalize a panel either whose status is not Removable or that has an unignored Needs Attention set.	If panel is Ongoing, wait until it becomes Removable before attempting to finalize it. If panel has a Needs Attention set, resolve the reason before attempting to finalize the panel.

W602 Invalid Date		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	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.	Enter a valid date.

W604 Panel Still Testing		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to save a Final ID to an ID or Combination panel that has not reported an Instrument organism ID.	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.

W606 Cannot Modify Date for a Finalized Panel		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	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.	If information for a finalized panel must be modified, recall the panel and un-finalize it by disabling the Finalize field. Make the required changes and save the information.

W607 Missing Date		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	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.	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		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	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).	Verify which field is currently active and check what type of barcode you are trying to scan.

W609 Database Full		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	An attempt was made to log in a new panel and 50 panels exist in the instrument database with a pending record status, with no panels eligible for deletion.	Pending panels should be placed in the instrument and allowed to complete an inventory scan before you attempt to log in any new panels.

W700 Invalid LIS Code		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	An invalid LIS code was entered in the Organism Configuration or Antimicrobial Configuration screen.	LIS Codes can be up to 20 alphanumeric characters.

W701 Duplicate LIS Code		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	A duplicate LIS code was entered in the Organism Configuration or Antimicrobial Configuration screen.	LIS Codes must be unique in the system.

W800 Panel Lot Undefined		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	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.	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		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	During Panel Lot Definition, an attempt was made to save a panel lot but one or both panel sequence number fields were blank.	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. You cannot type in a sequence number on the Panel Lot Definition screen.

W802 Panel Lot Range Invalid		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	During Panel Lot Definition, an attempt was made to save a panel lot but the two panels scanned were different panel types.	Both panels must be the same type for any panel lot to be saved.

W803 Panel Lot Range Conflict		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	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.	A panel sequence number can only belong to one defined/ saved panel lot. Contact your local BD representative.

W806 Panel Lot Expired		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	A panel lot number barcode is scanned containing an expired expiration date.	Enter an unexpired panel log number barcode.

W900 Commission Duplicate Serial Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	There is an instrument with the same serial number already commissioned.	Enter a unique serial number.

W901 Commission Duplicate Instrument Identifier		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	There is an instrument with the same designation already commissioned.	Check for instrument designation duplication.

W904 Commission Invalid Serial Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	The serial number must be a minimum of six characters.	The serial number must be six characters.

W905 Decommission of Connected Instrument		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	An attempt is being made to decommission an instrument.	Disconnect the instrument prior to decommissioning.

6.4 Event Log Messages

6.4.1 LIS Related Messages

The Event Log tab, located on the bottom right of the Maintenance screen enables the user 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 that may be performed 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 your 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.

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.

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 your 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 your 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 your 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 M50 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 M50 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 M50 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.

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 your 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 your local BD representative.

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 your 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 Canceled 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 3.3 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 and 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.

7 – Panel Information Inserts

7.1 BD Phoenix Gram Negative Panel Information

BD Phoenix™ Automated Microbiology System

BD Phoenix™ NMIC/ID Panels
BD Phoenix™ NMIC Panels
BD Phoenix™ NID Panels
BD Phoenix™ UNMIC Panels
BD Phoenix™ UNMIC/ID Panels

INTENDED USE

The BD Phoenix™ Automated Microbiology System is intended for the *in vitro* rapid identification (ID) and quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of Gram Negative aerobic and facultative anaerobic bacteria belonging to the family *Enterobacteriaceae* and non-*Enterobacteriaceae*.

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. Many of the tests used in the 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 Phoenix system utilizes chromogenic and fluorogenic substrates as well as single carbon source substrates in the identification of organisms.[10,11]

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.[12] The broth dilution technique involves exposing bacteria to decreasing concentrations of antimicrobial agents in liquid media by serial two-fold dilutions. The lowest concentration of an antimicrobial agent in which no visible growth occurs is defined as the minimal inhibitory concentration (MIC).

The introduction in 1956 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 antimicrobial susceptibility test (AST).[13] 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.[14]

The Phoenix AST is a modified miniaturized version of the micro-broth doubling dilution technique. Susceptibility testing in the Phoenix system is performed through determination of bacterial growth in the presence of various concentrations of the antimicrobial agent tested.

PRINCIPLES OF THE PROCEDURE

A maximum of 50 identification and antimicrobial susceptibility tests can be performed in the Phoenix instrument at a time using Phoenix combination panels. A sealed and self-inoculating molded polystyrene tray, with 136 micro-wells containing dried reagents, serves as the Phoenix disposable. The combination panel includes an ID side with dried substrates for bacterial identification and an AST side with varying concentrations of antimicrobial agents, growth and fluorescent controls at appropriate well locations. The 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^{++} and Mg^{++}) to optimize susceptibility testing performance.

The 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 contains 84 wells with dried antimicrobial agents and 1 growth control well. Panels are available as ID only (Phoenix™ NID Panels and Phoenix™ PID Panels), AST only (Phoenix™ NMIC Panels and Phoenix™ PMIC Panels), or ID/AST combination (Phoenix™ NMIC/ID Panels and Phoenix™ PMIC/ID Panels). BD Phoenix Emerge™ (AST136) panels contain wells for antimicrobial susceptibility on both the 51-well and 85-well sides. BD Phoenix Emerge panels are available for Gram Positive (PMIC), Gram Negative (NMIC) and *Streptococcus* (SMIC) panels. Unused wells are reserved for future use.

Phoenix panels are inoculated with a standardized inoculum. 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 up to 16 hours if necessary. Phoenix panels are read only by the instrument. Phoenix panels cannot be read manually.

Bacterial Identification: The ID portion of the 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 in 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 the 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 Phoenix ID Database is provided in Section 8.3. Reactions employed by various substrates and the principles employed in the Phoenix ID reactions are described in Section 8.2.

Antimicrobial Susceptibility Testing: The Phoenix AST method is a broth based microdilution test. The Phoenix system utilizes a redox indicator for the detection of organism growth in the presence of an antimicrobial agent[15]. 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 producing Susceptible, Intermediate, or Resistant (SIR) result classifications.

A complete list of taxa for which the Phoenix system can provide AST results is provided in Section 8.3. The list of antimicrobial agents and concentrations available for susceptibility testing in the BD Phoenix system is provided at the end of this sub-section.

There are antimicrobial agents for use with the BD Phoenix System that are not proven to be effective for treating infections for all organisms listed in the taxa. For interpreting and reporting results of antimicrobial agents that have been shown to be active against organism groups both *in vitro* and in clinical infections refer to the individual pharmaceutical antimicrobial agent labeling. Alternatively, refer to the most recent CLSI M100 Performance Standard, Table 1.[16]

The components required for testing using the BD Phoenix system include: 1) BD Phoenix panels with panel closures, 2) BD Phoenix ID Broth, 3) BD Phoenix AST Broth, 4) BD Phoenix AST Indicator solution, 5) BD Phoenix Inoculation Station, 6) BD Phoenix Panel Carrier, 7) BD BBL CrystalSpec Nephelometer, the BD PhoenixSpec Nephelometer, or the BD Phoenix AP instrument, and 8) 25 µL pipettor and tips, 9) Miscellaneous lab supplies (listed under Materials Required but Not Provided).

Prior to inoculation the Phoenix panel is placed on the Inoculation Station with the inoculation ports at the top for filling. Separate inocula are added manually to the ID and AST ports. The inocula flow down the panel in serpentine fashion, filling the panel wells as the liquid front progresses toward the pad. The pad absorbs excess inoculum. Closures are manually inserted in the fill ports. An air admittance port is located in the divider area of the panel lid to ensure adequate oxygen tension in the panel for the duration of the test.

INGREDIENTS:

For a listing of biochemical substrates used in the Phoenix panel refer to Section 8.2. The package insert enclosed in the panel box provides a listing of the specific antimicrobial agents and concentrations found in the panel.

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*, 5th Edition, 2009, as well as other recommended literature.

Prior to discarding, sterilize specimen containers and other contaminated materials by autoclaving.

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

STORAGE AND HANDLING

BD Phoenix Panels: Panels are individually packaged and must be stored unopened at room temperature (15–25 °C). Do not refrigerate or freeze. Visually inspect the package for holes or cracks in the foil package. Do not use if the packaging or panel appears to be damaged. 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: 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: 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 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.**

SPECIMEN COLLECTION AND PROCESSING

The Phoenix system is not for use directly with clinical specimens. Only pure culture isolates of aerobic and/or facultatively anaerobic Gram Negative organisms are acceptable for testing. The test isolate **must** be a pure culture. It is recommended that cultures be no more than 24 hours old unless additional incubation is required to achieve sufficient growth.

Isolates must be tested with a Gram stain test to assure the appropriate selection of Phoenix panel type. Once the Gram stain reaction is confirmed select the appropriate Phoenix panel for inoculation (e.g., NMIC/ID panel for use with Gram Negative organisms). Selection of the incorrect panel type could lead to incorrect results.

For AST testing in the Phoenix system, isolates recovered from non-selective media are recommended. It is recommended that media containing antibiotics not be used for organisms to be tested in the Phoenix system. Selective media may inhibit some strains of bacteria therefore caution must be used when selecting isolated colonies from these media.

For ID and AST testing, refer to Table 4-1 in Section 4.3.

When swabs are used, only cotton-tipped applicators should be used to prepare the inoculum suspensions. Some polyester swabs may cause problems with inoculation of the panels.

The usefulness of the 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*[17] for specimen collection, transport, and placement on primary isolation media.

Inoculum for use on the Phoenix system is prepared by the CLSI-recommended direct colony suspension method[18]. Due to variations in inoculum concentrations prepared with McFarland standards, use of the BD BBL CrystalSpec Nephelometer, the BD PhoenixSpec Nephelometer, or the BD Phoenix AP instrument is required for adjusting the test inoculum prior to use in the BD Phoenix system.

It is highly recommended that the purity of both the ID and AST inocula be checked by preparing a purity plate. Instructions for the recommended purity check are provided in Section 4.3.

MATERIALS REQUIRED

Materials Provided

- BD Phoenix Panels
- BD Phoenix ID Broth
- BD Phoenix AST Broth
- BD Phoenix AST Indicator Solution
- 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 sterile tips
- 50 µL pipettor and sterile tips

Materials Required But Not Provided:

- Gram stain reagents
- Sterile cotton swabs
- Nonselective culture plated media (e.g., Trypticase Soy agar with 5% Sheep Blood)
- Incubators
- Biohazard disposable container
- Markers etc

PHOENIX TEST PROCEDURE

Note: The BD Phoenix M50 instrument should always be powered on. If it is not, power on the instrument and allow 2 hours for the instrument to warm up before loading panels. Prepare the BD Phoenix M50 instrument to receive new panels as described in Section 5.2.

Care should be exercised in handling BD Phoenix panels. You should handle panels by the sides only to avoid marking, smudging or obscuring the bottom or top of the panel in any way.

Accession barcode labels affixed to a BD Phoenix panel should:

- Not be of fluorescent material
- Not cover any BD Phoenix panel reaction wells
- Not cover the BD Phoenix panel sequence number barcode

Broth and Panel Preparation: Prepare the BD Phoenix ID Broth, BD Phoenix AST Broth and BD Phoenix panels as described in Section 4.3.

If you are using the BD Phoenix AP instrument, refer to the BD Phoenix AP Instrument User's Manual for panel preparation.

Test inoculum should be prepared from one of the recommended primary media by selecting well isolated colonies of similar morphology that are less than 24 hours old and suspending the inoculum in the BD Phoenix ID Broth with a sterile cotton swab or a wooden applicator.

Only cotton tipped swabs are recommended as inoculum prepared with some polyester swabs may cause problems with the inoculation of the panels.

After inoculation of the ID broth, vortex and allow air bubbles to surface for approximately 10 seconds prior to reading in the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer. Refer to the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer product insert for correct usage and calibration verification. 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**, you can add colonies 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 in Section 4.3 Preparing Panels, Step 9 to dilute the broth.

Confirm current instrument settings for inoculum density before inoculating panels.

Only the BD PhoenixSpec Nephelometer can be used to make inoculum densities of 0.25 McFarland.

Refer to Section 4.3 Preparing Panels for additional information on inoculum density procedures.

The standardized bacterial suspension in BD Phoenix ID broth must be used within 60 minutes of preparation.

For AST testing, the tube of AST broth is prepared by adding one free-falling drop of AST Indicator Solution.

After the addition of the indicator to the AST Broth, the mixed solution can be stored in the dark, at room temperature (15–25 °C), for up to 8 hours. The mixed solution must be used within 2 hours if exposed to light.

If an inoculum density of 0.50–0.60 was used, transfer 25 µL 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 µL (use two shots if utilizing a 25 µL pipettor) of the bacterial suspension from the ID tube into the AST Broth tube.

Panels must be inoculated within 30 minutes of the time that the BD Phoenix AST Broth is inoculated. Panels must be loaded into the BD Phoenix M50 instrument within 30 minutes of inoculation.

For instructions for panel login and loading, refer to Section 3.3.

USER QUALITY CONTROL

In order to ensure appropriate set up procedure and acceptable performance of the system with BD Phoenix panels, the following organisms are recommended to be tested as described in this user's manual. The user is advised to review the individual AST panel formats to determine if all test strains need to be tested for routine laboratory Quality Control. Refer to the Package Insert that accompanies the BD Phoenix panels for expected ID reactions and AST results for QC organisms.

ID (NMIC/ID and NID panels):

Escherichia coli ATCC® 25922

Pseudomonas aeruginosa ATCC 27853

AST (NMIC/ID, NMIC panels):

Escherichia coli ATCC 25922

Pseudomonas aeruginosa ATCC 27853

Escherichia coli ATCC 35218

Klebsiella pneumoniae ATCC 700603

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

Compare recorded reactions to those listed in the Package Insert. If discrepant results are obtained, review test procedure as well as confirm purity of the quality control strain used before contacting BD Diagnostics Technical Services Department. Unacceptable QC results are documented as Fail and acceptable QC results are documented as Pass on the QC Report.

RESULTS

Organism identification will appear on the Phoenix Report Form with a probability percentage from the BD Phoenix database based on the substrate reaction profile. Results from each substrate will appear as +, -, V or X for each reaction. The MIC results will be shown for antimicrobial agents, and Interpretive Categorical Results (SIR) will be shown for the appropriate organism/ antimicrobial agent combinations.

Special messages will be shown when the BDXpert System detects results that are of particular clinical interest.

Further information concerning results obtained from the BD Phoenix system can be found in Section 3.4 Results Tab.

Messages

Error messages may appear if the system detects unexpected reactivity due to inappropriate procedure or instrument malfunction. For a complete listing of error codes and their meaning refer to Sections 2.3.2.7 and 3.4.9.

Special Notes

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/organism combinations a specific minimum or maximum MIC is reported even if there is a lower or higher concentration on the panel. These MIC values are applied by the software and are reported out as less than or equal to (≤) for the minimum MIC or greater than (>) for the maximum MIC. The table below provides the range for these special drug/organism combinations.

Antimicrobial Agent	Organism(s)	Applied Range (µg/mL)
Amikacin	*Morganella morganii*	2–64
	Proteus penneri	2–64
	Proteus vulgaris	2–64
	Providencia species	2–64
Cefotaxime	*Providencia* species	2–64
Cefotetan	*Proteus mirabilis*	4–64
Ertapenem	*Enterobacter aerogenes*	0.0625–4
Gentamicin	*Escherichia coli*	1–16
Piperacillin	*Achromobacter* species	4–128
Piperacillin-tazobactam	*Achromobacter* species	2/4–128/4
	Serratia marcescens	4/4–128/4
	Serratia species	4/4–128/4
Tetracycline	*Morganella morganii*	1–16
Antimicrobial Agent	**Organism(s)**	**Applied Range (µg/mL)**
Ticarcillin	*Achromobacter* species	4–128
	Alcaligenes species	4–128
	Brevundimonas species	4–128
	Chryseobacterium species	4–128
	Cupriavidus species	4–128
	Delftia acidoverans	4–128
	Elizabethkingia meningoseptica	4–128

	Myroides species	4–128
	Ochrobactrum anthropi	4–128
	Providencia species	4–128
	Salmonella species	4–128
	Serratia species	4–128
	Shewanella species	4–128
	Sphingobacterium species	4–128
Ticarcillin-clavulanate	*Citrobacter freundii*	4/2–128/2
	Morganella morganii	4/2–128/2
Tobramycin	*Enterobacter aerogenes*	0.5–16
Trimethoprim	*Enterobacter aerogenes*	1–16
	Proteus mirabilis	1–16

LIMITATIONS OF THE PROCEDURE

See the package insert shipped with the panel 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 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 Nephelometer, the BD PhoenixSpec Nephelometer, or the BD Phoenix AP instrument 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 or BD Phoenix AP instrument can be used to measure the inoculum density for this range.
- BD Phoenix panels can be read only by the BD Phoenix M50 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.

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

- 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 or special growth requirements, 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 or rare occurrence 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 dilution method.

PERFORMANCE CHARACTERISTICS

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 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
Species Level	0.5	95.6%	3.6%	0.8%
	0.25	98.1%	1.4%	0.5%

An internal study was performed to simulate inter-site reproducibility. The identification results obtained using the BD Phoenix system were compared with expected results. This performance testing demonstrated intra-site and inter-site reproducibility of at least 95% or greater.

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. Additionally, a challenge set of 30 previously characterized organisms was tested at one site.

Positive Percent Agreement = 183/189 = 96.8% Negative Percent Agreement = 780/812 = 96.1% Overall Percent Agreement = 963/1001 = 96.2%

Gram Negative Susceptibility

Clinical, stock, and challenge isolates were tested across multiple clinical sites to determine Essential Agreement (EA) and Category Agreement (CA) of the BD Phoenix system to the CLSI broth microdilution reference method. Essential Agreement occurs when the MIC of the BD Phoenix system and the reference method agree exactly or is within ± 1 dilution of each other. Category Agreement occurs when the BD Phoenix system results agree with the reference method with respect to the CLSI categorical interpretative criteria (susceptible, intermediate, resistant). The table below summarizes the data from these studies.

Additionally testing performed at multiple clinical sites demonstrated at least 95% reproducibility or greater within ± 1 doubling dilution for all antimicrobial agents listed in the table below.

Gram-negative Susceptibility Performance Table

DRUG CLASS	DRUG NAME	DRUG CODE	DRUG RANGE (*µg*/mL)	EA N	EA %	CA N	CA %
Aminoglycoside	Amikacin	AN	0.5–64	2598	94.7	2598	96.7
Beta-lactam	Amoxicillin-Clavulanate	AMC	0.5/0.25– 32/16	2249	96.7	2249	90.9
Beta-lactam	Ampicillin	AM	0.5–32	1712	97.0	1712	94.6
Beta-lactam	Ampicillin-sulbactam	SAM	1.0/0.5–32/16	1106	95.8	1106	86.6
Beta-lactam	Aztreonam	ATM	0.5–64	1403	97.6	1355	95.1
Beta-lactam	Cefazolin	CZ	0.5–32	1056	96.5	1056	95.9
Beta-lactam	Cefepime	FEP	0.5–64	1384	98.0	1384	96.7
Beta-lactam	Cefotaxime	CTX	0.5–64	2268	95.0	2268	92.7
Beta-lactam	Cefotetan	CTT	2–64	1175	96.6	1175	96.8
Beta-lactam	Cefoxitin	FOX	0.5–64	1397	96.9	1397	93.3
Beta-lactam	Cefpodoxime	CPD	0.125–8	1533	95.9	1533	97.3
Beta-lactam	Ceftazidime	CAZ	0.5–64	2388	96.6	2388	94.7
Beta-lactam	Ceftriaxone	CRO	0.5–64	2416	96.1	2416	91.6
Beta-lactam	Cefuroxime	CXM	1–64	1868	95.6	1868	93.3
Beta-lactam	Cephalothin	CF	1–64	2025	96.4	2025	89.0
Quinolone	Ciprofloxacin	CIP	0.25–4	2853	98.8	2853	95.1
Beta-lactam	Ertapenem*	ETP	0.0625–8	1469	98.4	1469	97.6
Quinolone	Gatifloxacin	GAT	0.25–8	2213	98.8	2213	95.8
Aminoglycoside	Gentamicin	GM	0.25–16	2751	96.2	2751	96.3
Beta-lactam	Imipenem	IPM	0.0625–32	1348	94.6	1348	95.3
Quinolone	Levofloxacin	LVX	0.25–8	2934	98.5	2934	95.8
Beta-lactam	Meropenem	MEM	0.125–32	1202	97.8	1202	98.5
Tetracycline	Minocycline	MI	1–32	2081	94.2	1711	92.0
Quinolone	Moxifloxacin	MXF	0.125–8	2202	98.3	2202	97.6
Quinolone	Nalidixic Acid	NA	2–32	2103	96.2	2103	98.6
Nitrofuran	Nitrofurantoin	FM	8–512	2130	95.8	2130	84.4
Quinolone	Norfloxacin	NOR	0.25–16	2792	97.5	2792	94.3
Quinolone	Ofloxacin	OFX	0.25–8	2926	98.5	2926	94.6
Beta-lactam	Piperacillin	PIP	2–128	1151	96.1	1151	94.7
Beta-lactam	Piperacillin-tazobactam	TZP	0.5/4–128/4	1546	93.2	1546	94.9
Tetracycline	Tetracycline	TE	0.5–16	2837	95.5	2837	92.3
Beta-lactam	Ticarcillin	TIC	1–128	3428	94.9	3428	93.1
Beta-lactam	Ticarcillin-Clavulanate	TIM	1/2–128/2	2114	93.0	2114	89.4
Glycylcycline	Tigecycline	TGC	0.25–16	884	97.5	884	97.4

DRUG CLASS	DRUG NAME	DRUG CODE	DRUG RANGE (µg/mL)	EA N	EA %	CA N	CA %
Aminoglycoside	Tobramycin	NN	0.125–16	2658	93.3	2658	95.3
Folate Antagonist	Trimethoprim	TMP	0.5–16	1856	95.5	1856	98.7
Folate Antagonist	Trimethoprim-sulfamethoxazole	SXT	0.5/9.5–16/304	2212	96.0	2212	97.7

* See information in table below

NOTE

MIC dilutions appearing in this manual are actual serial 2-fold dilution concentrations. MIC values appearing on reports may be rounded.

