BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

Prepared by	Date Adopted	Supersedes Procedure #

Review Date	Revision Date	Signature

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BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure*

8081409(04)

INTENDED USE

The **BD ProbeTec™** *Neisseria gonorrhoeae* Q^x Amplified DNA Assay, when tested with either the **BD Viper™** System in Extracted Mode or the **BD Viper** LT System, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Neisseria gonorrhoeae* DNA in clinician-collected female endocervical and male urethral swab specimens, patient-collected vaginal swab specimens (in a clinical setting), and male and female urine specimens (both UPT and Neat). The assay is also intended for use with gynecological specimens collected in **BD SurePath™** Preservative Fluid or PreservCyt™ Solution using an aliquot that is removed prior to processing for either the **BD SurePath** or ThinPrep™ Pap test. The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of gonococcal urogenital disease.

SUMMARY AND EXPLANATION

The World Health Organization estimates the total number of new cases of *Neisseria gonorrhoeae* in adults between the ages of 15 and 49 in was106.1 million in 2008.[1] In the United States, gonorrhea is the second most commonly reported infectious disease. In 2012, a total of 334,826 cases of gonorrhea were reported in the United States.[2] During 2011–2012, gonorrhea rates were similar between genders with the rate among women at 108.7 and the rate among men at 105.8 cases per 100,000 population.[2] Infection of women is often asymptomatic and if left untreated can lead to pelvic inflammatory disease, infertility, ectopic pregnancy and chronic pelvic pain. In men, symptoms of acute urethritis and dysuria usually cause infected individuals to present for treatment before serious sequelae result. Transmission of *N. gonorrhoeae* occurs through sexual contact but can also take place in the birth canal leading to neonatal conjunctivitis.

Because of the high frequency of asymptomatic infections, the US Preventive Services Task Force has published recommendations for screening young, sexually active women and those who are older and considered at increased risk of infection in order to prevent complications and reduce transmission.[3] The Advisory Committee on Human Immunodeficiency Virus (HIV) and Sexually Transmitted Disease (STD) Prevention also encourages active control programs that target treatable STDs as a primary intervention in the HIV epidemic.[4] Nevertheless, quinolone-resistant *N. gonorrhoeae* strains are now widely disseminated throughout the United States and the world. Furthermore, decreased susceptibility of *N. gonorrhoeae* to cephalosporins, the only class of antimicrobials recommended and available for treatment of gonorrhoeae in the U.S., and other antimicrobials is expected to continue to spread, thus reducing the options available to combat *N. gonorrhoeae* infection.[5]

N. gonorrhoeae are gram-negative, oxidase-positive diplococci that can be observed in Gram-stained smears of urethral discharge, usually within neutrophils. Culture of *N. gonorrhoeae* can be difficult because the organism does not survive long outside the host and is highly susceptible to adverse environmental conditions such as lack of humidity and temperature extremes. Although culture of urogenital swabs remains an important tool in the diagnosis of *N. gonorrhoeae* infection due to the continued need for monitoring of antimicrobial susceptibility, use of molecular methods that amplify and detect specific nucleic acid sequences is increasing due to their applicability to both swab specimens and more easily collected urine specimens.[5,6]

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*For use with Package Insert "**BD ProbeTec** Neisseria gonorrhoeae (GC) Q^x Amplified DNA Assay [8081409(04) 2015-08]"*

When used with the **BD Viper** System or the **BD Viper** LT System, the **BD ProbeTec** GC Q^x Amplified DNA Assay involves automated ferric oxide-based extraction of DNA from clinical specimens using **BD FOX™** Extraction technology after the chemical lysis of cells, followed by binding of DNA to para-magnetic particles, washing of the bound nucleic acid and elution in an amplification-compatible buffer. When present, *N. gonorrhoeae* DNA is then detected by real-time Strand Displacement Amplification (SDA) of a specific target sequence in the presence of a fluorescently-labeled detector probe.[7,8]

BD VIPER SYSTEM IN EXTRACTED MODE (BD VIPER SYSTEM)

PRINCIPLES OF THE PROCEDURE

The **BD ProbeTec** GC Q^x Amplified DNA Assay is designed for use with the **BD ProbeTec** *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/GC) Q^x specimen collection and transport devices, applicable reagents, the **BD Viper** System and **BD FOX** Extraction. Specimens are collected and transported in their respective transport devices which preserve the integrity of the *N. gonorrhoeae* DNA over the specified ranges of temperature and time. Urine and swab specimens undergo a pre-warm step in the **BD Viper** Lysing Heater to dissolve mucus and homogenize the specimen. After cooling, the specimens are loaded onto the **BD Viper** System which then performs all the steps involved in extraction and amplification of target DNA, without further user intervention. For gynecological specimens that are collected and transported in **BD SurePath** Preservative Fluid or PreservCyt Solution, the pre-warm step is not necessary; i.e., an aliquot is simply transferred to a Liquid-Based Cytology Specimen (LBC) Dilution Tube for the **BD ProbeTec** Q^x Amplified DNA Assays prior to loading on the instrument. The specimen is transferred to an Extraction Tube that contains ferric oxide particles in a dissolvable film and dried Extraction Control. A high pH is used to lyse the bacterial cells and liberate their DNA into solution. Acid is then added to lower the pH and induce a positive charge on the ferric oxide, which in turn binds the negatively charged DNA. The particles and bound DNA are then pulled to the sides of the Extraction Tube by magnets and the treated specimen is aspirated to waste. The particles are washed and a high pH Elution Buffer is added to recover the purified DNA. Finally, a Neutralization Buffer is used to bring the pH of the extracted solution to the optimum for amplification of the target.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

The **BD ProbeTec** GC Q^x Amplified DNA Assay is based on the simultaneous amplification and detection of target DNA using amplification primers and a fluorescently-labeled detector probe.[8,9] The reagents for SDA are dried in two separate disposable microwells: the Priming Microwell contains the amplification primers, fluorescently-labeled detector probe, nucleotides and other reagents necessary for amplification, while the Amplification Microwell contains the two enzymes (a DNA polymerase and a restriction endonuclease) that are required for SDA. The **BD Viper** System pipettes a portion of the purified DNA solution from each Extraction Tube into a Priming Microwell to rehydrate the contents. After a brief incubation, the reaction mixture is transferred to a corresponding, pre-warmed Amplification Microwell which is sealed to prevent contamination and then incubated in one of the two thermally-controlled fluorescent readers. The presence or absence of *N. gonorrhoeae* DNA is determined by calculating the peak fluorescence (Maximum Relative Fluorescent Units [MaxRFU]) over the course of the amplification process and by comparing this measurement to a predetermined threshold value.

In addition to the fluorescent probe used to detect amplified *N. gonorrhoeae* target DNA, a second fluorescently-labeled oligonucleotide is incorporated in each reaction. The Extraction Control (EC) oligonucleotide is labeled with a different dye than that used for detection of the *N. gonorrhoeae*-specific target and is used to confirm the validity of the extraction process. The EC is dried in the Extraction Tubes and is re-hydrated upon addition of the specimen and extraction reagents.

At the end of the extraction process, the EC fluorescence is monitored by the **BD Viper** instrument and an automated algorithm is applied to both the EC and *N. gonorrhoeae*-specific signals to report specimen results as positive, negative, or EC failure.

REAGENTS

Each **BD ProbeTec** GC Q^x Reagent Pack contains:

- GC Q^x Amplified DNA Assay Priming Microwells, 12 x 96: each Priming Microwell contains approximately 30 pmol oligonucleotides, 45 pmol fluorescently-labeled detector probe, 100 nmol dNTPs, with stabilizers and buffer components.
- GC Q^x Amplified DNA Assay Amplification Microwells, 12 x 96: each Amplification Microwell contains approximately 14 units DNA polymerase and 50 units restriction enzyme, with stabilizers and buffer components.

NOTE: Each microwell pouch contains one desiccant bag.

MATERIALS REQUIRED BUT NOT PROVIDED:

Control Set for the **BD ProbeTec** CT/GC Q^x Amplified DNA Assays: 24 CT/GC Q^x Positive Control Tubes containing approximately 2400 copies each of pCTB4 and pGCint3 linearized plasmids in carrier nucleic acid, and 24 CT/GC Q^x Negative Controls Tubes containing carrier nucleic acid alone. The concentrations of the pCTB4 and pGCint3 plasmids are determined by UV spectrophotometry.

Q^x Swab Diluent for the **BD ProbeTec** Q^x Amplified DNA Assays: 48 tubes each containing approximately 2 mL of potassium phosphate/potassium hydroxide buffer with DMSO and preservative.

Liquid-Based Cytology Specimen (LBC) Dilution Tube for the **BD ProbeTec** Q^x Amplified DNA Assays (LBC Specimen Dilution Tube): 400 tubes each containing approximately 1.7 mL of Tris/Sodium Chloride solution and preservative.

BD FOX Extraction Tubes: 48 strips of 8 tubes, each containing approximately 10 mg of iron oxide in a dissolvable film and approximately 240 pmol fluorescently-labeled Extraction Control oligonucleotide.

BD Viper Extraction Reagent and Lysis Trough: each 4-cavity Extraction Reagent trough contains approximately 16.5 mL Binding Acid, 117 mL Wash Buffer, 35 mL Elution Buffer, and 29 mL Neutralization Buffer with preservative; each Lysis Trough contains approximately 11.5 mL Lysis Reagent.

INSTRUMENT, EQUIPMENT AND SUPPLIES

Materials Available from BD: BD Viper Instrument, **BD Viper** Instrument Plates, **BD Viper** Pipette Tips, **BD Viper** Tip Waste Boxes, **BD Viper** Amplification Plate Sealers (Black), **BD Viper** Lysing Heater, **BD Viper** Lysing Rack, **BD Viper** Neutralization Pouches, Specimen Tubes and Caps for use on the **BD Viper** (Extracted Mode), Urine Preservative Transport for the **BD ProbeTec** Q^x Amplified DNA Assays (Q^x UPT), **BD ProbeTec** Q^x Collection Kit for Endocervical or Lesion Specimens, Male Urethral Specimen Collection Kit for the **BD ProbeTec** Q^x Amplified DNA Assays, Vaginal Specimen Transport for the **BD ProbeTec** Q^x Amplified DNA Assays, **BD ProbeTec** Accessories, Liquid-Based Cytology Specimen (LBC) Dilution Tube Caps for the **BD ProbeTec** Q^x Amplified DNA Assays, **BD Viper** Liquid-Based Cytology Specimen Rack.

Materials Required But Not Available from BD: Nitrile gloves, 3% (w/v) hydrogen peroxide*, 1% (v/v) sodium hypochlorite**, DNA *AWAY*™, *Neisseria gonorrhoeae* ATCC® 19424 (diluted in phosphate buffered saline), *Chlamydia trachomatis* ATCC VR-879 (Serovar H) or VR-902B (LGV II) (diluted in phosphate buffered saline) or Bio-Rad AmpliTrol™ CT/GC, displacement pipettes, polypropylene aerosol-resistant pipette tips capable of delivering 0.5 ± 0.05 mL, and a vortex mixer.

* Do not use hydrogen peroxide from a bottle that has remained open for longer than 8 days.
** Prepare fresh daily.

Storage and Handling Requirements: Reagents may be stored at 2 – 33 ºC. Unopened Reagent Packs are stable until the expiration date. Once a pouch is opened, the microwells are stable for 6 weeks if properly sealed or until the expiration date, whichever comes first. Do not freeze.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

Warnings and Precautions

General:

1. For *in vitro* Diagnostic Use.
2. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions" [10-13] and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.
3. For additional specific warnings, cautions and notes specific to the **BD Viper** System, consult the **BD Viper** System User's Manual.

Specimen:

4. For collection of endocervical swab specimens, use only the **BD ProbeTec** Q^x Collection Kit for Endocervical or Lesion Specimens.
5. For patient-collection and transport of vaginal swabs, use only the Vaginal Specimen Transport for the **BD ProbeTec** Q^x Amplified DNA Assays.
6. For collection of male urethral swab specimens, use only the Male Urethral Specimen Collection Kit for the **BD ProbeTec** Q^x Amplified DNA Assays.
7. For urine specimens, use only the Q^x UPT or unpreserved (neat) urine.
8. Under or over filling Specimen Tubes or the Q^x UPT with urine may affect assay performance. Over filling the tubes may also result in liquid overflow on the **BD Viper** deck, and could cause contamination.
9. For male urethral and female endocervical swab specimens, specimens must be collected and tested before the expiration date of the Q^x Swab Diluent tube.
10. For vaginal specimens, specimens must be collected and processed before the expiration date of the Vaginal Specimen Transport. Once expressed, specimens must be tested before the expiration date of the Q^x Swab Diluent tube.
11. For urine specimens, specimens must be tested before the expiration date of the Q^x UPT.
12. For liquid-based cytology specimens, use only the Liquid-Based Cytology Specimen (LBC) Dilution Tube for the **BD ProbeTec** Q^x Amplified DNA Assays.
13. Liquid-based cytology solutions contain flammable substances. Do not place specimens transferred to the LBC Specimen Dilution Tubes in the **BD Viper** Lysing Rack or the Lysing Heater. Specimens transferred to the LBC Specimen Dilution Tubes should be placed in the **BD Viper** LBC Specimen Rack.
14. For testing with the **BD ProbeTec** CT/GC Q^x Amplified DNA Assays on the **BD Viper** System in Extracted Mode, be sure to obtain aliquots of specimens collected in **BD SurePath** Preservative Fluid or PreservCyt Solution prior to processing for either the **BD SurePath** or ThinPrep Pap test. Failure to do so may result in erroneous results.
15. The **BD ProbeTec** CT/GC Q^x Amplified DNA Assays may not be used with **BD SurePath** or PreservCyt residual specimens.
16. Do not run PreservCyt specimens that have been treated with glacial acetic acid on the **BD Viper** System in Extracted Mode. Extraction Control failures or False Negative results may occur.
17. Use only polypropylene aerosol-resistant pipette tips to transfer specimens to the LBC Specimen Dilution Tubes.
18. Liquid-based cytology specimens must be tested before the expiration date of the LBC Specimen Dilution Tube.

