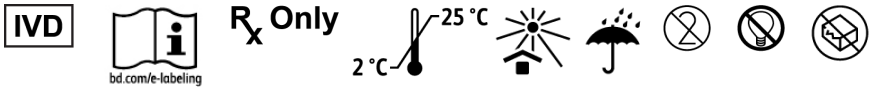
BD CTGCTV2 for BD MAX™ System



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REF **443904**

For use with the BD MAX™ System

INTENDED USE

The BD CTGCTV2 for BD MAX™ System, performed on the BD MAX™ System, incorporates automated DNA extraction and real-time polymerase chain reaction (PCR) for the direct, qualitative detection of DNA from:

- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (GC)
- *Trichomonas vaginalis* (TV)

The assay may be used for detection of CT, GC and/or TV DNA in patient- or clinician-collected vaginal swab specimens (in a clinical setting) and male and female urine specimens. The assay may also be used for the detection of CT and GC DNA in endocervical swab and Liquid-Based Cytology (LBC) specimens in ThinPrep® PreservCyt® Solution using an aliquot that is removed prior to processing for the ThinPrep® Pap test. The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of chlamydial urogenital disease, gonococcal urogenital disease and/or trichomoniasis.

SUMMARY AND EXPLANATION OF THE PROCEDURE

The World Health Organization estimates that 130.9 million new cases of infection due to *Chlamydia trachomatis* are diagnosed each year.[1] Genital infection with *Chlamydia trachomatis* is the most frequently reported sexually transmitted disease in the United States and the infection can lead to several important sequelae in women, the most serious of which include pelvic inflammatory disease (PID), ectopic pregnancy, and infertility.[2] Asymptomatic infection with chlamydia is common among both men and women, and detection of the disease frequently relies upon screening of the populations considered to be most at risk of infection.

The World Health Organization estimates that 78.3 million new cases of infection due to *Neisseria gonorrhoeae* are diagnosed each year.[1] In the United States, 820,000 new infections with *Neisseria gonorrhoeae* are estimated to occur each year.[2] Among men, the onset of symptoms such as dysuria and acute urethritis usually leads to presentation for treatment sufficiently early in the course of disease to prevent serious sequelae but transmission to others may still occur. In women, gonococcal infections are more frequently asymptomatic and if left untreated can lead to pelvic inflammatory disease, infertility, ectopic pregnancy and chronic pelvic pain. Transmission of *Neisseria gonorrhoeae* occurs through sexual contact but can also take place in the birth canal leading to neonatal conjunctivitis.

Vaginal infection with *Trichomonas vaginalis* are among the most common conditions transmitted sexually. Worldwide, it is estimated that 142.6 million cases occur each year.[1] The infection causes some women to have symptoms which are characterized by a diffuse, malodorous, yellow-green vaginal discharge with vulvar irritation. The infection may cause discomfort during intercourse and urination, as well as irritation and itching of the female genital area. The genital inflammation caused by trichomoniasis can increase a woman's susceptibility to HIV infection if exposed to the virus and also may increase the likelihood that an HIV-infected woman will transmit the virus to her sex partner(s).[3] Infected women may have mild or no symptoms of the disease. As a result, screening for *Trichomonas vaginalis* is generally considered only for those at high risk of infection (i.e., women who have new or multiple partners, have a history of sexually transmitted diseases, exchange sex for payment, or use injection drugs).[2]

PRINCIPLES OF THE PROCEDURE

The BD CTGCTV2 assay is designed for use with the applicable BD MAX™ specimen collection and transport devices, including the BD Molecular Urine Transport Kit, the BD Molecular LBC Sample Buffer Tubes or the BD Molecular Swab Collection Kit. The specimen is collected from the patient and transported to the testing laboratory using the appropriate transport device under conditions of time and temperature that have been determined to maintain the integrity of the target nucleic acids.

PreservCyt® LBC samples are pre-warmed on the BD Pre-warm Heater before testing on the BD MAX™ System. None of the other specimen types undergo a pre-warm step. A worklist is created and the Sample Buffer Tube, the BD CTGCTV2 Unitized Reagent Strip and the BD PCR Cartridge are loaded onto the BD MAX™ System. The BD MAX™ System automates sample preparation, including target organism lysis, DNA extraction and concentration, reagent rehydration, and target nucleic acid amplification and detection using real-time PCR. The BD MAX™ System performs results interpretation automatically. The assay also includes a Sample Processing Control (SPC) that is present in the Extraction Tube. The Sample Processing Control monitors DNA extraction steps, thermal cycling steps, reagent integrity and presence of inhibitory substances.

Nucleic acids that are released from the target organisms as a result of cell lysis during the extraction process are captured on magnetic affinity beads. The beads, together with the bound nucleic acids, are washed using Wash Buffer and the nucleic acids are eluted by a combination of heat and pH. Eluted DNA is neutralized using Neutralization Buffer and transferred to the Master Mix to rehydrate the PCR reagents. After reconstitution, the BD MAX™ System dispenses a fixed volume of PCR-ready solution containing extracted nucleic acids into the BD PCR Cartridge. Microvalves in the BD PCR Cartridge are sealed by the system prior to initiating PCR in order to contain the amplification mixture, thus preventing evaporation and contamination.

The BD CTGCTV2 assay is comprised of two targets for *Chlamydia trachomatis* (detected on the same optical channel), two targets for *Neisseria gonorrhoeae* (detected on two different optical channels) and one target for *Trichomonas vaginalis* (detected on one optical channel). Only one *Chlamydia trachomatis* target is required to be positive in order to report a positive result. Both *Neisseria gonorrhoeae* targets are required to be positive in order to report a positive result. The amplified DNA targets are detected using hydrolysis (TaqMan®) probes, labeled at one end with a fluorescent reporter dye (fluorophore), and at the other end, with a quencher moiety. Probes labeled with different fluorophores are used to detect amplicons for target analytes and the Sample Processing Control in five different optical channels of the BD MAX™ System. When the probes are in their native state, the fluorescence of the fluorophore is quenched due to its proximity to the quencher. However, in the presence of target DNA, the probes hybridize to their complementary sequences and are hydrolyzed by the 5'–3' exonuclease activity of the DNA polymerase as it synthesizes the nascent strand along the DNA template. As a result, the fluorophores are separated from the quencher molecules and fluorescence is emitted. The BD MAX™ System monitors these signals at the end of each cycle and interprets the data at the end of the reaction to provide qualitative test results for each analyte (i.e., positive or negative).

REAGENTS AND MATERIALS

Materials Provided

Catalog Number	Contents	Quantity
443904	**BD CTGCTV2 for BD MAX™ System Master Mix (D3)** Dried PCR Master Mix containing nucleotides and specific molecular primers (0.01% w/v) and probes (0.004% w/v) along with Sample Processing Control and PCR enzyme (1.9E-15% w/v).	24 tests (2 x 12 tubes)
	BD CTGCTV2 for BD MAX™ System Unitized Reagent Strip containing wash buffer 0.1% v/v Tween® 20 (0.7 mL), elution buffer (0.7 mL) and neutralization buffer with 0.02% v/v Tween® 20 (0.7 mL) reagents and disposable pipette tips necessary for specimen processing and DNA Extraction.	24 tests
	BD CTGCTV2 for BD MAX™ System Extraction Tubes (B2) Dried extraction reagent containing DNA magnetic affinity beads (6.4% w/v), protease reagents (6.7% w/v) and Sample Processing Control	24 tests (2 x 12 tubes)

Equipment and Materials Required But Not Provided

- BD MAX™ System (BD Catalog Number 441916)
- BD MAX™ Sample Rack (BD Catalog Number 444807 or 444808)
- BD Pre-warm Heater Kit (BD Heater and BD MAX™ Rack) (BD Catalog Number 443159)
- BD Molecular LBC Sample Buffer Tubes (BD Catalog Number 443923)
- BD Molecular Urine Transport Kit (BD Catalog Number 443924)
- BD Molecular Swab Collection Kit (BD Catalog Number 443925)
- BD PCR Cartridges (BD Catalog Number 437519)
- BD Molecular Swab Sample Buffer Tubes (BD Catalog Number 440296)
- BD Pierceable Caps (BD Catalog Number 440295)
- Vortex Genie 2 (VWR Catalog Number 58815-234 or equivalent)
- Multi-Tube Vortex Mixer (VWR Catalog Number 558816-115 or equivalent)
- Rack compatible with a multi-tube vortex mixer (e.g., Cryogenic Vial Holder or equivalent)
- Fixed Volume Calibrated Pipettor, 500 µL (VWR Catalog Number 53514-044 or equivalent) and aerosol-resistant tips
- Disposable gloves, powderless

WARNINGS AND PRECAUTIONS

For in vitro diagnostic use. For Use by Trained Laboratory Personnel.

Extraction Tube

Danger

H312 Harmful in contact with skin. **H315** Causes skin irritation. **H319** Causes serious eye irritation. **H334** May cause allergy or asthma symptoms or breathing difficulties if inhaled. **H335** May cause respiratory irritation. **H401** Toxic to aquatic life. **H412** Harmful to aquatic life with long lasting effects.

P261 Avoid breathing dust/fume/gas/mist/vapors/spray. **P264** Wash face, hands and any exposed skin thoroughly after handling. **P271** Use only outdoors or in a well-ventilated area. **P273** Avoid release to the environment. **P280** Wear protective gloves/protective clothing/eye protection/face protection. **P284** [In case of inadequate ventilation] wear respiratory protection. **P302+P352** IF ON SKIN: Wash with plenty of water. **P363** Wash contaminated clothing before reuse. **P332+P313** If skin irritation occurs: Get medical advice/attention. **P362** Take off contaminated clothing. **P312** Call a POISON CENTER/doctor if you feel unwell. **P321** Specific treatment (see supplemental first aid instructions on this label). **P304+P340** IF INHALED: Remove person to fresh air and keep comfortable for breathing. **P342+P311** If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. **P305+P351+P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **P337+P313** If eye irritation persists: Get medical advice/attention. **P403+P233** Store in a well-ventilated place. Keep container tightly closed. **P405** Store locked up. **P501** Dispose of contents/container to an approved facility in accordance with local, regional, national and international regulations.

Elution Buffer

Danger

H314 Causes severe skin burns and eye damage.

P260 Do not breathe dust/fume/gas/mist/vapors/spray. **P264** Wash face, hands and any exposed skin thoroughly after handling. **P280** Wear protective gloves/protective clothing/eye protection/face protection. **P301+P330+P331** IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. **P303+P361+P353** IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. **P363** Wash contaminated clothing before reuse. **P321** Specific treatment (see supplemental first aid instructions on this label). **P304+P340** IF INHALED: Remove person to fresh air and keep comfortable for breathing. **P310** Immediately call a POISON CENTER/doctor. **P305+P351+P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **P405** Store locked up. **P501** Dispose of contents/container to an approved facility in accordance with local, regional, national and international regulations.

- The BD CTGCTV2 for the BD MAX™ System assay is for in vitro diagnostic use.
- The BD CTGCTV2 for the BD MAX™ System can only be used on the BD MAX™ System by trained laboratory personnel.
- Do not use expired reagents and/or materials.
- Do not use the kit if the label that seals the outer box is broken upon arrival.
- Do not use reagents if the protective pouches are open or broken upon arrival.
- Do not use reagents if desiccant is not present or is broken inside reagent pouches.
- Do not remove desiccant from reagent pouches.
- Close protective pouches of reagents promptly with the zip seal after each use. Remove any excess air in the pouches prior to sealing.
- Protect reagents against heat and humidity. Prolonged exposure to humidity may affect product performance.
- Do not use reagents if the foil has been broken or damaged.
- Do not mix reagents from different pouches and/or kits and/or lots.
- Do not interchange or reuse caps, as contamination may occur and compromise test results.
- Check Unitized Reagent Strips for proper liquid fills (ensure that the liquids are at the bottom of the tubes) (refer to Figure 1).
- Check Unitized Reagent Strips to ensure that all pipette tips are present (refer to Figure 1).
- Check Unitized Reagent Strips to ensure that all liquid reagents are seated at the bottom of each well.
- Proceed with caution when using chemical solutions as Master Mix and Extraction Tube barcode readability may be altered.
- Good laboratory technique is essential to the proper performance of this assay. Due to the high analytical sensitivity of this test, extreme care should be taken to preserve the purity of all materials and reagents.

- In cases where other PCR tests are conducted in the same general area of the laboratory, care must be taken to ensure that the BD CTGCTV2 assay, any additional reagents required for testing, and the BD MAX™ System are not contaminated. Avoid microbial and deoxyribonuclease (DNase) contamination of reagents at all times. Gloves must be changed before manipulating reagents and cartridges.
- To avoid contamination of the environment by amplicons, do not break apart the BD PCR Cartridges after use. The seals of the BD PCR Cartridges are designed to prevent contamination.
- The laboratory should routinely perform environmental monitoring to minimize the risk of cross-contamination.
- Performing the BD CTGCTV2 assay outside the recommended time ranges can produce invalid results. Assays not performed within the specified time ranges should be repeated.
- Additional controls may be tested according to guidelines or requirements of local, state, provincial and/or federal regulations or accrediting organizations.
- Always handle specimens as if they are infectious and in accordance with safe laboratory procedures such as those described in the CLSI Document M29[4] and in Biosafety in Microbiological and Biomedical Laboratories.[5]
- Wear protective clothing and disposable gloves while handling all reagents.
- Wash hands thoroughly after performing the test.
- Do not pipette by mouth.
- Do not smoke, drink, chew or eat in areas where specimens or kit reagents are being handled.
- Consult the BD MAX™ System User's Manual[6] for additional warnings, precautions and procedures.

Collect and dispose of all used and unused reagents and any other contaminated disposable materials following procedures for biohazardous or potentially biohazardous waste. It is the responsibility of each laboratory to handle solid and liquid waste according to their nature and degree of hazardousness and to adequately treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations. Do not discharge liquid waste down the drain where prohibited.

STORAGE AND STABILITY

Specimen Stability

Swab specimens must be transferred to a BD Molecular Swab Sample Buffer Tube immediately after collection. First void urine specimens must be transferred from the collection cup to the BD Molecular Urine Sample Buffer Tube immediately after collection. Once in the BD Molecular Sample Buffer Tube, swab and urine specimens can be stored for a total of 21 days at 2–30 °C. A Sample Buffer Tube with a pierced cap can be stored upright for up to 4 days at 2–30 °C (Table 1).

Table 1: Swab and Urine Specimen Storage and Transport

Specimen Stability	Transport and/or Storage Time/Temperature
In BD Molecular Swab or Urine Sample Buffer Tube	Up to 21 days at 2–30 °C
In BD Molecular Swab or Urine Sample Buffer Tube (after cap is pierced)	Up to 4 days at 2–30 °C

PreservCyt® LBC specimens in the vial prior to transfer to the BD Molecular LBC Sample Buffer Tube can be stored up to 14 days at 2–30 °C. Once in the BD Molecular LBC Sample Buffer Tube, samples can be stored for a total of 21 days at 2–30 °C. A Sample Buffer Tube with a pierced cap can be stored upright for up to 4 days at 2–30 °C (Table 2).

Table 2: PreservCyt® LBC Specimen Storage and Transport

Specimen Stability	Transport and/or Storage Time/Temperature
Prior to transfer to BD Molecular LBC Sample Buffer Tube	Up to 14 days at 2–30 °C
In BD Molecular LBC Sample Buffer Tube (prior to or after pre-warm)	Up to 21 days at 2–30 °C
In BD Molecular LBC Sample Buffer Tube (after cap is pierced)	Up to 4 days at 2–30 °C

Reagent Stability

BD CTGCTV2 assay components are stable at 2–25 °C through the stated expiration date. Do not use components after the expiration date.

NOTE: The reagents are considered unusable by the BD MAX™ System on the expiration date printed on the product label.

BD CTGCTV2 Master Mix and Extraction Tubes are provided in sealed pouches with a desiccant. To protect the product from humidity, immediately re-seal after opening. Reagent tubes are stable for up to 14 days after initial opening and re-sealing (or until printed expiration, whichever is first).

Table 3: BD CTGCTV2 Assay for BD MAX™ System Reagent Stability

Kit Components	Temperature	Stability
Master Mix		
Sealed pouch (not opened)	2–25 °C	Until printed expiration date
Open pouch (resealed)	2–25 °C	Up to 14 days[a]
Extraction Tubes		
Sealed pouch (not opened)	2–25 °C	Until printed expiration date
Open pouch (resealed)	2–25 °C	Up to 14 days[a]
Unitized Reagent Strips	2–25 °C	Until printed expiration date
Sample Buffer Tubes	2–25 °C	Until printed expiration date

[a] Once the original seal is broken, carefully close the pouch containing the desiccant with the zip seal, removing as much air as possible, after each use and store at the appropriate temperature.

INSTRUCTIONS FOR USE

Swab Specimen Transport

Swab specimens must be collected with the BD Molecular Swab Collection Kit and following the package insert instructions. Specimens collected using the BD Molecular Collection Swab must be transferred to the BD Molecular Swab Sample Buffer Tube immediately after collection. Wear clean gloves when handling the BD Molecular Swab Collection Kit components and specimens. If gloves come in contact with the specimen, immediately change them to prevent contamination of other specimens.