Performance Notes:.

Drug	
Ertapenem	The performance of the BD Phoenix System with ertapenem for *Proteus vulgaris* and *Providencia rettgeri* was determined using 5 isolates of *P. vulgaris* and 6 isolates of *P. rettgeri*, The BD Phoenix MIC values for ertapenem tended to be one doubling dilution higher when testing *Enterobacter aerogenes* (n=268) by the manual and BD Phoenix AP inoculation methods compared to reference broth microdilution. Due to an insufficient number of on-scale resistant *E. aerogenes* available during comparative testing, the performance of BD Phoenix Automated System for *E. aerogenes* isolates with MIC range of 2–4 µg/mL is unknown.

The ability of the BD Phoenix System to detect resistance for the following drug/organism combinations is unknown because resistant organisms were not available at the time of comparative testing:

Drug	
Ertapenem	*Citrobacter koseri, Klebsiella oxytoca, Proteus vulgaris, Providencia rettgeri, Providencia stuartii*
Meropenem	*Citrobacter freundii, Citrobacter koseri, Enterobacter aerogenes, Klebsiella oxytoca, Morganella morganii, Proteus vulgaris, Providencia* species
Tigecycline	*Enerobacteriaceae* species

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Manufactured by

Becton, Dickinson and Company

7 Loveton Circle

Sparks, MD 21152 USA

Made in USA

7.2 BD Phoenix Gram Positive Panel Information Insert

BD Phoenix™ Automated Microbiology System

BD Phoenix™ PMIC/ID Panels
BD Phoenix™ PMIC Panels
BD Phoenix™ PID Panels

INTENDED USE

The BD Phoenix Automated Microbiology System is intended for the *in vitro* rapid identification (ID) of Gram Positive bacteria from pure culture belonging to the genera *Staphylococcus, Enterococcus,* other Gram Positive cocci and Gram Positive bacilli. The BD Phoenix Automated Microbiology System is also intended for the quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of most Gram Positive bacteria from pure culture belonging to the genera *Staphylococcus* and *Enterococcus.*

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.

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.[10,11]

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.[12] The broth dilution technique involves exposing bacteria to decreasing concentrations of antimicrobial agents in liquid media by serial two-fold dilutions. The lowest concentration of an antimicrobial agent in which no visible growth occurs is defined as the minimal inhibitory concentration (MIC).

The introduction in 1956 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 antimicrobial susceptibility test (AST).[13] 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.[14]

The BD Phoenix AST is a modified miniaturized version of the micro-broth doubling dilution technique. Susceptibility testing in the Phoenix system is performed through determination of bacterial growth in the presence of various concentrations of the antimicrobial agent tested.

PRINCIPLES OF THE PROCEDURE

A maximum of 50 identification and antimicrobial susceptibility tests can be performed in the BD Phoenix instrument at a time using BD Phoenix ID/AST combination panels. A sealed and self-inoculating molded polystyrene tray, with 136 micro-wells containing dried reagents, serves as the Phoenix disposable. The combination panel includes an ID side with dried substrates for bacterial 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^{++} and $Mg^{++)}$ to optimize susceptibility testing performance.

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 contains 84 wells with dried antimicrobial agents and 1 growth control well. Panels are available as ID only (BD Phoenix™ NID Panels, BD Phoenix™ PID Panels), AST only (BD Phoenix™ NMIC Panels, BD Phoenix™ PMIC Panels), or ID/AST combination (BD Phoenix™ NMIC/ID Panels, BD Phoenix™ PMIC/ID Panels). BD Phoenix Emerge (AST136) panels contain wells for antimicrobial susceptibility on both the 51-well and 85-well sides. BD Phoenix Emerge panels are available for Gram Positive (PMIC), Gram Negative (NMIC) and *Streptococcus* panels (SMIC). Unused wells are reserved for future use.

BD Phoenix panels are inoculated with a standardized inoculum. 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 up to 16 hours if necessary. BD Phoenix panels are read only by the instrument. BD Phoenix panels cannot be read manually.

Bacterial 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 in 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 the 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 ID Database is provided in Section 8.3. Reactions employed by various substrates and the principles employed in the Phoenix ID reactions are described in Section 8.2.

Antimicrobial Susceptibility Testing: The BD Phoenix AST method 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.[15] 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 producing Susceptible, Intermediate, or Resistant (SIR) result classifications.

A complete list of taxa for which the Phoenix system can provide AST results is provided in Section 8.3. The list of antimicrobial agents and concentrations available for susceptibility testing in the BD Phoenix system is provided at the end of this sub-section.

There are antimicrobial agents for use with the BD Phoenix System that are not proven to be effective for treating infections for all organisms listed in the taxa. For interpreting and reporting results of antimicrobial agents that have been shown to be active against organism groups both *in vitro* and in clinical infections refer to the individual pharmaceutical antimicrobial agent labeling. Alternatively, refer to the most recent CLSI M100 Performance Standard, Table 1.[16]

The components required for testing using the BD Phoenix system include: 1) BD Phoenix panels with panel closures, 2) BD Phoenix ID Broth, 3) BD Phoenix AST Broth, 4) BD Phoenix AST Indicator solution 5) BD Phoenix Inoculation Station, 6) BD Phoenix Panel Carrier, 7) BD BBL CrystalSpec Nephelometer, the BD PhoenixSpec Nephelometer, or the BD Phoenix AP instrument, and 8) 25 µL pipettor and tips, 9) Miscellaneous lab supplies (listed under Materials Required but Not Provided).

Prior to inoculation, the Phoenix panel is placed on the Inoculation Station with the inoculation ports at the top for filling. Separate inocula are added manually to the ID and AST ports. The inocula flow down the panel in serpentine fashion, filling the panel wells as the liquid front progresses toward the pad. The pad absorbs excess inoculum. Closures are manually inserted in the fill ports. An air admittance port is located in the divider area of the panel lid to ensure adequate oxygen tension in the panel for the duration of the test.

INGREDIENTS:

For a listing of biochemical substrates used in the Phoenix panel refer to Section 8.2. The package insert enclosed in the panel box provides a listing of the specific antimicrobial agents and concentrations found in the panel.

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*, 5th Edition, 2009, as well as other recommended literature.

Prior to discarding, sterilize specimen containers and other contaminated materials by autoclaving. Panels once inoculated should be handled carefully until placed in the instrument.

STORAGE AND HANDLING

BD Phoenix Panels: Panels are individually packaged and must be stored unopened at room temperature (15–25 °C). Do not refrigerate or freeze. Visually inspect the package for holes or cracks in the foil package. Do not use if the panel or packaging appears to be damaged. 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: 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: 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 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**.

SPECIMEN COLLECTION AND PROCESSING

The BD Phoenix system is not for use directly with clinical specimens. Only pure culture isolates of Gram Positive organisms are acceptable for testing. The test isolate must be a pure culture. It is recommended that cultures be no more than 24 hours old unless additional incubation is required to achieve sufficient growth.

Isolates must be tested with a Gram stain test to assure the appropriate selection of BD Phoenix panel type. Once the Gram stain reaction is confirmed select the appropriate BD Phoenix panel for inoculation (e.g., PMIC/ID panel for use with Gram Positive organisms). Selection of the incorrect panel type could lead to incorrect results.

For AST testing in the BD Phoenix system, isolates recovered from non-selective media are recommended. It is recommended that media containing antibiotics not be used for organisms to be tested in the BD Phoenix system. Selective media may inhibit some strains of bacteria therefore caution must be used when selecting isolated colonies from these media.

For ID and AST testing, refer to Table 4-1 in Section 4.3.

For ID only testing of Gram Positive organisms, isolates from one of the following media may be used: Trypticase Soy Agar without blood, Columbia Colistin Nalidixic Acid (CNA) Agar with 5% sheep blood and Phenylethanol Agar (PEA).

When swabs are used, only cotton-tipped applicators should be used to prepare the inoculum suspensions. Some polyester swabs may cause problems with inoculation of the panels.

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*[17] for specimen collection, transport, and placement on primary isolation media.

Inoculum for use on the BD Phoenix system is prepared by the CLSI-recommended direct colony suspension method.[18] Due to variations in inoculum concentrations prepared with McFarland standards, use of the BD BBL CrystalSpec Nephelometer, the BD PhoenixSpec Nephelometer, or the BD Phoenix AP instrument is required for adjusting the test inoculum prior to use in the BD Phoenix system.

It is highly recommended that the purity of both the ID and AST inocula be checked by preparing a purity plate. Instructions for the recommended purity check are provided in Section 4.3.

MATERIALS REQUIRED

Materials Provided

- BD Phoenix Panels
- BD Phoenix ID Broth
- BD Phoenix AST Broth
- BD Phoenix AST Indicator Solution
- 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 sterile tips
- 50 µL pipettor and sterile tips

Materials Required But Not Provided:

- Gram stain reagents
- Sterile cotton swabs
- Nonselective culture plated media (e.g., Trypticase Soy agar with 5% Sheep Blood)
- Incubators
- Biohazard disposable container
- Markers etc

PHOENIX TEST PROCEDURE

Note: The BD Phoenix instrument should always be powered on. If it is not, power on the instrument and allow 2 hours for the instrument to warm up before loading panels. Prepare the Phoenix instrument to receive new panels as described in Section 5.2.

Care should be exercised in handling BD Phoenix panels. You should handle panels by the sides only to avoid marking, smudging or obscuring the bottom or top of the panel in any way.

Accession barcode labels affixed to a BD Phoenix panel should:

- Not be of fluorescent material
- Not cover any BD Phoenix panel reaction wells
- Not cover the BD Phoenix panel sequence number barcode

Broth and Panel Preparation: Prepare the BD Phoenix ID Broth, BD Phoenix AST Broth and BD Phoenix panels as described in Section 4.3.

If you are using the BD Phoenix AP instrument, refer to the BD Phoenix AP Instrument User's Manual for panel preparation.

Test inoculum should be prepared from one of the recommended primary media by selecting well isolated colonies of similar morphology that are less than 24 hours old and suspending the inoculum in the BD Phoenix ID broth with a sterile cotton swab or a wooden applicator.

Only cotton tipped swabs are recommended as inoculum prepared with some polyester swabs may cause problems with the inoculation of the panels.

After inoculation of the ID broth, vortex and allow air bubbles to surface for approximately 10 seconds prior to reading in the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer. Refer to the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer product insert for correct usage and calibration verification. 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**, you can add colonies 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 in Section 4.3, Step 9 to dilute the broth.

Confirm current instrument settings for inoculum density before inoculating panels.

Only the BD PhoenixSpec Nephelometer can be used to make inoculum densities of 0.25 McFarland.

Refer to Section 4.3 Preparing Panels for additional information on inoculum density procedures.

The standardized bacterial suspension in BD Phoenix ID broth must be used within 60 minutes of preparation.

For AST testing, the tube of AST broth is prepared by adding one free-falling drop of AST Indicator Solution.

After the addition of the indicator to the AST Broth, the mixed solution can be stored in the dark, at room temperature (15–25 °C), for up to 8 hours. The mixed solution must be used within 2 hours if exposed to light.

If an inoculum density of 0.50–0.60 was used, transfer 25 µL 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 µL (use two shots if utilizing a 25 µL pipettor) of the bacterial suspension from the ID tube into the AST Broth tube.

Panels must be inoculated within 30 minutes of the time that the BD Phoenix AST Broth is inoculated. Panels must be loaded into the BD Phoenix instrument within 30 minutes of inoculation.

For instructions for panel login and loading, refer to Sections 3.3 and Section 3.3.2.

USER QUALITY CONTROL

In order to ensure appropriate set up procedure and acceptable performance of the system with Phoenix panels, the following organisms are recommended to be tested as described in this user's manual. The user is advised to review the individual AST panel formats to determine if all test strains need to be tested for routine laboratory Quality Control. Refer to the Package Insert that accompanies the BD Phoenix panels for expected ID reactions and AST results for QC organisms.

ID (PMIC/ID and PID panels):

Staphylococcus aureus ATCC 29213

Enterococcus faecalis ATCC 29212

AST (PMIC/ID, PMIC panels):

Staphylococcus aureus ATCC 29213

Enterococcus faecalis ATCC 29212

Staphylococcus aureus ATCC 25923

Enterococcus faecalis ATCC 51299

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

Compare recorded reactions to those listed in the Package Insert. If discrepant results are obtained, review test procedure as well as confirm purity of the quality control strain used before contacting BD Diagnostics Technical Services Department. Unacceptable QC results are documented as Fail and acceptable QC results are documented as Pass on the QC Report.

RESULTS

Organism identification will appear on the BD Phoenix Report Form with a probability percentage from the BD Phoenix database based on the substrate reaction profile. Results from each substrate will appear as +, -, V, or X for each reaction. The MIC results will be shown for all antimicrobial agents, and Interpretive Categorical Results (SIR) will be shown for the appropriate organism/ antimicrobial agent combinations.

Special messages will be shown when the BDXpert System detects results that are of particular clinical interest.

Further information concerning results obtained from the BD Phoenix system can be found in Section 3.4 Results Tab.

Messages

Error messages may appear if the system detects unexpected reactivity due to inappropriate procedure or instrument malfunction. For a complete listing of error codes and their meaning refer to Sections 2.3.2.7 and 3.4.9.

SPECIAL NOTES

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/organism combinations a specific minimum or maximum MIC is reported even if there is a lower or higher concentration on the panel. These MIC values are applied by the software and are reported out as less than or equal to (≤) for the minimum MIC or greater than (>) for the maximum MIC. The table below provides the range for these special drug/organism combinations.

Antimicrobial Agent	Organism(s)	Applied Range (µg/mL)
Oxacillin	Coagulase negative staphylococci	0.0625–1.0
Penicillin	*Staphylococcus* spp.	0.0625–1.0
	Enterococcus spp.	1.0–32
Gentamicin	*Staphylococcus epidermidis*	<4 and >16*
Moxifloxacin	*Enterococcus* spp. other than *E. faecium*	0.25–8

* MICs of 4, 8, 16 not reported

LIMITATIONS OF THE PROCEDURE

See the package insert shipped with the panel for specific organism/antimicrobial limitations.

General

- A Gram stain test is required for the selection of the appropriate Phoenix panel types. Accurate identification and/or AST results may not be made without this test.
- Use only well-isolated bacterial 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 Nephelometer, the BD PhoenixSpec Nephelometer, or the BD Phoenix AP instrument 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 or BD Phoenix AP instrument can be used to measure the inoculum density for this range.
- 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.

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

- After the addition of the 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 or special growth requirements 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 or rare occurrence 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 dilution method.

PERFORMANCE CHARACTERISTICS

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
Species Level	0.5	95.4%	3.9%	0.7%
	0.25	98.0%	1.6%	0.4%

An internal study was performed to simulate inter-site reproducibility. The identification results obtained using the BD Phoenix system were compared with expected results. This performance testing demonstrated intra-site and inter-site reproducibility of at least 95% or greater.

Gram Positive Susceptibility

Clinical, stock, and challenge isolates were tested across multiple clinical sites to determine Essential Agreement (EA) and Category Agreement (CA) of the BD Phoenix system to the CLSI broth microdilution reference method. Essential Agreement occurs when the MIC of the Phoenix system and the reference method agree exactly or is within ± 1 dilution of each other. Category Agreement occurs when the BD Phoenix system results agree with the reference method with respect to the CLSI categorical interpretative criteria (susceptible, intermediate, resistant). The table below summarizes the data from these studies.

Additionally testing performed at multiple clinical sites demonstrated at least 95% reproducibility or greater within ± 1 doubling dilution for all antimicrobial agents listed in the table below.

Gram-positive Susceptibility Performance Table

DRUG CLASS	DRUG NAME	DRUG CODE	DRUG RANGE (*µg*/mL)	EA N	EA %	CA N	CA %
Beta-lactam	Amoxicillin-Clavulanate	AMC	0.25/0.12–32/16	871	94.1	871	96.7
Beta-lactam	Ampicillin	AM	0.0625–32	475	93.3	475	98.5
Beta-lactam	Ampicillin-sulbactam	SAM	2/1–32/16	1240	97.2	1240	97.3
Beta-lactam	Cefazolin	CZ	2–32	597	99.5	597	99.7
Beta-lactam	Cefoxitin	FOX	1–32	1164	96.3	1164	90.1
Cephem	Ceftaroline*	CPT	0.0625–4	866	94.7	866	98.2
Beta-lactam	Cephalothin	CF	0.5–64	904	96.2	904	98.0
Phenicol	Chloramphenicol	C	1–32	1447	93.4	1447	93.4
Macrolide Lincosamide Streptogramin	Clindamycin	CC	0.125–8	1242	98.2	1242	98.7
Cyclic lipopeptide	Daptomycin*	DAP	0.125–32	1568	97.4	1568	98.8
Tetracycline	Doxycycline	D	0.25–16	1211	96.3	1211	94.8
Macrolide Lincosamide Streptogramin	Erythromycin	E	0.625–8	1395	95.0	1395	94.6
Quinolone	Gatifloxacin	GAT	0.25–8	1180	98.6	1180	90.1
Aminoglycoside	Gentamicin	GM	0.25–16	1223	91.9	1223	95.2
Aminoglycoside	Gentamicin- Syn	GMS	500	NA	NA	763	98.6
Quinolone	Levofloxacin	LVX	0.25–8	1878	96.8	1878	95.1
Oxazolidinone	Linezolid	LZD	0.25–32	1454	91.1	1454	95.3
Beta–lactam	Meropenem	MEM	0.5–16	620	98.4	1198	96.6

DRUG CLASS	DRUG NAME	DRUG CODE	DRUG RANGE (µg/mL)	EA N	EA %	CA N	CA %
Tetracycline	Minocycline	MI	1–32	1619	98.8	745	98.5
Quinolone	Moxifloxacin	MXF	0.125–8	1777	96.0	1777	90.1
Nitrofuran	Nitrofurantoin*	FM	4–128	979	98.5	979	100.0
Quinolone	Norfloxacin	NOR	0.25–16	1252	96.9	1252	97.4
Quinolone	Ofloxacin	OFX	0.25–8	1184	98.7	1184	98.2
Beta–lactam	Oxacillin	OX	0.0625–4	1231	95.4	1231	96.6
Beta–lactam	Penicillin	P	0.0625–32	1256	93.6	1256	97.5
Beta–lactam	Piperacillin–Tazobactam	TZP	1/4–128/4	1348	95.8	585	100.0
Macrolide Lincosamide Streptogramin	Quinupristin–dalfopristin	SYN	0.25–4	2019	94.5	1500	95.5
Rifamycin	Rifampin	RA	0.25–32	1261	98.3	1261	98.2
Aminoglycoside	Streptomycin Syn	STS	1000	NA	NA	756	97.8
Tetracycline	Tetracycline	TE	0.5–16	2040	96.9	2040	96.5
Glycylcycline	Tigecycline*	TGC	0.0313–4	1021	98.0	1021	100.0
Aminoglycoside	Tobramycin	NN	0.5–16	953	93.5	797	98.5
Folate Antagonist	Trimethoprim–sulfamethoxazole	SXT	0.5/9.5– 16/304	634	96.4	634	97.9
Glycopeptide	Vancomycin	VA	0.5–32	1538	99.0	1538	99.6
NA	Inducible Macrolide Resistance (iMLSb) Test	ECC	NA	NA	NA	295	97.6

* See information in the table below.

NOTE

MIC dilutions appearing in this manual are actual serial 2-fold dilution concentrations. MIC values appearing on reports may be rounded.

Performance Notes:

Drug	
Ceftaroline	BD Phoenix MIC values tended to be higher by one dilution compared to reference broth micro-dilution. *Staphylococcus aureus* with an interpretation of 'resistant' for ceftaroline is uncommon in most institutions or may result from technical errors. Verify ID/AST if this phenotype has not been previously encountered from this patient or institution.
Tigecycline	BD Phoenix MIC values for isolates of *Staphylococcus aureus* may be lower by one dilution compared to reference broth microdilution.

The ability of the BD Phoenix System to detect nonsusceptible/resistance for the following drug/organism combinations is unknown because nonsusceptible/resistant organisms were not available at the time of comparative testing:

Drug	
Ceftaroline	*Staphylococcus aureus*
Daptomycin	*Staphylococcus* spp.; *Enterococcus* spp.
Nitrofurantoin	*Staphylococcus* spp.; *Enterococcus* spp.
Tigecycline	*Enterococcus faecalis; Staphylococcus aureus*

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Manufactured by

Becton, Dickinson and Company

7 Loveton Circle

Sparks, MD 21152 USA

Made in USA

7.3 BD Phoenix Strep Panel Information Insert

BD Phoenix™ Automated Microbiology System

BD Phoenix™ SMIC/ID Panels
BD Phoenix™ SMIC Panels

INTENDED USE

The BD Phoenix Automated Microbiology System is intended for the *in vitro* rapid identification (ID) of bacteria from pure culture belonging to the genera *Streptococcus.* The BD Phoenix Automated Microbiology System is also intended for the quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of most bacteria isolates from pure culture belonging to the genera *Streptococcus*.

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.

