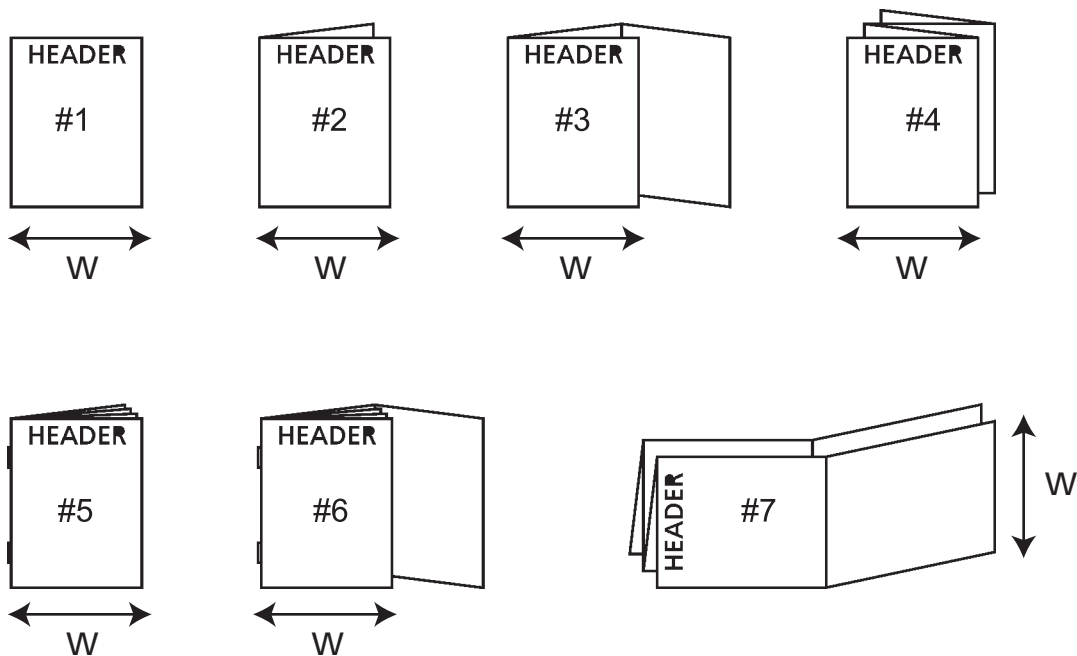



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Part Number:  8089063		Category and Description  Package Insert, TV Q <sup>x</sup> Amplified DNA Assay	Sheet: 1 of 25	A
			Scale: N/A	

# **BD ProbeTec™ *Trichomonas vaginalis* (TV) Q<sup>x</sup>** **Amplified DNA Assay**

English: pages 1 – 19



8089063(03)  
2013-09

REF 441917, 443433

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## INTENDED USE

The **BD ProbeTec™ *Trichomonas vaginalis* (TV) Q<sup>x</sup>** Amplified DNA Assay, when tested with the **BD Viper™** System in Extracted Mode, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Trichomonas vaginalis* DNA in clinician-collected female endocervical swab specimens, patient-collected vaginal swab specimens (in a clinical setting), and female urine specimens. The assay is indicated for use with asymptomatic and symptomatic females to aid in the diagnosis of trichomoniasis.

## SUMMARY AND EXPLANATION

Vaginal infections caused by *Trichomonas vaginalis* are among the most common conditions transmitted sexually.<sup>1</sup> It is estimated that in the United States 7.4 million new cases of trichomoniasis appear annually compared with 3 million cases of chlamydia and 718,000 cases of gonorrhea.<sup>2</sup> Despite being a readily diagnosed and treatable sexually transmitted disease, trichomoniasis is not a reportable infection, and control of the infection has received relatively little emphasis from public health STD control programs.<sup>3</sup>

Trichomoniasis is caused by the parasitic protozoan *Trichomonas vaginalis*. The infection causes some women to have symptoms which are characterized by a diffuse, malodorous, yellow-green vaginal discharge with vulvar irritation. The infection may cause discomfort during intercourse and urination, as well as irritation and itching of the female genital area. The genital inflammation caused by trichomoniasis can increase a woman's susceptibility to HIV infection if she is exposed to the virus. Having trichomoniasis may increase the chance that an HIV-infected woman passes HIV to her sex partner(s).<sup>4</sup> Infected women may have minimal or no symptoms of the disease. Because of this, screening for *T. vaginalis* in women can be considered in those at high risk for infection (i.e., women who have new or multiple partners, have a history of STDs, exchange sex for payment, and use injection drugs).<sup>5</sup>

Today, a commonly used test for a patient presenting with symptoms of vaginitis is the wet mount. This is an easy to perform test that affords several results for the clinician to utilize in determining the cause of the vaginitis symptoms. Another commonly used test is culture for *Trichomonas vaginalis*. The sensitivity of the wet mount and TV culture under optimal conditions can range from 40 – 60%<sup>6</sup> when compared to PCR. The wet mount result can be influenced by factors such as microscopist experience, length of time from preparation until interpretation, the ambient temperature, and the collection devices used. The wet mount result can only be interpreted as positive if the microscopist can visualize motile trichomonads. Culture performance can be influenced by the time between inoculation and incubation as well as the temperature at which the culture is stored prior to and during incubation. Trichomonads are extremely susceptible to cold temperatures and the culture can be adversely affected if allowed to become cold. Controlled room temperature of 15 – 30 °C should be maintained after inoculation of the culture but prior to incubation. One or all of these factors can contribute to the poor sensitivity of the culture method.

The **BD Viper** System in Extracted Mode utilizes the newly developed **BD ProbeTec *Trichomonas vaginalis* (TV) Q<sup>x</sup>** Amplified DNA Assay. Automated extraction of DNA from clinical samples occurs on the **BD Viper** System through **BD FOX™** extraction technology that incorporates chemical lysis, followed by binding of DNA to magnetic particles, washing and elution. The system is based on simultaneous amplification and detection of target DNA using amplification primers along with a fluorescently-labeled detector probe.<sup>7,8</sup>

## PRINCIPLES OF THE PROCEDURE

The **BD ProbeTec TV Q<sup>x</sup>** Amplified DNA Assay is designed for use with the **BD ProbeTec Q<sup>x</sup>** specimen collection and transport devices, applicable reagents, the **BD Viper** System and **BD FOX™** Extraction Tubes. Female urine specimens are collected and transported as a neat urine specimen. All specimens undergo a pre-warm step in the **BD Viper** Lysing Heater to dissolve mucus which may be present in certain specimens and to 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. 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 microorganisms 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** TV Q<sup>x</sup> Amplified DNA Assay is based on the simultaneous amplification and detection of target DNA using amplification primers and a fluorescently-labeled detector probe. 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 and then incubated in one of the two thermally controlled fluorescent readers. The presence or absence of *T. vaginalis* 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 *T. vaginalis* 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 *T. vaginalis*-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 *T. vaginalis*-specific signals to report specimen results as positive, negative, or EC failure.

When analyzing the TV Q<sup>x</sup> Assay for *T. vaginalis* DNA, an aliquot of the eluate will be removed and transferred to a blank microwell. When analyzing for CT/GC/TV, CT/TV or GC/TV an aliquot of the eluate will be removed and transferred to the first non-TV microwell. This provides the EC result for the TV Q<sup>x</sup> Assay. The process flow requires an additional dilution step to allow for eluate transfer to the TV Q<sup>x</sup> Priming Microwell.

## REAGENTS

Each **BD ProbeTec** TV Q<sup>x</sup> Assay Reagent Pack contains:

**BD ProbeTec** TV Q<sup>x</sup> Amplified DNA Assay Priming Microwells, (12 x 96, 1152 test kit or 4 x 96, 384 test kit): each Priming Microwell contains approximately 123 pmol oligonucleotides, 54 pmol fluorescently labeled detector probe, 80 nmol dNTPs, with stabilizers and buffer components.

**BD ProbeTec** TV Q<sup>x</sup> Amplified DNA Assay Amplification Microwells, (12 x 96, 1152 test kit or 4 x 96, 384 test kit): each Amplification Microwell contains approximately 25 units of DNA polymerase and 62 units restriction enzyme, with stabilizers and buffer components.

NOTE: Each microwell pouch contains one desiccant bag.

Additional Reagents:

Control Set for the **BD ProbeTec**™ *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (GC), and *Trichomonas vaginalis* (TV) Q<sup>x</sup> Amplified DNA Assays: 24 CT/GC/TV Q<sup>x</sup> Positive Control Tubes containing approximately 2400 copies of pCTB4 and pGCINT3 and approximately 4000 copies of TVAP651 linearized plasmids in carrier nucleic acid, and 24 CT/GC/TV Q<sup>x</sup> Negative Control Tubes containing carrier nucleic acid alone. The concentration of the CTB4, GCINT3, and TVAP651 plasmids are determined by UV spectrophotometry.

**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: 12 Reagent and 12 Lysis troughs, 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 Provided:** **BD Viper** Instrument, Instrument Plates, **BD Viper** Pipette Tips, **BD Viper** Tip Waste Boxes, **BD Viper** Amplification Plate Sealers (Black) and Seal Tool, **BD Viper** Lysing Heater, **BD Viper** Lysing Rack, **BD Viper** Neutralization Pouches, Specimen Tubes and Pierceable Caps for use on the **BD Viper** System (Extracted Mode), Q<sup>x</sup> Swab Diluent tubes, **BD ProbeTec** Q<sup>x</sup> Collection Kit for Endocervical or Lesion Specimens, and Vaginal Specimen Transport for the **BD ProbeTec** Q<sup>x</sup> Amplified DNA Assays. **BD Viper** Accessory Kit and Microwell Package for the **BD Viper** System.

**Materials Required But Not Provided:** Nitrile gloves, 3% (w/v) hydrogen peroxide\*, 1% (v/v) sodium hypochlorite\*\*, DNA AWAY™, displacement pipettes, polypropylene aerosol-resistant pipette tips capable of delivering 0.5 mL ± 0.05 mL, and serological pipettes.

\* 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 °C. 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"<sup>9-12</sup> 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**, consult the **BD Viper** Instrument User's Manual.

