

**BD ProbeTec™ ET *Chlamydia trachomatis* and
Neisseria gonorrhoeae Amplified DNA Assays
for use on the BD Viper™ System**

This document is to be used in conjunction with the **BD ProbeTec** ET *Chlamydia trachomatis* Amplified DNA Assay and /or the **BD ProbeTec** ET *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) Amplified DNA Assays package inserts.

I. INTENDED USE

The **BD ProbeTec**™ ET *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) Amplified DNA Assays, when tested with the **BD ProbeTec** ET System, use Strand Displacement Amplification (SDA) technology for the direct, qualitative detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA in endocervical swabs, male urethral swabs, and in female and male urine specimens as evidence of infection with *C. trachomatis*, *N. gonorrhoeae*, or of co-infection with both *C. trachomatis* and *N. gonorrhoeae*. Specimens may be from symptomatic or asymptomatic females and males. A separate Amplification Control is an option for inhibition testing (**BD ProbeTec** ET CT/GC/AC Reagent Pack). The **BD ProbeTec** ET CT/GC assays may be performed using either the **BD ProbeTec** ET System or a combination of the **BD ProbeTec** ET System and **BD Viper** instrument.

The Amplification Control (AC) is not supported on the **BD Viper** System.

II. SUMMARY AND EXPLANATION

Chlamydia trachomatis and *Neisseria gonorrhoeae* infections are the most common sexually transmitted bacterial diseases in the United States. Approximately 4 million new chlamydia cases are estimated to occur each year in the United States with worldwide estimates of approximately 50 million new cases annually.¹⁻³ The incidence of chlamydial infections in women in the US in 1996 was 186.6 per 100,000. The total number of chlamydial infections and gonorrhea cases reported in the US in 1996 were 490,080 and 325,883, respectively.²

Chlamydiae are gram-negative, obligate intracellular bacteria. They form characteristic intracellular inclusions which can be observed in cell culture by light microscopy after special staining is applied.⁴ *Chlamydia trachomatis* causes cervicitis, urethritis, salpingitis, proctitis and endometritis in women and urethritis, epididymitis and proctitis in men. Acute infections are reported more frequently in men because women often have no symptoms of infection. It has been estimated that 70-80% of women and up to 50% of men who are infected experience no symptoms. Many chlamydial infections in women remain untreated which may result in low-grade inflammation in the Fallopian tubes, a leading contributor to infertility. This organism can also be transmitted in the birth canal, potentially resulting in infant conjunctivitis and/or chlamydial pneumonia in newborns.^{4,5}

Neisseria gonorrhoeae are gram-negative, oxidase positive diplococci which can be observed in Gram-stained smears of urethral discharges, usually within neutrophils. Culture of *N. gonorrhoeae* can be difficult because the organism does not survive long outside its host and is highly susceptible to adverse environmental conditions such as drying and extreme temperatures.⁶ *Neisseria gonorrhoeae* causes acute urethritis in males, which if untreated can develop into epididymitis, prostatitis, and urethral stricture. In females, the primary site of infection is the endocervix. An important complication in females is development of pelvic inflammatory disease which contributes to infertility.⁷ Asymptomatic infections occur often in females but infrequently in males.

The current methods for detection of *C. trachomatis* and/or *N. gonorrhoeae* include culture, immunoassays, nonamplified probes, and amplified probes.^{4,6,7} The development of amplified methods has demonstrated two advantages over non-amplified methods: increased sensitivity, and applicability to a variety of sample types. Historically, culture has been the "gold standard" for detection of *C. trachomatis*. However, the culture yield varies widely among laboratories, and culture in routine practice is less sensitive than amplified methods. Combining results from multiple methods of CT detection improves accuracy for evaluating new tests in that infected and uninfected patients can be more reliably identified. For identification of GC, optimized culture methods continue to be the standard for diagnosing patients with gonococcal infections.

The **BD ProbeTec** ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assays, when used with the **BD ProbeTec** ET System, utilize homogeneous Strand Displacement Amplification (SDA) technology as the amplification method and fluorescent energy transfer (ET) as the detection method to test for the presence of *C. trachomatis* and *N. gonorrhoeae* DNA in clinical specimens.⁸⁻¹⁰

III. PRINCIPLES OF THE PROCEDURE

The **BD ProbeTec** ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assays are based on the simultaneous amplification and detection of target DNA using amplification primers and a fluorescent labeled detector probe.^{9,10} The SDA reagents are dried in two separate disposable microwell strips. The processed sample is added to the Priming Microwell which contains the amplification primers, fluorescent labeled detector probe, and other reagents necessary for amplification. After incubation, the reaction mixture is transferred to the Amplification Microwell, which contains two enzymes (a DNA polymerase and a restriction endonuclease) necessary for SDA. The Amplification Microwells are sealed to prevent contamination and then incubated in a thermally controlled fluorescent reader which monitors each reaction for the generation of amplified products. The presence or absence of CT and GC is determined by relating the **BD ProbeTec** ET MOTA (Method Other Than Acceleration) scores for the sample to

pre-determined cutoff values. The MOTA score is a metric used to assess the magnitude of signal generated as a result of the reaction.

IV. REAGENTS

Each **BD ProbeTec** ET CT/GC Reagent Pack contains:

Chlamydia trachomatis (CT) Priming Microwells, 4 x 96:

4 Oligonucleotides ≥ 7 pmol; dNTP ≥ 35 nmol; Detector probe ≥ 25 pmol; with buffers and stabilizers.

Neisseria gonorrhoeae (GC) Priming Microwells, 4 x 96:

4 Oligonucleotides ≥ 7 pmol; dNTP ≥ 35 nmol; Detector probe ≥ 25 pmol; with buffers and stabilizers.

Chlamydia trachomatis (CT) Amplification Microwells, 4 x 96:

Restriction enzyme ≥ 30 Units; DNA Polymerase ≥ 25 Units; dNTP's ≥ 80 nmol; with buffers and stabilizers.

Neisseria gonorrhoeae (GC) Amplification Microwells, 4 x 96:

Restriction enzyme ≥ 15 Units; DNA Polymerase ≥ 2 Units; dNTP's ≥ 80 nmol; with buffers and stabilizers.

NOTE: Each microwell pouch contains one desiccant bag.

Accessories: Priming Covers; Amplification Sealers, 40 each; Disposal Bags, 20 each.

BD ProbeTec ET (CT/GC) Control Set, 20 CT/GC Positive Controls (50 μ L dried) containing 750 copies per reaction of pCT16 linearized plasmid* and 250 copies per reaction of pGC10 linearized plasmid* with ≥ 5 μ g Salmon testes DNA; 20 CT/GC Negative Controls (50 μ L dried) with ≥ 5 μ g Salmon testes DNA; **BD ProbeTec** ET CT/GC Diluent Tubes – 400 tubes each containing 2 mL of Sample Diluent, which contains potassium phosphate, DMSO, glycerol, Polysorbate 20, and 0.03% Proclin™ (preservative); **BD ProbeTec** ET Diluent (CT/GC) - 225 mL Sample Diluent which contains potassium phosphate, DMSO, glycerol, Polysorbate 20, and 0.03% Proclin (preservative).

* The concentration of this DNA was determined spectrophotometrically at 260 nm.

Instrument, equipment and supplies:

- **BD Viper** Instrument and Instrument Plates
- **BD Viper** Lysing Heater
- **BD Viper** Lysing Rack with locking base
- Amplification (Black) plate sealers
- **BD ProbeTec** Urine Preservative Transport Kit
- **BD ProbeTec** ET Urine Processing Pouch
- **BD ProbeTec** ET Sample Tubes, Caps
- **BD Viper** Pipette Tips, tip waste boxes and bags

- Empty Microwells
- **BD ProbeTec** ET *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/GC) Amplified DNA Assay Endocervical Specimen Collection and DRY TRANSPORT Kit or **BD ProbeTec** ET CT/GC Amplified DNA Assay Collection Kit for Endocervical Specimens
- **BD ProbeTec** ET *Chlamydia trachomatis/Neisseria gonorrhoeae* CT/GC Amplified DNA Assay Male Urethral Specimen Collection and DRY TRANSPORT Kit or **BD ProbeTec** ET CT/GC Amplified DNA Assay Collection Kit for Male Urethral Specimens.

Materials Required But Not Provided: Centrifuge capable of 2000 x g, vortex mixer, gloves, pipettes capable of delivering 1 mL, 2 mL and 4 mL, 3% (w/v) hydrogen peroxide, DNA AWAY™ or 1% (v/v) sodium hypochlorite*, clean container suitable for holding aliquotted Diluent, timer and absorbent paper, sterile urine specimen collection cups, Alcohol wipes (70% Isopropanol).

*Mix 200 mL of bleach with 800 mL of warm water. 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 4 weeks if properly sealed or until the expiration date, whichever comes first. Do not freeze.

Warnings and Precautions:

For *in vitro* Diagnostic Use

1. This reagent pack is for testing endocervical and male urethral swabs and male and female urine specimens with the **BD Viper** System.
2. For collection of endocervical swab specimens, only the **BD ProbeTec** ET *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/GC) Amplified DNA Assay Endocervical Specimen Collection and DRY TRANSPORT Kit and the **BD ProbeTec** ET CT/GC Amplified DNA Assay Collection Kit for Endocervical Specimens have been validated.
3. For collection of male urethral swab specimens, only the **BD ProbeTec** ET *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/GC) Amplified DNA Assay Male Urethral Specimen Collection and DRY TRANSPORT Kit and the **BD ProbeTec** ET CT/GC Amplified Assay Collection Kit for Male Urethral Specimens have been validated.
4. For urine specimens, only the **BD ProbeTec** ET Urine Processing Pouch (UPP), the **BD ProbeTec** Urine Preservative Transport (UPT), and unpreserved (neat) urine have been validated.
5. The **BD ProbeTec** Urine Preservative Transport (UPT) Kit contains **NAP Guard™** (≥ 742.5 mM K₂EDTA). **NAP Guard** may be irritating to the eyes, skin and respiratory system. In case of contact with eyes, rinse opened eye immediately with plenty of water and seek medical advice if symptoms persist. After contact with skin, wash immediately with plenty of soap and water. If inhaled, seek medical attention in case of problems.

6. Laboratories may validate other swab or urine collection and transport devices for use with the **BD ProbeTec** ET CT/GC assays according to the “Verification and Validation Procedures in the Clinical Microbiology Laboratory,” Cumitech 31, B.L. Elder et al., American Society for Microbiology, Washington D.C., February, 1997.
7. Do not test the CT/GC Diluent tube from the **BD ProbeTec** ET CT/GC Amplified Assay Collection Kits if received in the laboratory without the swab present. A false negative test result may occur.
8. Use only the **BD Viper** pipette tips as supplied by BD with the **BD Viper** System.
9. Do not interchange or mix kit reagents from kits with different lot numbers.
10. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. “Standard Precautions”¹¹⁻¹⁴ and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.
11. Use established laboratory practices when disposing of used pipette tips, sample tubes, Priming Microwells and other disposables. Discard disposables carefully. Seal and dispose of waste containers when they are 3/4 full or daily (whichever comes first).
12. The **BD ProbeTec** ET Diluent (CT/GC) and CT/GC Diluent tube contain dimethyl sulfoxide (DMSO). DMSO is harmful by inhalation, contact with skin or 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.
13. Reagent pouches containing unused Priming Microwells and Amplification Microwells **MUST** be carefully resealed after opening. Verify that a desiccant is present prior to resealing the reagent pouches.
14. Use **only the Amplification (Black) plate sealers** on the Amplification plates with the **BD Viper** System. Using the clear sealers for sealing the Amplification plates may cause erroneous results. 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.**
15. Priming Microwells with residual fluid (after transfer of fluid from the Priming Microwells to the Amplification Microwells) represent a source of target contamination. Carefully seal Priming Microwells with plate sealer prior to disposal.
16. To prevent contamination of the work environment with amplification products, use the disposal bags provided in the Reagent Packs to dispose of tested Amplification Microwells. Make sure the bags are properly closed before disposal.
17. Although dedicated work areas are not required because the **BD Viper** System design reduces the possibility of amplicon contamination in the testing environment, other precautions for controlling contamination, particularly to avoid contamination of specimens during processing, are necessary.

18. Because of the potential for false positivity with some non-gonococcal *Neisseria* found in the respiratory tract (see “Limitations of the Procedure,” #20), contamination of reagents and specimens with respiratory aerosols should be avoided.
19. CHANGE GLOVES after removing and discarding caps from lysed samples and controls to avoid cross-contamination of specimens. If gloves come in contact with specimen or appear to be wet, immediately change gloves 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 1% (v/v) sodium hypochlorite, DNA AWAY™ or 3% (w/v) hydrogen peroxide 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, DNA AWAY or 3% (w/v) hydrogen peroxide for 1-2 min. Do not exceed 2 min. Thoroughly rinse the rack with water and allow to air dry.
22. Do Not Use ELIMINase™ or Alconox™ for cleaning the **BD Viper** System.
23. Clean the entire work area - counter tops and instrument surfaces – with 1% (v/v) sodium hypochlorite, DNA AWAY or 3% (w/v) hydrogen peroxide on a daily basis. Thoroughly rinse with water. Allow surfaces to dry completely before proceeding with additional testing.
24. When using hydrogen peroxide as a cleaning agent, do not use the hydrogen peroxide from a bottle that has been open for > 8 days.
25. Contact 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.

V. SAMPLE COLLECTION AND TRANSPORT

The **BD Viper** System is designed to detect the presence of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in endocervical swabs, male urethral swabs and male and female urine specimens using the appropriate collection method.

The only devices that have been validated for collecting swab specimens for testing on the **BD Viper** Instrument are:

- **BD ProbeTec** ET *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/GC) Amplified DNA Assay Endocervical Specimen Collection and DRY TRANSPORT Kit
- **BD ProbeTec** ET *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/GC) Amplified DNA Assay Male Urethral Specimen Collection and DRY TRANSPORT Kit
- **BD ProbeTec** ET *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/GC) Amplified DNA Assay Collection Kit for Endocervical Specimens

- **BD ProbeTec ET *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/GC) Amplified DNA Assay Collection Kit for Male Urethral Specimens**

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 specimens must be collected in a sterile, plastic, preservative-free, specimen collection cup. For urine specimens, only the **BD ProbeTec ET Urine Processing Pouch (UPP)**, the **BD ProbeTec Urine Preservative Transport (UPT)**, and unpreserved (neat) urine have been validated.

Swab Specimen Collection

Endocervical Swab Specimen Collection using BD ProbeTec ET CT/GC Amplified DNA Assay Endocervical Specimen Collection and DRY TRANSPORT Kit:

1. Remove excess mucus from the cervical os with the large-tipped cleaning swab provided in the **BD ProbeTec ET CT/GC Amplified DNA Assay Endocervical Specimen Collection and DRY TRANSPORT Kit** and discard.
2. Insert the Endocervical Specimen Collection and DRY TRANSPORT swab into the cervical canal and rotate for 15-30 s.
3. Withdraw the swab carefully. Avoid contact with the vaginal mucosa.
4. Immediately place the cap/swab into the transport tube. Make sure the cap is tightly secured to the tube.
5. Label the tube with patient information and date/time collected.
6. Transport to laboratory.

Endocervical Swab Specimen Collection using BD ProbeTec ET CT/GC Amplified DNA Assay Collection Kit for Endocervical Specimens:

1. Remove the cleaning swab from packaging.
2. Using cleaning swab, remove excess mucus from the cervical os.
3. **Discard** the used cleaning swab.
4. Remove the 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 CT/GC Diluent tube.
8. Fully insert the collection swab into the CT/GC 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.

Male Urethral Swab Specimen Collection using BD ProbeTec ET CT/GC Amplified DNA Assay Male Urethral Collection and DRY TRANSPORT Kit:

1. Insert the Male Urethral Collection and DRY TRANSPORT swab 2-4 cm into the urethra and rotate for 3-5 s.
2. Withdraw the swab and place the cap/swab into the transport tube. Make sure the cap is tightly secured to the tube.
3. Label the tube with patient information and date/time collected.
4. Transport to laboratory.

Male Urethral Swab Specimen Collection using BD ProbeTec ET CT/GC Amplified Assay Collection Kit for Male Urethral Specimens:

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 CT/GC Diluent tube.
5. Fully insert the swab into the CT/GC 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

After collection, the endocervical swabs and the male urethral swabs must be stored and transported to the laboratory and/or test site at 2-27°C within 4-6 days. Storage up to 4 days has been validated with clinical specimens; storage up to 6 days has been demonstrated with seeded specimens. Refer to “Performance Characteristics.” **NOTE:** If specimens cannot be transported directly to the testing laboratory under ambient temperatures (15-27°C) and must be shipped, an insulated container with ice should be used with either an overnight or 2-day delivery vendor.

Urine Specimen Collection, Storage and Transport

Collect urine specimen in a sterile, preservative-free collection cup. Urine specimens may be stored and transported in three ways – (1) unpreserved (neat), (2) using the **BD ProbeTec** Urine Preservative Transport (UPT) and (3) using the **BD ProbeTec** ET Urine Processing Pouch (UPP). The following chart provides a summary of storage and transport conditions for neat urine, UPT and UPP.

Urine Specimen Type to be Processed	NEAT			UPT			UPP		
				Urine Stored at 2-30°C - Transfer to UPT Within 8 Hours of Collection	Urine Stored at 2-8°C - Transfer to UPT Within 24 Hours of Collection		UPP Added at Specimen Collection Site	UPP Added at Testing Site	
Temperature Condition for Transport to Test Site and Storage	2-30°C	2-8°C	-20°C	2-30°C	2-30°C	-20°C	Transport to Lab at 2-8°C	Transport to Lab at 15-27°C	Transport to Lab at 2-8°C
Process Specimen According to Instructions	Within 30 hours of collection	Within 7 days of collection	Within 2 months of collection	Within 30 days after transfer to UPT	Within 30 days after transfer to UPT	Within 2 months after transfer to UPT	Within 4-6 days of collection	Within 2 days of collection	Within 4-6 days of collection

Unpreserved (Neat) Urine

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 15-60 mL of voided urine (the first part of the stream - not midstream) into a urine collection cup.
4. Cap and label the urine collection cup with patient identification and date/time collected.

Storage and Transport

1. Store and transport neat urine from the collection site to the test site at 2-30°C.
2. Sample processing must be completed within 30 h of collection if stored at 2-30°C or within 7 days of collection if stored at 2-8°C.

NOTE: Specimens must be shipped in an insulated container with ice using either an overnight or 2-day delivery vendor. Storage up to 7 days at 2-8°C has been demonstrated with seeded specimens.

Using BD ProbeTec Urine Preservative Transport Kit (UPT)

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 15-60 mL of voided urine (the first part of the stream - not midstream) into a urine collection cup.
4. Cap and label the urine collection cup with patient identification and date/time collected.

Urine Transfer to UPT

NOTES: Urine should be transferred from collection cup to the UPT within 8 h of collection provided the urine has been stored at 2-30°C. Urine can be held for up to 24 h prior to transfer to the UPT provided that the urine has been stored at 2-8°C. Wear clean gloves when handling the UPT and the urine specimen. If gloves come in contact with the specimen, immediately change gloves to prevent contamination of other specimens.

1. After the patient has collected the urine sample, label the urine collection cup.
2. Open the Urine Preservative Transport Kit and remove the UPT and the transfer pipette. Label the UPT with the patient identification and date/time collected.
3. Hold the 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 UPT and use the transfer pipette to transfer urine into the tube. The correct volume of urine has been added when the fluid level is between the black lines on the fill window on the UPT label. This volume corresponds to approximately 2.5-3.45 mL of urine. DO NOT overfill or under fill the tube.
5. Discard the transfer pipette. **NOTE:** The transfer pipette is intended for use with a single specimen.
6. Tighten the cap securely on the UPT.

7. Invert the UPT 3-4 times to ensure that the specimen and reagent are well mixed.

UPT Storage and Transport

Store and transport urine specimens in UPT at 2-30°C and process within 30 days of collection. Specimens may be stored at -20°C for up to two months.

Using the BD ProbeTec ET Urine Processing Pouch (UPP)

The Urine Processing Pouch (UPP) can be added at either the test site or at the collection site. Instructions are provided for each option.

Urine Collection (UPP Added at Test Site)

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 15-20 mL of voided urine (the first part of the stream - NOT midstream) into a urine collection cup.
NOTE: During the clinical evaluation, testing urine volumes up to 60 mL was included in the performance estimates.
4. Cap and label the urine collection cup with patient identification and date/time collected.

Urine Storage and Transport (Addition of UPP at Test Site):

NOTE: Specimens must be shipped in an insulated container with ice using either an overnight or 2-day delivery vendor. Storage up to 4 days has been validated with clinical specimens; storage up to 6 days has been demonstrated with seeded specimens. Refer to “Performance Characteristics.”

1. Store and transport urine specimens to the test site at 2-8°C within 4-6 days of collection.
2. Add the UPP to the urine specimen collection cup. Wear clean gloves when handling the UPP and urine specimen.
NOTE: Do not place UPP on any work surface. Remove UPP from pouch with a freshly gloved hand or with clean, sterile forceps.
NOTE: Add UPP carefully to avoid splashing.
3. Cap the collection cup and swirl gently to ensure that the UPP is completely submerged in urine.
4. The UPP must be in contact with the urine specimen for at least 2 h prior to processing.
5. Do not freeze the urine specimen.

Urine Collection (UPP Added at Collection Site)

1. The patient should not have urinated for at least 1h prior to specimen collection.
2. Collect specimen in a sterile, plastic, preservative-free specimen collection cup.
3. The patient should collect the first 15-20 mL of voided urine (the first part of the stream - NOT midstream).
NOTE: During the clinical evaluation, testing urine volumes up to 60 mL was included in the performance estimates.
4. Immediately add the UPP to the specimen collection cup. Wear clean gloves when handling the UPP and urine specimen.

NOTE: Do not place UPP on any work surface. Remove UPP from pouch with a freshly gloved hand or with clean, sterile forceps.

NOTE: Add UPP carefully to avoid splashing.

5. Cap collection cup and swirl gently to ensure that the UPP is completely submerged in urine. Label with patient identification and date/time collected.

Urine Storage and Transport (UPP Added at Collection Site)

NOTE: If specimens cannot be transported directly to the testing laboratory under ambient temperatures (15-27°C) and must be shipped, an insulated container with ice should be used with either an overnight or 2-day delivery vendor. Storage up to 4 days has been validated with clinical specimens; storage up to 6 days has been demonstrated with seeded specimens. Refer to “Performance Characteristics.”

1. Store and transport urine specimens containing a UPP to the laboratory or test site at 2-8°C within 4-6 days of collection or at 15-27°C within 2 days of collection.
2. Do not freeze the urine specimen.
3. The UPP must be in contact with the urine specimen for at least 2 h prior to processing.