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.[10,11]

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.[12] The broth dilution technique involves exposing bacteria to decreasing concentrations of antimicrobial agents in liquid media by serial two-fold dilutions. The lowest concentration of an antimicrobial agent in which no visible growth occurs is defined as the minimal inhibitory concentration (MIC).

The introduction in 1956 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 antimicrobial susceptibility test (AST).[13] 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.[14]

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.

PRINCIPLES OF THE PROCEDURE

A maximum of 50 identification and antimicrobial susceptibility tests can be performed in the Phoenix instrument at a time using BD Phoenix ID/AST 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 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-S Broth is cation-adjusted (e.g., Ca^{++} and Mg^{++}) to optimize susceptibility testing performance.

The 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 contains 84 wells with dried antimicrobial agents and 1 growth control well. Panels are available as ID only (BD Phoenix NID Panels, BD Phoenix PID Panels), AST only (BD Phoenix™ NMIC Panels, Phoenix PMIC Panels, BD Phoenix SMIC Panels), or ID/AST combination (BD Phoenix NMIC/ID Panels, BD Phoenix PMIC/ID Panels, BD Phoenix SMIC/ID Panels). BD Phoenix Emerge (AST136) panels contain wells for antimicrobial susceptibility on both the 51-well and 85-well sides. BD Phoenix Emerge panels are available for Gram Positive (PMIC), Gram Negative (NMIC) and *Streptococcus* panels (SMIC). Unused wells are reserved for future use.

BD Phoenix panels are inoculated with a targeted organism density of 0.5 McFarland (0.5–0.6 McFarland is acceptable). Organism suspensions must be prepared only with the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer. 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 up to 16 hours if necessary. BD Phoenix panels are read only by the instrument. BD Phoenix panels cannot be read manually.

Bacterial 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 in 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 the 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 ID Database is provided in Section 8.3. Reactions employed by various substrates and the principles employed in the BD Phoenix ID reactions are described in Section 8.2.

Antimicrobial Susceptibility Testing: The BD Phoenix AST method 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.[15] 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 system can provide AST results is provided in Section 8.3. The list of antimicrobial agents and concentrations available for susceptibility testing in the BD Phoenix system is provided in this sub-section.

There are antimicrobial agents for use with the BD Phoenix System that are not proven to be effective for treating infections for all organisms listed in the taxa. For interpreting and reporting results of antimicrobial agents that have been shown to be active against organism groups both *in vitro* and in clinical infections refer to the individual pharmaceutical antimicrobial agent labeling. Alternatively, refer to the most recent CLSI M100 Performance Standard, Table 1.[16]

The components required for testing using the Phoenix system include: 1) BD Phoenix panels with panel closures, 2) BD Phoenix ID Broth, 3) BD Phoenix AST-S Broth, 4) BD Phoenix AST-S Indicator solution 5) BD Phoenix Inoculation Station, 6) BD Phoenix Panel Carrier, 7) BD BBL CrystalSpec or BD PhoenixSpec Nephelometer and standards, and 8) Miscellaneous lab supplies (listed under Materials Required but Not Provided).

Prior to inoculation, the BD Phoenix panel is placed on the Inoculation Station with the inoculation ports at the top for filling. Separate inocula are added manually to the ID and AST ports. The inocula flow down the panel in serpentine fashion, filling the panel wells as the liquid front progresses toward the pad. The pad absorbs excess inoculum. Closures are manually inserted in the fill ports. An air admittance port is located in the divider area of the panel lid to ensure adequate oxygen tension in the panel for the duration of the test.

INGREDIENTS:

For a listing of biochemical substrates and/or antimicrobial agents found in the Phoenix panel refer to Section 8.2. The package insert enclosed in the panel box provides a listing of the specific antimicrobial agents and concentrations found in the panel.

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*, 5th Edition, 2009, as well as other recommended literature.

Prior to discarding, sterilize specimen containers and other contaminated materials by autoclaving. Panels, once inoculated, should be handled carefully until placed in the instrument.

STORAGE AND HANDLING

BD Phoenix Panels: Panels are individually packaged and must be stored unopened at room temperature (15–25 °C). Do not refrigerate or freeze. Visually inspect the package for holes or cracks in the foil package. Do not use if the panel or packaging appears to be damaged. 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-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-S Broth tubes at 2–25 °C. Expiration dating is shown on the tube label.

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 BD Phoenix AST-S 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-S Indicator Solution**.

SPECIMEN COLLECTION AND PROCESSING

The BD Phoenix system is not for use directly with clinical specimens. Only pure culture isolates of aerobic and/or facultatively anaerobic gram negative and gram positive organisms are acceptable for testing. The test isolate *must* be a pure culture. It is recommended that cultures be no more than 24 hours old unless additional incubation is required to achieve sufficient growth.

Isolates must be tested with a Gram stain test to assure the appropriate selection of BD Phoenix panel type Once the Gram stain reaction is confirmed select the appropriate BD Phoenix panel for inoculation (e.g., SMIC/ID panel for use with streptococcal organisms). Selection of the incorrect panel type could lead to incorrect results.

For AST testing in the BD Phoenix system, isolates recovered from non-selective media are recommended. It is recommended that media containing antibiotics not be used for organisms to be tested in the BD Phoenix system. Selective media may inhibit some strains of bacteria therefore caution must be used when selecting isolated colonies from these media.

For ID and AST testing, use isolates from Trypticase Soy Agar with 5% Sheep Blood (TSAII). Other recommended media that may be used for ID and AST testing of streptococcal organisms include Columbia Agar with 5% Sheep Blood or Phenylethyl Alcohol Agar. Chocolate agar should not be used for Streptococcal identification with SMIC/ID panels. Chocolate agar may be used for Streptococcal susceptibility testing only.

When swabs are used, only cotton-tipped applicators should be used to prepare the inoculum suspensions. Some polyester swabs may cause problems with inoculation of the panels.

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*[17] for specimen collection, transport, and placement on primary isolation media.

Inoculum for use on the BD Phoenix system is prepared by CLSI-recommended direct colony suspension method.[18] Due to variations in inoculum concentrations prepared with McFarland standards, use of the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer is required for adjusting the test inoculum prior to use in the BD Phoenix system.

It is highly recommended that the purity of the ID or AST inocula be checked by preparing a purity plate. Instructions for the recommended purity check are provided in Section 4.3.

MATERIALS REQUIRED

Materials Provided

- BD Phoenix Panels
- BD Phoenix ID Broth
- BD Phoenix AST-S Broth
- BD Phoenix AST-S Indicator Solution
- BD Phoenix Inoculation Station
- BD Phoenix Transport Caddy
- BD BBL CrystalSpec Nephelometer or BD PhoenixSpec Nephelometer
- 25 µl pipettor and sterile tips

Materials Required but Not Provided:

- Gram stain reagents
- Sterile cotton swabs
- Nonselective culture plated media (e.g., Trypticase Soy agar with 5% Sheep Blood)
- Incubators
- Biohazard disposable container
- Markers etc

PHOENIX TEST PROCEDURE

Note: The BD Phoenix instrument should always be powered on. If it is not, power on the instrument and allow 2 hours for the instrument to warm up before loading panels. Prepare the BD Phoenix M50 instrument to receive new panels as described in Section 5.2.

Care should be exercised in handling BD Phoenix panels. You should 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 should:

- Not be of fluorescent material
- Not cover any BD Phoenix panel reaction wells
- Not cover the BD Phoenix panel sequence number barcode

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. These reagents are not interchangeable with the AST Broth and AST Indicator Solution that are used with BD Phoenix Gram positive and Gram negative panels.

Broth and Panel Preparation: Prepare the BD Phoenix ID Broth, BD Phoenix AST-S Broth and Phoenix panels as described in Section 4.3 under BD Phoenix Strep Panels.

The BD Phoenix AP instrument should not be used to prepare BD Phoenix Strep inoculum.

Test inoculum should be prepared from one of the recommended primary media by selecting well isolated colonies of similar morphology that are 18–24 hours old and suspending the inoculum in the BD Phoenix ID broth with a sterile cotton swab or a wooden applicator.

Only cotton tipped swabs are recommended as inoculum prepared with some polyester swabs may cause problems with the inoculation of the panels.

After inoculation of the ID Broth, vortex and allow air bubbles to surface for approximately 10 seconds prior to reading in the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer. Refer to the Nephelometer product insert for correct usage and calibration verification. Inoculum prepared in the BD Phoenix ID Broth should be adjusted to be approximately equivalent to a 0.5 or 0.6 McFarland units when measured by the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer. If the inoculation density is too low, you can add colonies from the isolate. If the inoculum concentration in the tube exceeds 0.6 McFarland, it is recommended that the tube be discarded. A new tube should be used for inoculation preparation.

The standardized bacterial suspension in BD Phoenix ID broth must be used within 60 minutes of preparation.

For AST testing, the tube of AST-S broth is prepared by adding one free-falling drop of AST-S Indicator Solution.

After the addition of the indicator to the AST-S Broth, the mixed solution can be stored in the dark, at room temperature (15–25 °C), for up to 8 hours. The mixed solution must be used within two hours if exposed to light.

Using a pipettor transfer 25 ul of the standardized bacterial suspension from the ID tube into the tube of AST-S Broth.

Panels must be inoculated within 30 minutes of the time that the BD Phoenix AST-S Broth is inoculated. Panels must be loaded into the BD Phoenix instrument within 30 minutes of inoculation.

For instructions for panel login and loading, refer to Sections 3.3 and 3.3.2.

USER QUALITY CONTROL

In order to ensure appropriate set up procedure and acceptable performance of the system with BD Phoenix panels, the following organisms are recommended to be tested as described in this user's manual. The user is advised to review the individual AST panel formats to determine if all test strains need to be tested for routine laboratory Quality Control. Refer to the Package Insert that accompanies the BD Phoenix panels for expected ID reactions and AST results for QC organisms.

ID (SMIC/ID panels):

Streptococcus pneumoniae ATCC 49619

Streptococcus agalactiae ATCC 13813

AST (SMIC/ID, SMIC panels):

Streptococcus pneumoniae ATCC 49619

For the most reliable results, it is recommended that the QC organisms are sub-cultured at least twice on two consecutive days onto TSA II with 5% Sheep Blood agar before use in the BD Phoenix system.

Compare recorded reactions to those listed in the Package Insert. If discrepant results are obtained, review test procedure as well as confirm purity of the quality control strain used before contacting BD Diagnostic Systems Technical Services Department. Unacceptable QC results are documented as Fail and acceptable QC results are documented as Pass on the QC Report.

RESULTS

Organism identification will appear on the BD Phoenix Report Form with a probability percentage from the BD Phoenix database based on the substrate reaction profile. Results from each substrate will appear as +, -, V, or X for each reaction. The MIC results will be shown for all antimicrobial agents, and Interpretive Categorical Results (SIR) will be shown for the appropriate organism/ antimicrobial agent combinations.

Special messages will be shown when the BDXpert System detects results that are of particular clinical interest.

Further information concerning results obtained from the BD Phoenix system can be found in Section 3.4.

Messages

Error messages may appear if the system detects unexpected reactivity due to inappropriate procedure or instrument malfunction. For a complete listing of error codes and their meaning refer to Sections 2.3.2.7 and 3.4.9.

In general, the Sections 2.3.2.7 and 3.4.9 System provides a MIC for all organisms at any of the concentrations defined on a specific panel. For certain drug/organism combinations a specific minimum or maximum MIC is reported even if there is a lower or higher concentration on the panel. These MIC values are applied by the software and are reported out as less than or equal to (≤) for the minimum MIC or greater than (>) for the maximum MIC. The table below provides the range for these special drug/organism combinations.

Antimicrobial Agent	**Organism(s)**	**Applied Range (µg/mL)**
Penicillin	*Streptococcus agalactiae*	0.0313–8
	Streptococcus viridans group	0.0313–8
Moxifloxacin	*Beta hemolytic Streptococcus* other than *S. agalactiae* (Group B)	0.25–8
	Streptococcus bovis	0.25–8
	Streptococcus acidominimus	0.25–8
	Streptococcus uberis	0.25–8
	Streptococcus porcinus	0.25–8

LIMITATIONS OF THE PROCEDURE

See the package insert shipped with the panel 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 colonies from one of the recommended primary isolation media. Use of mixed colonies could result in inaccurate identification and/or AST interpretations.
- A suspension equivalent of 0.5–0.6 McFarland standard must be met and prepared only with the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer. Use of alternate methods for suspension preparation may cause erroneous identification and/or AST 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.

Identification

- The unique panel environment combined with the shortened incubation time may result in Phoenix panel reactions varying from those obtained using conventional biochemical media.

Antimicrobial Susceptibility Testing

- After the addition of the BD Phoenix AST-S Indicator Solution to the AST-S broth tubes, mix by inversion. DO NOT VORTEX. Vortexing may cause air bubbles to form in the AST-S broth, which can result in inappropriate filling of the BD Phoenix panel during inoculation.
- Because of the low probability of occurrence or special growth requirements some organisms included in the ID taxa are not included in the AST database. These organisms will display the message – This species is not included in the BD Phoenix AST taxonomy; perform an alternate method.
- For some organism/antimicrobial combinations, the absence or rare occurrence 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 dilution method.

PERFORMANCE CHARACTERISTICS

Identification of *Streptococcus* species (SMIC/ID)

In an internal study, the performance of the BD Phoenix for identification of *Streptococcus* species 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
Genus/Species Level	96.3%	2.4%	1.2%

An internal study was performed to simulate inter-site reproducibility. The identification results obtained using the BD Phoenix system were compared with expected results. This performance testing demonstrated intra-site and inter-site reproducibility of at least 95% or greater.

Susceptibility

Clinical, stock, and challenge isolates were tested across multiple clinical sites to determine Essential Agreement (EA) and Category Agreement (CA) of the BD Phoenix system to the CLSI Broth Microdilution reference method with lysed horse blood. Essential Agreement occurs when the MIC of the BD Phoenix system and the reference method agree exactly or is within ± 1 dilution of each other. Category Agreement occurs when the BD Phoenix system results agree with the reference method with respect to the CLSI categorical interpretative criteria (susceptible, intermediate, resistant). The table below summarizes the data from these studies.

Additionally, testing performed at multiple clinical sites demonstrated at least 95% reproducibility or greater within ± 1 doubling dilution for all antimicrobial agents listed in the table below.

DRUG CLASS	DRUG NAME	DRUG CODE	DRUG RANGE (µg/mL)	EA N	EA %	CA N	CA %
Beta-lactam	Amoxicillin	AMX	0.03125–32	1932	96.8	1932	97.0
Beta-lactam	Cefepime	FEP	0.0625–4	1890	97.7	1890	94.3
Beta-lactam	Cefotaxime	CTX	0.0625–4	2009	97.8	2009	97.4
Beta-lactam	Ceftriaxone	CRO	0.0625–4	2013	98.3	2013	97.0
Beta-lactam	Cefuroxime	CXM	0.125–4	1938	97.2	915	97.3
Macrolide Lincosamide Streptogramin	Clindamycin	CC	0.0313–4	1942	94.3	1942	97.3
Lipopeptide	Daptomycin	DAP	0.0313–16	668	94.9	668	99.7
Macrolide Lincosamide Streptogramin	Erythromycin	E	0.0156–4	1593	94.4	1593	98.1
Quinolone	Gatifloxacin	GAT	0.0625–8	1939	95.0	1939	99.1
Quinolone	Levofloxacin	LVX	0.25–16	1955	97.6	1955	99.3
Oxazolidinone	Linezolid*	LZD	0.25–16	1934	96.9	1934	98.6
Beta-lactam	Meropenem	MEM	0.0313–2	1558	97.0	1558	99.4
Quinolone	Moxifloxacin	MXF	0.0625–8	1950	97.3	1950	99.5
Beta-lactam	Penicillin	P	0.0156–32	1941	96.6	1941	94.7
Tetracycline	Tetracycline	TE	0.0625–16	1568	95.2	1568	97.8
Folate Antagonist	Trimethoprim-sulfamethoxazole	SXT	0.0625/1.1875–16/304	906	95.8	906	95.3
Glycopeptide	Vancomycin	VA	0.0625–32	1939	98.2	1939	99.8

* The ability of the BD Phoenix system to detect resistance for this drug with *Streptococcus* species is unknown because a sufficient number of resistant strains were not encountered at the time of comparative clinical testing.

NOTE

MIC dilutions appearing in this manual are actual serial 2-fold dilution concentrations. MIC values appearing on reports may be rounded.

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Manufactured by

Becton, Dickinson and Company

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Sparks, MD 21152 USA

Made in USA

7.4 BD Phoenix Yeast and Yeast-like Species Panel Information Insert

BD Phoenix™ Automated Microbiology System

BD Phoenix™ Yeast ID Panels

INTENDED USE

The BD Phoenix Automated Microbiology System is intended for the *in vitro* rapid identification (ID) of yeast and yeast-like organisms.

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.

Many of the tests used in the BD Phoenix Yeast 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.[10,11,12]

PRINCIPLES OF THE PROCEDURE

A maximum of 50 tests can be performed in the BD Phoenix M50 instrument at a time using BD Phoenix panels. A sealed and self-inoculating molded polystyrene tray, with micro-wells containing dried reagents, serves as the Phoenix disposable. The BD Phoenix Yeast ID panel is comprised of a 51 well ID side, consisting of 47 wells with dried biochemical substrates and 3 control wells. Unused wells are reserved for future use.

BD Phoenix Yeast ID panels are inoculated with a targeted organism density of 2.0 McFarland (2.00–2.40 McFarland is acceptable). Organism suspensions must be prepared only with the BD PhoenixSpec Nepehlometer. 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 up to 16 hours if necessary. BD Phoenix panels are read only by the instrument. BD Phoenix panels cannot be read manually.

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 in 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 the 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 Phoenix ID Database is provided in Section 8.3. Reactions employed by various substrates and the principles employed in the Phoenix ID reactions are described in Section 8.2.

The components required for testing using the Yeast ID panel and Phoenix system include:

1) BD Phoenix panels with panel closures, 2) BD Phoenix ID Broth, 3) BD Phoenix Inoculation Station, 4) BD Phoenix Panel Carrier, 5) BD PhoenixSpec Nephelometer and standards, and 6) Miscellaneous lab supplies (listed under Materials Required but Not Provided).

Prior to inoculation, the BD Phoenix panel is placed on the Inoculation Station with the inoculation ports at the top for filling. Inoculum is added manually to the ID side of the panel. The inocula flow down the panel in serpentine fashion, filling the panel wells as the liquid front progresses toward the pad. The pad absorbs excess inoculum. Closures are manually inserted in the fill ports. An air admittance port is located in the divider area of the panel lid to ensure adequate oxygen tension in the panel for the duration of the test.

INGREDIENTS:

For a listing of biochemical substrates in the BD Phoenix Yeast ID panel refer to Section 8.2.

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*, 5th Edition, 2009, as well as other recommended literature.

Prior to discarding, sterilize specimen containers and other contaminated materials by autoclaving. Panels, once inoculated, should be handled carefully until placed in the instrument.

STORAGE AND HANDLING

BD Phoenix Panels: Panels are individually packaged and must be stored unopened at room temperature (15–25 °C). Do not refrigerate or freeze. Visually inspect the package for holes or cracks in the foil package. Do not use if the panel or packaging appears to be damaged. 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.

SPECIMEN COLLECTION AND PROCESSING

The BD Phoenix system is not for use directly with clinical specimens. Only pure culture isolates are acceptable for testing. The test isolate must be a pure culture. It is recommended that cultures be 18–48 hours old for Yeast testing unless additional incubation is required to achieve sufficient growth.

Isolates must be tested with a Gram stain test to assure the appropriate selection of BD Phoenix panel type Once the Gram stain reaction is confirmed select the appropriate BD Phoenix panel for inoculation. Selection of the incorrect panel type could lead to incorrect results.

For Yeast ID testing, use isolates from Sabouraud Dextrose Agar. Other recommended media that may be used for testing of yeast organisms include Trypticase Soy Agar with 5% Sheep Blood (TSAII), Sabouraud Brain Heart Infusion Agar, Columbia Agar with 5% Sheep Blood, Sabouraud Dextrose Agar-Emmons and Chocolate Agar.

When swabs are used, only cotton-tipped applicators should be used to prepare the inoculum suspensions. Some polyester swabs may cause problems with inoculation of the panels.

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*[13] for specimen collection, transport, and placement on primary isolation media.

Due to variations in inoculum concentrations prepared with McFarland standards, use of the BD PhoenixSpec Nephelometer is required for adjusting the test inoculum prior to use in the BD Phoenix system.

It is highly recommended that the purity of the ID inoculum be checked by preparing a purity plate. Instructions for the recommended purity check are provided as a Note in Section 4.3 under General Panel Preparation.

MATERIALS REQUIRED

Materials Provided

- BD Phoenix Panels
- BD Phoenix Broth
- BD Phoenix Inoculation Station
- BD Phoenix Transpot Caddy
- BD PhoenixSpec Nephelometer

Materials Required But Not Provided:

- Gram stain reagents
- Sterile cotton swabs
- Culture plated media
- Incubators
- Biohazard disposable container
- Markers etc

PHOENIX TEST PROCEDURE

Note: The BD Phoenix M50 instrument should always be powered on. If it is not, power on the instrument and allow two hours for the instrument to warm up before loading panels. Prepare the Phoenix instrument to receive new panels as described in Section 5.2.

Care should be exercised in handling BD Phoenix panels. You should handle panels by the sides only to avoid marking, smudging or obscuring the bottom or top of the panel in any way.

Accession barcode labels affixed to a BD Phoenix panel should:

- Not be of fluorescent material
- Not cover any BD Phoenix panel reaction wells
- Not cover the BD Phoenix panel sequence number barcode

BD Phoenix Yeast ID Panels

BD Phoenix Yeast ID panels are for the identification of yeast and yeast-like organisms.