Assay/Reagent:

19. This reagent pack is for testing endocervical and patient-collected vaginal swabs (in a clinical setting), male urethral swabs, liquid-based cytology specimens, and male and female urine specimens with the **BD Viper** System in Extracted Mode.
20. The Q^x UPT contains **NAP Guard** (approximately 742.5 mM K_2EDTA).

WARNING

H315 Causes skin irritation. **H319** Causes serious eye irritation. **H355** May cause respiratory irritation.
P280 Wear protective gloves/protective clothing/eye protection/face protection. **P264** Wash thoroughly after handling.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
P302+P352 IF ON SKIN: Wash with plenty of soap and water. **P403+P233** Store in a well-ventilated place. Keep container tightly closed. **P501** Dispose of contents/container in accordance with local/regional/national/ international regulations.

21. Use only sample and control tubes with pierceable caps on the **BD Viper** System in Extracted Mode. Do not remove pierceable caps prior to running the instrument. Be sure to replace any punctured pierceable caps with new pierceable caps prior to running the instrument.
22. Do not interchange or mix kit reagents from kits with different lot numbers.
23. The Q^x Swab Diluent for the **BD ProbeTec** Q^x Amplified DNA Assays contains dimethyl sulfoxide (DMSO). DMSO is harmful by inhalation, in contact with skin and if swallowed. Avoid contact with eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. After contact with skin, wash immediately with plenty of water.
24. Do not test the Q^x Swab Diluent tube from the Endocervical/Lesion or the Male Urethral Specimen Collection Kits if received in the laboratory without the swab present. A false negative test result may occur.
25. Use only the **BD Viper** pipette tips as supplied by BD with the **BD Viper** System.

26. The **BD Viper** Extraction Reagent and Lysis Troughs contain corrosive substances. These solutions have a strong caustic effect, and may cause severe burns to skin and mucous membranes.

    WARNING

    H302 Harmful if swallowed. **H314** Causes severe skin burns and eye damage.
    P260 Do not breathe dust/fume/gas/mist/vapours/spray. **P264** Wash thoroughly after handling. **P270** Do not eat, drink or smoke when using this product. **P280** Wear protective gloves/protective clothing/eye protection/face protection. **P301+P312** IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. **P301+P330+P331** IF SWALLOWED: rinse mouth. Do NOT induce vomiting. **P303+P361+P353** IF ON SKIN (or hair): Remove/take off immediately all contaminated clothing. Rinse skin with water/shower. **P304+P340** IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. **P305+P351+P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **P310** Immediately call a POISON CENTER or doctor/physician. **P312** Call a POISON CENTER or doctor/physician if you feel unwell. **P321** Specific treatment (see on this label). **P330** Rinse mouth. **P363** Wash contaminated clothing before reuse. **P405** Store locked up. **P501** Dispose of contents/container in accordance with local/regional/national/international regulations.
27. Use **only the BD Viper** Amplification Plate Sealers (Black) on the Amplification plates with the **BD Viper** System. Using the clear sealers for sealing the Amplification plates may cause erroneous results.
28. Reagent pouches containing unused Priming Microwells and Amplification Microwells MUST be carefully resealed after opening. Verify that desiccant is present prior to resealing the reagent pouches.
29. Because the CT/GC Q^x Positive control is used for both CT Q^x and GC Q^x testing, correct positioning of the microwell strips is important for final results reporting.
30. The plate containing the Amplification Microwells MUST be properly sealed with the **BD Viper** Amplification Plate Sealer (Black) prior to moving the plate from the **BD Viper** System. Sealing ensures a closed reaction for amplification and detection and is necessary to avoid contamination of the instrument and work area with amplification products. **Do not remove sealing material from microwells at any time.**
31. Priming Microwells with residual fluid (after transfer of liquid from the Priming Microwells to the Amplification Microwells) represent a source of target contamination. Carefully seal Priming Microwells with plate sealer prior to disposal.
32. To prevent contamination of the work environment with amplification products, use the disposal bags provided in the Accessory kit to dispose of tested Amplification Microwells. Make sure the bags are properly closed before disposal.
33. Although dedicated work areas are not required because the **BD Viper** design reduces the possibility of amplicon contamination in the testing environment, other precautions for controlling contamination, particularly to avoid contamination of specimens during manipulation, are necessary.
34. CHANGE GLOVES if they come in contact with specimen or appear to be wet, to avoid contaminating other specimens. Change gloves before leaving work area and upon entry into work area.
35. In the event of contamination of the work area or equipment with specimens or controls, thoroughly clean the contaminated area with 3% (w/v) hydrogen peroxide (do not use hydrogen peroxide from a bottle that has remained open for longer than 8 days), 1% (v/v) sodium hypochlorite, or DNA *AWAY* and rinse thoroughly with water. Allow surface to dry completely before proceeding.
36. In case of a spill on the **BD Viper** Lysing Rack, immerse the rack in 1% (v/v) sodium hypochlorite for 1 - 2 min. Do not exceed 2 min. Thoroughly rinse the rack with water and allow to air dry.
37. Clean the entire work area – counter tops and instrument surfaces – with 3% (w/v) hydrogen peroxide (do not use hydrogen proxide from a bottle that has remained open for longer than 8 days), 1% (v/v) sodium hypochlorite, or DNA *AWAY* on a daily basis. Thoroughly rinse with water. Allow surfaces to dry completely before proceeding with additional testing.
38. Contact BD Technical Service and Support in the event of an unusual situation, such as a spill into the **BD Viper** instrument or DNA contamination that cannot be removed by cleaning.
39. Acid and Base spill kits should be on hand in the event of a spill of extraction reagents.

SWAB SPECIMEN COLLECTION, STORAGE AND TRANSPORT

For swab specimens, performance data in this package insert have been established with the **BD ProbeTec** collection kits listed. Performance with collection devices other than those listed has not been evaluated.

- **BD ProbeTec** Q^x Collection Kit for Endocervical or Lesion Specimens.
- Vaginal Specimen Transport for the **BD ProbeTec** Q^x Amplified DNA Assays.
- Male Urethral Specimen Collection Kit for the **BD ProbeTec** Q^x Amplified DNA Assays.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

Swab Specimen Collection

Endocervical Swab Specimen Collection using BD ProbeTec Q^x Collection Kit for Endocervical or Lesion Specimens.

1. Remove the cleaning swab from packaging.
2. Using the polyester fiber-tipped cleaning swab with the white shaft, remove excess blood and mucus from the cervical os.
3. Discard the used cleaning swab.
4. Remove the pink collection swab from packaging.
5. Insert the collection swab into the cervical canal and rotate for 15 – 30 s.
6. Withdraw the swab carefully. Avoid contact with the vaginal mucosa.
7. Uncap the Q^x Swab Diluent tube.
8. Fully insert the collection swab into the Q^x Swab Diluent tube.
9. Break the shaft of the swab at the score mark. Use care to avoid splashing of contents.
10. **Tightly** recap the tube.
11. Label the tube with patient information and date/time collected.
12. Transport to laboratory.

Vaginal Swab Patient-Collection Procedure using Vaginal Specimen Transport for the BD ProbeTec Q^x Amplified DNA Assays.

NOTE: Ensure that patients read the Patient Collection Instructions before providing them with a collection kit.

1. Wash hands with soap and water. Rinse and dry.
2. It is important to maintain a comfortable balance during the collection procedure.
3. Twist the cap to break the seal. Pull the cap with attached swab from the tube. Do not touch the soft tip or lay the swab down. If you touch or drop the swab tip or the swab is laid down, discard the swab and request a new vaginal swab.
4. Hold the swab by the cap with one hand so that the swab tip is pointing toward you.
5. With your other hand, gently spread the skin outside the vagina. Insert the tip of the swab into the vaginal opening. Point the tip toward your lower back and relax your muscles.
6. Gently slide the swab no more than 2 inches into the vagina. If the swab does not slide easily, gently rotate the swab as you push. If it is still difficult, do not attempt to continue. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab.
7. Rotate the swab for 10 – 15 s.
8. Withdraw the swab without touching the skin. Place the swab in the tube and cap securely.
9. After collection, wash hands with soap and water, rinse, and dry.
10. Return the tube with the swab to the nurse or clinician as instructed.
11. Label with patient information and date/time collected.
12. Transport to laboratory.

Male Urethral Swab Specimen Collection using Male Urethral Specimen Collection Kit for the BD ProbeTec Q^x Amplified DNA Assays.

1. Remove the swab from packaging.
2. Insert the swab 2 – 4 cm into the urethra and rotate for 3 – 5 s.
3. Withdraw the swab.
4. Uncap the Q^x Swab Diluent tube.
5. Fully insert the collection swab into the Q^x Swab Diluent tube.
6. Break the shaft of the swab at the score mark. Use care to avoid splashing of contents.
7. Tightly recap the tube.
8. Label the tube with patient information and date/time collected.
9. Transport to laboratory.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

Swab Storage and Transport

Table 1 provides instructions for storage and transport conditions to the laboratory and/or test site for swab specimens. The endocervical and the male urethral swab specimens must be stored and transported to the laboratory and/or test site within 30 days after collection if kept at 2 – 30 ºC or within 180 days after collection if kept frozen at -20 ºC. Patient-collected vaginal swab specimens must be stored and transported to the laboratory and/or test site within 14 days after collection if kept at 2 – 30 ºC or within 180 days after collection if kept frozen at -20 ºC.

Patient-collected vaginal swab specimens that are expressed in Q^x Swab Diluent may be stored and processed within 30 days after expression if kept at 2 – 30 ºC or within 180 days after the date of expression if kept frozen at -20 °C.

Table 1: Swab Specimen Storage and Transport

SWAB SPECIMEN TYPE TO BE PROCESSSED	FEMALE ENDOCERVICAL SWAB SPECIMEN/MALE URETHRAL SWAB SPECIMEN		VAGINAL SWAB SPECIMEN			
			DRY VAGINAL SWAB SPECIMEN (COLLECTION SITE)		EXPRESSED VAGINAL SWAB SPECIMEN (TEST SITE)	
Temperature Condition for Transport to Test Site and Storage	2 – 30 °C	-20 °C	2 – 30 °C	-20 °C	2 – 30 °C	-20 °C
Process Specimen According to Instructions	Within 30 days of collection	Within 180 days of collection	Express and process within 14 days of collection	Express and process within 180 days of collection	Within 30 days of expression	Within 180 days of expression

For U.S. and international shipments, specimens should be labeled in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and etiologic agents/infectious substances. Time and temperature conditions for storage must be maintained during transport.

URINE SPECIMEN COLLECTION, STORAGE AND TRANSPORT

For urine specimens, performance has been established with the Q^x UPT and with urine collected in a sterile, plastic, preservative-free, specimen collection cup (i.e., neat urine without preservatives). Performance with other collection methods and collection devices has not been established.

Urine Specimen Collection

1. The patient should not have urinated for at least 1 h prior to specimen collection.
2. Collect the specimen in a sterile, preservative-free specimen collection cup.
3. The patient should collect the first 20 – 60 mL of voided urine (the first part of the stream – NOT midstream) into a urine collection cup.
4. Cap and label with patient identification and date/time collected.

Urine Transfer to Q^x UPT

NOTE: Urine specimens should be transferred from the collection cup to the Q^x UPT within 8 h of collection if the urine specimen has been stored at 2 – 30 °C. Urine specimens stored at 2 – 8 °C can be held up to 24 h prior to transfer to the Q^x UPT.

Wear clean gloves when handling the Q^x UPT tube and urine specimen. If gloves come in contact with the specimen, immediately change them to prevent contamination of other specimens.

1. Open the Q^x UPT Collection and Transport Kit and remove the Q^x UPT and transfer pipette from their packaging.
2. Label the Q^x UPT with the patient identification and date/time collected.
3. Hold the Q^x UPT upright and firmly tap the bottom of the tube on a flat surface to dislodge any large drops from inside the cap. Repeat if necessary.
4. Uncap the Q^x UPT and use the transfer pipette to dispense urine into the tube. The correct volume of urine has been added when the fluid level is between the purple lines on the fill window located on the Q^x UPT label. This volume corresponds to approximately 2.0 – 3.0 mL of urine. DO NOT overfill or under fill the tube.
5. Discard the transfer pipette in a biohazard waste container.

