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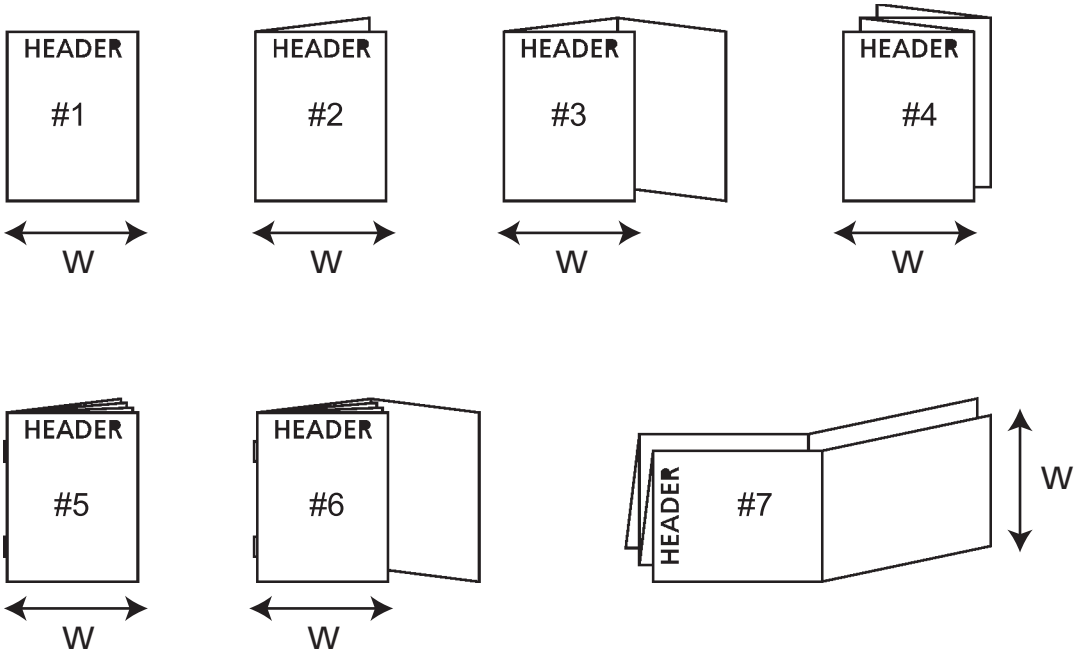

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BD Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152 USA

Category and Description
Package Insert,
BD ProbeTec™ ET GC/AC Amplified DNA Assay

Sheet: 1 of 17

Scale: N/A

A

BD ProbeTec™ ET *Neisseria gonorrhoeae* Amplified DNA Assay

CE 8080185(04)
2017-02

Contact your local BD representative for instructions. / Свържете се с местния представител на BD за инструкзии. / Pokyny vám poskytne místní zástupce společnosti BD. / Kontakt den lokale BD repræsentant for at få instruktioner. / Die Packungsbeilage erhalten Sie bei Ihrer örtlichen BD-Vertretung. / Póngase en contacto con su representante local de BD para instrucciones. / Contacter le représentant local de BD pour les instructions. / Επικοινωνήστε με τον τοπικό αντιπρόσωπο της BD για οδηγίες. / Kasutusjuhiste suhtes kontakteeruge oma kohaliku BD esindajaga. / Ota yhteys lähimpään BD:n edustajaan ohjeiden saamiseksi. / Kontaktiraj lokalnog predstavnika BD za upute. / A használati utasítást kérje a BD helyi képviseletétől. / Rivolgersi al rappresentante BD di zona per istruzioni. / Нұсқаулар үшін жергілікті BD өкілімен хабарласыңыз. / Naudojimo instrukcijų teiraukitės vietos BD įgaliotojo atstovo. / Neem contact op met uw plaatselijke BD-vertegenwoordiger voor instructies. / Kontakt din lokale BD-representant for mer informasjon. / Aby uzyskać instrukcje użytkowania, skontaktuj się z lokalnym przedstawicielstwem BD. / Contacte o representante local da BD para instruções. / Pentru instrucţiuni, contactaţi reprezentantul local BD. / Для получения указаний обратитесь к местному представителю компании BD. / Inštrukcie získate u miestneho zástupcu spoločnosti BD. / Obratite se svom lokalnom predstavniku kompanije BD za uputstva. / Kontakta närmaste BD-representant för anvisningar. / Talimatlar için yerel BD temsilcinizle temasa geçin. / За інструкціями зверніться до місцевого представника компанії BD.