Broth and Panel Preparation: Prepare the Phoenix ID Broth and Phoenix panels as described under BD Phoenix Yeast ID Panels in Section 4.3.

Test inoculum should be prepared from one of the recommended primary media by selecting well isolated colonies of similar morphology that are 18 to 48 hours old and suspending the inoculum in the BD Phoenix ID broth with a sterile cotton swab or a wooden applicator.

Only cotton tipped swabs are recommended as inoculum prepared with some polyester swabs may cause problems with the inoculation of the panels.

After inoculation of the ID Broth, vortex and allow air bubbles to surface for approximately 10 seconds prior to reading in the BD PhoenixSpec Nephelometer. Refer to the nephelometer product insert for correct usage and calibration verification. Inoculum prepared in the BD Phoenix ID Broth should be adjusted to be approximately equivalent to a 2.00–2.40 McFarland units when measured by the BD PhoenixSpec Nephelometer.

The standardized bacterial suspension in BD Phoenix ID broth must be used within 60 minutes of preparation.

Panels must be loaded into the BD Phoenix instrument within 30 minutes of inoculation.

For instructions for panel login and loading, refer to Sections 3.3 and 3.3.2.

For BD Phoenix Yeast ID panels, the appropriate primary media type must be selected during panel login to ensure optimal system performance.

USER QUALITY CONTROL

In order to ensure appropriate set up procedure and acceptable performance of the system with Phoenix panels, the following organisms are recommended to be tested as described in this user's manual). Refer to the Package Insert that accompanies the BD Phoenix panels for expected ID reactions for QC organisms.

ID (Yeast ID panels):

Candida albicans ATCC 24433

Candida parapsilosis ATCC 22019

For the most reliable results, it is recommended that the QC organisms are sub-cultured at least twice on two consecutive days onto Sabouraud Dextrose Agar or TSA with 5% Sheep Blood before use in the BD Phoenix system.

Compare recorded reactions to those listed in the Package Insert. If discrepant results are obtained, review test procedure as well as confirm purity of the quality control strain used before contacting BD Diagnostic Systems Technical Services Department. Unacceptable QC results are documented as Fail and acceptable QC results are documented as Pass on the QC Report.

RESULTS

Organism identification will appear on the BD Phoenix Report Form with a probability percentage from the Phoenix database based on the substrate reaction profile. Results from each substrate will appear as +, -, V, or X for each reaction.

Special messages will be shown when the BDXpert System detects results that are of particular clinical interest.

Further information concerning results obtained from the BD Phoenix system can be found in Section 3.4 Results Tab.

Messages

Error messages may appear if the system detects unexpected reactivity due to inappropriate procedure or instrument malfunction. For a complete listing of error codes and their meaning refer to Sections 2.3.2.7 and 3.4.9.

LIMITATIONS OF THE PROCEDURE

General

- A Gram stain test is required for the selection of the appropriate BD Phoenix panel types. Accurate identification results may not be made without this test.
- Use only well-isolated yeast colonies from one of the recommended primary isolation media. Use of mixed colonies could result in inaccurate identification.
- 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.
- Phoenix panels can be read only by the BD Phoenix M50 instrument. Visual interpretation of the Phoenix panels is not possible. Any attempt to manually interpret results from the panel may lead to misidentification.

Identification

- The unique panel environment combined with the shortened incubation time may result in Phoenix panel reactions varying from those obtained using conventional biochemical media.

PERFORMANCE CHARACTERISTICS

Identification of Yeast species

The performance of the BD Phoenix Yeast identification was evaluated across multiple sites using pure colonies isolated from Sabouraud Dextrose Agar (SAB) and Trypticase Soy Agar with 5% Sheep Blood (TSA). Results from 519 (SAB) and 510 (TSA) clinical and challenge isolates were evaluated against conventional and molecular methods.

The BD Phoenix Yeast identification performance is outlined below:

Source MediaAgreementNo AgreementNo ID

Genus/Species LevelSAB95.2%3.8%1.0%

TSA96.5%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%.

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Manufactured by

Becton, Dickinson and Company

7 Loveton Circle

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Made in USA

8 – Organism Codes and Panel Information

8.1 Organism Codes, Short Names, Long Names

Long Name	Short Name	Code
Achromobacter denitrificans	Achr. denitrificans	ALCDEN
Achromobacter piechaudii	Achr. piechaudii	ALCPIE
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 calcoaceticus	Acinet. calcoaceticus	ACINCAL
Acinetobacter haemolyticus	Acinet. haemolyticus	ACINHAE
Acinetobacter johnsonii	Acinet. johnsonii	ACINJOH
Acinetobacter junii	Acinet. junii	ACINJUN
Acinetobacter lwoffii	Acinet. lwoffii	ACINLWO
Acinetobacter lwoffii/haemolyticus	Acinet. lwoffii/haemol.	ACINLWOHAE
Acinetobacter radioresistens	Acinet. radioresistens	ACINRAD
Acinetobacter species	Acinet. species	ACINSPE
Actinobacillus lignieresii	Actinob. lignieresii	ACTBLIG
Actinobacillus suis	Actinob. suis	ACTBSUI
Actinobacillus ureae	Actinob. ureae	ACTBURE
Aerococcus species	Aeroc. species	AERCSPE
Aerococcus urinae	Aeroc. urinae	AERCURI

Long Name	Short Name	Code
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
Bacillus cereus	Baci. cereus	BACICER
Bacillus circulans	Baci. circulans	BACICIR
Bacillus coagulans	Baci. coagulans	BACICOA
Bacillus licheniformis	Baci. licheniformis	BACILIC

Long Name	Short Name	Code
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 cepacia complex	Burk. cepacia complex	BURCEP
Burkholderia cepacia/Ralstonia pickettii	Burk. cepacia/Ral. pickettii	BURCEPRALPIC
Burkholderia gladioli	Burk. gladioli	BURGLA
Burkholderia species/Ralstonia species	Burk. species/Ral. species	BURSPERALSPE
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	Can. haemulonii	CANHAE

Long Name	Short Name	Code
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
Candida utilis	Can. utilis	CANUTI
Candida viswanathii	Can. viswanathii	CANVIS
Candida zeylanoides	Can. zeylanoides	CANZEY
Cardiobacterium hominis	Card. hominis	CARHOM
CDC group Vb-3	CDCVb-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

Long Name	Short Name	Code
Cellulomonas turbata	Cell. turbata	OERTUR
Cellulosimicrobium cellulans	Cellulo. cellulans	OERXAN
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
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

Long Name	Short Name	Code
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
Cosenzaea myxofaciens	Cosen. myxofaciens	PROTMYX
Cronobacter sakazakii complex	Cronob. sakazakii complex	ENTBSAK
Cryptococcus albidus	Cryp. albidus	CRYALB
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
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

Long Name	Short Name	Code
Edwardsiella tarda	Ed. tarda	EDWTAR
Edwardsiella tarda biogroup 1	Ed. tarda biogr. 1	EDWTAR1
Eikenella corrodens	Eik. corrodens	EIKCOR
Elizabethkingia meningoseptica	Eliz. meningosept.	CHRBMEN
Empedobacter brevis	Emp. brevis	EMPBRE
Enterobacter aerogenes	Enterob. aerogenes	ENTBAER
Enterobacter asburiae	Enterob. asburiae	ENTBASB
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 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
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

Long Name	Short Name	Code
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 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
Escherichia vulneris	Esch. vulneris	ESCVUL
Ewingella americana	Ew. americana	EWIAME
Exophiala dermatitidis	Exo. dermatitidis	WANDER
Exophiala species	Exo. species	EXOSPE
Gardnerella vaginalis	Gard. vaginalis	GARVAG
Gemella haemolysans	Gem. haemolysans	GEMHAE

Long Name	Short Name	Code
Gemella morbillorum	Gem. morbillorum	GEMMOR
Gemella species	Gem. species	GEMSPE
Geotrichum species	Geo. species	GEOSPE
Globicatella sanguinis	Glob. sanguinis	GLOSAN
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	PICBUR
Kingella denitrificans	King. denitrificans	KINDEN
Kingella kingae	King. kingae	KINKIN
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
Kloeckera species	Kloeck. species	KLOSPE
Kluyvera ascorbata	Kluyvera ascorbata	KLUASC
Kluyvera cryocrescens	Kluyvera cryocres.	KLUCRY
Kluyvera georgiana	Kluyvera georgiana	KLUGEO
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
Kosakonia cowanii	Kosak. cowanii	ENTBCOW

Long Name	Short Name	Code
Kytococcus sedentarius	Kyto. sedentarius	MICSED
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	Lell. amnigena	ENTBAMN
Lelliottia amnigena biogroup 1	Lell. amnigena biogr. 1	ENTBAMN1
Lelliottia amnigena biogroup 2	Lell. amnigena biogr. 2	ENTBAMN2
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
Listeria monocytogenes/innocua	Lis. monocytogenes/innocua	LISMONINN
Listeria species	Lis. species	LISSPE

Long Name	Short Name	Code
Listeria welshimeri	Lis. welshimeri	LISWEL
Lysinibacillus sphaericus	Lysini. sphaericus	BACISPH
Macrococcus caseolyticus	Macroc. caseolyticus	STACAS
Magnusiomyces capitatus	Magnus. capitatus	BLACAP
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	PICFAR
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 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	CDCEF4a
Neisseria zoodegmatis	Nei. zoodegmatis	CDCEF4b
Ochrobactrum anthropi	Och. anthropi	OCHANT
Oligella ureolytica	Olig. ureolytica	OLIURO

Long Name	Short Name	Code
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 dispersa	Pan. dispersa	PANDIS
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	CDCEO2
Pasteurella aerogenes	Past. aerogenes	PASAER
Pasteurella multocida	Past. multocida	PASMUL
Pasteurella pneumotropica	Past. pneumotropica	PASPNE
Pediococcus acidilactici	Ped. acidilactici	PEDACI
Pediococcus damnosus	Ped. damnosus	PEDDAM
Pediococcus dextrinicus	Ped. dextrinicus	PEDDEX
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	ENTBGER
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

Long Name	Short Name	Code
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. 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
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 ssp *pseudoalcaligenes*	Pseud. pseudoal. ssp pseud.	PSEPSEP
Pseudomonas putida	Pseud. putida	PSEPUT
Pseudomonas species	Pseud. species	PSESPE
Pseudomonas stutzeri	Pseud. stutzeri	PSESTU
Pseudomonas veronii	Pseud. veronii	PSEVER
Rahnella aquatilis	Rah. aquatilis	RAHAQU
Ralstonia pickettii	Ral. pickettii	BURPIC

Long Name	Short Name	Code
Ralstonia solanacearum	Ral. solanacearum	BURSOL
Ralstonia species	Ral. species	RALSPE
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
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

Long Name	Short Name	Code
Serratia ficaria	Ser. ficaria	SERFIC
Serratia fonticola	Ser. fonticola	SERFON
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
Shimwellia blattae	Shim. blattae	ESCBLA
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

Long Name	Short Name	Code
Sporobolomyces salmonicolor	Sporobol. salmonicolor	SPOBSAL
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
Staphylococcus 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	Code
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 pettenkoferi	Staph. pettenkoferi	STAPET
Staphylococcus piscifermentans	Staph. piscifermentans	STAPIS
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
Staphylococcus species	Staph. species	STASPE

Long Name	Short Name	Code
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 beta-hemolytic ACG (large colony)	Strep. beta-hemo ACG (lg col)	STRBHE
Streptococcus bovis (Strep. group D)	Strep. bovis (Str. gr. D)	STRBOV
Streptococcus bovis I (Strep. group D)	Strep. bovis I (Str. gr. D)	STRBOVI
Streptococcus bovis II (Strep. group D)	Strep. bovis II (Str. gr. D)	STRBOVII
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	Code
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 ssp *macedonicus*	Strep. gallolyti. ssp macedon.	STRMAC
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
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

Long Name	Short Name	Code
Streptococcus iniae	Strep. iniae	STRINI
Streptococcus intermedius	Strep. intermedius	STRINR
Streptococcus milleri group	Strep. milleri gr.	STRMILGR
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 pyogenes (Strep. group A)	Strep. pyogenes (Str. gr. A)	STRPYO
Streptococcus ratti	Strep. ratti	STRRAT
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 sobrinus	Strep. sobrinus	STRSOB
Streptococcus suis	Strep. suis	STRSUI
Streptococcus uberis	Strep. uberis	STRUBE
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

Long Name	Short Name	Code
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
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

Panel Information

8.2 List of Reagents and Principles Employed in the BD Phoenix System

8.2.1 Gram Negative

L-PHENYLALANINE-AMC	A_LPHET	Enzymatic hydrolysis of the amide or glycosidic bond results in the release of a fluorescent coumarin or 4-methylumbelliferone derivative.
4MU-N-ACETYL-BD-GLUCOS-AMINIDE	M_NAG	
L-GLUTAMIC ACID-AMC	A_LGTA	
L-TRYPTOPHAN-AMC	A_LTRY	
L-PYROGLUTAMIC ACID-AMC	A_LPYR	
L-PROLINE-AMC	A_LPROB	
L-ARGININE-AMC	A_LARGH	
ARGININE-ARGININE-AMC	A_ARARR	
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	
COLISTIN	C_CLST	Resistance to the antimicrobial agent results in a reduction of the resazurin based indicator.
POLYMYXIN B	C_PXB	
D-MANNITOL	C_DMNT	Utilization of a carbon source results in a reduction of the resazurin based indicator.
CITRATE	C_CIT	
ACETATE	C_ACT	
ADONITOL	C_ADO	
MALONATE	C_MLO	
ALPHA-KETOGLUTARIC ACID	C_KGA	
TIGLIC ACID	C_TIG	
FLUORESCENT POSITIVE CONTROL	FLR_CTL	Control to standardize fluorescent substrate results.
FLUORESCENT POSITIVE CONTROL	FLR_CTL	
L-PROLINE-NA	N_LPROT	Enzymatic hydrolysis of the colorless amide substrate releases yellow *p*-nitroaniline.
GAMMA-L-GLUTAMYL-NA	N_LGGH	
BIS (PNP) PHOSPHATE	P_BPHO	Enzymatic hydrolysis of the colorless aryl substituted glycoside releases yellow *p*-nitrophenol.
PNP-BD-GLUCOSIDE	P_BDGLU	

BETA-ALLOSE	R_BALL	Utilization of carbohydrate results in lower pH and change in indicator (phenol red).
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	
BETA-GENTIOBIOSE	R_BGEN	
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	
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.

8.2.2 Gram Positive

4MU-BD-CELLOBIOSIDE	M_BDCEL	Enzymatic hydrolysis of the amide or glycosidic bond results in the release of a fluorescent coumarin or 4-methylumbelliferone derivative.
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	P_ADGLU	
ARGININE-ARGININE-AMC	A_ARARR	
GLYCINE-PROLINE-AMC	A_GLPRB	
4MU-BD-GLUCURONIDE	M_BDGLC	
L-LEUCINE-AMC	A_LLEUH	
4MU-N-ACETYL-BD-GLUCOS-AMINIDE	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	

COLISTIN	C_CLST	Resistance to the antimicrobial agent results in a reduction of the resazurin based indicator.
POLYMYXIN B	C_PXB	
D-GLUCONIC ACID	C_DGUA	Utilization of a carbon source results in a reduction of the resazurin based indicator.
3-METHYL GLUTARIC ACID	C_3MGA	
D-FRUCTOSE	C_DFRU	
IMINODIACETIC ACID	C_IMN	
ALPHA-KETOGLUTARIC ACID	C_KGA	
D-MANNITOL	C_DMNT	
3-METHYLADIPIC ACID	C_MAA	
THYMIDINE	C_THY	
FLUORESCENT POSITIVE CONTROL	FLR_CTL	Control to standardize fluorescent substrate results.
FLUORESCENT POSITIVE CONTROL	FLR_CTL	
ALANINE-ALANINE-PNA	N_ALALH	Enzymatic hydrolysis of the colorless amide substrate releases yellow *p*-nitroaniline.
L-PROLINE-PNA	N_LPROT	
VALINE-ALANINE-PNA	N_VAALA	
PNP-AD-GLUCOSIDE	P_PAGLU	Enzymatic hydrolysis of the colorless aryl substituted glycoside releases yellow *p*-nitrophenol.
PNP-PHOSPHATE	P_PHOL	
BETA-GENTIOBIOSE	R_BGEN	Utilization of carbohydrate results in lower pH and change in indicator (phenol red).
D-SUCROSE	R_DSUC	
MALTOTRIOSE	R_MTT	
N-ACETYL-GLUCOSAMINE	R_NGU	
D-TREHALOSE	R_DTRE	
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.
NITROCEFIN	L_NCF	Enzymatic hydrolysis of the ß-Lactam ring results in a color change.

8.2.3 Streptococci Panel

AMYGDALIN	R_AMY	Utilization of carbohydrate results in lower pH and change in indicator (Phenol red).
D-GALACTOSE	R_DGAL	
D-MANNITOL	R_DMTL	
D-RAFFINOSE	R_DRAF	
D-SORBITOL	R_DSBT	
D-TREHALOSE	R_DTRE	
DEXTRIN	R_DXN	
N-ACETYL-GLUCOSAMINE	R_NGU	
PHENYL GLUCOSIDE	R_PHG	
SALICIN	R_SAL	

ONP-BD-GLUCOSIDE	O_BOGLU	Enzymatic hydrolysis of the colorless aryl substituted glycoside releases yellow *p*-nitrophenol.
PNP-AD-GALACTOSIDE	P_ADGAL	
PNP-BD-CELLOBIOSIDE	P_CELB	
PNP-BD-GALACTOSIDE	P_GALB	
PNP-AD-GLUCOSIDE	P_PAGLU	
PNP-PHOSPHATE	P_PHOL	
ALANINE-ALANINE-PNA	N_ALALH	Enzymatic hydrolysis of the colorless amide substrate releases yellow *p*-nitroanilide.
VALINE-ALANINE-PNA	N_VAALA	
L-LYSINE-PNA	N_LLYSB	
FLUORESCENT POSITIVE CONTROL	FLR_CTL	Control to standardize fluorescent substrate results.
FLUORESCENT POSITIVE CONTROL	FLR_CTL	
THYMIDINE	THY	Utilization of a carbon source resulting in a reduction of the indicator (Resazurin based).
PULLULAN	PUL	
D-TREHALOSE	TRL	
D-LACTOSE	DLAC	
LYSINE-AMC	A_LYSA	Enzymatic hydrolysis of the amide or glycosidic bond results in the release of a fluorescent coumarin or 4-methylumbelliferone derivative.
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	
L-ARGININE-AMC	A_LARGH	
L-HISTIDINE-AMC	A_LHIST	
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.

8.2.4 Yeast Panel

PNP-BD-GLUCOSIDE	P_BDGLU	Enzymatic hydrolysis of the colorless aryl substituted glycoside releases yellow *p*-nitrophenol.
PNP-AD-GLUCOSIDE	P_PAGLU	
ONP-BD-GLUCOSIDE	O_BOGLU	
L-SORBOSE	C_LSBO	Utilization of a carbon source results in a reduction of the resazurin based indicator.
DEXTROSE	C_DEX	
D-MANNITOL	C_DMNT	
D-SUCROSE	C_DSUC	
METHYL-AD-GLUCOPYRANOSIDE	C_MGP	
N-ACETYL-BD-GLUCOSAMINIDE	C_NAG	
DEXTROSE	R_DEX	Utilization of carbohydrate results in lower pH and change in indicator (phenol red).
D-FRUCTOSE	R_DFRU	
D-GALACTOSE	R_DGAL	
SUCROSE	R_DSUC	
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 NEGATIVE CONTROL	Z_FTST	Control to check for fluorescent interference.
FLUORESCENT POSITIVE CONTROL	FLR_CTL	Control to standardize fluorescent substrate results.
FLUORESCENT POSITIVE CONTROL	FLR_CTL	
GAMMA-L-GLUTAMYL-NA	N_LGGH	Enzymatic hydrolysis of the colorless amide substrate releases yellow *p*-nitroaniline.
L-PROLINE-PNA	N_LPROT	

ASPARAGINE-AMC	A_APGT	Enzymatic hydrolysis of the amide or glycosidic bond results in the release of a fluorescent coumarin or 4-methylumbelliferone derivative.
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	
ALANINE-AFC	Z_ALFT	
GLYCINE-AMC	A_GLYB	
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.