Transfer of Swab Specimens to the BD Molecular Swab Sample Buffer Tube

1. Unscrew the cap of the BD Molecular Swab Sample Buffer Tube, taking care not to contaminate the contents or the outside of the tube.
2. Immediately after collection, insert the BD Molecular Collection Swab into the tube so that the score mark indicated by the black line is at the lip of the tube. Carefully break the swab shaft at the score mark. Use caution to avoid splashing of the tube contents.
3. Tighten the cap securely on the BD Molecular Swab Sample Buffer Tube.
4. Label the BD Molecular Swab Sample Buffer Tube with patient information and date/time collected.
   NOTE: Do not obscure the barcodes on the tube. Obscuring the barcode may result in BD MAX™ System catalog failure and inability to test the sample.
5. Transport to the testing laboratory.

Urine Specimen Transport

First void urine specimens must be collected in a sterile, plastic, preservative-free, specimen collection cup. Urine must be transferred from the collection cup to a BD Molecular Urine Sample Buffer Tube immediately after collection. Wear clean gloves when handling the BD Molecular Urine Transport Kit components and specimens. If gloves come in contact with the specimen, immediately change them to prevent contamination of other specimens.

Transfer of Urine to the BD Molecular Urine Sample Buffer Tube

1. Uncap the BD Molecular Urine Sample Buffer Tube and the urine specimen cup.
2. Immediately after collection, use the graduated transfer pipette to mix the urine specimen gently in the collection cup and transfer approximately 2 mL into the BD Molecular Urine Sample Buffer Tube.
   NOTE: Use the graduations on the transfer pipette as a guide.
3. Use the viewing window on the BD Molecular Urine Sample Buffer Tube label to ensure urine specimen was added to the tube.
4. Discard the transfer pipette in a biohazard waste container.
   NOTE: The transfer pipette is intended for use with a single specimen.
5. Tighten the cap securely on the BD Molecular Urine Sample Buffer Tube.
6. Invert the BD Molecular Urine Sample Buffer Tube 3 to 4 times to ensure that the specimen and reagent are well mixed.
7. Label the BD Molecular Urine Sample Buffer Tube with the patient identification and date/time collected.
   NOTE: Do not obscure the barcodes on the tube. Obscuring the barcode may result in BD MAX™ System catalog failure and inability to test the sample.
8. Transport to the testing laboratory.

PreservCyt® LBC Specimen Transport and Preparation

PreservCyt® LBC specimens must be collected using either an endocervical broom or a brush/spatula combination as described in the PreservCyt® product insert. PreservCyt® LBC specimens must be aliquoted into a BD Molecular LBC Sample Buffer Tube prior to processing the specimen for the Pap test. PreservCyt® specimens can be stored and transported in the original vials for up to 14 days at 2–30 °C prior to transfer to the BD Molecular LBC Sample Buffer Tube. Residual PreservCyt® LBC specimens cannot be used with the BD CTGCTV2 assay. Wear gloves when handling the BD Molecular LBC Sample Buffer Tube and the PreservCyt® specimen vial. If gloves come in contact with the specimen, immediately change them to prevent contamination of other specimens.

Transfer of PreservCyt® LBC Specimen to the BD Molecular LBC Sample Buffer Tube

NOTE: For PreservCyt® LBC specimens, ensure the collection devices are not present in the vial.

1. Remove the cap from the BD Molecular LBC Sample Buffer Tube.
2. Vortex the PreservCyt® specimen vial for 8–12 seconds in order to ensure a homogenous mixture, and then uncap.
3. Immediately after vortexing, using a fixed volume calibrated pipettor, transfer 0.5 mL from the PreservCyt® specimen vial to the BD Molecular LBC Sample Buffer Tube. Discard pipette tip after each specimen.
4. Tighten the cap on the BD Molecular LBC Sample Buffer Tube securely.
5. Invert the BD Molecular LBC Sample Buffer Tube 3 to 4 times to ensure that the specimen and buffer are well mixed.
6. Label the BD Molecular LBC Sample Buffer Tube with patient identification information and date/time collected.
   NOTE: Do not obscure the barcodes on the tube. Obscuring the barcode may result in BD MAX™ System catalog failure and inability to test the sample.
7. Transport to the testing laboratory.

Specimen Preparation

NOTE: One (1) Sample Buffer Tube, one (1) Master Mix, one (1) Extraction Tube and one (1) Unitized Reagent Strip are required for each specimen and each External Control to be tested.

1. Prepare each sample type as follows:
   Swab Samples:
   a. Briefly vortex each BD Molecular Swab Sample Buffer Tube for 5 seconds or, alternatively, place multiple BD Molecular Swab Sample Buffer Tubes on a multi-tube vortexer for up to 1 minute.
      NOTE: DO NOT pre-warm BD Molecular Swab Sample Buffer Tubes.
   b. Proceed directly to the BD MAX™ System Operation section.
      NOTE: If the BD MAX™ System run cannot be started within 4 hours of the vortexing step, briefly vortex again for 5 seconds.

   Urine Samples:
   a. Briefly vortex each BD Molecular Urine Sample Buffer Tube for 5 seconds or, alternatively, place multiple BD Molecular Urine Sample Buffer Tubes on a multi-tube vortexer for up to 1 minute.
      NOTE: DO NOT pre-warm BD Molecular Urine Sample Buffer Tubes.
   b. Proceed directly to the BD MAX™ System Operation section.
      NOTE: If the BD MAX™ System run cannot be started within 4 hours of the vortexing step, briefly vortex again for 5 seconds.

   PreservCyt® LBC Samples:
   a. Briefly vortex each BD Molecular LBC Sample Buffer Tube for 5 seconds or, alternatively, place multiple BD Molecular LBC Sample Buffer Tubes on a multi-tube vortexer for up to 1 minute.
   b. Pre-warm BD Molecular LBC Sample Buffer Tubes on the BD Pre-warm Heater (refer to the BD Pre-warm Heater Operation section).
   c. Proceed directly to the BD MAX™ System Operation section.
      NOTE: If the BD MAX™ System run cannot be started within 4 hours of this vortexing step, briefly vortex again for 5 seconds.

BD Pre-warm Heater Operation

NOTE: Refer to the BD Pre-warm Heater Manual[7] for operating instructions.

NOTE: Only PreservCyt® LBC samples should be pre-warmed. DO NOT pre-warm urine or swab samples.

1. Enter the barcode from each BD Molecular LBC Sample Buffer Tube in the Sample Tube field using the barcode scanner along with the patient accession ID.
2. The Assay Definition File <BD CTGC2 LBC 57> will be automatically selected by the instrument.
3. Enter the kit lot number from the Run > Kit Inventory screen for the BD CTGCTV2 assay kit (for lot traceability) by scanning the barcode with the scanner or by manual entry.
   NOTE: Ensure Lot Number tracking is enabled in Configuration > System.
4. The pending worklist now will be updated and display a check box for the pre-warm step to be scheduled.
5. Schedule the sample by checking the box in the worklist.
6. Place the BD Molecular LBC Sample Buffer Tube (containing the specimen) on the BD Pre-warm Heater. The station accommodates up to 24 Sample Buffer Tubes.
7. Close the rack lid on the BD Pre-warm Heater and select 'Start Pre-warm' on the Run > Worklist screen.
   NOTE: Confirm tubes were physically placed in the BD Pre-warm rack and that the rack was loaded in the BD Pre-warm Heater, and then select OK on the 'Start Pre-warm' message.
   A specific heating and cooling profile for BD Molecular LBC samples is started.
8. The completion time of the pre-warm run will display on the Status screen and the Worklist screen will indicate that the pre-warm is "In progress."
9. In the Worklist screen, the selected sample/test will be displayed as 'Pre-warm Complete' upon successful pre-warm.

10. After successful completion of the pre-warm step, remove the BD Molecular LBC Sample Buffer Tube from the BD Pre-warm Heater.
11. Proceed directly to the BD MAX™ System Operation section to set up the BD MAX™ System Rack.

NOTE: In the event of an unsuccessful pre-warm step, the BD MAX™ System Timer Status will display Failed / Cooling. It is necessary to repeat the pre-warm step prior to testing on the BD MAX™ System.

NOTE: The BD CTGCTV2 assay can only be performed for PreservCyt® LBC samples after successful completion of the pre-warm step. PreservCyt® LBC samples that have completed the pre-warm cycle successfully should not be reheated in the event retesting is necessary.

NOTE: For laboratories with more than one BD MAX™ System and BD Pre-warm Heater, samples must be tested and/or retested on the same BD MAX™ System on which the pre-warm step was performed.

NOTE: Refer to Table 2 for sample stability after successful completion of the pre-warm step. BD Molecular LBC Sample Buffer Tubes are not required to be re-vortexed after pre-warm if the BD MAX™ System run is started within 4 hours of the initial vortex (before pre-warm). Briefly vortex for 5 seconds if the BD MAX™ System run is not started within 4 hours.

Stored samples must be equilibrated to ambient temperature and briefly vortexed for 5 seconds prior to testing on the BD MAX™ System.

BD MAX™ System Operation

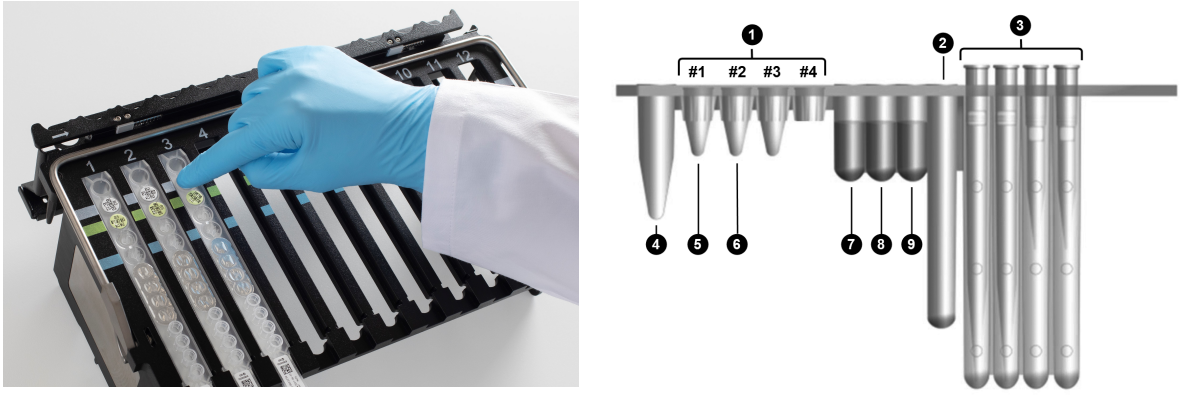
NOTE: Refer to the BD MAX™ System User's Manual[6] (Operation section) for detailed instructions.

NOTE: Testing specimens with the BD CTGCTV2 assay must be performed within 4 hours after the vortexing step (see the Specimen Preparation section) or vortexing must be repeated.

NOTE: One (1) Master Mix (D3), one (1) Extraction Tube (B2) and one (1) Unitized Reagent Strip are required for each specimen. If External Controls are to be tested one (1) BD Molecular Swab Sample Buffer Tube is required for each control (e.g., one for the external positive control and one for the negative control). Set aside the required number of BD MAX™ materials from their protective pouches or boxes. To store opened Master Mix or Extraction Tube pouches, remove excess air and close using the zip seal, ensuring that the desiccant pack is present in the pouch.

1. Power on the BD MAX™ System (if not already done) and log in by entering **<user name>** and **<password>**.
2. Gloves must be changed before manipulating reagents and cartridges.
3. Remove the required number of Unitized Reagent Strips from the BD CTGCTV2 assay kit.
   NOTE: Tap each Unitized Reagent Strip onto a hard surface and visually inspect to ensure that all liquids are at the bottom of the tubes.
4. Remove the required number of Extraction Tube(s) and Master Mix Tube(s) from their protective pouches. Remove excess air, and close pouches with the zip seal.
5. For each sample to be tested, place one (1) Unitized Reagent Strip on the BD MAX™ System Rack, starting with Position 1 of Rack A.
6. Snap one (1) Extraction Tube (white foil) into each Unitized Reagent Strip in Position 1 as shown in Figure 1.
7. Snap one (1) Master Mix Tube (green foil) into each Unitized Reagent Strip in Position 2 as shown in Figure 1.

Figure 1: Snap BD CTGCTV2 Extraction Tubes and Master Mix Tubes into Unitized Reagent Strips



BD CTGCTV2 Unitized Reagent Strips: (1) Snap-in Tubes **(2)** Waste Reservoir **(3)** Pipette Tips **(4)** Lysis Tube **(5)** Extraction Tube **(6)** BD CTGCTV2 Master Mix **(7)** Wash Buffer **(8)** Elution Buffer **(9)** Neutralization Buffer

8. Enter the kit lot number for the BD CTGCTV2 assay kit (for lot traceability) on Run > Kit Inventory screen by either scanning the barcode with the scanner or by manual entry.
   NOTE: Ensure Lot Number tracking is enabled in Configuration > System.
   NOTE: Repeat this step each time a new kit lot is used.

9. Navigate to the Run > Worklist screen.
10. Enter the Sample Buffer Tube ID, Patient ID and Accession Number (if applicable) into the Worklist, either by scanning the barcode using the barcode scanner or by manual entry.
11. Select the appropriate Assay Definition File according to the sample type from the drop down menu (see Table 4):

Table 4: Assay Definition Files by Sample Type

Specimen Type	Assay Definition Files
Vaginal Swab	BD CTGCTV2 VAG 57
Endocervical Swab	BD CTGC2 ENDO 57
Urine	BD CTGCTV2 URINE 57
LBC	BD CTGC2 LBC 57

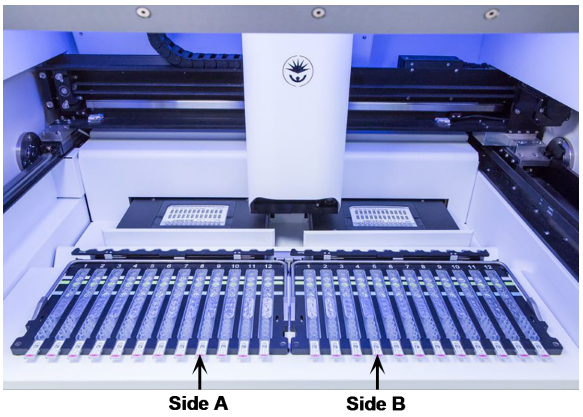
NOTE: Selection of the Endocervical Swab or LBC Assay Definition File will result in reporting of results for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* only.

12. Select the appropriate kit lot number (found on the outer box) from the pull down menu. Once an ADF is selected, if the next sample requires the same ADF (i.e., if two swab samples are scanned in a row) the ADF selected will remain populated.
13. Repeat steps 9 to 12 for all remaining Sample Buffer Tubes.
14. Place the Sample Buffer Tubes in the BD MAX™ System Rack(s) corresponding to the Unitized Reagent Strips assembled in steps 5 to 7.
15. Place the required number of BD PCR Cartridge(s) into the BD MAX™ System (refer to Figure 2).
    - Each BD PCR Cartridge accommodates up to 24 samples.
    - The BD MAX™ System will automatically select the position and row on the PCR Cartridge for each run. BD PCR Cartridges may be used multiple times until all lanes have been utilized.
    - To maximize use of BD PCR Cartridges, using 2000 Sample Mode, select Run Wizard under the Worklist tab for lane assignments.
    - Consult the BD MAX™ System User's Manual[6] for more details.

Figure 2: Load BD PCR Cartridges

16. Load rack(s) onto the BD MAX™ System (refer to Figure 3).

Figure 3: Load Rack(s) onto the BD MAX™ System



17. Close the BD MAX™ System lid and select **<Start>** to begin processing.
18. At the end of the run, check results immediately or store the Sample Buffer Tubes according to the temperature and time represented in Tables 1 and 2 until the results are checked.

NOTE: Prior to storage, replace pierced cap with a new BD Pierceable Cap.

NOTE: When an Indeterminate (IND), Unresolved (UNR), or Incomplete (INC) result is obtained, or when an External Control failure occurs, a repeat test from the same BD Molecular Sample Buffer Tube must be performed (refer to the Repeat Test Procedure section) within the time frame designated in Tables 1 and 2.

QUALITY CONTROL

Quality control procedures monitor the performance of the assay. Laboratories must establish the number, type and frequency of testing of control materials according to guidelines or requirements of local, provincial, state and federal and/or country regulations or accreditation organizations in order to monitor the effectiveness of the entire analytical process. For general Quality Control guidance, the user may wish to refer to CLSI MM3[8] and EP12.[9]

1. External Control materials are not provided by BD. External Positive and Negative Controls are not used by the BD MAX™ System software for the purpose of sample test result interpretation. External Controls are treated as if they were patient samples. (Refer to the table in the Results Interpretation section for the interpretation of External Control assay results.)
2. It is recommended that one (1) External Positive Control and one (1) External Negative Control be run at least daily until adequate process validation is achieved on the BD MAX™ System in each laboratory setting. Reduced frequency of control testing should be in accordance with applicable regulations.
3. The External Positive Control is intended to monitor for substantial reagent failure. The External Negative Control is intended to detect reagent or environmental contamination (or carry-over) by target nucleic acids.
4. Various types of External Controls are recommended to allow the user to select the most appropriate for their laboratory quality control program.
   a. External Negative Control: BD Molecular Swab Sample Buffer Tube without the addition of organism or a previously characterized sample known to be negative. BD recommends that the External Negative Control be prepared prior to the External Positive Control in order to reduce the potential for contamination as a result of control preparation.
   b. External Positive Control: Commercially available control material (e.g., *Chlamydia trachomatis* serovar H [ATCC® VR-879], *Neisseria gonorrhoeae* ATCC® 19424]*, Trichomonas vaginalis* ATCC® 30001], or a previously characterized sample known to be positive.