VI. TEST PROCEDURE

Refer to the **BD Viper** System User’s Manual for specific instructions for operating and maintaining the components of the system. The optimum environmental conditions for the CT/GC assay were found to be 18-23°C at 25-75% Relative Humidity and 23-28°C at 25-50% Relative Humidity. The performance of the CT/GC assay at temperatures in excess of 28°C is not recommended. Refer to the **BD Viper** Instrument User’s Manual for specific instructions for operating the instrument. Refer to the **BD ProbeTec** ET CT/GC assay insert addendum (in **BD Viper** Instrument User’s Manual) for specific test procedures when using the **BD Viper** instrument.

A. Instrument Preparation:

1. Instrument power must be on and instruments allowed to warm up prior to beginning the assay.
 - a. The **BD Viper** Lysing Heater requires approximately 90 min for warm-up and stabilization.
 - b. The Set point for the **BD Viper** Lysing Heater is 114°C.
 - c. The **BD Viper** is under software control and requires approximately 10 min to boot up. It is recommended that the power to the instrument be left on.
2. Check the **BD Viper** Lysing Heater temperature prior to beginning the assay. Remove the plastic cover and allow temperature to equilibrate for 15 min. The thermometer must read between 112-116°C.
3. The **BD Viper** report displays the Priming and Warming heater temperatures. Verify the temperature when the run is complete. The Warming Heater temperature must read between 51-54°C and the Priming temperature must read 68-72°C.

B. Swab Processing:

Swab specimens must be processed within 4-6 days of collection if stored at 2-27°C.

NOTE: Swabs and CT/GC Diluent Tubes should be at room temperature prior to use.

Processing Procedure for swabs collected with the BD ProbeTec ET CT/GC Amplified DNA Assay Endocervical Specimen Collection and DRY TRANSPORT Kit or the BD ProbeTec ET CT/GC Amplified DNA Assay Male Urethral Specimen Collection and DRY TRANSPORT Kit :

1. Label a CT/GC Diluent Tube for each swab specimen to be processed.
2. Remove the cap from the tube and insert the swab. Mix by swirling the swab into diluent for 5-10 s.
3. Express the specimen swab along the inside of the tube so that the liquid runs back into the bottom of the tube.
4. Remove swab carefully to avoid splashing.
NOTE: Droplets may cause contamination of work area.
5. Place swab back into transport tube and discard.
6. Tightly replace the cap on the CT/GC Diluent tube.
7. Vortex tube for 5 s.
8. Using the Plate Layout Report, place tube in order in the **BD Viper** Lysing Rack.
9. Repeat steps 1-8 for additional swab specimens.
10. Lock the samples into place in the **BD Viper** Lysing Rack.
11. Specimens are ready to be lysed.

NOTE: Alternatively, if a multi-tube vortexer is available, skip step 7 and vortex the entire **BD Viper** Lysing Rack for 15-20 s after step 10 and before Lysing.

NOTE: Specimens processed, but not yet lysed, may be stored at room temperature for up to 6 h or overnight at 2-8°C.

Processing Procedure for swabs collected with the BD ProbeTec ET CT/GC Amplified DNA Assay Collection Kit for Endocervical Specimens or the BD ProbeTec ET CT/GC Amplified DNA Assay Collection Kit for Male Urethral Specimens:

1. Vortex the CT/GC Diluent Tube for 5 s.
NOTE: Alternatively, if a multi-tube vortexer is available, perform steps 2 and 3; then vortex the entire **BD Viper** Lysing Rack for 15-20 s and proceed to step 4.
2. Using the Plate Layout Report, place sample and control tubes in order in the **BD Viper** Lysing Rack.
3. Lock the samples into place in the **BD Viper** Lysing Rack.
4. Specimens are ready to be lysed.

C. Urine Processing:

Processing Procedure for Unpreserved (Neat) Urine Specimens

Neat urine specimens must be processed within 30 h of collection if stored at 2-30°C, within 7 days of collection if stored at 2-8°C, and within 2 months from the date of collection if stored at -20°C.

NOTES:

BD ProbeTec ET Diluent (CT/GC) should be at room temperature prior to use. Aliquot the needed quantity of **BD ProbeTec ET Diluent (CT/GC)** into a clean container. To estimate the quantity needed, multiply the number of samples by 2 and add another 1-2 mL for pipetting ease. **To avoid contamination of the Diluent - Do not pour leftover Diluent back into the bottle.**

1. Label an empty **BD ProbeTec ET Sample Tube** for each urine to be processed.
2. Swirl the container to mix the urine and open carefully.
NOTE: Open carefully to avoid spills or droplets which may cause contamination of work area.
NOTE: Frozen urine specimens must be thawed and mixed completely before transfer to the Sample Tube.
3. Pipette 4.0 mL of urine into the appropriately labeled tube and tightly recap the tube.
4. Repeat steps 2-3 for additional neat urine samples. Use a new pipette or pipette tip for each sample.
5. Insert sample tubes into the **BD Viper Lysing Rack**.
6. Insert the **BD Viper Lysing Rack** into the **BD Viper Lysing Heater** to prewarm the samples.
7. Heat the samples for 10 min.
8. After 10 min, remove the **BD Viper Lysing Rack** from the **BD Viper Lysing Heater** and cool the tubes at room temperature for a minimum of 15 min, or a maximum of 6 h.
NOTE: Do not refrigerate or freeze the sample tubes after the 10 min pre-warm.
9. Centrifuge the tubes at 2000 x g for 30 min.
10. At the end of centrifugation, carefully remove the tubes from the centrifuge.
11. Uncap the first tube and carefully decant the supernatant. End the decanting motion with a gentle "flick" of the wrist to remove residual fluid from the tube.
NOTE: This is a critical step - excess residual specimen may cause inhibition. Tubes may be individually blotted on a separate sheet of absorbent paper to enhance removal of residual urine.
12. Place the cap loosely on the tube.
13. Repeat steps 11-12 for each centrifuged urine specimen.
14. Pipette 2.0 mL of Diluent into each tube. Use a new pipette or pipette tip for each tube.
15. Tightly recap the sample tubes and vortex 5 s to completely resuspend the sediment in the Diluent.
16. Samples are ready to be lysed.

NOTE: Specimens processed, but not yet lysed, may be stored at room temperature for up to 6 h or overnight at 2-8°C.

Processing Procedure Using Urine Specimens Collected Using the BD ProbeTec Urine Preservative Transport Kit (UPT)

NOTES:

UPT samples may be stored at 2-30°C and processed within 30 days of collection or frozen at -20°C and processed within 2 months of collection.

BD ProbeTec ET Diluent (CT/GC) should be at room temperature prior to use. Aliquot the needed quantity of **BD ProbeTec ET Diluent (CT/GC)** into a clean container. To estimate the quantity needed, multiply the number of samples by 2 and add another 1-2 mL for pipetting ease. **To avoid contamination of the Diluent - Do Not Pour leftover Diluent back into the bottle.**

Make sure the urine volume in each tube falls between the lines indicated on the tube label. Under filling and over filling the tube may affect assay performance.

1. Insert UPT tubes into the **BD Viper** Lysing Rack.
NOTE: If specimens were frozen, make sure they are thawed completely and mixed by inversion prior to heating.
2. Insert the **BD Viper** Lysing Rack into the **BD Viper** Lysing Heater to pre-warm the samples.
3. Heat the samples for 10 min.
4. After 10 min, remove the **BD Viper** Lysing Rack from the **BD Viper** Lysing Heater and cool the tubes at room temperature for a minimum of 15 min, or a maximum of 6 h.
NOTE: Do not refrigerate or freeze the sample tubes after the 10 min pre-warm.
5. Centrifuge the tubes at 2000 x g for 30 min.
6. At the end of centrifugation, carefully remove the tubes from the centrifuge.
7. Uncap the first UPT and carefully decant the supernatant. End the decanting motion with a gentle "flick" of the wrist to remove residual fluid from the tube and blot the tube on a separate piece of absorbent paper.
8. Place the cap loosely on the tube.
9. Repeat steps 7-8 for each centrifuged urine specimen.
10. Pipette 2.0 mL of Diluent into each tube. Use a new pipette or pipette tip for each tube.
11. Tightly recap the UPT tubes and vortex 5 s to completely resuspend the sediment in the Diluent.
12. Samples are ready to be lysed.
NOTE: Specimens processed, but not yet lysed, may be stored at room temperature for up to 6 h or overnight at 2-8°C.

Processing Procedure for Specimens Collected Using the BD ProbeTec ET Urine Processing Pouch (UPP)

Urine specimens must be processed within 4-6 days of collection if stored at 2-8°C (UPP added at either collection or testing site) or within 2 days of collection if stored at 15-27°C (UPP added at collection site).

Notes:

BD ProbeTec Diluent (CT/GC) should be at room temperature prior to use.

Urine must be in contact with the UPP for at least 2 h before processing.

Aliquot the needed quantity of **BD ProbeTec** ET Diluent (CT/GC) into a clean container. To estimate the quantity needed, multiply the number of samples by 2 and add another 1-2 mL for pipetting ease. **To avoid contamination of the Diluent - Do Not Pour leftover Diluent back into the bottle.**

1. Label an empty **BD ProbeTec** ET Sample Tube for each urine to be processed.
2. Swirl the container to mix the urine and open carefully.
Note: Open carefully to avoid spills or droplets which may cause contamination of work area.
3. Pipette 4.0 mL of urine into the appropriately labeled tube and tightly recap the tube.
4. Repeat steps 2-3 for additional samples. Use a new pipette or pipette tip for each sample.
5. Centrifuge the tubes at 2000 x g for 30 minutes.
6. At the end of centrifugation, carefully remove the tubes from the centrifuge.
7. Uncap the first tube and carefully decant the supernatant. End the decanting motion with a gentle “flick” of the wrist to remove residual fluid from the tube.
Note: This is a critical step- excess residual specimen may cause inhibition. Tubes may be individually blotted on a separate sheet of absorbent paper to enhance removal of residual urine.
8. Place the cap loosely on the tube.
9. Repeat steps 7-8 for each centrifuged urine specimen.
10. Pipette 2.0 mL of Diluent into each tube. Use a new pipette or pipette tip for each tube.
11. Tightly recap the sample tubes and vortex 5 s to completely resuspend the sediment in the Diluent.
12. Samples are ready to be lysed.

Note: Specimens processed, but not yet lysed, may be stored at room temperature for up to 6 h or overnight at 2-8°C.

D. Quality Control Preparation:

NOTE: The **BD ProbeTec ET (CT/GC) Controls and Diluent** should be at room temperature prior to use.

1. For each run (plate) to be tested, prepare one CT/GC Negative Control Tube and one CT/GC Positive Control Tube. If a plate contains more than one Reagent Pack lot number, controls must be tested with each lot.
2. Remove the cap from the CT/GC Negative Control Tube. Using a new pipette tip or pipette, add 2.0 mL of Diluent.
3. Recap the tube and vortex for 5 s.
4. Remove the cap from the CT/GC Positive Control Tube. Using a new pipette tip or pipette, add 2.0 mL of Diluent.
5. Recap the tube and vortex for 5 s.
6. Controls are ready to be lysed.

E. Lysing the Samples and Controls

BD recommends that processed specimens are scanned or entered into the **BD Viper** System interface prior to lysing. At the **BD Viper** interface, select the assay type, control and kit lot numbers and select the Tube Rack Login Display. Place the **BD Viper** Lysing Rack on the Locking Plate in the Staging Area. Scan the barcode (or enter the identification Number of the first sample tube and place it in the **BD Viper** Lysing Rack as indicated on the screen). Repeat with the additional samples until the rack is full or all samples have been added.

1. Insert the **BD Viper** Lysing Rack into the **BD Viper** Lysing Heater.
2. Heat the samples for 30 min.
3. After 30 min, remove the **BD Viper** Lysing Rack from the **BD Viper** Lysing Heater and allow to cool at room temperature for at least 15 min.

NOTE: After lysing samples:

- a. They may be stored at 18-30°C for up to 6 h and may be tested without re-lysing.
- b. They may be stored up to 5 days at 2-8°C. Samples must be vortexed and re-lysed prior to testing.
- c. They may be stored up to 98 days at -20°C. Samples must be thawed at room temperature, vortexed and re-lysed prior to testing. Lysed samples may be frozen and thawed twice.

F. Testing with the BD Viper System

NOTE: The Priming and Amplification Microwells should be at room temperature prior to use.

NOTE: Review **BD Viper** Instrument User's Manual for detailed setup and operation procedure.

1. Put on gloves.
2. Load pipette tips and lock the pipette tip station covers.
3. Peel one black plate sealer for each amplification plate to be tested (one or two), and place a sealer sticky-side down on each plate sealer station to be used. Do not press down on sealers.
4. Make sure the tip exchange stations are empty.

5. Make sure that both the Priming and Warming Heaters are free of debris.
6. Change gloves before proceeding to avoid contamination.
7. For specimens collected with the **BD ProbeTec** ET CT/GC Amplified DNA Assay Endocervical Specimen Collection and DRY TRANSPORT Kit, or the **BD ProbeTec** ET CT/GC Amplified DNA Assay Male Urethral Specimen Collection and DRY TRANSPORT Kit, or processed urine specimens, remove and discard the caps from the lysed and cooled samples and controls.
8. For swabs collected with the **BD ProbeTec** ET CT/GC Amplified DNA Assay Collection kit for Endocervical Specimens or the **BD ProbeTec** ET CT/GC Amplified DNA Assay Collection Kit for Male Urethral Specimens, do the following:
 - a. Uncap the tube and gently press the swab against the side of the tube to remove excess fluid.
 - b. Pull the cap/swab out of the tube. Do not press against the wall of the tube to avoid splattering droplets that may cause cross-contamination.
 - c. Discard the cap/swab.
9. **Change gloves** before proceeding to avoid contamination.
10. Using the Plate Layout Screen, prepare the corresponding priming plate(s).
 - a. If using the CT Amplified DNA Assay, place the CT (solid green) Priming Microwells into the plate. The Priming Microwells must be placed in a plate exactly as represented on the Plate Layout Screen. Place plate on designated Priming heater.
 - b. If using the CT/GC Amplified Assays, place the CT (solid green) and GC (solid yellow) Priming Microwells into the plate(s). The Priming Microwells must be placed in a plate exactly as represented on the Plate Layout Screen. Place plate(s) on designated Priming heaters.
11. Using the Plate Layout Screen, prepare the corresponding Amplification plate(s).
 - a. If using the CT Amplified DNA Assay, place the CT (striped green) Amplification Microwells into the plate. Place plate on the designated Warming heater.
 - b. If using the CT/GC Amplified Assays, place the CT (solid green) and GC (solid yellow) Priming Microwells into the plate(s). The Priming Microwells must be placed in a plate exactly as represented on the Plate Layout Screen. Place plate(s) on designated Priming heaters.
 - c. Use empty microwells to completely fill the amplification plate(s) with microwells.
12. Reseal the Microwell pouches as follows:
 - a. Place pouch on flat surface. Hold the open end flat with one hand.
 - b. While applying pressure, slide finger across outside of seal moving from one edge of pouch to the other.
 - c. Inspect to insure pouch is sealed.
13. Carefully remove the **BD Viper** Lysing Rack from the Locking Plate and place it into the Tube Alignment Block. Apply the Tube Lockdown Cover and lock the rack into position.
14. Make sure no foreign objects (e.g., sample caps, racks, pipette tip containers, etc.) are inside the instrument.

15. Close the **BD Viper** instrument door.
16. Enter the **BD Viper** instrument run parameters (enable or disable Walkaway mode as desired) and initiate the run. (See **BD Viper** System User's Manual section 4.7).
17. After samples are automatically transferred to the Priming Microwells a 20 min quiescent incubation takes place.
18. If WALKAWAY was selected in Step 16, the **BD Viper** System transfers samples to Priming microwells, incubates 20 min, proceeds to a heat step and then transfers samples from the Priming Microwells to the Amplification Microwells. (The user may start the next run after a cooldown is completed and the door unlocks – See **BD Viper** Instrument User's Manual section 5.5).
19. If WALKAWAY was disabled in Step 16, the **BD Viper** System will transfer samples to Priming microwells and incubate 20 min. At that point, a message appears notifying the user that the next step (heating) is time critical and heating will not start until the user acknowledges the message. If this is the first run of the day, verify that Amplification plates have been loaded and tap the "Yes" button to proceed. If this is not the first run of the day, open the upper door, remove and discard the sealed Amplification wells (see step 25 for detailed instructions). Change gloves, place new Amplification plates onto the Warming heaters/stages, replace used tip racks and black sealers. Close the door and press "Yes" to proceed.
20. Once the Priming well to Amplification well transfer is complete the plates are automatically sealed and carried into the reader(s) on board.
21. After the plate(s) have been automatically moved into the reader(s) there is a 10 min cool down time. An alert indicates when the cooldown time is complete.
22. Manually seal and remove the Priming Microwells from the plate by holding the top and bottom of the sealer and lifting the wells straight up as a unit. The clear sealers that come in the reagent kits may be used for this purpose. Place the sealed Microwells into a Disposal Bag and seal.
23. Clean the metal plate(s):
 - Rinse the plate with 1% (v/v) sodium hypochlorite, DNA AWAY or 3% (w/v) hydrogen peroxide.
 - Rinse the plate with water.
 - Wrap the plate in a clean towel and allow to completely dry prior to reuse.
24. When the **BD Viper** System run is complete, a printout of the test results is generated.
25. Remove the sealed Amplification Microwells from the metal plate.

Caution: Do Not Remove Sealing Material from Microwells. The sealed microwells may be easily removed as a unit by holding the sealer at the top and bottom and lifting straight up and out of the plate. Place the sealed microwells into the Disposal Bag and seal the bag.
26. Clean the metal plates:
 - Rinse the plate with 1% (v/v) sodium hypochlorite, DNA AWAY or 3% (w/v) hydrogen peroxide. Rinse the plate with water.
 - Wrap the plate in a clean towel and allow to completely dry prior to reuse.

27. After the last run of the day, perform the following clean up procedures.
- a. Clean the **BD Viper** Lysing rack and **BD Viper** Lysing Heater cover by immersing in 1% (v/v) sodium hypochlorite, DNA AWAY or 3% (w/v) hydrogen peroxide for 1-2 min. Rinse thoroughly with water and allow to air dry.
 - b. Clean the exterior surfaces of the Lysing Heater with gauze wetted with 1% (v/v) sodium hypochlorite, DNA AWAY or 3% (w/v) hydrogen peroxide then wipe with water.
 - c. Pour approximately 100 mL of 1% (v/v) sodium hypochlorite into the waste (liquid) station and allow to drain completely.
 - d. Pour approximately 100 mL of water into the waste (liquid) station and allow to drain completely. Repeat with an additional 100 mL of water.
 - e. Open the lower **BD Viper** instrument door and empty the tip waste box. Remove the box, seal the protective bag and close the box. Replace with a new box, lined with a bag.
 - f. Unscrew the waste bottle and remove. Add approximately 100 mL of undiluted bleach to the waste bottle and allow to sit overnight. Replace the bottle with a clean, dry waste bottle and close the lower door.

NOTE: The next morning, pour the solution down the drain with plenty of running water. Rinse the bottle thoroughly and allow to air dry.

- g. Dampen gauze pads with 1% (v/v) sodium hypochlorite, DNA AWAY or 3% (w/v) hydrogen peroxide and wipe the entire **BD Viper** instrument deck.
 - Starting in the back left, wipe the surface of the pipette tip station cover.
 - Lift the cover and wipe the under surface.
 - Wipe the entire surface of the left side.
 - Change gauze pads and wipe the tube processing station and the surrounding area.
 - Change gauze pads and clean around the pipette tip disposal station and the waste station.
 - Change gauze pads and wipe the heaters and surrounding areas.
 - Change gauze pads and wipe the surface of the pipette tip station cover, lift the cover and wipe under the surface.
 - Change gauze pads and wipe the surface of the staging area locking plate.
 - Change gauze pads and wipe the door handle.
 - After 2-3 min, repeat the entire process with gauze pads dampened with water. Change gauze pads as previously indicated. Make sure all traces of cleaning solution are rinsed away.
 - Repeat the rinse step if necessary.

NOTE: Make sure that the **BD Viper** heaters are free of debris. The presence of debris (such as bits of paper, gauze, etc.) will interfere with temperature uniformity.

- Dampen gauze pads with 1% (v/v) sodium hypochlorite, DNA AWAY or 3% (w/v) hydrogen peroxide and wipe the surface of the touch screen. After 2-3 min, wipe the surface thoroughly with gauze pads dampened with water. Wipe the surface with a dry clean gauze pad.

- Clean the plate seal tool suction cups and the pins on the plate sealer station with a 70% Isopropanol wipes.
- Wipe the exterior of the **BD Viper** instrument with gauze dampened with the 1% (v/v) sodium hypochlorite, DNA AWAY or 3% (w/v) hydrogen peroxide. Rinse all surfaces thoroughly with gauze dampened with water. Allow surfaces to air dry.
- Dispose of sealed Disposal Bag, biohazard bag and biohazard waste box according to established procedures for disposal of contaminated waste material.

VII. QUALITY CONTROL

The **BD ProbeTec** ET *Chlamydia trachomatis/Neisseria gonorrhoeae* positive and negative control set is provided separately. One positive and one negative control must be included in each assay run and for each new reagent kit lot number. The CT/GC positive control will monitor for substantial reagent failure only. The CT/GC negative control monitors for reagent and/or environmental contamination.

The positive control has both cloned CT and GC target regions that are not necessarily representative of organism target DNA detected by the assay nor do they represent specimen matrices (urine and epithelial cell suspensions) indicated for use with the **BD ProbeTec** ET System. These controls may be used for internal quality control or users may develop their own internal quality control material, as described by NCCLS C24-A2.¹⁵ Additional controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations. Refer to NCCLS C24-A2 for additional guidance on appropriate internal quality control testing practices. The positive control contains 750 copies per reaction of pCT16 linearized plasmid and 250 copies per reaction of pGC10 linearized plasmid. Both organisms have multiple copies of the target. The **BD ProbeTec** ET amplification reaction volume is 100 µL of rehydrated control.

Because the CT/GC positive control is used for both CT and GC testing, correct positioning of the microwell strips is important for proper result reporting. Refer to Section H of the "Test Procedure" for correct microwell strip positioning.

The CT/GC positive and CT/GC negative control must test as positive and negative, respectively, in order to report patient results. If controls do not perform as expected, the assay run is considered invalid and patient results will not be reported by the instrument. If the QC does not meet the expected results, repeat the entire run using a new set of controls, new microwells, and the processed specimens. If the repeat QC does not provide the expected results, contact Technical Services. (See "Interpretation of Results.")