8.3 Taxa for ID/AST Determination

8.3.1 Gram Negative (0.5 McFarland)

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
Achromobacter denitrificans	AST
Achromobacter piechaudii	AST
Achromobacter species	ID/AST
Achromobacter xylosoxidans	AST
Acinetobacter baumannii[2]	ID/AST
Acinetobacter baumannii/ calcoaceticus complex[2]	ID/AST
Acinetobacter baumannii/ haemolyticus	AST
Acinetobacter calcoaceticus	AST
Acinetobacter haemolyticus	ID/AST
Acinetobacter johnsonii	AST
Acinetobacter junii	AST
Acinetobacter lwoffii	ID/AST
Acinetobacter lwoffii/ haemolyticus	ID/AST
Acinetobacter radioresistens	AST
Acinetobacter species	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

GRAM NEGATIVE TAXA[1]	ID, AST, ID/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 cepacia complex	ID/AST
Burkholderia cepacia/ Ralstonia pickettii	ID/AST
Burkholderia gladioli	ID
Burkholderia species/ *Ralstonia* species	ID
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
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

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
Citrobacter species	AST
Citrobacter werkmanii	ID/AST
Citrobacter youngae	ID/AST
Comamonas terrigena	ID
Comamonas testosteroni	ID
Cosenzaea myxofaciens	AST
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 meningoseptica	ID/AST
Empedobacter brevis	ID
Enterobacter aerogenes[2]	ID/AST
Enterobacter asburiae	ID/AST
Enterobacter cancerogenus	ID/AST
Enterobacter cloacae[2]	ID/AST
Enterobacter cloacae ssp *dissolvens*	AST
Enterobacter hormaechei	ID/AST
Enterobacter kobei	AST
Enterobacter nimipressuralis	AST
Enterobacter species	AST
Escherichia coli[2]	ID/AST
Escherichia coli serotype O111	AST
Escherichia coli serotype O157	AST
Escherichia fergusonii	ID/AST
Escherichia hermannii	ID/AST
Escherichia species	AST
Escherichia vulneris	ID/AST
Ewingella americana	ID
Grimontia hollisae	ID
Hafnia alvei	ID/AST
Hafnia alvei group 1	AST
Kingella denitrificans	ID
Kingella kingae	ID
Klebsiella granulomatis	AST
Klebsiella oxytoca[2]	ID/AST
Klebsiella ozaenae	ID/AST
Klebsiella pneumoniae[2]	ID/AST
Klebsiella rhinoscleromatis	ID/AST
Klebsiella species	AST
Kluyvera ascorbata	ID/AST
Kluyvera cryocrescens	ID/AST
Kluyvera georgiana	AST
Kluyvera intermedia	ID/AST
Kluyvera species	AST
Kosakonia cowanii	AST
Leclercia adecarboxylata	ID/AST
Lelliottia amnigena	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[2]	ID/AST
Morganella morganii ssp *morganii*	AST
Morganella morganii ssp *morganii* biogroup 1	AST
Morganella morganii ssp sibonii	AST
Morganella species	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
Oligella ureolytica	ID
Oligella urethralis	ID

* Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (Section 3.10.6).

[1]Not all species encountered during clinical performance evaluations.

[2]Organism encountered in clinical trials and ≥ 20 strains available for antimicrobial/organism performance analysis.

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
Pantoea agglomerans	ID/AST
Pantoea ananatis	AST
Pantoea dispersa	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
Pasteurella pneumotropica	ID
Photobacterium damselae	ID
Plesiomonas shigelloides	ID
Pluralibacter gergoviae	ID/AST
Pragia fontium	ID
Proteus hauseri	AST
Proteus mirabilis[2]	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
Providencia species	AST
Providencia stuartii	ID/AST
Pseudomonas aeruginosa[2]	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 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
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[2]	ID/AST
Serratia odorifera	AST
Serratia odorifera 1	ID/AST
Serratia odorifera 2	ID/AST

* Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (Section 3.10.6).

[1]Not all species encountered during clinical performance evaluations.

[2]Organism encountered in clinical trials and ≥ 20 strains available for antimicrobial/organism performance analysis.

GRAM NEGATIVE TAXA[1]	ID, AST, 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
Shigella boydii	ID/AST
Shigella dysenteriae	ID/AST
Shigella flexneri	ID/AST
Shigella sonnei	ID/AST
Shigella species	ID/AST
Shimwellia blattae	AST
Sphingobacterium multivorum	ID/AST
Sphingobacterium multivorum/ thalpophilum	ID/AST
Sphingobacterium species	AST
Sphingobacterium spiritivorum	ID/AST
Sphingobacterium thalpophilum	ID/AST
Sphingomonas paucimobilis	ID
Stenotrophomonas africana	AST
Stenotrophomonas maltophilia[2]	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
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

* Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (Section 3.10.6).

[1]Not all species encountered during clinical performance evaluations.

[2]Organism encountered in clinical trials and ≥ 20 strains available for antimicrobial/organism performance analysis.

8.3.2 Gram Negative (0.25 McFarland)

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
Achromobacter species	ID/AST
Acinetobacter baumannii/calcoaceticus complex	ID/AST
Acinetobacter haemolyticus	ID/AST
Acinetobacter lwoffii	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
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
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

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
Comamonas terrigena	ID
Comamonas testosteroni	ID
Cronobacter sakazakii complex	ID/AST
Cupriavidus pauculus	ID/AST
Delftia acidovorans	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 aerogenes	ID/AST
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
Escherichia vulneris	ID/AST
Ewingella americana	ID
Grimontia hollisae	ID
Hafnia alvei	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
Mannheimia haemolytica	ID
Moellerella wisconsensis	ID/AST
Morganella morganii	ID/AST
Myroides odoratus/odoratimimus	ID/AST

* Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (Section 3.10.6).

1 Not all species encountered during clinical performance evaluations.

2 Organism encountered in clinical trials and ≥ 20 strains available for antimicrobial/organism performance analysis.

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
Neisseria animaloris	ID
Neisseria zoodegmatis	ID
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
Pasteurella pneumotropica	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
Pseudomonas aeruginosa	ID/AST
Pseudomonas fluorescens	ID/AST
Pseudomonas luteola	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
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
Shigella sonnei	ID/AST
Sphingobacterium multivorum	ID/AST
Sphingobacterium spiritivorum	ID/AST
Sphingobacterium thalpophilum	ID/AST
Sphingomonas paucimobilis	ID
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

* Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (Section 3.10.6).

1 Not all species encountered during clinical performance evaluations.

8.3.3 Gram Positive (0.5 McFarland)

GRAM POSITIVE TAXA[1]	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
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
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
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

* Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (Section 3.10.6).

1 Not all species encountered during clinical performance evaluations.

GRAM POSITIVE TAXA[1]	ID, AST, ID/AST*
Leuconostoc citreum	ID
Leuconostoc lactis	ID
Leuconostoc mesenteroides ssp *cremoris*	ID
Leuconostoc mesenteroides ssp *mesenteroides*	ID
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 dextrinicus	ID
Pediococcus parvulus	ID
Pediococcus pentosaceus	ID
Rhodococcus equi	ID
Rothia dentocariosa	ID
Rothia mucilaginosa	ID
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
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
Staphylococcus muscae	AST
Staphylococcus pasteuri	ID/AST
Staphylococcus pettenkoferi	ID/AST
Staphylococcus piscifermentans	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

* Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (Section 3.10.6).

1 Not all species encountered during clinical performance evaluations.

GRAM POSITIVE TAXA[1]	ID, AST, ID/AST*
Staphylococcus sciuri ssp *rodentium*	AST
Staphylococcus sciuri ssp *sciuri*	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
Streptococcus anginosus	ID
Streptococcus bovis (Strep. group D)	ID
Streptococcus bovis I (Strep. group D)	ID
Streptococcus bovis II (Strep. group D)	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 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
Streptococcus vestibularis	ID
Trueperella pyogenes	ID

* Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (Section 3.10.6).
1 Not all species encountered during clinical performance evaluations.

8.3.4 Gram Positive (0.25 McFarland)

GRAM POSITIVE TAXA[1]	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
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 dextrinicus	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

GRAM POSITIVE TAXA[1]	ID, AST, 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
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 bovis (Strep. group D)	ID
Streptococcus bovis I (Strep. group D)	ID
Streptococcus bovis II (Strep. group D)	ID
Streptococcus constellatus	ID
Streptococcus cristatus	ID
Streptococcus equi	ID
Streptococcus gordonii	ID
Streptococcus group C/G (large colony)	ID
Streptococcus intermedius	ID
Streptococcus mitis	ID
Streptococcus mutans	ID
Streptococcus oralis	ID
Streptococcus parasanguinis	ID
Streptococcus pneumoniae	ID

* Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (Section 3.10.6).

1 Not all species encountered during clinical performance evaluations.

GRAM POSITIVE TAXA[1]	ID, AST, ID/AST*
Streptococcus porcinus	ID
Streptococcus pyogenes (Strep. group A)	ID
Streptococcus salivarius	ID
Streptococcus sanguinis	ID
Streptococcus sobrinus	ID
Streptococcus uberis	ID
Streptococcus vestibularis	ID

* Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (Section 3.10.6).

[1] Not all species encountered during clinical performance evaluations.

8.3.5 Streptococci

STREPTOCOCCI TAXA[1]	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 beta-hemolytic ACG (large colony)	AST
Streptococcus bovis (Strep. group D)	AST
Streptococcus bovis I (Strep. group D)	ID/AST
Streptococcus bovis II (Strep. group D)	ID/AST
Streptococcus canis	ID/AST
Streptococcus constellatus	ID/AST
Streptococcus constellatus ssp *constellatus*	AST
Streptococcus constellatus ssp *pharyngis*	AST
Streptococcus criceti	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 ssp *macedonicus*	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/G (small colony)	AST
Streptococcus group CFG (small colony)	AST
Streptococcus group D (non-*enterococcus)*	AST
Streptococcus group E	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 milleri group	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 pyogenes (Strep. group A)	ID/AST

STREPTOCOCCI TAXA[1]	ID, AST, ID/AST*	STREPTOCOCCI TAXA[1]	ID, AST, ID/AST*
Streptococcus ratti	AST	*Streptococcus sobrinus*	ID/AST
Streptococcus salivarius	ID/AST	*Streptococcus suis*	AST
Streptococcus salivarius group	AST	*Streptococcus uberis*	ID/AST
Streptococcus salivarius ssp *thermophilus*	AST	*Streptococcus vestibularis*	ID/AST
Streptococcus sanguinis	ID/AST	*Streptococcus viridans beta-hemolytic* (small colony)	AST
Streptococcus sanguinis group	AST	*Streptococcus viridans* group	AST

*Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (Section 3.10.6).
[1]Not all species encountered during clinical performance evaluations.

8.3.6 Yeast

YEAST TAXA[2]	SABDX SABEM SABHI	CHOC COLSB TSASB
Candida albicans	√	√
Candida apicola	√	√
Candida boidinii		√
Candida bracarensis	√	
Candida catenulata	√	√
Candida ciferrii	√	√
Candida dubliniensis	√	√
Candida firmetaria	√	√
Candida freyschussii	√	√
Candida glabrata	√	√
Candida guilliermondii	√	√
Candida guilliermondii var *membranaefaciens*	√	√
Candida haemulonii	√	√
Candida inconspicua	√	√
Candida kefyr	√	√
Candida krusei	√	√
Candida lipolytica	√	√
Candida lusitaniae	√	√
Candida magnoliae	√	√
Candida melibiosica	√	√
Candida membranaefaciens	√	√
Candida norvegensis	√	√
Candida parapsilosis complex	√	√
Candida pararugosa	√	√
Candida pelliculosa	√	√
Candida pulcherrima	√	√
Candida rugosa	√	√
Candida sake	√	√
Candida sphaerica	√	

YEAST TAXA[2]	SABDX SABEM SABHI	CHOC COLSB TSASB
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	√	
Millerozyma farinosa	√	√
Prototheca wickerhamii	√	√
Prototheca zopfii	√	√
Rhodotorula glutinis	√	√
Rhodotorula minuta	√	√
Rhodotorula mucilaginosa var *mucilaginosa*	√	√
Saccharomyces cerevisiae	√	√
Sporobolomyces salmonicolor	√	√
Trichosporon asahii	√	√
Trichosporon inkin	√	
Trichosporon loubieri	√	
Trichosporon mucoides	√	√
Trichosporon ovoides		√
Zygosaccharomyces bailii	√	

9 – Glossaries

9.1 Glossary

Term	Definition
AIO	All-in-one
Alert Indicator	LED indicator that represents the current alert status. It may stay off, blink or remain on to indicate various conditions of the instrument.
AST	Antimicrobial Susceptibility Test(ing)
ATCC	American Type Culture Collection
BP	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 50 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
demographic data	Accession information for a panel record
DTG	Drug Test Group
EMB	Eosin Methylene Blue agar
error station	Station that has sustained an optical or electromechanical error and has been blocked.
EUCAST	European Committee on Antimicrobial Susceptibility Testing
HE	Hektoen Enteric media agar
ID	Microbial Identification

Term	Definition
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 Summary Group	This is the information that appears in the center of the header which appears on all screens of the BD Phoenix M50 instrument.
Instrument Door/ Panel Button Status	The instrument has an indicator that provides the current panel button and door status to the user.
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.
Isolation Mode	The condition that exists when communication between the BD Phoenix M50 instrument and the AIO PC is lost. Isolation Mode is designed to allow the ID/AST system to avoid test cycle gaps when the AIO PC is temporarily disconnected from the instrument.
MIC	Minimum Inhibitory Concentration; the lowest concentration of an antimicrobic which prohibits continued growth of the tested organism.
Needs Attention	Panels in the instrument's database that have encountered a condition that requires operator attention.
normalizer	A reference panel for use in the BD Phoenix M50 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 52 inserts, 26 in each of two 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.
PEA	Phenylethyl Alcohol agar
Panel In/Out Indicator	An indicator on the instrument that provides the current panel button and door status to the user.

Term	Definition
PHI	Protected Health Information
PII	Personally Identifiable Information
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.
station	The instrument carousel is divided vertically into two tiers (A & B or 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 50 total locations. Each location is assigned a tier letter and a number to determine the location on the tier. Indicator LEDs located behind each panel 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
XLD	Xylose Lysine Deoxycholate agar

9.2 Supplemental ID Test Abbreviations

Test	Description	Test	Description
10C	Growth at 10 degrees Celsius	CAT	Catalase
42C	Growth at 42 degrees Celsius	CEL	Cellobiose
45C	Growth at 45 degrees Celsius	CIT	Citrate
50C	Growth at 50 degrees Celsius	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 *Staphylococcus aureus*	H^2S	Hydrogen Sulfide
HGN	Hemolysis - Gram Negative	OPS	Optochin susceptibility
HGP	Hemolysis - Gram Positive	ORN	Ornithine
HIP	Hippurate	OX	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
MOT	Motility	VAN	Vancomycin
MR	Methyl Red	VP	Voges Proskauer

Test	Description	Test	Description
NIT	Nitrate	XYL	Xylose
NVR	Novobiocin Resistance	YEL	Yellow/orange pigment

9.3 Symbol Glossary

Symbol	Meaning
	Manufacturer
REF	Catalog Number
IVD	In Vitro Diagnostic Medical Device

10 – Replacement Parts

The following items may be ordered by contacting your local BD representative (See Section 12).

Catalog Number	Item
443809	Barcode Scanner (external)
443866	System Software
448047	BD Phoenix™ Update Data (PUD) US
443390	Barcode Scanner Stand
443842	Air Filter
443865	User Manual US Spare PHX50
443894	Quick Reference Guide
443431	Laser Printer
448984	Temperature Standard Panel

11 – 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

12 – BD Contact Information

BD
7 Loveton Circle
Sparks, MD 21152 USA
Voice: (410) 316.4000 • Fax: (410) 527.0244
Technical Service and Support: 1.800.638.8663
Customer Service: 1.800.675.0908
www.bd.com

13 – Yeast Laboratory Procedure

BD Phoenix™ Automated Microbiology System

BD Phoenix™ Yeast ID Panels

13.1 Intended Use

The BD Phoenix Automated Microbiology System is intended for the *in vitro* rapid identification (ID) of yeast and yeast-like organisms.

13.1.1 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.

Many of the tests used in the BD Phoenix Yeast 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.[10,11,12]

A maximum of 50 tests can be performed in the BD Phoenix M50 instrument at a time using BD Phoenix panels. A sealed and self-inoculating molded polystyrene tray, with micro-wells containing dried reagents, serves as the Phoenix disposable. The BD Phoenix Yeast ID panel is comprised of a 51 well ID side, consisting of 47 wells with dried biochemical substrates and three control wells. Unused wells are reserved for future use.

BD Phoenix Yeast ID panels are inoculated with a targeted organism density of 2.0 McFarland (2.00–2.40 McFarland is acceptable). Organism suspensions must be prepared only with the BD PhoenixSpec Nepehlometer. 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 up to 16 hours if necessary. BD Phoenix panels are read only by the instrument. BD Phoenix panels cannot be read manually.

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 in 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 the 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 ID Database is provided in Section 8.3. Reactions employed by various substrates and the principles employed in the Phoenix ID reactions are described in Section 8.2.

The components required for testing using the Yeast ID panel and BD Phoenix system include:

1) BD Phoenix panels with panel closures, 2) BD Phoenix ID Broth, 3) BD Phoenix Inoculation Station, 4) BD Phoenix Panel Carrier, 5) BD PhoenixSpec Nephelometer and standards, and 6) Miscellaneous lab supplies (listed under Materials Required but Not Provided).

Prior to inoculation, the BD Phoenix panel is placed on the Inoculation Station with the inoculation ports at the top for filling. Inoculum is added manually to the ID side of the panel. The inocula flow down the panel in serpentine fashion, filling the panel wells as the liquid front progresses toward the pad. The pad absorbs excess inoculum. Closures are manually inserted in the fill ports. An air admittance port is located in the divider area of the panel lid to ensure adequate oxygen tension in the panel for the duration of the test.

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 *Enterobacteriaceae*; 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 *mec*A-mediated Resistance with *S. aureus* (*mec*A); 8) detection of Vancomycin Resistant *Staphylococcus aureus* (VRSA); 9) detection of BD Phoenix Inducible Macrolide Resistance (IMLS) in *Staphylococcus* spp. For further information, consult the BDXpert manual.

INGREDIENTS

For a listing of biochemical substrates in the BD Phoenix Yeast ID panel refer to Section 8.2

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*, 5th Edition, 2009, as well as other recommended literature.

Prior to discarding, sterilize specimen containers and other contaminated materials by autoclaving. Panels, once inoculated, should be handled carefully until placed in the instrument.

STORAGE AND HANDLING

BD Phoenix Panels: Panels are individually packaged and must be stored unopened at room temperature (15–25 °C). Do not refrigerate or freeze. Visually inspect the package for holes or cracks in the foil package. Do not use if the panel or packaging appears to be damaged. 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.

SPECIMEN COLLECTION AND PROCESSING

The BD Phoenix system is not for use directly with clinical specimens. Only pure culture isolates are acceptable for testing. The test isolate must be a pure culture. It is recommended that cultures be 18–48 hours old for Yeast testing unless additional incubation is required to achieve sufficient growth.

Isolates must be tested with a Gram stain test to assure the appropriate selection of BD Phoenix panel type Once the Gram stain reaction is confirmed select the appropriate BD Phoenix panel for inoculation. Selection of the incorrect panel type could lead to incorrect results.

For Yeast ID testing, use isolates from Sabouraud Dextrose Agar. Other recommended media that may be used for testing of yeast organisms include Trypticase Soy Agar with 5% Sheep Blood (TSAII), Sabouraud Brain Heart Infusion Agar, Columbia Agar with 5% Sheep Blood, Sabouraud Dextrose Agar-Emmons and Chocolate Agar.

When swabs are used, only cotton-tipped applicators should be used to prepare the inoculum suspensions. Some polyester swabs may cause problems with inoculation of the panels.

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*[13] for specimen collection, transport, and placement on primary isolation media.

Due to variations in inoculum concentrations prepared with McFarland standards, use of the BD PhoenixSpec Nephelometer is required for adjusting the test inoculum prior to use in the BD Phoenix system.

It is highly recommended that the purity of the ID inoculum be checked by preparing a purity plate. Instructions for the recommended purity check are provided as a Note in Section 4.3 under General Panel Preparation.

MATERIALS REQUIRED

Materials Provided

- BD Phoenix Panels
- BD Phoenix Broth
- BD Phoenix Inoculation Station
- BD Phoenix Transpot Caddy
- BD PhoenixSpec Nephelometer

Materials Required But Not Provided:

- Gram stain reagents
- Sterile cotton swabs
- Culture plated media
- Incubators
- Biohazard disposable container
- Markers etc

BD PHOENIX TEST PROCEDURE

Note: The BD Phoenix M50 instrument should always be powered on. If it is not, power on the instrument and allow 2 hours for the instrument to warm up before loading panels. Prepare the BD Phoenix instrument to receive new panels as described in Section 5.2.

Care should be exercised in handling BD Phoenix panels. You should handle panels by the sides only to avoid marking, smudging or obscuring the bottom or top of the panel in any way.

Accession barcode labels affixed to a BD Phoenix panel should:

- Not be of fluorescent material
- Not cover any BD Phoenix panel reaction wells
- Not cover the BD Phoenix panel sequence number barcode

BD Phoenix Yeast Panels

BD Phoenix Yeast ID panels are for the identification of yeast and yeast-like organisms.

Broth and Panel Preparation: Prepare the BD Phoenix ID Broth and BD Phoenix panels as described under BD Phoenix Yeast ID Panels in Section 4.3.

Test inoculum should be prepared from one of the recommended primary media by selecting well isolated colonies of similar morphology that are 18 to 48 hours old and suspending the inoculum in the BD Phoenix ID broth with a sterile cotton swab or a wooden applicator.

Only cotton tipped swabs are recommended as inoculum prepared with some polyester swabs may cause problems with the inoculation of the panels.

After inoculation of the ID Broth, vortex and allow air bubbles to surface for approximately 10 seconds prior to reading in the BD PhoenixSpec Nephelometer. Refer to the nephelometer product insert for correct usage and calibration verification. Inoculum prepared in the BD Phoenix ID Broth should be adjusted to be approximately equivalent to a 2.00–2.40 McFarland units when measured by the BD PhoenixSpec Nephelometer.

The standardized bacterial suspension in BD Phoenix ID broth must be used within 60 minutes of preparation.

Panels must be loaded into the BD Phoenix instrument within 30 minutes of inoculation.

For instructions for panel login and loading, refer to Sections 3.3 and 3.3.2.

For BD Phoenix Yeast ID panels, the appropriate primary media type must be selected during panel login to ensure optimal system performance.

13.2 Quality Control

In order to ensure appropriate set up procedure and acceptable performance of the system with BD Phoenix panels, the following organisms are recommended to be tested as described in this user's manual). Refer to the Package Insert that accompanies the BD Phoenix panels for expected ID reactions for QC organisms.

