BD Affirm™ VPIII
Microbial Identification Test

R_x Only CE IVD

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English

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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 Affirm™ VPIII Microbial Identification Test is a DNA probe test intended for use in the detection and identification of *Candida* species, *Gardnerella vaginalis* and *Trichomonas vaginalis* nucleic acid in vaginal fluid specimens from patients with symptoms of vaginitis/vaginosis.

SUMMARY AND EXPLANATION

Vaginitis, one of the most common problems in clinical medicine, accounts for more than 10 million office visits each year.[1] The three main categories of vaginitis are bacterial vaginosis (BV), yeast vaginitis (candidiasis) and *T. vaginalis* vaginitis (trichomoniasis). BV is the most common vaginal infection, and accounts for 15 to 50% of vaginitis/vaginosis depending upon the patient population.[2,3] While *G. vaginalis* is no longer thought to be the only etiologic agent of BV, it is still considered to be one of the major bacteria contributing to the infection which involves an increase in anaerobic bacteria and reduction in the normal *Lactobacillus* flora. The complications of BV can be especially significant in pregnant women, resulting in increased risk of adverse pregnancy outcome,[4,5] including pre-term labor[6] and birth.[7,8] In addition, recent data suggest BV-associated bacteria in the endometrium may be etiologic agents of endometritis and pelvic inflammatory disease, independent of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* infection.[9] BV is also a risk factor for the development of post-hysterectomy cuff cellulitis.[10] Vaginal candidiasis is the second most common form of vaginal infection seen in varied clinical settings.[3] Three quarters of all adult women will experience at least one episode of vaginal candidiasis during their lifetime, with 40 to 50% experiencing a second episode. Approximately 5% of the adult female population suffers from recurrent, often intractable yeast infection.[3] Trichomoniasis, a non-reportable sexually transmitted disease, has been estimated to affect 180 million annually worldwide.[11] In the United States, an estimated 3 million women contract trichomoniasis each year.[12] Pregnant women positive for *T. vaginalis* are more likely to have pre-term rupture of membranes,[7] as well as pre-term labor and birth.[13] *T. vaginalis* is a risk factor for the development of post-surgical gynecologic infections.[14,15] In addition, *T. vaginalis* is a risk factor for the development of post-hysterectomy cuff cellulitis.[16]

Laboratory methods for the identification of these organisms include microscopic evaluation, amine test, Gram stain, pH and culture.

PRINCIPLES OF THE PROCEDURE

The BD Affirm VPIII Microbial Identification Test is based on the principles of nucleic acid hybridization. In nucleic acid hybridization tests, complementary nucleic acid strands align to form specific, double-stranded complexes called hybrids.

The test uses two distinct single-stranded nucleic acid probes for each organism, a capture probe and a color development probe, that are complementary to unique genetic sequences of the target organisms. The capture probes are immobilized on a bead embedded in a Probe Analysis Card (PAC), which contains a separate bead for each target organism. The color development probes are contained in a multi-well Reagent Cassette (RC).

During sample preparation, the sample is treated with the Lysis Solution (L) and heated. This process ruptures the walls of the organism, releasing the nucleic acid analyte. A second solution, the Buffer Solution (B), is added. This solution stabilizes the nucleic acid and establishes the stringency conditions necessary for specific hybridization. At this point, the sample is added to the first well of the Reagent Cassette (RC) along with the PAC, and automated processing begins. The BD MicroProbe™ Processor moves the PAC from one well of the Reagent Cassette (RC) to another. Hybridization occurs on the PAC beads in the first and second wells of the Reagent Cassette (RC). Hybridization of the analyte to the capture probe on the bead occurs in well 1, and the hybridization of the color development probes occurs in well 2. All unbound sample components and probes are washed away in well 3. Enzyme conjugate binds to the captured analyte in well 4. Unbound conjugate is washed away in wells 5 and 6. In well 7, the indicator substrate is converted to a blue-colored product if bound enzyme conjugate is present on the bead. The final step is reading the results of color development on each of the target organism beads and controls.

REAGENTS

Materials Provided

Probe Analysis Cards (PAC) (24 or 120 tests): Individually packaged cards, wrapped in an absorbent paper towel moistened with a solution containing sodium azide (0.1%, w/v) as a preservative. Each card contains the following five beads: Negative Control, *Trichomonas, Gardnerella, Candida,* and Positive Control.