   For the preparation of External Control suspensions, it is recommended that cell stocks be obtained from ATCC® and diluted in phosphate buffered saline to a final 10^{-6} dilution of the parental cell stock for *Chlamydia trachomatis* serovar H and *Neisseria gonorrhoeae* and to a final 10^{-3} dilution of the parental cell stock for *Trichomonas vaginalis*. *Neisseria gonorrhoeae* ATCC® cell stocks are lyophilized and must be rehydrated with 1 mL phosphate buffer saline prior to dilution. Subsequently dilute the solution by transferring 200 µL into a BD Molecular Swab Sample Buffer Tube for a final concentration of 10^{-7} for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, and a final concentration of 10^{-4} for *Trichomonas vaginalis*.
5. All External Controls should yield the expected results (positive for External Positive Control, negative for External Negative Control) and no failed Sample Processing Controls (Unresolved or Indeterminate results).
6. An External Negative Control that yields a positive result is indicative of sample handling and/or contamination. An External Positive Control that yields a negative result is indicative of a specimen handling/preparation problem. Review the specimen handling/preparation technique.
7. An External Control that yields an Unresolved, Indeterminate or Incomplete test result is indicative of a reagent or a BD MAX™ System failure. Check the BD MAX™ System monitor for any error messages. Refer to the System Error Summary section of the BD MAX™ System User's Manual[6] for interpretation of warning and error codes. If the problem persists, use reagents from an unopened pouch or use a new assay kit.
8. Each Extraction Tube contains a Sample Processing Control which is a plasmid containing a synthetic target DNA sequence. The Sample Processing Control monitors the efficiency of DNA capture, washing and elution during the sample processing steps, as well as the efficiency of DNA amplification and detection during PCR analysis. If the Sample Processing Control result fails to meet the acceptance criteria, the result of the specimen will be reported as Unresolved; however, any positive (POS) assay results will be reported and no targets will be called NEG. An Unresolved result is indicative of specimen-associated inhibition or reagent failure. Repeat any specimen reported as Unresolved according to the Repeat Test Procedure section below.

RESULTS INTERPRETATION

Results are available on the Results tab in the Results window on the BD MAX™ System Monitor. The BD MAX™ System automatically interprets test results. A test result may be called NEG (negative), POS (positive), or UNR (unresolved) based on the amplification status of the target and the Sample Processing Control. IND (indeterminate) or INC (incomplete) results are due to a BD MAX™ System failure. Results are based on the following decision algorithm:

Table 5: BD CTGCTV2 Assay Result Interpretation

Assay Result Reported	Interpretation of Result
CT POS	*Chlamydia trachomatis* DNA Detected
CT NEG	No *Chlamydia trachomatis* DNA Detected
CT UNR	Unresolved – inhibitory sample or reagent failure; no target or Sample Processing Control amplification
GC POS[b]	*Neisseria gonorrhoeae* DNA Detected
GC NEG	No *Neisseria gonorrhoeae* DNA Detected
GC UNR	Unresolved – inhibitory sample or reagent failure; no target or Sample Processing Control amplification
TV POS	*Trichomonas vaginalis* DNA Detected
TV NEG	No *Trichomonas vaginalis* DNA Detected
TV UNR	Unresolved – inhibitory sample or reagent failure; no target or Sample Processing Control amplification
IND	Indeterminate result due to BD MAX™ System failure (with Warning or Error Codes)[a]
INC	Incomplete Run (with Warning or Error Codes)[a]

[a] Refer to the Troubleshooting section of the BD MAX™ System User's Manual[6] for interpretation of warning and error codes.
[b] Both *Neisseria gonorrhoeae* targets are required to be positive for the BD CTGCTV2 assay to report a GC POS result.

Repeat Test Procedure

Sufficient volume is available for one repeat each from the BD Molecular LBC Sample Buffer Tubes and the BD Molecular Urine Sample Buffer Tubes, resulting in a total of two BD MAX™ System runs. Sufficient volume is available for two repeat tests from the BD Molecular Swab Sample Buffer Tube, resulting in a total of three BD MAX™ System runs. Repeat testing must be performed within the time frames represented in Tables 1 and 2. Equilibrate stored samples to ambient temperature and briefly vortex for 5 seconds prior to testing. Retest samples beginning at the BD MAX™ System Operation Section.

New samples may be tested in the same run as samples undergoing retest.

Repeat testing from a single BD Molecular Sample Buffer Tube must be performed on the same BD MAX™ System as the original test.

Unresolved Result

Unresolved results may be obtained in the event that specimen-associated inhibition or reagent failure prevents proper target or Sample Processing Control amplification. If the Sample Processing Control does not amplify, the sample will be reported as UNR; however, any positive (POS) assay results will be reported and no targets will be called NEG.

The BD MAX™ System reports results for each target individually and a UNR result may be obtained for one or more BD CTGCTV2 assay targets. In the case of a complete UNR, where all targets have a UNR result, it is necessary to repeat the test. In the case of a partial UNR, when one or more targets have a POS result and all other targets have a UNR result, it is recommended that the test be repeated as described below. In rare cases, discrepant results may be observed when a repeat test is run for those targets that were initially reported as POS. Follow appropriate procedures in accordance with current laboratory procedures.

Sample(s) can be repeated from their corresponding BD Molecular Sample Buffer Tube(s) within the timeframes defined above. Restart following the BD MAX™ System Operation section.

Indeterminate Result

Indeterminate results may be obtained in the event that a System failure occurs. Sample(s) can be repeated from their corresponding BD Molecular Sample Buffer Tube(s) within the timeframes defined above. Restart following the BD MAX™ System Operation section. For the interpretation of warning or error code messages, refer to the BD MAX™ System User's Manual[6] (Troubleshooting section).

Incomplete Result

Incomplete results may be obtained in the event that Specimen Preparation or the PCR failed to complete. Sample(s) can be repeated from their corresponding BD Molecular Sample Buffer Tube(s) within the timeframes defined above. Restart following BD MAX™ System Operation section. For the interpretation of warning or error code messages, refer to the BD MAX™ System User's Manual[6] (Troubleshooting section).

External Control Failure

External Controls should yield the expected results when tested. If samples have to be repeated due to an incorrect External Control result, they should be repeated from their BD Molecular Sample Buffer Tubes along with freshly prepared External Controls within the timeframes defined above. Restart following the BD MAX™ System Operation section.

LIMITATIONS OF THE PROCEDURE

- Performance characteristics have not been established for the use of the BD CTGCTV2 assay for the detection of *Trichomonas vaginalis* in endocervical or PreservCyt® LBC specimens.
- First catch urine from women, while acceptable for screening, may detect up to 10% fewer infections when compared with vaginal and endocervical swab samples.[11]
- Collection and testing of urine and patient-collected vaginal swab specimens with the BD CTGCTV2 assay is not intended to replace cervical exam and endocervical sampling for diagnosis of urogenital infection. Cervicitis, urethritis, urinary tract infections and vaginal infections may result from other causes or concurrent infections may occur.
- The BD CTGCTV2 assay for male and female urine testing should be performed on first catch urine specimens. During the clinical evaluation, urine volumes from 20 mL to 60 mL were included in the performance estimates. Dilution effects of larger urine volumes may result in reduced assay sensitivity. The effects of other variables such as mid-stream collection have not been determined.
- The BD CTGCTV2 assay has not been validated for use with vaginal swab specimens collected by patients at home.
- Lubricants or other products containing substances such as carbomers, can increase the non-reportable rate obtained with BD CTGCTV2 assay.
- Interference with the BD CTGCTV2 assay was observed for vaginal swab matrix in the presence of Aquagel (>0.0345 mg/mL), McKesson Lubricating Jelly (>0.445 mg/mL), Surgilube (>0.41 mg/mL), VCF contraceptive foam (>15 µL/mL), VCF contraceptive film (>0.5 µL/mL), Conceptrol contraceptive gel (>3 µL/mL), vaginal anti-itch cream/Monistat/Replens (>0.1 µL/mL), acyclovir (>0.01 µL/mL), metronidazole (>1.25 µL/mL), mucous (>4.5% v/v) and whole blood (>8 µL/mL).
- Interference with the BD CTGCTV2 assay was observed for urine matrix in the presence of whole blood (>0.6% v/v).
- Interference with the BD CTGCTV2 assay was observed for PreservCyt® matrix in the presence of Aquagel (>0.276 mg/mL), McKesson Lubricating Jelly (>3.56 mg/mL), Surgilube (>328 mg/mL), vaginal anti-itch cream (>1% v/v), metronidazole (>0.01% v/v), Replens (>0.1% v/v), mucous (>1.9% v/v) and whole blood (>0.5% v/v).
- *Trichomonas tenax*, a commensal of the oral cavity, was found to cross-react with the BD CTGCTV2 assay at levels above ≥1.88 TV/mL. *Pentatrichomonas hominis*, a commensal of the large intestine, was found to cross-react at levels above ≥1.00 x 10^5 TV/mL.
- The effects of other potential variables such as vaginal discharge, use of tampons and specimen collection variables have not been determined.
- As with many diagnostic tests, results from the BD CTGCTV2 assay should be interpreted in conjunction with other laboratory and clinical data available to the physician.
- Erroneous results may occur from improper specimen collection, handling or storage, technical error, sample mix-up, or because the number of organisms in the specimen is below the analytical sensitivity of the test.
- If the BD CTGCTV2 assay result is IND, INC, or UNR (for one or more targets) then the test should be repeated.
- A BD CTGCTV2 assay result does not necessarily indicate the presence of viable organisms. A positive result is indicative of the presence of *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae* and/or *Trichomonas vaginalis* DNA.
- The BD CTGCTV2 assay cannot be used to assess therapeutic success or failure since nucleic acids from *Chlamydia trachomatis* and *Neisseria gonorrhoeae* and *Trichomonas vaginalis* may persist following antimicrobial therapy.
- False negative results may occur due to loss of nucleic acid from inadequate collection, transport, or storage of specimens, or due to inadequate bacterial cell lysis. The Sample Processing Control has been added to the test to aid in the identification of samples that contain inhibitors to PCR amplification. The Sample Processing Control does not indicate if nucleic acid has been lost due to inadequate collection, transport, or storage of specimens, or if bacterial cells have been adequately lysed.
- The BD CTGCTV2 assay should not be used for the evaluation of suspected sexual abuse or for other medico-legal indications. Additional testing is recommended in any circumstance when false positive or false negative results could lead to adverse medical, social, or psychological consequences.
- As with all in vitro diagnostic tests, positive and negative predictive values are highly dependent on prevalence. BD CTGCTV2 assay performance may vary depending on the prevalence and population tested.
- As with all PCR-based in vitro diagnostic tests, extremely low levels of target below the Limit of Detection or LoD of the assay may be detected, but results may not be reproducible.
- This test is a qualitative test and does not provide quantitative values nor indicate the quantity of organisms present.

EXPECTED VALUES

The positivity rate of the BD CTGCTV2 assay, as observed during the multi-center clinical study, is shown by specimen type in Tables 6 and 7.

Table 6: BD CTGCTV2 Assay Clinical Study Female Positivity

% Positive (Number positive/Number of valid results)													
Site	***Chlamydia trachomatis***					***Neisseria gonorrhoeae***					***Trichomonas vaginalis***		
	CCVS[a]	**SCVS[b]**	**Endo**	**LBC[c]**	**Urine**	**CCVS[a]**	**SCVS[b]**	**Endo**	**LBC[c]**	**Urine**	**CCVS[a]**	**SCVS[b]**	**Urine**
1	3.4% 10/294	3.4% 10/297	3.3% 10/299	2.7% 8/298	3.1% 9/295	0.3% 1/294	0.7% 2/297	0.3% 1/299	0.3% 1/298	0.3% 1/295	23.1% 68/295	23.7% 71/299	23.4% 69/295
2	3.7% 18/486	5.1% 25/490	4.7% 489	3.8% 18/471	4.7% 23/489	1.0% 5/486	0.8% 4/489	0.6% 3/489	0.4% 2/471	0.8% 4/489	10.7% 52/486	12.0% 59/490	11.6% 57/491
3	5.3% 7/132	6.0% 8/133	4.5% 6/132	3.8% 5/133	4.5% 6/134	2.3% 3/132	2.3% 3/133	2.3% 3/132	2.3% 3/133	2.2% 3/134	6.8% 9/132	7.5% 10/133	7.5% 10/134
4	17.2% 5/29	17.2% 5/29	17.2% 5/29	13.8% 4/29	10.3% 3/29	3.4% 1/29	3.4% 1/29	3.4% 1/29	3.4% 1/29	3.4% 1/29	20.7% 6/29	20.7% 6/29	20.7% 6/29
5	7.1% 13/182	7.1% 13/182	5.5% 10/182	6.0% 11/182	7.7% 14/182	3.3% 6/182	3.3% 6/182	2.7% 5/182	2.7% 5/182	2.7% 5/182	14.8% 27/182	14.3% 26/182	14.3% 26/182
6	7.3% 35/482	7.0% 34/483	5.4% 26/481	5.2% 25/484	6.2% 28/453	1.5% 7/482	1.7% 8/482	1.5% 7/481	1.2% 6/484	1.5% 7/453	6.6% 32/482	7.9% 38/482	6.6% 30/453
7	6.7% 5/75	6.7% 5/75	7.9% 6/76	6.4% 5/78	7.9% 6/76	0.0% 0/75	0.0% 0/75	0.0% 0/76	0.0% 0/78	0.0% 0/76	10.7% 8/75	12.0% 9/75	11.8% 9/76
8	3.9% 11/283	4.6% 13/283	3.9% 11/282	3.6% 10/276	3.7% 10/272	0.0% 0/283	0.0% 0/282	0.0% 0/282	0.0% 0/276	0.0% 0/272	1.4% 4/283	1.1% 3/282	1.1% 3/272
9	12.8% 33/257	11.6% 30/259	11.2% 29/259	10.6% 25/235	10.9% 28/256	6.2% 16/257	6.6% 17/259	6.2% 16/257	6.8% 16/235	5.5% 14/256	18.7% 48/257	18.1% 47/259	16.8% 43/256
10	9.4% 12/127	11.0% 14/127	10.2% 13/127	7.9% 10/127	7.9% 10/127	4.7% 6/127	4.7% 6/127	4.7% 6/127	4.7% 6/127	4.7% 6/127	7.9% 10/127	7.9% 10/127	7.9% 10/127
11	2.5% 4/157	1.9% 3/156	0.6% 1/157	0.0% 0/157	1.9% 3/157	0.0% 0/157	0.0% 0/156	0.0% 0/157	0.0% 0/157	0.0% 0/157	1.3% 2/157	1.3% 2/156	1.3% 2/157
Total	6.1% 153/2,504	6.4% 160/2,514	5.6% 140/2,513	4.9% 121/2,470	5.7% 140/2,470	1.8% 45/2,504	1.9% 47/2,511	1.7% 42/2,511	1.6% 40/2,470	1.7% 41/2,470	10.6% 266/2,505	11.2% 281/2,514	10.7% 265/2,472

[a] Clinician-collected vaginal swab

[b] Patient-collected vaginal swab

[c] PreservCyt® LBC

Table 7: BD CTGCTV2 Assay Clinical Study Male Urine Positivity

% Positive (Number positive/Number of valid results)			
Site	***Chlamydia trachomatis***	***Neisseria gonorrhoeae***	***Trichomonas vaginalis***
1	17.0% 8/47	2.1% 1/47	0.0% 0/47
2	18.9% 28/148	23.6% 35/148	2.0% 3/148
3	12.0% 35/291	9.6% 28/291	5.2% 15/291
4	10.0% 36/359	7.2% 26/359	3.3% 12/359
5	13.3% 13/98	4.1% 4/98	5.1% 5/98
6	17.6% 35/199	14.6% 29/199	7.5% 15/199
Total	13.6% 155/1,142	10.8% 123/1,142	4.4% 50/1,142

Positive and Negative Predictive Value

Hypothetical Positive Predictive Value (PPV) and Negative Predictive Value (NPV) were calculated for patient- and clinician-collected vaginal swabs, endocervical swabs, male urine and PreservCyt® LBC specimens and are shown in Table 8. The calculations are based on observed sensitivity and specificity for each specimen type, as compared to the Patient Infected Status.