ID (Yeast ID panels):

Candida albicans ATCC 24433

Candida parapsilosis ATCC 22019

For the most reliable results, it is recommended that the QC organisms are sub-cultured at least twice on two consecutive days onto Sabouraud Dextrose Agar or TSA with 5% Sheep Blood before use in the BD Phoenix system.

Compare recorded reactions to those listed in the Package Insert. If discrepant results are obtained, review test procedure as well as confirm purity of the quality control strain used before contacting BD Diagnostic Systems Technical Services Department. Unacceptable QC results are documented as Fail and acceptable QC results are documented as Pass on the QC Report.

13.3 Results

Organism identification will appear on the BD Phoenix Report Form with a probability percentage from the BD Phoenix database based on the substrate reaction profile. Results from each substrate will appear as +, -, V, or X for each reaction.

Special messages will be shown when the BDXpert System detects results that are of particular clinical interest.

Further information concerning results obtained from the BD Phoenix system can be found in Section 3.4.

13.3.1 Messages

Error messages may appear if the system detects unexpected reactivity due to inappropriate procedure or instrument malfunction. For a complete listing of error codes and their meaning refer to Sections 2.3.2.7 and 3.4.9.

13.3.2 Limitations of the Procedure

General

- A Gram stain test is required for the selection of the appropriate BD Phoenix panel types. Accurate identification results may not be made without this test.
- Use only well-isolated yeast colonies from one of the recommended primary isolation media. Use of mixed colonies could result in inaccurate identification.
- 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 M50 instrument. Visual interpretation of the BD Phoenix panels is not possible. Any attempt to manually interpret results from the panel may lead to misidentification.

PERFORMANCE CHARACTERISTICS

Identification of Yeast species

The performance of the BD Phoenix Yeast identification was evaluated across multiple sites using pure colonies isolated from Sabouraud Dextrose Agar (SAB) and Trypticase Soy Agar with 5% Sheep Blood (TSA). Results from 519 (SAB) and 510 (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	95.2%	3.8%	1.0%
	TSA	96.5%	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%.

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Manufactured by
Becton, Dickinson and Company
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Sparks, MD 21152 USA
Made in USA

13.4 Procedure Form

Procedure* BD Phoenix Yeast Panels
Laboratory kit configured for the biochemical identification and antimicrobial susceptibility or microorganisms.

Facility Name

Prepared by	Date Adopted	Supercedes Procedure #

Review Date	Revision Date	Signature

Distributed to	# of copies	Distributed to	# of copies

*Any modifications to this document are the sole responsibility of the facility. This Sample Procedure is not intended as a substitute for your facility procedure manual, instrument manual, or reagent labeling/package insert. This Sample Procedure is intended as a model for use by your facility to meet the needs of your laboratory.

14 – Strep Laboratory Procedure

BD Phoenix™ SMIC/ID Panels

BD Phoenix™ SMIC Panels

14.1 Intended Use

The BD Phoenix Automated Microbiology System is intended for the *in vitro* rapid identification (ID) of bacteria from pure culture belonging to the genera *Streptococcus.* The BD Phoenix Automated Microbiology System is also intended for the quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of most bacteria isolates from pure culture belonging to the genera *Streptococcus*.

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.

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.[10,11]

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.[12] The broth dilution technique involves exposing bacteria to decreasing concentrations of antimicrobial agents in liquid media by serial two-fold dilutions. The lowest concentration of an antimicrobial agent in which no visible growth occurs is defined as the minimal inhibitory concentration (MIC).

The introduction in 1956 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 antimicrobial susceptibility test (AST).[13] 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.[14]

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.

14.1.1 Principles of the Procedure

A maximum of 50 identification and antimicrobial susceptibility tests can be performed in the BD Phoenix instrument at a time using BD Phoenix ID/AST 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 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-S Broth is cation-adjusted (e.g., Ca^{++} and Mg^{++}) to optimize susceptibility testing performance.

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 contains 84 wells with dried antimicrobial agents and 1 growth control well. Panels are available as ID only (BD Phoenix NID Panels, BD Phoenix PID Panels), AST only (BD Phoenix™ NMIC Panels, BD Phoenix PMIC Panels, BD Phoenix SMIC Panels), or ID/AST combination (BD Phoenix NMIC/ID Panels, BD Phoenix PMIC/ID Panels, BD Phoenix SMIC/ID Panels). BD Phoenix Emerge (AST136) panels contain wells for antimicrobial susceptibility on both the 51-well and 85-well sides. BD Phoenix Emerge panels are available for Gram Positive (PMIC), Gram Negative (NMIC) and *Streptococcus* panels (SMIC). Unused wells are reserved for future use.

BD Phoenix panels are inoculated with a targeted organism density of 0.5 McFarland (0.5 to 0.6 McFarland is acceptable). Organism suspensions must be prepared only with the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer. 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 up to 16 hours if necessary. BD Phoenix panels are read only by the instrument. BD Phoenix panels cannot be read manually.

Bacterial 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 in 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 the 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 ID Database is provided in Section 8.3. Reactions employed by various substrates and the principles employed in the BD Phoenix ID reactions are described in Section 8.2.

Antimicrobial Susceptibility Testing

The BD Phoenix AST method 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.[15] 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 system can provide AST results is provided in Section 8.3. The list of antimicrobial agents and concentrations available for susceptibility testing in the BD Phoenix system is provided in this sub-section.

There are antimicrobial agents for use with the BD Phoenix System that are not proven to be effective for treating infections for all organisms listed in the taxa. For interpreting and reporting results of antimicrobial agents that have been shown to be active against organism groups both *in vitro* and in clinical infections refer to the individual pharmaceutical antimicrobial agent labeling. Alternatively, refer to the most recent CLSI M100 Performance Standard, Table 1.[16]

The components required for testing using the BD Phoenix system include: 1) BD Phoenix panels with panel closures, 2) BD Phoenix ID Broth, 3) BD Phoenix AST-S Broth, 4) BD Phoenix AST-S Indicator solution 5) BD Phoenix Inoculation Station, 6) BD Phoenix Panel Carrier, 7) BD BBL CrystalSpec or BD PhoenixSpec Nephelometer and standards, and 8) Miscellaneous lab supplies (listed under Materials Required but Not Provided).

Prior to inoculation, the BD Phoenix panel is placed on the Inoculation Station with the inoculation ports at the top for filling. Separate inocula are added manually to the ID and AST ports. The inocula flow down the panel in serpentine fashion, filling the panel wells as the liquid front progresses toward the pad. The pad absorbs excess inoculum. Closures are manually inserted in the fill ports. An air admittance port is located in the divider area of the panel lid to ensure adequate oxygen tension in the panel for the duration of the test.

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 *Enterobacteriaceae*; 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 *mec*A-mediated Resistance with S. *aureus* (*mec*A); 8) detection of Vancomycin Resistant *Staphylococcus aureus* (VRSA); 9) detection of BD Phoenix Inducible Macrolide Resistance (IMLS) in *Staphylococcus* spp. For further information, consult the BDXpert manual.

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.[22]

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. BD Phoenix cefoxitin MIC result is used to predict *mec*A-mediated resistance in *Staphylococcus aureus.* 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 *mec*A in staphylococci. The breakpoint selected in the instrument configuration is used for the categorical interpretation.

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 *mec*A-mediated Resistance Marker for *Staphylococcus aureus* (mecA)

The BD Phoenix *mec*A test is used to predict *mec*A-mediated resistance in *Staphylococcus aureu*s. The principle is similar to the CLSI-recommended Disk Diffusion test, which uses a cefoxitin (FOX) disk to predict *mec*A-mediated resistance in *S. aureu*s. The performance of the test was established against multiplex PCR methods[25] as well as the Disk Diffusion test. With the BD Phoenix *mec*A test, the *mec*A-specific FOX MICs used for detection of the resistance marker will be configured in the instrument. When the *mec*A resistance marker is detected, the interpretations for all beta-lactam drugs on the same BD Phoenix panel are changed to resistant,[22] and the BD Phoenix *mec*A 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 aureu*s. 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-S25 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.

INGREDIENTS

For a listing of biochemical substrates and/or antimicrobial agents found in the BD Phoenix panel refer to Section 8.2. The package insert enclosed in the panel box provides a listing of the specific antimicrobial agents and concentrations found in the panel.

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*, 5th Edition, 2009, as well as other recommended literature.

Prior to discarding, sterilize specimen containers and other contaminated materials by autoclaving. Panels, once inoculated, should be handled carefully until placed in the instrument.

STORAGE AND HANDLING

BD Phoenix Panels: Panels are individually packaged and must be stored unopened at room temperature (15–25 °C). Do not refrigerate or freeze. Visually inspect the package for holes or cracks in the foil package. Do not use if the panel or packaging appears to be damaged. 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-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-S Broth tubes at 2–25 °C. Expiration dating is shown on the tube label.

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 BD Phoenix AST-S 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-S Indicator Solution**.

SPECIMEN COLLECTION AND PROCESSING

The BD Phoenix system is not for use directly with clinical specimens. Only pure culture isolates of aerobic and/or facultatively anaerobic gram negative and gram positive organisms are acceptable for testing. The test isolate *must* be a pure culture. It is recommended that cultures be no more than 24 hours old unless additional incubation is required to achieve sufficient growth.

Isolates must be tested with a Gram stain test to assure the appropriate selection of BD Phoenix panel type Once the Gram stain reaction is confirmed select the appropriate BD Phoenix panel for inoculation (e.g., SMIC/ID panel for use with streptococcal organisms). Selection of the incorrect panel type could lead to incorrect results.

For AST testing in the BD Phoenix system, isolates recovered from non-selective media are recommended. It is recommended that media containing antibiotics not be used for organisms to be tested in the BD Phoenix system. Selective media may inhibit some strains of bacteria therefore caution must be used when selecting isolated colonies from these media.

For ID and AST testing, use isolates from Trypticase Soy Agar with 5% Sheep Blood (TSAII). Other recommended media that may be used for ID and AST testing of streptococcal organisms include Columbia Agar with 5% Sheep Blood or Phenylethyl Alcohol Agar. Chocolate agar should not be used for Streptococcal identification with SMIC/ID panels. Chocolate agar may be used for Streptococcal susceptibility testing only.

When swabs are used, only cotton-tipped applicators should be used to prepare the inoculum suspensions. Some polyester swabs may cause problems with inoculation of the panels.

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*[17] for specimen collection, transport, and placement on primary isolation media.

Inoculum for use on the BD Phoenix system is prepared by CLSI-recommended direct colony suspension method.[18] Due to variations in inoculum concentrations prepared with McFarland standards, use of the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer is required for adjusting the test inoculum prior to use in the BD Phoenix system.

It is highly recommended that the purity of the ID or AST inocula be checked by preparing a purity plate. Instructions for the recommended purity check are provided in Section 4.3.

Materials Required:

- BD Phoenix Panels
- BD Phoenix ID Broth
- BD Phoenix AST-S Broth
- BD Phoenix AST-S Indicator Solution
- BD Phoenix Inoculation Station
- BD Phoenix Transport Caddy
- BD BBL CrystalSpec Nephelometer or BD PhoenixSpec Nephelometer
- 25 µL pipettor and sterile tips

Materials Required but Not Provided:

- Gram stain reagents
- Sterile cotton swabs
- Nonselective culture plated media (e.g., Trypticase Soy agar with 5% Sheep Blood)
- Incubators
- Biohazard disposable container
- Markers etc

BD PHOENIX TEST PROCEDURE

> NOTE
>
> The BD Phoenix instrument should always be powered on. If it is not, power on the instrument and allow two hours for the instrument to warm up before loading panels. Prepare the BD Phoenix M50 instrument to receive new panels as described in Section 5.2.

Care should be exercised in handling BD Phoenix panels. You should 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 should:

- Not be of fluorescent material
- Not cover any BD Phoenix panel reaction wells
- Not cover the BD Phoenix panel sequence number barcode

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. These reagents are not interchangeable with the AST Broth and AST Indicator Solution that are used with BD Phoenix Gram positive and Gram negative panels.

Broth and Panel Preparation: Prepare the BD Phoenix ID Broth, BD Phoenix AST-S Broth and BD Phoenix panels as described in Section 4.3 under BD Phoenix Strep Panels.

The BD Phoenix AP instrument should not be used to prepare BD Phoenix Strep inoculum.

Test inoculum should be prepared from one of the recommended primary media by selecting well isolated colonies of similar morphology that are 18–24 hours old and suspending the inoculum in the BD Phoenix ID broth with a sterile cotton swab or a wooden applicator.

Only cotton tipped swabs are recommended as inoculum prepared with some polyester swabs may cause problems with the inoculation of the panels.

After inoculation of the ID Broth, vortex and allow air bubbles to surface for approximately 10 seconds prior to reading in the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer. Refer to the Nephelometer product insert for correct usage and calibration verification. Inoculum prepared in the BD Phoenix ID Broth should be adjusted to be approximately equivalent to a 0.5 or 0.6 McFarland units when measured by the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer. If the inoculation density is too low, you can add colonies from the isolate. If the inoculum concentration in the tube exceeds 0.6 McFarland, it is recommended that the tube be discarded. A new tube should be used for inoculation preparation.

The standardized bacterial suspension in BD Phoenix ID broth must be used within 60 minutes of preparation.

For AST testing, the tube of AST-S broth is prepared by adding one free-falling drop of AST-S Indicator Solution.

After the addition of the indicator to the AST-S Broth, the mixed solution can be stored in the dark, at room temperature (15–25 °C), for up to 8 hours. The mixed solution must be used within 2 hours if exposed to light.

Using a pipettor transfer 25 uL of the standardized bacterial suspension from the ID tube into the tube of AST-S Broth.

Panels must be inoculated within 30 minutes of the time that the BD Phoenix AST-S Broth is inoculated. Panels must be loaded into the BD Phoenix instrument within 30 minutes of inoculation.

For instructions for panel login and loading, refer to Sections 3.3 and 3.3.2.

14.2 Quality Control

In order to ensure appropriate set up procedure and acceptable performance of the system with BD Phoenix panels, the following organisms are recommended to be tested as described in this user's manual. The user is advised to review the individual AST panel formats to determine if all test strains need to be tested for routine laboratory Quality Control. Refer to the Package Insert that accompanies the BD Phoenix panels for expected ID reactions and AST results for QC organisms.

ID (SMIC/ID panels):

Streptococcus pneumoniae ATCC 49619

Streptococcus agalactiae ATCC 13813

AST (SMIC/ID, SMIC panels):

Streptococcus pneumoniae ATCC 49619

For the most reliable results, it is recommended that the QC organisms are sub-cultured at least twice on two consecutive days onto TSA II with 5% Sheep Blood agar before use in the BD Phoenix system.

Compare recorded reactions to those listed in the Package Insert. If discrepant results are obtained, review test procedure as well as confirm purity of the quality control strain used before contacting BD Life Sciences Technical Services Department. Unacceptable QC results are documented as Fail and acceptable QC results are documented as Pass on the QC Report.

14.3 Results

Organism identification will appear on the BD Phoenix Report Form with a probability percentage from the BD Phoenix database based on the substrate reaction profile. Results from each substrate will appear as +, -, V, or X for each reaction. The MIC results will be shown for all antimicrobial agents, and Interpretive Categorical Results (SIR) will be shown for the appropriate organism/ antimicrobial agent combinations.

Special messages will be shown when the BDXpert System detects results that are of particular clinical interest. Further information concerning results obtained from the BD Phoenix system can be found in Section 3.4.

14.3.1 Messages

Error messages may appear if the system detects unexpected reactivity due to inappropriate procedure or instrument malfunction. For a complete listing of error codes and their meaning refer to Sections 2.3.2.7 and 3.9.4.

In general, the Sections 2.3.2.7 and 3.9.4 provide a MIC for all organisms at any of the concentrations defined on a specific panel. For certain drug/organism combinations a specific minimum or maximum MIC is reported even if there is a lower or higher concentration on the panel. These MIC values are applied by the software and are reported out as less than or equal to (≤) for the minimum MIC or greater than (>) for the maximum MIC. The table below provides the range for these special drug/organism combinations.

Antimicrobial Agent	Organism(s)	Applied Range (µg/mL)
Penicillin	*Streptococcus agalactiae*	0.0313–8
	Streptococcus viridans group	0.0313–8
Moxifloxacin	*Beta hemolytic Streptococcus* other than *S. agalactiae* (Group B)	0.25–8
	Streptococcus bovis	0.25–8
	Streptococcus acidominimus	0.25–8
	Streptococcus uberis	0.25–8
	Streptococcus porcinus	0.25–8

14.3.2 Limitations of the Procedure

See the package insert shipped with the panel for specific organism/antimicrobial limitations.

See the package insert shipped with the panel 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 colonies from one of the recommended primary isolation media. Use of mixed colonies could result in inaccurate identification and/or AST interpretations.
- A suspension equivalent of 0.5–0.6 McFarland standard must be met and prepared only with the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer. Use of alternate methods for suspension preparation may cause erroneous identification and/or AST 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.

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

- After the addition of the BD Phoenix AST-S Indicator Solution to the AST-S broth tubes, mix by inversion. DO NOT VORTEX. Vortexing may cause air bubbles to form in the AST-S broth, which can result in inappropriate filling of the BD Phoenix panel during inoculation.
- Because of the low probability of occurrence or special growth requirements some organisms included in the ID taxa are not included in the AST database. These organisms will display the message – This species is not included in the BD Phoenix AST taxonomy; perform an alternate method.
- For some organism/antimicrobial combinations, the absence or rare occurrence 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 dilution method.

14.3.3 Performance Characteristics

Identification of *Streptococcus* species (SMIC/ID)

In two internal studies, the performance of the BD Phoenix Gram Positive identification was In an internal study, the performance of the BD Phoenix for identification of *Streptococcus* species 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
Genus/Species Level	96.3%	2.4%	1.2%

An internal study was performed to simulate inter-site reproducibility. The identification results obtained using the BD Phoenix system were compared with expected results. This performance testing demonstrated intra-site and inter-site reproducibility of at least 95% or greater.

Susceptibility

Clinical, stock, and challenge isolates were tested across multiple clinical sites to determine Essential Agreement (EA) and Category Agreement (CA) of the BD Phoenix system to the CLSI Broth Microdilution reference method with lysed horse blood.Essential Agreement occurs when the MIC of the BD Phoenix system and the reference method agree exactly or is within ± 1 dilution of each other. Category Agreement occurs when the BD Phoenix system results agree with the reference method with respect to the CLSI categorical interpretative criteria (susceptible, intermediate, resistant). The table below summarizes the data from these studies.

Additionally, testing performed at multiple clinical sites demonstrated at least 95% reproducibility or greater within ± 1 doubling dilution for all antimicrobial agents listed in the following table.

DRUG CLASS	DRUG NAME	DRUG CODE	DRUG RANGE (µg/mL)	EA N	EA %	CA N	CA %
Beta-lactam	Amoxicillin	AMX	0.03125–32	1,932	96.8	1,932	97.0
Beta-lactam	Cefepime	FEP	0.0625–4	1,890	97.7	1,890	94.3
Beta-lactam	Cefotaxime	CTX	0.0625–4	2,009	97.8	2,009	97.4
Beta-lactam	Ceftriaxone	CRO	0.0625–4	2,013	98.3	2,013	97.0
Beta-lactam	Cefuroxime	CXM	0.125–4	1,938	97.2	915	97.3
Macrolide Lincosamide Streptogramin	Clindamycin	CC	0.0313–4	1,942	94.3	1,942	97.3
Lipopeptide	Daptomycin	DAP	0.0313–16	668	94.9	668	99.7
Macrolide Lincosamide Streptogramin	Erythromycin	E	0.0156–4	1,593	94.4	1,593	98.1
Quinolone	Gatifloxacin	GAT	0.0625–8	1,939	95.0	1,939	99.1
Quinolone	Levofloxacin	LVX	0.25–16	1,955	97.6	1,955	99.3
Oxazolidinone	Linezolid*	LZD	0.25–16	1,934	96.9	1,934	98.6
Beta-lactam	Meropenem	MEM	0.0313–2	1,558	97.0	1,558	99.4
Quinolone	Moxifloxacin	MXF	0.0625–8	1,950	97.3	1,950	99.5
Beta-lactam	Penicillin	P	0.0156–32	1,941	96.6	1,941	94.7
Tetracycline	Tetracycline	TE	0.0625–16	1,568	95.2	1,568	97.8
Folate Antagonist	Trimethoprim-sulfamethoxazole	SXT	0.0625/1.1875–16/304	906	95.8	906	95.3
Glycopeptide	Vancomycin	VA	0.0625–32	1,939	98.2	1,939	99.8

* The ability of the BD Phoenix system to detect resistance for this drug with *Streptococcus* species is unknown because a sufficient number of resistant strains were not encountered at the time of comparative clinical testing.

NOTE

MIC dilutions appearing in this manual are actual serial 2-fold dilution concentrations. MIC values appearing on reports may be rounded.

14.4 References

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Becton, Dickinson and Company

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Made in USA

14.5 Procedure Form

Procedure* BD Phoenix SMIC/ID, SMIC Panels
Laboratory kit configured for the biochemical identification and antimicrobial susceptibility or microorganisms.

Facility Name

Prepared by	Date Adopted	Supercedes Procedure #

Review Date	Revision Date	Signature

Distributed to	# of copies	Distributed to	# of copies

*Any modifications to this document are the sole responsibility of the facility. This Sample Procedure is not intended as a substitute for your facility procedure manual, instrument manual, or reagent labeling/package insert. This Sample Procedure is intended as a model for use by your facility to meet the needs of your laboratory.