Reagent Cassettes (RC) (24 or 120 tests): Reagents are sealed in multi-well, foil-covered cassettes. Each cassette has seven wells. From front to back the wells contain:

Well No. 1 Patient Sample Reservoir, supplied empty

Well No. 2 Hybridization Solution, 350 µL: Color development probe, Formamide, Buffered chaotropic solution

Well No. 3 Wash Solution, 750 µL: Detergent, Buffer solution, Preservative (Proclin™)

Well No. 4 Conjugate, 500 µL: Enzyme conjugate, Preservative (Proclin)

Well No. 5 Wash Solution, 750 µL: Detergent, Buffer solution, Preservative (Proclin)

Well No. 6 Wash Solution, 750 µL: Detergent, Buffer solution, Preservative (Proclin)

Well No. 7 Substrate Buffer, 500 µL: Buffered peroxide solution

Substrate Solution (S) (Red Cap, 3.4 mL for 24 tests; Bottle, 12 mL for 120 tests): Individually packaged solution in foil pouch; Indicator substrate, Stabilizing agent, Alcohol.

Lysis Solution (L) (Blue Cap, 10.8 mL for 24 tests; Bottle, 48 mL for 120 tests): Detergent, Buffer solution, Preservative (Proclin).

Buffer Solution (B) (Green Cap, 15 mL for 24 tests; Bottle, 72 mL for 120 tests): Buffered chaotropic solution, Formamide.

Filter Tips (FT) (24 or 120 tests)

Sample Collection Caps (SCC) (24 tests)*

Sample Collection Tubes (SCT) (24 tests)*

Individually wrapped, pre-scored, sterile swabs (24 tests)*

***Not included with 120 test kit.**

Materials Required But Not Provided

Available from BD:

- BD Affirm VPIII Ambient Temperature Transport System
- BD Affirm VPIII Sample Collection Sets
- BD MicroProbe Processor
- BD MicroProbe Lysis Block
- Thermometer
- Suitable Pipette for dispensing 120 test Lysis Solution and Buffer Solution

Warnings and Precautions

For *in vitro* Diagnostic Use.

Read all instructions carefully before use.

For specimen collection, use only the BD Affirm VPIII Ambient Temperature Transport System, the BD Affirm VPIII Sample Collection Set or the swabs provided in the BD Affirm VPIII Microbial Identification Test Kit. Use only vaginal fluid specimens from patients with symptoms of vaginitis/vaginosis. With each test run, monitor the temperature of Lysis Block, 85 ± 5 °C and verify that the testing environment temperature is between 22 and 28 °C.

Danger

H225 Highly flammable liquid and vapor. **H302** Harmful if swallowed. **H315** Causes skin irritation. **H319** Causes serious eye irritation. **H336** May cause drowsiness or dizziness.

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **P241** Use explosion-proof electrical/ventilating/lighting equipment. **P261** Avoid breathing dust/fume/gas/mist/vapors/spray. **P280** Wear protective gloves/protective clothing/eye protection/face protection. **P240** Ground/bond container and receiving equipment. **P242** Use only non-sparking tools. **P243** Take precautionary measures against static discharge. **P264** Wash thoroughly after handling. **P270** Do not eat, drink or smoke when using this product. **P271** Use only outdoors or in a well-ventilated area. **P303+P361+P353** IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. **P305+P351+P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **P321** Specific treatment (see on this label). **P304+P340** IF INHALED: Remove person to fresh air and keep comfortable for breathing. **P312** Call a POISON CENTER or doctor/physician if you feel unwell. **P301+P312** IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. **P332+P313** If skin irritation occurs: Get medical advice/attention. **P337+P313** If eye irritation persists: Get medical advice/attention. **P370+P378** In case of fire: Use for extinction: CO2, powder or water spray. **P330** Rinse mouth. **P302+P352** IF ON SKIN: Wash with plenty of soap and water. **P362+P364** Take off contaminated clothing and wash it before reuse. **P405** Store locked up. **P403+P233** Store in a well-ventilated place. Keep container tightly closed. **P403+P235** Store in a well-ventilated place. Keep cool. **P501** Dispose of contents/container in accordance with local/regional/national/international regulations.

Pathogenic microorganisms including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions"[17-20] and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.

Proper handling and disposal methods should be established. Wipe up spillage of patient specimens immediately and disinfect with an appropriate disinfectant. Treat the cleaning materials as biohazardous waste.