Table 8: Hypothetical Positive and Negative Predictive Values for BD CTGCTV2 Assay

Specimen Type	Hypothetical Prevalence	*Chlamydia trachomatis*		*Neisseria gonorrhoeae*		*Trichomonas vaginalis*	
		% PPV 95% CI	% NPV 95% CI	% PPV 95% CI	% NPV 95% CI	% PPV 95% CI	% NPV 95% CI
Vaginal[a]	1%	44.9% (36.3%, 53.9%)	100% (99.9%, 100%)	87.5% (73.8%, 96.1%)	100% (99.9%, 100%)	61.7% (47.3%, 76.4%)	100% (99.9%, 100%)
	2%	62.2% (53.5%, 70.3%)	100% (99.9%, 100%)	93.4% (85.1%, 98.0%)	100% (99.8%, 100%)	76.5% (64.5%, 86.7%)	100% (99.9%, 100%)
	5%	80.9% (74.8%, 85.9%)	99.9% (99.7%, 100%)	97.3% (93.6%, 99.2%)	99.9% (99.6%, 100%)	89.4% (82.4%, 94.4%)	99.9% (99.7%, 100%)
	10%	90.0% (86.2%, 92.8%)	99.8% (99.4%, 100%)	98.7% (96.9%, 99.6%)	99.9% (99.1%, 100%)	94.7% (90.8%, 97.3%)	99.8% (99.4%, 99.9%)
	15%	93.4% (90.9%, 95.3%)	99.7% (99.0%, 99.9%)	99.2% (98.0%, 99.8%)	99.8% (98.5%, 100%)	96.6% (94.0%, 98.3%)	99.6% (99.1%, 99.9%)
	20%	95.3% (93.4%, 96.7%)	99.6% (98.6%, 99.9%)	99.4% (98.6%, 99.8%)	99.7% (97.9%, 100%)	97.6% (95.7%, 98.8%)	99.5% (98.7%, 99.8%)
	25%	96.4% (94.9%, 97.5%)	99.5% (98.2%, 99.9%)	99.6% (98.9%, 99.9%)	99.6% (97.3%, 100%)	98.2% (96.7%, 99.1%)	99.3% (98.2%, 99.7%)
Endocervical	1%	55.8% (44.5%, 66.7%)	99.9% (99.9%, 100%)	96.0% (80.8%, 99.3%)	100% (99.8%, 100%)	–	–
	2%	71.9% (61.8%, 80.2%)	99.9% (99.8%, 99.9%)	98.0% (89.5%, 99.6%)	99.9% (99.7%, 100%)	–	–
	5%	86.8% (80.7%, 91.2%)	99.7% (99.4%, 99.9%)	99.2% (95.6%, 99.9%)	99.8% (99.2%, 99.9%)	–	–
	10%	93.3% (89.8%, 95.7%)	99.4% (98.8%, 99.7%)	99.6% (97.9%, 99.9%)	99.5% (98.3%, 99.9%)	–	–
	15%	95.7% (93.3%, 97.2%)	99.0% (98.1%, 99.5%)	99.8% (98.7%, 100%)	99.2% (97.3%, 99.8%)	–	–
	20%	96.9% (95.2%, 98.0%)	98.6% (97.3%, 99.3%)	99.8% (99.0%, 100%)	98.9% (96.3%, 99.7%)	–	–
	25%	97.7% (96.4%, 98.5%)	98.2% (96.5%, 99.1%)	99.9% (99.3%, 100%)	98.5% (95.1%, 99.6%)	–	–
LBC PreservCyt®	1%	81.5% (65.2%, 91.1%)	99.9% (99.9%, 100%)	95.8% (80.1%, 99.2%)	99.9% (99.8%, 100%)	–	–
	2%	89.9% (79.1%, 95.4%)	99.9% (99.7%, 99.9%)	97.9% (89.0%, 99.6%)	99.9% (99.6%, 99.9%)	–	–
	5%	95.8% (90.7%, 98.2%)	99.6% (99.3%, 99.8%)	99.2% (95.4%, 99.9%)	99.6% (99.0%, 99.9%)	–	–
	10%	98.0% (95.4%, 99.1%)	99.2% (98.5%, 99.6%)	99.6% (97.8%, 99.9%)	99.2% (97.9%, 99.7%)	–	–
	15%	98.7% (97.0%, 99.4%)	98.7% (97.7%, 99.3%)	99.7% (98.6%, 100%)	98.8% (96.8%, 99.6%)	–	–
	20%	99.1% (97.9%, 99.6%)	98.2% (96.8%, 99.0%)	99.8% (99.0%, 100%)	98.2% (95.5%, 99.4%)	–	–
	25%	99.3% (98.4%, 99.7%)	97.6% (95.8%, 98.7%)	99.9% (99.3%, 100%)	97.7% (94.0%, 99.2%)	–	–

Specimen Type	Hypothetical Prevalence	*Chlamydia trachomatis*		*Neisseria gonorrhoeae*		*Trichomonas vaginalis*	
		% PPV 95% CI	% NPV 95% CI	% PPV 95% CI	% NPV 95% CI	% PPV 95% CI	% NPV 95% CI
Urine[b]	1%	61.6% (42.5%, 77.8%)	100% (99.9%, 100%)	91.1% (64.4%, 98.3%)	100% (100%, 100%)	78.3% (55.1%, 91.4%)	100% (99.9%, 100%)
	2%	76.5% (59.9%, 87.6%)	99.9% (99.8%, 100%)	95.4% (78.5%, 99.2%)	100% (99.9%, 100%)	87.9% (71.3%, 95.5%)	100% (99.8%, 100%)
	5%	89.3% (79.4%, 94.8%)	99.8% (99.6%, 99.9%)	98.2% (90.4%, 99.7%)	100% (99.8%, 100%)	94.9% (86.5%, 98.2%)	99.9% (99.4%, 100%)
	10%	94.6% (89.1%, 97.5%)	99.6% (99.2%, 99.8%)	99.1% (95.2%, 99.8%)	99.9% (99.5%, 100%)	97.5% (93.1%, 99.1%)	99.8% (98.8%, 100%)
	15%	96.6% (92.8%, 98.4%)	99.4% (98.7%, 99.8%)	99.4% (96.9%, 99.9%)	99.9% (99.2%, 100%)	98.4% (95.5%, 99.5%)	99.6% (98.1%, 99.9%)
	20%	97.5% (94.8%, 98.9%)	99.2% (98.2%, 99.6%)	99.6% (97.8%, 99.9%)	99.8% (98.9%, 100%)	98.9% (96.8%, 99.6%)	99.5% (97.3%, 99.9%)
	25%	98.1% (96.1%, 99.1%)	98.9% (97.6%, 99.5%)	99.7% (98.4%, 99.9%)	99.7% (98.5%, 100%)	99.2% (97.6%, 99.7%)	99.3% (96.5%, 99.9%)

[a] The sensitivity and specificity estimates for the patient- and clinician-collected vaginal swabs are similar; the PPV and NPV for vaginal swabs was calculated based on the averages of those estimates.

[b] The performance of the urine specimen only includes male urine for all three targets (CT GC TV).

PERFORMANCE CHARACTERISTICS

Twelve geographically diverse clinical sites in North America participated in the clinical trial to evaluate the BD CTGCTV2 assay. Eleven sites enrolled female subjects, five enrolled female and male subjects, and one site enrolled male subjects only. Two thousand five hundred and forty-seven (2,547) female subjects and 1,159 male subjects representing ages 18 and over were enrolled from sexually transmitted disease (STD), OB/GYN, and family planning clinics. Pregnant women were not excluded from the clinical study. Subjects were classified as symptomatic if they reported symptoms such as dysuria, urethral discharge, itching, odor, coital pain/difficulty/bleeding, testicular or scrotum pain/swelling, abnormal vaginal discharge, or pelvic/ uterine/adnexal pain. Subjects were classified as asymptomatic if they did not report these symptoms.

Eight specimens were collected from each eligible female subject: one first-catch urine, two randomized patient-collected vaginal swab specimens, two randomized clinician-collected vaginal swab specimens, two randomized endocervical swab specimens and one PreservCyt® LBC specimen (collected using either the cervical broom or brush/spatula). One urine specimen was collected from each of the eligible male subjects. Samples were prepared for BD CTGCTV2 assay testing in accordance with the appropriate BD Molecular specimen collection kit package insert instructions. Specimens intended for reference testing were prepared in accordance with the instructions for use in the appropriate specimen collection kit package insert.

There were 11 female subjects and 10 male subjects that were excluded from the data analysis due to enrollment issues such as, patient withdrew from study, duplicate enrollment and inclusion criteria not met. Specimens from all compliant subjects (2,536 female subjects and 1,149 male subjects) were tested using the BD CTGCTV2 assay across five clinical trial testing sites. Samples with initial non-reportable (Unresolved, Indeterminate or Incomplete) results were repeated from the BD Molecular Sample Buffer Tube. Following a valid repeat test, 0.3% (38/13,649) specimens remained non-reportable and were excluded from the sensitivity and specificity statistical analysis (refer to BD CTGCTV2 assay Non-Reportable Results section). The estimates of performance of the BD CTGCTV2 assay for *Chlamydia trachomatis*, based on evaluable results, included: 2,508 patient-collected vaginal swabs, 2,502 clinician-collected vaginal swabs, 2,512 endocervical swabs, 2,469 PreservCyt® LBC, 2,416 female urine and 1,140 male urine specimens. The estimates of performance of the BD CTGCTV2 assay for *Neisseria gonorrhoeae*, based on evaluable results included: 2,506 patient-collected vaginal swabs, 2,503 clinician-collected vaginal swabs, 2,511 endocervical swabs, 2,470 PreservCyt® LBC, 2,419 female urine and 1,142 male urine specimens. The estimates of performance of the BD CTGCTV2 assay for *Trichomonas vaginalis*, based on evaluable results included: 1,742 patient-collected vaginal swabs, 1,732 clinician-collected vaginal swabs, 1,646 female urine and 1,141 male urine specimens. Exclusions included but were not limited to: missing specimens and/or reference test results, transport, collection, shipping, and/or processing errors.

Clinical Performance of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

The clinical performance of the BD CTGCTV2 assay for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections in females and males was calculated compared to a Patient Infected Status (PIS). The female PIS was established by testing urine and cervical specimens with two different FDA cleared NAATs (Nucleic Acid Amplification Test) where female subjects were designated as infected if at least two different reference NAATs were positive for urine and cervical specimens. For the purpose of data analysis, females who tested positive with the two comparator NAATs in urine only (negative in swabs with both NAATs), were considered non-infected (Negative PIS) when calculating the performance of the assay for swab specimens. The male PIS was established by testing urine specimens using up to three different FDA cleared NAATs where male subjects were designated as infected if at least 2 out of 3 reference NAAT results were positive. Subjects were categorized as non-infected if at least 2 out of 3 reference NAAT results were negative. The clinical performance of the BD CTGCTV2 assay for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections in female urine was calculated compared to a Composite Comparator Algorithm (CCA) as described in the Clinical Performance of Female Urine section.

The clinical sensitivity of the BD CTGCTV2 assay for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections in female vaginal swabs (patient- and clinician-collected vaginal swabs) and cervical specimens (endocervical swab and PreservCyt® LBC) is shown in Table 9. The clinical sensitivity of the assay for male urine is also included.

Table 9: *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Performance Compared to PIS

Gender	Specimen Type	Symptom Status	*Chlamydia trachomatis*		*Neisseria gonorrhoeae*	
			% Sens	% Spec	% Sens	% Spec
Female	Vaginal Clinician	A	98.2 55/56 90.6–99.7	98.8 1,076/1,089 98.0–99.3	100 15/15 79.6–100	99.8 1,129/1,131 99.4–100
		S	98.6 71/72 92.5–99.8	99.0 1,272/1,285 98.3–99.4	96.4 27/28 82.3–99.4	99.9 1,328/1,329 99.6–100
		All	98.4 126/128 94.5–99.6	98.9 2,348/2,374 98.4–99.3	97.7 42/43 87.9–99.6	99.9 2,457/2,460 99.6–100
	Vaginal Patient	A	98.2 55/56 90.6–99.7	98.9 1,077/1,089 98.1–99.4	100 15/15 79.6–100	99.6 1,126/1,130 99.1–99.9
		S	98.6 71/72 92.5–99.8	98.5 1,271/1,291 97.6–99.0	100 28/28 87.9–100	100 1,333/1,333 99.7–100
		All	98.4 126/128 94.5–99.6	98.7 2,348/2,380 98.1–99.0	100 43/43 91.8–100	99.8 2,459/2,463 99.6–99.9
	Endocervical	A	96.4 54/56 87.9–99.0	99.4 1,084/1,090 98.8–99.7	100 15/15 79.6–100	99.9 1,131/1,132 99.5–100
		S	93.1 67/72 84.8–97.0	99.1 1,282/1,294 98.4–99.5	92.9 26/28 77.4–98.0	100 1,336/1,336 99.7–100
		All	94.5 121/128 89.1–97.3	99.2 2,366/2,384 98.8–99.5	95.3 41/43 84.5–98.7	100 2,467/2,468 99.8–100
	LBC PreservCyt®	A	92.6 50/54 82.4–97.1	99.7 1,076/1,079 99.2–99.9	100 15/15 79.6–100	99.9 1,118/1,119 99.5–100
		S	92.9 65/70 84.3–96.9	99.8 1,264/1,266 99.4–100	88.9 24/27 71.9–96.1	100 1,309/1,309 99.7–100
		All	92.7 115/124 86.8–96.1	99.8 2,340/2,345 99.5–99.9	92.9 39/42 81.0–97.5	100 2,427/2,428 99.8–100
Male	Urine	A	97.3 71/73 90.5–99.2	99.6 667/670 98.7–99.8	100 12/12 75.8–100	100 732/732 99.5–100
		S	96.3 77/80 89.5–98.7	99.1 314/317 97.3–99.7	99.1 110/111 95.1–99.8	99.7 286/287 98.1–99.9
		All	96.7 148/153 92.6–98.6	99.4 981/987 98.7–99.7	99.2 122/123 95.5–99.9	99.9 1,018/1,019 99.4–100

Clinical Performance of *Trichomonas vaginalis*

Based on available data generated in the study, the clinical performance of the BD CTGCTV2 assay for female vaginal swabs (patient- and clinician-collected vaginal swabs) and cervical specimens (endocervical swab and PreservCyt®LBC) was also assessed against a PIS algorithm composed of vaginal swab and urine specimens. Comparative reference methods included two different FDA cleared molecular tests where female subjects were designated as infected if at least two different reference NAATs were positive for urine and vaginal specimens. Females who tested positive with the two comparator NAATs in urine only (negative in swabs with both NAATs), were considered non-infected (Negative PIS) when calculating the performance of the assay for swab specimens.

The resulting clinical performance of the BD CTGCTV2 assay with the vaginal/urine reference algorithm for the detection of *Chlamydia trachomatis* infection in females included: 95.0% (132/139) sensitivity and 99.2% (2,340/2,359) specificity for clinician-collected vaginal swabs, 97.9% (137/140) sensitivity and 99.2% (2,348/2,368) specificity for patient-collected vaginal swabs, 89.2% (124/139) sensitivity and 99.4% (2,354/2,368) specificity for endocervical swabs, and 85.8% (115/134) sensitivity and 99.8% (2,326/2,330) specificity for PreservCyt® LBC specimens.

The resulting clinical performance of the BD CTGCTV2 assay with the vaginal/urine reference algorithm for the detection of *Neisseria gonorrhoeae* infection in females included: 100% (44/44) sensitivity and 100% (2,454/2,455) specificity for clinician-collected vaginal swabs, 97.8% (44/45) sensitivity and 99.9% (2,458/2,461) specificity for patient-collected vaginal swabs, 93.3% (42/45) sensitivity and 100% (2,461/2,461) specificity for endocervical swabs, and 90.9% (40/44) sensitivity and 100% (2,421/2,421) specificity for PreservCyt® LBC specimens.

The clinical performance of the BD CTGCTV2 assay for the detection of *Trichomonas vaginalis* infection in females and males was calculated compared to a PIS. The female PIS was established by testing vaginal specimens with two different FDA cleared molecular tests, across three different instrument platforms, where female subjects were designated as infected if at least 2 out of 3 reference test results were positive. Subjects were categorized as non-infected if at least 2 out of 3 reference test results were negative. The male PIS was established by testing urine specimens using up to three different FDA cleared NAATs where male subjects were designated as infected if at least 2 out of 3 reference test results were positive. Subjects were categorized as non-infected if at least 2 out of 3 reference test results were negative. The clinical performance of the BD CTGCTV2 assay for the detection of *Trichomonas vaginalis* infection in female urine was calculated compared to a Composite Comparator Algorithm (CCA) as described in the Clinical Performance of Female Urine section.

The clinical sensitivity of the BD CTGCTV2 assay for the detection of *Trichomonas vaginalis* infection in female vaginal swabs (patient- and clinician-collected vaginal swabs) and male urine is shown in Table 10.

Table 10: *Trichomonas vaginalis* Performance Compared to the PIS

Gender	Specimen Type	Symptom Status	*Trichomonas vaginalis*	
			% Sens	% Spec
Female	Vaginal Clinician	A	98.5 66/67 92.0–99.7	99.6 687/690 98.7–99.9
		S	97.5 116/119 92.8–99.1	99.6 853/856 99.0–99.9
		All	97.8 182/186 94.6–99.2	99.6 1,540/1,546 99.2–99.8
	Vaginal Patient	A	97.0 65/67 89.8–99.2	99.1 685/691 98.1–99.6
		S	98.4 120/122 94.2–99.5	99.2 855/862 98.3–99.6
		All	97.9 185/189 94.7–99.2	99.2 1,540/1,553 98.6–99.5
Male	Urine	A	96.2 25/26 81.1–99.3	99.6 678/681 98.7–99.9
		S	100 22/22 85.1–100	100 412/412 99.1–100
		All	97.9 47/48 89.1–99.6	99.7 1,090/1,093 99.2–99.9

Clinical Performance of Female Urine

The clinical performance of the BD CTGCTV2 assay for the detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* infection in female urine was calculated compared to a Composite Comparator Algorithm (CCA) utilizing urine samples from up to three reference NAATs to generate reference results for each analyte. Female subjects were designated as positive if at least 2 out of 3 reference NAAT results were positive. Subjects were categorized as negative if at least 2 out of 3 reference NAAT results were negative. The resulting performance expressed as positive percent agreement (PPA) and negative percent agreement (NPA) is shown in Table 11.