   NOTE: The transfer pipette is intended for use with a single specimen.

6. Tighten the cap securely on the Q^x UPT.
7. Invert the Q^x UPT 3 – 4 times to ensure that the specimen and reagent are well mixed.

Q^x UPT Urine Storage and Transport

Store and transport Q^x UPT urine specimens at 2 – 30 °C and pre-warm them within 30 days of transfer to the Q^x UPT. Specimens may be stored in the Q^x UPT at -20 ºC for up to 180 days prior to pre-warming.

Neat Urine Storage and Transport

Store and transport neat urine specimens from the collection site to the test site at 2 – 8 °C and pre-warm them within 7 days of collection. Neat urine stored at 2 – 30 °C must be pre-warmed within 30 h of collection. Neat urine specimens may also be stored frozen at -20 °C for up to 180 days prior to pre-warming.

Table 2: Urine Specimen Storage and Transport

Urine Specimen Type to be Processed	**Q^x UPT**			**NEAT**		
Urine Handling Options Prior To Transfer to Q^x UPT	Store urine specimen 2 – 30 °C and transfer to Q^x UPT within 8 h of collection or Store urine specimen 2 – 8 °C and transfer to Q^x UPT within 24 h of collection or Transfer to Q^x UPT immediately					
Process Specimen According to Instructions	2 – 8 °C	2 – 30 °C	-20 °C	2 – 8 °C	2 – 30 °C	-20 °C
Process and Test Specimen According to Instructions	Within 30 days after transfer to Q^x UPT		Within 180 days after transfer to Q^x UPT	Within 7 days of collection	Within 30 hours of collection	Within 180 days of collection

LBC SPECIMEN COLLECTION, STORAGE AND TRANSPORT

BD SurePath or PreservCyt specimens must be collected using either an endocervical broom or a brush/spatula combination as described in the **BD SurePath** or PreservCyt product insert. Once collected, **BD SurePath** or PreservCyt specimens can be stored and transported in their original vials for up to 30 days at 2 – 30 °C prior to transfer to LBC Specimen Dilution Tubes.

Specimen Transfer to LBC Specimen Dilution Tubes

A 0.5 mL aliquot of either the **BD SurePath** or PreservCyt specimen must be transferred from the original vial to the LBC Specimen Dilution Tube prior to processing for either the **BD SurePath** or ThinPrep Pap test. Wear gloves when handling the LBC Specimen Dilution Tube and the **BD SurePath** or PreservCyt specimen vial. If gloves come in contact with the specimen, immediately change them to prevent contamination of other specimens.

BD SurePath Specimen Transfer

NOTE: Refer to the BD PrepStain Slide Processor Product Insert for instructions on removing an aliquot from the BD SurePath specimen vial prior to performing the BD SurePath liquid-based Pap test.

1. Label an LBC Specimen Dilution Tube with patient identification information.
2. Remove the cap from the LBC Specimen Dilution Tube.
3. Transfer 0.5 mL from the specimen vial to the LBC Specimen Dilution Tube. Avoid pipetting fluid from the bottom of the vial. Discard pipette tip.

   NOTE: A separate pipette tip must be used for each specimen.
4. Tighten the cap on the LBC Specimen Dilution Tube securely.
5. Invert the LBC Specimen Dilution Tube 3 – 4 times to ensure that the specimen and diluent are well mixed.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

PreservCyt Specimen Transfer

NOTE: **Refer to the ThinPrep 2000/3000 System Operator's Manual Addendum for instructions on removing an aliquot from the PreservCyt specimen vial prior to performing the ThinPrep Pap test.**

1. Label an LBC Specimen Dilution Tube with patient identification information.
2. Remove the cap from the LBC Specimen Dilution Tube.
3. Transfer 0.5 mL from the specimen vial to the LBC Specimen Dilution Tube. Avoid pipetting fluid from the bottom of the vial. Discard pipette tip.

   NOTE: A separate pipette tip must be used for each specimen.
4. Tighten the cap on the LBC Specimen Dilution Tube securely.
5. Invert the LBC Specimen Dilution Tube 3 – 4 times to ensure that the specimen and diluent are well mixed.

Storage and Transport of Specimens Transferred to the LBC Specimen Dilution Tubes

After transfer to an LBC Specimen Dilution Tube, the diluted specimen can be stored at 2 – 30 °C for up to 30 days. Diluted specimens may also be stored at -20 °C for up to 90 days.

SWAB SPECIMEN PROCESSING

Processing procedure for the BD ProbeTec Q^x Collection Kit for Endocervical or Lesion Specimens or the Male Urethral Specimen Collection Kit for the BD ProbeTec Q^x Amplified DNA Assays

NOTE: If specimens are refrigerated or frozen, make sure they are brought to room temperature and mixed by inversion prior to proceeding.

1. Using the tube layout report, place the Q^x Swab Diluent Tube with **black pierceable cap** in order in the **BD Viper** Lysing Rack and lock into place.
2. Repeat step 1 for additional swab specimens.
3. Specimens are ready to be pre-warmed.
4. **Change gloves** before proceeding to avoid contamination.

Processing procedure for the Vaginal Specimen Transport for the BD ProbeTec Q^x Amplified DNA Assays

NOTE: Wear clean gloves when handling the vaginal swab specimen. If gloves come in contact with specimen, immediately change them to prevent contamination of other specimens.

NOTE: If specimens are refrigerated or frozen, make sure they are brought to room temperature prior to expression.

1. Label a pre-filled **BD ProbeTec** Q^x Swab Diluent tube for each swab specimen to be processed.
2. Remove the cap and insert the swab specimen into the Q^x Swab Diluent. Mix by swirling the swab in the Q^x Swab Diluent for 5 – 10 s.
3. Express the swab along the inside of the tube so that liquid runs back into the bottom of the tube.
4. Remove the swab carefully from the Q^x Swab Diluent tube to avoid splashing.
5. Place the expressed swab back into the transport tube and discard with biohazardous waste.
6. Tightly recap the Q^x Swab Diluent tube with the **black pierceable cap**.
7. Repeat steps 1 – 6 for additional swab specimens.
8. Using the tube layout report, place the tube in order in the **BD Viper** Lysing Rack and lock into place.
9. Specimens are ready to be pre-warmed.
10. **Change gloves** before proceeding to avoid contamination.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

URINE SPECIMEN PROCESSING

NOTE: If specimens are refrigerated or frozen, make sure they are brought to room temperature and mixed by inversion prior to proceeding.

Processing procedure for the Q^x UPT

1. Make sure the urine volume in each Q^x UPT tube falls between the lines indicated on the tube label. Under or over filling the tube may affect assay performance. Over filling the tube may also result in liquid overflow on the **BD Viper** deck, and could cause contamination.
2. Make sure the Q^x UPT tube has a **black pierceable cap**.
3. Repeat steps 1 and 2 for additional Q^x UPT tube specimens.
4. Using the tube layout report, place the Q^x UPT tube in order in the **BD Viper** Lysing Rack and lock into place.
5. Specimens are ready to be pre-warmed.
6. **Change gloves** before proceeding to avoid contamination.

Processing procedure for unpreserved (Neat) urine specimens

NOTE: Wear clean gloves when handling the urine specimen. If gloves come in contact with specimen, immediately change them to prevent contamination of other specimens.

1. Label a Specimen Tube for use on the **BD Viper** System (Extracted Mode) with the patient identification and date/time collected.
2. Swirl the urine cup to mix the urine specimen and open carefully.

   NOTE: Open carefully to avoid spills which may contaminate gloves or the work area.
3. Uncap the tube and use a pipette to transfer the urine specimen into the tube. The correct volume of urine has been added when the fluid level is between the purple lines on the fill window located on the label. This volume corresponds to approximately 2.0 – 3.0 mL of urine. DO NOT overfill or under fill the tube.
4. Tighten a **black pierceable cap** securely on each tube.
5. Repeat steps 1 through 4 for each urine specimen. Use a new pipette or pipette tip for each sample.
6. Using the tube layout report, place the neat urine specimens in order in the **BD Viper** Lysing Rack and lock into place.
7. Specimens are ready to be pre-warmed.
8. **Change gloves** before proceeding to avoid contamination.

NOTE: The pre-warm step must be started within 30 h of collection if the urine has been stored at 2 – 30 °C; within 7 days of collection if stored at 2 – 8 °C; or within 180 days if stored frozen at -20 °C.

PROCESSING PROCEDURE FOR LBC SPECIMENS TRANSFERRED TO THE LBC SPECIMEN DILUTION TUBES

NOTE: Do not place specimens transferred to the LBC Specimen Dilution Tubes in the BD Viper Lysing Rack or the BD Viper Lysing Heater. Specimens transferred to the LBC Specimen Dilution Tubes should be placed in the BD Viper LBC Specimen Rack.

NOTE: If specimens are frozen, make sure they are thawed completely at room temperature and mixed by inversion prior to proceeding.

1. Make sure the LBC Specimen Dilution Tube has a blue pierceable cap.
2. Using the tube layout report, place the LBC Specimen Dilution Tube containing the specimen in order in the **BD Viper** LBC Specimen Rack and lock into place.
3. Specimens are ready to be tested on the **BD Viper** System in Extracted Mode.
4. **Change gloves** prior to proceeding to avoid contamination.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

QUALITY CONTROL

Quality control must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

The Control Set for the **BD ProbeTec** CT/GC Q^x Amplified DNA Assays is provided separately. One Positive and one Negative Control must be included in each assay run and for each new reagent kit lot number. Controls must be positioned according to the **BD Viper** Instrument User's Manual. The CT/GC Q^x Positive Control will monitor for substantial reagent failure only. The CT/GC Q^x Negative Control monitors for reagent and/or environmental contamination. Additional controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations. Refer to CLSI C24-A3 for additional guidance on appropriate internal quality control testing practices.[14] The Positive Control contains approximately 2400 copies per mL of pCTB4 and pGCint3 linearized plasmids.

The Extraction Control (EC) oligonucleotide is used to confirm the validity of the extraction process. The EC is dried in the Extraction Tubes and is re-hydrated by the **BD Viper** System upon addition of the specimen and extraction reagents. At the end of the extraction process, the EC fluorescence is monitored by the instrument and an automated algorithm is applied to both the EC and *N. gonorrhoeae*-specific signals to report specimen results as positive, negative, or EC failure.

QUALITY CONTROL PREPARATION

NOTE: Do not re-hydrate the controls prior to loading in the BD Viper Lysing Rack.

1. Using the tube layout report, place CT/GC Q^x Negative Controls into the appropriate positions in the **BD Viper** Lysing Rack.
2. Using the tube layout report, place CT/GC Q^x Positive Controls into the appropriate positions in the **BD Viper** Lysing Rack.
3. Controls are ready to be pre-warmed with the specimens, if desired.

SPECIMEN PROCESSING CONTROLS

Specimen Processing Controls may be tested in accordance with the requirements of appropriate accrediting organizations. A positive Specimen Processing Control tests the entire assay system. For this purpose, known positive specimens can serve as controls by being processed and tested in conjunction with unknown specimens. Specimens used as processing controls must be stored, processed, and tested according to the package insert instructions. If a known positive specimen is not available, additional options for Specimen Processing Controls are described below:

Preparation of Specimen Processing Controls in BD ProbeTec Q^x Swab Diluent

ATCC *Neisseria gonorrhoeae*:

1. Thaw a vial of *Neisseria gonorrhoeae* stock culture, received from ATCC and immediately inoculate a chocolate agar plate.
2. Incubate at 37 ºC in 3 – 5 % CO_2 for 24 – 48 h.
3. Resuspend colonies from the chocolate agar plate with phosphate buffered saline (PBS).
4. Dilute cells in PBS to a 1.0 McFarland turbidity standard (approximately 3 x 10^8 cells/mL).
5. Prepare 10-fold serial dilutions to a 10^{-5} dilution of the McFarland (at least 4 mL final volume) in PBS.
6. Place 0.1 mL of the 10^{-5} dilution in a **BD ProbeTec** Q^x Swab Diluent tube and tightly recap using a **black pierceable cap**.
7. Using the tube layout report, place the Specimen Processing Control(s) in order in the **BD Viper** Lysing Rack, and lock into place.
8. Process the controls according to the Pre-warming Procedure and then follow the Test Procedure.

Bio-Rad AmpliTrol - *Chlamydia trachomatis* & *Neisseria gonorrhoeae*:

NOTE: Refer to manufacturer's processing instructions.