INTENDED USE

The **BD ProbeTec**™ ET *Neisseria gonorrhoeae* (GC) Amplified DNA Assay, when tested with the **BD Viper™** System, uses Strand Displacement Amplification (SDA) technology for the direct, qualitative detection of *Neisseria gonorrhoeae* DNA in endocervical swabs, male urethral swabs, and in female and male urine specimens as evidence of infection with *N. gonorrhoeae*. Specimens may be from symptomatic or asymptomatic females and males. A separate Amplification Control is used for inhibition testing.

SUMMARY AND EXPLANATION

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.[1] *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.[2] Asymptomatic infections occur often in females but infrequently in males.

The current methods for detection of *N. gonorrhoeae* include culture, immunoassays, non-amplified probes, and amplified probes.[1,2] The development of amplified methods has demonstrated two advantages over non-amplified methods: increased sensitivity, and applicability to a variety of sample types. For identification of GC, optimized culture methods continue to be the standard for diagnosing patients with gonococcal infections.

The **BD ProbeTec** ET *Neisseria gonorrhoeae* Amplified DNA Assay, when used with the **BD Viper** System, utilizes 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 *N. gonorrhoeae* DNA in clinical specimens.[3-5]

PRINCIPLES OF THE PROCEDURE

The **BD ProbeTec** ET *Neisseria gonorrhoeae* Amplified DNA Assay is based on the simultaneous amplification and detection of target DNA using amplification primers and a fluorescent labeled detector probe.[4,5] 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 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.

Each sample and control are tested in two discrete microwells: one for *N. gonorrhoeae* and one for the Amplification Control. The purpose of the Amplification Control is to identify a sample that may inhibit the SDA reaction.

REAGENTS

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

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

4 Oligonucleotides ≥ 7 pmol; dNTP ≥ 35 nmol; Detector probe ≥ 25 pmol; 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.

Amplification Control (AC) Priming Microwells, 4 x 96:

4 Oligonucleotides ≥ 7 pmol; dNTP ≥ 35 nmol; Detector probe ≥ 25 pmol; ≥ 1,000 copies per reaction of pGC10 linearized plasmid; with buffers and stabilizers.

Amplification Control (AC) 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.

BD ProbeTec ET (CT/GC) Control Set, 20 CT/GC Positive Controls (50 µL dried) containing 750 copies per reaction of pCT16 linearized plasmid* and 250 copies per reaction of pGC10 linearized plasmid* with ≥ 5 µg Salmon testes DNA; 20 CT/GC Negative Controls (50 µL dried) with ≥ 5 µg 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, **BD Viper** Lysing Heater, **BD Viper** Lysing Rack and base, **BD ProbeTec** Urine Preservative Transport Kit, **BD ProbeTec** ET Sample Tubes and Caps. **BD Viper** pipette tips, tip waste boxes and bags, Amplification (Black) plate sealers, **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, DNA *AWAY*™, 3% (w/v) hydrogen peroxide* or 1% (v/v) sodium hypochlorite, **clean container suitable for holding aliquotted Diluent, timer and absorbent paper, sterile urine specimen collection cups. Empty microwells and alcohol wipes (70% Isopropanol).

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

**Prepare fresh daily.

Storage and Handling Requirements: Reagents may be stored at 2–33 °C. Unopened Reagent Packs are stable until the expiration date. Once a pouch is opened, the microwells are stable for 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. Wear personal protective equipment, including eye protection, when handling biological specimens.
2. This reagent pack is for testing endocervical and male urethral swabs and male and female urine specimens with the **BD Viper** System.
3. 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.
4. 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.
5. For urine specimens, the **BD ProbeTec** Urine Preservative Transport (UPT), and unpreserved (neat) urine have been validated.
6. Laboratories may validate other swab or urine collection and transport devices for use with the **BD ProbeTec** ET GC assay 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. Do not interchange or mix kit reagents from kits with different lot numbers.
9. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions" [6-9] and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.
10. 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).
11. 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.
12. The plate containing the Amplification Microwells MUST be properly sealed with the black Amplification sealer. Sealing ensures a closed reaction for amplication 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.**

13. 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 a plate sealer prior to disposal.
14. 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.
15. 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.
16. Because of the potential for false positivity with some non-gonococcal *Neisseria* found in the respiratory tract (see "Limitations of the Procedure," #19), contamination of reagents and specimens with respiratory aerosols should be avoided.
17. 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.
18. In the event of contamination of the work area or equipment with samples or controls, thoroughly clean the contaminated area with DNA *AWAY, 3% (w/v) hydrogen peroxide* or 1% (v/v) sodium hypochlorite and rinse thoroughly with water. Allow surface to dry completely before proceeding.
19. Clean the entire work area – counter tops and instrument surfaces – with DNA *AWAY, 3% hydrogen peroxide* or 1% (v/v) sodium hypochlorite on a daily basis. Thoroughly rinse with water. Allow surfaces to dry completely before proceeding with additional testing.
20. Do not use ELIMINase or Alconox for cleaning the **BD Viper** System.
21. When using hydrogen peroxide as a cleaning agent, do not use hydrogen peroxide from a bottle that has been open > 8 days.
22. 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.