Additionally, the results obtained when using urine specimens in females were evaluated against the PIS based on cervical and urine algorithm. In the clinical study conducted for the BD CTGCTV2 assay, female urine detected 5.8% fewer *Chlamydia trachomatis* infections than clinician- and patient-collected vaginal swabs and 1.9% fewer *Chlamydia trachomatis* infections than endocervical swabs. Female urine detected 2.4% fewer *Neisseria gonorrhoeae* infections than clinician-collected vaginal swabs and 4.7% fewer *Neisseria gonorrhoeae* infections than patient-collected vaginal swabs. There was no difference in the detection of *Neisseria gonorrhoeae* infections when comparing female urine and endocervical swabs.

Table 11: Clinical Performance of BD CTGCTV2 Assay in Female Urine, Compared to the CCA

Specimen Type	Symptom Status	*Chlamydia trachomatis*		*Neisseria gonorrhoeae*		*Trichomonas vaginalis*	
		PPA	NPA	PPA	NPA	PPA	NPA
Female Urine	A	98.1 51/52 89.9–99.7	99.2 1,037/1,045 98.5–99.6	100 14/14 78.5–100	99.9 1,085/1,086 99.5–100	100 58/58 93.8–100	99.8 646/647 99.1–100
	S	98.6 70/71 92.4–99.8	99.4 1,241/1,248 98.8–99.7	100 25/25 86.7–100	100 1,294/1,294 99.7–100	100 115/115 96.8–100	99.4 821/826 98.6–99.7
	All	98.4 121/123 94.3–99.6	99.3 2,278/2,293 98.9–99.6	100 39/39 91.0–100	100 2,379/2,380 99.8–100	100 173/173 97.8–100	99.6 1,467/1,473 99.1–99.8

Tables 12 and 14 summarize the number of results from symptomatic and asymptomatic female subjects designated as infected or non-infected with *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, respectively, according to the PIS algorithm. Tables 13 and 15 summarize the number of results from symptomatic and asymptomatic male subjects designated as infected or non-infected with *Chlamydia trachomatis* or *Neisseria gonorrhoeae*, respectively, according to the PIS algorithm.

Table 12: Results Summary for *Chlamydia trachomatis* - Female Subjects Compared to PIS or CCA

PIS	CCA[a]	NAAT 1		NAAT 2		NAAT 3	BD MAX™					Symptomatic Status		
VC/VP/EN/LBC	U	LBC	U	EN	U	U	VC	VP	EN	LBC	U	No	Yes	Total
I	+	+	+	+	+	+	+	+	+	+	+	30	53	83
I	+	+	+	+	+	+	+	+	+	+	NA	1	1	2
I	+	+	+	+	+	+	+	+	+	–	+	1	0	1
I	+	+	+	+	+	+	+	+	+	NA	+	1	0	1
I	+	+	+	+	+	+	+	+	+	NR	+	1	0	1
I	+	+	+	+	+	–	+	+	+	+	–	0	1	1
I	+	+	+	+	+	–	+	+	–	+	+	1	0	1
I	+	+	+	+	+	NA	+	+	+	+	+	1	2	3
I	+	+	+	+	NA	+	+	+	+	+	+	0	1	1
I	+	+	+	–	+	+	+	+	+	+	+	2	1	3
I	+	+	+	–	+	+	+	+	–	+	+	0	1	1
I	+	+	+	–	+	+	+	+	–	–	+	0	1	1
I	+	+	+	–	+	+	+	–	–	–	+	0	1	1
I	+	+	+	–	+	+	–	+	–	–	+	0	1	1
I	+	+	+	NA	+	+	+	+	+	+	+	1	0	1
I	+	+	–	+	+	+	+	+	+	+	+	2	0	2
I	+	+	NA	+	+	+	+	+	+	+	+	1	2	3
I	+	–	+	+	+	+	+	+	+	–	+	2	0	2
I	+	–	+	+	+	+	+	+	–	–	+	1	0	1
I	+	NA	+	+	+	+	+	+	+	+	+	1	0	1
I	+	NA	+	+	+	+	+	+	+	NA	+	0	2	2
I	–	+	+	+	–	–	+	+	+	+	–	1	0	1
I	–	+	–	+	+	–	+	+	+	+	+	2	0	2
I	–	+	–	+	–	+	+	+	+	+	+	1	1	2
I	–	+	–	+	–	–	+	+	+	+	+	0	1	1
I	–	+	–	+	–	–	–	–	+	+	–	1	0	1
I	–	+	–	+	–	NA	+	+	+	+	–	4	0	4
I	–	+	–	+	–	NA	+	+	–	–	–	0	1	1

PIS	CCA[a]	NAAT 1		NAAT 2		NAAT 3	BD MAX™					Symptomatic Status		
VC/VP/EN/LBC	U	LBC	U	EN	U	U	VC	VP	EN	LBC	U	No	Yes	Total
I	–	–	+	+	–	–	+	+	+	–	–	0	1	1
I	NA	+	NA	+	–	+	+	+	+	+	+	1	0	1
I	NA	+	NA	+	NA	NA	+	+	+	+	+	0	1	1
NI	+	+	+	–	–	+	+	+	+	+	+	1	0	1
NI	+	–	+	–	+	+	+	+	–	–	+	1	1	2
NI	+	–	+	–	+	+	–	+	+	–	+	0	1	1
NI	+	–	+	–	+	+	–	+	–	–	+	1	0	1
NI	+	–	+	–	+	+	–	+	–	NA	+	0	1	1
NI	+	–	+	–	+	+	–	–	–	–	+	0	1	1
NI	+	–	+	–	+	–	+	+	+	–	–	1	0	1
NI	+	–	+	–	+	–	–	NR	–	–	+	1	0	1
NI	+	–	+	–	–	+	–	+	–	–	+	1	0	1
NI	+	–	–	–	+	+	–	–	–	–	+	1	0	1
NI	–	+	+	–	–	–	–	+	–	+	+	1	0	1
NI	–	+	–	–	–	–	+	+	+	–	–	0	1	1
NI	–	+	–	–	–	–	–	–	+	+	–	0	1	1
NI	–	+	–	–	–	–	–	–	–	–	–	1	0	1
NI	–	–	–	+	+	–	+	–	–	–	–	1	0	1
NI	–	–	–	+	–	–	+	–	+	–	–	2	0	2
NI	–	–	–	+	–	–	–	+	–	–	+	0	1	1
NI	–	–	–	+	–	–	–	–	+	–	–	0	2	2
NI	–	–	–	+	–	–	–	–	–	–	–	1	2	3
NI	–	–	–	+	–	NA	+	+	+	–	–	0	1	1
NI	–	–	–	+	–	NA	–	–	–	–	–	0	1	1
NI	–	–	–	–	+	–	–	+	–	–	NA	1	0	1
NI	–	–	–	–	+	–	–	–	–	–	–	3	1	4
NI	–	–	–	–	–	–	+	+	+	+	+	1	0	1
NI	–	–	–	–	–	–	+	+	+	–	–	0	1	1
NI	–	–	–	–	–	–	+	+	–	–	–	0	1	1
NI	–	–	–	–	–	–	+	–	–	–	–	4	6	10
NI	–	–	–	–	–	–	–	+	+	–	–	0	1	1
NI	–	–	–	–	–	–	–	+	–	–	+	0	1	1
NI	–	–	–	–	–	–	–	+	–	–	–	0	5	5
NI	–	–	–	–	–	–	–	–	+	–	–	0	2	2
NI	–	–	–	–	–	–	–	–	–	+	–	0	1	1
NI	–	–	–	–	–	–	–	–	–	–	+	1	3	4
NI	–	–	–	–	–	–	–	–	–	–	–	562	621	1,183
NI	–	–	–	–	–	–	–	–	–	–	NA	5	3	8
NI	–	–	–	–	–	–	–	–	–	–	NR	0	2	2
NI	–	–	–	–	–	–	–	–	–	NA	–	1	11	12
NI	–	–	–	–	–	–	–	–	NA	–	–	4	0	4
NI	–	–	–	–	–	–	–	–	NR	–	–	1	1	2
NI	–	–	–	–	–	–	–	NA	–	–	–	1	0	1
NI	–	–	–	–	–	–	–	NA	–	–	NA	0	2	2
NI	–	–	–	–	–	–	–	NR	–	–	–	4	2	6
NI	–	–	–	–	–	–	NA	–	–	–	–	3	2	5
NI	–	–	–	–	–	–	NA	NA	NA	NA	NA	1	2	3
NI	–	–	–	–	–	–	NR	–	–	–	–	3	2	5
NI	–	–	–	–	–	–	NR	–	–	–	NR	1	0	1
NI	–	–	–	–	–	NA	+	–	–	–	–	1	0	1
NI	–	–	–	–	–	NA	–	+	+	–	–	0	1	1
NI	–	–	–	–	–	NA	–	+	–	–	–	2	1	3
NI	–	–	–	–	–	NA	–	–	–	–	–	332	475	807
NI	–	–	–	–	–	NA	–	–	–	–	NA	9	17	26
NI	–	–	–	–	–	NA	–	–	–	–	NR	2	1	3
NI	–	–	–	–	–	NA	–	–	–	NA	–	8	9	17
NI	–	–	–	–	–	NA	–	–	–	NA	NA	1	1	2

PIS	CCA[a]	NAAT 1		NAAT 2		NAAT 3	BD MAX™					Symptomatic Status		
VC/VP/EN/LBC	U	LBC	U	EN	U	U	VC	VP	EN	LBC	U	No	Yes	Total
NI	–	–	–	–	–	NA	–	–	NA	–	NA	1	0	1
NI	–	–	–	–	–	NA	–	–	NR	–	–	1	2	3
NI	–	–	–	–	–	NA	–	–	NR	–	NR	0	1	1
NI	–	–	–	–	–	NA	–	NA	–	–	–	0	1	1
NI	–	–	–	–	–	NA	–	NA	–	NA	–	0	1	1
NI	–	–	–	–	–	NA	–	NR	–	–	–	3	1	4
NI	–	–	–	–	–	NA	NA	–	–	–	–	0	5	5
NI	–	–	–	–	–	NA	NR	–	–	–	–	0	6	6
NI	–	–	–	–	NA	–	+	+	–	–	–	1	0	1
NI	–	–	–	–	NA	–	–	+	+	–	+	1	0	1
NI	–	–	–	–	NA	–	–	–	–	–	–	56	15	71
NI	–	–	–	–	NA	–	NR	–	–	–	–	1	0	1
NI	–	–	–	NA	–	–	+	+	+	–	–	0	1	1
NI	–	–	–	NA	–	–	–	–	–	–	–	8	8	16
NI	–	–	–	NA	–	–	–	NA	–	–	–	0	1	1
NI	–	–	–	NA	–	–	NA	–	–	–	NA	1	0	1
NI	–	–	–	NA	–	NA	–	–	–	–	–	0	1	1
NI	–	–	–	NA	–	NA	–	–	–	–	NA	0	1	1
NI	–	–	–	NA	–	NA	–	–	NA	–	–	1	1	2
NI	–	–	NA	–	–	–	+	+	–	–	–	0	1	1
NI	–	–	NA	–	–	–	–	–	–	–	+	1	0	1
NI	–	–	NA	–	–	–	–	–	–	–	–	18	33	51
NI	–	NA	–	–	–	–	–	–	–	NA	–	4	9	13
NI	–	NA	–	–	–	NA	–	–	–	NA	–	2	1	3
NI	–	NA	NA	–	–	–	–	–	–	–	–	0	1	1
NI	NA	–	+	–	–	NA	–	–	–	–	–	0	1	1
NI	NA	–	–	–	+	NA	–	–	–	–	+	1	0	1
NI	NA	–	–	–	NA	NA	–	–	–	–	–	19	4	23
NI	NA	–	–	–	NA	NA	–	–	–	–	NA	3	4	7
NI	NA	–	–	–	NA	NA	–	–	–	NR	–	1	1	2
NI	NA	–	NA	–	–	NA	–	–	–	–	–	8	8	16
NI	NA	–	NA	–	–	NA	–	–	–	–	NR	1	0	1
NI	NA	–	NA	–	–	NA	–	–	–	NA	–	1	0	1
NI	NA	–	NA	–	–	NA	–	–	NA	–	–	0	1	1
NI	NA	–	NA	–	–	NA	–	NA	–	–	–	0	1	1
NI	NA	–	NA	–	NA	NA	–	+	–	–	–	0	1	1
NI	NA	–	NA	–	NA	NA	–	–	–	–	–	0	2	2
NI	NA	–	NA	–	NA	NA	–	–	–	–	NA	1	1	2
NI	NA	NA	NA	–	–	NA	–	–	–	NA	–	1	0	1
UNK	+	NA	+	NA	+	+	NA	+	NA	NA	+	0	1	1
UNK	–	NA	–	–	NA	–	NA	NA	NA	NA	NA	1	0	1
UNK	–	NA	–	NA	–	NA	–	–	NA	NA	–	1	0	1
UNK	–	NA	–	NA	–	NA	NA	–	NA	NA	–	1	0	1
UNK	–	NA	–	NA	–	NA	NA	–	NA	NA	NA	0	1	1
UNK	NA	NA	NA	+	+	–	+	+	+	+	+	1	0	1
UNK	NA	NA	NA	NA	–	NA	NA	–	NA	NA	–	0	1	1
Total												**1,159**	**1,377**	**2,536**

[a] The comparator result used for the evaluation of clinical performance of the BD CTGCTV2 assay with female urine is designated as positive or negative based on the CCA.

VC=Vaginal Clinician; VP=Vaginal Patient; EN=Endocervical; U=Urine;
'+'=Positive; '–'=Negative; NA=Not Available; NR=Not Reportable;
NI=Non-Infected; I=Infected; UNK=Unknown

Table 13: Results Summary for *Chlamydia trachomatis* - Male Subjects Compared to the PIS

Male CT PIS	NAAT 1	NAAT 2	NAAT 3	BD MAX™	Symptomatic Status		
Urine	Urine	Urine	Urine	Urine	No	Yes	Total
I	+	+	+	+	63	74	137
I	+	+	+	-	1	1	2
I	+	+	+	NA	1	0	1
I	+	+	–	+	1	0	1
I	+	+	–	–	0	1	1
I	+	+	NA	+	2	0	2
I	+	NA	+	+	4	3	7
I	–	+	+	+	1	0	1
I	–	+	+	–	1	1	2
NI	+	–	–	+	2	1	3
NI	+	–	–	–	1	1	2
NI	–	+	–	+	0	1	1
NI	–	+	–	–	1	0	1
NI	–	–	–	+	1	1	2
NI	–	–	–	–	574	291	865
NI	–	–	–	NA	1	2	3
NI	–	–	–	NR	0	1	1
NI	–	–	NA	–	60	9	69
NI	–	NA	–	–	29	13	42
NI	–	NA	–	NA	1	0	1
NI	NA	–	–	–	2	0	2
UNK	–	+	NA	–	1	0	1
UNK	NA	NA	+	+	0	1	1
UNK	NA	NA	NA	NA	1	0	1
Total					**748**	**401**	**1,149**

'+'=Positive; '-'=Negative; NA=Not Available; NR=Not Reportable;
NI=Non-Infected; I=Infected; UNK=Unknown

Table 14: Results Summary for *Neisseria gonorrhoeae* - Female Subjects Compared to PIS or CCA

PIS	CCA[a]	NAAT 1		NAAT 2		NAAT 3	BD MAX™					Symptomatic Status		
VC/VP/EN/LBC	U	LBC	U	EN	U	U	VC	VP	EN	LBC	U	No	Yes	Total
I	+	+	+	+	+	+	+	+	+	+	+	12	20	32
I	+	+	+	+	+	+	+	+	+	–	+	0	1	1
I	+	+	+	+	+	+	+	+	+	NA	+	0	1	1
I	+	+	+	+	+	+	+	+	–	–	+	0	1	1
I	+	+	+	NA	+	+	+	+	+	+	+	1	0	1
I	+	+	–	+	+	+	+	+	+	+	+	0	2	2
I	+	+	NA	+	+	+	+	+	+	+	+	1	0	1
I	–	+	+	+	–	–	+	+	+	+	–	0	1	1
I	–	+	–	+	–	NA	–	+	–	–	–	0	1	1
I	–	+	–	–	+	–	+	+	+	+	+	1	0	1
I	NA	+	–	+	+	NA	+	+	+	+	+	0	1	1
NI	–	+	–	–	–	–	–	–	–	–	–	1	0	1
NI	–	–	–	+	+	–	–	–	–	–	–	0	1	1
NI	–	–	–	+	–	–	–	–	–	–	–	2	2	4
NI	–	–	–	+	–	–	NR	+	+	+	–	1	0	1
NI	–	–	–	+	–	NA	–	–	–	–	–	0	1	1
NI	–	–	–	–	+	–	–	–	–	–	–	3	0	3
NI	–	–	–	–	+	–	–	–	NA	–	–	1	0	1
NI	–	–	–	–	–	–	+	+	–	–	–	1	0	1
NI	–	–	–	–	–	–	–	–	–	–	–	608	684	1,292
NI	–	–	–	–	–	–	–	–	–	–	NA	7	4	11
NI	–	–	–	–	–	–	–	–	–	–	NR	0	2	2