### Specimen

4. For female urine specimens, use only unpreserved (neat) urine.
5. Under or over dispensing of urine into Specimen Tubes may affect assay performance.

#### Assay/Reagents

6. 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.
7. Do not interchange or mix kit reagents from kits with different lot numbers.
8. The **BD Q<sup>x</sup> Swab Diluent** contains dimethyl sulfoxide (DMSO) which 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.
9. Only use the **BD Viper** pipette tips as supplied by BD with the **BD Viper** System.
10. The **BD Viper** Extraction Reagent and Lysis Troughs contain corrosive substances. The use of personal protection equipment, such as nitrile gloves, safety glasses, and lab coats is strongly recommended when handling these reagents. Solutions have a strong caustic effect, including severe burns on skin and mucous membranes. Avoid contact with the eyes and skin. Avoid breathing fumes, vapors, or spray. Harmful if swallowed. Do not eat or drink in the vicinity of these reagents. In case of contact, immediately remove contaminated clothing, wash the skin with water and soap and rinse thoroughly. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
11. **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.
12. 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.
13. Because the blank microwell is required to produce the EC results for the Negative Control and to verify extraction for negative specimens in the TV Q<sup>x</sup> Assay when run as a stand alone assay, correct positioning of the microwell strips is important for final results reporting.
14. The Microwell Package for the **BD Viper** System contains blank microwells that are packaged in a zip lock bag. To ensure that these do not become contaminated or acquire debris, microwells **MUST** remain in the sealed zip lock bag until they are to be used.
15. The plate containing the Amplification Microwells **MUST** be properly sealed with the black Amplification Plate Sealer prior to removing 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.**
16. Priming Microwells with residual fluid (after transfer of fluid from the Priming Microwells to the Amplification Microwells) represent a potential source of target contamination. Carefully seal Priming Microwells with plate sealer prior to disposal.
17. 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.
18. 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.
19. **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.
20. In the event of contamination of the work area or equipment with samples 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.
21. 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.
22. Clean the entire work area – counter tops and instrument surfaces – 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** on a daily basis. Thoroughly rinse with water. Allow surfaces to dry completely before proceeding with additional testing.
23. Contact BD Technical Services 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.
24. Store reagents at the specified temperature and do not use them after the expiration date.

#### SWAB SPECIMEN COLLECTION, STORAGE, TRANSPORT, AND PROCESSING

##### Endocervical Swab Specimen Collection

Endocervical swab specimens should be collected using the **BD ProbeTec Q<sup>x</sup> Collection Kit** for Endocervical or Lesion Specimens.

**NOTE:** All specimens should be obtained from the patient by appropriately trained individuals.

1. Remove the **white** cleaning swab from packaging.
2. Using **white** cleaning swab, remove excess blood and mucus from the cervical os.
3. Discard the used **white** cleaning swab.
4. Remove the **pink** collection swab from packaging.
5. Insert the **pink** collection swab into the cervical canal and rotate for 15 – 30 s.
6. Withdraw the **pink** collection swab carefully. Avoid contact with the vaginal mucosa.
7. Uncap the Q<sup>x</sup> Swab Diluent Tube.
8. Fully insert the **pink** collection swab into the Q<sup>x</sup> Swab Diluent Tube.
9. Break the shaft of the **pink** collection swab at the score mark. Use care to avoid splashing of contents of the Q<sup>x</sup> Swab Diluent Tube.

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

Vaginal swab specimens should be collected using the Vaginal Specimen Transport for the **BD ProbeTec Q<sup>x</sup> 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 two 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 tube with swab as instructed.

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

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 – 8 °C, within 3 days if kept at 30 °C or within 180 days after collection if kept frozen at -20 °C. Patient-collected vaginal swab specimens that are expressed in Q<sup>x</sup> Swab Diluent may be stored and processed within 30 days after expression if kept at 2 – 30 °C 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 Processed	Endocervical Swab Specimens and Expressed Vaginal Swab Specimens		Dry Vaginal Swab Specimens		
	2 – 30 °C	-20 °C	2 – 8 °C	30 °C	-20 °C
Temperature Condition for Storage and Transport to Test Site	2 – 30 °C	-20 °C	2 – 8 °C	30 °C	-20 °C
Process and Test Specimen According to Instructions	Within 30 days of collection	Within 180 days of collection	Within 14 days of collection	Within 3 days of collection	Within 180 days of collection

#### Swab Specimen Processing

##### Processing procedure for the BD ProbeTec Q<sup>x</sup> Collection Kit for Endocervical or Lesion Specimens

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

1. Using a tube layout report, place the Q<sup>x</sup> 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 TV Q<sup>x</sup> 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 Q<sup>x</sup> Swab Diluent Tube for each vaginal swab specimen to be processed.
2. Remove the cap and insert the swab specimen into the Q<sup>x</sup> Swab Diluent Tube. Mix by swirling the swab in the Q<sup>x</sup> Swab Diluent Tube 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<sup>x</sup> Swab Diluent Tube to avoid splashing.
5. Place the expressed swab back into the transport tube and discard with biohazard waste.
6. Tightly recap the Q<sup>x</sup> 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.

#### URINE SPECIMEN COLLECTION, STORAGE, TRANSPORT, AND PROCESSING

Performance for female urine specimens has been established with urine collected in a sterile, plastic, preservative-free, specimen collection cup (i.e., neat urine without preservatives). Performance with other 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.

##### 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 that is not refrigerated at 2 – 8 °C after collection (stored at temperatures up to 30 °C ) must be pre-warmed and processed within 24 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)

##### Neat Urine Processing Procedure

**NOTE: Wear clean gloves when handling the urine specimen. If gloves come in contact with specimen, immediately change to prevent contamination of other specimens. If specimens are refrigerated or frozen, make sure they are brought to room temperature and mixed by inversion prior to proceeding.**

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 neat urine 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 – 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.

**Table 2. Urine Specimen Storage and Transport**

Urine Specimen Type to be Processed	Neat Urine		
	2 – 8 °C	2 – 30 °C	-20 °C
Temperature Condition for Storage and Transport to Test Site	2 – 8 °C	2 – 30 °C	-20 °C
Process and Test Specimen According to Instructions	Within <b>7 days</b> of collection*	Within <b>24 h</b> of collection*	Within <b>180 days</b> of collection

\*Urine specimens that are refrigerated at 2 – 8 °C after collection may be stored for up to 7 days prior to testing. Urine specimens that are not refrigerated at 2 – 8 °C after collection (stored at temperatures up to 30 °C) must be tested within 24 hours.

#### 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/TV Q<sup>+</sup> Negative Controls into the appropriate positions in the **BD Viper** Lysing Rack.
2. Using the tube layout report, place CT/GC/TV Q<sup>+</sup> Positive Controls into the appropriate positions in the **BD Viper** Lysing Rack.
3. Controls and specimens are ready to be pre-warmed.

#### PRE-WARM PROCEDURE

**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 System. Failure to pre-warm specimens may have an adverse impact on performance of the BD ProbeTec TV Q<sup>+</sup> Amplified DNA Assay and/or BD Viper System. Pre-warming of the controls is optional.**

1. Insert the **BD Viper** Lysing Rack into the **BD Viper** Lysing Heater.
2. Pre-warm the samples for 15 min at 114 °C +/- 2 °C.

- Remove the Lysing Rack from the Lysing Heater and let cool at room temperature for a minimum of 15 min before loading into the **BD Viper** instrument.
- Refer to the Test Procedure for testing specimens and controls.

**Table 3. Post Pre-Warm Storage Conditions**

Specimen type	Temperature Condition for Storage after Pre-Warm		
	2 – 8 °C	30 °C	-20 °C
Expressed Vaginal Swabs (in Q <sup>+</sup> Swab Diluent)	Within 30 days after pre-warm	Within 30 days after pre-warm	Within 180 days after pre-warm
Endocervical Swabs	Within 30 days after pre-warm	Within 30 days after pre-warm	Within 180 days after pre-warm
Neat Urine stored 30 °C for 18 h	NA	NA	Within 180 days after pre-warm
Neat Urine stored at 2 – 8 °C	Within 7 days after pre-warm	NA	Within 30 days after pre-warm

**NOTE: Frozen specimens must be brought to room temperature prior to pre-warming or testing.**

#### 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 TV Q<sup>+</sup> Assay were found to be 18 – 27 °C and 20 – 85% Relative Humidity.

#### 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/TV Q<sup>+</sup> 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/TV Q<sup>+</sup> Positive Control will monitor for substantial reagent failure only. The CT/GC/TV Q<sup>+</sup> Negative Control monitors for reagent and/or environmental contamination.

The CT/GC/TV Q<sup>+</sup> Positive Control comprises recombinant plasmids that contain the SDA target regions for the CT Q<sup>+</sup>, GC Q<sup>+</sup> and TV Q<sup>+</sup> Assays. The plasmids are not necessarily representative of native target DNA detected by the assay (e.g., their overall length is shorter than that of the complete gene or genomic sequence), nor are the controls representative of the specimen matrices indicated for use with the assays on the **BD Viper** System in extracted mode. The Positive Control, when it is rehydrated by the **BD Viper** System, contains approximately 2400 copies per mL of pCTB4 and pGCINT3, as well as approximately 4000 copies per mL of pTVAP651 linearized plasmids. The TV Q<sup>+</sup> Negative Control comprises the same milieu as the Positive Control but without the plasmid DNA. The Positive and Negative Control formulations are dried in separate 4.5 mL specimen tubes. A QC pair (Positive Control and Negative Control) must be logged in for each plate to be tested and for each reagent kit lot number.

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

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

#### 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 the last two positions after the last patient sample are assigned as the positive and negative controls, respectively.

The CT/GC/TV Q<sup>+</sup> Positive Control and the CT/GC/TV Q<sup>+</sup> Negative Control must test as positive and negative, respectively. If controls do not perform as expected, the run is considered invalid and 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 trough, new lysis trough and new microwells.

The Extraction Control (EC) oligonucleotide is labeled with a fluorescent dye and is used to confirm the validity of the extraction process. The EC is dried in the Extraction Tubes and is rehydrated 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 TV Q<sup>+</sup> Assay specific signals to report results as positive, negative, or EC failure.