Refer to Section D of the "Test Procedure" for directions on preparing the controls. Once the controls have been prepared, continue with testing as described in Section E of the "Test Procedure."

General QC information for the **BD Viper** System:

- The Amplification Control (AC) is not supported on 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 plate to be tested and for each reagent kit lot number. For each plate, if you have not logged in QC samples, 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 controls may be added, provided they are logged in as samples.

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 patient sample must be logged in at position C1 and consecutively down the column (C1, D1, E1, etc.).

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 patient sample must be logged in at position C1 and consecutively down the column (C1, D1, E1, etc.).
- 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 assigned as the positive and negative controls, respectively. Controls must be placed in the same column.

Interpretation of Control Results:

Control Interpretation without the AC

	<u>CT or GC MOTA Score</u>	<u>Result</u>
<u>CT/GC Positive Control</u>	<u>MOTA \geq 2000</u>	<u>Acceptable</u>
<u>CT/GC Negative Control</u>	<u>MOTA $<$ 2000</u>	<u>Acceptable</u>

Specimen Processing Controls:

Specimen processing controls may be tested in accordance with the requirements of appropriate accrediting organizations. A positive 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. As an alternative to using positive specimens, specimen processing controls simulating urine processing can be prepared as described below.

***Chlamydia trachomatis*:**

If a known positive specimen is not available, another approach is to assay a stock culture of *C. trachomatis* LGV2 (ATCC™# VR-902B) prepared as described below:

1. Thaw a vial of *C. trachomatis* LGV2 cells received from ATCC.
2. Prepare 10-fold serial dilutions to a 10⁵ dilution (at least 5 mL final volume) in phosphate buffered saline (PBS).
3. Place 4 mL of 10⁵ dilution in a **BD ProbeTec** ET sample tube.
4. Process as a urine sample starting at Section C, step 5 of the “Test Procedure.”
5. After processing, lyse sample as described in Section E of the “Test Procedure.”
6. Continue testing as described in Section F of the “Test Procedure.”

***Neisseria gonorrhoeae*:**

If a known positive specimen is not available, another approach is to assay a stock culture of *N. gonorrhoeae* (available from the ATCC, strain # 19424) prepared as described below:

1. Thaw a vial of *N. gonorrhoeae* stock culture, received from ATCC and immediately inoculate a chocolate agar plate.
2. Incubate at 37°C in 3-5% CO₂ 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 10⁸ cells/mL).
5. Prepare 10-fold serial dilutions to a 10⁵ dilution of the McFarland (at least 5 mL final volume) in PBS.
6. Place 4 mL of the 10⁵ dilution in a **BD ProbeTec** ET sample tube.
7. Process as a urine sample starting at Section C, step 5 of the “Test Procedure.”
8. After processing, lyse sample as described in Section E of the “Test Procedure.”
9. Continue testing as described in Section F of 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.

Laboratories may monitor more frequently based on laboratory workflow and volume of testing. 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 either of the **BD ProbeTec** ET Endocervical Specimen Collection and Transport systems and a CT/GC Diluent tube. [Alternatively, a sample tube containing 2 mL of Diluent (CT/GC) may be used.]
2. Dip the swab into the CT/GC Diluent and wipe the first area* using a broad sweeping motion.
3. Express the swab in the CT/GC Diluent tube. Recap the tube and vortex for 5 s.
4. Repeat for each desired area.
5. After all swabs have been collected, expressed in diluent and vortexed, the tubes are ready to be lysed (Section E) and assayed (Section F) according to the “Test Procedure.”

*The 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; Plate Sealing Tool; Tip Exchange Stations (2); **Instrument Exterior**: Upper Door Handle; Lower Door Handle; 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; Centrifuge; Vortex/Timer; Laboratory Bench Surfaces.

If an area gives a positive result, suspect areas should be cleaned according to the recommended procedure in the **BD Viper** System User's Manual and retested. If contamination does not resolve contact Technical Services for additional information.

BD conducted environmental monitoring for eight consecutive weeks over 42 different sampling areas as recommended in the **BD Viper** System User's Manual on three different **BD Viper** instruments. During the monitoring period, no CT DNA contamination was detected on any of the instruments. During the first month, GC contamination was detected on two different areas and two different instruments (2/168 observations = 1.2%). During the second monitoring month, GC contamination was detected on two different areas from an instrument that showed no contamination during the first month (2/168 observations = 1.2%). Each area resulting in detectable levels of GC contamination was cleaned as recommended in the **BD Viper** System User's Manual. Upon retesting, no contamination was detected.

VII. INTERPRETATION OF TEST RESULTS

The **BD ProbeTec** ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assay uses fluorescent energy transfer as the detection method to test for the presence of *C. trachomatis* and *N. gonorrhoeae* in clinical specimens. All calculations are performed automatically by the instrument software.

The presence or absence of *C. trachomatis* and *N. gonorrhoeae* is determined by relating the **BD Viper** MOTA scores for the specimen to pre-determined cutoff values. The MOTA score is a metric used to assess the magnitude of signal generated as a result of the reaction. The magnitude of the MOTA score is not indicative of the level of organism in the specimen.

If assay controls are not as expected, patient results should not be reported. See QC section for expected control values. Reported results are determined as follows.

For the CT/GC Reagent Pack:

***C. trachomatis* and *N. gonorrhoeae* Result Interpretation Without AC**

CT or GC			
MOTA Score Report	Interpretation	Result	
≥10,000	<i>C. trachomatis</i> plasmid DNA and/or <i>N. gonorrhoeae</i> DNA detected by SDA	Positive for <i>C. trachomatis</i> and/or <i>N. gonorrhoeae</i> . <i>C. trachomatis</i> and/or <i>N. gonorrhoeae</i> organism viability and/or infectivity cannot be inferred since target DNA may persist in the absence of viable organisms.	Positive ¹
2,000-9,999	<i>C. trachomatis</i> plasmid DNA and/or <i>N. gonorrhoeae</i> detected by SDA	<i>C. trachomatis</i> and/or <i>N. gonorrhoeae</i> likely. Supplemental testing may be useful for verifying presence of <i>C. trachomatis</i> and/or <i>N. gonorrhoeae</i> . ²	Low Positive ^{1,2,3}
< 2000	<i>C. trachomatis</i> plasmid DNA and/or <i>N. gonorrhoeae</i> not detected by SDA	Presumed negative for <i>C. trachomatis</i> and/or <i>N. gonorrhoeae</i> . A negative result does not preclude <i>C. trachomatis</i> and/or <i>N. gonorrhoeae</i> infection because results are dependent on adequate specimen collection, absence of inhibitors, and sufficient DNA to be detected.	Negative

¹ According to CDC guidelines, “consideration should be given to routine additional testing for persons with positive *C. trachomatis* or *N. gonorrhoeae* screening tests when risk-factor information or actual surveys indicate that the prevalence is low, resulting in a lower PPV (e.g., < 90%).” Regardless of the screening method used (e.g. NAAT, DFA, EIA, Nucleic Acid Probe), “all positive screening tests should be considered presumptive evidence of infection.”¹⁶ Refer to CDC guidelines for details on additional testing and patient management after a positive screening test.

² Refer to cutoff description below and Figures 2 and 3 in “Performance Characteristics” for additional information on the distribution of CT and GC MOTA values by specimen type observed in the clinical trials.

³ The magnitude of the MOTA score is not indicative of the level of organism in the specimen.

Determination of CT/GC Cutoff:

The assay and amplification control cutoffs for CT and GC specimen results were determined based on Receiver Operating Characteristic (ROC) curve analysis of MOTA values obtained with patient specimens (male urethral swab, female endocervical swab, male and female urine) tested using both the **BD ProbeTec ET CT/GC** assay and another amplified method during preclinical studies. The cutoffs were confirmed in clinical studies by using the **BD ProbeTec ET CT/GC** assay and culture, Direct Fluorescence Antibody (DFA) (CT only) and another amplified method. These studies show that for the majority of the time, CT and/or GC MOTA values greater than 2,000 will indicate the presence of *C. trachomatis* and/or *N. gonorrhoeae*. CT and/or GC MOTA values less than 2000 correlate with negative *C. trachomatis* and/or *N. gonorrhoeae* culture results the majority of the time. Male urethral swab, female endocervical swab and male urine specimens with CT MOTA values between 2,000 and 4,000 had a decreased likelihood of being true positive compared to results with MOTA values above 4,000. For female urine specimens, CT positive results with MOTA values between 2,000 and 10,000 also had a decreased likelihood of being true positive compared to results with MOTA values above 10,000. GC positive results with MOTA values between 2,000 and 10,000 also had a decreased likelihood of being true positive compared to results with MOTA values above 10,000. Refer to Figures 2 and 3 for the distribution of CT and GC MOTA values by specimen type observed in the clinical study. The positive predictive value (PPV) for the data in these figures was calculated using the following formula: True Positive/True Positive + False Positive. The data are not adjusted for prevalence. CT results between 2,000-10,000 MOTA had a PPV ranging from 56%-83% compared to a PPV range of 82%-100% for MOTA values above 10,000. GC results between 2,000-10,000 MOTA had a PPV ranging from 44%-75% compared to a PPV range of 90%-100% for

MOTA values above 10,000. Depending on the types of specimens tested, populations sampled, and laboratory practices, supplemental testing for specimens with MOTA values between 2,000-10,000 may be useful. Refer to CDC guidelines for details on additional testing and patient management after a positive screening test.

N. cinerea has been shown to cross-react in the **BD ProbeTec** ET GC assay and other *Neisseria* species may also cause false positive results. In settings with a high prevalence of sexually transmitted disease, positive assay results have a high likelihood of being truly positive. In settings with a low prevalence of sexually transmitted disease, or in any setting in which a patient's clinical signs and symptoms or risk factors are inconsistent with gonococcal or chlamydial urogenital infection, positive results should be carefully assessed and the patient retested by other methods (e.g., culture for GC) if appropriate.

IX. LIMITATIONS OF THE PROCEDURE

1. This method has been tested only with endocervical swabs, male urethral swabs, 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 "Sample Collection and Transport" sections of this insert.
3. Endocervical specimen adequacy can only be assessed by microscopic visualization of columnar epithelial cells in the specimens.
4. Collection and testing of urine specimens with the **BD ProbeTec** ET *Chlamydia trachomatis/Neisseria gonorrhoeae* 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** ET *Chlamydia trachomatis/Neisseria gonorrhoeae* Amplified DNA Assay for male and female urine testing should be performed on first catch random urine specimens (defined as the first 15-20 mL of the urine stream when using the UPP). During the clinical evaluation, testing urine volumes up to 60 mL was included in the performance estimates. Dilutional effects of larger urine volumes may result in reduced assay sensitivity. The effects of other variables such as mid-stream collection have not been determined. Performance has not been established when the UPP is added to the collection cup prior to collection.
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** ET *Chlamydia trachomatis/Neisseria gonorrhoeae* Amplified DNA Assay should be interpreted in conjunction with other laboratory and clinical data available to the physician.

9. The **BD ProbeTec** ET *Chlamydia trachomatis/Neisseria gonorrhoeae* Amplified DNA Assay does not detect plasmid-free variants of *C. trachomatis*.
10. The **BD ProbeTec** ET *Chlamydia trachomatis/Neisseria gonorrhoeae* 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.
11. The **BD Viper** system cannot be used to assess therapeutic success or failure since nucleic acids from *Chlamydia trachomatis* and *Neisseria gonorrhoeae* may persist following antimicrobial therapy.
12. The **BD ProbeTec** ET *Chlamydia trachomatis/Neisseria gonorrhoeae* Amplified DNA Assay provides qualitative results. No correlation can be drawn between the magnitude of MOTA score and the number of cells in an infected sample.
13. The predictive value of an assay depends on the prevalence of the disease in any particular population. See Tables 1 and 2 for hypothetical predictive values when testing varied populations.
14. Because the CT/GC positive control is used for both CT and GC testing, correct positioning of the microwell strips is important for final results reporting. Refer to Section F of the “Test Procedure” for correct microwell strip positioning.
15. Use of the **BD ProbeTec** ET *Chlamydia trachomatis/Neisseria gonorrhoeae* Amplified DNA Assay is limited to personnel who have been trained in the assay procedure and the **BD Viper** system.
16. In laboratory studies, blood > 5% (v/v) was shown to cause indeterminate (inhibitory) results in both urine and swab specimens (with AC) and false negative results in urine specimens (with and without AC). Blood > 5% (v/v) may cause false negative results in swab specimens (with and without AC). Specimens with moderate to gross blood may interfere with **BD ProbeTec** ET CT/GC Assay results. Refer to “Performance Characteristics” for specific performance of female swab specimens with observed blood.
17. The presence of highly pigmented substances in urine, such as bilirubin (10 mg/mL) and Phenazopyridine (10 mg/mL), may cause indeterminate or false negative results.
18. Leukocytes in excess of 250,000 cells/mL (swab specimens) may cause indeterminate or false negative results.
19. The presence of serum, feminine deodorant sprays or talcum powder may cause false negative results (urine specimens).
20. The **BD ProbeTec** ET *C. trachomatis/N. gonorrhoeae* Amplified DNA Assays may cross-react with *N. cinerea* and *N. lactamica*. Refer to “Performance Characteristics” for further information.
21. The reproducibility of the **BD ProbeTec** ET CT/GC Assay was established using seeded swab specimens and seeded buffer to simulate urine specimens. These specimens were inoculated with both *C. trachomatis* and *N. gonorrhoeae*. Reproducibility when testing urine samples and samples with *C. trachomatis* only and *N. gonorrhoeae* only has not been determined.

22. Performance characteristics for detecting *N. gonorrhoeae* in males are based on testing patients with infection rates of 0-43%; the male populations sampled were primarily from STD clinics where the prevalence of GC is higher than in other clinical settings. In males, 16 gonococcal infections were identified in the low prevalence setting (0-8% prevalence). Likewise, the majority of females in the study with GC infections were from STD clinics. In females, only six gonococcal infections were identified in the low prevalence setting (1.2% prevalence). Positive results in low prevalence populations should be interpreted carefully in conjunction with clinical signs and symptoms, patient risk profile, and other findings with the understanding that the likelihood of a false positive may be higher than a true positive.
23. Testing urine specimens from female patients as the sole test for identifying chlamydial or gonococcal infections may miss infected individuals (17/100 or 17% of females with CT-positive cultures and 11/80 or 13.8% of females with GC-positive cultures had negative results when urine only was tested) with the **BD ProbeTec** ET CT/GC Assay.
24. Performance has not been established for UPT fill volumes other than volumes falling within the black lines on the fill window (approximately 2.5 mL to 3.45 mL).
25. UPT performance has not been established on **BD Viper** instruments that do not have onboard readers (Cat # 440740).
26. The **BD Viper** System does not support the use of the Amplification Control (AC).
27. For the **BD Viper** System, black plate sealers are required to eliminate the presence of stray light which may impact the accuracy of results.

X. EXPECTED RESULTS

A. Prevalence

The prevalence of positive *C. trachomatis* or *N. gonorrhoeae* specimens in patient populations depends on: clinic type, age, risk factors, gender, and test method. The prevalence observed with the **BD ProbeTec** ET CT/GC amplified DNA assay during a multi-center clinical trial ranged from 4.5 to 28.6% for CT (Table 6 page 41) and from 0 to 42.9% for GC (Table 12 page 46). Coinfections ranged from 0% to 5.4%.

B. Positive and Negative Predictive Values

Hypothetical positive and negative predictive values (PPV & NPV) for the **BD ProbeTec** ET CT/GC amplified DNA assays are shown in Tables 1 and 2 (page 38), respectively. These calculations are based on hypothetical prevalence and overall CT sensitivity and specificity (as compared to the patient infected status) of 90.7 and 96.6%, respectively, and overall GC sensitivity and specificity of 96.0 and 98.8%, respectively. In addition, PPV and NPV based on actual prevalence, sensitivity and specificity are shown in Table 6 (page 41) and Table 12 (page 46).

C. MOTA Score Frequency Distribution

A total of 5119 specimens collected from clinics in nine different geographic locations were assayed with the **BD ProbeTec** ET system for *C. trachomatis* and/or *N. gonorrhoeae* in seven clinical laboratories. A frequency distribution of the initial MOTA scores for AC is shown in Figure 1 by specimen type (page 35).

A total of 4108 **BD ProbeTec** ET *C. trachomatis* results were evaluated at seven clinical sites. A frequency distribution of the initial MOTA scores for CT is shown in Figure 2 (see page 36). The distribution of uniquely **BD ProbeTec** ET false positive (test which was positive in the **BD ProbeTec** ET but not positive by cell culture, DFA or AMP1 in either specimen type) and false negative results are shown below Figure 2 (page 36).

A total of 5093 **BD ProbeTec** ET *N. gonorrhoeae* results were evaluated at nine clinical sites. A frequency distribution of the initial MOTA scores for GC is shown in Figure 3 (see page 37). The distribution of uniquely **BD ProbeTec** ET false positive (test which was positive in the **BD ProbeTec** ET but not positive by culture or AMP1 in either specimen type) and false negative results are shown below Figure 3 (page 37).

D. Controls

During the clinical evaluation, CT/GC positive control failures were observed in 22 of 518 CT and GC assay runs. For the negative CT/GC control, failures were observed in 19 of 518 CT assay runs and in 12 of 518 GC assay runs. Eight of these observed CT and GC control failures occurred as a result of the operator switching the positive and negative control.

The CT/GC positive and negative control MOTA scores observed in the clinical trials are shown in the following table

Control	Range	5th Percentile	MOTA Score		
			Mean	Median	95th Percentile
CT Negative	0 – 499	0	113	109.5	262
CT Positive	2055 – 67281	8222	26816	24681	52725
GC Negative	0 – 800	0	90	71.5	245
GC Positive	2013 - 54240	7404	22452	21228	41405

XI. PERFORMANCE CHARACTERISTICS:

Clinical Performance

Performance characteristics for the **BD ProbeTec** ET *C. trachomatis* and *N. gonorrhoeae* (CT/GC) Amplified DNA Assay were established in a multi-center study at seven geographically diverse clinical sites. Each site was required to pass a proficiency panel prior to enrolling patients in the study. The study included 4131 specimens collected from 2109 patients attending sexually transmitted disease (STD) clinics, OB/GYN Clinics, Family Planning Clinics, Adolescent Clinics, and

Emergency Rooms. A total of 22 CT results were excluded from the data analysis due to cell culture contamination. One additional specimen was excluded due to a missing DFA result. A total of 26 GC results were excluded from the data analysis. Of these 26, 15 were excluded due to culture contamination and 11 were excluded due to failure to collect a swab for culture. Therefore, a total of 4108 CT and 4105 GC results from 2109 patients were used in the final data analysis. Paired specimens (swab and urine) were collected from 2020 of the 2109 patients. The majority of these were from patients in STD and family planning clinics. Four endocervical swabs and one urine specimen were collected from female patients. The swabs were tested by cell culture for CT, culture for GC, the **BD ProbeTec** ET assay, and a commercially available amplification method (AMP1). The endocervical swab collection order was rotated throughout the study to minimize effects of collection order. For males, two urethral swabs and one urine specimen were collected. The first swab was used for GC culture and then the **BD ProbeTec** ET assay. The second swab was used for CT cell culture. The UPP was added to the urine at the collection site prior to transporting to the laboratory.

C. trachomatis was detected by cell culture of endocervical and male urethral swabs. Positivity was based on detecting at least one inclusion-forming unit (IFU) in either first or second passage. Female and male urine **BD ProbeTec** ET results were compared to culture results of endocervical and male urethral swab specimens, respectively. In addition, a commercially available amplification assay (AMP1) was performed on all endocervical swabs and urine specimens. If cell culture was negative but either amplification assay was positive, a DFA test was performed from the cell culture transport medium. For male urethral swab specimens, testing included cell culture but not the AMP1 method. If the cell culture was negative, but **BD ProbeTec** ET (swab or urine) and/or the AMP1 CT urine test were positive, DFA was performed from the cell culture transport medium. A different commercially available amplification assay (AMP2) was performed from culture transport medium for those male patients who had a positive urine AMP1 test and the corresponding swabs were culture negative.

N. gonorrhoeae was detected by recovery of gram-negative, oxidase-positive colonies on agar. Culture identification was confirmed by two methods, one biochemical and one either immunological or fluorometric. **BD ProbeTec** ET assay results were compared to culture and a commercially available amplification assay (AMP1). All GC cultures were incubated between 48 - 72 h prior to reporting a final result.

Performance characteristics for CT and GC were calculated both with and without the amplification control (AC). All data are presented without the amplification control. Assay interpretation differences resulting from use of the amplification control are footnoted at the bottom of each table. For true CT and/or GC positives, the target level is generally high enough to overcome the inhibitory effects of the specimen matrix. These specimens are interpreted as positive by the instrument algorithm even if the AC is negative (MOTA < 1000). All initially indeterminate

results were repeated. Performance was calculated based on the results of repeat testing. Specimens were classified as positive, negative or indeterminate. Repeatedly inhibitory specimens were considered uninterpretable and excluded from sensitivity and specificity calculations. To calculate performance without the AC, indeterminate results (results with negative AC) were interpreted as negative for CT and/or GC. The numbers of initial and final indeterminate results by patient infected status are shown in Table 3 (CT) and Table 4 (GC). The numbers of initial and final indeterminate results by specimen type are shown in Table 5 (CT) and Table 11 (GC).

In the previous multi-center study, the seven sites collected 183 and 184 asymptomatic male GC swab and urine specimens, respectively. To supplement this data, a similar study was conducted at three clinical sites; one of which participated in the original evaluation. The study included specimens collected from two STD clinics and a teaching hospital. The male patients attending the STD clinics may have had a prior STD infection, an infected partner, or attending for a routine visit. A total of 560 patients were enrolled in the study, 41 of which were excluded from the data analysis due to noncompliance issues (e.g. patients enrolled prior to proficiency completed, symptomatic patients enrolled, GC culture not performed). From the remaining 519 patients, 1038 paired specimens (swab and urine) were collected. A total of 50 specimens were excluded for various reasons (e.g. urine frozen prior to testing, incomplete proficiency testing, specimens older than six days). Therefore, a total of 988 specimens collected from 519 patients were used in the final data analysis. The swab specimen was used for GC culture and then the **BD ProbeTec** ET assay. The urine specimen was tested using both the **BD ProbeTec** ET assay and a commercially available amplification assay (AMP1). The UPP was added to the urine at the test site. The **BD ProbeTec** ET urine results were compared to the culture results of the male urethral swab specimens. Results were combined with the data collected in the original multicenter study and are included in the data presented in Figures 1 and 3 and Tables 2, 4, 11, 12, 13, 14, and 16.