1. Add the appropriate volume of Bio-Rad AmpliTrol CT/GC to a **BD ProbeTec** Q^x Swab Diluent tube and tightly recap using a **black pierceable cap**.
2. Mix the solution by vortexing or with inversion.
3. Using the tube layout report, place the Specimen Processing Control(s) in order in the **BD Viper** Lysing Rack and lock into place.
4. Process the controls according to the Pre-warming Procedure and then follow the Test Procedure.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

Preparation of Specimen Processing Controls in LBC Specimen Dilution Tubes
ATCC – *Neisseria gonorrhoeae*

1. Grow *N. gonorrhoeae* culture overnight on chocolate agar plates.
2. Resuspend *N. gonorrhoeae* colonies in phosphate buffered saline (PBS).
3. Prepare a McFarland #1 turbidity standard from the resuspended colonies.
4. Prepare 10-fold serial dilutions of the McFarland #1 suspension to 10^{-5}.
5. Add 0.1 mL of 10^{-5} dilution of *N. gonorrhoeae* to an LBC Specimen Dilution Tube containing 0.5 mL of **BD SurePath** Preservative Fluid or PreservCyt Solution. Tightly recap the LBC Specimen Dilution Tube using the blue pierceable cap.
6. Invert the LBC Specimen Dilution Tube 3 – 4 times to ensure that the contents are well mixed.
7. Using the tube layout report, place the Specimen Processing Control(s) in order in the **BD Viper** LBC Specimen Rack and lock into place.
8. Specimen Processing Controls are ready to be tested on the **BD Viper** System in Extracted Mode.
9. **Change gloves** prior to proceeding to avoid contamination.

ATCC – *Chlamydia trachomatis* and *Neisseria gonorrhoeae*:

1. Thaw vial of *C. trachomatis* serovar H or LGV II cells received from ATCC.
2. Prepare 10-fold serial dilutions to 10^{-5} in PBS.
3. Grow *N. gonorrhoeae* culture overnight on chocolate agar plates.
4. Resuspend *N. gonorrhoeae* colonies in PBS.
5. Prepare a McFarland #1 turbidity standard from the resuspended colonies.
6. Prepare 10-fold serial dilutions of the McFarland #1 suspension to 10^{-5}.
7. Add 0.1 mL of 10^{-5} dilution of *C. trachomatis* and 0.1 mL of 10^{-5} dilution of *N. gonorrhoeae* to an LBC Specimen Dilution Tube containing 0.5 mL of **BD SurePath** Preservative Fluid or PreservCyt Solution. Tightly recap the LBC Specimen Dilution Tube using the blue pierceable cap.
8. Invert the LBC Specimen Dilution Tube 3 – 4 times to ensure that the contents are well mixed.
9. Using the tube layout report, place the Specimen Processing Control(s) in order in the **BD Viper** LBC Specimen Rack and lock into place.
10. Specimen Processing Controls are ready to be tested on the **BD Viper** System in Extracted Mode.
11. **Change gloves** prior to proceeding to avoid contamination.

Bio-Rad AmpliTrol – *Chlamydia trachomatis* and *Neisseria gonorrhoeae*:

NOTE: Refer to manufacturer's processing instructions.

1. Add the appropriate volume of Bio-Rad AmpliTrol CT/GC to an LBC Specimen Dilution Tube containing 0.5 mL of **BD SurePath** Preservative Fluid or PreservCyt Solution. Tightly recap the LBC Specimen Dilution Tube using the blue pierceable cap.
2. Invert the LBC Specimen Dilution Tube 3 – 4 times to ensure that the contents are well mixed.
3. Using the tube layout report, place the Specimen Processing Control(s) in order in the **BD Viper** LBC Specimen Rack and lock into place.
4. Specimen Processing Controls are ready to be tested on the **BD Viper** System in Extracted Mode.
5. **Change gloves** prior to proceeding to avoid contamination.

General QC Information for the BD Viper System:

The location of the microwells is shown in a color-coded plate layout screen on the LCD Monitor. The plus symbol (+) within the microwell indicates the positive QC sample. The minus symbol (-) within the microwell indicates the negative QC sample.

A QC pair must be logged in for each reagent kit lot number and for each plate to be tested. If QC pairs have not been properly logged in, a message box appears that prevents saving the rack and proceeding with the run until complete. A maximum of two QC pairs per rack is permitted. Additional control materials may be added provided they are logged in as samples.

NOTE: **The BD Viper System will re-hydrate the controls during the assay run. Do not attempt to hydrate the assay controls prior to loading them into the BD Viper Lysing Rack.**

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

Running one plate on a BD Viper System:

The first two positions (A1 and B1) are reserved for the positive (A1) and negative (B1) controls, respectively. The first available position for a patient sample is C1.

Running two plates on a BD Viper System:

For plate one, the first two positions (A1 and B1) are reserved for the positive (A1) and negative (B1) controls, respectively. The first available position for a patient sample is C1. For plate two (full plate) the last two positions (G12 and H12) are reserved for the positive (G12) and negative (H12) controls, respectively. For plate two (partial plate) the last two positions after the last patient sample are automatically assigned as the positive and negative controls, respectively.

PRE-WARM PROCEDURE FOR SWAB AND URINE SPECIMENS

NOTE: The pre-warm procedure must be applied to all swab and urine specimens to ensure that the specimen matrix is homogenous prior to loading on the BD Viper System. Failure to pre-warm specimens may have an adverse impact on the performance of the BD ProbeTec CT/GC Q^x Assays and/or BD Viper System. Swabs and urine specimens must be pre-warmed; however, pre-warming of the controls is optional.

NOTE: Refrigerated or frozen specimens must be brought to room temperature prior to pre-warming.

1. Insert the **BD Viper** Lysing Rack into the **BD Viper** Lysing Heater.
2. Pre-warm the specimens for 15 min at 114 °C ± 2 °C.
3. Remove the Lysing Rack from the Lysing Heater and let specimens cool at room temperature for a minimum of 15 min before loading into the **BD Viper** instrument.
4. Refer to the Test Procedure for testing specimens and controls.
5. After pre-warming, specimens may be stored for 7 days at 2 – 30 °C or for 180 days at -20 °C without additional pre-warming prior to testing on the **BD Viper** System.

TEST PROCEDURE

Refer to the **BD Viper** Instrument User's Manual (Extracted Mode Operation) for specific instructions for operating and maintaining the components of the system. The optimum environmental conditions for the GC Q^x Assays were found to be 18 – 27 °C and 20 – 85% Relative Humidity.

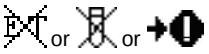
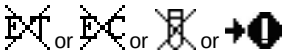
INTEPRETATION OF QUALITY CONTROL RESULTS

Interpretation of Quality Control Results:

The CT/GC Q^x Positive Control and the CT/GC Q^x Negative Control must test as positive and negative, respectively, in order to obtain patient results. If controls do not perform as expected, the run is considered invalid and patient results will not be reported by the instrument. If either of the controls does not provide the expected results, repeat the entire run using a new set of controls, new extraction tubes, new extraction reagent trough, new lysis trough and new microwells. If the repeat QC does not provide the expected results, contact BD Technical Services.

If the *N. gonorrhoeae*-specific signal is greater than or equal to a threshold of 125 Maximum Relative Fluorescent Units (MaxRFU), the EC fluorescence is ignored by the algorithm. If the *N. gonorrhoeae* -specific signal is less than a threshold of 125 MaxRFU, the EC fluorescence is utilized by the algorithm in the interpretation of the result.

Table 3: Interpretation of Quality Control Results

Control Type	Tube Result Report Symbol	GC Q^x MaxRFU	QC Disposition
GC Q^x Positive Control	OK	≥125	QC Pass
GC Q^x Positive Control		<125	QC Failure
GC Q^x Positive Control		Any value	QC Failure
GC Q^x Negative Control	OK	<125	QC Pass
GC Q^x Negative Control		≥125	QC Failure
GC Q^x Negative Control		Any value	QC Failure

Refer to the Interpretation of Test Results for a description of Tube Result Report symbols.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

INTEPRETATION OF TEST RESULTS

The **BD ProbeTec** GC Q^x Amplified DNA Assay uses fluorescent energy transfer as the detection method to test for the presence of *N. gonorrhoeae* in clinical specimens. All calculations are performed automatically by the **BD Viper** software.

The presence or absence of *N. gonorrhoeae* DNA is determined by calculating the peak fluorescence (MaxRFU) over the course of the amplification process and by comparing this measurement to a predetermined threshold value. The magnitude of the MaxRFU score is not indicative of the level of organism in the specimen. If the *N. gonorrhoeae*-specific signal is greater than or equal to a threshold of 125 MaxRFU, the EC fluorescence is ignored by the algorithm. If the *N. gonorrhoeae*-specific signal is less than a threshold of 125 MaxRFU, the EC fluorescence is utilized by the algorithm in the interpretation of the result. If assay control results are not as expected, patient results are not reported. See the Quality Control section for expected control values. Reported results are determined as follows.

Table 4: Interpretation of Test Results for GC Q^x Assays

Tube Report Result	GC Q^x MaxRFU	Report	Interpretation	Result
	≥125	*N. gonorrhoeae* plasmid DNA detected by SDA.	Positive for *N. gonorrhoeae*. *N. gonorrhoeae* organism viability and/or infectivity cannot be inferred since target DNA may persist in the absence of viable organisms.	Positive
	<125	*N. gonorrhoeae* plasmid DNA not detected by SDA.	Presumed negative for *N. gonorrhoeae*. A negative result does not preclude *N. gonorrhoeae* infection because results are dependent on adequate specimen collection, absence of inhibitors, and the presence of sufficient DNA to be detected.	Negative
	<125	Extraction control failure. Repeat test from initial specimen tube or obtain another specimen for testing.	*N. gonorrhoeae*, if present, not detectable.	Extraction Control Failure
	Any value	Extraction Transfer Failure. Repeat test from initial specimen tube or obtain another specimen for testing.	*N. gonorrhoeae*, if present, not detectable.	Extraction Transfer Failure
	Any value	Liquid Level Failure. Repeat test from initial specimen tube or obtain another specimen for testing.	*N. gonorrhoeae*, if present, not detectable.	Liquid Level Failure
	Any value	Error. Repeat test from initial specimen tube or obtain another specimen for testing.	*N. gonorrhoeae*, if present, not detectable.	Error

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

MONITORING FOR THE PRESENCE OF DNA CONTAMINATION

At least monthly, the following test procedure should be performed to monitor the work area and equipment surfaces for the presence of DNA contamination. Environmental monitoring is essential to detect contamination prior to the development of a problem.

1. For each are to be tested, use a clean collection swab from the **BD ProbeTec** Q^x Collection Kit for Endocervical or Lesion Specimens.
2. Dip the swab into the **BD ProbeTec** Q^x Swab Diluent Tube and wipe the first area* using a broad sweeping motion.
3. Fully insert the collection swab into the **BD ProbeTec** Q^x Swab Diluent tube.
4. Break the shaft of the swab at the score mark. Use care to avoid splashing of contents.
5. Tightly recap the tube using the **black pierceable cap**.
6. Repeat for each desired area.
7. After all swabs have been collected and processed according to the Pre-warming Procedure, and then follow the Test Procedure.

*Recommended areas to test include: **Instrument deck**: Pipette Tip Station Covers (2); Tube Processing Station: Tube Alignment Block and Fixed Metal Base; Deck Waste Area, Priming and Warming Heaters/ Stage; Extraction Block; Plate Sealing Tool; Tip Exchange Stations (2); **Instrument Exterior**: Upper Door Handle; Lower Door Handle; Waste Liquid Quick Release Valve; LCD Monitor (Touchscreen); Keyboard/ Scanner; Staging Area; Locking Plate and Fixed Metal Base; Accessories: Tube Lockdown cover, **BD Viper** Lysing Rack/Table Base; **BD Viper** Lysing Heater; Metal Microwell Plates; Timer; Laboratory Bench Surfaces.

If an area gives a positive result or if contamination is suspected, clean the area with fresh 1% (v/v) sodium hypochlorite, DNA *AWAY*, or 3% (w/v) hydrogen peroxide. (Do not use hydrogen peroxide from a bottle that has remained open for longer than 8 days). Make sure the entire area is wetted with the solution and allowed to remain on the surface for at least 2 min or until dry. If necessary, remove excess cleaning solution with a clean towel. Wipe the area with a clean towel saturated with water and allow the surface to dry. Retest the area. Repeat cleaning process until negative results are obtained. If the contamination does not resolve, contact BD Technical Service and Support for additional information.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

BD VIPER LT SYSTEM

PRINCIPLES OF THE PROCEDURE

The **BD ProbeTec** GC Q^x Amplified DNA Assay Gray Amp Reagent Pack is designed for use with the **BD ProbeTec** *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/GC) Q^x specimen collection and transport devices, applicable reagents, the **BD Viper** LT System and **BD FOX** Extraction. Specimens are collected and transported in their respective transport devices which preserve the integrity of *Neisseria gonorrhoeae* DNA over the specified ranges of temperature and time. All specimens undergo a pre-warm step in the **BD** Pre-warm Heater to dissolve mucus and homogenize the specimen. After cooling, the specimens are loaded onto the **BD Viper** LT System which then performs all of the steps involved in extraction and amplification of target DNA, without further user intervention.