**Table 4. Interpretation of Quality Control Results**

Control Type	Tube Result Report Symbol	TV Q <sup>x</sup> MaxRFU	QC Disposition
CT/GC/TV Q <sup>x</sup> Positive Control	OK	≥125	QC Pass
CT/GC/TV Q <sup>x</sup> Positive Control		<125	QC Failure
CT/GC/TV Q <sup>x</sup> Positive Control	or  or	Any value	QC Failure
CT/GC/TV Q <sup>x</sup> Negative Control	OK	<125	QC Pass
CT/GC/TV Q <sup>x</sup> Negative Control		≥125	QC Failure
CT/GC/TV Q <sup>x</sup> Negative Control	or  or  or	Any value	QC Failure
CT/GC/TV Q <sup>x</sup> Negative Control		<125	QC Failure

= Fail, = Extraction Transfer failure, = Liquid Level failure, = Extraction Control failure, = Error, = ROX failure ROX = Sulforhodamine dye used to monitor EC performance. Consult the **BD Viper** Instrument User's Manual for additional information.

#### INTERPRETATION OF TEST RESULTS

The **BD ProbeTec Trichomonas vaginalis** (TV) Q<sup>x</sup> Amplified DNA Assay uses fluorescent energy transfer as the detection method to test for the presence of *T. vaginalis* DNA in clinical specimens. All calculations are performed automatically by the **BD Viper** software.

The presence or absence of *T. vaginalis* 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 *T. vaginalis*-specific signal is greater than or equal to a threshold of 125 MaxRFU, the EC fluorescence is ignored by the algorithm. If the *T. vaginalis*-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 5. Interpretation of Test Results for the TV Q<sup>x</sup> Assay**

Tube Report Result	TV Q <sup>x</sup> MaxRFU	Report	Interpretation	Result
	≥125	<i>T. vaginalis</i> DNA detected by SDA	Positive for <i>T. vaginalis</i> DNA. <i>T. vaginalis</i> organism viability and/or infectivity cannot be inferred since target DNA may persist in the absence of viable organisms.	Positive
	<125	<i>T. vaginalis</i> DNA not detected by SDA	Presumed negative for <i>T. vaginalis</i> DNA. A negative result does not preclude <i>T. vaginalis</i> 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.	<i>T. vaginalis</i> , if present, is not detectable.	Extraction Control Failure
	Any value	Extraction Transfer Failure. Repeat test from initial specimen tube or obtain another specimen for testing.	<i>T. vaginalis</i> , if present, is not detectable.	Extraction Transfer Failure
	Any value	Liquid Level Failure. Repeat test from initial specimen tube or obtain another specimen for testing.	<i>T. vaginalis</i> , if present, is not detectable.	Liquid Level Failure
	Any value	Error. Repeat test from initial specimen tube or obtain another specimen for testing.	<i>T. vaginalis</i> , if present, is not detectable.	Error
	<125	ROX Channel Failure. Repeat test from initial specimen tube or obtain another specimen for testing.	<i>T. vaginalis</i> , if present, is not detectable.	ROX Failure



## SPECIMEN PROCESSING CONTROLS

Specimen Processing Controls may be tested in accordance with the requirements of appropriate accrediting organizations. A positive Specimen Processing Control should test 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. Specimen processing controls for *T. vaginalis* may also be prepared in the laboratory using commercially available Gibson Laboratories Tri-Valent™ Swab Positive Control (Cat. # TVS-01).

### Gibson Laboratories Processing Control Preparation:

1. Obtain Gibson Laboratories Tri-Valent Swab Positive Control (Cat. # TVS-01) from Gibson Laboratories.
2. Store at 2 – 8 °C per manufacturer's instructions.
3. Remove control swab from container and express into a Q<sup>x</sup> Swab Diluent Tube and tightly recap using a **black pierceable cap**.
4. Process the controls according to the Pre-warm Procedure and then follow the Test 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 area to be tested, use a clean collection swab from the **BD ProbeTec** Q<sup>x</sup> Collection Kit for Endocervical or Lesion Specimens.
2. Dip the swab into the Q<sup>x</sup> Swab Diluent Tube and wipe the first area\* using a broad sweeping motion.
3. Fully insert the collection swab into the Q<sup>x</sup> 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, process 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. Make sure the entire area is wetted with the solution and allowed to remain on the surface for at least two minutes 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 Services for additional information.

## LIMITATIONS OF THE PROCEDURE

1. This method has been tested only with female symptomatic and asymptomatic neat urine specimens, vaginal specimens and endocervical 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, Storage and Transport" section of this insert.
3. A negative test does not exclude the possibility of infection because test results may be affected by improper specimen collection, technical error, specimen mix-up, concurrent antiprotozoal therapy, or the quantity of organism in the specimen may be below the sensitivity of the test.
4. As with many diagnostic tests, results from the **BD ProbeTec** *Trichomonas vaginalis* (TV) Q<sup>x</sup> Amplified DNA Assay should be interpreted in conjunction with other laboratory and clinical data available to the physician.
5. The **BD ProbeTec** *Trichomonas vaginalis* (TV) Q<sup>x</sup> Amplified DNA Assay provides qualitative results. No correlation can be drawn between the magnitude of the positive assay signal (MaxRFU) and the quantity of nucleic acid in a patient sample.
6. The Positive Control for the **BD ProbeTec** *Trichomonas vaginalis* (TV) Q<sup>x</sup> Amplified DNA Assay is used in testing for TV, therefore correct positioning of the microwell strips is important for final results reporting.
7. The blank microwell is required to produce the EC results for the Negative Control and to verify extraction for negative specimens, therefore correct positioning of the microwell strips is important for final results reporting.
8. Use of the **BD ProbeTec** *Trichomonas vaginalis* (TV) Q<sup>x</sup> Amplified DNA Assay is limited to personnel who have been trained in the assay procedure and the **BD Viper** System.
9. *Trichomonas tenax* was found to cross-reactant with the TV Q<sup>x</sup> Assay at levels above 1.0 x 10<sup>4</sup> organisms/mL. *T. tenax* is a commensal of the oral cavity. See TV Q<sup>x</sup> Analytical Specificity for details.
10. The performance of the **BD ProbeTec** *Trichomonas vaginalis* (TV) Q<sup>x</sup> Amplified DNA Assay has not been evaluated in pregnant women or in patients less than 18 years of age.
11. The performance of the **BD ProbeTec** *Trichomonas vaginalis* (TV) Q<sup>x</sup> Amplified DNA Assay has not been evaluated in the presence of *Dientamoeba fragilis*.

## CLINICAL PERFORMANCE

### EXPECTED RESULTS

#### A. Prevalence

The prevalence of *Trichomonas vaginalis* observed in symptomatic and asymptomatic female subjects during a multi-center trial (April/2012-August/2012) was determined by the composite reference method result. The prevalence for *Trichomonas vaginalis* for the neat urine specimens was 15.2%. Prevalence was 13.5% and 13.8% respectively for the endocervical and vaginal swab specimens.

Table 6 summarizes the prevalence overall and by site. Also provided are the number of positive results and total number of results by site from subjects designated by the composite reference as positive or negative.

**Table 6. TV Q<sup>x</sup> Assay Prevalence by Specimen Type and Collection Site**

Specimen Type	Prevalence (%) (# positive/# tested)							
	All Sites	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7
Neat Urine	15.2 (112/735)	29.1 (16/55)	27.4 (26/95)	14.4 (18/125)	2.8 (4/142)	9.9 (7/71)	7.4 (9/122)	25.6 (32/125)
Vaginal	13.8 (116/838)	28.6 (16/56)	27.1 (26/96)	14.4 (18/125)	2.8 (4/142)	6.5 (11/169)	7.4 (9/122)	25.0 (32/128)
Endocervical	13.5 (134/995)	24.7 (24/97)	23.9 (27/113)	15.6 (24/154)	3.8 (8/213)	6.5 (11/170)	7.4 (9/121)	24.4 (31/127)

#### B. Positive and Negative Predictive Value

Hypothetical positive and negative predictive values (PPV and NPV) for the TV Q<sup>x</sup> Assay are shown in Table 7. These calculations are based on hypothetical prevalence and overall sensitivity and specificity per specimen type as determined in the clinical trial for each specimen type (Table 8). For the TV Q<sup>x</sup> Assay, these calculations are based upon an overall sensitivity and specificity of 95.5% and 98.7%, respectively, for the neat urine specimen type, 98.3% and 99.0% respectively, for the vaginal swab specimen type and 96.3% and 99.4%, respectively, for the endocervical swab specimen type.

PPV was calculated using: (Sensitivity x Prevalence) / (Sensitivity x Prevalence + [1 – Specificity] x [1 – Prevalence]).

NPV was calculated using: (Specificity x [1 – Prevalence]) / ([1 – Sensitivity] x Prevalence + Specificity x [1 – Prevalence]).

**Table 7. Prevalence vs Hypothetical Predictive Values for TV Q<sup>x</sup> Assay**

Prevalence (%)	Neat Urine		Vaginal		Endocervical	
	PPV (%)	NPV (%)	PPV (%)	NPV (%)	PPV (%)	NPV (%)
2	60.3	99.9	67.4	100	77.2	99.9
5	79.7	99.8	84.2	99.9	89.7	99.8
10	89.2	99.5	91.8	99.8	94.9	99.6
20	94.9	98.9	96.2	99.6	97.6	99.1
30	97.0	98.1	97.7	99.3	98.6	98.4
40	98.0	97.1	98.5	98.9	99.1	97.6
50	98.7	95.7	99.0	98.3	99.4	96.4

### PERFORMANCE CHARACTERISTICS

First void urine specimens between 20 – 60 mL, self-collected vaginal swabs in a clinical setting and clinician-collected endocervical swabs were collected from 1222 symptomatic and asymptomatic female subjects attending family planning, OB/GYN, and sexually transmitted disease clinics at 7 geographically diverse clinical sites in North America. Subjects were classified as symptomatic if they presented to the clinic with abnormal vaginal discharge, itching, dysuria or odor as determined by the inclusion/exclusion criteria. The final data analysis included 1197 evaluable subjects. Exclusions from the data analysis were made due to specimens not collected, enrollment issues, transport errors, collection errors, shipping errors, processing errors, or **BD Viper** System operating errors. The final data analysis included 735 compliant results for the neat urine specimen type, 838 compliant results for the vaginal swab specimen type and 995 compliant results for the endocervical swab specimen type.