The sterile swab should not be used if the packaging is open or damaged. Avoid touching the beads. Avoid contaminating tips of dropper bottles. Do not use a reagent after its expiration date.

The swab is for single use only; reuse may cause a risk of infection and/or inaccurate results.

Preparation of Reagents

All reagents are supplied ready for use.

Storage of Reagents

The BD Affirm VPIII test kit is stable until the expiration date indicated on the kit box when stored at 2 to 8 °C. Alternatively, store at room temperature (up to 30 °C) no more than 3 months. All reagents and PACs must be at 22 to 28 °C prior to use. For convenience, store all reagents at room temperature once opened. If refrigerated, allow to sit at room temperature a minimum of 30 min prior to use.

Note: The Buffer Solution (B) precipitates under refrigeration. Allow the solution to come to room temperature for at least 30 min and then agitate the bottle for 10 to 15 s until any precipitate is dissolved.

Indications of Instability

Indications of possible reagent deterioration noted at the end of testing are: a positive control that is NOT blue, a negative control that is NOT colorless.

SPECIMEN COLLECTION AND TRANSPORTATION

Specimen Collection

Specimen collection is a critical step. Personnel collecting vaginal fluid specimens should be well-trained to minimize the possibility of inadequate specimens. For specimen collection, use only the BD Affirm VPIII Ambient Temperature Transport System, the BD Affirm VPIII Sample Collection Set or the swabs provided in the BD Affirm VPIII Microbial Identification Test Kit. **Separate swabs should be used for other tests, e.g. culture or microscopic slide samples.**

Vaginal Sample Collection

1. Label the Sample Collection Tube (SCT) with the patient identification information. Include the time the sample was collected.
2. Place the patient in position for a pelvic examination. Insert a speculum into the vagina to permit visualization of the posterior vaginal fornix.*
3. Using the sterile swab, obtain a sample from the posterior vaginal fornix. Twist or roll the swab against the vaginal wall two or three times, ensuring the entire circumference of the swab has touched the vaginal wall. Swab the lateral vaginal wall while removing the swab.
4. Immediately place the swab into the Sample Collection Tube (SCT).
5. With the swab touching the **BOTTOM** of the collection tube, grasp the pre-scored handle of the swab just above the top of the tube and bend until the swab breaks. When the swab is fully inserted into the collection tube, the score mark on the swab is approximately 1 cm above the top of the collection tube. Discard the broken handle into an infectious waste container.
6. Place the cap over the exposed end of the swab and firmly press the cap onto the tube. The cap will "snap" onto the tube when it is properly seated.

*During clinical trials, sites were provided with instructions to use an unlubricated speculum. Refer to the section on "Interfering Substances."

Specimen Storage and Transporation

When using the BD Affirm VPIII Ambient Temperature Transport System (ATTS): The total time between sample collection and proceeding with sample preparation should be no longer than 72 h when the specimen is stored at ambient conditions (15 to 30 °C). The system has also been qualified for transport use at refrigerated conditions (2 to 8 °C).

When using either the BD Affirm VPIII Sample Collection Set or the swabs contained in the BD Affirm VPIII Microbial Identification Test Kit: The total time between placing the swab into the sample collection tube and proceeding with the sample preparation should be no longer than 1 h if the sample is stored at room temperature, or 4 h if the sample is stored at 2 to 8 °C.

PROCEDURE

Read all instructions carefully before proceeding.

Sample Preparation

Refer to Procedural Chart Illustrations that came with the BD MicroProbe Processor

1. Verify that the BD MicroProbe Lysis Block is at 85 ± 5 °C, and that reagents are at 22–28 °C and well mixed.
2. Uncap the sample collection tube (SCT), making sure the swab shaft is firmly seated in the cap. Add 12 drops or Pipette 0.4 mL of Lysis Solution (L) to the tube. Hold the dropper bottle vertically when adding drops.
3. Mix the swab in the tube by vigorously swirling and moving the swab up and down against the side of the tube for at least 10 s, or vortex tube for 2–4 s.
4. Place the swab with cap back into the tube and recap to prevent evaporation.