For gynecological specimens that are collected and transported in **BD SurePath** Preservative Fluid or PreservCyt Solution, an aliquot is y transferred to a Liquid-Based Cytology Specimen (LBC) Dilution Tube for the **BD ProbeTec** Q^x Amplified DNA Assays prior to pre-warming the specimen. The specimen is transferred to an Extraction Tube that contains ferric oxide particles in a dissolvable film and dried Extraction Control. A high pH is used to lyse the bacterial cells and liberate their DNA into solution. Acid is then added to lower the pH and induce a positive charge on the ferric oxide, which in turn binds the negatively charged DNA.

The particles and bound DNA are then pulled to the sides of the Extraction Tube by magnets and the treated specimen is aspirated to waste. The particles are washed and a high pH Elution Buffer is added to recover the purified DNA. Finally, a Neutralization Buffer is used to bring the pH of the extracted solution to the optimum for amplification of the target.

The **BD ProbeTec** GC Q^x Amplified DNA Assay is based on the simultaneous amplification and detection of target DNA using amplification primers and a fluorescently-labeled detector probe.[8,9] The reagents for SDA are dried in two separate disposable microwells: the Priming Microwell contains the amplification primers, fluorescently-labeled detector probe, nucleotides and other reagents necessary for amplification, while the Gray Amplification Microwell contains the two enzymes (a DNA polymerase and a restriction endonuclease) that are required for SDA. The **BD Viper** LT System pipettes a portion of the purified DNA solution from each Extraction Tube into a Priming Microwell to rehydrate the contents. After a brief incubation, the reaction mixture is transferred to a corresponding, pre-warmed Gray Amplification Microwell which is sealed to prevent contamination and then incubated in a thermally controlled fluorescent reader. The presence or absence of *N. gonorrhoeae* DNA is determined by calculating the peak fluorescence (Maximum Relative Fluorescent Units [MaxRFU]) over the course of the amplification process and by comparing this measurement to a predetermined threshold value.

In addition to the fluorescent probe used to detect amplified *N. gonorrhoeae* target DNA, a second fluorescently labeled oligonucleotide is incorporated in each reaction. The Extraction Control (EC) oligonucleotide is labeled with a different dye than that used for detection of the *N. gonorrhoeae*-specific target and is used to confirm the validity of the extraction process. The EC is dried in the Extraction Tubes and is re-hydrated upon addition of the specimen and extraction reagents. At the end of the extraction process, the EC fluorescence is monitored by the **BD Viper** LT instrument and an automated algorithm is applied to both the EC and *N. gonorrhoeae*-specific signals to report specimen results as positive, negative, or EC failure.

REAGENTS

Each **BD ProbeTec** GC Q^x Assay Gray Amp Reagent Pack contains:

- GC Q^x Amplified DNA Assay Priming Microwells, 12 x 96: each Priming Microwell contains approximately 30 pmol oligonucleotides, 45 pmol fluorescently-labeled detector probe, 100 nmol dNTPs, with stabilizers and buffer components.
- GC Q^x Amplified DNA Assay Gray Amplification Microwells, 12 x 96: each Amplification Microwell contains approximately 14 units DNA polymerase and 50 units restriction enzyme, with stabilizers and buffer components.

NOTE: Each microwell pouch contains one desiccant bag.

MATERIALS REQUIRED BUT NOT PROVIDED:

Control Set for the **BD ProbeTec** CT/GC Q^x Amplified DNA Assays: 24 CT/GC Q^x Positive Control Tubes containing approximately 2400 copies each of pCTB4 and pGCint3 linearized plasmids in carrier nucleic acid, and 24 CT/GC Q^x Negative Control Tubes containing carrier nucleic acid alone. The concentrations of the pCTB4 and pGCint3 plasmids are determined by UV spectrophotometry.

Swab Diluent for the **BD ProbeTec** Q^x Amplified DNA Assays (Q^x Swab Diluent): 48 tubes each containing approximately 2 mL of potassium phosphate/potassium hydroxide buffer with DMSO and preservative.

Liquid Based Cytology Specimen (LBC) Dilution Tubes for the **BD ProbeTec** Q^x Amplified DNA Assays (LBC Specimen Dilution Tube): 400 tubes each containing approximately 1.7 mL of Tris/Sodium Chloride solution and preservative.

BD FOX Extraction Tubes: 48 strips of 8 tubes, each containing approximately 10 mg of iron oxide in a dissolvable film and approximately 240 pmol fluorescently labeled Extraction Control oligonucleotide.

BD Viper SDA Extraction Reagent Trough with Piercing Tool: 5-cavity Extraction Reagent trough contains approximately 11.5 mL Lysis Reagent, 16.5 mL Binding Acid, 72.5 mL Wash Buffer, 25.4 mL Elution Buffer, and 19.4 mL Neutralization Buffer with preservative.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

INSTRUMENT, EQUIPMENT AND SUPPLIES

Materials Available from BD: **BD Viper** LT Instrument, **BD Viper** Instrument Plates, **BD Viper** LT Amplification Plate Carriers, **BD Viper** LT Pipette Tips, **BD Viper** LT Solid Waste Liners, **BD Viper** LT Waste Bottle, **BD Viper** LT Clear Plate Sealers, **BD Viper** Black Plate Sealers, **BD** Pre-warm Heater, **BD Viper** LT Specimen Rack, **BD Viper** LT Extraction Rack, **BD Viper** Neutralization Pouches, Specimen Tubes and Caps for use on the **BD Viper** System (Extracted Mode), Urine Preservative Transport for the **BD ProbeTec** Q^x Amplified DNA Assays (Q^x UPT), **BD ProbeTec** Q^x Collection Kit for Endocervical or Lesion Specimens, Male Urethral Specimen Collection Kit for the **BD ProbeTec** Q^x Amplified DNA Assays, Vaginal Specimen Transport for the **BD ProbeTec** Q^x Amplified DNA Assays, **BD Viper** LT System SDA Accessory Kit.

Materials Required But Not Available from BD: Nitrile gloves, 3% (w/v) hydrogen peroxide*, 1% (v/v) sodium hypochlorite**, DNA *AWAY*, *Neisseria gonorrhoeae* ATCC 19424 (diluted in phosphate buffered saline) or Bio-Rad AmpliTrol CT/GC, displacement pipettes, polypropylene aerosol-resistant pipette tips capable of delivering 0.5 ± 0.05 mL, molecular biology nuclease- free water, and a vortex mixer.

* Do not use hydrogen peroxide from a bottle that has remained open for longer than 8 days.

** Prepare fresh daily.

Storage and Handling Requirements: Reagents may be stored at 2 - 33 ºC. Unopened Reagent Packs are stable until the expiration date. Once a pouch is opened, the microwells are stable for 6 weeks if properly sealed or until the expiration date, whichever comes first. Do not freeze.

WARNINGS AND PRECAUTIONS

General:

1. For *in vitro* Diagnostic Use.
2. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions"[10-13] and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.
3. For additional specific warnings, cautions and notes specific to the **BD Viper** LT, consult the **BD Viper** LT System User's Manual.

Specimen:

4. For collection of endocervical swab specimens, use only the **BD ProbeTec** Q^x Collection Kit for Endocervical or Lesion Specimens.
5. For patient-collection and transport of vaginal swabs, use only the Vaginal Specimen Transport for the **BD ProbeTec** Q^x Amplified DNA Assays.
6. For collection of male urethral swab specimens, use only the Male Urethral Specimen Collection Kit for the **BD ProbeTec** Q^x Amplified DNA Assays.
7. For urine specimens, use only the Q^x UPT or unpreserved (neat) urine.
8. Under or over dispensing of urine into Specimen Tubes or the Q^x UPT may affect assay performance. Over filling the tube may also result in liquid overflow on the **BD Viper** LT deck, and could cause contamination.
9. For male urethral and female endocervical swab specimens, specimens must be collected and tested before the expiration date of the Q^x Swab Diluent tube.
10. For vaginal specimens, specimens must be collected and processed before the expiration date of the Vaginal Specimen Transport. Once expressed, specimens must be tested before the expiration date of the Q^x Swab Diluent tube.
11. For urine specimens, specimens must be tested before the expiration date of the Q^x UPT.
12. For liquid-based cytology specimens, use only the Liquid Based Cytology Specimen (LBC) Dilution Tube for the **BD ProbeTec** Q^x Amplified DNA Assays.
13. Liquid-based cytology solutions contain flammable substances.
14. For testing with the **BD ProbeTec** CT/GC Q^x Amplified DNA Assay on the **BD Viper** LT System, be sure to obtain aliquots of specimens collected in **BD SurePath** Preservative Fluid or PreservCyt Solution prior to processing for either the **BD SurePath** or ThinPrep Pap test. Failure to do so may result in erroneous results.
15. The **BD ProbeTec** CT/GC Q^x Amplified DNA Assay may not be used with **BD SurePath** or PreservCyt residual specimens.
16. Do not run PreservCyt specimens that have been treated with glacial acetic acid on the **BD Viper** LT System. Extraction Control failures or False Negative results may occur.
17. Use only polypropylene aerosol-resistant pipette tips to transfer specimens to the LBC Specimen Dilution Tube.
18. Liquid-based cytology specimens must be tested before the expiration date of the LBC Specimen Dilution Tube.
19. Specimens should not be pre-warmed more than two times.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

Assay/Reagent:

20. This reagent pack is for testing endocervical and patient-collected vaginal swabs (in a clinical setting), male urethral swabs male and female urine specimens, and **BD SurePath** and PreservCyt specimens with the **BD Viper** LT System.
21. The Q^x UPT contains **NAP Guard** (approximately 742.5 mM K_2EDTA).

    WARNING

    H315 Causes skin irritation. **H319** Causes serious eye irritation. **H355** May cause respiratory irritation.
    P280 Wear protective gloves/protective clothing/eye protection/face protection. **P264** Wash thoroughly after handling.
    P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
    P302+P352 IF ON SKIN: Wash with plenty of soap and water. **P403+P233** Store in a well-ventilated place. Keep container tightly closed. **P501** Dispose of contents/container in accordance with local/regional/national/ international regulations.
22. Use only sample and control tubes with pierceable caps on the **BD Viper** LT System. Do not remove pierceable caps prior to running the instrument. Be sure to replace any punctured pierceable caps with new pierceable caps prior to running the instrument.
23. Do not interchange or mix kit reagents from kits with different lot numbers.
24. The Q^x Swab Diluent for the **BD ProbeTec** Q^x Amplified DNA Assays contains dimethyl sulfoxide (DMSO). DMSO is harmful by inhalation, in contact with skin and if swallowed. Avoid contact with eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. After contact with skin, wash immediately with plenty of water.
25. Do not test the Q^x Swab Diluent tube from the Endocervical/Lesion or the Male Urethral Specimen Collection Kits if received in the laboratory without the swab present. A false negative test result may occur.
26. Use only the **BD Viper** LT pipette tips as supplied by BD with the **BD Viper** LT System.
27. Use only Gray Amp Microwells as supplied in the **BD ProbeTec** GC Q^x Assay Gray Amp Reagent Pack with the **BD Viper** LT System.
28. Use only the **BD Viper** SDA Extraction Reagent Trough with Piercing Tool with the **BD ProbeTec** *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay Gray Amp Reagent Pack on the **BD Viper** LT System.
29. The **BD Viper** SDA Extraction Reagent Trough and Piercing Tool contains corrosive substances. These solutions have a strong caustic effect, and may cause severe burns to skin and mucous membranes.

    DANGER

    H302 Harmful if swallowed. **H314** Causes severe skin burns and eye damage.
    P260 Do not breathe dust/fume/gas/mist/vapors/spray. **P280** Wear protective gloves/protective clothing/eye protection/face protection. **P303+P361+P353** IF ON SKIN (or hair): Remove/take off immediately all contaminated clothing. Rinse skin with water/shower. **P304+P340** IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
    P405 Store locked up. **P501** Dispose of contents/container in accordance with local/regional/national/international regulations.
30. Use only the Clear Plate Seals from the **BD Viper** LT System SDA Accessory Kit on the Gray Amp plates with the **BD Viper** LT System. Using other seals for sealing the Gray Amp plates may cause erroneous results.
31. Reagent pouches containing unused Priming Microwells and Amplification Microwells MUST be carefully resealed after opening. Verify that desiccant is present prior to resealing the reagent pouches.
32. Because the CT/GC Q^x Positive Control is used for both CT Q^x and GC Q^x testing, correct positioning of the microwell strips is important for final results reporting.
33. The plate containing the Gray Amp Microwells MUST be properly sealed with the **BD Viper** LT Clear Plate Sealer prior to moving the plate from the **BD Viper** LT System. Sealing ensures a closed reaction for amplification and detection and is necessary to avoid contamination of the instrument and work area with amplification products. Do not remove sealing material from microwells at any time.
34. Priming Microwells with residual fluid (after transfer of liquid from the Priming Microwells to the Gray Amp Microwells) represent a source of target contamination. Carefully seal Priming Microwells with **BD Viper** Black Plate Sealers prior to disposal.
35. To prevent contamination of the work environment with amplification products, use the disposal bags provided in the **BD Viper** LT System SDA Accessory Kit to dispose of tested Amplification Microwells. Make sure the bags are properly closed before disposal.
36. Although dedicated work areas are not required because the **BD Viper** LT design reduces the possibility of amplicon contamination in the testing environment, other precautions for controlling contamination, particularly to avoid contamination of specimens during manipulation, are necessary.
37. CHANGE GLOVES if they come in contact with specimen or appear to be wet, to avoid contaminating other specimens. Change gloves before leaving work area and upon entry into work area.
38. In the event of contamination of the work area or equipment with specimens or controls, thoroughly clean the contaminated area with 3% (w/v) hydrogen peroxide (do not use hydrogen peroxide from a bottle that has remained open for longer than 8 days), 1% (v/v) sodium hypochlorite, or DNA *AWAY* and rinse thoroughly with water. Allow surface to dry completely before proceeding.
39. In case of a spill on the **BD Viper** LT Specimen Rack, immerse the rack in 1% (v/v) sodium hypochlorite for 1 – 2 min. Do not exceed 2 min. Thoroughly rinse the rack with water and allow to air dry.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

40. Clean the entire work area including counter tops with 1% (v/v) sodium hypochlorite on a daily basis. Thoroughly rinse with water. Allow surfaces to dry completely before proceeding with additional testing. Clean instrument surfaces with 3% hydrogen peroxide only – sodium hypochlorite can damage the electronics located under the deck of the **BD Viper** LT instrument.
41. Contact BD Technical Service and Support in the event of an unusual situation, such as a spill into the **BD Viper** LT instrument or DNA contamination that cannot be removed by cleaning.
42. Acid and Base spill kits should be on hand in the event of a spill of extraction reagents.