For each subject, a first void urine was collected in a sterile urine cup. The urine was aliquoted into **BD Viper** Specimen Tubes. Subsequent to the urine being collected, the subject self-collected a **BD ProbeTec** Vaginal Swab for testing on the **BD ProbeTec** TV Q<sup>x</sup> Assay. This was followed by two clinician-collected vaginal swabs obtained for composite reference testing of the wet mount and TV culture for detection of *Trichomonas vaginalis* and one clinician-collected vaginal swab for discrepant testing. Lastly the clinician collected an endocervical swab for testing on the **BD ProbeTec** TV Q<sup>x</sup> Assay. The wet mount was performed at the bedside and the TV cultures were transported to the assigned testing facility. The **BD ProbeTec** neat urines, vaginal and endocervical swab specimens were transported to one of the three **BD Viper** testing laboratories where they were tested using the **BD ProbeTec** TV Q<sup>x</sup> Assay on the **BD Viper** System in Extracted Mode.

All sensitivity and specificity calculations were based on the total number of **BD ProbeTec** TV Q<sup>x</sup> Assay results for the neat urines, vaginal and endocervical specimens as compared to the composite reference of the wet mount and the commercially available TV culture test method.

The subject was considered to be positive for *Trichomonas vaginalis* if either the wet mount or TV culture result was positive. Subjects were considered negative for *Trichomonas vaginalis* if both of the reference methods were negative. The sensitivity and specificity by specimen type and symptomatic status for the compliant TV Q<sup>x</sup> Assay PIS evaluable subjects are seen in Table 8. The initial instrument error rate during the clinical study was 0.1%, or 3 indeterminate results out of 2,568 tests. The final error rate after repeat testing performed on indeterminate results was 0.04%, or 1 indeterminate result out of 2,568 tests.

**Table 8. TV Q<sup>x</sup> Assay Performance Compared to Composite Reference by Symptomatic Status**

			Performance Compared to Composite Reference			
Specimen Type	Status	n	Sensitivity	95% C.I.	Specificity	95% C.I.
Neat Urine	A	289	93.1% (27/29)	(78.0%, 98.1%)	99.6% (259/260)	(97.9%, 99.9%)
	S	446	96.4% (80/83)	(89.9%, 98.8%)	98.1% (356/363)	(96.1%, 99.1%)
	Total	735	95.5% (107/112) <sup>A</sup>	(90.0%, 98.1%)	98.7% (615/623) <sup>B</sup>	(97.5%, 99.3%)
Vaginal	A	343	93.5% (29/31)	(79.3%, 98.2%)	99.0% (309/312)	(97.2%, 99.7%)
	S	495	100.0% (85/85)	(95.7%, 100.0%)	99.0% (406/410)	(97.5%, 99.6%)
	Total	838	98.3% (114/116)	(93.9%, 99.5%)	99.0% (715/722) <sup>C</sup>	(98.0%, 99.5%)
Endocervical	A	505	92.2% (47/51)	(81.5%, 96.9%)	99.1% (450/454)	(97.8%, 99.7%)
	S	490	98.8% (82/83)	(93.5%, 99.8%)	99.8% (406/407)	(98.6%, 100.0%)
	Total	995	96.3% (129/134)	(91.6%, 98.4%)	99.4% (856/861) <sup>D</sup>	(98.6%, 99.8%)
All Specimen Types Combined	A	1137	92.8% (103/111)	(86.4%, 96.3%)	99.2% (1018/1026)	(98.5%, 99.6%)
	S	1431	98.4% (247/251)	(96.0%, 99.4%)	99.0% (1168/1180)	(98.2%, 99.4%)
	Overall	2568	96.7% (350/362)	(94.3%, 98.1%)	99.1% (2186/2206)	(98.6%, 99.4%)

A = asymptomatic, C.I. = confidence interval, n = number, S = symptomatic

<sup>A</sup> Of the five neat urine Viper negative, composite reference positive, one was also negative by alternate NAAT test.

<sup>B</sup> Of the eight neat Viper positive, composite reference negative, six were also positive by alternate NAAT test.

<sup>C</sup> Of the seven vaginal Viper positive, composite reference negative, four were also positive by alternate NAAT test.

<sup>D</sup> Of the two endocervical Viper positive, composite reference negative, both were also positive in at least one specimen tested by alternate NAAT test.

Table 9 shows the sensitivity, specificity, PPV and NPV of the TV Q<sup>x</sup> Assay by specimen type and collection site.

**Table 9. TV Q<sup>+</sup> Assay Performance Compared to Wet Mount and TV Culture Composite Reference Result (by collection site)**

Specimen Type	Clinical Site	Prev	n	Performance Compared to Composite Reference				PPV%	NPV%
				Sensitivity	95% C.I.	Specificity	95% C.I.		
Neat Urine	1	29.1%	55	81.3% (13/16)	(57.0%, 93.4%)	100.0% (39/39)	(91.0%, 100.0%)	100.0%	92.9%
	2	27.4%	95	100.0% (26/26)	(87.1%, 100.0%)	98.6% (68/69)	(92.2%, 99.7%)	96.3%	100.0%
	3	14.4%	125	94.4% (17/18)	(74.2%, 99.0%)	97.2% (104/107)	(92.1%, 99.0%)	85.0%	99.0%
	4	2.8%	142	100.0% (4/4)	(51.0%, 100.0%)	99.3% (137/138)	(96.0%, 99.9%)	80.0%	100.0%
	5	9.9%	71	100.0% (7/7)	(64.6%, 100.0%)	98.4% (63/64)	(91.7%, 99.7%)	87.5%	100.0%
	6	7.4%	122	100.0% (9/9)	(70.1%, 100.0%)	100.0% (113/113)	(96.7%, 100.0%)	100.0%	100.0%
	7	25.6%	125	96.9% (31/32)	(84.3%, 99.4%)	97.8% (91/93)	(92.5%, 99.4%)	93.9%	98.9%
Vaginal	1	28.6%	56	100.0% (16/16)	(80.6%, 100.0%)	100.0% (40/40)	(91.2%, 100.0%)	100.0%	100.0%
	2	27.1%	96	100.0% (26/26)	(87.1%, 100.0%)	100.0% (70/70)	(94.8%, 100.0%)	100.0%	100.0%
	3	14.4%	125	94.4% (17/18)	(74.2%, 99.0%)	98.1% (105/107)	(93.4%, 99.5%)	89.5%	99.1%
	4	2.8%	142	100.0% (4/4)	(51.0%, 100.0%)	97.8% (135/138)	(93.8%, 99.3%)	57.1%	100.0%
	5	6.5%	169	90.9% (10/11)	(62.3%, 98.4%)	100.0% (158/158)	(97.6%, 100.0%)	100.0%	99.4%
	6	7.4%	122	100.0% (9/9)	(70.1%, 100.0%)	100.0% (113/113)	(96.7%, 100.0%)	100.0%	100.0%
	7	25.0%	128	100.0% (32/32)	(89.3%, 100.0%)	97.9% (94/96)	(92.7%, 99.4%)	94.1%	100.0%
Endocervical	1	24.7%	97	91.7% (22/24)	(74.2%, 97.7%)	100.0% (73/73)	(95.0%, 100.0%)	100.0%	97.3%
	2	23.9%	113	100.0% (27/27)	(87.5%, 100.0%)	100.0% (86/86)	(95.7%, 100.0%)	100.0%	100.0%
	3	15.6%	154	95.8% (23/24)	(79.8%, 99.3%)	100.0% (130/130)	(97.1%, 100.0%)	100.0%	99.2%
	4	3.8%	213	100.0% (8/8)	(67.6%, 100.0%)	98.0% (201/205)	(95.1%, 99.2%)	66.7%	100.0%
	5	6.5%	170	81.8% (9/11)	(52.3%, 94.9%)	100.0% (159/159)	(97.6%, 100.0%)	100.0%	98.8%
	6	7.4%	121	100.0% (9/9)	(70.1%, 100.0%)	100.0% (112/112)	(96.7%, 100.0%)	100.0%	100.0%
	7	24.4%	127	100.0% (31/31)	(89.0%, 100.0%)	99.0% (95/96)	(94.3%, 99.8%)	96.9%	100.0%

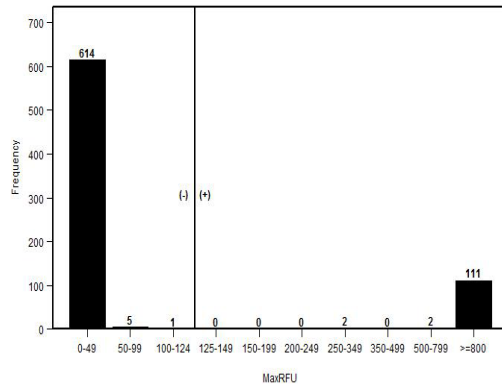
C.I. = confidence interval, n = number, NPV = negative predictive value, PPV = positive predictive value, Prev = prevalence, Spec = specimen

#### C. MaxRFU Frequency Distributions

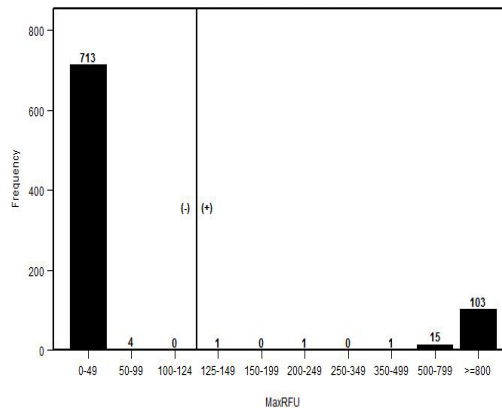
A total of 2568 TV Q<sup>+</sup> Assay results were evaluated at 7 geographically diverse clinical sites. A frequency distribution of the initial MaxRFU values for the TV Q<sup>+</sup> Assay for the Neat urines, vaginal and endocervical swab specimens is shown in Figures A - C. The distribution of MaxRFU values from TV Q<sup>+</sup> true positive (TP), true negative (TN), false positive (FP), and false negative (FN) specimens (i.e., from those specimens that yielded results which were discordant with the composite reference methods of wet mount and TV culture) is shown in Table 10.\*

\*Any MaxRFU value below 125 is considered negative for TV while MaxRFU values ≥125 are considered positive for TV.