C. trachomatis

BD ProbeTec ET *C. trachomatis* results were compared to culture and patient infected status. Performance estimates for each specimen type and symptomatic status are shown in Table 5. A patient was considered infected if (1) the culture was positive, or (2) positive results were obtained for both AMP1 (in either the swab or urine) and DFA, or (3) AMP1 was positive in both swab and urine paired specimens. Data on pregnant females are footnoted at the bottom of Table 5. Of the 1,419 female swab specimens tested in the clinical evaluations by the **BD ProbeTec** ET CT Assay, 101 (7.1%) were classified as grossly bloody and 242 (17.1%) as moderately bloody. Assay performance with moderately to grossly bloody swabs was not statistically different than assay performance with non-bloody or lightly bloody swabs. Table 6 shows performance estimates for the **BD ProbeTec** ET CT assay as compared to patient infected status for each clinical site differentiated by specimen type.

In the clinical trial, the AMP1 assay was performed on all endocervical swabs and urine specimens (males and females). A comparison of the **BD ProbeTec** ET assay and AMP1 CT assay to culture and DFA (on culture negative, assay positive specimens) is presented in Table 7. Table 8 shows the percent agreement between **BD ProbeTec** ET CT results and AMP1 results.

A summary of test results on paired specimens is contained in Tables 9 (females) and 10 (males). Patient infected status is also shown in these tables.

N. gonorrhoeae

BD ProbeTec ET *N. gonorrhoeae* results were compared to culture and patient infected status. Performance estimates for each specimen type and symptomatic status are shown in Table 11. A patient was considered infected if (1) the culture was positive or (2) in females, if AMP1 was positive in both swab and urine (paired specimens). Data on pregnant females are footnoted at the bottom of Table 11. Of the 1,411 female swab specimens tested in the clinical evaluations by the **BD ProbeTec** ET GC assay, 102 (7.2%) were classified as grossly bloody and 242 (17.2%) as moderately bloody. Assay performance with moderately to grossly bloody swabs was not statistically different than assay performance with non-bloody or lightly bloody swabs. Table 12 shows performance estimates for the **BD ProbeTec** ET GC assay as compared to patient infected status for each clinical site differentiated by specimen type.

In the clinical trial the AMP1 assay was performed on all endocervical swabs and urine specimens (males and females). A comparison of the **BD ProbeTec** ET assay and AMP1 GC assay against culture is presented in Table 13. Table 14 shows the percent agreement between **BD ProbeTec** ET GC results and AMP1 results. A summary of test results on paired specimens is contained in Tables 15 (females) and 16 (males). Patient infected status is also shown in these tables.

***C. trachomatis* and *N. gonorrhoeae* co-infection**

In the clinical trial, both **BD ProbeTec** ET CT and GC results were available for 4082 specimens. A summary of **BD ProbeTec** ET performance for detecting both CT and GC in specimens from patients considered co-infected by the patient infected status is presented in Table 17.

Analytical Studies

Note: The **BD ProbeTec** ET CT/GC amplification reaction volume is 100 µL of processed sample.

Precision

Precision of the **BD ProbeTec** ET CT/GC Amplified DNA Assays was demonstrated by testing a five-member panel consisting of four dilutions co-inoculated with *C. trachomatis* and *N. gonorrhoeae* in Diluent (CT/GC) and a negative (uninoculated Diluent). The five member panel was made up of samples

containing 0-100 *C. trachomatis* Elementary Bodies per reaction (EBs/rxn) and 0-100 *N. gonorrhoeae* cells/rxn. This precision panel was run at two clinical sites and internally. Six replicates of each panel were run twice a day for three days. Because no significant run-to-run or site-to-site variability was observed, the data were combined and presented in Table 18. No positive or negative CT/GC control failures were observed in the Precision study.

Proficiency / Reproducibility

Prior to data collection for the clinical trial, each technologist processed and performed two proficiency panels. One panel consisted of seeded swab specimens; the other panel consisted of seeded buffer to simulate testing urine specimens. Each 30-member swab panel contained 12 replicates of a level seeded with both 500 EBs/rxn (CT) and 500 cells/rxn (GC), 12 replicates of a level seeded with both 50 EBs/rxn (CT) and 30 cells/rxn (GC) and six unseeded samples. Each 30 member urine panel contained 12 replicates of a level seeded with both 600 EBs/rxn (CT) and 500 cells/rxn (GC), 12 replicates of a level seeded with both 115 EBs/rxn (CT) and 100 cells/rxn (GC) and six unseeded samples.

Results from this proficiency study were combined across 23 operators and across all sample levels (negative, low level, high-level) to estimate reproducibility. Reproducibility estimates are presented in Table 19 as percent correct versus expected results. No positive or negative CT/GC control failures were observed in the Proficiency/Reproducibility study. At three of the clinical sites designated technologists with various levels of experience ran panels twice in one day to show that multiple runs in the same room do not adversely affect results. No decrease in correct results was seen between first and second runs. Separate chi-square tests were performed to compare the two runs for swab and urine samples. No statistical differences were observed (p-value for swab samples: 0.1769; p-value for urine samples: 0.7691).

Specimen Stability Studies

Transport and storage of specimens for testing were evaluated using the information collected during the clinical studies as well as by conducting internal analytical studies. The majority of the clinical specimens were transported to the laboratory within one day and held refrigerated or at room temperature and tested within four days of collection.

Recommendations to support an additional two days of specimen stability at 2-8°C were based on in-house studies that were conducted by seeding swabs and human urine with approximately 200 CT EBs and 200 GC cells per reaction. Both seeded and unseeded swabs and urine were held at refrigerated conditions and tested on Days 0,1,2,4,5 and 6. Each positive and negative sample was tested in triplicate for a total of 18 positive and nine negative data points on each day. The data demonstrated that both swabs and urines were stable up to Day 6.

Recommendations to support an additional two days of swab specimen stability at

15-27°C were based on in-house studies that were conducted as described above. The data demonstrated that the swabs were stable up to Day 6.

In addition, a separate stability study was conducted at two clinical sites to verify room temperature stability with clinical swabs and urine specimens. Five swabs were collected from female patients (one for AMP1 and four for **BD ProbeTec ET**). Urine specimens were collected from both male and female patients. Baseline (Day 0) specimens were processed within 24 h of collection. Additional samples were held at room temperature and processed on Days 2, 4 and 5. Each timepoint was compared to **BD ProbeTec ET** results on Day 0. **CT Results:** Of the 101 swab specimens, 29 were positive and 57 negative at each time point. The remaining 15 specimens (14.9%) were variable from day to day. Of the 107 urine specimens, 27 were positive and 68 negative at each time point. The remaining 12 urine specimens (11.2%) varied between days. **GC Results:** Of the 101 swab specimens, 28 were positive and 67 negative at each time point. The remaining 7 swab specimens (6.9%) were variable from day to day. Of the 107 urine specimens, 30 were positive and 69 negative at all time points. The remaining 8 specimens (7.5%) varied from day to day. **Conclusion:** Day to day variability for both swabs and urines ranged from 5.6-10.9% for CT and 1.9-5.9% for GC. It is unknown whether specimens stored at 2-8°C would have less variability in day to day testing.

Analytical Sensitivity

The analytical sensitivity (Limit of Detection or LOD) of the **BD ProbeTec ET** *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assay was determined by diluting 15 *C. trachomatis* serovars and 39 *N. gonorrhoeae* strains in Diluent (CT/GC). Quantitated CT cultures were diluted to 0,5,15,35,70 and 200 EBs per reaction for each serovar. Quantitated GC cultures were diluted to 0,5,10,15 and 25 cells per reaction for each strain. Samples were processed and assayed in triplicate.

The LOD of the *C. trachomatis* serovars ranged from 5-200 EBs per reaction with a median of 35 EBs per reaction. The 15 CT serovars, with the corresponding LOD for each in parentheses (expressed as EBs/reaction) are as follows: A (15), B (35), Ba (35), C (5), D (70), E (35), F (200), G (35), H (15), I (200), J (70), K (200), LGV-1 (35), LGV-2 (15), LGV-3 (35).

Quantitation of *C. trachomatis* (CT) based on EBs was found to be more accurate and reproducible than quantitation by inclusion-forming units (IFU). Quantitation of IFU tends to be variable and consistently gives a lower number when compared with direct (DFA) quantitation of EBs. To determine the correlation between quantitation by DFA and IFU titers, all 15 CT serovars were grown in tissue culture, then the EBs were collected and quantitated by both DFA and IFU. The ratio of the EB counts (from DFA) to IFU titers for each serovar was calculated. The mean EB to IFU ratio for the 15 CT serovars (A through LGV-3) was determined to be 167 EBs per IFU. For the STD group (CT serovars D-K), the mean ratio was 317 EBs per IFU. These ratios are representative of the variation found between serovars. With these conversions, the analytical sensitivity of the CT assay would be < 1 IFU.

The LOD of the 39 *N. gonorrhoeae* strains ranged from 5-25 cells per reaction with a median of 10 cells per reaction. These strains included 14 ATCC strains (including six different *N. gonorrhoeae* auxotypes) and 25 clinical isolates obtained from geographically diverse sites.

Analytical Specificity

Table 20 (see page 51) identifies the bacteria, viruses, and yeasts evaluated using the **BD ProbeTec** ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assays. Bacterial isolates were tested using at least 10⁸ Colony Forming Units (CFU)/mL or equivalent copies of genomic DNA except as indicated. Viruses were tested using at least 10⁸ Plaque Forming Units (PFU)/mL or equivalent copies of genomic DNA. The tested organisms include those commonly found in the urogenital tract as well as others.

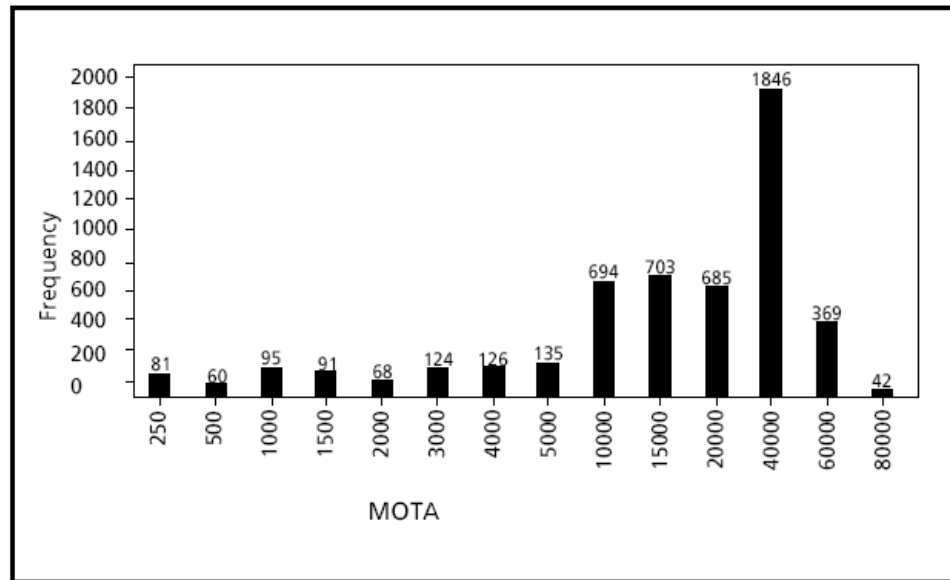
For *Chlamydia trachomatis*, all results were negative as expected.

Three *N. cinerea* strains were tested in the **BD ProbeTec** ET GC assay. Of these, two were repeatedly positive. Sixteen *N. subflava* strains were tested in triplicate. Two strains were positive in one of three replicates. When the two strains were prepared and tested again, all results were negative. Eight *N. lactamica* strains were tested in triplicate. One strain was positive in one of the three replicates. When that strain was prepared and tested again, all results were negative.

Interfering Substances

Potential interfering substances which may be encountered in swab and/or urine specimens were tested with the **BD ProbeTec** ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assay. Potential interfering substances were evaluated in the absence of target or with 200 CT EBs per reaction (i.e., 1000 EBs/mL of urine or 4000 EBs per swab) and 200 GC cells per reaction (i.e., 1000 cells/mL of urine or 4000 cells per swab). Results are summarized in Table 21.

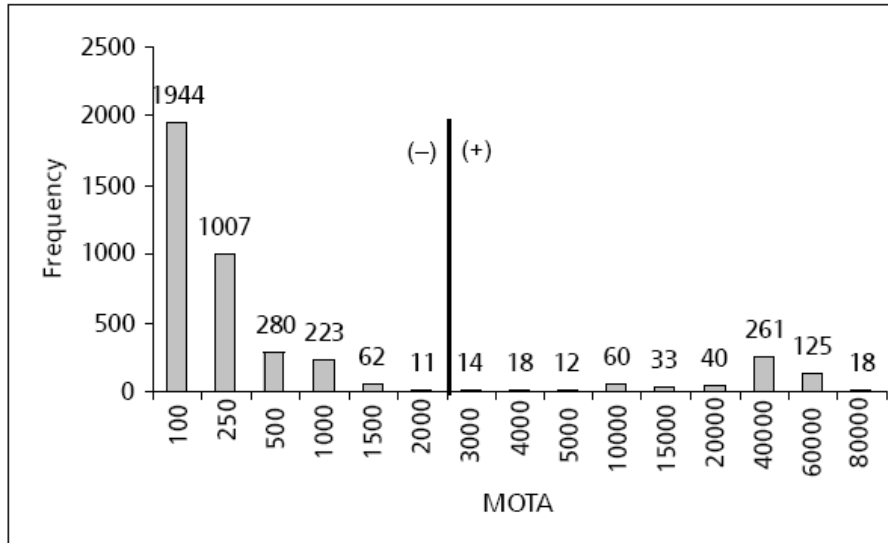
Figure / Abbildung / Figura 1: Frequency Distribution for BD ProbeTec™ ET AC Assay – Initial Results / Distribution de la fréquence pour le test à amplification d'ADN BD ProbeTec ET AC – Résultats initiaux / Häufigkeitsverteilung beim BD ProbeTec ET AC-Assay – Anfängliche Ergebnisse / Distribuzione della frequenza per il test AC BD ProbeTec ET – Risultati iniziali / Distribución de frecuencia para los resultados iniciales del análisis AC BD ProbeTec ET



AC MOTA (All Specimens) / MOTA AC (tous les échantillons) / AC-MOTA (Alle Proben) / AC MOTA (tutti i campioni) / MOTA AC (todas las muestras)

Specimen Type	0-250	251-500	501-1000	1001-1500	1501-2000	2001-3000	3001-4000	4001-5000	5001-10000	10001-15000	15001-20000	20001-40000	40001-60000	60001-80000	Total
FS	7	1	1	2	5	13	15	22	185	266	287	566	51	5	1426
FU	63	43	70	56	45	77	72	71	305	198	135	200	7	0	1342
MS	0	1	2	0	0	0	4	5	49	88	127	657	235	27	1195
MU	11	15	22	33	18	34	35	37	155	151	136	423	76	10	1156
Total	81	60	95	91	68	124	126	135	694	703	685	1846	369	42	5119

Figure / Abbildung / Figura 2: Frequency Distribution for BD ProbeTec™ ET CT Assay – Initial Results / Distribution de la fréquence pour le test à amplification d'ADN BD ProbeTec ET CT – Résultats initiaux / Häufigkeitsverteilung beim BD ProbeTec ET CT-Assay – Anfängliche Ergebnisse / Distribuzione della frequenza per il test CT BD ProbeTec ET – Risultati iniziali / Distribución de frecuencia para los resultados iniciales del análisis CT BD ProbeTec ET

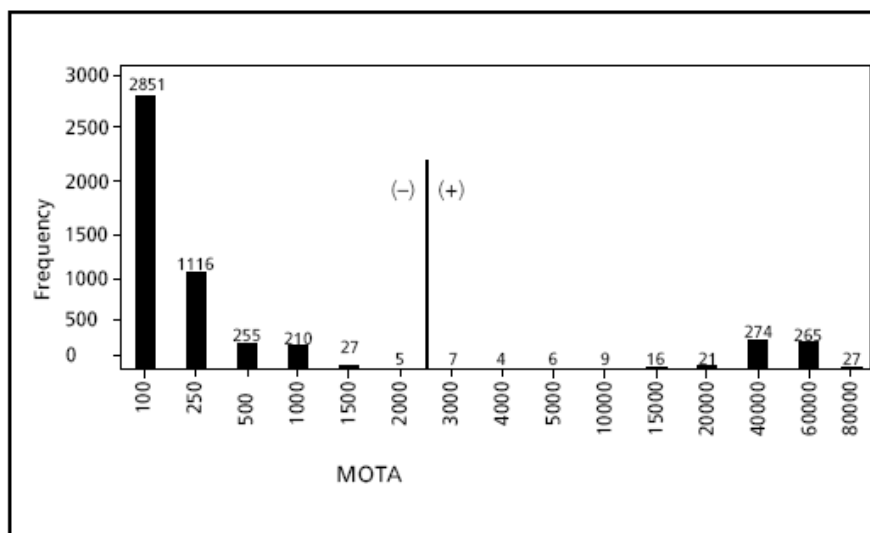


CT MOTA / MOTA CT / CT-MOTA

		0-100	101-250	251-500	501-1000	1001-1500	1501-2000	2001-3000	3001-4000	4001-5000	5001-10000	10001-15000	15001-20000	20001-40000	40001-60000	60001-80000
n		1944	1007	280	223	62	11	14	18	12	60	33	40	261	125	18
FP ¹	Total							5	8	2	15	6	4	10	2	0
	FS							3	3	0	3	0	1	3	0	0
	FU							0	1	0	6	1	0	3	0	0
	MS							1	1	0	5	0	3	3	1	0
	MU							1	3	2	1	5	0	1	1	0
FN	Total	24	12	4	3	2	2									
	FS	5	1	2	1	0	0									
	FU	14	6	1	1	0	2									
	MS	3	2	1	0	1	0									
	MU	2	3	0	1	1	0									

¹ Includes only uniquely **BD ProbeTec** ET False Positives (specimens which are positive in the **BD ProbeTec** ET instrument, but not positive by cell culture, DFA, or AMP1 in either specimen type). / Comprend seulement les faux positifs **BD ProbeTec** ET (échantillons qui sont positifs selon l'instrument **BD ProbeTec** ET, mais non positif en culture cellulaire, par DFA ou AMP1 pour l'un ou l'autre des types d'échantillon). / Enthält nur einzigartig falschpositive **BD ProbeTec** ET-Proben (d.h. Proben, die auf dem **BD ProbeTec** ET-Gerät positiv sind, die jedoch für alle Probenarten in der Zellkultur, nach der DIF-Methode oder im AMP1-Test nicht positiv sind). / Comprende soltanto falsi positivi unicamente **BD ProbeTec** ET (campioni risultati positivi con lo strumento **BD ProbeTec** ET, ma non positivi con coltura cellulare, DFA, o AMP1 in entrambi i tipi di campione). / Incluye sólo únicamente los falsos positivos **BD ProbeTec** ET (muestras que dan positivo en el Instrumento **BD ProbeTec** ET, pero no dan positivo en el cultivo celular, DAF, o AMP1 en cualquier tipo de muestra).

Figure / Abbildung / Figura 3: Frequency Distribution for BD ProbeTec™ ET GC Assay – Initial Results / Distribution de la fréquence pour le test à amplification d'ADN BD ProbeTec ET GC – Résultats initiaux / Häufigkeitsverteilung beim BD ProbeTec ET GC-Assay – Anfängliche Ergebnisse / Distribuzione della frequenza per il test GC BD ProbeTec ET – Risultati iniziali / Distribución de frecuencia para los resultados iniciales del análisis GC BD ProbeTec ET



GC MOTA / MOTA GC / GC-MOTA

		0-100	101-250	251-500	501-1000	1001-1500	1501-2000	2001-3000	3001-4000	4001-5000	5001-10000	10001-15000	15001-20000	20001-40000	40001-60000	60001-80000
n		2851	1116	255	210	27	5	7	4	6	9	16	21	274	265	27
FP ¹	Total							2	1	3	5	1	2	3	3	0
	FS							1	0	1	1	0	0	0	2	0
	FU							0	1	0	0	1	2	1	1	0
	MS							0	0	0	2	0	1	1	0	0
	MU							1	0	2	2	0	0	1	0	0
FN	Total	10	2	5	3	2	2									
	FS	2	0	1	0	0	0									
	FU	5	0	3	2	1	2									
	MS	2	1	0	1	0	0									
	MU	1	1	1	0	1	0									

¹ Includes only uniquely **BD ProbeTec ET** False Positives (specimens which are positive in the **BD ProbeTec ET** instrument, but not positive by culture or AMP1 in either specimen type). / Comprend seulement les faux positifs **BD ProbeTec ET** (échantillons qui sont positifs selon l'instrument **BD ProbeTec ET**, mais non positif en culture cellulaire, par DFA ou AMP1 pour l'un ou l'autre des types d'échantillon). / Enthält nur einzigartig falschpositive **BD ProbeTec ET**-Ergebnisse (d.h. Proben, die auf dem **BD ProbeTec ET**-Gerät positiv sind, die jedoch für alle Probenarten bei der Kultur oder im AMP1-Test nicht positiv sind). / Comprende soltanto falsi positivi unicamente **BD ProbeTec ET** (campioni risultati positivi sullo strumento **BD ProbeTec ET**, ma non positivi con coltura o AMP1 in entrambi i tipi di campione). / Incluye sólo únicamente los falsos positivos **BD ProbeTec ET** (muestras que dan positivo en el instrumento **BD ProbeTec ET**, pero no dan positivo en el cultivo o AMP1 en cualquier tipo de muestra).