SWAB SPECIMEN COLLECTION, STORAGE AND TRANSPORT

For swab specimens, performance data in this package insert have been established with the **BD ProbeTec** collection kits listed. Performance with collection devices other than those listed has not been evaluated.

- **BD ProbeTec** Q^x Collection Kit for Endocervical or Lesion Specimens.
- Vaginal Specimen Transport for the **BD ProbeTec** Q^x Amplified DNA Assays.
- Male Urethral Specimen Collection Kit for the **BD ProbeTec** Q^x Amplified DNA Assays.

Swab Specimen Collection

Endocervical Swab Specimen Collection using BD ProbeTec Q^x Collection Kit for Endocervical or Lesion Specimens.

1. Remove the cleaning swab from packaging.
2. Using the polyester fiber-tipped cleaning swab with the white shaft, remove excess blood and mucus from the cervical os.
3. Discard the used cleaning swab.
4. Remove the pink collection swab from packaging.
5. Insert the collection swab into the cervical canal and rotate for 15 – 30 s.
6. Withdraw the swab carefully. Avoid contact with the vaginal mucosa.
7. Uncap the Q^x Swab Diluent tube.
8. Fully insert the collection swab into the Q^x Swab Diluent tube.
9. Break the shaft of the swab at the score mark. Use care to avoid splashing of contents.
10. **Tightly** recap the tube.
11. Label the tube with patient information and date/time collected.
12. Transport to laboratory.

Vaginal Swab Patient-Collection Procedure using Vaginal Specimen Transport for the BD ProbeTec Q^x Amplified DNA Assays.

NOTE: Ensure that patients read the Patient Collection Instructions before providing them with a collection kit.

1. Wash hands with soap and water. Rinse and dry.
2. It is important to maintain a comfortable balance during the collection procedure.
3. Twist the cap to break the seal. Pull the cap with attached swab from the tube. Do not touch the soft tip or lay the swab down. If you touch or drop the swab tip or the swab is laid down, discard the swab and request a new vaginal swab.
4. Hold the swab by the cap with one hand so that the swab tip is pointing toward you.
5. With your other hand, gently spread the skin outside the vagina. Insert the tip of the swab into the vaginal opening. Point the tip toward your lower back and relax your muscles.
6. Gently slide the swab no more than 2 inches into the vagina. If the swab does not slide easily, gently rotate the swab as you push. **If it is still difficult, do not attempt to continue**. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab.
7. Rotate the swab for 10 – 15 s.
8. Withdraw the swab without touching the skin. Place the swab in the tube and cap securely.
9. After collection, wash hands with soap and water, rinse, and dry.
10. Return the tube with the swab to the nurse or clinician as instructed.
11. Label with patient information and date/time collected.
12. Transport to laboratory.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

Male Urethral Swab Specimen Collection using Male Urethral Specimen Collection Kit for the BD ProbeTec Q^x Amplified DNA Assays.

1. Remove the swab from packaging.
2. Insert the swab 2 – 4 cm into the urethra and rotate for 3 – 5 s.
3. Withdraw the swab.
4. Uncap the Q^x Swab Diluent tube.
5. Fully insert the collection swab into the Q^x Swab Diluent tube.
6. Break the shaft of the swab at the score mark. Use care to avoid splashing of contents.
7. Tightly recap the tube.
8. Label the tube with patient information and date/time collected.
9. Transport to laboratory.

Swab Storage and Transport

Table 17 provides instructions for storage and transport conditions to the laboratory and/or test site for swab specimens. The endocervical and the male urethral swab specimens must be stored and transported to the laboratory and/or test site within 30 days after collection if kept at 2 – 30 ºC or within 180 days after collection if kept frozen at -20 ºC. Patient-collected vaginal swab specimens must be stored and transported to the laboratory and/or test site within 14 days after collection if kept at 2 – 30 ºC or within 180 days after collection if kept frozen at -20 ºC. Patient-collected vaginal swab specimens that are expressed in Q^x Swab Diluent may be stored and processed within 30 days after expression if kept at 2 – 30 ºC or within 180 days after the date of expression if kept frozen at -20 °C.

Table 17: Swab Specimen Storage and Transport

SWAB SPECIMEN TYPE TO BE PROCESSSED	FEMALE ENDOCERVICAL SWAB SPECIMEN/MALE URETHRAL SWAB SPECIMEN		VAGINAL SWAB SPECIMEN			
			DRY VAGINAL SWAB SPECIMEN (COLLECTION SITE)		EXPRESSED VAGINAL SWAB SPECIMEN (TEST SITE)	
Temperature Condition for Transport to Test Site and Storage	2 – 30 °C	-20 °C	2 – 30 °C	-20 °C	2 – 30 °C	-20 °C
Process Specimen According to Instructions	Within 30 days of collection	Within 180 days of collection	Express and process within 14 days of collection	Express and process within 180 days of collection	Within 30 days of expression	Within 180 days of expression

For U.S. and international shipments, specimens should be labeled in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and etiologic agents/infectious substances. Time and temperature conditions for storage must be maintained during transport.

URINE SPECIMEN COLLECTION, STORAGE AND TRANSPORT

For urine specimens, performance has been established with the Q^x UPT and with urine collected in a sterile, plastic, preservative-free, specimen collection cup (i.e., neat urine without preservatives). Performance with other collection methods and collection devices has not been established.

Urine Specimen Collection

1. The patient should not have urinated for at least 1 h prior to specimen collection.
2. Collect the specimen in a sterile, preservative-free specimen collection cup.
3. The patient should collect the first 20 – 60 mL of voided urine (the first part of the stream – NOT midstream) into a urine collection cup.
4. Cap and label with patient identification and date/time collected.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

Urine Transfer to Q^x UPT

NOTE: Urine specimens should be transferred from the collection cup to the Q^x UPT within 8 h of collection if the urine specimen has been stored at 2 – 30 °C. Urine specimens stored at 2 – 8 °C can be held up to 24 h prior to transfer to the Q^x UPT.

Wear clean gloves when handling the Q^x UPT tube and urine specimen. If gloves come in contact with the specimen, immediately change them to prevent contamination of other specimens.

1. Open the Q^x UPT Collection and Transport Kit and remove the Q^x UPT and transfer pipette from their packaging.
2. Label the Q^x UPT with the patient identification and date/time collected.
3. Hold the Q^x UPT upright and firmly tap the bottom of the tube on a flat surface to dislodge any large drops from inside the cap. Repeat if necessary.
4. Uncap the Q^x UPT and use the transfer pipette to dispense urine into the tube. The correct volume of urine has been added when the fluid level is between the purple lines on the fill window located on the Q^x UPT label. This volume corresponds to approximately 2.0 – 3.0 mL of urine. DO NOT overfill or under fill the tube.
5. Discard the transfer pipette in a biohazard waste container.

   NOTE: The transfer pipette is intended for use with a single specimen.
6. Tighten the cap securely on the Q^x UPT.
7. Invert the Q^x UPT 3 – 4 times to ensure that the specimen and reagent are well mixed.

Q^x UPT Urine Storage and Transport

Store and transport Q^x UPT urine specimens at 2 – 30 °C and pre-warm them within 30 days of transfer to the Q^x UPT.

Specimens may be stored in the Q^x UPT at -20 ºC for up to 180 days prior to pre-warming.

Neat Urine Storage and Transport

Store and transport neat urine specimens from the collection site to the test site at 2 – 8 °C and pre-warm them within 7 days of collection. Neat urine stored at 2 – 30 °C must be pre-warmed within 30 h of collection. Neat urine specimens may also be stored frozen at -20 °C for up to 180 days prior to pre-warming.

Table 18: Urine Specimen Storage and Transport

Urine Specimen Type to be Processed	**Q^x UPT**			**NEAT**		
Urine Handling Options Prior To Transfer to Q^x UPT	Store urine specimen 2 – 30 °C and transfer to Q^x UPT within 8 h of collection or Store urine specimen 2 – 8 °C and transfer to Q^x UPT within 24 h of collection or Transfer to Q^x UPT immediately					
Process Specimen According to Instructions	2 – 8 °C	2 – 30 °C	-20 °C	2 – 8 °C	2 – 30 °C	-20 °C
Process and Test Specimen According to Instructions	Within 30 days after transfer to Q^x UPT		Within 180 days after transfer to Q^x UPT	Within 7 days of collection	Within 30 hours of collection	Within 180 days of collection

LBC SPECIMEN COLLECTION, STORAGE AND TRANSPORT

BD SurePath or PreservCyt specimens must be collected using either an endocervical broom or a brush/spatula combination as described in the **BD SurePath** or PreservCyt product insert. Once collected, **BD SurePath** or PreservCyt specimens can be stored and transported in their original vials for up to 30 days at 2 – 30 °C prior to transfer to LBC Specimen Dilution Tubes.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

Specimen Transfer to LBC Specimen Dilution Tubes

A 0.5 mL aliquot of either the **BD SurePath** or PreservCyt specimen must be transferred from the original vial to the LBC Specimen Dilution Tube prior to processing for either the **BD SurePath** or ThinPrep Pap test. Wear gloves when handling the LBC Specimen Dilution Tube and the **BD SurePath** or PreservCyt specimen vial. If gloves come in contact with the specimen, immediately change them to prevent contamination of other specimens.

BD SurePath Specimen Transfer

NOTE: **Refer to the BD PrepStain Slide Processor Product Insert for instructions on removing an aliquot from the BD SurePath specimen vial prior to performing the BD SurePath liquid-based Pap test.**

1. Label an LBC Specimen Dilution Tube with patient identification information.
2. Remove the cap from the LBC Specimen Dilution Tube.
3. Transfer 0.5 mL from the specimen vial to the LBC Specimen Dilution Tube. Avoid pipetting fluid from the bottom of the vial. Discard pipette tip.

   NOTE: A separate pipette tip must be used for each specimen.
4. Tighten the cap on the LBC Specimen Dilution Tube securely.
5. Invert the LBC Specimen Dilution Tube 3 – 4 times to ensure that the specimen and diluent are well mixed.

PreservCyt Specimen Transfer

NOTE: **Refer to the ThinPrep 2000/3000 System Operator's Manual Addendum for instructions on removing an aliquot from the PreservCyt specimen vial prior to performing the ThinPrep Pap test.**

1. Label an LBC Specimen Dilution Tube with patient identification information.
2. Remove the cap from the LBC Specimen Dilution Tube.
3. Transfer 0.5 mL from the specimen vial to the LBC Specimen Dilution Tube. Avoid pipetting fluid from the bottom of the vial. Discard pipette tip.

   NOTE: A separate pipette tip must be used for each specimen.
4. Tighten the cap on the LBC Specimen Dilution Tube securely.
5. Invert the LBC Specimen Dilution Tube 3 – 4 times to ensure that the specimen and diluent are well mixed.

Storage and Transport of Specimens Transferred to the LBC Specimen Dilution Tubes

After transfer to an LBC Specimen Dilution Tube, the diluted specimen can be stored at 2 – 30 °C for up to 30 days. Diluted specimens may also be stored at -20 °C for up to 90 days.

SWAB SPECIMEN PROCESSING

NOTE: The optional Lighted Login Rack assists in correct specimen tube placement during specimen login. The Lighted Login Rack is connected to the BD Viper LT instrument. Before starting specimen login, the Specimen Rack is placed on the Lighted Login Rack. As a specimen is logged, the assigned location on the rack lights to indicate where to place the tube. This continues until all specimens are logged in.

Processing procedure for the BD ProbeTec Q^x Collection Kit for Endocervical or Lesion Specimens or the Male Urethral Specimen Collection Kit for the BD ProbeTec Q^x Amplified DNA Assays

NOTE: If specimens are refrigerated or frozen, make sure they are brought to room temperature and mixed by inversion prior to proceeding.