**Figure A. MaxRFU Distribution for Neat Urine**



**Figure B. MaxRFU Distribution for Vaginal Swab Specimen**



**Figure C. MaxRFU Distribution for Endocervical Swab Specimen**

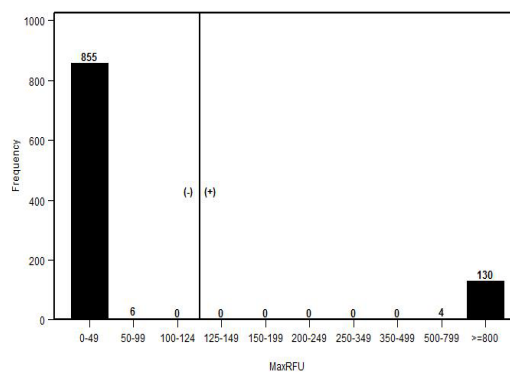


Table 10. MaxRFU ranges for FN, FP, TN and TP

MAX RFU range		0-49	50-99	100-124	125-149	200-249	250-349	350-499	500-799	>=800
n		2182	15	1	1	1	2	1	21	344
FN	Endocervical	4	1	0	0	0	0	0	0	0
	Neat Urine	5	0	0	0	0	0	0	0	0
	Vaginal	2	0	0	0	0	0	0	0	0
	Total	11	1	0	0	0	0	0	0	0
FP	Endocervical	0	0	0	0	0	0	0	0	5
	Neat Urine	0	0	0	0	0	1	0	2	5
	Vaginal	0	0	0	1	0	0	1	2	3
	Total	0	0	0	1	0	1	1	4	13
TN	Endocervical	851	5	0	0	0	0	0	0	0
	Neat Urine	609	5	1	0	0	0	0	0	0
	Vaginal	711	4	0	0	0	0	0	0	0
	Total	2171	14	1	0	0	0	0	0	0
TP	Endocervical	0	0	0	0	0	0	0	4	125
	Neat Urine	0	0	0	0	0	1	0	0	106
	Vaginal	0	0	0	0	1	0	0	13	100
	Total	0	0	0	0	1	1	0	17	331

FN = false negative, FP = false positive, TN = true negative, TP = true positive, n = number

#### D. Controls

During the clinical evaluation, there were no CT/GC/TV Q<sup>+</sup> Positive Control Failures from 235 TV Q<sup>+</sup> runs. For the CT/GC/TV Q<sup>+</sup> Negative Control, there was 1 CT/GC/TV Q<sup>+</sup> Negative control failure from the 235 TV Q<sup>+</sup> runs. The CT/GC/TV Q<sup>+</sup> Positive and Negative Control MaxRFU values observed in the clinical trial are shown in Table 11.

Table 11. CT/GC/TV Q<sup>+</sup> Control Information

Control	MaxRFU					
	n	Range	5th Percentile	Mean	Median	95th Percentile
Negative Control	234	0 – 56	0	11	8	32
Positive Control	235	724 – 2304	982	1419	1335	1960

n = number

# PERFORMANCE CHARACTERISTICS

**Table 12. Analysis of TV Positive/Negative Specimens from Subjects as Compared to Composite Reference**

PIS	Wet Mount	TV Culture	TVQ			Symptomatic		
			Vaginal	Endocervical	Neat Urine	Yes	No	Total
P	P	P	P	P	P	58	14	72
	P	P	P	P	N	0	1	1
	P	P	P	P	NA	2	0	2
	P	P	P	NA	P	0	1	1
	P	P	NA	P	NA	0	14	14
	P	N	P	P	P	2	1	3
	N	P	P	P	P	17	9	26
	N	P	P	P	N	2	0	2
	N	P	P	P	NA	0	1	1
	N	P	P	N	P	0	1	1
	N	P	P	N	N	1	1	2
	N	P	P	NA	P	2	0	2
	N	P	N	P	P	0	1	1
	N	P	N	N	NA	0	1	1
	N	P	NA	P	NA	0	6	6
	N	P	NA	N	NA	0	1	1
	NA	P	P	P	P	1	0	1
N	N	N	P	P	P	1	0	1
	N	N	P	P	N	0	1	1
	N	N	P	N	P	2	1	3
	N	N	P	N	N	1	1	2
	N	N	N	N	P	4	0	4
	N	N	N	N	N	352	255	607
	N	N	N	N	NA	46	53	99
	N	N	N	NA	N	3	1	4
	N	N	N	NA	NA	1	0	1
	N	N	NA	P	NA	0	3	3
	N	N	NA	N	NA	1	140	141
	N	N	NA	NA	N	0	1	1

PIS = patient infected status, P = positive, N = negative, NA = Not Available

## ANALYTICAL PERFORMANCE

### TV Q<sup>x</sup> Assay Analytical Sensitivity

The analytical sensitivity (Limit of Detection or LOD) for the **BD ProbeTec** TV Q<sup>x</sup> Assay was determined for two strains of *T. vaginalis*, (one Metronidazole-sensitive and one Metronidazole-resistant) by diluting in specimen matrix at varying concentrations of organisms to create an LOD panel consisting of six target levels. Data were generated for each target level (n = 60 per level), and resulting MaxRFU values were analyzed to determine proportion positive at each level. Proportion positive was used to generate positivity curves from which each 95% LOD was calculated.

The Limits of Detection (LODs) for the TV Q<sup>x</sup> Assay with *T. vaginalis* ATCC strains 30001 and 50143 in **BD Q<sup>x</sup> Swab Diluent** when extracted on the **BD Viper** System were 54.5 and 55.5 trichomonads/mL, respectively. The LODs for neat urine, vaginal and endocervical specimen matrices are presented in Table 13.

The TV Q<sup>x</sup> Assay on the **BD Viper** system in extracted mode could detect with ≥ 95% proportion positive four additional ATCC strains (30237, 50144, 30184, and 30185) in urine matrix and three ATCC strains (30185, 30237, and 50144) in vaginal swab specimen matrix at a concentration of 122.1 TV/mL.

**Table 13. LOD Estimates for TV Q<sup>x</sup> Assay**

Specimen type	ATCC Strain	LOD (TV/mL)
Neat Urine	30001	109.7
	50143	108.2
Vaginal	30001	74.4
	50143	88.4
	30184*	152.8
Endocervical	30001	64.8
	50143	76.2

\*LOD for *T. vaginalis* ATCC strain 30184 was determined in vaginal swab specimen matrix only.

#### TV Q<sup>x</sup> Analytical Specificity

DNA from 54 organisms listed in Table 14 was extracted on the **BD Viper** System and tested with the **BD ProbeTec TV Q<sup>x</sup>** Amplified DNA Assay. All potential cross-reactive species were tested at approximately  $\geq 1 \times 10^6$  CFU/mL (bacteria and yeast),  $\geq 1 \times 10^6$  vp/mL (viral particles), or organisms/mL (viruses and pathogens), except where noted. The TV Q<sup>x</sup> Assay did not cross-react with 53 of the 54 organisms tested with the assay at the above mentioned concentrations. One organism, *T. tenax*, was identified as a cross-reactant at concentrations  $>1 \times 10^4$  organisms/mL.