15 – Gram Positive Laboratory Procedure

BD Phoenix™ PMIC/ID Panels
BD Phoenix™ PMIC Panels
BD Phoenix™ PID Panels

15.1 Intended Use

The BD Phoenix Automated Microbiology System is intended for the *in vitro* rapid identification (ID) of Gram Positive bacteria from pure culture belonging to the genera *Staphylococcus*, *Enterococcus*, other Gram Positive cocci and Gram Positive bacilli. The BD Phoenix Automated Microbiology System is also intended for the quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of most Gram Positive bacteria from pure culture belonging to the genera *Staphylococcus* and *Enterococcus*.

15.1.1 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.

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.[10,11]

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.[12] The broth dilution technique involves exposing bacteria to decreasing

concentrations of antimicrobial agents in liquid media by serial two-fold dilutions. The lowest concentration of an antimicrobial agent in which no visible growth occurs is defined as the minimal inhibitory concentration (MIC).

The introduction in 1956 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 antimicrobial susceptibility test (AST).[13] 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.[14]

The BD Phoenix AST is a modified miniaturized version of the micro-broth doubling dilution technique. Susceptibility testing in the Phoenix system is performed through determination of bacterial growth in the presence of various concentrations of the antimicrobial agent tested.

15.1.2 Principles of the Procedure

A maximum of 50 identification and antimicrobial susceptibility tests can be performed in the BD Phoenix instrument at a time using BD Phoenix ID/AST 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 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++ and Mg++) to optimize susceptibility testing performance.

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 contains 84 wells with dried antimicrobial agents and 1 growth control well. Panels are available as ID only (BD Phoenix™ NID Panels, BD Phoenix™ PID Panels), AST only (BD Phoenix™ NMIC Panels, BD Phoenix™ PMIC Panels), or ID/AST combination (BD Phoenix™ NMIC/ID Panels, BD Phoenix™ PMIC/ID Panels). BD Phoenix Emerge (AST136) panels contain wells for antimicrobial susceptibility on both the 51-well and 85-well sides. BD Phoenix Emerge panels are available for Gram Positive (PMIC), Gram Negative (NMIC) and Streptococcus panels (SMIC). Unused wells are reserved for future use.

BD Phoenix panels are inoculated with a standardized inoculum. 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 up to 16 hours if necessary. BD Phoenix panels are read only by the instrument. BD Phoenix panels cannot be read manually.

Bacterial 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 in 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 the 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 ID Database is provided in Section 8.3. Reactions employed by various substrates and the principles employed in the BD Phoenix ID reactions are described in Section 8.2.

Antimicrobial Susceptibility Testing

The BD Phoenix AST method 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.[15] 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 producing Susceptible, Intermediate, or Resistant (SIR) result classifications.

A complete list of taxa for which the BD Phoenix system can provide AST results is provided in Section 8.3. The list of antimicrobial agents and concentrations available for susceptibility testing in the BD Phoenix system is provided at the end of this sub-section.

There are antimicrobial agents for use with the BD Phoenix System that are not proven to be effective for treating infections for all organisms listed in the taxa. For interpreting and reporting results of antimicrobial agents that have been shown to be active against organism groups both in vitro and in clinical infections refer to the individual pharmaceutical antimicrobial agent labeling. Alternatively, refer to the most recent CLSI M100 Performance Standard, Table 1.16.

The components required for testing using the BD Phoenix system include: 1) BD Phoenix panels with panel closures, 2) BD Phoenix ID Broth, 3) BD Phoenix AST Broth, 4) BD Phoenix AST Indicator solution 5) BD Phoenix Inoculation Station, 6) BD Phoenix Panel Carrier, 7) BD BBL CrystalSpec Nephelometer, the BD PhoenixSpec Nephelometer, or the BD Phoenix AP instrument, and 8) 25 µL pipettor and tips, 9) Miscellaneous lab supplies (listed under Materials Required but Not Provided).

Prior to inoculation, the BD Phoenix panel is placed on the Inoculation Station with the inoculation ports at the top for filling. Separate inocula are added manually to the ID and AST ports. The inocula flow down the panel in serpentine fashion, filling the panel wells as the liquid front progresses toward the pad. The pad absorbs excess inoculum. Closures are manually inserted in the fill ports. An air admittance port is located in the divider area of the panel lid to ensure adequate oxygen tension in the panel for the duration of the test.

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 *Enterobacteriaceae*; 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 *mec*A-mediated Resistance with *S. aureus* (*mec*A); 8) detection of Vancomycin Resistant *Staphylococcus aureus* (VRSA); 9) detection of BD Phoenix Inducible Macrolide Resistance (IMLS) in *Staphylococcus* spp. For further information, consult the BDXpert manual.

BD Phoenix Extended Spectrum β-Lactamase (ESBL) Test[16]

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.[22, 23] 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.[22]

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.[22]

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. BD Phoenix cefoxitin MIC result is used to predict *mec*A-mediated resistance in *Staphylococcus aureus*. 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 *mec*A in staphylococci. The breakpoint selected in the instrument configuration is used for the categorical interpretation.

BD Phoenix Gram-Positive β-lactamase (BL) Test[16]

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.[22]

BD Phoenix Inducible Macrolide Resistance (IMLS) Test in *Staphylococcus* species

The BD Phoenix Inducible Macrolide Resistance (IMLS) Test is used to detect inducible macrolide lincosamide-streptogramin B (MLSb) resistance in *Staphylococcus* species. MLSb 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 MLSb resistance to distinguish them from isolates that are resistant to macrolides alone by efflux mechanism.

INGREDIENTS

For a listing of biochemical substrates used in the BD Phoenix panel refer to Section 8.2. The package insert enclosed in the panel box provides a listing of the specific antimicrobial agents and concentrations found inthe panel.

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, 5th Edition, 2009, as well as other recommended literature.

Prior to discarding, sterilize specimen containers and other contaminated materials by autoclaving.

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

STORAGE AND HANDLING

BD Phoenix Panels: The 25 panels in the box are individually packaged and must be stored unopened at room temperature (15-25 °C). Do not refrigerate or freeze. Visually inspect the package for holes or cracks in the foil package. Do not use if the panel or packaging appears to be damaged. 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: 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: 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 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 is 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.**

SPECIMEN COLLECTION AND PROCESSING

The BD Phoenix system is not for use directly with clinical specimens. Only pure culture isolates of aerobic and/or facultatively anaerobic Gram Negative organisms are acceptable for testing. The test isolate must be a pure culture. It is recommended that cultures be no more than 24 hours old unless additional incubation is required to achieve sufficient growth.

Isolates must be tested with a Gram stain test to assure the appropriate selection of BD Phoenix panel type. Once the Gram stain reaction is confirmed, select the appropriate BD Phoenix panel for inoculation (e.g., NMIC/ID panel for use with Gram Negative organisms). Selection of the incorrect panel type could lead to incorrect results.

For AST testing in the BD Phoenix system, isolates recovered from non-selective media are recommended. It is recommended that media containing antibiotics not be used for organisms to be tested in the BD Phoenix system. Selective media may inhibit some strains of bacteria; therefore, caution must be used when selecting isolated colonies from these media.

For ID and AST testing, refer to the user's manual, Table 4-1 in Section 4.3.

When swabs are used, only cotton-tipped applicators should be used to prepare the inoculum suspensions. Some polyester swabs may cause problems with inoculation of the panels.

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[17] for specimen collection, transport, and placement on primary isolation media.

Inoculum for use on the BD Phoenix system is prepared by the CLSI-recommended direct colony suspension method[18]. Due to variations in inoculum concentrations prepared with McFarland standards, use of the BD PhoenixSpec Nephelometer or BD Phoenix AP is required for adjusting the test inoculum prior to use in the BD Phoenix system.

It is highly recommended that the purity of both the ID and AST inocula be checked by preparing a purity plate. Instructions for the recommended purity check are provided in the user's manual, Section 4.3. See Purity Check below.

Materials Required:

- BD Phoenix Panels
- BD Phoenix ID Broth
- BD Phoenix AST Broth
- BD Phoenix AST Indicator Solution
- 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
- Nonselective culture plated media (e.g., Trypticase Soy agar with 5% Sheep Blood)
- Incubators
- Biohazard disposable container
- Markers etc

NOTES

Care should be exercised in handling BD Phoenix panels. You should 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 you are using a combination panel for only ID or only AST testing, note that certain steps are not applicable in the procedure.

General Panel Preparation

1. Confirm the Gram stain reaction of the isolate before proceeding with the inoculum preparation for use in the BD Phoenix instrument. Once the Gram stain reaction is confirmed, select the appropriate BD Phoenix panel for inoculation.
2. Examine the pouch, and do not use the panel if the pouch is punctured or opened. 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.

NOTE

Panels must be inoculated within two 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. 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.
5. Suspend the colonies in the BD Phoenix ID broth (4.5 mL).
6. Cap the tube and vortex for five seconds.
7. Allow approximately ten seconds for air bubbles to surface. You can tap the tube gently to aid in eliminating bubbles.
8. Insert the tube into the 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.)

9 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, you can add colonies 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.

c 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.

f 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.

g Broth may now be used to inoculate the BD Phoenix AST Broth and/or the BD Phoenix Panel.

NOTES

- 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.

10 If you are performing identification only, proceed to Step 15 and continue the procedure. If you are inoculating a BD Phoenix Emerge Panel, refer to the section below, BD Phoenix Emerge Panels.

11 Label a BD Phoenix AST broth tube (8.0 mL) with the patient's specimen number. Add one freefalling drop of AST Indicator solution to the AST broth tube. Invert to mix. DO NOT VORTEX.

NOTES

- Allow AST Indicator Solution to warm to room temperature before dispensing into AST broth.
- 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 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 the addition of the Indicator to AST broth, the mixed solution can be stored in the dark, at room temperature, for as long as 8 hours.
- Tubes must be used within 2 hours after the addition of AST Indicator Solution if exposed to light.

12 If an inoculum density of 0.50 – 0.60 was used, transfer 25 µL 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 µL (use two shots if utilizing a 25 µL 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.

13 Cap the AST tube and invert several times to mix.

14 Wait a few seconds for air bubbles to surface. You can tap the tube gently to aid in eliminating bubbles.

15 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 an AST (only) panel, DO NOT inoculate the ID side of the panel. Retain the ID tube for an optional purity check (see below).

16 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.

17 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.

18 Snap on the panel closures. Make sure that the closures are fully seated. Use 2 closures regardless of panel type.

19 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.

NOTES

- 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.

BD Phoenix Test Procedure

NOTE

The BD Phoenix instrument should always be powered on. If it is not, power on the instrument and allow two hours for the instrument to warm up before loading panels. Prepare the BD Phoenix instrument to receive new panels as described in Section 5.2.

Care should be exercised in handling BD Phoenix panels. You should handle panels by the sides only to avoid marking, smudging or obscuring the bottom or top of the panel in any way.

Accession barcode labels affixed to a BD Phoenix panel should:

- Not be of fluorescent material
- Not cover any BD Phoenix panel reaction wells
- Not cover the BD Phoenix panel sequence number barcode

Broth and Panel Preparation: Prepare the BD Phoenix ID Broth, BD Phoenix AST Broth and BD Phoenix panels as described in Section 4.3.

If you are using the BD Phoenix AP instrument, refer to the BD Phoenix AP Instrument User's Manual for panel preparation.

Test inoculum should be prepared from one of the recommended primary media by selecting well isolated colonies of similar morphology that are less than 24 hours old and suspending the inoculum in the BD Phoenix ID broth with a sterile cotton swab or a wooden applicator.

Only cotton tipped swabs are recommended as inoculum prepared with some polyester swabs may cause problems with the inoculation of the panels.

After inoculation of the ID broth, vortex and allow air bubbles to surface for approximately 10 seconds prior to reading in the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer. Refer to the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer product insert for correct usage and calibration verification. 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**, you can add colonies 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 in Section 4.3, Step 9 to dilute the broth.

Confirm current instrument settings for inoculum density before inoculating panels.

Only the BD PhoenixSpec Nephelometer can be used to make inoculum densities of 0.25 McFarland.

Refer to Section 4.3 for additional information on inoculum density procedures.

The standardized bacterial suspension in BD Phoenix ID broth must be used within 60 minutes of preparation.

For AST testing, the tube of AST broth is prepared by adding one free-falling drop of AST Indicator Solution.

After the addition of the indicator to the AST Broth, the mixed solution can be stored in the dark, at room temperature (15–25 °C), for up to 8 hours. The mixed solution must be used within 2 hours if exposed to light.

If an inoculum density of 0.50–0.60 was used, transfer 25 µL 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 µL (use 2 shots if utilizing a 25 µL pipettor) of the bacterial suspension from the ID tube into the AST Broth tube.

Panels must be inoculated within 30 minutes of the time that the BD Phoenix AST Broth is inoculated. Panels must be loaded into the BD Phoenix instrument within 30 minutes of inoculation.

For instructions for panel login and loading, refer to Sections 3.3 and Section 3.3.2.

ID Inoculum Density Flexibility

You may run the ID portion of a panel 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 you to run a panel at an inoculum density of 0.20–0.30 even if you are configured for a density of 0.5 for that particular panel type. Likewise, you can run a panel at an inoculum density of 0.50–0.60 if you are configured for a density of 0.25.

There is no way to alter the density setting during Panel Login. To use a panel in the opposite density mode, using a black Sharpie™ (permanent marker) blacken the entire well. For instructions for panel login and loading, refer to the user's manual, Sections 3.3 and Section 3.3.2.

15.2 Quality Control

In order to ensure appropriate set up procedure and acceptable performance of the system with BD Phoenix panels, the following organisms are recommended to be tested as described in this user's manual. The user is advised to review the individual AST panel formats to determine if all test strains need to be tested for routine laboratory Quality Control. Refer to the Package Insert that accompanies the BD Phoenix panels for expected ID reactions and AST results for QC organisms

ID (PMIC/ID and PID panels):

Staphylococcus aureus ATCC 29213

Enterococcus faecalis ATCC 29212

AST (PMIC/ID, PMIC panels):

Staphylococcus aureus ATCC 29213

Enterococcus faecalis ATCC 29212

Staphylococcus aureus ATCC 25923

Enterococcus faecalis ATCC 51299

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

Compare recorded reactions to those listed in the Package Insert. If discrepant results are obtained, review test procedure as well as confirm purity of the quality control strain used before contacting BD Diagnostics Technical Services Department. Unacceptable QC results are documented as Fail and acceptable QC results are documented as Pass on the QC Report.

15.3 Results

Organism identification will appear on the BD Phoenix Report Form with a probability percentage from the BD Phoenix database based on the substrate reaction profile. Results from each substrate will appear as +, -, V, or X for each reaction. The MIC results will be shown for all antimicrobial agents, and Interpretive Categorical Results (SIR) will be shown for the appropriate organism/ antimicrobial agent combinations.

Special messages will be shown when the BDXpert System detects results that are of particular clinical interest. Further information concerning results obtained from the BD Phoenix system can be found in Section 3.4.

15.3.1 Messages

Error messages may appear if the system detects unexpected reactivity due to inappropriate procedure or instrument malfunction. For a complete listing of error codes and their meaning refer to Sections 2.3.2.7 and 3.4.9.

15.3.2 Special Notes

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/organism combinations a specific minimum or maximum MIC is reported even if there is a lower or higher concentration on the panel. These MIC values are applied by the software and are reported out as less than or equal to (≤) for the minimum MIC or greater than (>) for the maximum MIC. The table below provides the range for these special drug/organism combinations.

Antimicrobial Agent	Organism(s)	Applied Range (µg/mL)
Oxacillin	Coagulase negative staphylococci	0.0625–1.0
Penicillin	*Staphylococcus* spp.	0.0625–1.0
	Enterococcus spp.	1.0–32
Gentamicin	*Staphylococcus epidermidis*	<4 and >16*
Moxifloxacin	*Enterococcus* spp. other than *E. faecium*	0.25–8

* MICs of 4, 8, 16 not reported

15.4 Limitations of the Procedure

See the package insert shipped with the panel 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 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 Nephelometer, the BD PhoenixSpec Nephelometer, or the BD Phoenix AP instrument 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 or BD Phoenix AP instrument can be used to measure the inoculum density for this range.
- 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.

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

- After the addition of the 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 or special growth requirements 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 or rare occurrence 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 dilution method.

15.4.1 Performance Characteristics

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
Species Level	0.5	95.4%	3.9%	0.7%
	0.25	98.0%	1.6%	0.4%

An internal study was performed to simulate inter-site reproducibility. The identification results obtained using the BD Phoenix system were compared with expected results. This performance testing demonstrated intra-site and inter-site reproducibility of at least 95% or greater.

Gram Positive Susceptibility

Clinical, stock, and challenge isolates were tested across multiple clinical sites to determine Essential Agreement (EA) and Category Agreement (CA) of the BD Phoenix system to the CLSI broth microdilution reference method. Essential Agreement occurs when the MIC of the BD Phoenix system and the reference method agree exactly or is within ± 1 dilution of each other. Category Agreement occurs when the BD Phoenix system results agree with the reference method with respect to the CLSI categorical interpretative criteria (susceptible, intermediate, resistant). The table below summarizes the data from these studies.

Additionally testing performed at multiple clinical sites demonstrated at least 95% reproducibility or greater within ± 1 doubling dilution for all antimicrobial agents listed in the table below.

Gram-positive Susceptibility Performance Table

DRUG CLASS	DRUG NAME	DRUG CODE	DRUG RANGE (*µg*/mL)	EA N	EA %	CA N	CA %
Beta-lactam	Amoxicillin-Clavulanate	AMC	0.25/0.12–32/16	871	94.1	871	96.7
Beta-lactam	Ampicillin	AM	0.0625–32	475	93.3	475	98.5
Beta-lactam	Ampicillin-sulbactam	SAM	2/1–32/16	1,240	97.2	1,240	97.3
Beta-lactam	Cefazolin	CZ	2–32	597	99.5	597	99.7
Beta-lactam	Cefoxitin	FOX	1–32	1,164	96.3	1,164	90.1
Cephem	Ceftaroline*	CPT	0.0625–4	866	94.7	866	98.2
Beta-lactam	Cephalothin	CF	0.5–64	904	96.2	904	98.0
Phenicol	Chloramphenicol	C	1–32	1,447	93.4	1,447	93.4
Macrolide Lincosamide Streptogramin	Clindamycin	CC	0.125–8	1,242	98.2	1,242	98.7
Cyclic lipopeptide	Daptomycin*	DAP	0.125–32	1,568	97.4	1,568	98.8
Tetracycline	Doxycycline	D	0.25–16	1,211	96.3	1,211	94.8
Macrolide Lincosamide Streptogramin	Erythromycin	E	0.625–8	1,395	95.0	1,395	94.6
Quinolone	Gatifloxacin	GAT	0.25–8	1,180	98.6	1,180	90.1
Aminoglycoside	Gentamicin	GM	0.25–16	1,223	91.9	1,223	95.2
Aminoglycoside	Gentamicin- Syn	GMS	500	NA	NA	763	98.6
Quinolone	Levofloxacin	LVX	0.25–8	1,878	96.8	1,878	95.1
Oxazolidinone	Linezolid	LZD	0.25–32	1,454	91.1	1,454	95.3
Beta–lactam	Meropenem	MEM	0.5–16	620	98.4	1,198	96.6
Tetracycline	Minocycline	MI	1–32	1,619	98.8	745	98.5
Quinolone	Moxifloxacin	MXF	0.125–8	1,777	96.0	1,777	90.1
Nitrofuran	Nitrofurantoin*	FM	4–128	979	98.5	979	100.0
Quinolone	Norfloxacin	NOR	0.25–16	1,252	96.9	1,252	97.4
Quinolone	Ofloxacin	OFX	0.25–8	1,184	98.7	1,184	98.2
Beta–lactam	Oxacillin	OX	0.0625–4	1,231	95.4	1,231	96.6
Beta–lactam	Penicillin	P	0.0625–32	1,256	93.6	1,256	97.5
Beta–lactam	Piperacillin–Tazobactam	TZP	1/4–128/4	1,348	95.8	585	100.0
Macrolide Lincosamide Streptogramin	Quinupristin–dalfopristin	SYN	0.25–4	2,019	94.5	1,500	95.5
Rifamycin	Rifampin	RA	0.25–32	1,261	98.3	1,261	98.2
Aminoglycoside	Streptomycin Syn	STS	1000	NA	NA	756	97.8
Tetracycline	Tetracycline	TE	0.5–16	2,040	96.9	2,040	96.5
Glycylcycline	Tigecycline*	TGC	0.0313–4	1,021	98.0	1,021	100.0
Aminoglycoside	Tobramycin	NN	0.5–16	953	93.5	797	98.5
Folate Antagonist	Trimethoprim–sulfamethoxazole	SXT	0.5/9.5– 16/304	634	96.4	634	97.9
Glycopeptide	Vancomycin	VA	0.5–32	1,538	99.0	1,538	99.6

DRUG CLASS	DRUG NAME	DRUG CODE	DRUG RANGE (µg/mL)	EA N	EA %	CA N	CA %
NA	Inducible Macrolide Resistance (iMLSb) Test	ECC	NA	NA	NA	295	97.6

* See information in the table below.

NOTE

MIC dilutions appearing in this manual are actual serial 2-fold dilution concentrations. MIC values appearing on reports may be rounded.

Performance Notes

Drug	
Ceftaroline	BD Phoenix MIC values tended to be higher by one dilution compared to reference broth micro-dilution. *Staphylococcus aureus* with an interpretation of 'resistant' for ceftaroline is uncommon in most institutions or may result from technical errors. Verify ID/AST if this phenotype has not been previously encountered from this patient or institution.
Tigecycline	BD Phoenix MIC values for isolates of *Staphylococcus aureus* may be lower by one dilution compared to reference broth microdilution.