1. Using the tube layout report, scan the Q^x Swab Diluent tube with black pierceable cap and place in order in the **BD Viper** LT Specimen Rack. If using the Lighted Login Rack, place specimen tube in the position that is lit on the Lighted Login Rack.
2. Repeat step 1 for additional swab specimens.
3. Specimens are ready to be pre-warmed.
4. **Change gloves** before proceeding to avoid contamination.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

Processing procedure for the Vaginal Specimen Transport for the BD ProbeTec Q^x Amplified DNA Assays

NOTE: Wear clean gloves when handling the vaginal swab specimen. If gloves come in contact with specimen, immediately change them to prevent contamination of other specimens.

NOTE: If specimens are refrigerated or frozen, make sure they are brought to room temperature prior to expression.

1. Label a pre-filled **BD ProbeTec** Q^x Swab Diluent tube for each swab specimen to be processed.
2. Remove the cap and insert the swab specimen into the Q^x Swab Diluent. Mix by swirling the swab in the Q^x Swab Diluent for 5 – 10 s.
3. Express the swab along the inside of the tube so that liquid runs back into the bottom of the tube.
4. Remove the swab carefully from the Q^x Swab Diluent tube to avoid splashing.
5. Place the expressed swab back into the transport tube and discard with biohazardous waste.
6. Tightly recap the Q^x Swab Diluent tube with the **black pierceable cap**.
7. Repeat steps 1 – 6 for additional swab specimens.
8. Using the tube layout report, scan the Q^x Swab Diluent tube with black pierceable cap and place in order in the **BD Viper** LT Specimen Rack. If using the Lighted Login Rack, place specimen tube in the position that is lit on the Lighted Login Rack.
9. Specimens are ready to be pre-warmed.
10. **Change gloves** before proceeding to avoid contamination.

URINE SPECIMEN PROCESSING

NOTE: If specimens are refrigerated or frozen, make sure they are brought to room temperature and mixed by inversion prior to proceeding.

Processing procedure for the Q^x UPT

1. Make sure the urine volume in each Q^x UPT tube falls between the lines indicated on the tube label. Under or over filling the tube may affect assay performance. Over filling the tube may also result in liquid overflow on the **BD Viper** deck, and could cause contamination.
2. Make sure the Q^x UPT tube has a **black pierceable cap**.
3. Repeat steps 1 and 2 for additional Q^x UPT tube specimens.
4. Using the tube layout report, scan the Q^x UPT Tube with black pierceable cap and place in order in the **BD Viper** LT Specimen Rack. If using the Lighted Login Rack, place specimen tube in the position that is lit on the Login Rack.
5. Specimens are ready to be pre-warmed.
6. **Change gloves** before proceeding to avoid contamination.

Processing procedure for unpreserved (Neat) urine specimens

NOTE: Wear clean gloves when handling the urine specimen. If gloves come in contact with specimen, immediately change them to prevent contamination of other specimens.

1. Label a Specimen Tube for use on the **BD Viper** System with the patient identification and date/time collected.
2. Swirl the urine cup to mix the urine specimen and open carefully.

   NOTE: Open carefully to avoid spills which may contaminate gloves or the work area.
3. Uncap the tube and use a pipette to transfer the urine specimen into the tube. The correct volume of urine has been added when the fluid level is between the purple lines on the fill window located on the label. This volume corresponds to approximately 2.0 – 3.0 mL of urine. DO NOT overfill or under fill the tube.
4. Tighten a **black pierceable cap** securely on each tube.
5. Repeat steps 1 through 4 for each urine specimen. Use a new pipette or pipette tip for each sample.
6. Using the tube layout report, scan the Specimen Tube with black pierceable cap and place in order in the **BD Viper** LT Specimen Rack. If using the Lighted Login Rack, place tube in the position that is lit on the Login Rack.
7. Specimens are ready to be pre-warmed.
8. **Change gloves** before proceeding to avoid contamination.

NOTE: The pre-warm step must be started within 30 h of collection if the urine has been stored at 2 – 30 °C; within 7 days of collection if stored at 2 – 8 °C; or within 180 days if stored frozen at -20 °C.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

PROCESSING PROCEDURE FOR LBC SPECIMENS TRANSFERRED TO THE LBC SPECIMEN DILUTION TUBES

NOTE: If specimens are frozen, make sure they are thawed completely at room temperature and mixed by inversion prior to proceeding.

1. Make sure the LBC Specimen Dilution Tube has a **pierceable cap**.
2. Using the tube layout report, scan the Specimen Tube with black pierceable cap and place in order in the **BD Viper** LT Specimen Rack. If using the Lighted Login Rack, place tube in the position that is lit on the Login Rack.
3. Specimens are ready to be pre-warmed.
4. **Change gloves** prior to proceeding to avoid contamination.

QUALITY CONTROL

Quality control must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

The Control Set for the **BD ProbeTec** CT/GC Q^x Amplified DNA Assays is provided separately. One Positive and one Negative Control must be included in each assay run and for each new reagent kit lot number. Controls must be positioned according to the **BD Viper** LT System User's Manual. The CT/GC Q^x Positive Control will monitor for substantial reagent failure only. The CT/GC Q^x Negative Control monitors for reagent and/or environmental contamination. Additional controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations. Refer to CLSI C24-A3 for additional guidance on appropriate internal quality control testing practices.[14] The Positive Control contains approximately 2400 copies per mL of pCTB4 and pGCint3 linearized plasmids. The Extraction Control (EC) oligonucleotide is used to confirm the validity of the extraction process. The EC is dried in the Extraction Tubes and is re-hydrated by the **BD Viper** LT System upon addition of the specimen and extraction reagents. At the end of the extraction process, the EC fluorescence is monitored by the instrument and an automated algorithm is applied to both the EC and *N. gonorrhoeae*-specific signals to report specimen results as positive, negative, or EC failure.

QUALITY CONTROL PREPARATION

NOTE: Do not re-hydrate the controls prior to loading in the BD Viper LT Specimen Rack.

1. Using the tube layout report, scan the CT/GC Q^x Negative Control and place in the appropriate position in the **BD Viper** LT Specimen Rack. Likewise, scan the CT/GC Q^x Positive Control and place in the appropriate position in the **BD Viper** LT Specimen Rack. If using the Lighted Login Rack, place tube in the position that is lit on the Lighted Login Rack.
2. Using the tube layout report, place CT/GC Q^x Negative Controls into the appropriate positions in the **BD Viper** LT Specimen Rack.
3. Using the tube layout report, place CT/GC Q^x Positive Controls into the appropriate positions in the **BD Viper** LT Specimen Rack.
4. Controls are ready to be pre-warmed with the specimens.

SPECIMEN PROCESSING CONTROLS

Specimen Processing Controls may be tested in accordance with the requirements of appropriate accrediting organizations. A positive Specimen Processing Control tests the entire assay system. For this purpose, known positive specimens can serve as controls by being processed and tested in conjunction with unknown specimens. Specimens used as processing controls must be stored, processed, and tested according to the package insert instructions. If a known positive specimen is not available, additional options for Specimen Processing Controls are described below:

Preparation of Specimen Processing Controls in BD ProbeTec Q^x Swab Diluent

ATCC *Neisseria gonorrhoeae*:

1. Thaw a vial of *Neisseria gonorrhoeae* stock culture, received from ATCC and immediately inoculate a chocolate agar plate.
2. Incubate at 37 ºC in 3 – 5 % CO_2 for 24 – 48 h. Resuspend colonies from the chocolate agar plate with phosphate buffered saline (PBS).
3. Dilute cells in PBS to a 1.0 McFarland turbidity standard (approximately 3×10^8 cells/mL).
4. Prepare 10-fold serial dilutions to a 10^{-5} (at least 4 mL final volume) in PBS.
5. Place 0.1 mL of the 10^{-5} dilution in a **BD ProbeTec** Q^x Swab Diluent tube and tightly recap using a **black pierceable cap**.
6. Using the tube layout report, place the Specimen Processing Control(s) in order in the **BD Viper** LT Specimen Rack.
7. Process the controls according to the Pre-warm Procedure and then follow the Test Procedure.
8. Specimen Processing Controls are ready to be tested on the **BD Viper** LT System.
9. **Change gloves** prior to proceeding to avoid contamination.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

Bio-Rad AmpliTrol – *Chlamydia trachomatis* & *Neisseria gonorrhoeae*:

NOTE: Refer to manufacturer's processing instructions.

1. Add the appropriate volume of Bio-Rad AmpliTrol CT/GC to a **BD ProbeTec** Q^x Swab Diluent tube and tightly recap using a **black pierceable cap**.
2. Mix the solution by vortexing or with inversion.
3. Using the tube layout report, place the Specimen Processing Control(s) in order in the **BD Viper** LT Specimen Rack.
4. Process the controls according to the Pre-warm Procedure and then follow the Test Procedure.
5. Specimen Processing Controls are ready to be tested on the **BD Viper** LT System.
6. **Change gloves** prior to proceeding to avoid contamination.

Preparation of Specimen Processing Controls in LBC Specimen Dilution Tubes

ATCC – *Neisseria gonorrhoeae*

1. Grow *N. gonorrhoeae* culture overnight on chocolate agar plates.
2. Resuspend *N. gonorrhoeae* colonies in phosphate buffered saline (PBS).
3. Prepare a 1.0 McFarland turbidity standard from the resuspended colonies.
4. Prepare 10-fold serial dilutions to a 10^{-5} (at least 4 mL final volume) in phosphate buffered saline (PBS).
5. Place 0.1 mL of 10^{-5} dilution in an LBC Specimen Dilution Tube containing 0.5 mL of **BD SurePath** Preservative Fluid or PreservCyt Solution. Tightly recap the LBC Specimen Dilution Tube using the blue pierceable cap.
6. Invert the LBC Specimen Dilution Tube 3 – 4 times to ensure that the contents are well mixed.
7. Using the tube layout report, place the Specimen Processing Control(s) in order in the **BD Viper** LT Specimen Rack.
8. Process the controls according to the Pre-warm Procedure and then follow the Test Procedure.
9. Specimen Processing Controls are ready to be tested on the **BD Viper** LT System.
10. **Change gloves** prior to proceeding to avoid contamination.

Bio-Rad AmpliTrol – *Chlamydia trachomatis* and *Neisseria gonorrhoeae*:

NOTE: Refer to manufacturer's processing instructions.

1. Add the appropriate volume of Bio-Rad AmpliTrol CT/GC to an LBC Specimen Dilution Tube containing 0.5 mL of **BD SurePath** Preservative Fluid or PreservCyt Solution. Tightly recap the LBC Specimen Dilution Tube using the blue pierceable cap.
2. Invert the LBC Specimen Dilution Tube 3 – 4 times to ensure that the contents are well mixed.
3. Using the tube layout report, place the Specimen Processing Control(s) in order in the **BD Viper** LT Specimen Rack.
4. Process the controls according to the Pre-warm Procedure and then follow the Test Procedure.
5. Specimen Processing Controls are ready to be tested on the **BD Viper** LT System.
6. **Change gloves** prior to proceeding to avoid contamination.

General QC Information for the BD Viper LT System:

The location of the microwells is shown in a color-coded plate layout screen on the LCD Monitor. The plus symbol (+) within the microwell indicates the positive QC sample. The minus symbol (-) within the microwell indicates the negative QC sample. A QC pair must be logged in for each reagent kit lot number. If QC pairs have not been properly logged in, a message box appears that prevents saving the rack and proceeding with the run until complete. A maximum of two QC pairs per rack is permitted. Additional (optional) QC tubes for testing may be logged in. These tubes are tested as regular samples and do not affect the Pass/Fail status of the run. Refer to the **BD Viper** LT System User's Manual for instructions.

NOTE: The BD Viper LT System will re-hydrate the controls during the assay run. Do not attempt to hydrate the assay controls prior to loading them into the BD Viper LT Specimen Rack.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

PRE-WARM PROCEDURE SPECIMENS AND CONTROLS

NOTE: The pre-warm procedure must be applied to all specimens to ensure that the specimen matrix is homogeneous prior to loading on the BD Viper LT System. Failure to pre-warm specimens may have an adverse impact on performance of the BD ProbeTec CT/GC Q^x assays and/or BD Viper LT System.

NOTE: Refrigerated or frozen specimens must be brought to room temperature prior to pre-warming.

1. Insert the **BD Viper** LT Specimen Rack into the **BD** Pre-warm Heater. The **BD** Pre-warm Heater scanner reads the specimen rack barcode and begins the appropriate heating and cooling protocol.
2. When the Instrument indicates that the pre-warm cycle is complete, remove the **BD Viper** LT Specimen Rack from the **BD** Pre-warm Heater and load into the **BD Viper** LT instrument.
3. Refer to the Test Procedure for testing specimens and controls.
4. After pre-warming, urine and swab specimens may be stored for up to 7 days at 2 – 30 °C or up to 180 days at -20 °C without additional pre-warming prior to testing on the BD Viper LT System. LBC specimens that have been pre-warmed may be stored for up to 7 days at 2 – 30 °C or up to 90 days at -20 °C without additional pre-warming prior to testing on the **BD Viper** LT System.