Table / Tableau / Tabelle / Tabella / Tabla 1: CT Hypothetical Positive and Negative Predictive Values Compared to Patient Infected Status / Valeurs prédictives théoriques positives et négatives pour CT comparées au statut infecté du patient / Hypothetische positive und negative CT-Vorhersagewerte im Vergleich zum Infektionsstatus des Patienten / Valori predittivi positivi e negativi ipotetici per CT rispetto a stato di infezione del paziente / Hipotéticos positivos CT y valores predictivos negativos comparados con el estado del paciente infectado

Prevalence (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
2	90.7	96.6	35.3	99.8
5	90.7	96.6	58.4	99.5
10	90.7	96.6	74.8	98.9
15	90.7	96.6	82.5	98.3
20	90.7	96.6	87.0	97.7

Table / Tableau / Tabelle / Tabella / Tabla 2: GC Hypothetical Positive and Negative Predictive Values Compared to Patient Infected Status / Valeurs prédictives théoriques positives et négatives pour GC comparées au statut infecté du patient / Hypothetische positive und negative GC-Vorhersagewerte im Vergleich zum Infektionsstatus des Patienten / Valori predittivi positivi e negativi ipotetici per GC rispetto a stato di infezione del paziente / Hipotéticos positivos GC y valores predictivos negativos comparados con el estado del paciente infectado

Prevalence (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
2	96	98.8	62.0	99.9
5	96	98.8	80.8	99.8
10	96	98.8	89.9	99.6
15	96	98.8	93.4	99.3
20	96	98.8	95.2	99.0

Table / Tableau / Tabelle / Tabella / Tabla 3: BD ProbeTec™ ET CT Assay – Indeterminate Results by Patient Infected Status / Test BD ProbeTec ET CT – Resultats indeterminés par statut infecté du patient / BD ProbeTec ET CT-Assay – Unbestimmte Ergebnisse nach Infektionsstatus des Patienten / Dosaggio BD ProbeTec ET CT – Risultati indeterminati per stato di infezione del paziente / Resultados indeterminados del análisis CT BD ProbeTec ET – según estado del paciente infectado

Patient Infected Status	Specimen Type	S/A	n	Initial (≡) (%)	Repeat (≡)1 (%)
(+)	FS	S	62	0	0
		A	63	0	0
	FU	S	61	4 (6.6%)	2 (3.3%)
		A	62	1 (1.6%)	1 (1.6%)
	MS	S	111	0	0
		A	19	0	0
MU	S	110	0	0	
	A	19	0	0	
(-)	FS	S	537	3 (0.6%)	1 (0.2%)
		A	757	6 (0.8%)	0
	FU	S	513	67 (13.1%)	32 (6.2%)
		A	700	89 (12.7%)	46 (6.6%)
	MS	S	381	1 (0.3%)	0
		A	167	1 (0.6%)	0
	MU	S	378	20 (5.3%)	10 (2.6%)
		A	168	14 (8.3%)	3 (1.8%)

Table / Tableau / Tabelle / Tabella / Tabla 4: BD ProbeTec™ ET GC Assay – Indeterminate Results by Patient Infected Status / Test BD ProbeTec ET GC – Résultats indéterminés par statut infecté du patient / BD ProbeTec ET GC-Assay – Unbestimmte Ergebnisse nach Infektionsstatus des Patienten / Dosaggio BD ProbeTec ET GC – Risultati indeterminati per stato di infezione del paziente / Resultados indeterminados del análisis GC BD ProbeTec ET – según estado del paciente infectado

Patient Infected Status	Specimen Type	S/A	n	Initial (≡) (%)	Repeat (≡) ¹ (%)
(+)	FS	S	51	1 (2.0%)	0
		A	38	0	0
	FU	S	49	1 (2.0%)	0
		A	37	0	0
	MS	S	190	0	0
		A	22	0	0
MU	S	189	0	0	
	A	22	0	0	
(-)	FS	S	549	2 (0.4%)	1 (0.2%)
		A	773	5 (0.6%)	0
	FU	S	528	78 (14.8%)	38 (7.2%)
		A	717	95 (13.2%)	48 (6.7%)
	MS	S	306	1 (0.3%)	0
		A	676	1 (0.1%)	0
	MU	S	303	28 (9.2%)	15 (5.0%)
		A	642	20 (3.1%)	4 (0.6%)

¹ During the clinical study, specimens with initial indeterminate results were repeated from the processed sample. Many of the indeterminate results in this study may have been caused by residual urine after inadequate decanting. / Pendant l'étude clinique, les échantillons donnant des résultats initiaux indéterminés ont été retestés à partir de l'échantillon préparé. La plupart des résultats indéterminés de cette étude pourrait avoir pour origine les résidus d'urine dus à une décantation inadéquate. / Während der klinischen Studie wurden Proben mit anfänglich unbestimmten Ergebnissen mit den aufbereiteten Proben wiederholt. Viele der unbestimmten Ergebnisse in dieser Studie wurden möglicherweise durch Urinreste infolge unzureichenden Dekantierens verursacht. / Durante lo studio clinico, i test di campioni con risultati iniziali indeterminati sono stati ripetuti con il campione trattato. Molti dei risultati indeterminati in questo studio possono essere imputati a residui di urina in seguito a una decantazione inadeguata. / Durante el estudio clínico, las muestras con resultados iniciales indeterminados se repitieron utilizando la muestra procesada. Muchos de los resultados indeterminados en este estudio pueden haberse producido por la existencia de orina residual como consecuencia de una decantación inadecuada.

Table / Tableau / Tabelle / Tabella / Tabla 5: BD ProbeTec™ ET CT Results Compared to Culture and Patient Infected Status / Résultats BD ProbeTec ET CT comparés à la mise en culture et au statut infecté du patient / BD ProbeTec ET CT-Ergebnisse im Vergleich zur Kultur und zum Infektionsstatus des Patienten / Risultati CT BD ProbeTec ET rispetto a cultura e stato di infezione del paziente / Resultados CT BD ProbeTec ET comparados con el cultivo y estado del paciente infectado

Specimen Type	S/A	Performance Compared to Culture		Performance Compared to Patient Infected Status		# (≡) Initial/Final (With AC)	# DFA or AMP1 (+) in swab or urine / # BD ProbeTec ET (+); Patient Infected Status (-)
		Sensitivity 95% C.I.	Specificity 95% C.I.	Sensitivity 95% C.I.	Specificity 95% C.I.		
FS	S	90.9% (50/55) 80.0 – 97.0	97.6% (531/544) 95.9 – 98.7	88.7% (55/62) 78.1 – 95.3	98.5% (529/537) 97.1 – 99.4	3/1	3/8
	A	100% (47/47) 92.5 – 100	96.1% (743/773) 94.5 – 97.4	96.8% (61/63) 89.0 – 99.6	97.9% (741/757) 96.6 – 98.8	6/0	8/16
	Total	95.1% (97/102) 88.9 – 98.4	96.7% (1274/1317) 95.6 – 97.6	92.8% (116/125) 86.8 – 96.7	98.1% (1270/1294) 97.3 – 98.8	9/1	11/24
FU ¹	S	75.9% (41/54) ² 62.4 – 86.5	97.3% (506/520) 95.5 – 98.5	77.0% (47/61) ³ 64.5 – 86.8	98.2% (505/513) 97.0 – 99.3	71/34	4/8
	A	91.3% (42/46) 79.2 – 97.6	96.9% (694/716) 95.4 – 98.1	83.9% (52/62) ⁴ 72.3 – 92.0	98.3% (688/700) 97.0 – 99.1	90/47	5/12
	Total ⁵	83.0% (83/100) 74.2 – 88.2	97.1% (1200/1236) 96.0 – 98.0	80.5% (99/123) 72.4 – 87.1	98.4% (1193/1213) 97.4 – 99.0	161/81	9/20
MS	S	95.8% (92/96) 89.7 – 98.3	89.9% (356/396) 86.5 – 92.7	95.5% (105/110) 89.7 – 98.5	92.9% (355/382) 89.9 – 95.3	1/0	16/27
	A	88.2% (15/17) 63.6 – 98.5	95.9% (162/169) 91.7 – 98.3	89.5% (17/19) 66.9 – 98.7	97.0% (162/167) 93.2 – 99.0	1/0	2/5
	Total	94.7% (107/113) 88.8 – 98.0	91.7% (518/565) 89.1 – 93.8	94.6% (122/129) 89.1 – 97.8	94.2% (517/549) 91.9 – 96.0	2/0	18/32 ⁶
MU ¹	S	95.8% (91/95) 89.6 – 98.8	86.5% (340/393) 82.7 – 89.7	95.4% (104/109) 89.6 – 98.5	89.4% (339/379) 85.9 – 92.4	20/10	28/40
	A	88.2% (15/17) 63.6 – 98.5	94.7% (161/170) 90.2 – 97.6	89.5% (17/19) 66.9 – 98.7	95.8% (161/168) 91.6 – 98.3	16/3	5/7
	Total	94.6% (106/112) 88.7 – 98.0	89.0% (501/563) 86.1 – 91.5	94.5% (121/128) 89.1 – 97.8	91.4% (500/547) 88.7 – 93.6	36/13	33/47 ⁷
Total ⁸	92.0% (393/427) 89.1 – 94.4	94.9% (3493/3681) 94.1 – 95.6	90.7% (458/505) 87.8 – 93.1	96.6% (3480/3603) 95.9 – 97.1	208/95	71/123	

(continued / suite / Fortsetzung / cont. / continuado)

1 Comparison cultures for female and male urine specimens were performed on endocervical and male urethral swab specimens, respectively. / Les cultures de comparaison pour les échantillons d'urine masculins et féminins ont été réalisées à partir des écouvillons d'urètre masculins et des écouvillons de col utérin respectivement. / Vergleichskulturen für weibliche und männliche Urinproben wurden mit Endozervikal- bzw. männlichen Urethralabstrichproben durchgeführt. / Sono state eseguite colture comparate di campioni di urina di soggetti di sesso femminile e maschiliterispettivamente su campioni endocervicali e uretrali maschili su tampone. / La comparación de cultivos para muestras de orina de hombres y mujeres se realizó en muestras en torunda de uretra masculina o endocérvix, respectivamente.

2 With AC, two final indeterminates reported (instead of false negative), resulting in an increase in sensitivity from 75.9 to 80.8% and a decrease in specificity from 97.3 to 96.9%. / Avec AC, rapport final de deux indéterminés (au lieu de faux négatifs), entraînant une augmentation de la sensibilité de 75,9 à 80,8 % et une diminution de la spécificité de 97,3 à 96,9 %. / Mit AC wurden zwei endgültig unbestimmte Ergebnisse berichtet (anstatt falschnegative), was zu einem Anstieg der Empfindlichkeit von 75,9 % auf 80,8 % und zu einer Abnahme der Spezifität von 97,3 % auf 96,9 % führte. / Con AC, sono stati riportati due risultati finali indeterminati (invece di falsi negativi), con conseguente aumento della sensibilità da 75,9 a 80,8% e riduzione di specificità da 97,3 a 96,9%. / Con AC, se comunicaron dos resultados indeterminados finales (en vez de falsos negativo) resultando en un incremento de la sensibilidad de 75,9 a 80,8% y una disminución de la especificidad de 97,3 a 96,9%.

3 With AC, two final indeterminates reported (instead of false negative) and one positive recovered (instead of false negative), resulting in an increase in sensitivity from 77.0% to 81.4% and a decrease in specificity from 98.2% to 98.1%. / Avec AC, rapport final de deux indéterminés (au lieu de faux négatifs) et obtention d'un positif (au lieu de faux négatifs), entraînant une augmentation de la sensibilité de 77,0 % à 81,4 % et une diminution de la spécificité de 98,2 % à 98,1 %. / Mit AC wurden zwei endgültig unbestimmte Ergebnisse berichtet (anstatt falschnegative) und ein positives Ergebnis wurde wiederhergestellt (anstatt falschnegativ), was zu einem Anstieg der Empfindlichkeit von 77,0 % auf 81,4 % und zu einer Abnahme der Spezifität von 98,2 % auf 98,1 % führte. / Con AC, sono stati riportati due risultati finali indeterminati (invece di falsi negativi) e un risultato positivo (invece di falso negativo), con conseguente aumento della sensibilità da 77,0 a 81,4% e riduzione di specificità da 98,2 a 98,1%. / Con AC, se comunicaron dos resultados indeterminados finales (en vez de falsos negativo) y se recuperó un positivo (en vez de falso negativo) resultando en un incremento de la sensibilidad de 77,0% a 81,4% y una disminución de la especificidad de 98,2% a 98,1%.

4 With AC, one final indeterminate reported (instead of false negative), resulting in an increase in sensitivity from 83.9% to 85.2% and a decrease in specificity from 98.3% to 98.2%. / Avec AC, rapport final d'un seul indéterminé (au lieu de faux négatifs), entraînant une augmentation de la sensibilité de 83,9 % à 85,2 % et une diminution de la spécificité de 98,3 % à 98,2 %. / Mit AC wurde ein endgültig unbestimmtes Ergebnis berichtet (anstatt falschnegativ), was zu einem Anstieg der Empfindlichkeit von 83,9 % auf 85,2 % und zu einer Abnahme der Spezifität von 98,3 % auf 98,2 % führte. / Con AC, è stato riportato un risultato finale indeterminato (invece di falso negativo), con conseguente aumento della sensibilità da 83,9 a 85,2% e riduzione di specificità da 98,3 a 98,2%. / Con AC, se comunicó un resultado indeterminado final (en vez de falso negativo), resultando en un incremento de la sensibilidad de 83,9% a 85,2% y una disminución en la especificidad de 98,3% a 98,2%.

5 With AC, female urine sensitivity and specificity for culture were 85.7% and 96.8%, respectively; and for patient infected status were 83.3% and 98.1%, respectively. / Avec AC, la sensibilité et la spécificité des échantillons d'urine féminine en culture étaient respectivement de 85,7 % et 96,8 % ; et respectivement de 83,3 % et 98,1 % pour le statut infecté du patient. / Mit AC betrug die Empfindlichkeit und Spezifität der weiblichen Urinproben für die Kultur 85,7 % bzw. 96,8 %, und für den Infektionsstatus des Patienten 83,3 % bzw. 98,1 %. / Con AC, la sensibilità e specificità dei campioni di urina femminile per la coltura sono risultate rispettivamente pari a 85,7% e 96,8% mentre per lo stato di infezione del paziente sono state rispettivamente dell'83,3% e 98,1%. / Con AC, la sensibilidad y especificidad de las muestras de orina de mujeres para cultivo fue 85,7% y 96,8%, respectivamente; y para estado del paciente infectado fue 83,3% y 98,1%, respectivamente.

6 13 of 16 of the AMP1 urine positives were confirmed by AMP2 testing. / 13 des 16 des urines positives par AMP1 ont été confirmées positives par le test AMP2. / 13 von 16 der AMP1-positiven Urinproben wurden durch AMP2-Prüfung bestätigt. / 13 dei 16 risultati positivi dei campioni di urina con AMP1 sono stati confermati con il test AMP2. / 13 de los positivos en orina AMP1 se confirmaron por un análisis AMP2.

7 14 of 30 of the AMP1 urine positives were confirmed by AMP2 testing. / 14 des 30 des urines positives par AMP1 ont été confirmées positives par le test AMP2. / 14 von 30 der AMP1-positiven Urinproben wurden durch AMP2-Prüfung bestätigt. / 14 dei 30 risultati positivi dell'urina con AMP1 sono stati confermati con il test AMP2. / 14 de 30 de los positivos en orina AMP1 se confirmaron por un análisis AMP2.

8 With AC, total sensitivity and specificity for culture were 92.7% and 94.7%, respectively; and for patient infected status were 91.4% and 96.5%, respectively. / Avec AC, la sensibilité et la spécificité totales en culture étaient respectivement de 92,7 % et 94,7 % ; et respectivement de 91,4 % et 96,5 % pour le statut infecté du patient. / Mit AC betrug die Gesamtempfindlichkeit und -spezifität für die Kultur 92,7 % bzw. 94,7 %, und für den Infektionsstatus des Patienten 91,4 % bzw. 96,5 %. / Con AC, la sensibilità e specificità totale per la coltura sono risultate rispettivamente pari a 92,7% e 94,7% mentre per lo stato di infezione del paziente sono state rispettivamente del 91,4% e 96,5%. / Con AC, la sensibilidad y especificidad total para cultivo fue 92,7% y 94,7%, respectivamente; y para estado del paciente infectado

Note: Separate performance characteristics were calculated for specimens collected from pregnant females. Sensitivity compared to patient infected status for swabs was 94.4% (17/18), and for urine was 83.3% (15/18). Specificity compared to patient infected status for swabs was 98.4% (122/124) and for urine was 100% (120/120). / **Remarque :** des caractéristiques de performances différentes ont été calculées pour les échantillons prélevés sur des femmes enceintes. La sensibilité par comparaison au statut infecté du malade pour les écouvillons était de 94,4 % (17/18), et pour l'urine elle était de 83,3 % (15/18). La spécificité comparée au statut infecté du patient pour les écouvillons était de 98,4 % (122/124) et de 100 % pour l'urine (120/120). / **Hinweis:** Für die von schwangeren Frauen entnommenen Proben wurden separate Leistungsmerkmale berechnet. Die Empfindlichkeit im Vergleich zum Infektionsstatus des Patienten betrug 94,4 % (17/18) für Abstriche und 83,3 % (15/18) für Urin. Die Spezifität im Vergleich zum Infektionsstatus des Patienten betrug 98,4 % (122/124) für Abstriche und 100 % (120/120) für Urin. / **Nota:** per campioni prelevati da donne in gravidanza, sono state calcolate caratteristiche di performance separate. La sensibilità rispetto allo stato di infezione del paziente per i tamponi è stata del 94,4% (17/18) e per

l'urina dell'83,3% (15/18). La specificità rispetto allo stato di infezione del paziente per i tamponi è stata del 98,4% (122/124) e per l'urina del 100% (120/120). / **Nota:** Se calcularon características de rendimiento separadas para las muestras recogidas de mujeres embarazadas. La sensibilidad comparada con el estado del paciente infectado para muestras en torunda fue 94,4% (17/18), y para muestras de orina fue 83,3% (15/18). La especificidad comparada con el estado del paciente infectado para muestras en torunda fue 98,4% (122/124) y para muestras de orina fue 100% (120/120).

Table / Tableau / Tabelle / Tabella / Tabla 6: Performance of the BD ProbeTec™ ET CT Assay Compared to Patient Infected Status (by Clinical Site) / Performance du test BD ProbeTec ET CT par comparaison au statut infecté du patient (par site clinique) / Leistung des BD ProbeTec ET CT-Assays im Vergleich zum Infektionsstatus der Patienten (nach klinischem Untersuchungsort) / Performance del test CT BD ProbeTec ET rispetto allo stato di infezione del paziente (per centro clinico) / Rendimiento del análisis CT BD ProbeTec ET comparado con el estado del paciente infectado (según clínicas)

Specimen Type	Clinical Site	Prevalence	n	Performance Compared to Patient Infected Status							
				Sensitivity	95% C.I.	Specificity	95% C.I.	# CT (+) and GC (+)	%PPV	%NPV	# (≡) Initial/Final
FS	1	11.5%	26	100% (3/3)	29.2-100	95.7% (22/23)	78.1-99.9	0	75.1	100	0/0
	2	13.4%	186	92.0% (23/25)	74.0-99.0	95.7% (154/161)	91.2-98.2	10	76.8	98.7	1/0
	3*	9.0%	111	70% (7/10)	34.8-93.3	99.0% (100/101)	94.6-100.0	2	87.4	97.1	0/0
	4	5.3%	133	100% (7/7)	59.0-100	100% (126/126)	97.1-100	1	100	100	4/0
	5	4.4%	498	95.5% (21/22)	77.2-99.9	99.2% (472/476)	97.9-99.8	3	84.6	99.8	2/0
	6	15.1%	171	92.3% (24/26)	74.9-99.1	98.6% (143/145)	95.1-99.8	7	92.1	98.6	2/1
	7	10.9%	294	96.9% (31/32)	83.8-99.9	96.6% (253/262)	93.6-98.4	7	77.7	99.6	0/0
FU	1	12.5%	24	100% (3/3)	29.2-100	100% (21/21)	83.9-100	0	100	100	0/0
	2	13.5%	185	72.0% (18/25)	50.6-87.9	97.5% (156/160)	93.7-99.3	10	81.8	95.7	15/8
	3*	9.0%	111	50.0% (5/10)	18.7-81.3	100% (101/101)	96.4-100	2	100	95.3	8/7
	4	4.8%	125	100% (6/6)	54.1-100	99.2% (118/119) ¹	95.4-100	1	86.3	100	11/1
	5	4.8%	439	95.5% (21/22) ²	77.2-99.9	98.3% (410/417)	96.6-99.3	3	73.9	99.8	62/37
	6	15.1%	164	76.0% (19/25) ²	54.9-90.6	97.1% (135/139)	92.8-99.2	7	82.3	95.8	22/11
	7	11.6%	275	84.4% (27/32) ³	67.2-94.7	98.4% (252/256)	96.1-99.6	7	87.4	98.0	43/17
MS	2	19.4%	294	98.2% (56/57)	90.6-99.9	94.5% (224/237)	90.8-97.0	16	81.1	99.5	2/0
	3*	19.8%	197	89.7% (35/39)	75.8-97.1	98.1% (155/158)	94.6-99.6	9	92.1	97.5	0/0
	4	9.1%	11	100% (1/1)	2.5-100	100% (10/10)	69.2-100	0	100	100	0/0
	6	17.8%	169	96.7% (29/30)	82.8-99.9	89.2% (124/139)	82.8-93.8	7	66.0	99.2	0/0
	7	28.6%	7	50% (1/2)	1.3-98.7	80.0% (4/5)	28.4-99.5	1	50.0	80.0	0/0
MU	2	19.4%	295	98.2% (56/57)	90.6-99.9	92.4% (220/238)	88.3-95.5	16	75.6	99.5	12/3
	3*	19.4%	196	89.5% (34/38)	75.2-97.1	93.7% (148/158)	88.7-96.9	9	77.4	97.4	15/5
	4	10.0%	10	100% (1/1)	2.5-100	100% (9/9)	66.4-100	0	100	100	0/0
	6	18.0%	167	96.7% (29/30)	82.8-99.9	86.9% (119/137)	80.0-92.0	7	61.8	99.2	9/5
	7	28.6%	7	50% (1/2)	1.3-98.7	80.0% (4/5)	28.4-99.5	1	50	80.0	0/0

1 With AC, one false positive reported resulting in a decrease in specificity from 99.2% to 98.3%. / Avec AC, rapport d'un faux positif entraînant une diminution de la spécificité de 99,2 % à 98,3 %. / Mit AC wurde ein falschpositives Ergebnis berichtet, was zu einer Abnahme der Spezifität von 99,2 % auf 98,3 % führte. / Con AC, è stato riportato un falso positivo con conseguente riduzione della specificità da 99,2% a 98,3%. / Con AC, se comunicò un falso positivo, resultando en un descenso en la especificidad de 99,2% a 98,3%.