The ability of the BD Phoenix System to detect nonsusceptible/resistance for the following drug/organism combinations is unknown because nonsusceptible/resistant organisms were not available at the time of comparative testing:

Drug	
Ceftaroline	*Staphylococcus aureus*
Daptomycin	*Staphylococcus* spp.; *Enterococcus* spp.
Nitrofurantoin	*Staphylococcus* spp.; *Enterococcus* spp.
Tigecycline	*Enterococcus faecalis; Staphylococcus aureus*

15.5 References

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Manufactured by
Becton, Dickinson and Company
Sparks, MD 21152 USA
Made in USA

15.6 Procedure Form

Procedure* BD Phoenix NMIC/ID, NMIC, NID Panels
Laboratory kit configured for the biochemical identification and antimicrobial susceptibility or microorganisms.

Facility Name

Prepared by	Date Adopted	Supercedes Procedure #

Review Date	Revision Date	Signature

Distributed to	# of copies	Distributed to	# of copies

*Any modifications to this document are the sole responsibility of the facility. This Sample Procedure is not intended as a substitute for your facility procedure manual, instrument manual, or reagent labeling/package insert. This Sample Procedure is intended as a model for use by your facility to meet the needs of your laboratory.

User's Manual
www.e-labeling.eu/BDX18592

16 – Gram Negative Laboratory Procedure

BD Phoenix™ NMIC/ID Panels
BD Phoenix™ NMIC Panels
BD Phoenix™ NID Panels

16.1 Intended Use

The BD Phoenix™ Automated Microbiology System Automated Microbiology System is intended for the *in vitro* rapid identification (ID) and quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of Gram Negative aerobic and facultative anaerobic bacteria belonging to the family *Enterobacteriaceae* and non-*Enterobacteriaceae*.

16.1.1 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.

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.[10,11]

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.[12] The broth dilution technique involves exposing bacteria to decreasing concentrations of antimicrobial agents in liquid media by serial two-fold dilutions. The lowest concentration of an antimicrobial agent in which no visible growth occurs is defined as the minimal inhibitory concentration (MIC).

The introduction in 1956 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 antimicrobial susceptibility test (AST).[13] 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.[14]

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.

16.1.2 Principles of the Procedure

A maximum of 50 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++ and Mg++) to optimize susceptibility testing performance.

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 contains 84 wells with dried antimicrobial agents and 1 growth control well. Panels are available as ID only (BD Phoenix™ NID Panels and BD Phoenix™ PID Panels), AST only (BD Phoenix™ NMIC Panels and BD Phoenix™ PMIC Panels), or ID/AST combination (BD Phoenix™ NMIC/ID Panels and BD Phoenix™ PMIC/ID Panels). BD Phoenix Emerge™ (AST136) panels contain wells for antimicrobial susceptibility on both the 51-well and 85-well sides. BD Phoenix Emerge panels are available for Gram Positive (PMIC), Gram Negative (NMIC) and Streptococcus (SMIC) panels. Unused wells are reserved for future use.

BD Phoenix panels are inoculated with a standardized inoculum. 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 up to 16 hours if necessary. BD Phoenix panels are read only by the instrument. BD Phoenix panels cannot be read manually.

Bacterial 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 in 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 the 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 ID Database is provided in the user's manual, Section 8.3 Taxa for ID/AST Determination. Reactions employed by various substrates and the principles employed in the BD Phoenix ID reactions are described in the user's manual, Section 8.2

Antimicrobial Susceptibility Testing

The BD Phoenix AST method is a broth based microdilution test. The Phoenix system utilizes a redox indicator for the detection of organism growth in the presence of an antimicrobial agent.[15] 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 producing Susceptible, Intermediate, or Resistant (SIR) result classifications.

A complete list of taxa for which the Phoenix panels can provide AST results is shown in Section 8.3. The list of antimicrobial agents and concentrations available for susceptibility testing in the Phoenix system is provided in the user's manual, Section 6.3.

There are antimicrobial agents for use with the Phoenix System that are not proven to be effective for treating infections for all organisms listed in the taxa. For interpreting and reporting results of antimicrobial agents that have been shown to be active against organism groups both *in vitro* and in clinical infections refer to the individual pharmaceutical antimicrobial agent labeling. Alternatively, refer to the most recent CLSI M100 Performance Standard, Table 1.[16]

The components required for testing using the BD Phoenix system include: 1) BD Phoenix panels with panel closures, 2) BD Phoenix ID Broth, 3) BD Phoenix AST Broth, 4) BD Phoenix AST Indicator solution, 5) BD Phoenix Inoculation Station, 6) BD Phoenix Panel Carrier, 7) BD BBL CrystalSpec Nephelometer, the BD PhoenixSpec Nephelometer, or the BD Phoenix AP instrument, and 8) 25 µL pipettor and tips, 9) Miscellaneous lab supplies (listed under Materials Required but Not Provided).

Prior to inoculation the BD Phoenix panel is placed on the Inoculation Station with the inoculation ports at the top for filling. Separate inocula are added manually to the ID and AST ports. The inocula flow down the panel in serpentine fashion, filling the panel wells as the liquid front progresses toward the pad. The pad absorbs excess inoculum. Closures are manually inserted in the fill ports. An air admittance port is located in the divider area of the panel lid to ensure adequate oxygen tension in the panel for the duration of the test.

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 *Enterobacteriaceae*; 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 *mec*A-mediated Resistance with S. *aureus* (*mec*A); 8) detection of Vancomycin Resistant *Staphylococcus aureus* (VRSA); 9) detection of BD Phoenix Inducible Macrolide Resistance (IMLS) in *Staphylococcus* spp. For further information, consult the BDXpert manual.

BD Phoenix Extended Spectrum β-Lactamase (ESBL) Test[16]

The BD Phoenix ESBL test evolved from published data of known ESBL antibiogram patterns in the current literature.[18-21] Selected strains of various species with known β-lactamase genotype/ phenotypes in the family *Enterobacteriaceae*, 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.[22] The BD Phoenix ESBL test is applied to *E. coli, K. pneumoniae* and *K. oxytoca*. Additionally, at the customers discretion, it can be applied to other enteric species where production of ESBL has been reported in literature. 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** with BDXpert rule 1529. Customers can enable specific rules to reported as tested.[22]

INGREDIENTS

For a listing of biochemical substrates used in the BD Phoenix panel refer to the user's manual, Section 8.2. The package insert enclosed in the panel box provides a listing of the specific antimicrobial agents and concentrations found in the panel.

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, 5th Edition, 2009, as well as other recommended literature.

Prior to discarding, sterilize specimen containers and other contaminated materials by autoclaving.

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

STORAGE AND HANDLING

BD Phoenix Panels: The 25 panels in the box are individually packaged and must be stored unopened at room temperature (15–25 °C). Do not refrigerate or freeze. Visually inspect the package for holes or cracks in the foil package. Do not use if the panel or packaging appears to be damaged. 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: 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: 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 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 is 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.**

SPECIMEN COLLECTION AND PROCESSING

The BD Phoenix system is not for use directly with clinical specimens. Only pure culture isolates of aerobic and/or facultatively anaerobic Gram Negative organisms are acceptable for testing. The test isolate must be a pure culture. It is recommended that cultures be no more than 24 hours old unless additional incubation is required to achieve sufficient growth.

Isolates must be tested with a Gram stain test to assure the appropriate selection of BD Phoenix panel type. Once the Gram stain reaction is confirmed, select the appropriate BD Phoenix panel for inoculation (e.g., NMIC/ID panel for use with Gram Negative organisms). Selection of the incorrect panel type could lead to incorrect results.

For AST testing in the BD Phoenix system, isolates recovered from non-selective media are recommended. It is recommended that media containing antibiotics not be used for organisms to be tested in the BD Phoenix system. Selective media may inhibit some strains of bacteria; therefore, caution must be used when selecting isolated colonies from these media.

For ID and AST testing, refer to the user's manual, Table 1 – Recommended Media in Section 4.3.

When swabs are used, only cotton-tipped applicators should be used to prepare the inoculum suspensions. Some polyester swabs may cause problems with inoculation of the panels.

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[17] for specimen collection, transport, and placement on primary isolation media.

Inoculum for use on the BD Phoenix system is prepared by the CLSI-recommended direct colony suspension method[18]. Due to variations in inoculum concentrations prepared with McFarland standards, use of the BD PhoenixSpec Nephelometer or BD Phoenix AP is required for adjusting the test inoculum prior to use in the BD Phoenix system.

It is highly recommended that the purity of both the ID and AST inocula be checked by preparing a purity plate. Instructions for the recommended purity check are provided in the user's manual, Section 4.3 Preparing Panels. See Purity Check below.

Materials Required:

- BD Phoenix Panels
- BD Phoenix ID Broth
- BD Phoenix AST Broth
- BD Phoenix AST Indicator Solution
- 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
- Nonselective Culture Plated Media
- Incubators
- Biohazard Disposable Container
- Markers, etc.
- Vortex mixer

NOTES

Care should be exercised in handling BD Phoenix panels. You should 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 you are using a combination panel for only ID or only AST testing, note that certain steps are not applicable in the procedure.

General Panel Preparation

1. Confirm the Gram stain reaction of the isolate before proceeding with the inoculum preparation for use in the BD Phoenix instrument. Once the Gram stain reaction is confirmed, select the appropriate BD Phoenix panel for inoculation.
2. Examine the pouch, and do not use the panel if the pouch is punctured or opened. 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.

> NOTE
>
> Panels must be inoculated within two 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. 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.
5. Suspend the colonies in the BD Phoenix ID broth (4.5 mL).
6. Cap the tube and vortex for five seconds.
7. Allow approximately ten seconds for air bubbles to surface. You can tap the tube gently to aid in eliminating bubbles.
8. Insert the tube into the 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.)
9. 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, you can add colonies 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.

c 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.

f 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.

g Broth may now be used to inoculate the BD Phoenix AST Broth and/or the BD Phoenix Panel.

NOTES

- 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.

10 If you are performing identification only, proceed to Step 15 and continue the procedure. If you are inoculating a BD Phoenix Emerge Panel, refer to the section below, BD Phoenix Emerge Panels.

11 Label a BD Phoenix AST broth tube (8.0 mL) with the patient's specimen number. Add one freefalling drop of AST Indicator solution to the AST broth tube. Invert to mix. DO NOT VORTEX.

NOTES

- Allow AST Indicator Solution to warm to room temperature before dispensing into AST broth.
- 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. 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 the addition of the Indicator to AST broth, the mixed solution can be stored in the dark, at room temperature, for as long as eight hours.
- Tubes must be used within two hours after the addition of AST Indicator Solution if exposed to light.

12 If an inoculum density of 0.50–0.60 was used, transfer 25 µL 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 µL (use 2 shots if utilizing a 25 µL 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.

13 Cap the AST tube and invert several times to mix.

14 Wait a few seconds for air bubbles to surface. You can tap the tube gently to aid in eliminating bubbles.

15 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 an AST (only) panel, DO NOT inoculate the ID side of the panel. Retain the ID tube for an optional purity check (see below).

16 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.

17 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.

18 Snap on the panel closures. Make sure that the closures are fully seated. Use two closures regardless of panel type.

19 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.

NOTES

- 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.

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. Two tubes of AST broth will be required.

1 Follow **Steps 1–9** (General Panel Preparation) to prepare the suspension of bacteria.

2 Add one drop of the BD Phoenix AST Indicator to each AST broth tube.

3 Transfer 25 µL (50 µL if low inoculum option is used) of the suspension to two BD Phoenix AST broth tubes. Cap and gently invert.

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. Pour the other BD Phoenix AST broth tube into the right side of the BD Phoenix Emerge panel.

6 Cap the panel and follow the normal panel login procedure.

7 Using a pipettor, transfer 25 µL 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.

8 Cap the AST-S tube and invert several times to mix.

9 Wait a few seconds for air bubbles to surface. You can tap the tube gently to aid in eliminating bubbles.

10 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).

11 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.

12 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.

13 Snap on the panel closures. Make sure that the closures are fully seated.

14 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.

NOTES

- 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.

ID Inoculum Density Flexibility

You may run the ID portion of a panel 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 you to run a panel at an inoculum density of 0.20–0.30 even if you are configured for a density of 0.5 for that particular panel type. Likewise, you can run a panel at an inoculum density of 0.50–0.60 if you are configured for a density of 0.25.

There is no way to alter the density setting during Panel Login. To use a panel in the opposite density mode, using a black Sharpie™ (permanent marker) blacken the entire well. For instructions for panel login and loading, refer to the user's manual, Section 3.3 and Section 3.3.2.

16.2 Quality Control

In order to ensure appropriate set up procedure and acceptable performance of the system, the following organisms are recommended for testing. The user is advised to review the individual AST panel formats to determine if all test strains need to be tested for routine laboratory Quality Control. Refer to the Package Insert that accompanies the BD Phoenix panels for expected ID and AST results for QC organisms.

For instructions for QC panel login and loading, refer to the user's manual, Section 3.3 and Section 3.3.2.

ID (NMIC/ID and NID panels):

Escherichia coli ATCC 25922

Pseudomonas aeruginosa ATCC 27853

AST (NMIC/ID, NMIC panels):

Escherichia coli ATCC 25922

Pseudomonas aeruginosa ATCC 27853

Escherichia coli ATCC 35218

Klebsiella pneumoniae ATCC 700603

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

Compare recorded results to those listed in the Package Insert. If discrepant results are obtained, review test procedures as well as confirm purity of the quality control strain used before contacting BD Technical Service and Support.

16.3 Results

Organism identification will appear on the BD Phoenix Report Form with a probability percentage from the BD Phoenix database based on the substrate reaction profile. Results from each substrate will appear as +, -, V or X for each reaction. The MIC results will be shown for all antimicrobial agents, and Interpretive Categorical Results (SIR) will be shown for the appropriate organism/antimicrobial agent combinations.

Special messages will be shown when the BDXpert System detects results that are of particular clinical interest.

Further information concerning results obtained from the BD Phoenix system can be found in the user's manual, Section 3.4.

16.3.1 Messages

Error messages may appear if the system detects unexpected reactivity due to inappropriate procedure or instrument malfunction. For a complete listing of error codes and their meaning refer to the user's manual, Sections 2.3.2.7 and 3.4.9.

16.3.2 Special Notes

In general, the BD Phoenix System provides a MIC for all organisms at any of the concentrations defined on a specific panel. For certain antimicrobic/organism combinations a specific minimum or maximum MIC is reported even if there is a lower or higher concentration on the panel. These MIC values are applied by the software and are reported out as less than or equal to (</=) for the minimum MIC or greater than (>) for the maximum MIC. The table below provides the range for these special antimicrobic/organism combinations.

Antimicrobial Agent	Organism(s)	Applied Range (µg/mL)
Amikacin	*Morganella morganii*	2–64
	Proteus penneri	2–64
	Proteus vulgaris	2–64
	Providencia species	2–64
Cefotaxime	*Providencia species*	2–64
Cefotetan	*Proteus mirabilis*	4–64
Ertapenem	*Enterobacter aerogenes*	0.0625–4
Gentamicin	*Escherichia coli*	1–16
Piperacillin	*Achromobacter species*	4–128
Piperacillin-tazobactam	*Achromobacter species*	2/4–128/4
	Serratia marcescens	4/4–128/4
	Serratia species	4/4–128/4
Tetracycline	*Morganella morganii*	1–16
Ticarcillin	*Achromobacter species*	4–128
	Alcaligenes species	4–128
	Brevundimonas species	4–128
	Chryseobacterium species	4–128
	Cupriavidus species	4–128
	Delftia acidoverans	4–128
	Elizabethkingia meningoseptica	4–128
	Myroides species	4–128
	Ochrobactrum anthropi	4–128
	Providencia species	4–128

Antimicrobial Agent	Organism(s)	Applied Range (µg/mL)
	Salmonella species	4–128
	Serratia species	4–128
	Shewanella species	4–128
	Sphingobacterium species	4–128
Ticarcillin-clavulanate	*Citrobacter freundii*	4/2–128/2
	Morganella morganii	4/2–128/2
Tobramycin	*Enterobacter aerogenes*	0.5–16
Trimethoprim	*Enterobacter aerogenes*	1–16
	Proteus mirabilis	1–16

16.4 Limitations of the Procedure

See the package insert shipped with the panel 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 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 BBL CrystalSpec Nephelometer, the BD PhoenixSpec Nephelometer, or the BD Phoenix AP instrument 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 or BD Phoenix AP instrument can be used to measure the inoculum density for this range.
- BD Phoenix panels can be read only by the BD Phoenix M50 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.

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

- 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 or special growth requirements, 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 or rare occurrence 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 dilution method.

16.4.1 Performance Characteristics

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 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
Species Level	0.5	95.6%	3.6%	0.8%
	0.25	98.1%	1.4%	0.5%

An internal study was performed to simulate inter-site reproducibility. The identification results obtained using the BD Phoenix system were compared with expected results. This performance testing demonstrated intra-site and inter-site reproducibility of at least 95% or greater.

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. Additionally, a challenge set of 30 previously characterized organisms was tested at one site.

Positive Percent Agreement = 183/189 = 96.8%
Negative Percent Agreement = 780/812 = 96.1%
Overall Percent Agreement = 963/1001 = 96.2%

Gram Negative Susceptibility

Clinical, stock, and challenge isolates were tested across multiple clinical sites to determine Essential Agreement (EA) and Category Agreement (CA) of the BD Phoenix system to the CLSI broth microdilution reference method. Essential Agreement occurs when the MIC of the BD Phoenix system and the reference method agree exactly or is within ± 1 dilution of each other. Category Agreement occurs when the BD Phoenix system results agree with the reference method with respect to the CLSI categorical interpretative criteria (susceptible, intermediate, resistant). The table below summarizes the data from these studies.

Additionally testing performed at multiple clinical sites demonstrated at least 95% reproducibility or greater within ± 1 doubling dilution for all antimicrobial agents listed in the table below.

DRUG CLASS	DRUG NAME	DRUG CODE	DRUG RANGE (*µg*/mL)	EA N	EA %	CA N	CA %
Aminoglycoside	Amikacin	AN	0.5–64	2,598	94.7	2,598	96.7
Beta-lactam	Amoxicillin-Clavulanate	AMC	0.5/0.25– 32/16	2,249	96.7	2,249	90.9
Beta-lactam	Ampicillin	AM	0.5–32	1,712	97.0	1,712	94.6
Beta-lactam	Ampicillin-sulbactam	SAM	1.0/0.5–32/16	1,106	95.8	1,106	86.6
Beta-lactam	Aztreonam	ATM	0.5–64	1,403	97.6	1,355	95.1
Beta-lactam	Cefazolin	CZ	0.5–32	1,056	96.5	1,056	95.9
Beta-lactam	Cefepime	FEP	0.5–64	1,384	98.0	1,384	96.7
Beta-lactam	Cefotaxime	CTX	0.5–64	2,268	95.0	2,268	92.7
Beta-lactam	Cefotetan	CTT	2–64	1,175	96.6	1,175	96.8
Beta-lactam	Cefoxitin	FOX	0.5–64	1,397	96.9	1,397	93.3
Beta-lactam	Cefpodoxime	CPD	0.125–8	1,533	95.9	1,533	97.3
Beta-lactam	Ceftazidime	CAZ	0.5–64	2,388	96.6	2,388	94.7
Beta-lactam	Ceftriaxone	CRO	0.5–64	2,416	96.1	2,416	91.6
Beta-lactam	Cefuroxime	CXM	1–64	1,868	95.6	1,868	93.3
Beta-lactam	Cephalothin	CF	1–64	2,025	96.4	2,025	89.0
Quinolone	Ciprofloxacin	CIP	0.25–4	2,853	98.8	2,853	95.1
Beta-lactam	Ertapenem*	ETP	0.0625–8	1,469	98.4	1,469	97.6
Quinolone	Gatifloxacin	GAT	0.25–8	2,213	98.8	2,213	95.8
Aminoglycoside	Gentamicin	GM	0.25–16	2,751	96.2	2,751	96.3
Beta-lactam	Imipenem	IPM	0.0625–32	1,348	94.6	1,348	95.3
Quinolone	Levofloxacin	LVX	0.25–8	2,934	98.5	2,934	95.8
Beta-lactam	Meropenem	MEM	0.125–32	1,202	97.8	1,202	98.5
Tetracycline	Minocycline	MI	1–32	2,081	94.2	1,711	92.0
Quinolone	Moxifloxacin	MXF	0.125–8	2,202	98.3	2,202	97.6
Quinolone	Nalidixic Acid	NA	2–32	2,103	96.2	2,103	98.6
Nitrofuran	Nitrofurantoin	FM	8–512	2,130	95.8	2,130	84.4
Quinolone	Norfloxacin	NOR	0.25–16	2,792	97.5	2,792	94.3
Quinolone	Ofloxacin	OFX	0.25–8	2,926	98.5	2,926	94.6
Beta-lactam	Piperacillin	PIP	2–128	1,151	96.1	1,151	94.7
Beta-lactam	Piperacillin-tazobactam	TZP	0.5/4–128/4	1,546	93.2	1,546	94.9
Tetracycline	Tetracycline	TE	0.5–16	2,837	95.5	2,837	92.3
Beta-lactam	Ticarcillin	TIC	1–128	3,428	94.9	3,428	93.1
Beta-lactam	Ticarcillin-Clavulanate	TIM	1/2–128/2	2,114	93.0	2,114	89.4
Glycylcycline	Tigecycline	TGC	0.25–16	884	97.5	884	97.4
Aminoglycoside	Tobramycin	NN	0.125–16	2,658	93.3	2,658	95.3
Folate Antagonist	Trimethoprim	TMP	0.5–16	1,856	95.5	1,856	98.7
Folate Antagonist	Trimethoprim-sulfamethoxazole	SXT	0.5/9.5–16/304	2,212	96.0	2,212	97.7

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