SAMPLE COLLECTION AND TRANSPORT

The **BD Viper** System is designed to detect the presence of *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** System 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 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, 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. In addition, storage up to 30 days at 2–8 °C 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.

Specimen Type to be Processed	**Female Endocervical**		**Male Urethral**	
Temperature Condition for Transport to Test Site and Storage	2–27 °C	2–8 °C	2–27 °C	2–8 °C
Process Specimen According to Instructions	Within 4–6 days of collection	Within 30 days of collection	Within 4–6 days of collection	Within 30 days of collection

URINE SPECIMEN COLLECTION, STORAGE AND TRANSPORT

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

Urine Specimen Type to be Processed	**NEAT**			**UPT**		
				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**	
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
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

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.

TEST PROCEDURE

The optimum environmental conditions for the 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 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 and maintaining the instrument.

TESTING PROCEDURE FOR THE GC/AC REAGENT PACK: REFER TO THE BD VIPER INSTRUMENT USER'S MANUAL ADDENDUM FOR THE TEST PROCEDURE.

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. Controls may be randomly positioned. 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 CLSI C24-A3.[10] Additional controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations. Refer to CLSI C24-A3 for additional guidance on appropriate internal quality control testing practices. 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.

Correct positioning of the microwell strips is important for proper result reporting. Refer to the **BD Viper** Instrument User's Manual Addendum 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.")

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 a fresh CT/GC Negative Control Tube and a fresh 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.

Once the controls have been prepared, continue with testing as described in the **BD Viper** Instrument User's Manual Addendum.

When the GC/AC Reagent Pack is used, the AC must be included for each patient sample and control. The Amplification Control microwells contain ≥ 1,000 copies per reaction of pGC10 linearized plasmid that should be amplified in the sample matrix. The amplification control is designed to identify samples that may contain amplification inhibitors that could prevent detection of GC DNA if present. (See "Interpretation of Results.")

Intepretation of Control Results:

Control Interpretation without the AC

	GC MOTA Score	**Result**
CT/GC Positive Control	MOTA ≥ 2000	Acceptable
CT/GC Negative Control	MOTA < 2000	Acceptable

Control Interpretation with the AC

	GC MOTA Score	**AC MOTA Score***	**Result**
CT/GC Positive Control	MOTA ≥ 2000	MOTA ≥ 1000	Acceptable
CT/GC Negative Control	MOTA < 2000	MOTA ≥ 1000	Acceptable

* If the AC fails (MOTA < 1000), the control fails.

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.

***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% CO_2 for 24–48 h.
3. Resuspend colonies from the chocolate agar plate with phosphate buffered saline (PBS).
4. Dilute cells in PBS to a 1.0 McFarland turbidity standard (approximately 3 X 10^8 cells/mL).
5. Prepare 10-fold serial dilutions to a 10^5 dilution of the McFarland (at least 5 mL final volume) in PBS.
6. Place 4 mL of the 10^5 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: Refer to the BD Viper Instrument User’s Manual Addendum.

INTERPRETATION OF TEST RESULTS

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

The presence or absence of *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 GC/AC Reagent Pack:

***N. gonorrhoeae* Result Interpretation with AC**

GC MOTA Score	AC MOTA Score	Report	Interpretation	Result
≥ 10,000	Any	*N. gonorrhoeae* detected by SDA	Positive for *N. gonorrhoeae*. *N. gonorrhoeae* organism viability and/or infectivity cannot be inferred since target DNA may persist in the absence of viable organisms.	Positive[1]
2,000–9,999	Any	*N. gonorrhoeae* detected by SDA	*N. gonorrhoeae* likely. Supplemental testing may be useful for verifying presence of *N. gonorrhoeae*.[2]	Low Positive[1,2,3]
< 2,000	≥ 1,000	*N. gonorrhoeae* not detected by SDA	Presumed negative for *N. gonorrhoeae*. A negative result does not preclude *N. gonorrhoeae* infection because results are dependent on adequate specimen collection, absence of inhibitors, and sufficient DNA to be detected.	Negative
< 2,000	< 1,000	Amplification control inhibited. Repeat test [4]	Repeatedly inhibitory specimen. *N. gonorrhoeae*, if present, would not be detectable using SDA. Submit another specimen for testing.	Indeterminate

[1] According to CDC guidelines, "consideration should be given to routine additional testing for persons with positive *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."[11] Refer to CDC guidelines for details on additional testing and patient management after a positive screening test.