2 With AC, one indeterminate from site 5 and two final indeterminate results from site 6 reported (instead of false negative(s)), resulting in an increase in sensitivity from 95.5% to 100% and from 76.0% to 82.6%, respectively. / Avec AC, rapport final d'un indéterminé au site 5 et de deux indéterminés au site 6 (au lieu de faux négatif(s)), entraînant une augmentation de la sensibilité de 95,5 % à 100% et de 76,0 % à 82,6 %, respectivement. / Mit AC wurden ein unbestimmtes Ergebnis vom Untersuchungsort 5 und zwei endgültig unbestimmte Ergebnisse vom Untersuchungsort 6 berichtet (anstatt falschnegativ), was zu einem Anstieg der Empfindlichkeit von 95,5 % auf 100 % bzw. von 76,0 % auf 82,6 % führte. / Con AC, sono stati riportati un risultato indeterminato dal centro 5 e due risultati finali indeterminati dal centro 6 (invece di falsi negativi), con conseguente aumento della sensibilità rispettivamente dal 95,5% al 100% e dal 76,0% all.82,6%. / Con AC, se reportaron un resultado indeterminado del lugar 5 y dos resultados indeterminados finales del lugar 6 (en vez de falso negativo(s)), resultando en un incremento en la sensibilidad de 95,5% a 100% y de 76,0% a 82,6%, respectivamente.

3 With AC, recovered one false negative resulting in an increase in sensitivity from 84.4% to 87.5%. / Avec AC, obtention d'un faux négatif entraînant une augmentation de la sensibilité de 84,4 % à 87,5 %. / Mit AC wurde ein falschnegatives Ergebnis wiederhergestellt, was zu einem Anstieg der Empfindlichkeit von 84,4 % auf 87,5 % führte. / Con AC, è stato recuperato un falso negativo con conseguente aumento della sensibilità dall.84,4% all.87,5%. / Con AC, se recuperò un falso negativo, resultando en un incremento en la sensibilidad de 84,4% a 87,5%.

***Note:** Specimens from four patients, three female and one male, had positive culture results, but were negative in **BD ProbeTec ET** and **AMPI** tests with swab and urine. The DFA was also negative. When culture was repeated from the same specimens, the cultures were negative. / ***Remarque :** les échantillons de quatre patients dont trois femmes et un homme, ont donné des résultats positifs en culture mais des résultats négatifs pour les écouvillons et l'urine avec les tests **BD ProbeTec ET** et **AMPI**. Le test DFA a aussi donné des résultats négatifs. Lorsque les cultures ont été refaites à partir des mêmes échantillons, elles ont donné des résultats négatifs. / ***Hinweis:** Proben von vier Patienten, und zwar drei weiblichen Patientinnen und einem männlichen Patienten, zeigten positive Kulturergebnisse, waren jedoch negativ im **BD ProbeTec ET**-Assay und im **AMPI**-Test mit Abstrichen und mit Urin. Der DIF-Test war ebenfalls negativ. Wenn die Kultur mit denselben Proben wiederholt wurde, waren die Kulturen negativ. / ***Nota:** i campioni di quattro pazienti (tre soggetti di sesso femminile

e uno maschile) hanno dato risultati colturali positivi ma sono risultati negativi ai test **BD ProbeTec ET** e **AMPI** con tampone e urina. Anche il **DFA** è stato negativo. Alla ripetizione della coltura con gli stessi campioni, le colture sono risultate negative. / *Nota: Muestras procedentes de 4 pacientes, tres mujeres y un hombre, tuvieron resultados en cultivo positivos, pero resultados negativos en los análisis **BD ProbeTec ET** y **AMPI** con muestras en torunda y orina. **DAF** fue también negativo. Cuando se repitió el cultivo utilizando las mismas muestras, los cultivos fueron negativos.

Table / Tableau / Tabelle / Tabella / Tabla 7: BD ProbeTec™ ET and AMPI CT Assay Performance Compared to Cell Culture and DFA in Symptomatic and Asymptomatic Populations / Performance des tests BD ProbeTec ET et AMPI CT par comparaison à la culture cellulaire et DFA sur des populations symptomatiques et asymptomatiques / BD ProbeTec ET- und AMPI CT- Assayleistung im Vergleich zur Zellkultur und zum DIF-Test bei symptomatischen und asymptomatischen Populationen / Performance del test CT BD ProbeTec ET e AMPI rispetto a cultura cellulare e DFA in popolazioni sintomatiche e asintomatiche / Rendimiento del análisis CT BD ProbeTec ET y análisis CT AMPI comparado con el cultivo celular y DAF en poblaciones sintomáticas y asintomáticas

Specimen Type	S/A	BD ProbeTec ET				AMPI			
		Sensitivity	95% C.I.	Specificity	95% C.I.	Sensitivity	95% C.I.	Specificity	95% C.I.
FS	S	91.2% (52/57)	80.7–97.1	98.0% (531/542)	96.4–99.0	89.7% (52/58)	78.8–96.1	98.5% (533/541)	97.1–99.4
	A	100% (55/55)	93.5–100	97.1% (743/765)	95.7–98.2	100% (54/54)	93.4–100	98.0% (751/766)	96.8–98.9
FS Total		95.5% (107/112)	89.9–98.5	97.5% (1274/1307)	96.5–98.3	94.6% (106/112)	88.7–98.0	98.2% (1284/1307)	97.4–98.9
FU ¹	S	77.2% (44/57) ²	64.2–87.3	97.9% (506/517) ³	96.2–98.9	71.9% (41/57)	58.5–83.0	98.1% (507/517)	96.5–99.1
	A	92.2% (47/51)	81.1–97.8	97.6% (694/711)	96.2–98.6	84.0% (42/50)	70.9–92.8	98.0% (698/712)	96.7–98.9
FU Total		84.3% (91/108)	76.0–90.6	97.7% (1200/1228)	96.7–98.5	77.6% (83/107)	68.5–85.1	98.0% (1205/1229)	97.1–98.7
MU ¹	S	96.4% (106/110)	91.0–99.0	89.9% (340/378)	86.5–92.8	93.6% (102/109)	87.2–97.4	92.3% (350/379)	89.2–94.8
	A	89.5% (17/19)	66.9–98.7	95.8% (161/168)	91.6–98.3	89.5% (17/19)	66.9–98.7	95.2% (160/168)	90.8–97.9
MU Total		95.3% (123/129)	90.2–98.3	91.8% (501/546)	89.1–93.9	93.0% (119/128)	87.1–96.7	93.2% (510/547)	90.8–95.2
Total ⁴		92.0% (321/349)	88.6–94.6	96.6% (2975/3081)	95.9–97.2	88.8% (308/347)	85.0–91.9	97.3% (2999/3083)	96.6–97.8

1 Comparison cultures for female and male urine specimens were performed on endocervical and male urethral swab specimens, respectively. DFA testing was performed from the swab's culture transport medium. / Les cultures de comparaison pour les échantillons d'urine masculins et féminins ont été réalisées à partir des écouvillons d'urètre masculins et des écouvillons de col utérin respectivement. Le test DFA a été effectué sur le milieu de transport pour la mise en culture de l'écouvillon. / Vergleichskulturen für weibliche und männliche Urinproben wurden mit Endozervikal- bzw. männlichen Urethralabstrichproben durchgeführt. DIF-Tests wurden mit den Kulturtransportmedien der Abstriche durchgeführt. / Sono state eseguite colture comparate di campioni di urina di soggetti di sesso femminile e maschile rispettivamente su campioni endocervicali e uretrali maschili su tampone. È stato eseguito il test DFA sul terreno di trasporto della coltura del tampone. / Se realizó una comparación de muestras de orina de mujeres y hombres sobre muestras en torunda de uretra masculina y endocérvix, respectivamente. El análisis DAF fue realizado con el medio para el transporte del cultivo de la torunda.

2 With AC, two final indeterminates reported (instead of false negatives), resulting in an increase in sensitivity from 77.2% to 81.8%. / Avec AC, rapport final de deux indéterminés (au lieu de faux négatifs), entraînant une augmentation de la sensibilité de 77,2 % à 81,8 %. / Mit AC wurden zwei endgültig unbestimmte Ergebnisse berichtet (anstatt falschnegativer), was zu einem Anstieg der Empfindlichkeit von 77,2 % auf 81,8 % führte. / Con AC, sono stati riportati due risultati finali indeterminati (invece di falsi negativi), con conseguente aumento della sensibilità dal 77,2% all'81,8%. / Con AC, se comunicaron dos resultados indeterminados finales (en vez de falso negativos), resultando en un incremento en la sensibilidad de 77,2% a 81,8%.

3 With AC, one false positive reported resulting in a decrease in specificity from 97.9% to 97.5%. / Avec AC, rapport d'un faux positif entraînant une diminution de la spécificité de 97,9 % à 97,5 %. / Mit AC wurde ein falschpositives Ergebnis berichtet, was zu einer Abnahme der Spezifität von 97,9 % auf 97,5 % führte. / Con AC, è stato riportato un falso positivo con conseguente riduzione della specificità da 97,9% a 97,5%. / Con AC, se comunicò un falso positivo resultando en una disminución de la especificidad de 97,9% a 97,5%.

4 With AC, the total sensitivity and specificity for all specimen types were 92.8% and 96.1%, respectively. / Avec AC, la sensibilité et la spécificité totales pour tous les types d'échantillon étaient respectivement de 92,8 % et 96,1 %. / Mit AC betrug die Gesamtempfindlichkeit und -spezifität für alle Probenarten 92,8 % bzw. 96,1 %. / Con AC, la sensibilidad e specificità totali per tutti i tipi di campioni sono state rispettivamente pari a 92,8% e 96,1%. / Con AC, la sensibilidad y especificidad total para todos los tipos de muestras fue 92,8% y 96,1%, respectivamente.

Table / Tableau / Tabelle / Tabella / Tabla 8: BD ProbeTec™ ET CT Results Compared to AMPI / Résultats BD ProbeTec ET CT comparés à AMPI / BD ProbeTec ET CT-Ergebnisse im Vergleich zu AMPI / Risultati CT BD ProbeTec ET rispetto ad AMPI / Resultados CT BD ProbeTec ET comparados a AMPI

Specimen Type	S/A	% Agreement	95% C.I.
FS	S	98.2% (588/599)	96.7–99.1
	A	98.0% (804/820)	96.9–98.9
	Total	98.1% (1392/1419)	97.2–98.7
FU	S	97.4% (559/574)	95.7–98.5
	A	96.6% (736/762)	95.0–97.8
	Total	97.0% (1296/1336)	96.0–97.8
MU	S	94.9% (463/488)	92.5–96.7
	A	96.3% (180/187)	92.4–98.5
	Total	95.3% (643/675)	93.4–96.7
Total		97.1% (3331/3430)	96.5–97.6

Table / Tableau / Tabelle / Tabella / Tabla 9: CT Paired Specimen Analysis for Female Patients (without AC) / Analyse des échantillons appariés CT pour les patientes (sans AC) / Analyse gepaarter CT-Proben bei weiblichen Patienten (ohne AC) / Analisi di campioni CT in doppio per pazienti di sesso femminile (senza AC) / Análisis CT de muestras dobles para pacientes mujeres (sin AC)

Patient Infected Status	Endocervical Culture	AMP1 Swab	AMP1 Urine	DFA	BD ProbeTec ET		# Patients	
					Swab	Urine	S	A
(+)	+	+	+		+	+	36	35
	+	+	+		+	-	1	2
	+	+	+		-	+	1	0
	+	+	-		+	+	3	6
	+	+	-		+	-	7	2
	+	-	-	+	+	+	1	0
	+	-	-		+	-	1	0
	+	-	-		-	-	4	0
	-	+	+	+	+	+	2	3
	-	+	+	+	-	+	1	0
	-	+	+	-	+	+	3	5
	-	+	+	-	-	+	0	2
	-	+	+	-	-	-	1	1
	-	-	+	+	-	-	0	1
	-	+	-	+	+	+	0	2
-	+	-	+	+	-	0	2	
(-)	-	+	-	-	+	+	1	1
	-	+	-	-	+	-	2	3
	-	+	-	-	-	+	0	1
	-	-	+	-	+	+	0	2
	-	-	+	-	+	-	1	0
	-	-	+	-	-	+	3	1
	-	-	-	+	+	-	0	1
	-	-	-	-	+	+	0	1
	-	+	-	-	-	-	1	2
	-	-	+	-	-	-	2	3
	-	-	-	-	-	+	4	8
	-	-	-	+	-	-	1	1
	-	-	-	-	-	+	4	6
	-	-	-	-	-	-	21	46
	-	-	-	-	-	-	473	624
Total							574	761

Table / Tableau / Tabelle / Tabella / Tabla 10: CT Paired Specimen Analysis for Male Patients (without AC) / Analyse des échantillons appariés CT pour les patients (sans AC) / Analyse gepaarter CT-Proben bei männlichen Patienten (ohne AC) / Analisi di campioni CT in doppio per pazienti di sesso maschile (senza AC) / Análisis CT de muestras dobles para pacientes hombres (sin AC)

Patient Infected Status	Urethral Culture	AMP1 Urine	DFA	BD ProbeTec ET		# AMP2	# AMP2 (+)	# Patients	
				Swab	Urine			S	A
(+)	+	+	+	+	+			5	0
	+	+		+	+			80	12
	+	+	+	-	+			0	1
	+	+		+	-			1	1
	+	+	-	+	+			0	1
	+	+		-	+			2	0
	+	-		+	+			4	1
	+	-		+	-			1	0
	+	-		-	-			3	1
	-	+	+	+	+	15	14	13	2
-	+	+	-	-			1	0	
(-)	-	+	-	+	+	13	11	14	0
	-	+	-	+	-	2	2	1	1
	-	+	-	-	+	15	3	11	4
	-	-	+	+	+			1	0
	-	-	+	-	+			1	0
	-	-	+	+	-			1	1
	-	-	-	+	+			5	1
	-	+	-	-	-	5	1	3	2
	-	-	-	+	-			5	2
	-	-	-	-	+			8	1
	-	-	-	-	-			4	1
	-	-	-	-	-			324	154
	-	-	-	-/na	-				
Total								488	186

Table / Tableau / Tabelle / Tabella / Tabla 11: BD ProbeTec™ ET GC Results Compared to Culture and Patient Infected Status / Risultati BD ProbeTec ET GC comparés à la mise en culture et au statut infecté du patient / BD ProbeTec ET GC-Ergebnisse im Vergleich zur Kultur und zum Infektionsstatus des Patienten / Risultati GC BD ProbeTec ET rispetto a cultura e stato di infezione del paziente / Resultados GC BD ProbeTec ET comparados con el cultivo y estado del paciente infectado

Specimen Type	S/A	Performance Compared to Culture		Performance Compared to Patient Infected Status		# (±) Initial / Final	# AMP1 (+) in swab or urine / # BD ProbeTec ET (+); Patient Infected Status
		Sensitivity 95% C.I.	Specificity 95% C.I.	Sensitivity 95% C.I.	Specificity 95% C.I.		
FS	S	95.8% (46/48) ² 85.7-99.5	98.7% (545/552) 97.4-99.5	96.1% (49/51) ³ 86.5-99.5	99.3% (545/549) 98.1-99.8	3/1	1/4
	A	97.1% (34/35) 85.1-99.9	99.2% (770/776) 98.3-99.7	97.4% (37/38) 86.2-99.9	99.6% (770/773) 98.9-99.9	5/0	1/3
	Total ⁴	96.4% (80/83) 89.8-99.2	99.0% (1315/1328) 98.3-99.5	96.6% (86/89) 90.5-99.3	99.5% (1315/1322) 98.9-99.8	8/1	2/7
FU ¹	S	84.8% (39/46) 71.1-93.7	99.2% (527/531) 98.1-99.8	83.7% (41/49) 70.3-92.7	99.6% (526/528) 98.6-100	79/38	0/2
	A	88.2% (30/34) 72.5-96.7	99.0% (713/720) 98.0-99.6	86.5% (32/37) 71.2-95.5	99.3% (712/717) 98.4-99.8	75/48	1/5
	Total	86.3% (69/80) 76.7-92.9	99.1% (1240/1251) 98.4-99.6	84.9% (73/86) 75.5-91.7	99.4% (1238/1245) 98.8-99.8	154/86	1/7
MS ²	S	98.4% (187/190) 95.5-99.7	94.8% (290/306) 91.6-97.0	98.4% (187/190) 95.5-99.7	94.8% (290/306) 91.6-97.0	1/0	16/16
	A	95.5% (21/22) 72.7-99.9	99.3% (672/677) 98.3-99.8	95.5% (21/22) 72.7-99.9	99.3% (672/677) 98.3-99.8	1/0	1/5
	Total	98.1% (208/212) 95.2-99.5	97.9% (962/983) 96.8-98.7	98.1% (208/212) 95.2-99.5	97.9% (962/983) 96.8-98.7	2/0	17/21
MU ¹	S	97.9% (185/189) 94.7-99.4	94.4% (286/303) 91.2-96.7	97.9% (185/189) 94.7-99.4	94.4% (286/303) 91.2-96.7	28/15	14/17
	A	100% (22/22) 84.6-100	99.5% (639/642) 98.6-99.9	100% (22/22) 84.6-100	99.5% (639/642) 98.6-99.9	20/4	0/3
	Total	98.1% (207/211) 95.2-99.5	97.9% (925/945) 96.8-98.7	98.1% (207/211) 95.2-99.5	97.9% (925/945) 96.8-98.7	48/19	14/20
Total	96.2% (564/586) 94.4-97.6	98.6% (4442/4507) 98.2-98.9	96.0% (574/598) 94.1-97.4	98.8% (4440/4495) 98.4-99.1	212/106	34/55	

1 Comparison cultures for female and male urine specimens were performed on endocervical and male urethral swab specimens, respectively. / Les cultures de comparaison pour les échantillons d'urine masculins et féminins ont été réalisées à partir des écouvillons d'urètre masculins et des écouvillons de col utérin respectivement. / Vergleichskulturen für weibliche und männliche Urinproben wurden mit Endozervikal- bzw. männlichen Urethralabstrichproben durchgeführt. / Sono state eseguite colture comparate di campioni di urina di soggetti di sesso femminile e maschile rispettivamente su campioni endocervicali e uretrali maschili su tampone. / Se realizó una comparación de cultivos para muestras de orina de mujeres y hombres sobre muestras en torunda de uretra y endocervix, respectivamente.

2 With AC one indeterminate reported (instead of false negative), resulting in an increase in sensitivity from 95.8 to 97.9%. / Avec AC rapport d'un indéterminé (au lieu d'un faux négatif), entraînant une augmentation de la sensibilité de 95,8 à 97,9%. / Mit AC wurde ein endgültig unbestimmtes Ergebnis berichtet (anstatt falschnegativ), was zu einem Anstieg der Empfindlichkeit von 95,8% auf 97,9% führte. / Con AC, è stato riportato un risultato indeterminato (invece di falso negativo), con conseguente aumento della sensibilità dal 95,8% al 97,9%. / Con AC se comunicó un resultado indeterminado (en vez de falso negativo), resultando en un incremento en la sensibilidad de 95,8 a 97,9%.

3 With AC, one indeterminate reported (instead of false negative), resulting in an increase in sensitivity from 96.1 to 98.0%. / Avec AC rapport d'un indéterminé (au lieu d'un faux négatif), entraînant une augmentation de la sensibilité de 96,1 à 98,0%. / Mit AC wurde ein endgültig unbestimmtes Ergebnis berichtet (anstatt falschnegativ), was zu einem Anstieg der Empfindlichkeit von 96,1% auf 98,0% führte. / Con AC, è stato riportato un risultato indeterminato (invece di falso negativo), con conseguente aumento della sensibilità dal 96,1 al 98,0%. / Con AC se comunicó un resultado indeterminado (en vez de falso negativo), resultando en un incremento en la sensibilidad de 96,1 a 98,0%.

4 With AC, female swabs sensitivity and specificity for culture were 97.6% and 99.0%, respectively; and for patient infected status were 97.8% and 99.5%, respectively. / Avec AC, la sensibilité et la spécificité des écouvillons féminins en culture étaient de 97,6% et 99,0%, respectivement; et respectivement de 97,8% et 99,5% pour le statut infecté du patient. / Mit AC betrug die Empfindlichkeit und Spezifität der weiblichen Abstrichproben bei der Kultur 97,6% bzw. 99,0%, und für den Infektionsstatus des Patienten 97,8% bzw. 99,5%. / Con AC, la sensibilità e specificità dei tamponi femminili per la coltura sono risultate rispettivamente pari a 97,6% e 99,0% mentre per lo stato di infezione del paziente sono state rispettivamente dell'97,8% e 99,5%. / Con AC, la sensibilidad y especificidad de muestras en torunda de mujeres para cultivo fue 97,6% y 99,0%, respectivamente; y para estado del paciente infectado fue 97,8% y 99,5%, respectivamente.

Note: Separate performance characteristics were calculated for specimens collected from pregnant females. Sensitivity compared to patient infected status for swabs was 100% (2/2) and for urines was 100% (2/2). Specificity compared to patient infected status for swabs was 98.6% (137/139) and for urine was 98.5% (133/135). / **Remarque :** des caractéristiques de performances différentes ont été calculées pour les échantillons prélevés sur des femmes enceintes. La sensibilité par comparaison au statut infecté du malade pour les écouvillons était de 100% (2/2), et pour l'urine elle était de 100% (2/2). La spécificité comparée au statut infecté du patient pour les écouvillons était de 98,6% (137/139) et de 98,5% pour l'urine (133/135). / **Hinweis:** Für die von schwangeren Frauen entnommenen Proben wurden separate Leistungsmerkmale berechnet. Die Empfindlichkeit im Vergleich zum Infektionsstatus des Patienten betrug 100% (2/2) für Abstriche und 100%

% (2/2) für Urin. Die Spezifität im Vergleich zum Infektionsstatus des Patienten betrug 98,6 % (137/139) für Abstriche und 98,5 % (133/135) für Urin. / **Nota:** per campioni prelevati da donne in gravidanza, sono state calcolate caratteristiche di performance separate. La sensibilità rispetto allo stato di infezione del paziente per i tamponi è stata del 100% (2/2) e per l'urina del 100% (2/2). La specificità rispetto allo stato di infezione del paziente per i tamponi è stata del 98,6% (137/139) e per l'urina del 98,5% (133/135). / **Nota:** Se calcularon características de rendimiento separadas para muestras recogidas de mujeres embarazadas. La sensibilidad comparada con el estado del paciente infectado para muestras en torunda fue 100% (2/2) y para muestras de orina fue 100% (2/2). La especificidad comparada con el estado del paciente infectado para muestras en torunda fue 98,6% (137/139) y para muestras de orina fue 98,5% (133/135).