**Table 14. Potentially Cross-reacting Microorganisms**

Organism	Final Concentration	Organism	Final Concentration
<i>Acinetobacter baumannii</i>	$1.03 \times 10^9$ CFU/mL	HPV-18	$6.13 \times 10^8$ cells/mL
<i>Actinomyces israelii</i>	$6.23 \times 10^7$ CFU/mL	Human Immunodeficiency Virus (HIV-1)	$1.00 \times 10^8$ vp/mL
<i>Atopobium vaginae</i>	$5.70 \times 10^7$ CFU/mL	<i>Klebsiella oxytoca</i>	$6.27 \times 10^8$ CFU/mL
<i>Bacteroides fragilis</i>	$1.04 \times 10^9$ CFU/mL	<i>Lactobacillus acidophilus</i>	$1.37 \times 10^7$ CFU/mL
<i>Bifidobacterium bifidum</i>	$7.57 \times 10^7$ CFU/mL	<i>Lactobacillus jensenii</i>	$4.00 \times 10^7$ CFU/mL
<i>Campylobacter jejuni</i>	$2.87 \times 10^7$ CFU/mL	<i>Lactobacillus vaginalis</i>	$6.10 \times 10^7$ CFU/mL
<i>Candida albicans</i>	$8.50 \times 10^6$ CFU/mL	<i>Listeria monocytogenes</i>	$8.50 \times 10^8$ CFU/ml
<i>Candida glabrata</i>	$2.05 \times 10^7$ CFU/mL	<i>Mobiluncus curtisii</i>	$6.47 \times 10^8$ CFU/mL
<i>Candida parapsilosis</i>	$2.20 \times 10^7$ CFU/mL	<i>Moraxella catarrhalis</i> ( <i>Branhamella</i> sp.)	$1.93 \times 10^8$ CFU/mL
<i>Candida tropicalis</i>	$7.00 \times 10^6$ CFU/mL	<i>Mycobacterium smegmatis</i>	$1.23 \times 10^7$ CFU/mL
<i>Chlamydia trachomatis</i>	$3.50 \times 10^6$ EB/mL	<i>Mycoplasma genitalium</i>	$1.00 \times 10^7$ CFU/mL
<i>Clostridium difficile</i>	$6.10 \times 10^7$ CFU/mL	<i>Mycoplasma hominis</i>	$1.00 \times 10^6$ CFU/mL
<i>Clostridium perfringens</i>	$5.63 \times 10^7$ CFU/mL	<i>Neisseria gonorrhoeae</i>	$4.63 \times 10^8$ CFU/mL
<i>Corynebacterium genitalium</i> biovar 1	$1.16 \times 10^8$ CFU/mL	<i>Pentatrichomonas hominis</i>	$3.39 \times 10^5$ Organisms/mL
<i>Cryptococcus neoformans</i>	$6.33 \times 10^6$ CFU/mL	<i>Peptostreptococcus anaerobius</i>	$2.37 \times 10^7$ CFU/mL
<i>Enterobacter aerogenes</i>	$8.23 \times 10^8$ CFU/mL	<i>Prevotella bivia</i>	$7.03 \times 10^8$ CFU/mL
<i>Enterobacter cloacae</i>	$1 \times 10^6$ CFU/mL	<i>Proteus mirabilis</i>	$7.97 \times 10^8$ CFU/mL
<i>Enterococcus faecalis</i>	$5.13 \times 10^8$ CFU/mL	<i>Pseudomonas aeruginosa</i>	$1.20 \times 10^9$ CFU/mL
<i>Escherichia coli</i>	$6.17 \times 10^8$ CFU/mL	<i>Staphylococcus aureus</i> , non-protein A	$4.14 \times 10^9$ CFU/mL
<i>Fusobacterium nucleatum</i>	$3.00 \times 10^6$ CFU/mL	<i>Staphylococcus aureus</i> , protein-A producing	$4.80 \times 10^9$ CFU/mL
<i>Gardnerella vaginalis</i>	$4.07 \times 10^8$ CFU/mL	<i>Staphylococcus epidermidis</i>	$1.80 \times 10^8$ CFU/mL
<i>Haemophilus ducreyi</i>	$9.93 \times 10^8$ CFU/mL	<i>Staphylococcus saprophyticus</i>	$3.47 \times 10^8$ CFU/mL
Herpes Simplex Virus Type 1	$1.00 \times 10^7$ vp/mL	<i>Streptococcus pyogenes</i> (Group A)	$3.73 \times 10^8$ CFU/mL
Herpes Simplex Virus Type 2	$1.00 \times 10^7$ vp/mL	<i>Streptococcus agalactiae</i> (Group B)	$5.67 \times 10^8$ CFU/mL
HPV-6	$1.57 \times 10^9$ cells/mL	<i>Trichomonas tenax</i>	$1.50 \times 10^6$ Organisms/mL
HPV-11	$4.87 \times 10^8$ cells/mL	<i>Ureaplasma urealyticum</i>	$1.00 \times 10^6$ CFU/mL
HPV-16	$8.43 \times 10^8$ cells/mL	<i>Veillonella parvula</i>	$7.47 \times 10^8$ CFU/mL



### TV Q<sup>+</sup> Interfering Substances

The performance of the **BD ProbeTec TV Q<sup>+</sup> Assay** on the **BD Viper** System in extracted mode was evaluated in the presence of potentially interfering substances which may be encountered in swab and urine specimens. Potentially interfering substances were spiked into vaginal swab specimen or urine matrix, in both the presence and the absence of *T. vaginalis* ATCC strain 30001 or 50143, respectively. The level tested was three times the determined limit of detection. The strain with the lowest LOD for that sample type as determined by the LOD validations was used for these studies. Results are summarized in Table 15.

**Table 15. TV Q<sup>+</sup> Assay Potentially Interfering Substances**

Interpretation	Swab	Urine Matrix
<b>No interference observed at levels listed</b>	Whole Blood (≤60%) Seminal Fluid Mucus Over the counter vaginal products and contraceptives Hemorrhoidal cream Prescription vaginal treatments Leukocytes (1 x 10 <sup>6</sup> cells/mL) Intravaginal hormones	Phenazopyridine Hydrochloride Whole Blood (< 1% v/v) Acidic urine (pH 5.0) Alkaline urine (pH 9.0) Hormone pool Analgesic pool Antibiotics Bilirubin Mucus Albumin (< 1 mg/mL) Glucose Semen (5% v/v) Over the counter deodorant spray and powder Leukocytes (2.5x10 <sup>6</sup> cells/mL)
<b>May cause extraction control (EC) failures</b>	Blood (>60%)	Not applicable
<b>May cause false negative results</b>	Not applicable	Not applicable

### Urine Specimen Stability

Pools of *T. vaginalis* negative female urine specimens were used in analytical experiments to support the urine storage and transport stability claims. Neat urine pools were spiked with TV ATCC strain 30001 at 330 trichomonads/mL (3x LOD in neat urine). The pools were dispensed in 2 mL volumes into **BD Viper** Specimen Tubes and stored at the following conditions: 2 – 8 °C for up to 7 days; 30 °C for 18 and 24 hours; -20 °C for up to 180 days. At each time point, samples were removed from storage and tested with the **BD ProbeTec TV Q<sup>+</sup> Assay** on the **BD Viper** System in extracted mode. Twenty-four assay replicates were generated for each condition (sample type/temperature/duration).

### Vaginal Dry and Expressed Swab Stability

Pools of TV negative vaginal swab matrix were used in analytical experiments to support the storage and transport stability claims for dry vaginal swab specimens. Pools were spiked with TV strain ATCC 30001 to give 222 trichomonads/mL (3x LOD), when seeded onto swabs and expressed in Q<sup>+</sup> Swab Diluent. Seeded dry swabs were stored at 2 – 8 °C for up to 14 days; or at 30 °C for up to 3 days; or at -20 °C for up to 180 days. At each time point, dry swabs were removed from storage and expressed into 2 mL of Q<sup>+</sup> Swab Diluent and evaluated with the **BD ProbeTec TV Q<sup>+</sup> Assay** on the **BD Viper** System in extracted mode. Twenty four assay replicates were generated for each condition (sample type/temperature/duration).

Pools of TV negative vaginal swab matrix were used in analytical experiments to support the storage and transport stability claims for expressed vaginal swab specimens. Pools were spiked with TV strain ATCC 30001 to give 222 trichomonads/mL (3x LOD). The spiked swab matrix was stored at 2 – 8 °C or 30 °C for up to 30 days; or at -20 °C for up to 180 days. At each time point, samples were removed from storage and evaluated with the **BD ProbeTec TV Q<sup>+</sup> Assay** on the **BD Viper** System in extracted mode. Twenty four assay replicates were generated for each condition (sample type/temperature/duration).

### Endocervical Swab Specimen Stability

Pools of TV negative endocervical swab matrix were used in analytical experiments to support the storage and transport stability claims for endocervical swab specimens. Pools were spiked with TV strain ATCC 30001 to give 195 trichomonads/mL (3x LOD). The spiked swab matrix was stored at 2 – 8 °C or 30 °C for up to 30 days; or at -20 °C for up to 180 days. At each time point, samples were removed from storage and evaluated with the **BD ProbeTec TV Q<sup>+</sup> Assay** on the **BD Viper** System in extracted mode. Twenty four assay replicates were generated for each condition (sample type/temperature/duration).

### Post Pre-Warm Specimen Stability

Pools of TV negative neat urine matrix were used in analytical experiments to support the storage claims for pre-warmed neat urine specimens. Pools of neat urine were spiked with *T. vaginalis* ATCC strain 30001 at 330 trichomonads/mL (3 x LOD). The neat urine pools were dispensed in 2 mL volumes into **BD Viper** specimen tubes. The specimen tubes were pre-warmed at 114 °C for 15 min and cooled for 15 min. After the pre-warm process, the specimen tubes were stored at 2 – 8 °C for up to 7 days, at 30 °C for up to 3 days, and at -20 °C for up to 180 days. At each time point, samples were removed from storage and tested with the **BD ProbeTec TV Q<sup>+</sup> Assay** on the **BD Viper** System in extracted mode. Twenty-four assay replicates were generated for each condition (sample type/temperature/duration).

Pools of TV negative vaginal and endocervical swab specimen matrices in Q<sup>+</sup> Swab Diluent were used in analytical experiments to support the storage stability claims for pre-warmed expressed vaginal and endocervical swab specimens. For both types of matrix, pools were spiked with TV strain ATCC 30001 at 3x LOD, 222 trichomonads/mL for vaginal matrix and 195 trichomonads/mL for endocervical matrix) and aliquoted into 2 mL volumes in **BD Viper** specimen tubes. The tubes were

pre-warmed at 114 °C for 15 min and cooled for 15 min. After the pre-warm process, the specimen tubes were stored either at 2 – 8 °C or 30 °C for up to 30 days, or at -20 °C for up to 180 days. At each time point, samples were removed from storage and evaluated with the **BD ProbeTec** TV Q<sup>x</sup> Assay on the **BD Viper** System in extracted mode. Twenty four assay replicates were generated for each condition (sample type/temperature/duration). The expected results were obtained with the TV Q<sup>x</sup> Assay under all conditions tested.

#### Reproducibility

Reproducibility of the **BD Viper** System using the **BD ProbeTec** TV Q<sup>x</sup> Assay was evaluated at three test sites (two external and one internal site) on one **BD Viper** System per site. Panels were comprised of four levels of *Trichomonas vaginalis* seeded into urine specimen matrix or vaginal matrix in Q<sup>x</sup> diluent. *Trichomonas vaginalis* organism was spiked into each specimen matrix at 1x and 3x LOD for the low positive and moderate positive panel members respectively. Uninoculated urine and vaginal matrix in Q<sup>x</sup> diluent were used as negative samples. An additional target level was included in the panel to evaluate the reproducibility of test results (i.e., proportion positive or negative) at target levels below the analytical LOD of the **BD ProbeTec** TV Q<sup>x</sup> Assay. This additional panel member was created in each matrix using 0.3x the LOD. This level was selected to fall within the dynamic range of the analytical LOD curves for the **BD ProbeTec** TV Q<sup>x</sup> Assay. Three replicates of each panel member were tested twice a day for five days on each **BD Viper** System in Extracted Mode. A summary of the reproducibility data for each specimen matrix for the **BD ProbeTec** TV Q<sup>x</sup> Assay is presented in Table 16.