[2] Refer to cutoff description and Figures 2 and 3 in "Performance Characteristics" of the **BD ProbeTec** ET CT/GC Amplified DNA Assay package insert for additional information on the distribution of 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.

[4] Repeat **BD Viper** test. For urines, repeat from the original specimen. If original specimen not available, repeat from the processed sample tube. For swabs, repeat from the processed sample tube. If repeat result is either positive or negative, interpret as described above. If results repeat as indeterminate, a new specimen should be requested.

Determination of GC/AC Cutoff:

The assay and amplification control cutoffs for 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 GC assay and culture and another amplified method. These studies show that for the majority of the time, GC MOTA values greater than 2,000 will indicate the presence of *N. gonorrhoeae*. GC MOTA values less than 2,000 correlate with negative *N. gonorrhoeae* culture results the majority of the time. GC positive results with MOTA values between 2,000 and 10,000 had a decreased likelihood of being true positive compared to results with MOTA values above 10,000. Refer to Figure 3 of the **BD ProbeTec** ET CT/GC Amplified DNA package insert for the distribution of 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. 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 urogenital infection, positive results should be carefully assessed and the patient retested by other methods (e.g., culture for GC) if appropriate.

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 *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 *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 neat urine and the UPT). 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.
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 *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 *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.
10. The **BD ProbeTec** ET system cannot be used to assess therapeutic success or failure since nucleic acids from *Neisseria gonorrhoeae* may persist following antimicrobial therapy.
11. The **BD ProbeTec** ET *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.
12. The predictive value of an assay depends on the prevalence of the disease in any particular population. Refer to the **BD ProbeTec** ET CT/GC Amplified DNA Assay package insert for hypothetical predictive values when testing varied populations.
13. Correct positioning of the microwell strips is important for final results reporting. Refer to the **BD Viper** Instrument User's Manual Addendum for correct microwell strip positioning.
14. Use of the **BD ProbeTec** ET *Neisseria gonorrhoeae* Amplified DNA Assay is limited to personnel who have been trained in the assay procedure and the **BD ProbeTec** ET system.
15. 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 GC Assay results. Refer to "Performance Characteristics" for specific performance of female swab specimens with observed blood.
16. 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.
17. Leukocytes in excess of 250,000 cells/mL (swab specimens) may cause indeterminate or false negative results.
18. The presence of serum, feminine deodorant sprays or talcum powder may cause false negative results (urine specimens).
19. The **BD ProbeTec** ET *N. gonorrhoeae* Amplified DNA Assays may cross-react with *N. cinerea* and *N. lactamica*. Refer to "Performance Characteristics" for further information.
20. The reproducibility of the **BD ProbeTec** ET 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 *N. gonorrhoeae* only has not been determined.
21. 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.
22. Testing urine specimens from female patients as the sole test for identifying gonococcal infections may miss infected individuals (11/80 or 13.8% of females with GC-positive cultures had negative results when urine only was tested) with the **BD ProbeTec** ET GC Assay.
23. Because the AC uses GC target, the efficacy of the AC for detecting inhibition is reduced in GC infected samples. Refer to "Performance Characteristics" for results with co-infected patients.
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).

EXPECTED RESULTS: Refer to the BD Viper Instrument User's Manual Addendum and the BD ProbeTec ET CT/GC Amplified DNA Assay package insert for expected results.

PERFORMANCE CHARACTERISTICS: Refer to the BD Viper Instrument User's Manual Addendum and the BD ProbeTec ET CT/GC Amplified DNA Assay package insert for performance characteristics.

AVAILABILITY

The following **BD ProbeTec** ET 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.
440461	**BD ProbeTec™** ET *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/GC) Amplified DNA Assay Male Urethral Specimen Collection and DRY TRANSPORT Kit, 1 x 100.
440476	**BD ProbeTec™** ET *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/GC) Amplified DNA Assay Endocervical Specimen Collection and DRY TRANSPORT Kit, 100 each.
440474	**BD ProbeTec™** ET CT/AC Reagent Pack, 384 tests.
440928	**BD ProbeTec™** Urine Preservative Transport Kit, 100/box.