PIS	CCA[a]	NAAT 1		NAAT 2		NAAT 3	BD MAX™					Symptomatic Status		
VC/VP/EN/LBC	U	LBC	U	EN	U	U	VC	VP	EN	LBC	U	No	Yes	Total
NI	–	–	–	–	–	–	–	–	–	NA	–	2	11	13
NI	–	–	–	–	–	–	–	–	–	NR	–	1	0	1
NI	–	–	–	–	–	–	–	–	NA	–	–	3	0	3
NI	–	–	–	–	–	–	–	–	NR	–	–	1	3	4
NI	–	–	–	–	–	–	–	NA	–	–	–	1	0	1
NI	–	–	–	–	–	–	–	NA	–	–	NA	0	2	2
NI	–	–	–	–	–	–	–	NR	–	–	–	6	4	10
NI	–	–	–	–	–	–	NA	–	–	–	–	3	2	5
NI	–	–	–	–	–	–	NA	NA	NA	NA	NA	1	2	3
NI	–	–	–	–	–	–	NR	–	–	–	–	2	2	4
NI	–	–	–	–	–	–	NR	–	–	–	NR	1	0	1
NI	–	–	–	–	–	NA	–	+	–	–	–	1	0	1
NI	–	–	–	–	–	NA	–	–	–	–	–	340	480	820
NI	–	–	–	–	–	NA	–	–	–	–	NA	9	17	26
NI	–	–	–	–	–	NA	–	–	–	–	NR	2	0	2
NI	–	–	–	–	–	NA	–	–	–	NA	–	8	9	17
NI	–	–	–	–	–	NA	–	–	–	NA	NA	1	1	2
NI	–	–	–	–	–	NA	–	–	NA	–	NA	1	0	1
NI	–	–	–	–	–	NA	–	–	NR	–	–	1	2	3
NI	–	–	–	–	–	NA	–	–	NR	–	NR	0	1	1
NI	–	–	–	–	–	NA	–	NA	–	–	–	0	1	1
NI	–	–	–	–	–	NA	–	NA	–	NA	–	0	1	1
NI	–	–	–	–	–	NA	–	NR	–	–	–	3	1	4
NI	–	–	–	–	–	NA	NA	–	–	–	–	0	5	5
NI	–	–	–	–	–	NA	NR	–	–	–	–	0	6	6
NI	–	–	–	–	NA	–	–	–	–	–	–	58	15	73
NI	–	–	–	–	NA	–	NR	–	–	–	–	1	0	1
NI	–	–	–	NA	–	–	–	–	–	–	–	8	9	17
NI	–	–	–	NA	–	–	–	NA	–	–	–	0	1	1
NI	–	–	–	NA	–	–	NA	–	–	–	NA	1	0	1
NI	–	–	–	NA	–	NA	–	–	–	–	–	0	1	1
NI	–	–	–	NA	–	NA	–	–	–	–	NA	0	1	1
NI	–	–	–	NA	–	NA	–	–	NA	–	–	1	1	2
NI	–	–	NA	–	–	–	+	+	–	–	–	1	0	1
NI	–	–	NA	–	–	–	–	–	–	–	–	19	36	55
NI	–	NA	–	–	–	–	–	–	–	NA	–	4	11	15
NI	–	NA	–	–	–	NA	–	–	–	NA	–	2	1	3
NI	–	NA	NA	–	–	–	–	–	–	–	–	0	1	1
NI	NA	–	–	–	NA	NA	–	–	–	–	–	19	4	23
NI	NA	–	–	–	NA	NA	–	–	–	–	NA	3	4	7
NI	NA	–	–	–	NA	NA	–	–	–	NR	–	1	1	2
NI	NA	–	NA	–	–	NA	–	–	–	–	–	8	8	16
NI	NA	–	NA	–	–	NA	–	–	–	–	NR	1	0	1
NI	NA	–	NA	–	–	NA	–	–	–	NA	–	1	0	1
NI	NA	–	NA	–	–	NA	–	–	NA	–	–	0	1	1
NI	NA	–	NA	–	–	NA	–	NA	–	–	–	0	1	1
NI	NA	–	NA	–	NA	NA	–	–	–	–	–	0	4	4
NI	NA	–	NA	–	NA	NA	–	–	–	–	NA	1	1	2
NI	NA	NA	+	–	–	NA	+	–	–	–	NR	0	1	1
NI	NA	NA	NA	–	–	NA	–	–	–	NA	–	1	0	1
UNK	–	NA	–	–	NA	–	NA	NA	NA	NA	NA	1	0	1
UNK	–	NA	–	NA	–	–	NA	–	NA	NA	–	0	1	1
UNK	–	NA	–	NA	–	NA	–	–	NA	NA	–	1	0	1
UNK	–	NA	–	NA	–	NA	NA	–	NA	NA	–	1	0	1

PIS	CCA[a]	NAAT 1		NAAT 2		NAAT 3	BD MAX™					Symptomatic Status		
VC/VP/EN/LBC	U	LBC	U	EN	U	U	VC	VP	EN	LBC	U	No	Yes	Total
UNK	–	NA	–	NA	–	NA	NA	–	NA	NA	NA	0	1	1
UNK	NA	NA	NA	NA	–	NA	NA	–	NA	NA	–	0	1	1
Total												**1,159**	**1,377**	**2,536**

[a] The comparator result used for the evaluation of clinical performance of the BD CTGCTV2 assay with female urine is designated as positive or negative based on the CCA.
VC=Vaginal Clinician; VP=Vaginal Patient; EN=Endocervical; U=Urine;
'+'=Positive; '–'=Negative; NA=Not Available; NR=Not Reportable;
NI=Non-Infected; I=Infected; UNK=Unknown

Table 15: Results Summary for *Neisseria gonorrhoeae* - Male Subjects Compared to the PIS

Male GC PIS	NAAT 1	NAAT 2	NAAT 3	BD MAX™	Symptomatic Status		
Urine	Urine	Urine	Urine	Urine	No	Yes	Total
I	+	+	+	+	11	107	118
I	+	+	+	–	0	1	1
I	+	+	+	NA	0	1	1
I	+	+	NA	+	0	1	1
I	+	NA	+	+	1	2	3
NI	–	+	–	–	2	1	3
NI	–	–	–	+	0	1	1
NI	–	–	–	–	633	262	895
NI	–	–	–	NA	2	1	3
NI	–	–	–	NR	0	1	1
NI	–	–	NA	–	63	8	71
NI	–	NA	–	–	32	15	47
NI	–	NA	–	NA	1	0	1
NI	NA	–	–	–	2	0	2
UNK	NA	NA	NA	NA	1	0	1
Total					**748**	**401**	**1,149**

'+'=Positive; '–'=Negative; NA=Not Available; NR=Not Reportable;
NI=Non-Infected; I=Infected; UNK=Unknown

BD CTGCTV2 Assay Non-Reportable Results

The initial total non-reportable rate representing all targets, specimens and types of non-reportable results (Unresolved/Indeterminate/Incomplete) combined was 2.4% (321/13,655; 95% CI: 2.1–2.6%). Following a valid repeat test, 0.3% (38/13,649; 95% CI: 0.2–0.4%) specimens remained non-reportable. Valid repeat results were not available for 6 samples that produced initial non-reportable results and therefore were not included in the final non-reportable rate calculation. Reasons include but are not limited to, missing or expired samples, or invalid repeat for one or more of the assay targets.

Of all the specimens initially evaluated with the BD CTGCTV2 assay, 1.1% of vaginal clinician-collected, 1.3% of patient-collected vaginal swab, 0.9% of endocervical swab, 0.2% of PreservCyt® LBC and 0.9% of urine specimens initially reported as Unresolved. Following a valid repeat test, 0.3% of clinician-collected vaginal swab, 0.4% of patient-collected vaginal swab, 0.1% of endocervical swab, 0.0% of PreservCyt® LBC and 0.1% of urine specimens remained Unresolved. The total numbers in Table 16 are based on evaluable specimens and BD CTGCTV2 assay results.

Table 16: Unresolved Rate for Combined Targets by Specimen Type

Specimen Type	Initial Unresolved Rate		Final Unresolved Rate[a]	
	Percent	95% CI	Percent	95% CI
Vaginal Clinician-Collected	1.1% (28/2,517)	(0.8%, 1.6%)	0.3% (7/2,517)	(0.1%, 0.6%)
Vaginal Patient-Collected	1.3% (34/2,525)	(1.0%, 1.9%)	0.4% (10/2,525)	(0.2%, 0.7%)
Endocervical	0.9% (22/2,519)	(0.6%, 1.3%)	0.1% (3/2,516)	(0.0%, 0.3%)
LBC PreservCyt®	0.2% (6/2,473)	(0.1%, 0.5%)	0.0% (0/2,471)	(0.0%, 0.2%)
Urine	0.9% (34/3,621)	(0.7%, 1.3%)	0.1% (3/3,620)	(0.0%, 0.2%)

[a]The final rate is calculated with valid repeats only.

Of all the specimens initially evaluated with the BD CTGCTV2 assay, 0.8% of clinician-collected vaginal swab, 0.9% of patient-collected vaginal swab, 0.8% of endocervical swab, 0.2% of PreservCyt® LBC and 0.2% of urine specimens initially reported as Indeterminate. Following a valid repeat test, 0.2% of clinician-collected vaginal swab, 0.1% of patient-collected vaginal swab, 0.1% of endocervical swab, 0.0% of PreservCyt® LBC and 0.1% of urine specimens remained Indeterminate. The total numbers in Table 17 are based on compliant specimens and BD CTGCTV2 assay results.

Table 17: Indeterminate Rate for Combined Targets by Specimen Type

Specimen Type	Initial Indeterminate Rate		Final Indeterminate Rate[a]	
	Percent	95% CI	Percent	95% CI
Vaginal Clinician-Collected	0.8% (20/2,517)	(0.5%, 1.2%)	0.2% (6/2,517)	(0.1%, 0.5%)
Vaginal Patient-Collected	0.9% (23/2,525)	(0.6%, 1.4%)	0.1% (3/2,525)	(0.0%, 0.3%)
Endocervical	0.8% (19/2,519)	(0.5%, 1.2%)	0.1% (2/2,516)	(0.0%, 0.3%)
LBC PreservCyt®	0.2% (6/2,473)	(0.1%, 0.5%)	0.0% (0/2,471)	(0.0%, 0.2%)
Urine	0.2% (9/3,621)	(0.1%, 0.5%)	0.1% (3/3,620)	(0.0%, 0.2%)

[a]The final rate is calculated with valid repeats only.

Of all the specimens initially evaluated with the BD CTGCTV2 assay, 0.7% of clinician-collected vaginal swab, 0.6% of patient-collected vaginal swab, 0.6% of endocervical swab, 1.2% of PreservCyt® LBC and 1.2% of urine specimens initially reported as Incomplete. Following a valid repeat test, 0.0% of all specimen types remained Incomplete. The total numbers in Table 18 are based on compliant specimens and BD CTGCTV2 assay results.

Table 18: Incomplete Rate for Combined Targets by Specimen Type

Specimen Type	Initial Incomplete Rate		Final Incomplete Rate[a]	
	Percent	95% CI	Percent	95% CI
Vaginal Clinician-Collected	0.7% (17/2,517)	(0.4%, 1.1%)	0.0% (0/2,517)	(0.0%, 0.2%)
Vaginal Patient-Collected	0.6% (14/2,525)	(0.3%, 0.9%)	0.0% (1/2,525)	(0.0%, 0.2%)
Endocervical	0.6% (14/2,519)	(0.3%, 0.9%)	0.0% (0/2,516)	(0.0%, 0.2%)
LBC PreservCyt®	1.2% (30/2,473)	(0.9%, 1.7%)	0.0% (0/2,471)	(0.0%, 0.2%)
Urine	1.2% (45/3,621)	(0.9%, 1.7%)	0.0% (0/3,620)	(0.0%, 0.1%)

[a]The final rate is calculated with valid repeats only.

Analytical Sensitivity

The analytical sensitivity/Limit of Detection (LoD) for the BD CTGCTV2 assay in urine, vaginal swab and PreservCyt® LBC specimen matrix was determined as follows: A microbial suspension was prepared from each of two (2) representative strains of the target organisms detected by the BD CTGCTV2 assay. Each target organism was quantified prior to testing. Positive specimens were prepared by inoculating pooled female urine, pooled vaginal swab and pooled PreservCyt® LBC matrix in sample buffer with multiple concentrations of each representative strain. Each matrix suspension was tested with at least 20 replicates per LoD concentration using at least 9 BD MAX™ Systems and 3 different lots of the BD CTGCTV2 assay. Analytical sensitivity (LoD), defined as the lowest concentration at which at least 95% of all replicates tested positive, ranged from 1.25 to 40 units/mL (Table 19).

Table 19: Limit of Detection by the BD CTGCTV2 Assay

Organism	Strain	Specimen	LoD Concentration (units/mL)[a]
Chlamydia trachomatis	Serovar H	Urine	2.5
		Swab	2.5
		PreservCyt®	5
	Serovar D	Urine	1.25
		Swab	5
		PreservCyt®	5
Neisseria gonorrhoeae	ATCC® 19424	Urine	30
		Swab	40
		PreservCyt®	30
	ATCC® 49226	Urine	20
		Swab	30
		PreservCyt®	40
Trichomonas vaginalis	ATCC® 30001	Urine	5
		Swab	7.5
	ATCC® 50143	Urine	2.5
		Swab	1.88

[a] Units/mL LoD concentration represented in Elementary Bodies (EB)/mL for *Chlamydia trachomatis*, CFU/mL for *Neisseria gonorrhoeae* and TV/mL for *Trichomonas vaginalis*.

Analytical Reactivity (Inclusivity)

The study evaluated the ability of the BD CTGCTV2 assay to detect clinically relevant and geographically diverse serovars and/or strains of *Chlamydia trachomatis, Neisseria gonorrhoeae* and *Trichomonas vaginalis* when tested in vaginal, urine and PreservCyt® LBC matrices. The study included thirteen (13) additional *Chlamydia trachomatis* serovars (A, B, C, E, F, G, I, J, K, LGV1, LGV2, LGV3, and vE), thirty (30) *Neisseria gonorrhoeae* strains and eight (8) *Trichomonas vaginalis* strains (ATCC® 30092, 30184, 30185, 30186, 30235, 30236, 30238, and 30240). These 50 serovars/strains, which represented public collections and well-characterized clinical isolates, were spiked into female urine, vaginal swab and PreservCyt® LBC pools prepared in sample buffer at concentrations targeting the predetermined LoD for each organism. Each serovar/strain was tested in 20 replicates with at least three different reagent lots. Of the 50 organisms tested, there were four (4) which did not confirm at 1X LoD upon initial testing and required titration to 1.5X LoD. The results for *Chlamydia trachomatis, Neisseria gonorrhoeae* and *Trichomonas vaginalis* are presented in Table 20 through Table 22 and show the concentrations which were detected in at least 19/20 replicates (≥95%).

Table 20: Inclusivity Results – *Chlamydia trachomatis*

Organism	Serovar	Swab		Urine		PreservCyt®	
		EBs/mL	% POS	EBs/mL	% POS	EBs/mL	% POS
Chlamydia trachomatis	A	5	100	2.5	100	5	100
	B	5	100	2.5	100	5	100
	C	5	≥95	2.5	100	5	100
	E	5	100	2.5	100	5	100
	F	5	100	2.5	100	5	100
	G	5	100	2.5	100	5	100
	I	5	100	2.5	100	5	100
	J	5	100	2.5	100	5	100
	K	5	100	2.5	100	5	100
	LGV1	5	100	2.5	100	5	100
	LGV2	5	100	2.5	100	5	100
	LGV3	5	100	2.5	100	5	100
	vE	5	100	2.5	100	5	100

Table 21: Inclusivity Results – *Neisseria gonorrhoeae*

Organism	Number Strains	Swab		Urine		PreservCyt®	
		CFU/mL	% POS	CFU/mL	% POS	CFU/mL	% POS
Neisseria gonorrhoeae	30	NA	NA	NA	NA	40	≥95
	27	30	≥95	NA	NA	NA	NA
	3	45	≥95	NA	NA	NA	NA
	29	NA	NA	30	≥95	NA	NA
	1	NA	NA	45	100	NA	NA

Table 22: Inclusivity Results – *Trichomonas vaginalis*

Organism	ATCC® Strain	Swab		Urine	
		TV/mL	% POS	TV/mL	% POS
Trichomonas vaginalis	30092	7.5	100	5	100
	30184	7.5	≥95	5	100
	30185	7.5	100	5	100
	30186	7.5	≥95	5	100
	30235	7.5	100	5	100
	30236	7.5	100	5	100
	30238	7.5	≥95	5	100
	30240	7.5	100	5	100

Analytical Specificity/Cross-Reactivity

The BD CTGCTV2 assay was performed on samples containing phylogenetically related microorganisms likely to be found in urogenital specimens. The bacterial cells, yeasts, viruses and parasites were tested in the Sample Buffer Tube at 2 x10^6 cells/mL, genomic DNA cp/mL, or EB/mL, and viruses were tested at 1x10^5 viral particles or genomic equivalents/mL. Organisms tested are represented in Table 23.