Table / Tableau / Tabelle / Tabella / Tabla 12: Performance of the BD ProbeTec™ ET GC Assay Compared to Patient Infected Status (by Clinical Site) / Performance du test BD ProbeTec ET GC par comparaison au statut infecté du patient (par site clinique) / Leistung des BD ProbeTec ET GC-Assays im Vergleich zum Infektionsstatus der Patienten (nach klinischem Untersuchungsort) / Performance del test GC BD ProbeTec ET rispetto allo stato di infezione del paziente (per centro clinico) / Rendimiento para el análisis GC BD ProbeTec ET comparado con el estado del paciente infectado (según clínicas)

Specimen Type	Clinical Site	Prevalence	n	Performance Compared to Patient Infected Status							
				Sensitivity	95% C.I.	Specificity	95% C.I.	CT (+) and GC (+)	%PPV	%NPV	(≡) Initial/Final
FS	1	na	26	0/0	na	100% (26/26)	86.8-100	0	na	100	0/0
	2	12.3%	187	100% (23/23)	85.2-100	100% (164/164)	97.8-100	10	100	100	1/0
	3	13.3%	113	93.3% (14/15)	68.1-99.8	99.0% (97/98)	94.4-100	2	93.5	99.0	0/0
	4	3.0%	132	100% (4/4)	39.8-100	100% (128/128)	97.2-100	1	100	100	3/0
	5	1.2%	486	100% (6/6)	54.1-100	99.6% (478/480)	98.5-100	3	75.2	100	2/0
	6	11.7%	171	90.0% (18/20) ¹	68.3-98.8	98.0% (148/151)	94.3-99.6	7	85.6	98.7	2/1
	7	7.1%	296	100% (21/21)	83.9-100	99.6% (274/275)	98-100	7	95.0	100	0/0
FU	1	na	24	0/0	na	100% (24/24)	85.8-100	0	na	100	0/0
	2	12.4%	186	91.3% (21/23)	72.0-98.9	99.4% (162/163)	96.6-100	10	95.6	98.8	16/8
	3	13.2%	113	66.7% (10/15)	38.4-88.2	100% (98/98)	96.3-100	2	100	95.2	9/7
	4	3.2%	124	100% (4/4)	39.8-100	100% (120/120)	97.0-100	1	100	100	11/2
	5	1.2%	430	80.0% (4/5)	28.4-99.5	99.2% (422/425)	98.0-99.9	3	54.8	99.8	64/38
	6	12.2%	164	90.0% (18/20)	68.3-98.8	100% (144/144)	97.5-100	7	100	98.6	25/14
	7	6.6%	290	84.2% (16/19)	60.4-96.6	98.9% (268/271)	96.8-99.8	7	84.4	98.9	49/17
MS	2	17.8%	482	98.8% (85/86)	93.7-99.9	99.5% (394/396)	98.2-99.9	16	97.7	99.7	2/0
	3	26.7%	202	100% (54/54)	93.4-100	91.9% (136/148)	86.3-95.7	9	81.8	100	0/0
	4	na	11	0/0	na	100% (11/11)	71.5-100	0	na	100	0/0
	6	31.4%	169	96.2% (51/53)	87.0-99.5	97.4% (113/116)	92.6-99.5	7	94.4	98.3	0/0
	7	42.9%	7	100% (3/3)	29.2-100	100% (4/4)	39.8-100	1	100	100	0/0
	8	8.0%	199	93.8% (15/16)	69.8-99.8	100% (183/183)	98.0-100	na	100	99.5	0/0
	9	na	124	0/0	na	96.8% (121/125)	92.0-99.1	na	0	100	0/0
MU	2	17.8%	483	95.3% (82/86)	88.5-98.7	98.7% (392/397)	97.1-99.6	16	94.1	99.0	16/3
	3	26.9%	201	100% (54/54)	93.4-100	92.5% (136/147) ²	87.0-96.2	9	83.1	100	16/8
	4	na	10	0/0	na	100% (10/10)	69.2-100	0	na	90.0	0/0
	6	31.1%	167	100% (52/52)	93.2-100	97.4% (112/115)	92.6-99.5	7	94.6	100	12/7
	7	42.9%	7	100% (3/3)	29.2-100	100% (4/4)	39.8-100	1	100	100	0/0
	8	8.0%	199	100% (16/16)	79.4-100	100% (183/183)	98.0-100	na	100	100	2/0
	9	na	89	0/0	na	98.9% (88/89)	93.9-99.9	na	0	100	2/1

1 With AC, recovered one false negative resulting in an increase in sensitivity from 90.0% to 95.0%. / Avec AC, obtention d'un faux négatif entraînant une augmentation de la sensibilité de 90,0 % à 95,0%. / Mit AC wurde ein falschnegatives Ergebnis wiederhergestellt, was zu einem Anstieg der Empfindlichkeit von 90,0 % auf 95,0 % führte. / Con AC, è stato recuperato un falso negativo con conseguente aumento della sensibilità dal 90,0% al 95,0%. / Con AC, se recuperó un falso negativo resultando en un incremento en sensibilidad de 90,0% a 95,0%.

2 With AC, caused one false positive resulting in a decrease in specificity from 92.5% to 91.4%. / Avec AC, a causé un faux positif entraînant la diminution de la sensibilité de 92,5 % à 91,4 %. / Mit AC wurde ein falschpositives Ergebnis verursacht, was zu einer Abnahme der Spezifität von 92,5 % auf 91,4 % führte. / Con AC, è risultato un falso positivo con conseguente riduzione della specificità da 92,5% a 91,4%. / Con AC, causó un falso positivo resultando en una disminución en especificidad de 92,5% a 91,4%.

Table / Tableau / Tabelle / Tabella / Tabla 13: BD ProbeTec™ ET and AMPI GC Assay Performance Compared to Culture in Symptomatic and Asymptomatic Populations / Performance des tests BD ProbeTec ET et AMPI GC par comparaison à la mise en culture dans des populations symptomatiques et asymptomatiques / BD ProbeTec ET- und AMPI GC-Assayleistung im Vergleich zur Kultur bei symptomatischen und asymptomatischen Populationen / Performance dei test GC BD ProbeTec ET e AMPI rispetto a cultura in popolazioni sintomatiche e asintomatiche / Rendimiento del análisis BD ProbeTec ET y análisis GC AMPI comparado con el cultivo en poblaciones sintomáticas y asintomáticas

Specimen Type	S/A	BD ProbeTec ET				AMPI			
		Sensitivity	95% C.I.	Specificity	95% C.I.	Sensitivity	95% C.I.	Specificity	95% C.I.
FS	S	95.8% (46/48) ²	85.7-99.5	98.7% (545/552)	97.4-99.5	95.8% (46/48)	85.7-99.5	99.3% (548/552)	98.2-99.8
	A	97.1% (34/35)	85.1-100	99.2% (770/776)	98.3-99.7	85.7% (30/35)	69.7-95.2	99.5% (772/776)	98.7-99.9
FS Total ³		96.4% (80/83)	89.8-99.3	99.0% (1315/1328)	98.3-99.5	91.6% (76/83)	83.4-96.5	99.4% (1320/1328)	98.8-99.7
FU ¹	S	84.8% (39/46)	71.1-93.7	99.2% (527/531)	98.1-99.8	87.0% (40/46)	73.7-95.1	98.9% (525/531)	97.6-99.6
	A	88.2% (30/34)	72.5-96.7	99.0% (713/720)	98.0-99.6	76.5% (26/34)	58.8-89.3	99.0% (713/720)	98.0-99.6
FU Total		86.3% (69/80)	76.7-92.9	99.1% (1240/1251)	98.4-99.6	82.5% (66/80)	72.4-90.1	99.0% (1238/1251)	98.2-99.5
MU ¹	S	97.9% (185/189)	94.7-99.4	94.4% (286/303) ⁴	91.2-96.7	93.7% (177/189)	89.2-96.7	94.4% (286/303)	91.2-96.7
	A	100% (22/22)	84.6-100	99.5% (639/642)	98.6-99.9	95.5% (21/22)	77.2-99.9	99.7% (640/642)	98.9-99.9
MU Total		98.1% (207/211)	95.2-99.5	97.9% (925/945)	96.8-98.7	93.8% (198/221)	89.7-96.7	98.0% (926/945)	96.9-98.8
Total ⁵		95.2% (356/374)	92.5-97.1	98.8% (3480/3524)	98.3-99.1	90.9% (340/374)	87.5-93.6	98.9% (3484/3524)	98.5-99.2

1 Comparison cultures for female and male urine specimens were performed on endocervical and male urethral swab specimens, respectively. / Les cultures de comparaison pour les échantillons d'urine masculins et féminins ont été réalisées à partir des écouvillons d'urètre masculins et des écouvillons de col utérin respectivement. / Vergleichskulturen für weibliche und männliche Urinproben wurden mit Endozervikal- bzw. männlichen Urethralabstrichproben durchgeführt. / Sono state eseguite colture comparate di campioni di urina di soggetti di sesso femminile e maschile rispettivamente su campioni endocervicali e uretrali maschili su tampone. / Comparación de cultivos para muestras de orina de mujeres y hombres se realizó sobre muestras en torunda de uretra masculina y endocérvix, respectivamente.

2 With AC, recovered one false negative resulting in an increase in sensitivity from 95.8% to 97.9%. / Avec AC, obtention d'un faux négatif entraînant une augmentation de la sensibilité de 95,8 % à 97,9 %. / Mit AC wurde ein falschnegatives Ergebnis wiederhergestellt, was zu einem Anstieg der Empfindlichkeit von 95,8 % auf 97,9 % führte. / Con AC, è stato recuperato un falso negativo con conseguente aumento della sensibilità dal 95,8% al 97,9%. / Con AC, se recuperó un falso negativo resultando en un incremento en la sensibilidad de 95,8% a 97,9%.

3 With AC, female swabs sensitivity and specificity were 97.6% and 99.0%, respectively / Avec AC, la sensibilité et la spécificité des écouvillons féminins étaient respectivement de 97,6 % et 99,0 %. / Mit AC betrug die Empfindlichkeit und Spezifität für weibliche Abstriche 97,6 % bzw. 99,0 %. / Con AC, la sensibilità e specificità dei tamponi femminili sono state rispettivamente del 97,6% e 99,0%. / Con AC, la sensibilidad y especificidad para muestras en torunda de mujeres fue de 97,6% y 99,0%, respectivamente.

4 With AC, caused one false positive resulting in a decrease in specificity from 94.4% to 93.8%. / Avec AC, a causé un faux positif entraînant la diminution de la sensibilité de 94,4 % à 93,8 %. / Mit AC wurde ein falschpositives Ergebnis verursacht, was zu einer Abnahme der Spezifität von 94,4 % auf 93,8 % führte. / Con AC, è stato riportato un falso positivo con conseguente riduzione della specificità da 94,4% a 93,8%. / Con AC, se produjo un falso positivo, resultando en una disminución en la especificidad de 94,4% a 93,8%.

5 With AC, total sensitivity and specificity for all specimen types were 95.2% and 98.6%, respectively. / Avec AC, la sensibilité et la spécificité totales pour tous les types d'échantillons étaient 95,2 % et 98,6 %, respectivement. / Mit AC betrug die Gesamtempfindlichkeit und -spezifität für alle Probenarten 95,2 % bzw. 98,6 %. / Con AC, la sensibilità e specificità totali per tutti i tipi di campioni sono state rispettivamente pari a 95,2% e 98,6%. / Con AC, la especificidad y sensibilidad total para todos los tipos de muestras fue 95,2% y 98,6%, respectivamente.

Table / Tableau / Tabelle / Tabella / Tabla 14: BD ProbeTec™ ET GC Results Compared to AMPI / Résultats BD ProbeTec ET GC comparés à AMPI / BD ProbeTec ET GC-Ergebnisse im Vergleich zu AMPI / Risultati GC BD ProbeTec ET rispetto ad AMPI / Resultados GC BD ProbeTec ET comparados con AMPI

Specimen Type	S/A	% Agreement	95% C.I.
FS	S	98.8% (593/600)	97.6-99.5
	A	99.3% (805/811)	98.4-99.7
	Total	99.1% (1398/1411)	98.4-99.5
FU	S	97.4% (562/577)	95.8-98.5
	A	97.9% (738/754)	96.6-98.8
	Total	97.7% (1300/1331)	96.7-98.4
MU	S	95.9% (472/492)	93.8-97.5
	A	99.1% (658/664)	98.0-99.7
	Total	97.9% (1132/1156)	96.9-98.7
Total		98.3% (3830/3898)	97.8-98.6

Table / Tableau / Tabelle / Tabella / Tabla 15: GC Paired Specimen Analysis for Female Patients (without AC) / Analyse des échantillons appariés GC pour les patientes (sans AC) / Analyse gepaarter GC-Proben bei weiblichen Patienten (ohne AC) / Analisi di campioni GC in doppio per pazienti di sesso femminile (senza AC) / Analisis GC de muestras dobles para pacientes mujeres (sin AC)

Patient Infected Status	Endocervical Culture	AMP1 Swab	AMP1 Swab	BD ProbeTec ET		# Patients	
				Swab	Urine	S	A
(+)	+	+	+	+	+	32	21
	+	+	+	+	-	5	2
	+	+	+	-	+	2	0
	+	+	-	+	-	2	1
	+	+	-	+	+	3	5
	+	-	+	+	+	1	3
	+	-	-	+	+	1	1
	+	-	-	-	-	0	1
	-	+	+	+	-	1	1
-	+	+	+	+	2	2	
(-)	-	+	-	+	-	1	1
	-	-	+	-	+	0	1
	-	-	-	+	+	0	1
	-	-	+	-	-	3	3
	-	-	-	+	-	2	1
	-	-	-	-	+	2	3
	-	-	-	-	-	520	705
Total						577	752

Table / Tableau / Tabelle / Tabella / Tabla 16: GC Paired Specimen Analysis for Male Patients (without AC) / Analyse des échantillons appariés GC pour les patients (sans AC) / Analyse gepaarter GC-Proben bei männlichen Patienten (ohne AC) / Analisi di campioni GC in doppio per pazienti di sesso maschile (senza AC) / Analisis GC de muestras dobles para pacientes hombres (sin AC)

Patient Infected Status	Urethral Culture	AMP1 Urine	BD ProbeTec ET		# Patients	
			Swab	Urine	S	A
(+)	+	+	+	+	173	20
	+	+	+	-	3	1
	+	+	-	+	1	0
	+	-	+	+	10	1
	+	-	-	-	1	0
	+	-	-	+	1	0
(-)	-	+	+	+	14	0
	-	+	+	-	2	1
	-	+	-	-	1	1
	-	-	+	-	0	3
	-	-	-	+	3	3
	-	-	-	-	283	633
Total					492	663

Table / Tableau / Tabelle / Tabella / Tabla 17: BD ProbeTec™ ET Performance for Detecting Both CT and GC in Specimens from Patients Considered Co-infected by Patient Infected Status / Performance de BD ProbeTec ET en termes de détection de CT et GC dans des échantillons provenant de patients considérés co-infectés par statut infecté du patient / BD ProbeTec ET-Leistung zum Nachweis von CT und GC in Proben von als co-infiziert beurteilten Patienten nach Infektionsstatus der Patienten / Performance BD ProbeTec ET per la rilevazione di CT e GC in campioni di pazienti considerati coinfectati per stato di infezione del paziente / Rendimiento BD ProbeTec ET para detectar ambos, CT y GC, en muestras de pacientes considerados co-infectados según estado del paciente infectado

Specimen Type	S/A	Patient Infected Status (CT + / GC +)	BD ProbeTec ET			
			CT +/GC +	CT +/GC-	CT-/GC +	CT -/GC -
FS	S	14	12	2	0	0
	A	16	16	0	0	0
	Total	30	28	2	0	0
FU	S	14	11	1	1	1
	A	16	12	2	2	0
	Total	30	23	3	3	1
MS	S	33	29	1	3	0
MU	S	33	30	1	2	0
Total		126	110	7	8	1

Table / Tableau / Tabelle / Tabella / Tabla 18: BD ProbeTec™ ET CT/GC Precision Data / Données de la précision pour BD ProbeTec ET / BD ProbeTec ET-Präzisionsdaten / Dati di precisione BD ProbeTec ET / Datos de precisión BD ProbeTec ET

CT (without AC)							
				Within Run		Between Run	
Panel Member	n	% Correct	Mean MOTA	SD	%CV	SD	%CV
0 EBs/rxn1	108	99.1%	192	380	–	NV	NV
25 EBs/rxn	108	100%	21426	10498	49	869	4
50 EBs/rxn	108	100%	27181	8818	32	NV	NV
75 EBs/rxn	108	100%	27878	9888	35	2209	8
100 EBs/rxn	108	100%	30534	9678	32	885	3
GC (without AC)							
				Within Run		Between Run	
Panel Member	n	% Correct	Mean MOTA	SD	%CV	SD	%CV
0 cells/rxn2	108	100%	85	74	–	6	–
15 cells/rxn	108	60.2%	6926	8052	116	NV	NV
25 cells/rxn3	108	81.5%	8605	7865	91	896	10
50 cells/rxn	108	94.4%	14374	8704	61	NV	NV
100 cells/rxn4	108	99.1%	24944	10828	43	996	4
AC							
				Within Run		Between Run	
CT/GC Panel Member	n		Mean MOTA	SD	%CV	SD	%CV
Negative	108		22201	10989	–	530	–
25 EBs/rxn CT + 15 cells/rxn GC	108		24100	12163	50	NV	NV
50 EBs/rxn CT + 25 cells/rxn GC	108		24830	13041	53	NV	NV
75 EBs/rxn CT + 50 cells/rxn GC	108		25949	12586	49	1546	6
100 EBs/rxn CT + 100 cells/rxn GC	108		28245	11431	40	1079	4

1 With AC: 1/108 (0.9%) Positive, 106/108 (98.1%) Negative, and 1/108 (0.9%) Indeterminate. / Avec AC: 1/108 (0,9 %) Positif, 106/108 (98,1 %) Négatifs, et 1/108 (0,9 %) Indéterminé. / Mit AC: 1/108 (0,9 %) positiv, 106/108 (98,1 %) negativ und 1/108 (0,9 %) unbestimmt. / Con AC: 1/108 (0,9%) positivo, 106/108 (98,1%) negativo e 1/108 (0,9%) indeterminato. / Con AC: 1/108 (0,9%) positivo, 106/108 (98,1%) negativo, y 1/108 (0,9%) indeterminado.

2 With AC: 0/108 (0%) Positive, 107/108 (99,1%) Negative, and 1/108 (0,9%) Indeterminate. / Avec AC: 0/108 (0 %) Positif, 107/108 (99,1 %) Négatifs, et 1/108 (0,9 %) Indéterminé. / Mit AC: 0/108 (0 %) positiv, 107/108 (99,1 %) negativ und 1/108 (0,9 %) unbestimmt. / Con AC: 0/108 (0%) positivo, 107/108 (99,1%) negativo e 1/108 (0,9%) indeterminato. / Con AC: 0/108 (0%) positivo, 107/108 (99,1%) negativo, y 1/108 (0,9%) indeterminado.

3 With AC: 88/108 (81,5%) Positive, 19/108 (17,6%) Negative, and 1/108 (0,9%) Indeterminate. / Avec AC: 88/108 (81,5 %) Positifs, 19/108 (17,6 %) Négatifs, et 1/108 (0,9 %) Indéterminé. / Mit AC: 88/108 (81,5 %) positiv, 19/108 (17,6 %) negativ und 1/108 (0,9 %) unbestimmt. / Con AC: 88/108 (81,5%) positivo, 19/108 (17,6%) negativo e 1/108 (0,9%) indeterminato. / Con AC: 88/108 (81,5%) positivo, 19/108 (17,6%) negativo, y 1/108 (0,9%) indeterminado.

4 With AC: 107/108 (99,1%) Positive, 0/108 (0%) Negative, and 1/108 (0,9%) Indeterminate. / Avec AC: 107/108 (99,1 %) Positifs, 0/108 (0 %) Négatif, et 1/108 (0,9 %) Indéterminé. / Mit AC: 107/108 (99,1 %) positiv, 0/108 (0 %) negativ und 1/108 (0,9 %) unbestimmt. / Con AC: 107/108 (99,1%) positivo, 0/108 (0%) negativo e 1/108 (0,9%) indeterminato. / Con AC: 107/108 (99,1%) positivo, 0/108 (0%) negativo, y 1/108 (0,9%) indeterminado

Table / Tableau / Tabelle / Tabella / Tabla 19: BD ProbeTec™ ET CT/GC Reproducibility / Reproductibilité BD ProbeTec ET CT/GC / BD ProbeTec ET CT/GC-Reproduzierbarkeit / Riproducibilità CT/GC BD ProbeTec ET / Reproducibilidad BD ProbeTec ET para CT/GC

CT ¹			
Swab seed level	0 EBs/rxn	50 EBs/rxn 1,000 EBs/swab	500 EBs/rxn 10,000 EBs/swab
% Correct vs. Expected	99.3% ² (137/138)	92.4% (255/276)	100% (276/276)
Buffer seed level	0 EBs/rxn	115 EBs/rxn 575 EBs/mL	600 EBs/rxn 3,000 EBs/mL
% Correct vs. Expected	97.1% ³ (134/138)	92.4% (255/276)	99.3% ² (274/276)
GC ¹			
Swab seed level	0 cells/rxn	30 cells/rxn 600 cells/swab	500 cells/rxn 10,000 cells/swab
% Correct vs. Expected	99.3% ² (137/138)	99.3% (274/276)	100% (276/276)
Buffer seed level	0 cells/rxn	100 cells/rxn 500 cells/mL	500 cells/rxn 2,500 cells/mL
% Correct vs. Expected	98.6% ³ (136/138)	96.4% (266/276)	99.3% ² (274/276)

1 Samples for the reproducibility study were inoculated with *C. trachomatis* and *N. gonorrhoeae*. CT and GC results are presented separately in table. Refer to the .Performance Characteristics. for detailed description of study design. / Les échantillons à analyser ont été inoculés conjointement avec *C. trachomatis* et *N. gonorrhoeae*. Les résultats CT et GC sont représentés séparément dans le tableau. Se reporter aux « Caractéristiques de performances » pour une description détaillée de la conduite de l'étude / Die in dieser Studie verwendeten Proben wurden mit *C. trachomatis* und *N. gonorrhoeae* inokuliert. Die CT- und GC-Ergebnisse sind in dieser Tabelle getrennt aufgeführt. Der Abschnitt .Leistungsmerkmale. enthält eine detaillierte Beschreibung der Studienkonzeption. / I campioni per lo studio sono stati inoculati sia con *C. trachomatis* che con *N. gonorrhoeae*. I risultati CT e GC sono riportati separatamente nella tabella. Per una descrizione dettagliata del progetto di studio, consultare le .Prestazioni metodologiche.. / Se inocularon muestras para estudio con *C. trachomatis* y *N. gonorrhoeae*. Los resultados de CT y de GC se presentan, por separado, en la tabla. Consulte la sección .Características de rendimiento. para ver una descripción detallada del diseño del estudio.

2 One sample indeterminate when the AC result was incorporated. / Un échantillon indéterminé quand le résultat d.AC est intégré. / Eine Probe war unbestimmt, wenn das AC-Ergebnis berücksichtigt wurde. / Un campione indeterminato quando è stato incorporato il risultato AC. / Una muestra fue indeterminada cuando se agregó el resultado AC.