The following strain is available from:

American Type Culture Collection (ATCC)
10801 University Boulevard
Manassas, VA 20110-2209, USA.
ATCC Strain # 19424 *Neisseria gonorrhoeae*

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

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For IVD Performance evaluation only / Само за оценка качеството на работа на IVD / Pouze pro vyhodnocení výkonu IVD / Kun til evaluering af IVD ydelse / Nur für IVD-Leistungsbewertungszwecke / Μόνο για αξιολόγηση απόδοσης IVD / Sólo para la evaluación del rendimiento en diagnóstico in vitro / Ainult IVD seadme hindamiseks / Réservé à l’évaluation des performances IVD / Samo u znanstvene svrhe za In Vitro Dijagnostiku / Kizárólag in vitro diagnosztikához / Solo per valutazione delle prestazioni IVD / Жасанды жағдайда «пробирка ішінде»,диагностикада тек жұмысты бағалау үшін / IVD 성능 평가에 대해서만 사용 / Tik IVD prietaisų veikimo charakteristikoms tikrinti / Vienīgi IVD darbības novērtēšanai / Uitsluitend voor doeltreffendheidsonderzoek / Kun for evaluering av IVD-ytelse / Tylko do oceny wydajności IVD / Uso exclusivo para avaliação de IVD / Numai pentru evaluarea performanţei IVD / Только для оценки качества диагностики in vitro / Určené iba na diagnostiku in vitro / Samo za procenu učinka u in vitro dijagnostici / Endast för utvärdering av diagnostisk användning in vitro / Yalnızca IVD Performans değerlendirmesi için / Тільки для оцінювання якості діагностики in vitro / 仅限 IVD 性能评估

For US: “For Investigational Use Only”

Lower limit of temperature / Долен лимит на температурата / Dolní hranice teploty / Nedre temperaturgrænse / Temperaturuntergrenze / Κατώτερο όριο θερμοκρασίας / Límite inferior de temperatura / Alumine temperatuuripiir / Limite inférieure de température / Najniža dozvoljena temperatura / Alsó hőmérsékleti határ / Limite inferiore di temperatura / Температураның төменгі рұқсат шеті / 하한 온도 / Žemiausia laikymo temperatūra / Temperatūras zemākā robeža / Laagste temperatuurlimiet / Nedre temperaturgrense / Dolna granica temperatury / Limite mínimo de temperatura / Limită minimă de temperatură / Нижний предел температуры / Spodná hranica teploty / Donja granica temperature / Nedre temperaturgräns / Sıcaklık alt sınırı / Мінімальна температура / 温度下限

CONTROL — Control / Контролно / Kontrola / Kontrol / Kontrolle / Μάρτυρας / Kontroll / Contrôle / Controllo / Бақылау / 컨트롤 / Kontrolė / Kontrole / Controle / Controlo / Контроль / kontroll / Контроль / 对照

CONTROL + — Positive control / Положителен контрол / Pozitivní kontrola / Positiv kontrol / Positive Kontrolle / Θετικός μάρτυρας / Control positivo / Positiivne kontroll / Contrôle positif / Pozitivna kontrola / Pozitív kontroll / Controllo positivo / Оң бақылау / 양성 컨트롤 / Teigiama kontrolė / Pozitīvā kontrole / Positieve controle / Kontrola dodatnia / Controlo positivo / Control pozitiv / Положительный контроль / Pozitif kontrol / Позитивний контроль / 阳性对照试剂

CONTROL – — Negative control / Отрицателен контрол / Negativní kontrola / Negativ kontrol / Negative Kontrolle / Αρνητικός μάρτυρας / Control negativo / Negatiivne kontroll / Contrôle négatif / Negativna kontrola / Negatív kontroll / Controllo negativo / Негативтік бақылау / 음성 컨트롤 / Neigiama kontrolė / Negatīvā kontrole / Negatieve controle / Kontrola ujemna / Controlo negativo / Control negativ / Отрицательный контроль / Negatif kontrol / Негативний контроль / 阴性对照试剂

STERILE EO — Method of sterilization: ethylene oxide / Метод на стерилизация: етиленов оксид / Způsob sterilizace: etylenoxid / Steriliseringsmetode: ethylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / Método de esterilización: óxido de etileno / Steriliseerimismeetod: etüleenoksiid / Méthode de stérilisation : oxyde d’éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszere: etilén-oxid / Metodo di sterilizzazione: ossido di etilene / Стерилизация әдісі – этилен тотығы / 소독 방법: 에틸렌옥사이드 / Sterilizavimo būdas: etileno oksidas / Sterilizēšanas metode: etilēnoksīds / Gesteriliseerd met behulp van ethyleenoxide / Steriliseringsmetode: etylenoksid / Metoda sterylizacji: tlenek etylu / Método de esterilização: óxido de etileno / Metodă de sterilizare: oxid de etilenă / Метод стерилизации: этиленоксид / Metóda sterilizácie: etylénoxid / Metoda sterilizacije: etilen oksid / Steriliseringsmetod: etenoxid / Sterilizasyon yöntemi: etilen oksit / Метод стерилізації: етиленоксидом / 灭菌方法：环氧乙烷