**Table 16. Summary of Reproducibility Data for Vaginal and Urine Matrix when tested on the BD Viper System with the TV Q<sup>x</sup> Assay**

Specimen type	Panel	Agreement	95% CI	Mean	Within Run		Between Run Within Day		Between Day Within Site		Between Site	
					SD	%CV	SD	%CV	SD	%CV	SD	%CV
Vaginal	Zero	100.0% (89/89)	(95.9%, 100.0%)	3.89	4.02	103.53	2.01	51.64	0.92	23.57	4.69	120.60
	High Negative (0.3X LOD)	43.3% (39/90)	(33.6%, 53.6%)	795.66	814.68	102.39	136.97	17.21	287.34	36.11	190.15	23.90
	Low Positive (1X LOD)	96.7% (87/90)	(90.7%, 98.9%)	1632.07	457.83	28.05	0.00	0.00	0.00	0.00	110.13	6.75
	High Positive (3X LOD)	100.0% (90/90)	(95.9%, 100.0%)	1756.68	297.78	16.95	0.00	0.00	104.51	5.95	260.45	14.83
Urine Matrix	Zero	100.0% (90/90)	(95.9%, 100.0%)	8.70	11.33	130.18	0.00	0.00	0.00	0.00	8.29	95.33
	High Negative (0.3X LOD)	39.3% (35/89)*	(29.8%, 49.7%)	976.96	913.87	93.54	0.00	0.00	0.00	0.00	0.00	0.00
	Low Positive (1X LOD)	92.1% (82/89)*	(84.6%, 96.1%)	1574.67	681.14	43.26	0.00	0.00	0.00	0.00	0.00	0.00
	High Positive (3X LOD)	100.0% (90/90)	(95.9%, 100.0%)	1822.52	364.46	20.00	0.00	0.00	0.00	0.00	172.88	9.49

\* Four non-reportable results were due to extraction control failures which caused a reduction in the full number of replicates at one test site.

#### System Cross Contamination and Carryover

An internal study was conducted to evaluate the risk of producing a false positive result with the TV Q<sup>x</sup> Assay protocol in either the same run on the **BD Viper** System in Extracted Mode (within run cross-contamination) or in a subsequent run (between run carryover). Testing was conducted using negative and positive samples on three **BD Viper** Systems. Positive samples were seeded with a representative analyte (10<sup>5</sup> CT EBs/mL). Two runs with alternating positive and negative samples arranged in the sample rack in a checkerboard pattern (at a positivity rate of 50%) were performed on each **BD Viper** System followed by a third run on each **BD Viper** System with negative samples. This sequence was repeated twice to determine the combined rate of crossover and carryover contamination. The overall rate of contamination was ≤0.49% (3/612) in TVQ mode and ≤0.39% (3/807) in CTQ/GCQ/TVQ panel mode (login mode in which a single sample tube may be tested with the CT Q<sup>x</sup>, GC Q<sup>x</sup>, and TV Q<sup>x</sup> Assays on the **BD Viper** System). See **BD Viper** Instrument User's Manual for more information on the CTQ/GCQ/TVQ mode.

## INTERPRETATION OF TABLES

### Symbols and Abbreviations

#### Symbols

(+)	positive
(-)	negative
#	number
%	percentage

#### Abbreviations

A	Asymptomatic
CI	Confidence Interval
CV	Coefficient of Variation
CFU	Colony Forming Units
EC	Extraction Control
ET	Extraction Transfer Error
FN	False Negative
FP	False Positive
HIV	Human Immunodeficiency Virus
I	Indeterminate
LBC	Liquid Based Cytology
LOD	Limit of Detection
MaxRFU	Maximum relative fluorescent units
N	Negative
n	number
NA	non-applicable
NAAT	Nucleic Acid Amplification Test
NPA	Negative Percent Agreement
NPV	Negative Predictive Value
OB/GYN	Obstetrics/Gynecology
P	Positive
PBS	Phosphate Buffered Saline
PCR	Polymerase Chain Reaction
PIS	Patient Infected Status
PPA	Positive Percent Agreement
PPV	Positive Predictive Value
QC	Quality Control
S	Symptomatic
SDA	Strand Displacement Amplification
StD	Standard Deviation
STD	Sexually Transmitted Disease
TN	True Negative
TP	True Positive
vp	viral particles

## AVAILABILITY

The following **BD ProbeTec™** TV Q<sup>x</sup> and **BD Viper** products are also available:

Cat. No.	Description
440724	<b>BD Viper™</b> Pipette Tips, 960
441392	<b>BD Viper™</b> Trash Box
441391	<b>BD Viper™</b> Trash Bags
440818	<b>BD Viper™</b> Trash Boxes and Bags
440974	<b>BD Viper™</b> Tube Lockdown Cover
440975	<b>BD Viper™</b> Lysing Heater (115V)
440976	<b>BD Viper™</b> Lysing Heater (230V)
440977	<b>BD Viper™</b> Lysing Rack
440984	<b>BD Viper™</b> Amplification Plate Sealers (Black)
441072	<b>BD Viper™</b> Liquid Waste Bottle
441074	<b>BD Viper™</b> Plate Seal Tool
440752	Microwell Package for the <b>BD Viper™</b> System
441091	<b>BD Viper™</b> System
441917	<b>BD ProbeTec™</b> <i>Trichomonas vaginalis</i> (TV) Q <sup>x</sup> Amplified DNA Assay Reagent Pack, 1152 tests
443433	<b>BD ProbeTec™</b> <i>Trichomonas vaginalis</i> (TV) Q <sup>x</sup> Amplified DNA Assay Reagent Pack, 384 tests
441925	Control Set for the <b>BD ProbeTec™</b> CT/GC/TV Q <sup>x</sup> Amplified DNA Assays, 24 positive and 24 negative
441128	<b>BD Viper™</b> Extraction Reagent and Lysis Trough, 12 Extraction Reagent Troughs and 12 Lysis Troughs
441129	<b>BD FOX™</b> Extraction Tubes
441354	<b>BD Viper™</b> Neutralization Pouch, 12 pouches
441357	<b>BD ProbeTec™</b> Q <sup>x</sup> Collection Kit for Endocervical or Lesion Specimens, 100 units
441359	Caps for use on the <b>BD Viper™</b> (Extracted Mode), 4 x 100
441360	Specimen Tubes and Caps for use on the <b>BD Viper™</b> (Extracted Mode), 4 x 100
441361	Swab Diluent for the <b>BD ProbeTec™</b> Q <sup>x</sup> Amplified DNA Assays, 2 mL x 48
441122	Vaginal Specimen Transport for <b>BD ProbeTec™</b> Q <sup>x</sup> Amplified DNA Assays

The TV preparations described previously are available from:

Gibson Laboratories, LLC  
1040 Manchester Street, Lexington KY 40508  
800-477-4763  
www.gibsonlabs.com

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STERILE R

Method of sterilization: irradiation / Způsob sterilizace: záření / Sterilisationsmåde: Bestråling / Sterilisatiewijze: bestraling / Sterilisierimismeetod: kiirgus / Sterilointimenetelmä: säteilytys / Méthode de stérilisation : irradiation / Sterilisationsmethode: Bestrahlung / Μέθοδος αποστείρωσης: ακτινοβολία / Sterilizálás módszere: besugárzás / Metodo di sterilizzazione: irradiazione / Sterilizavimo būdas: radiacija / Steriliseringmethode: bestråling / Metoda sterylizacji: napromienianie / Método de esterilização: irradiação / Metóda sterilizácie: ožiarenie / Método de esterilización: irradiación / Steriliseringmetod: stråling / Metód na sterilizácia: iradiácia / Metodă de sterilizare: iradiere / Sterilizasyon yöntemi: irradyasyon / Metoda sterilizacije: ozračavanje / Metód sterilizácii: ožblučenie / Sterilizacija әдісі – сәуле тусы / Metoda sterilizacije: zračenje (iridacija)



Manufacturer / Výrobce / Producent / Fabrikant / Tootja / Valmistaja / Fabricant / Hersteller / Κατασκευαστής / Gyártó / Ditta produttrice / Gamintojas / Producent / Fabricante / Výrobca / Tillverkare / Производител / Producător / Üretici / Proizvođač / Производитель / Атақарушы



Use by / Spotřebujte do / Anvendes før / Houdbaar tot / Kasutada enne / Viimeinkäyttöpäivä / A utiliser avant / Verwendbar bis / Ημερομηνία λήξης / Felhasználhatóság dátuma / Usare entro / Naudokite iki / Brukes før / Stosować do / Utilizar em / Pouzite do / Usar antes de / Använd före / Используйте до / A se utiliza până la / Son kullanma tarihi / Uptrebiti do / Использовать до / дейін пайдалануға / Uptrebiti do / YYYY-MM-DD / YYYY-MM (MM = end of month) / RRRR-MM-DD / RRRR-MM (MM = konec měsíce) / AAAA-MM-DD / AAAA-MM (MM = slutning af måned) / JJJJ-MM-DD / JJJJ-MM (MM = einde maand) / AAAA-KK-PP / AAAA-KK (KK = kuu lõpp) / VVVV-KK-PP / VVVV-KK (kuukauden loppuun mennessä) / AAAA-MM-JJ / AAAA-MM (MM = fin du mois) / JJJJ-MM-TT / JJJJ-MM (MM = Monatsende) / EEEE-MM-HH / EEEE-MM (MM = τέλος του μήνα) / EEEE-HH-NN / EEEE-HH (HH = hónap utolsó napja) / AAAA-MM-GG / AAAA-MM (MM = fine mese) / MMMM-MM-DD / MMMM-MM (MM = hónesi pabaja) / AAAA-MM-DD / AAAA-MM (MM = sluttet av måneden) / RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca) / AAAA-MM-DD / AAAA-MM (MM = fim do mês) / RRRR-MM-DD / RRRR-MM (MM = koniec mesiacu) / aaaa-mm-dd / aaaa-mm (mm = fin del mes) / AAAA-MM-DD / AAAA-MM (MM = sluet på månaden) / ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = края на месеца) / AAAA-LL-ZZ / AAAA-LL (LL = sfârșitul lunii) / YYYY-AA-GG / YYYY-AA (AA = аял sonu) / GGGG-MM-DD / GGGG-MM (MM = kraj meseca) / ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = конец месяца) / ЖЖЖЖ-АА-КК / ЖЖЖЖ-АА (АА = айдың соңы) / GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)