3 Three samples were indeterminate when the AC result was incorporated. / Trois échantillons indéterminés quand le résultat d.AC est intégré. / Drei Proben waren unbestimmt, wenn das AC-Ergebnis berücksichtigt wurde. / Tre campioni indeterminati quando è stato incorporato il risultato AC. / Tres muestras fueron indeterminadas cuando se agregó el resultado AC.

Note: In this study, results were combined across 23 operators and across all specimens (negative, low positive, high positive). Eighteen of 23 (78%) operators were at least 95% reproducible with CT swab specimens; 14/23 (61%) of the operators were at least 95% reproducible for CT buffer specimens. / Remarque : Dans cette étude, les résultats ont été regroupés sur les 23 techniciens et tous les échantillons (négatifs, faiblement positifs, fortement positifs). Dix-huit des 23 (78 %) techniciens ont donné une reproductibilité d'au moins 95 % avec les écouvillons CT ; 14/23 (61 %) des techniciens ont donnée une reproductibilité d'au moins 95 % avec les échantillons de tampons CT. / Hinweis: In dieser Studie wurden die Ergebnisse von 23 Labortechnikern und sämtlichen Proben (negativ, schwach positiv, stark positiv) zusammengefaßt. Achtzehn von 23 (78 %) Labortechnikern zeigten eine Reproduzierbarkeit von mindestens 95 % bei CT-Abstrichproben; 14/23 (61 %) der Labortechniker zeigten eine Reproduzierbarkeit von mindestens 95 % bei CT-Pufferproben.

/ Nota: In questo studio, sono stati combinati i risultati ottenuti da 23 operatori e da tutti i campioni (negativi, scarsamente positivi, altamente positivi). Diciotto operatori su 23 (78%) hanno presentato una riproducibilità di almeno il 95% con campioni CT su tampone; 14 operatori su 23 (61%) hanno presentato una riproducibilità di almeno il 95% per campioni CT su PBS. / Nota: En este estudio, los resultados se combinaron con 23 operadoras y con todas las muestras (negativas, positivo bajo, positivo alto). Dieciocho de los 23 (78%) operadores fueron reproducibles al menos en un 95% con muestras en torunda para CT; 14/23 (61%) de los operadores fueron reproducibles al menos en un 95% para muestras tampón CT.

Table / Tableau / Tabelle / Tabella / Tabla 20: Microorganisms Tested for Analytical Specificity / Microorganismes testés pour la spécificité analytique / Auf analytische Spezifität getestete Mikroorganismen / Microorganismi testati per la specificità analitica / Microorganismos analizados para especificidad analítica

<i>Acinetobacter calcoaceticus</i>	<i>Enterococcus faecalis</i>	<i>Mobiluncus mulerieris</i>	<i>Peptostreptococcus asaccharolyticus</i>
<i>Acinetobacter lwoffii</i>	<i>Enterococcus faecium</i>	<i>Moraxella lacunata</i>	<i>Peptostreptococcus productus</i>
<i>Actinomyces israelii</i>	Epstein-Barr Virus	<i>Moraxella osloensis</i>	<i>Plesiomonas shigelloides</i>
Adenovirus	<i>Escherichia coli</i>	<i>Morganella morganii</i>	<i>Propionibacterium acnes</i>
<i>Aeromonas hydrophila</i>	<i>Flavobacterium meningosepticum</i>	<i>Mycobacterium gordonae</i>	<i>Proteus mirabilis</i>
<i>Alcaligenes faecalis</i>	<i>Fusobacterium nucleatum</i>	<i>Mycobacterium smegmatis</i>	<i>Providencia stuartii</i>
<i>Bacillus subtilis</i>	<i>Gardnerella vaginalis</i>	<i>Mycoplasma hominis</i>	<i>Pseudomonas aeruginosa</i>
<i>Bacteroides fragilis</i>	<i>Gemella haemolysans</i>	<i>Neisseria cinerea</i> (3)	<i>Salmonella minnesota</i>
<i>Branhamella catarrhalis</i> (5)	Group A <i>Streptococcus</i>	<i>Neisseria elongata</i> (3)	<i>Salmonella typhimurium</i>
<i>Candida albicans</i>	<i>Haemophilus ducreyi</i>	<i>Neisseria flava</i> (5)	<i>Staphylococcus aureus</i>
<i>Candida glabrata</i>	<i>Haemophilus influenzae</i>	<i>Neisseria flavescens</i> (4)	<i>Staphylococcus epidermidis</i>
<i>Candida tropicalis</i>	Herpes Simplex Virus, type I	<i>Neisseria gonorrhoeae</i> ***	<i>Streptococcus agalactiae</i>
<i>Chlamydia pneumoniae</i>	Herpes Simplex Virus, type II	<i>Neisseria gonorrhoeae</i> ss. <i>kochii</i> (5) ***	<i>Streptococcus mitis</i>
<i>Chlamydia psittaci</i>	HIV-1	<i>Neisseria lactamica</i> (7)	<i>Streptococcus mutans</i>
<i>Chlamydia trachomatis</i> ***	HPV type 16	<i>Neisseria meningitidis</i> (11)	<i>Streptococcus pneumoniae</i>
<i>Citrobacter freundii</i>	HPV type 18	<i>Neisseria mucosa</i> (5)	<i>Streptomyces griseus</i>
<i>Clostridium perfringens</i>	<i>Kingella kingae</i>	<i>Neisseria perflava</i> (8)	<i>Treponema pallidum</i>
<i>Corynebacterium renale</i>	<i>Klebsiella pneumoniae</i>	<i>Neisseria polysaccharea</i> (2)	<i>Trichomonas vaginalis</i>
<i>Cryptococcus neoformans</i>	<i>Lactobacillus acidophilus</i>	<i>Neisseria sicca</i> (5)	<i>Ureaplasma urealyticum</i>
<i>Cytomegalovirus</i>	<i>Lactobacillus brevis</i>	<i>Neisseria subflava</i> (16)	<i>Veillonella parvula</i>
<i>Edwardsiella tarda</i>	<i>Lactobacillus jensenii</i>	<i>Neisseria weaverii</i> (3)	<i>Vibrio parahaemolyticus</i>
<i>Enterobacter cloacae</i>	<i>Listeria monocytogenes</i>	<i>Peptostreptococcus anaerobius</i>	<i>Yersinia enterocolitica</i>

*** Produced a positive result as expected. / A produit un résultat positif comme escompté. / Ergab erwartungsgemäß ein positives Ergebnis. / Ha generato un risultato positivo come atteso. / Produjeron un resultado positivo como se esperaba.

(n) = # of strains tested. / nbre de souches testées. / Anzahl getesteter Stämme. / numero di ceppi testati. / # de cepas analizadas.

Table / Tableau / Tabelle / Tabella / Tabla 21: Interfering Substances for the BD ProbeTec™ ET CT/GC Assays / Substances interférant avec les tests BD ProbeTec ET CT/GC / Interferierende Substanzen bei BD ProbeTec ET CT/GC-Assays / Sostanze interferenti per i test CT/GC BD ProbeTec ET / Sustancias que interfieren en los análisis CT/GC BD Probe Tec ET

Interpretation	Swab	Urine
No Interference Observed Aucune interférence observée Keine Störung beobachtet Nessuna interferenza osservata No se observó Interferencia	Blood 5% / Sang = 5% / Blut = 5% / Sangue = 5% / Sangre = 5% Seminal fluid / Liquide séminal / Samenflüssigkeit / Líquido seminal / Fluido seminal Mucus / Mukus / Muco / Moco Common vaginosis ointments and creams / Crèmes et onguents courants pour les vaginoses / Häufig verwendete Salben und Cremes für Vaginitis / Creme e pomate per vaginosi comuni / Ungüentos y cremas para vaginosis de uso común Vaginal lubricants / Lubrifiants vaginaux / Vaginale Gleitmittel / Lubrificanti vaginali / Lubrificantes vaginales Hemorrhoidal cream / Crème pour les hémorroïdes / Hämorrhoidensalbe / Crema emorroidaria / Crema para hemorroides Antiviral cream / Crème antivirale / Antivirencreme / Crema antivirale / Crema antivirica Nonoxinol-9 containing products / Produits contenant du Nonoxinol-9 / Produkte mit Nonoxinol-9 / Prodotti contenenti nonoxinolo-9 / Productos que contienen nonoxinol-9	Mucus / Mukus / Muco / Moco Seminal fluid / Liquide séminal / Samenflüssigkeit / Líquido seminal / Fluido seminal Albumin / Albumine / Albumina / Albumina Glucose / Glukose / Glucosio / Glucosa Acidic urine (pH 4) / urine acide (pH 4) / Saurer Urin (pH 4) / Urina acida (pH 4) / Orina acidica (pH 4) Alkaline urine (pH 8) / urine alcaline (pH 8) / Alkalischer Urin (pH 8) / Urina alcalina (pH 8) / Orina alcalina (pH 8) Amoxicillin / Amoxicilline / Amoxicillina / Amoxicilina Metronidazole / Métronidazole / Metronidazol / Metronidazolo / Metronidazola Tetracycline / Tétracycline / Tetracydin / Tetraddina / Tetraciclina Cefotaxime / Céfotaxime / Cefotaxim / Cefotaxima Sulfamethoxazole / Sulfaméthoxazole / Sulfamethoxazol / Sulfametossazolo / Sulfametoaxazola Trimethoprim / Triméthoprime / Trimetoprim Erythromycin / Erythromycine / Eritromicina Acetamidophen / Acétamidophène / Acetamidophen / Acetaminofene / Acetamidofén Acetylsalicylic / Acétylsalicylique / Acetylsalicyl / Acetilsalicílico / Addo acetilsalicílico Beta-naphthalene acetic acid / Acétylsalicylique / Beta- Naphthalinessigsäure / Beta-naftal ene acetato / Acido acético beta- naftaleno Ethinyl-estradiol / Ethinyl-estradiol / Ethinylestradiol / Etinil-estradiolo / Etinilestradiol Norethindrone / Noréthindrone / Norethindron / Noretindrone / noretindrona
May cause false negative results ¹ Peuvent causer des résultats faussement négatifs ¹ / Kann zu falsch-negativen Ergebnissen führen ¹ / Può causare risultati falsamente negativi ¹ / Puede producir resultados de falso negativo ¹	Leukocytes / Leucocytes / Leukozyten / Leucociti / Leucocitos Blood > 5% / Sang > 5% / Blut = 5% / Sangue > 5% / Sangre > 5%	Leukocytes / Leucocytes / Leukozyten / Leucociti / Leucocitos Blood / Sang / Blut / Sangue / Sangre Serum / Sérum / Siero / Suero Feminine deodorant sprays / Déodorants féminins / Intimsprays / Spray deodoranti femminili / Aerosoles de desodorante femenino Bilirubin / Bilirubine / Bilirubin / Bilirubina / Bilirubina Talcum powder / Talc en poudre / Talkumpuder / Talko in polvere / Polvos de talco Phenazopyridine / Phénazopyridine / Phenazopyridin / Fenazopiridina / Fenazopiridina

¹ When using the AC, these substances may also cause indeterminate results. / Quand AC est utilisé, ces substances peuvent aussi causer des résultats indéterminés. / Bei Verwendung der AC können diese Substanzen auch zu unbestimmten Ergebnissen führen. / In caso di utilizzo di AC, queste sostanze possono anch'esse causare risultati indeterminati. / Cuando se usa AC, estas sustancias pueden producir también resultados indeterminados.

Performance Characteristics for BD Viper System

Clinical Specimen Comparison

Three hundred and eighty-five clinical specimens (204 endocervical swabs and 181 urine specimens treated with UPP) were acquired from three geographically diverse high and low prevalence sites and tested with the **BD ProbeTec** ET CT/GC Amplified DNA Assays on both the **BD ProbeTec** ET and **BD Viper** Systems. Additionally, five hundred nineteen clinical urine specimens (UPT and neat) were acquired from four geographically diverse high and low prevalence sites and tested with the **BD ProbeTec** ET CT/GC Amplified DNA Assays on both the **BD ProbeTec** ET and **BD Viper** Systems.

The reference result (**BD ProbeTec** ET System) for both studies was derived from an algorithm which involved repeat testing of all specimens that yielded positive results on the **BD ProbeTec** ET System. If the repeat result was also positive, then the **BD ProbeTec** ET reference result was recorded as positive. If the repeat result was negative or if the initial **BD ProbeTec** ET result was negative, then the **BD ProbeTec** ET reference result was recorded as negative.

CT Assay Performance

The overall percent agreement between the two systems for the CT Assay was 98.53% (201/204; 95% CI: 95.76% - 99.7%) for endocervical swabs, 99.45% (180/181; 95%CI: 96.96% -99.99%) for UPP treated urine, 97.99% (244/249; 95% CI: 95.38% - 99.34%) for UPT urine and 97.78% (264/270; 95% CI: 95.23% - 99.18%) for neat urine.

The distribution of initial low positive (LP= 2000-9999 MOTA), positive (P ≥ 10,000 MOTA), and negative results (N = <2000 MOTA) for the CT assay on the **BD Viper** System compared to the **BD ProbeTec** ET System is presented in Tables 22–28.

Table 22 – Distribution of CT Assay Results (Endocervical Swabs) – **BD Viper** System vs. **BD ProbeTec** ET System

BD Viper Result	BD ProbeTec ET System - Initial Result			
	P	LP	N	Total
P	35	2	0	37
LP	0	1	3	4
N	0	0	163	163
Total	35	3	166	204

Table 23 – Distribution of CT Assay Results (Female UPP Urine) -
BD Viper System vs. **BD ProbeTec** ET System

BD Viper Result	BD ProbeTec ET System - Initial Result			
	P	LP	N	Total
P	20	0	0	20
LP	1	0	0	1
N	0	0	68	68
Total	21	0	68	89

Table 24 – Distribution of CT Assay Results (Male UPP Urine) –
BD Viper System vs. **BD ProbeTec** ET System

BD Viper Result	BD ProbeTec ET System - Initial Result			
	P	LP	N	Total
P	37	0	0	37
LP	1	0	0	1
N	1	1	52	54
Total	39	1	52	92

Table 25 – Distribution of CT Assay Results (Female UPT Urine) –
BD Viper System vs. **BD ProbeTec** ET System

BD Viper Result	BD ProbeTec ET System - Initial Result			
	P	LP	N	Total
P	33	0	2	35
LP	0	0	0	0
N	0	0	82	82
Total	33	0	84	117

Table 26 – Distribution of CT Assay Results (Male UPT Urine) –
BD Viper System vs. BD ProbeTec ET System

BD Viper Result	BD ProbeTec ET System - Initial Result			
	P	LP	N	Total
P	34	1	2	37
LP	1	0	0	1
N	0	0	94	94
Total	35	1	96	132

Table 27 – Distribution of CT Assay Results (Female Neat Urine) –
BD Viper System vs. BD ProbeTec ET System

BD Viper Result	BD ProbeTec ET System - Initial Result			
	P	LP	N	Total
P	37	0	0	37
LP	0	0	0	0
N	3	1	87	91
Total	40	1	87	128

Table 28 – Distribution of CT Assay Results (Male Neat Urine) –
BD Viper System vs. BD ProbeTec ET System

BD Viper Result	BD ProbeTec ET System - Initial Result			
	P	LP	N	Total
P	43	0	1	44
LP	0	1	1	2
N	2	1	93	96
Total	45	2	95	142

GC Assay Performance

The overall percent agreement between the two systems for the GC Assay was 97.55% (199/204; 95% CI: 94.37% - 99.2%) for endocervical swabs and 99.45% (180/181; 95% CI: 96.96% - 99.99%) for UPP treated urine, 99.92% (247/249; 95%

CI: 97.13% - 99.99%) for UPT urine and 98.89% (267/270; 95% CI: 96.79% - 99.77%) for neat urine.

The distribution of initial low positive (LP= 2000 –9999 MOTA), positive (P ≥ 10,000 MOTA), and negative results (N= < 2000 MOTA) for the **BD Viper** System compared to the **BD ProbeTec** ET System is presented in Tables 29 – 35.

Table 29 – Distribution of GC Assay Results (Endocervical Swabs) – **BD Viper** System vs. **BD ProbeTec** ET System

BD Viper Result	BD ProbeTec ET System - Initial Result			
	P	LP	N	Total
P	12	0	0	12
LP	1	1	1	3
N	0	2	187	189
Total	13	3	188	204

Table 30 - Distribution of GC Assay Results (Female UPP Urine) – **BD Viper** System vs. **BD ProbeTec** ET System

BD Viper Result	BD ProbeTec ET System - Initial Result			
	P	LP	N	Total
P	3	0	0	3
LP	0	1	0	1
N	0	0	85	85
Total	3	1	85	89

Table 31 - Distribution of GC Assay Results (Male UPP Urine) – **BD Viper** System vs. **BD ProbeTec** ET System

BD Viper Result	BD ProbeTec ET System - Initial Result			
	P	LP	N	Total
P	10	0	0	10
LP	0	0	0	0
N	0	0	82	82
Total	10	0	82	92

Table 32 – Distribution of GC Assay Results (Female UPT Urine) –
BD Viper System vs. **BD ProbeTec** ET System

BD Viper Result	BD ProbeTec ET System - Initial Result			
	P	LP	N	Total
P	29	0	1	30
LP	0	0	0	0
N	0	1	86	87
Total	29	1	87	117

Table 33 – Distribution of GC Assay Results (Male UPT Urine) –
BD Viper System vs. **BD ProbeTec** ET System

BD Viper Result	BD ProbeTec ET System - Initial Result			
	P	LP	N	Total
P	38	0	1	39
LP	0	0	0	0
N	0	0	93	93
Total	38	0	94	132

Table 34 - Distribution of GC Assay Results (Female Neat Urine) –
BD Viper System vs. **BD ProbeTec** ET System

BD Viper Result	BD ProbeTec ET System - Initial Result			
	P	LP	N	Total
P	27	0	1	28
LP	0	0	0	0
N	1	0	99	100
Total	28	0	100	128

Table 35 - Distribution of GC Assay Results (Male Neat Urine) –
BD Viper System vs. **BD ProbeTec** ET System

BD Viper Result	BD ProbeTec ET System - Initial Result			
	P	LP	N	Total
P	30	1	2	33
LP	0	0	0	0
N	2	0	107	109
Total	32	1	109	142

Precision

Precision of the **BD Viper** System using the **BD ProbeTec** ET CT/GC Amplified DNA Assays was evaluated internally at BD on three **BD Viper** Systems. A different operator performed the study on each **BD Viper** System. A panel of specimens was tested that comprised *C. trachomatis* and *N. gonorrhoeae* organisms seeded into **BD ProbeTec** ET CT/GC diluent at levels close to the analytical limits of detection of the assays as described in the **BD ProbeTec** ET CT/GC Assay and CT Assay inserts. Uninoculated BD ProbeTec ET CT/GC diluent was used for the CT/GC negative samples. Six replicates of each panel member were tested once a day for three days on each **BD Viper** System. The data are summarized in Tables 36 and 37.

Table 36 – Summary of CT Precision Data on the **BD Viper** System

CT (EBs/mL)	n	CT % Correct	CT 95% CI	Mean MOTA	Within Run within BD Viper		Between Run within BD Viper		Between BD Viper	
					SD	%CV	SD	%CV	SD	%CV
0	252	100%	(98.82%, 100%)	31	72	–	14	–	12	–
214	252	100%	(98.82%, 100%)	36782	5103	14	1018	3	1164	3
428	252	99.61%	(97.81%, 99.99%)	35860	5384	15	1442	4	592	2

Table 37 – Summary of GC Precision Data on the **BD Viper** System

GC (cells/mL)	n	GC % Correct	GC 95% CI	Mean MOTA	Within Run within BD Viper		Between Run within BD Viper		Between BD Viper	
					SD	%CV	SD	%CV	SD	%CV
0	252	99.61%	(97.81%, 99.99%)	78	571	–	0	–	0	–
144	252	99.61%	(97.81%, 99.99%)	28083	4956	18	3689	13	0	0
288	252	100%	(98.55%, 100%)	31760	3336	11	1740	5	0	0

Carryover and Cross-Contamination Evaluation

An internal study was conducted to evaluate the risk of producing a false positive result in either the same **BD Viper** System run (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. Negative samples consisted of **BD ProbeTec** ET CT/GC Diluent. Positive samples consisted of 10⁵ GC particles/mL spiked into **BD ProbeTec** ET CT/GC Diluent. The overall rate of cross-contamination (i.e., with alternating columns of positive and negative samples and a GC prevalence of 50%) was 0.54% (12/2208). The overall rate of carryover contamination (carryover between successive runs when the prevalence of GC was 50% in the previous run) was 0.45% (1/2202). Cross-contamination and carryover rates across the three **BD Viper** Systems are summarized in Table 38.

Table 38 – Cross-Contamination and Carryover Rates by **BD Viper** System

BD Viper System	Cross-Contamination Rate			Carryover Rate		
	n	Positive Results	Percent Positive Results	n	Positive Results	Percent Positive Results
1	736	4	0.54%	736	0	0.00%
2	736	2	0.27%	736	1	0.14%
3	736	6	0.82%	730 ¹	0	0.00%

XII. AVAILABILITY

The following **BD Viper**™ products are also available:

CAT. NO. DESCRIPTION

220142 **BD ProbeTec**™ ET *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/GC) Amplified DNA Assay Collection Kit for Endocervical Specimens, 100 units.

220143 **BD ProbeTec**™ ET *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/GC) Amplified DNA Assay Collection Kit for Male Urethral Specimens, 100 units.

440451 **BD ProbeTec**™ ET CT/GC Control Set, 20 positive and 20 negative.

440452 **BD ProbeTec**™ ET CT/GC Diluent Tubes, 2 mL x 400.

440453 **BD ProbeTec**™ ET Diluent (CT/GC), 4 x 225 mL.

440455 **BD ProbeTec**™ ET Sample Tubes and Caps, 4 x 100.

440456 **BD ProbeTec**™ ET Caps, 4 x 100.

440457 **BD ProbeTec**™ ET Accessories (20 Primer covers, Amplification sealers and Disposal bags, 20 each).

440461 **BD ProbeTec**™ ET *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/GC) Amplified DNA Assay Male Urethral Specimen Collection and DRY TRANSPORT Kit, 1 x 100.

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XIV. TECHNICAL INFORMATION

In the United States, telephone Technical Services, toll free (800) 638-8663.

Approved by:

Supervisor: _____

Date: _____

Director: _____

Date: _____

Effective Date: _____

Reviewed by:

PI Rev 07/2005

Rev 06/2006