STERILE R Method of sterilization: irradiation / Метод на стерилизация: ирадиация / Způsob sterilizace: záření / Steriliseringsmetode: bestråling / Sterilisationsmethode: Bestrahlung / Μέθοδος αποστείρωσης: ακτινοβολία / Método de esterilización: irradiación / Steriliseerimismeetod: kiirgus / Méthode de stérilisation : irradiation / Metoda sterilizacije: zračenje / Sterilizálás módszere: besugárzás / Metodo di sterilizzazione: irradiazione / Стерилизация әдісі – сәуле түсіру / 소독 방법: 방사 / Sterilizavimo būdas: radiacija / Sterilizēšanas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Steriliseringsmetode: bestråling / Metoda sterylizacji: napromienianie / Método de esterilização: irradiação / Metodă de sterilizare: iradiere / Метод стерилизации: облучение / Metóda sterilizácie: ožiarenie / Metoda sterilizacije: ozračavanje / Steriliseringsmetod: strålning / Sterilizasyon yöntemi: irradyasyon / Метод стерилізації: опроміненням / 灭菌方法：辐射

Biological Risks / Биологични рискове / Biologická rizika / Biologisk fare / Biogefährdung / Βιολογικοί κίνδυνοι / Riesgos biológicos / Bioloogilised riskid / Risques biologiques / Biološki rizik / Biológiailag veszélyes / Rischio biologico / Биологиялық тәуекелдер / 생물학적 위험 / Biologinis pavojus / Bioloģiskie riski / Biologisch risico / Biologisk risiko / Zagrożenia biologiczne / Perigo biológico / Riscuri biologice / Биологическая опасность / Biologické riziko / Biološki rizici / Biologisk risk / Biyolojik Riskler / Біологічна небезпека / 生物学风险

Caution, consult accompanying documents / Внимание, направете справка в придружаващите документи / Pozor! Prostudujte si přiloženou dokumentaci! / Forsigtig, se ledsagende dokumenter / Achtung, Begleitdokumente beachten / Προσοχή, συμβουλευτείτε τα συνοδευτικά έγγραφα / Precaución, consultar la documentación adjunta / Ettevaatust! Lugeda kaasnevat dokumentatsiooni / Attention, consulter les documents joints / Upozorenje, koristi prateću dokumentaciju / Figyelem! Olvassa el a mellékelt tájékoztatót / Attenzione: consultare la documentazione allegata / Абайлаңыз, тиісті құжаттармен танысыңыз / 주의, 동봉된 설명서 참조 / Dėmesio, žiūrėkite pridedamus dokumentus / Piesardzība, skatīt pavaddokumentus / Voorzichtig, raadpleeg bijgevoegde documenten / Forsiktig, se vedlagt dokumentasjon / Należy zapoznać się z dołączonymi dokumentami / Cuidado, consulte a documentação fornecida / Atenţie, consultaţi documentele însoţitoare / Внимание: см. прилагаемую документацию / Výstraha, pozri sprievodné dokumenty / Pažnja! Pogledajte priložena dokumenta / Obs! Se medföljande dokumentation / Dikkat, birlikte verilen belgelere başvurun / Увага: див. супутню документацію / 小心，请参阅附带文档。

Upper limit of temperature / Горен лимит на температурата / Horní hranice teploty / Øvre temperaturgrænse / Temperaturobergrenze / Ανώτερο όριο θερμοκρασίας / Límite superior de temperatura / Ülemine temperatuuripiir / Limite supérieure de température / Gornja dozvoljena temperatura / Felső hőmérsékleti határ / Limite superiore di temperatura / Температураның руқсат етілген жоғарғы шеті / 상한 온도 / Aukščiausia laikymo temperatūra / Augšējā temperatūras robeža / Hoogste temperatuurlimiet / Øvre temperaturgrense / Górna granica temperatury / Limite máximo de temperatura / Limită maximă de temperatură / Верхний предел температуры / Horná hranica teploty / Gornja granica temperature / Övre temperaturgräns / Sıcaklık üst sınırı / Максимальна температура / 温度上限