- 98% of bacterial strains, yeasts, parasites and viruses tested produced negative results with the BD CTGCTV2 assay.
- *Pentatrichomonas hominis* (commensal of the large intestine) produced positive results at a concentration ≥1.00 x 10^5 TV/mL for *Trichomonas vaginalis* and negative results for all other targets with the BD CTGCTV2 assay.
- *Trichomonas tenax* (commensal of the oral cavity) produced positive results at a concentration ≥1.88 TV/mL for *Trichomonas vaginalis* and negative results for all other targets with the BD CTGCTV2 assay.

Table 23: BD CTGCTV2 Assay Specificity Organisms (Bacteria, Yeasts, Parasites and Viruses)

Organism	Organism	Organism
Achromobacter xerosis	*Escherichia coli*	*Neisseria mucosa* (3)[a]
Acinetobacter calcoaceticus	*Escherichia vulneris*	*Neisseria perflava*
Acinetobacter lwoffi	*Fuseobacterium nucleatum*	*Neisseria polysaccharea*
Actinomyces israelii	*Gardnerella vaginalis*	*Neisseria sicca* (3)[a]
Actinomyces pyogenes	*Gemella haemolysans*	*Neisseria subflava* (14)[a]
Aerococcus viridans	*Haemophilus ducreyi*	*Paracoccus denitrificans*
Aeromonas hydrophilia	*Haemophilus influenzae*	*Pentatrichomonas hominis*
Agrobacterium radiobacter	Herpes Simplex Virus I	*Peptostreptococcus anaerobius*
Alcaligenes faecalis	Herpes Simplex Virus II	*Peptostreptococcus productus*
Atopobium vaginae	HIV 1	*Plesiomonas shigelloides*
Bacillus subtilis	HPV16	*Prevotella bivia*
Bacteroides fragilis	*Kingella dentrificans*	*Propionibacterium acnes*
Bacteroides ureoeolyticus	*Kingella kingae*	*Proteus mirabilis*
Bifidobacterium adolescentis	*Klebsiella oxytoca*	*Proteus vulgaris*
Bifidobacterium brevi	*Klebsiella pneumoniae*	*Providencia stuartii*
Blastocystis hominis	*Lactobacillus acidophilus*	*Pseudomonas aeruginosa*
Branhamella catarrhalis	*Lactobacillus brevis*	*Pseudomonas fluorescens*
Brevibacterium linens	*Lactobacillus jensenii*	*Pseudomonas putida*
Campylobacter jejuni	*Lactobacillus lactis*	*Rahnella aquatilis*
Candida albicans	*Lactobacillus vaginalis*	*Rhodospirilium rubrum*
Candida gabralta	*Legionella pneumophilia* (2)[a]	*Saccharomyces cerevisiae*
Candida parapsilosis	*Leuconostoc paramensenteroides*	*Salmonella minnesota*
Candida tropicalis	*Listeria monocytogenes*	*Salmonella* Typhimurium
Chlamydiophila pneumoniae	*Micrococcus leutus*	*Serratia marcescens*
Chlamydiophila psittaci (2)[a]	*Mobiluncus curtisii*	*Staphylococcus aureus*, non-protein A
Chromobacterium violaceum	*Moraxella lacunata*	*Staphylococcus aureus*, protein-A producing
Citrobacter freundii	*Moraxella osloensis*	*Staphylococcus epidermidis*
Clostridium difficile	*Morganella morganii*	*Staphylococcus saprophyticus*
Clostridium perfringens	*Mycobacterium smegmatis*	*Streptcoccus bovis*
Corynebacterium genitalium biovar1	*Mycoplasma genitalium*	*Streptococcus agalactiae* (Group B)
Corynebacterium xerosis	*Mycoplasma hominis*	*Streptococcus mitis*
Cryptococcus neoformans	*Neisseria cinerea* (4)[a]	*Streptococcus mutans*
Cytomegalovirus	*Neisseria denitrificans*	*Streptococcus pneumoniae*
Deinococcus radiodurans	*Neisseria elongate* (3)[a]	*Streptococcus pyogenes* (Group A)
Derxia gummosa	*Neisseria flava*	*Streptococcus salivarius*
Eikenella corrodens	*Neisseria flavescens* (2)[a]	*Streptococcus sanguis*
Elizabethkingia meningosepticum	*Neisseria lactamica* (9)[a]	*Streptomyces griseinus*
Enterobacter aerogenes	*Neisseria meningitidis* A	*Trichomonas tenax*
Enterobacter cloacae	*Neisseria meningitidis* B	*Ureaplasma urealyticum*
Enterococcus avium	*Neisseria meningitidis* C (4)[a]	*Vibrio parahaemolyticus*
Enterococcus faecalis	*Neisseria meningitidis* D	*Yersinia enterocolitica*
Enterococcus faecium	*Neisseria meningitidis* W135	
Erysipelothrix rhusiopathiae	*Neisseria meningitidis* Y	

[a] The number in parenthesis indicates the number of strains tested.

Interfering Substances

Forty-four (44) biological and chemical substances that may be present in urogenital specimens were evaluated for potential interference with the BD CTGCTV2 assay (Tables 26 through 28). Included in this study were antibiotic, analgesic, antifungal, hormonal, lubricants, and contraceptive pools which contained combinations of the various chemicals that were tested at a concentration that may be found in urogenital specimens. Negative urine, vaginal swab and PreservCyt® LBC pooled specimens and a target mix of *Chlamydia trachomatis, Neisseria gonorrhoeae* and *Trichomonas vaginalis* positive at 3X LoD were tested with the highest amount of each compound likely to be found in the specimens. Potentially interfering substances in urine specimens include whole blood. Potentially interfering substances in vaginal swab specimens include VCF* Contraceptive Foam and Film, Conceptrol* Contraceptive Gel, Monistat 3 cream, Vaginal Anti-Itch Cream, McKesson Lubricating Jelly, Surgilube, Aquagel, Acyclovir, Metronidazole, Replens, mucous and whole blood. Potentially interfering substances in PreservCyt® LBC specimens include Vaginal Anti-Itch Cream, Metronidazole Gel, Replens, mucous, whole blood, McKesson Lubricating Jelly, Surgilube and Aquagel. The following substances shown in Tables 24 through 26 did not cause interference with the BD CTGCTV2 assay at the concentrations shown below.

Table 24: Exogenous and Endogenous Substances Tested for Interference in Urine

Substance	Concentration
Norethindrone	16 ng/mL
17-α-Ethinylestradiol	0.96 ng/mL
4-Acetamidophenol	160 µg/mL
Acetylsalicylic Acid	521.6 µg/mL
Naproxen	400 µg/mL
Ibuprofen	400 µg/mL
Human Serum Albumin	0.8 mg/mL
Glucose	0.96 mg/mL
Amoxicillin Trihydrate	60.16 µg/mL
Metronidazole	96 µg/mL
Tetracycline Hydrochloride	12 µg/mL
Azithromycin	9.6 µg/mL
Ceftriaxone	648.8 µg/mL
Sulfamethoxazole	320 µg/mL
Trimethoprim	32 µg/mL
Erythromycin	48 µg/mL
Mucous (Bovine Cervical)	4% v/v
Whole Blood	0.6% v/v[a]
Semen	4% v/v
Leukocytes	2 x 10^6 cells/mL
Phenazopyridine Hydrochloride	160 µg/mL
High pH (NaOH)	pH 9
Low pH (HCl)	pH 4
Bilirubin	0.16 mg/mL
Feminine Deodorant Spray	0.68% v/v
Talcum Powder	2.64% v/v

[a] May interfere with the BD CTGCTV2 assay when at concentrations higher than shown.

Table 25: Exogenous and Endogenous Substances Tested for Interference in Swab Specimens

Substance	Concentration
VCF Contraceptive Foam	15 µL/mL[a]
VCF Contraceptive Film	0.5 µL/mL[a]
Conceptrol Contraceptive Gel	3 µL/mL[a]
Clotrimazole 7	50 µL/mL
Monistat 3 Cream	0.1 µL/mL[a]
Tioconazole 1	50 µL/mL
Vaginal Anti-Itch Cream	0.1 µL/mL[a]
Vaginal Lubricant Liquid – water based	50 µL/mL
Preparation H Hemorrhoid Gel	50 µL/mL
Antiviral (Zovirax – Acyclovir)	0.01 µL/mL[a]
Metronidazole Gel (AntiProtozoal)	1.25 µL/mL[a]

Substance	Concentration
Replens (Vaginal Moisturizer)	0.1 µL/mL[a]
Douche	50 µL/mL
Feminine Deodorant Spray	50 µL/mL
Progesterone	20 ng/mL
Estradiol	1.2 ng/mL
Mucous (Bovine Cervical)	4.5% v/v[a]
Semen	5% v/v
Whole Blood	8 µL/mL[a]
Leukocytes	1 x 10^6 cells/mL
Aquagel	0.0345 mg/mL[a]
McKesson Lubricating Jelly	0.445 mg/mL[a]
Surgilube	0.41 mg/mL[a]
KY Lubricating Jelly	137.5 mg/mL

[a] May interfere with the BD CTGCTV2 assay when at concentrations higher than shown.

Table 26: Exogenous and Endogenous Substances Tested for Interference in PreservCyt® LBC Specimens

Substance	Concentration
Vaginal Lubricant	2% v/v
Douche	2% v/v
Vaginal Deodorant Spray	2% v/v
Progesterone	20 ng/mL
Estradiol	1.2 ng/mL
Leukocytes	1 x 10^6 cells/mL
Semen	2% v/v
Monistat 3	2% v/v
Clotrimazole 7	2% v/v
Tioconazole 1	2% v/v
Vaginal contraceptive film	2% v/v
Vaginal contraceptive foam	2% v/v
Contraceptive gel	2% v/v
Vaginal anti-itch Cream	1% v/v[a]
Zovirax (Acyclovir) Cream	2% v/v
Metronidazole Gel 0.75%	0.01% v/v[a]
Replens (Vaginal Moisturizer)	0.1% v/v[a]
Mucous (Bovine Cervical)	1.9% v/v[a]
Whole Blood	0.5% v/v[a]
Aquagel	0.276 mg/mL[a]
McKesson Lubricating Jelly	3.56 mg/mL[a]
Surgilube	328 mg/mL[a]
KY Lubricating Jelly	1,100 mg/mL

[a] May interfere with the BD CTGCTV2 assay when at concentrations higher than shown.

Mixed Infection/Competitive Interference

The mixed infection/competitive interference study was designed to evaluate the ability of the BD CTGCTV2 assay to detect low concentrations of the target organisms in the presence of high concentration of the other two target organisms. Three test samples were prepared in pooled clinical matrix (swab, urine and PreservCyt® LBC) each containing one of the target organisms (*Chlamydia trachomatis, Neisseria gonorrhoeae* and *Trichomonas vaginalis*) at 1.5X their respective LoD. A high target mix comprised of organisms representative of the other two BD CTGCTV2 assay analytes at a concentration ≥1 x 10^6 EB, cells or TV/mL were spiked into each sample to simulate mixed infections. The samples were tested in 20 replicates. All three low target organisms were successfully detected at ≥95% by the BD CTGCTV2 assay in the presence of the other two organisms at high concentrations in urine, vaginal swab and PreservCyt® LBC specimens. When assessed across all organisms and sample types, the observed Ct. score shift ranged from -0.1 to 4.5 for *Chlamydia trachomatis*, from -1.8 to 5.8 for *Neisseria gonorrhoeae*, and from 1.0 to 4.8 for *Trichomonas vaginalis*.

Precision

Within-laboratory precision was evaluated for the BD CTGCTV2 assay at one site with one reagent lot. Testing was performed over 12 days, with 2 runs per day (2 technologists, alternating operators each day), for a total of 24 runs. Test samples were contrived in female urine, in vaginal swab clinical matrix and in PreservCyt® LBC specimen matrix and included *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* panel members. Each panel member was tested in two replicates. The following target concentrations were used for spiking levels of the target organisms contained in each panel member:

- Moderate Positive (MP): 3X LoD
- Low Positive (LP): 1.5X LoD
- High Negative (HN): <1X LoD
- True negative (TN): no target

Precision study results for the BD CTGCTV2 assay are described in Table 27.

Table 27: Overall Precision Study Results Using One Lot of the BD CTGCTV2 Assay (Percent Agreement with Expected Results)

Category	*Chlamydia trachomatis* (n), 95% CI			*Neisseria gonorrhoeae* (n), 95% CI			*Trichomonas vaginalis* (n), 95% CI	
	Swab	Urine	LBC[c]	Swab	Urine	LBC[c]	Swab	Urine
TN[a]	100% (336/336) 98.9–100	100% (336/336) 98.9–100	99.4% (334/336) 97.9–99.8	100% (336/336) 98.9–100	100% (336/336) 98.9–100	100% (336/336) 98.9–100	100% (336/336) 98.9–100	100% (336/336) 98.9–100
HN[b]	31.3% (15/48) 19.9–45.3	31.3% (15/48) 19.9–45.3	18.8% (9/48) 10.2–31.9	27.1% (13/48) 16.6–41.0	29.2% (14/48) 18.2–43.2	16.7% (8/48) 8.7–29.6	37.5% (18/48) 25.2–51.6	68.8% (33/48) 54.7–80.1
LP	100% (48/48) 92.6–100	100% (48/48) 92.6–100	100% (48/48) 92.6–100	97.9% (47/48) 89.1–99.6	100% (48/48) 92.6–100	100% (48/48) 92.6–100	97.9% (47/48) 89.1–99.6	100% (48/48) 92.6–100
MP	100% (48/48) 92.6–100	100% (48/48) 92.6–100	100% (48/48) 92.6–100	100% (48/48) 92.6–100	100% (48/48) 92.6–100	100% (48/48) 92.6–100	100% (48/48) 92.6–100	100% (48/48) 92.6–100

[a] For the True Negative (TN) category, the reported agreement indicates the percent of negative results.

[b] For the High Negative (HN) category, the reported agreement indicates the percent of positive results.

[c] PreservCyt® LBC

Reproducibility

For the Site-to-Site reproducibility study, three (3) sites (two external and one internal) were provided the same panels as described for the Precision study, above. Each site performed testing on eight (8) distinct days (consecutive or not), wherein each day, two (2) panels were tested by two (2) technologists (alternating operators each day).

All targets ranged from 99.6% to 100% for TN, 11.5% to 78.1% for HN, 97.9% to 100% for LP and 97.9% to 100% MP categories (refer to Table 28). The qualitative and quantitative reproducibility is presented below by target for each specimen matrix in Tables 29–31. Ct. score, internal criterion used to determine a final assay result, was selected as an additional means of assessing assay reproducibility. Overall mean Ct. score values with variance components (SD and %CV) are shown in Tables 29–31.

Table 28: Site-To-Site Reproducibility Study Results Using One Lot of the BD CTGCTV2 Assay (Percent Agreement with Expected Results)

Category	*Chlamydia trachomatis* (n), 95% CI			*Neisseria gonorrhoeae* (n), 95% CI			*Trichomonas vaginalis* (n), 95% CI	
	Swab	Urine	LBC[c]	Swab	Urine	LBC[c]	Swab	Urine
TN[a]	99.6% (669/672) 98.7–99.8	100% (672/672) 99.4–100	100% (672/672) 99.4–100	100% (672/672) 99.4–100	100% (672/672) 99.4–100	99.9% (671/672) 99.2–100	99.9% (671/672) 99.2–100	100% (672/672) 99.4–100
HN[b]	20.8% (20/96) 13.9–30.0	35.4% (34/96) 26.6–45.4	21.9% (21/96) 14.8–31.1	34.4% (33/96) 25.6–44.3	28.1% (27/96) 20.1–37.8	11.5% (11/96) 6.5–19.4	37.5% (36/96) 28.5–47.5	78.1% (75/96) 68.9–85.2
LP	100% (96/96) 96.2–100	100% (96/96) 96.2–100	100% (96/96) 96.2–100	99.0% (95/96) 94.3–99.8	99.0% (95/96) 94.3–99.8	97.9% (94/96) 92.7–99.4	99.0% (95/96) 94.3–99.8	99.0% (95/96) 94.3–99.8
MP	100% (96/96) 96.2–100	99.0% (95/96) 94.3–99.8	100% (96/96) 96.2–100	100% (96/96) 96.2–100	100% (96/96) 96.2–100	100% (96/96) 96.2–100	100% (96/96) 96.2–100	97.9% (94/96) 92.7–99.4

[a] For the True Negative (TN) category, the reported agreement indicates the percent of negative results.

[b] For the High Negative (HN) category, the reported agreement indicates the percent of positive results.