REF

Catalog number / Katalogové číslo / Katalognummer / Catalogusnummer / Kataloogi number / Tuotenumero / Numéro catalogue / Bestellnummer / Αριθμός καταλόγου / Katalógusszám / Numero di catalogo / Katalogo numeris / Numer katalogowy / Número do catálogo / Katalógové číslo / Número de catálogo / Каталог номер / Număr de catalog / Katalog numarasi / Kataloški broj / Номер по каталогу / Каталог номери

EC REP

Authorized Representative in the European Community / Autorizovaný zástupce pro Evropskou unii / Autoriseret repræsentant i EU / Erkend vertegenwoordiger in de Europese Unie / Volitatud esindaja Euroopa Nõukogus / Valtuutettu edustaja Euroopan yhteisössä / Représentant agréé pour la C.E.E. / Autorisierte EG-Vertretung / Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα / Hivatalos képviselő az Európai Unióban / Rappresentante autorizzato nella Comunità europea / Jgaliotasis atstovas Europos Bendrijoje / Autoriseret representant i EU / Autoryzowane przedstawicielstwo w Unii Europejskiej / Representante autorizado na União Europeia / Autorizovaný zástupca v Európskom spoločenstve / Representante autorizado en la Comunidad Europea / Auktoriserad representant i EU / Оторизован представитель в ЕС / Représentant autorizat în Uniunea Europeană / Avrupa Topluluğu Yetkili Temsilcisi / Ovlašćení představitel v Evropské zajednici / Уполномоченный представитель в Европейском сообществе / Европа қауымдастығындағы уәкілетті өкіл / Autorizuirani predstavnik u EU

IVD

In Vitro Diagnostic Medical Device / Lékařské zařízení určené pro diagnostiku in vitro / In vitro diagnostisk medicinsk anordning / Medisch hulpmiddel voor in vitro diagnose / In vitro diagnostika meditsiiniaparatuur / Lääkinnällinen in vitro -diagnostiikkalaitte / Dispositif médical de diagnostic in vitro / Medizinisches In-vitro-Diagnostikum / In vitro διαγνωστική ιατρική συσκευή / In vitro diagnosztikai orvosi eszköz / Dispositivo medico diagnostico in vitro. / In vitro diagnostikos prietaisas / In vitro diagnostisk medisinsk utstyr / Urządzenie medyczne do diagnostyki in vitro / Dispositivo médico para diagnóstico in vitro / Medicinska pomůcka na diagnostiku in vitro / Dispositivo médico de diagnóstico in vitro / Medicinsk anordning för in vitro-diagnostik / Медицински уред за диагностика ин витро / Aparatură medicală de diagnosticare in vitro / In Vitro Diagnostik Tibbi Cihaz / Medicinski uređaj za in vitro dijagnostiku / Медицинский прибор для диагностики ин витро / Жасанды жағдайда жүргізілетін медициналық диагностика аспабы / Medicinska pomagala za In Vitro Dijagnostiku

LOT

Batch Code (Lot) / Kód (číslo) šarže / Batch kode (Lot) / Chargennummer (lot) / Partii kood / Eräkoodi (LOT) / Code de lot (Lot) / Chargencode (Chargenbezeichnung) / Κωδικός παρτίδας (Παρτίδα) / Tétel száma (Lot) / Codice del lotto (partita) / Partijos numeris (Lot) / Batch-kode (Serie) / Kod partii (seria) / Código do lote (Lote) / Kód série (šarža) / Código de lote (Lote) / Satskod (parti) / Код (Партида) / Număr lot (Lotul) / Parti Kodu (Lot) / Kod serije / Код партии (лот) / Топтама коды / Lot (kod)

STERILE EO

Method of sterilization: ethylene oxide / Způsob sterilizace: etylenoxid / Sterilisationsmåde: Etylenoxid / Sterilisatiewijze: ethyleenoxide / Sterilisierimismeetod: etüleenoksiid / Sterilointimenetelmä: etyleenoksiidi / Méthode de stérilisation : oxyde d'éthylène / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / Sterilizálás módszere: etilén-oxid / Metodo di sterilizzazione: ossido di etilene / Sterilizavimo būdas: etileno oksidas / Steriliseringmethode: etylenoksid / Metoda sterylizacji: tlenek etylu / Método de esterilização: óxido de etileno / Metóda sterilizácie: etylénoxid / Método de esterilización: óxido de etileno / Steriliseringmetod: etylenoxid / Metód na sterilizácia: etilénov oxid / Metodă de sterilizare: oxid de etilenă / Sterilizasyon yöntemi: etilen oksit / Metoda sterilizacije: etilen oksid / Metód sterilizácii: etilénoksid / Sterilizacija әдісі – этилен тотығы



Contains sufficient for <n> tests / Dostatečné množství pro <n> testů / Indeholder tilstrækkeligt til <n> test / Voldoende voor <n> tests / Küllaldane <n> testide jaoks / Sisältöön riittävä <n> testejä varten / Contenu suffisant pour <n> tests / Ausreichend für <n> Tests / Περιέχει επαρκή ποσότητα <n> εξετάσεις / <n> teszthez elegendő / Contenuto sufficiente per <n> test / Pakankamas kiekis atlikti <n> testų / Innholder tilstrekkelig for <n> tester / Zawiera ilość wystarczającą do <n> testów / Contine suficiente para <n> testas / Obsah vystačí na <n> testov / Contenido suficiente para <n> pruebas / Räckertill <n> antal tester / Содержимое достаточно за <n> теста / Conține suficient pentru <n> teste / <n> testleri için yeterli miktarda içerir / Sadržaj dovoljan za <n> testova / Достаточно для <n> тестов(а) / <n> тесттері үшін жеткілікті / Sadržaj za (n) testova

	<p>Positive control / Pozitivní kontrola / Positiv kontrol / Positieve controle / Positiivne kontroll / Positiivinkontrolli / Contrôlé positif / Positive Kontrolle / Θετικός έλεγχος / Positiv kontroll / Controllo positivo / Teigiama kontrolė / Positiv kontroll / Kontrola dodatnia / Controllo positivo / Pozitivna kontrola / Control positivo / Положительен контрол / Etalon pozitiv / Pozitif kontrol / Pozitivna kontrola / Положительный контроль / Жатымды бақылау</p>
	<p>Temperature limitation / Teplotní omezení / Temperaturbegrænsning / Temperatuurlimiet / Temperatuuri piirang / Lämpötilarajoitus / Température limite / Zulässiger Temperaturenbereich / Οριο θερμοκρασίας / Hőmérsékleti határ / Temperatura limite / Laikymo temperatūra / Temperaturbegrænsning / Ograniczenie temperatury / Limitação da temperatura / Ohraničenie teploty / Limitación de temperatura / Temperaturbegrænsning / Температурни ограничения / Limitare de temperatură / Sıcaklık sınırlaması / Ograničenje temperature / Ограничение температуры / Температураны шектеу / Dozvoljena temperatura</p>
	<p>Consult Instructions for Use / Prostudujte pokyny k použití / Læs brugsanvisningen / Raadpleeg gebruiksaanwijzing / Lugeda kasutusjuhendit / Tarkista käyttöohjeista / Consulter la notice d'emploi / Gebrauchsanweisung beachten / Συμβουλευτείτε τις οδηγίες χρήσης / Olvassa el a használati utasítást / Consultare le istruzioni per l'uso / Skaitykite naudojimo instrukcijas / Se i bruksanvisningen / Zobacz instrukcja użytkowania / Consulte as instruções de utilização / Pozri Pokyny na používanie / Consultar las instrucciones de uso / Se bruksanvisningen / Направете справка в инструкциите за употреба / Consultați instrucțiunile de utilizare / Kullanım Talimatları'na başvurun / Pogledajte uputstvo za upotrebu / См. руководство по эксплуатации / Пайдалану нұсқаулығымен танысып алыңыз / Koristi upute za upotrebu</p>
	<p>Negative control / Negativní kontrola / Negativ kontrol / Negatieve controle / Negatiivne kontroll / Negatiivinkontrolli / Contrôlé négatif / Negative Kontrolle / Αρνητικός έλεγχος / Negativ kontroll / Controllo negativo / Neigiama kontrolė / Negativ kontroll / Kontrola ujemna / Controllo negativo / Negativna kontrola / Control negativo / Отрицателен контрол / Etalon negativ / Negatif kontrol / Negativna kontrola / Отрицательный контроль / Негативтік бақылау</p>
	<p>Peel / Otevfete zde / Åbnes her / Afpellen / Koorida / Vedä / Décoller / Abziehen / Σύμβολο αποκόλλησης / Húzza le / Strappare per aprire / Plěšti čia / Trekke av / Oderwać / Destacável / Odtrhnite / Desprender / Drag isär / Обелете / Se dezlipește / Ayırma / Oljuštiti / Отклеить / Ұстіңгі қабатын алып таста / Otvoriti skini</p>
	<p>Collection date / Datum odběru / Opsamlingsdato / Afnamedatum / Kogumiskuupäev / Keräyspäivä / Date de prélèvement / Entnahmedatum / Ημερομηνία συλλογής / Mintavétel ideje / Data prelievo / Paėmimo data / Dato provetaking / Data pobrania / Data da colheita / Dátum odberu / Fecha de coleccion / Uppsamlingsdatum / Дата на събиране / Data colectării / Toplama tarihi / Datum prikupljanja / Дата сбора / Жинаған тізбекүні / Dani sakupljanja</p>
	<p>Patient ID number / ID pacienta / Patient ID-nummer / Identificatienummer van de patiënt / Patsiendi ID / Potilaan tunnusnumero / Numéro d'identification du patient / Patienten-ID / Αριθμός μητρώου ασθενούς / Beteg azonosító száma / Numero di identificazione paziente / Paciento identifikavimo numeris / Pasientens ID-nummer / Numer ID patentu / Número da ID do doente / Identifikačné číslo pacienta / Número de identificación del paciente / Patientens ID-nummer / ИД номер на пациента / Număr ID pacient / Hasta kimlik numarası / ID broj pacijenta / Идентификационный номер пациента / Пациенттің идентификациялық нөмірі / Identifikacijski broj pacijenta</p>







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