Keep dry / Пазете сухо / Skladujte v suchém prostředí / Opbevares tørt / Trocklagern / Φυλάξτε το στεγνό / Mantener seco / Hoida kuivas / Conserver au sec / Držati na suhom / Száraz helyen tartandó / Tenere all'asciutto / Құрғақ күйінде ұста / 건조 상태 유지 / Laikykite sausai / Uzglabāt sausu / Droog houden / Holdes tørt / Przechowywać w stanie suchym / Manter seco / A se feri de umezeală / Не допускать попадания влаги / Uchovávajte v suchu / Držite na suvom mestu / Förvaras torrt / Kuru bir şekilde muhafaza edin / Берегти від вологи / 请保持干燥

Collection time / Време на събиране / Čas odběru / Opsamlingstidspunkt / Entnahmeuhrzeit / Ώρα συλλογής / Hora de recogida / Kogumisaeg / Heure de prélèvement / Sati prikupljanja / Mintavétel időpontja / Ora di raccolta / Жинау уақыты / 수집 시간 / Paėmimo laikas / Savākšanas laiks / Verzameltijd / Tid prøvetaking / Godzina pobrania / Hora de colheita / Ora colectării / Время сбора / Doba odberu / Vreme prikupljanja / Uppsamlingstid / Toplama zamanı / Час забору / 采集时间

Peel / Обелете / Otevřete zde / Åbn / Abziehen / Αποκολλήστε / Desprender / Koorida / Décoller / Otvoriti skini / Húzza le / Staccare / Ұстіңгі қабатын алып таста / 벗기기 / Plėšti čia / Atlīmēt / Schillen / Trekk av / Oderwać / Destacar / Se dezlipeşte / Отклеить / Odtrhnite / Oljuštiti / Dra isär / Ayırma / Відклеїти / 撕下

Perforation / Перфорация / Perforace / Perforering / Διάτρηση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Тесік тесу / 절취선 / Perforacija / Perforācija / Perforatie / Perforacja / Perfuração / Perforare / Перфорация / Perforácia / Perforasyon / Перфорація / 穿孔

Do not use if package damaged / Не използвайте, ако опаковката е повредена / Nepoužívejte, je-li obal poškozený / Må ikke anvendes hvis emballagen er beskadiget / Inhal beschädigter Packungnicht verwenden / Μη χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά. / No usar si el paquete está dañado / Mitte kasutada, kui pakend on kahjustatud / Ne pas l'utiliser si l'emballage est endommagé / Ne koristiti ako je oštećeno pakiranje / Ne használja, ha a csomagolás sérült / Non usare se la confezione è danneggiata / Егер пакет бұзылған болса, пайдаланба / 패키지가 손상된 경우 사용 금지 / Jei pakuotė pažeista, nenaudoti / Nelietot, ja iepakojums bojāts / Niet gebruiken indien de verpakking beschadigd is / Må ikke brukes hvis pakke er skadet / Nie używać, jeśli opakowanie jest uszkodzone / Não usar se a embalagem estiver danificada / A nu se folosi dacă pachetul este deteriorat / Не использовать при повреждении упаковки / Nepoužívajte, ak je obal poškodený / Ne koristite ako je pakovanje oštećeno / Använd ej om förpackningen är skadad / Ambalaj hasar görmüşse kullanmayın / Не використовувати за пошкодженої упаковки / 如果包装破损，请勿使用

Keep away from heat / Пазете от топлина / Nevystavujte přílišnému teplu / Må ikke udsættes for varme / Vor Wärme schützen / Κρατήστε το μακριά από τη θερμότητα / Mantener alejado de fuentes de calor / Hoida eemal valgusest / Protéger de la chaleur / Držati dalje od izvora topline / Óvja a melegtől / Tenere lontano dal calore / Салқын жерде сақта / 열을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt no karstuma / Beschermen tegen warmte / Må ikke utsettes for varme / Przechowywać z dala od źródeł ciepła / Manter ao abrigo do calor / A se feri de căldură / Не нагревать / Uchovávajte mimo zdroja tepla / Držite dalje od toplote / Får ej utsättas för värme / Isıdan uzak tutun / Берегти від дії тепла / 请远离热源

Cut / Срежете / Odstřihněte / Klip / Schneiden / Κόψτε / Cortar / Lõigata / Découper / Reži / Vágja ki / Tagliare / Кесіңіз / 잘라내기 / Kirpti / Nogriezt / Knippen / Kutt / Odciąć / Cortar / Decupaţi / Отрезать / Odstrihnite / Iseći / Klipp / Kesme / Розрізати / 剪下