TEST PROCEDURE

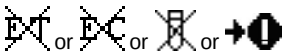
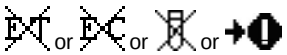
Refer to the **BD Viper** LT User's Manual for specific instructions for operating and maintaining the components of the system. The optimum environmental conditions for the GC Q^x Assays were found to be 18 – 27 °C and 20 – 85% Relative Humidity.

INTEPRETATION OF QUALITY CONTROL RESULTS

Interpretation of Quality Control Result:

The CT/GC Q^x Positive Control and the CT/GC Q^x Negative Control must test as positive and negative, respectively, in order to obtain patient results. If controls do not perform as expected, the run is considered invalid and patient results will not be reported by the instrument. If either of the controls does not provide the expected results, repeat the entire run using a new set of controls, new extraction tubes, new extraction reagent trough, and new microwells. If the repeat QC does not provide the expected results, contact BD Technical Services. If the *N. gonorrhoeae*-specific signal is greater than or equal to a threshold of 125 Maximum Relative Fluorescent Units (MaxRFU), the EC fluorescence is ignored by the algorithm. If the *N. gonorrhoeae*-specific signal is less than a threshold of 125 MaxRFU, the EC fluorescence is utilized by the algorithm in the interpretation of the result.

Table 19: Interpretation of Quality Control Results

Control Type	Tube Result Report Symbol	GC Q^x MaxRFU	QC Disposition
GC Q^x Positive Control	OK	≥125	QC Pass
GC Q^x Positive Control		<125	QC Failure
GC Q^x Positive Control		Any value	QC Failure
GC Q^x Negative Control	OK	<125	QC Pass
GC Q^x Negative Control		≥125	QC Failure
GC Q^x Negative Control		Any value	QC Failure

Refer to the Interpretation of Test Results for a description of Tube Result Report symbols.

INTEPRETATION OF TEST RESULTS

The **BD ProbeTec** GC Q^x Amplified DNA Assay uses fluorescent energy transfer as the detection method to test for the presence of *N. gonorrhoeae* in clinical specimens. All calculations are performed automatically by the **BD Viper** LT software. The presence or absence of *N. gonorrhoeae* DNA is determined by calculating the peak fluorescence (MaxRFU) over the course of the amplification process and by comparing this measurement to a predetermined threshold value. The magnitude of the MaxRFU score is not indicative of the level of organism in the specimen. If the *N. gonorrhoeae*-specific signal is greater than or equal to a threshold of 125 MaxRFU, the EC fluorescence is ignored by the algorithm.

If the *N. gonorrhoeae*-specific signal is less than a threshold of 125 MaxRFU, the EC fluorescence is utilized by the algorithm in the interpretation of the result. If assay control results are not as expected, patient results are not reported. See the Quality Control section for expected control values. Reported results are determined as follows.

Table 20: Interpretation of Test Results for the GC Q^x Assays

Tube Report Result	GC Q^x MaxRFU	Report	Interpretation	Result
	≥125	*N. gonorrhoeae* plasmid DNA detected by SDA.	Positive for *N. gonorrhoeae*. *N. gonorrhoeae* organism viability and/or infectivity cannot be inferred since target DNA may persist in the absence of viable organisms.	Positive
	<125	*N. gonorrhoeae* plasmid DNA not detected by SDA.	Presumed negative for *N. gonorrhoeae*. A negative result does not preclude *N. gonorrhoeae* infection because results are dependent on adequate specimen collection, absence of inhibitors, and the presence of sufficient DNA to be detected.	Negative
	<125	Extraction control failure. Repeat test from initial specimen tube or obtain another specimen for testing.	*N. gonorrhoeae*, if present, not detectable.	Extraction Control Failure
	Any value	Extraction Transfer Failure. Repeat test from initial specimen tube or obtain another specimen for testing.	*N. gonorrhoeae*, if present, not detectable.	Extraction Transfer Failure
	Any value	Liquid Level Failure. Repeat test from initial specimen tube or obtain another specimen for testing.	*N. gonorrhoeae*, if present, not detectable.	Liquid Level Failure
	Any value	Error. Repeat test from initial specimen tube or obtain another specimen for testing.	*N. gonorrhoeae*, if present, not detectable.	Error

MONITORING FOR THE PRESENCE OF DNA CONTAMINATION

At least monthly, the following test procedure should be performed to monitor the work area and equipment surfaces for the presence of DNA contamination. Environmental monitoring is essential to detect contamination prior to the development of a problem.

1. For each area to be tested, use a clean collection swab from the **BD ProbeTec** Q^x Collection Kit for Endocervical or Lesion Specimens.
2. Pour off some molecular biology grade nuclease-free water into a small clean container.
3. Dip the swab into the molecular biology grade nuclease-free water and wipe the first area using a broad sweeping motion.
4. Remove the cap of a tube of Swab Diluent for the **BD ProbeTec** Q^x Amplified DNA Assays and insert the swab into the diluent. Mix by swirling the swab in the diluent for 5 – 10 s.
5. Express the swab along the inside of the tube so that liquid runs back into the bottom of the tube.
6. Remove the swab carefully from the swab diluent tube to avoid splashing. Discard the swab.
7. Tightly recap the diluent tube with the black pierceable cap.
8. Repeat for each desired area.
9. After all swabs have been collected and expressed, process them according to the Pre-warming Procedure and then follow the Test Procedure.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

Consult the **BD Viper** LT System User's Manual for more information on Environmental Monitoring and Cleaning Procedures. If a contamination event does not resolve, contact BD Technical Service and Support for additional information.

LIMITATIONS OF THE PROCEDURE

1. This method has been tested only with endocervical, vaginal, male urethral swab specimens, **BD SurePath** or PreservCyt specimens collected with cytobrush/spatula or broom device, and male and female urine specimens. Performance with other specimen types has not been assessed.
2. Optimal performance of the test requires adequate specimen collection and handling. Refer to the "Specimen Collection and Transport" sections of this insert.
3. Endocervical specimen adequacy can only be assessed by microscopic visualization of columnar epithelial cells in the specimen.
4. Collection and testing of urine specimens with the **BD ProbeTec** GC Q^x Amplified DNA 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.
5. The **BD ProbeTec** GC Q^x Amplified DNA Assay for male and female urine specimen testing should be performed on first catch random urine specimens (defined as the first 20 – 60 mL of the urine stream).
6. The effects of other potential variables such as vaginal discharge, use of tampons, douching, and specimen collection variables have not been determined.
7. A negative test result does not exclude the possibility of infection because test results may be affected by improper specimen collection, technical error, specimen mix-up, concurrent antibiotic therapy, or the number of organisms in the specimen which may be below the sensitivity of the test.
8. As with many diagnostic tests, results from the **BD ProbeTec** GC Q^x Amplified DNA Assay should be interpreted in conjunction with other laboratory and clinical data available to the physician.
9. The **BD ProbeTec** GC Q^x Amplified DNA 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.
10. The **BD ProbeTec** GC Q^x Amplified DNA Assay cannot be used to assess therapeutic success or failure since nucleic acids from *N. gonorrhoeae* may persist following antimicrobial therapy.
11. The **BD ProbeTec** GC Q^x Amplified DNA Assay provides qualitative results. No correlation can be drawn between the magnitude of the positive assay signal (MaxRFU) and the number of cells in an infected sample.
12. The predictive value of an assay depends on the prevalence of the disease in any particular population.
13. Because the Positive Control for the **BD ProbeTec** CT/GC Q^x Amplified DNA Assays is used in testing for both *C. trachomatis* and *N. gonorrhoeae*, correct positioning of the microwell strips is important for final results reporting.
14. Use of the **BD ProbeTec** GC Q^x Amplified DNA Assay is limited to personnel who have been trained in the assay procedure and the **BD Viper** LT System.
15. The reproducibility of the **BD ProbeTec** GC Q^x Amplified DNA Assay was established on the **BD Viper** LT System using seeded simulated swab, urine and PreservCyt specimens. These specimens were inoculated with *C. trachomatis* and *N. gonorrhoeae*.
16. Performance has not been established for urine specimens in Q^x UPT when fill volumes other than those falling within the purple lines on the fill window (approximately 2.0 mL to 3.0 mL) are used.
17. The performance of the **BD ProbeTec** GC Q^x Amplified DNA Assay may cross-react with *N. cinerea* and *N. lactamica*. These organisms have only rarely been isolated from the genital tract[14-17].
18. The performance of the **BD ProbeTec** GC Q^x Amplified DNA Assay with swab specimens was evaluated for interference by blood, gynecological lubricants, and spermicides. The performance with urine specimens was evaluated for interference by blood and commonly used over-the-counter pain relievers. No interference was observed with any of the substances at the concentrations tested.
19. The patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated.
20. The patient-collected vaginal swab specimen application is limited to healthcare facilities where support/counseling is available to explain procedures and precautions.
21. The **BD ProbeTec** GC Q^x Amplified DNA Assay has not been validated for vaginal swab specimens collected by patients at home.
22. The performance of vaginal swab specimens has not been evaluated in patients less than 17 years of age.
23. The performance of vaginal swab specimens has not been evaluated in pregnant women.

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

AVAILABILITY

The following **BD ProbeTec** CT/GC Q^x and **BD Viper** products for use on the **BD Viper** LT are also available:

Cat. No.	Description
440724	**BD Viper**™ Pipette Tips, 960
441392	**BD Viper**™ Trash Box
441391	**BD Viper**™ Trash Bags
440818	**BD Viper**™ Trash Boxes and Bags
440974	**BD Viper**™ Tube Lockdown Cover
440975	**BD Viper**™ Lysing Heater (115V)
440976	**BD Viper**™ Lysing Heater (230V)
440977	**BD Viper**™ Lysing Rack
440984	Amplification Plate Sealers (Black)
441072	**BD Viper**™ Liquid Waste Bottle
441074	**BD Viper**™ Plate Seal Tool
440752	Microwell Package for **BD Viper**™ System
441091	**BD Viper**™ System
441122	Vaginal Specimen Transport for the **BD ProbeTec™** Q^x Amplified DNA Assays, 100 units
441124	**BD ProbeTec™** GC Q^x Amplified DNA Assay Reagent Pack, 1152 tests
441126	**BD ProbeTec™** CT Q^x Amplified DNA Assay Reagent Pack, 1152 tests
441125	Control Set for the **BD ProbeTec™** CT/GC Q^x Amplified DNA Assays, 24 positive and 24 negative
441128	**BD Viper**™ Extraction Reagent and Lysis Trough, 12 Extraction Reagent Troughs and 12 Lysis Troughs
441129	**BD FOX**™ Extraction Tubes
441354	**BD Viper**™ Neutralization Pouch, 12 pouches
441357	**BD ProbeTec**™ Q^x Collection Kit for Endocervical or Lesion Specimens, 100 units
441358	Male Urethral Specimen Collection Kit for the **BD ProbeTec™** Q^x Amplified DNA Assays,
441359	Caps for use on the **BD Viper™** (Extracted Mode), 4 x 100
441360	Specimen Tubes and Caps for use on the **BD Viper™** (Extracted Mode), 4 x 100
441361	Swab Diluent for the **BD ProbeTec™** Q^x Amplified DNA Assays, 2 mL x 48
441362	**BD™** Urine Preservative Transport for the Q^x Amplified DNA Assays, 100 units
441444	Liquid Based Cytology Specimen (LBC) Dilution Tubes for the **BD ProbeTec™** Q^x Amplified DNA Assays

441443	Liquid Based Cytology Specimen (LBC) Dilution Tube Caps for the **BD ProbeTec™** Q^x Amplified DNA Assays
441996	**BD Viper™** LT Pipette Tips, 3840
441995	**BD Viper™** LT Solid Waste Liners, 80
442950	**BD™** Pre-warming Heater
442958	**BD Viper™** LT System SDA Accessory Kit
442839	**BD Viper™** LT System
442842	**BD ProbeTec™** GC Q^x Assay Gray Amp Reagent Pack, 384 tests
442959	**BD ProbeTec™** CT Q^x Assay Gray Amp Reagent Pack, 384 tests
441994	**BD Viper™** SDA Extraction Reagent Trough with Piercing Tool, 12 Extraction Reagent Troughs

The following strains are available from:

American Type Culture Collection (ATCC)
10801 University Boulevard
Manassas, VA 20110-2209, USA.

ATCC # 19424 *Neisseria gonorrhoeae*
ATCC# VR-879 *Chlamydia trachomatis* (serotype H)
ATCC # VR-902B *Chlamydia trachomatis* LGV II

Bio-Rad AmpliTrol CT/GC is available from:

Bio-Rad Laboratories (Blackhawk Biosystems)
12945 Alcosta Blvd. 2nd Floor
San Ramon, CA 94583
1-800-866-0305
AmpliTrol CT/GC # 00126

BD Viper™ System with XTR™ Technology and BD Viper™ LT System CLSI Laboratory Procedure

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Technical Information: In the United States contact BD Technical Service and Support at 800-638-8663 or www.bd.com/ds.