[c] PreservCyt® LBC

Table 29: *Chlamydia trachomatis* Site-to-Site Quantitative Reproducibility Across Sites, Operators, Days, Runs and Replicates

Matrix Type	Cat	Agree/N	Mean	Within Run		Between Run		Between Day		Between Operator		Between Site		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Swab	HN	20/96	36.6	1.1	3.1	1.8	4.9	0.1	0.4	0.0	0.0	0.0	0.0	2.1	5.8
	LP	96/96	33.2	0.7	2.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.7	2.1
	MP	96/96	32.1	0.6	2.0	0.0	0.0	0.2	0.5	0.0	0.0	0.1	0.4	0.7	2.1
Urine	HN	34/96	36.8	1.6	4.3	0.0	0.0	0.8	2.1	0.0	0.0	0.4	1.0	1.8	4.9
	LP	96/96	32.9	0.7	2.3	0.0	0.0	0.7	2.0	0.3	0.9	0.0	0.0	1.1	3.2
	MP	95/96	33.9	1.1	3.1	0.1	0.4	0.2	0.4	0.0	0.0	0.0	0.0	1.1	3.2
LBC[a]	HN	21/96	38.1	0.7	1.9	2.0	5.1	0.0	0.0	1.4	3.8	0.0	0.0	2.5	6.6
	LP	96/96	34.6	1.1	3.2	0.4	1.2	0.3	0.9	0.0	0.0	0.7	2.0	1.4	4.0
	MP	96/96	33.1	0.6	1.8	0.0	0.0	0.2	0.7	0.0	0.0	0.2	0.7	0.7	2.1

[a] PreservCyt® LBC

Table 30: *Neisseria gonorrhoeae* Site-to-Site Quantitative Reproducibility Across Sites, Operators, Days, Runs and Within Run

Target	Matrix Type	Cat	Agree/N	Mean	Within Run		Between Run		Between Day		Between Operator		Between Site		Total	
					SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
GC1	Swab	HN	33/96	36.3	2.1	5.7	0.9	2.5	0.0	0.0	0.0	0.0	0.6	1.7	2.3	6.4
		LP	95/96	32.5	0.9	2.8	0.0	0.0	0.3	0.9	0.0	0.0	0.1	0.3	1.0	2.9
		MP	96/96	31.4	0.5	1.5	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.2	0.5	1.5
	Urine	HN	27/96	36.5	2.1	5.8	0.0	0.0	0.0	0.0	0.0	0.0	0.7	2.0	2.2	6.1
		LP	95/96	32.5	1.1	3.4	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.5	1.1	3.5
		MP	96/96	32.8	0.9	2.6	0.4	1.3	0.0	0.0	0.0	0.0	0.0	0.0	1.0	2.9
	LBC[a]	HN	11/96	35.5	1.4	3.9	0.0	0.0	0.9	2.7	0.0	0.0	0.0	0.0	1.7	4.7
		LP	94/96	32.1	0.5	1.6	0.4	1.2	0.3	1.0	0.1	0.4	0.1	0.4	0.7	2.3
		MP	96/96	30.7	0.5	1.5	0.5	1.5	0.0	0.0	0.0	0.0	0.4	1.2	0.7	2.4
GC2	Swab	HN	33/96	34.2	1.1	3.2	0.1	0.4	0.0	0.0	0.0	0.0	0.0	0.0	1.1	3.2
		LP	95/96	30.9	0.7	2.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.7	2.2
		MP	96/96	29.8	0.4	1.3	0.0	0.0	0.0	0.0	0.1	0.4	0.2	0.7	0.4	1.5
	Urine	HN	27/96	34.8	1.4	4.0	0.9	2.5	0.0	0.0	0.4	1.1	0.5	1.5	1.8	5.1
		LP	95/96	31.0	0.7	2.4	0.0	0.0	0.0	0.0	0.1	0.2	0.0	0.0	0.7	2.4
		MP	96/96	31.2	0.6	1.9	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.8	0.6	2.1
	LBC[a]	HN	11/96	35.3	0.8	2.2	1.1	3.1	0.0	0.0	0.0	0.0	0.8	2.3	1.6	4.5
		LP	94/96	30.5	0.4	1.2	0.4	1.3	0.3	1.1	0.0	0.0	0.2	0.8	0.7	2.2
		MP	96/96	29.2	0.3	1.1	0.4	1.3	0.2	0.7	0.1	0.5	0.3	1.0	0.6	2.2

[a] PreservCyt® LBC

Table 31: *Trichomonas vaginalis* Site-to-Site Quantitative Reproducibility Across Sites, Operators, Days, Runs and Within Run

Matrix Type	Cat	Agree/N	Mean	Within Run		Between Run		Between Day		Between Operator		Between Site		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Swab	HN	36/96	36.9	1.8	5.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.8	5.0
	LP	95/96	33.2	0.7	2.2	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.7	0.8	2.3
	MP	96/96	32.3	0.5	1.6	0.0	0.0	0.0	0.0	0.1	0.3	0.0	0.0	0.5	1.6
Urine	HN	75/96	37.2	2.4	6.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.4	6.6
	LP	95/96	32.5	0.7	2.2	0.0	0.0	0.3	0.9	0.2	0.6	0.2	0.5	0.8	2.5
	MP	94/96	33.7	0.8	2.4	0.3	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.9	2.6

For the Lot-to-Lot reproducibility study, two operators each completed a single run of each panel member on two instruments for each of three lots of reagents over an 8-day period, at one testing site. The panels used were the same as described under the Precision heading, above. Results from one reagent lot of the Site-to-Site reproducibility study were used to comprise data for one lot of reagents for the Lot-to-Lot study.

The overall Lot-to-Lot reproducibility percent agreement across all targets ranged from 99.4% to 100% for TN, 10.4% to 75.0% for HN, 95.8% to 100% for LP and 95.8% to 100% MP categories (refer to Table 32). The Lot-to-Lot quantitative reproducibility according to Ct. score is also shown in Table 33 to Table 35.

Table 32: Lot-to-Lot Reproducibility Study Results Using Three Lots of the BD CTGCTV2 Assay (Percent Agreement with Expected Results)

Category	*Chlamydia trachomatis*			*Neisseria gonorrhoeae*			*Trichomonas vaginalis*	
	Swab	Urine	LBC[c]	Swab	Urine	LBC[c]	Swab	Urine
TN[a]	99.4% (668/672) 98.5–99.8	100% (672/672) 99.4–100	99.6% (669/672) 98.7–99.8	99.9% (671/672) 99.2–100	100% (672/672) 99.4–100	100% (672/672) 99.4–100	100% (672/672) 99.4–100	100% (672/672) 99.4–100
HN[b]	22.9% (22/96) 15.6–32.3	37.5% (36/96) 28.5–47.5	15.6% (15/96) 9.7–24.2	24.0% (23/96) 16.5–33.4	24.0% (23/96) 16.5–33.4	10.4% (10/96) 5.8–18.1	40.6% (39/96) 31.3–50.6	63.5% (61/96) 53.6–72.5
LP	100% (96/96) 96.2–100	100% (96/96) 96.2–100	99.0% (95/96) 94.3–99.8	99.0% (95/96) 94.3–99.8	95.8% (92/96) 89.8–98.4	100% (96/96) 96.2–100	99.0% (95/96) 94.3–99.8	99.0% (95/96) 94.3–99.8
MP	100% (96/96) 96.2–100	100% (96/96) 96.2–100	100% (96/96) 96.2–100	100% (96/96) 96.2–100	95.8% (92/96) 89.8–98.4	100% (96/96) 96.2–100	100% (96/96) 96.2–100	100% (96/96) 96.2–100

[a] For the True Negative (TN) category, the reported agreement indicates the percent of negative results.
[b] For the High Negative (HN) category, the reported agreement indicates the percent of positive results.
[c] PreservCyt® LBC

Table 33: *Chlamydia trachomatis* Lot-to-Lot Quantitative Reproducibility Study Results Using Three Lots of the BD CTGCTV2 Assay

Matrix Type	Cat	Agree/N	Mean	Within Run		Between Run		Between Day		Between Operator		Between Lot		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Swab	HN	22/96	37.3	1.1	2.9	2.2	5.9	1.2	3.1	0.0	0.0	0.0	0.0	2.7	7.3
	LP	96/96	33.6	1.0	2.9	0.4	1.2	0.0	0.0	0.2	0.6	0.3	0.7	1.1	3.3
	MP	96/96	32.6	0.8	2.3	0.0	0.0	0.3	1.0	0.1	0.4	0.1	0.3	0.8	2.6
Urine	HN	36/96	38.0	2.9	7.8	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.8	3.0	7.8
	LP	96/96	32.9	0.6	1.8	0.5	1.6	0.0	0.0	0.2	0.5	0.0	0.0	0.8	2.4
	MP	96/96	34.0	1.0	3.0	0.1	0.4	0.0	0.0	0.3	0.8	0.2	0.6	1.1	3.2
LBC[a]	HN	15/96	38.8	1.8	4.7	1.4	3.6	0.0	0.0	1.2	3.0	0.0	0.0	2.6	6.7
	LP	95/96	34.8	1.1	3.0	0.4	1.0	0.0	0.0	0.3	0.9	0.0	0.0	1.2	3.3
	MP	96/96	33.4	0.7	2.0	0.3	1.0	0.4	1.3	0.2	0.7	0.0	0.0	0.9	2.7

[a] PreservCyt® LBC

Table 34: *Neisseria gonorrhoeae* Lot-to-Lot Quantitative Reproducibility Study Results Using Three Lots of the BD CTGCTV2 Assay

Target	Matrix Type	Cat	Agree/N	Mean	Within Run		Between Run		Between Day		Between Operator		Between Lot		Total	
					SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
GC1	Swab	HN	23/96	36.4	1.5	4.1	0.0	0.0	1.3	3.6	1.0	2.9	1.1	2.9	2.5	6.8
		LP	95/96	32.7	1.5	4.4	0.6	1.7	0.0	0.0	0.0	0.0	0.0	0.0	1.6	4.7
		MP	96/96	31.6	0.7	2.2	0.1	0.4	0.0	0.0	0.0	0.0	0.2	0.7	0.8	2.4
	Urine	HN	23/96	36.8	2.5	6.8	0.0	0.0	0.0	0.0	0.0	0.0	0.7	2.0	2.6	7.1
		LP	92/96	32.6	1.3	4.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.2	1.3	4.0
		MP	92/96	32.8	0.9	2.8	0.2	0.8	0.0	0.0	0.0	0.0	0.1	0.2	1.0	2.9
	LBC[a]	HN	10/96	37.8	2.9	7.6	0.0	0.0	0.0	0.0	0.0	0.0	3.5	9.4	4.6	12.1
		LP	96/96	32.1	0.6	1.8	0.0	0.1	0.1	0.5	0.2	0.7	0.0	0.0	0.6	2.0
		MP	96/96	30.7	0.5	1.7	0.3	0.9	0.4	1.4	0.3	1.0	0.0	0.0	0.8	2.6
GC2	Swab	HN	23/96	35.4	1.1	3.2	1.1	3.0	1.7	4.8	0.0	0.0	1.0	2.8	2.5	7.1
		LP	95/96	31.1	0.7	2.2	0.3	0.8	0.0	0.0	0.0	0.0	0.2	0.6	0.8	2.4
		MP	96/96	30.2	0.6	2.1	0.2	0.5	0.0	0.0	0.0	0.0	0.2	0.8	0.7	2.3
	Urine	HN	23/96	35.1	1.8	5.2	1.3	3.7	1.0	2.9	0.0	0.0	0.0	0.0	2.5	7.0
		LP	92/96	31.1	0.8	2.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.8	2.7
		MP	92/96	31.6	0.7	2.4	0.0	0.0	0.0	0.0	0.2	0.6	0.0	0.0	0.8	2.4
	LBC[a]	HN	10/96	36.0	1.1	3.0	0.0	0.0	1.2	3.3	0.0	0.0	1.1	3.0	1.9	5.3
		LP	96/96	30.6	0.4	1.2	0.5	1.5	0.1	0.3	0.2	0.8	0.0	0.0	0.7	2.1
		MP	96/96	29.4	0.4	1.5	0.3	1.1	0.3	1.2	0.3	1.0	0.0	0.0	0.7	2.4

[a] PreservCyt® LBC

Table 35: *Trichomonas vaginalis* Lot-to-Lot Quantitative Reproducibility Study Results Using Three Lots of the BD CTGCTV2 Assay

Matrix Type	Cat	Agree/N	Mean	Within Run		Between Run		Between Day		Between Operator		Between Lot		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Swab	HN	39/96	36.8	2.1	5.8	0.0	0.0	0.0	0.0	0.3	0.7	0.0	0.0	2.1	5.8
	LP	95/96	33.4	1.2	3.7	0.0	0.0	0.3	0.9	0.0	0.0	0.3	1.0	1.3	4.0
	MP	96/96	32.4	0.7	2.3	0.1	0.4	0.1	0.3	0.1	0.2	0.0	0.0	0.8	2.4
Urine	HN	61/96	37.0	1.9	5.2	0.0	0.0	0.5	1.2	0.0	0.0	0.0	0.0	2.0	5.4
	LP	95/96	32.5	0.7	2.1	0.1	0.3	0.0	0.0	0.0	0.0	0.1	0.4	0.7	2.1
	MP	96/96	33.8	1.0	3.1	0.0	0.0	0.0	0.0	0.2	0.5	0.0	0.0	1.1	3.1

Carryover / Cross-Contamination

A study was conducted to investigate within-run carryover and between-run carryover while processing samples with high microbial load of *Chlamydia trachomatis* in the BD CTGCTV2 assay. High positive samples contained *Chlamydia trachomatis* (VR-879, Serovar H) spiked into pooled PreservCyt® LBC matrix at a concentration of ≥1 x 10^6 EB/mL. The negative samples consisted of LBC Sample Buffer Tubes without any target analyte. Twelve (12) replicates of the high positive panel member and 12 replicates of the negative panel member were tested in 18 runs by alternating negative and positive samples, using three BD MAX™ Systems or a total of 216 positive and 216 negative samples tested. Of the 216 negative samples tested, two false positive results were obtained (0.93%, 95% CI: 0.25–3.31%).

AVAILABILITY

Catalog Number	Description
437519	BD PCR Cartridges
440295	BD Pierceable Caps
440296	BD Molecular Swab Sample Buffer Tubes
443904	BD CTGCTV2 for BD MAX™ System
443923	BD Molecular LBC Sample Buffer Tubes
443924	BD Molecular Urine Transport Kit
443925	BD Molecular Swab Collection Kit

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6. BD MAX™ System User's Manual (refer to latest version) BD Life Sciences, Sparks, MD 21152 USA.
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8. Clinical Laboratory Standards Institute. Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline Document MM03 (refer to the latest edition)
9. Clinical Laboratory Standards Institute. User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline, Document EP12 (Refer to latest edition).

Technical Service and Support: In the United States contact BD at 1.800.638.8663 or bd.com.

For regions outside of the United States, contact your local BD representative or bd.com.

Change History

Revision	Date	Change Summary
01	2021-01	Initial release.
02	2022-01	Added safety disposal statement to Warnings and Precautions. Updated Figure 1 illustration and added key. Updated Figure 2 image. Added Availability section. Updated Technical Service information. Updated Symbols Glossary. Made formatting and typographical updates.
03	2022-10	Updated Warnings and Precautions section. Added clarification for expected system behavior in regard to expired reagents. Made formatting and typographical updates.

SYMBOLS GLOSSARY [L006715(06) 2021-08]

Some symbols listed below may not apply to this product.
US Customers only: For symbol glossary, refer to **bd.com/symbols-glossary**

Symbol	Meaning
	Manufacturer
	Authorized representative in the European Community
	Authorised representative in Switzerland
	Date of manufacture
	Use-by date
	Batch code
	Catalogue number
	Serial number
	Sterile
	Sterilized using aseptic processing techniques
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Sterilized using steam or dry heat
	Do not resterilize
	Non-sterile
	Do not use if package is damaged and consult *instructions for use*
	Sterile fluid path
	Sterile fluid path (ethylene oxide)
	Sterile fluid path (irradiation)
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Lower limit of temperature
	Upper limit of temperature
	Temperature limit
	Humidity limitation
	Biological risks
	Do not re-use
	Consult *instructions for use* or consult electronic *instructions for use*
	Caution
	Contains or presence of natural rubber latex
	In vitro diagnostic medical device
	Negative control
	Positive control
	Contains sufficient for <*n*> tests
	For IVD performance evaluation only
	Non-pyrogenic

Symbol	Meaning
	Patient number
	This way up
	Do not stack
	Single sterile barrier system
	Contains or presence of phthalate: combination of bis(2-ethylhexyl) phthalate (DEHP) and benzyl butyl phthalate (BBP)
	Collect separately Indicates separate collection for waste of electrical and electronic equipment required.
	CE marking; Signifies European technical conformity
	Device for near-patient testing
	Device for self-testing
	This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."
	Country of manufacture "CC" shall be replaced by either the two letter or the three letter country code.
	Collection time
	Cut
	Peel here
	Collection date
	Keep away from light
	Hydrogen gas is generated
	Perforation
	Start panel sequence number
	End panel sequence number
	Internal sequence number
	Medical device
	Contains hazardous substances
	Ukrainian conformity mark
	Meets FCC requirements per 21 CFR Part 15
	UL product certification for US and Canada
	Unique device identifier

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