Collection date / Дата на събиране / Datum odběru / Opsamlingsdato / Entnahmedatum / Ημερομηνία συλλογής / Fecha de recogida / Kogumiskuupäev / Date de prélèvement / Dani prikupljanja / Mintavétel dátuma / Data di raccolta / Жинаған тізбекүні / 수집 날짜 / Paėmimo data / Savākšanas datums / Verzameldatum / Dato prøvetaking / Data pobrania / Data de colheita / Data colectării / Дата сбора / Dátum odberu / Datum prikupljanja / Uppsamlingsdatum / Toplama tarihi / Дата забору / 采集日期

µL/test / µL/тест / µL/Test / µL/εξέταση / µL/prueba / µL/teszt / µL/테스트 / мкл/тест / µL/tyrimas / µL/pārbaude / µL/teste / мкл/аналіз / µL/检测

Keep away from light / Пазете от светлина / Nevystavujte světlu / Må ikke udsættes for lys / Vor Licht schützen / Κρατήστε το μακριά από το φως / Mantener alejado de la luz / Hoida eemal valgusest / Conserver à l'abri de la lumière / Držati dalje od svjetla / Fény nem érheti / Tenere al riparo dalla luce / Қараңғыланған жерде ұста / 빛을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt no gaismas / Niet blootstellen aan zonlicht / Må ikke utsettes for lys / Przechowywać z dala od źródeł światła / Manter ao abrigo da luz / Feriţi de lumină / Хранить в темноте / Uchovávajte mimo dosahu svetla / Držite dalje od svetlosti / Får ej utsättas för ljus / Işıktan uzak tutun / Берегти від дії світла / 请远离光线

Hydrogen gas generated / Образуван е водород газ / Možnost úniku plynného vodíku / Frembringer hydrogengas / Wasserstoffgas erzeugt / Δημιουργία αερίου υδρογόνου / Producción de gas de hidrógeno / Vesinikgaasi tekitatud / Produit de l'hydrogène gazeux / Sadrži hydrogen vodik / Hidrogén gázt fejleszt / Produzione di gas idrogeno / Газтекгес сутегі пайда болды / 수소 가스 생성됨 / Išskiria vandenilio dujas / Rodas ūdeņradis / Waterstofgas gegenereerd / Hydrogengass generert / Powoduje powstawanie wodoru / Produção de gás de hidrogénio / Generare gaz de hidrogen / Выделение водорода / Vyrobené použitím vodíka / Oslobađa se vodonik / Genererad vätgas / Açığa çıkan hidrojen gazı / Реакція з виділенням водню / 会产生氢气

Patient ID number / ИД номер на пациента / ID pacienta / Patientens ID-nummer / Patienten-ID / Αριθμός αναγνώρισης ασθενούς / Número de ID del paciente / Patsiendi ID / No d'identification du patient / Identifikacijski broj pacijenta / Beteg azonosító száma / Numero ID paziente / Пациенттің идентификациялық нөмірі / 환자 ID 번호 / Paciento identifikavimo numeris / Pacienta ID numurs / Identificatienummer van de patiënt / Pasientens ID-nummer / Numer ID pacjenta / Número da ID do doente / Număr ID pacient / Идентификационный номер пациента / Identifikačné číslo pacienta / ID broj pacijenta / Patientnummer / Hasta kimlik numarası / Ідентифікатор пацієнта / 患者标识号

Fragile, Handle with Care / Чупливо, Работете с необходимото внимание. / Křehké. Při manipulaci postupujte opatrně. / Forsigtig, kan gå i stykker. / Zerbrechlich, vorsichtig handhaben. / Εύθραυστο. Χειριστείτε το με προσοχή. / Frágil. Manipular con cuidado. / Õrn, käsitsege ettevaatlikult. / Fragile. Manipuler avec précaution. / Lomljivo, rukujte pažljivo. / Törékeny! Óvatosan kezelendő. / Fragile, maneggiare con cura. / Сынғыш, абайлап пайдаланыңыз. / 조심 깨지기 쉬운 처리 / Trapu, elkitės atsargiai. / Trausls; rīkoties uzmanīgi / Breekbaar, voorzichtig behandelen. / Ømtålig, håndter forsiktig. / Krucha zawartość, przenosić ostrożnie. / Frágil, Manuseie com Cuidado. / Fragil, manipulaţi cu atenţie. / Хрупкое! Обращаться с осторожностью. / Krehké, vyžaduje sa opatrná manipulácia. / Lomljivo - rukujte pažljivo. / Bräckligt. Hantera försiktigt. / Kolay Kırılır, Dikkatli Taşıyın. / Тендітна, звертатися з обережністю / 易碎，小心轻放

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