5. Insert the tube into a well of the Lysis Block to heat.
6. Incubate the tube in the Lysis Block for 10 min (at least 10 min, but not longer than 20 min). Use a timer for this step.
7. Remove the tube from the Lysis Block.
8. Add 12 drops or Pipette 0.6 mL of well-mixed Buffer Solution (B) to the tube containing the swab. Avoid touching the tip of the bottle to the tube.
9. Replace the cap tightly on the tube and mix by flicking the tube briskly 10 times, or vortex tube for 2–4 s.
10. To proceed with automated processing of the prepared sample, remove as much fluid as possible from the swab by lifting the swab above the fluid level and pressing the swab firmly against the side of the tube for at least 10 s. Dispose of swabs in a biohazard container. Press a Filter Tip (FT) firmly onto each Sample Collection Tube (SCT).

NOTE: Prepared specimens may be stored at room temperature for up to 24 h.

Automated Processing

Note: Before proceeding, ensure that all reagents are at 22–28 °C. With each test run, verify that the testing environment is between 22 and 28 °C.

Refer to Procedural Chart Illustrations that came with the BD MicroProbe Processor

1. If the BD Affirm VPIII Microbial Identification Test Program Card is not already in the BD MicroProbe Processor, insert the Program Card, printed side up, arrow pointing towards the instrument, into the slot located on the front right side of the instrument. Make sure that the Processor is off when inserting the program card. There are no lights on the control panel if the Processor is off.
2. **Turn on the Processor**. The Processor arm will move to “home” during this initial step. As you move through the procedure, follow the prompts on the Processor Display. If additional help is needed, press the [HELP] key.
3. Remove the Cassette Caddy from the Processor. It is easier to add the samples with the Caddy off the Processor.
4. Select one Reagent Cassette (RC) for each sample to be tested, label with patient/sample identification on the front end of the Reagent Cassette (RC) using a permanent-marking pen. Carefully pull the foil covering off of the Cassette, lifting from the end WITHOUT the upward bent flap. Place the Reagent Cassettes (RC) on the Cassette Caddy, loading from the center to the sides and balance the number of cassettes on each side of the arm as evenly as possible.
5. Open pouch containing the PAC, remove PAC slightly from pouch, and label with patient/sample identification on the PAC in the space provided.
6. Press the [RUN] key. You will be prompted to “Add Substrate.” Add 4 drops (0.1 mL) of Substrate Solution (S) to well #7 of the Reagent Cassette (RC). Close the bottle cap to avoid evaporation.
7. Press the [RUN] key. You will be prompted to “Add Sample.” Match up each Sample Collection Tube (SCT)/Filter Tip (FT) with the corresponding labeled Reagent Cassette (RC). Invert the Sample Collection Tube (SCT) and firmly squeeze the entire contents of each tube through the Filter Tip (FT) into reservoir of well #1 of the appropriate Reagent Cassette (RC). Dispose of patient sample tube in a biohazard container. Foam at the filter tip is a good indication that the entire sample has been delivered.
8. Press the [RUN] key. You will be prompted to “Place PAC.” Place a labeled PAC into Well 1 of each corresponding labeled Reagent Cassette (RC). Avoid touching beads.
9. Press the [RUN] key. You will be prompted to “Place Caddy.” Carefully replace the Cassette Caddy on the Processor, taking care not to splash reagents. Assure that the Caddy is securely seated on all four locator pins.
10. Press the [RUN] key again. The arm of the Processor will start forward. The Processor will automatically pick up and move the PACs through the test procedure. The instrument will begin the processing time sequence and will indicate “Please wait. Processing 32:50” with minutes remaining on the timer indicated. At the end of the processing time, the instrument will beep and present the PAC for removal.
11. Remove the PAC, and gently blot dry with a paper towel. Interpret the results for each specimen as soon as possible after completion of the test. The PAC should be viewed against a white background, under normal intensity lighting.

Note: Remove PACs from the Processor before pressing the [RUN] key to start a second run.

QUALITY CONTROL

The BD Affirm VPIII Microbial Identification Test includes two internal controls on each PAC: a Positive Control bead and a Negative Control bead. These control beads are tested simultaneously with each patient specimen, ensuring the proper performance of PAC, Reagent Cassette (RC) and Processor. The Positive Control also ensures the absence of specimen interference. The Negative Control also ensures the absence of non-specific binding from the specimen.

In a properly functioning test, the Positive Control bead will be blue and the Negative Control bead remains colorless (i.e., absence of blue color) after processing. If the Positive Control does not turn blue, and/or the Negative Control does not stay colorless, the test results are invalid and patient results should not be reported.

Each reagent lot must be tested for adequate sample lysis and release of target nucleic acid using a swab streak of fresh indicator culture (18–24 h growth) or commercially prepared swab of *Candida albicans* (ATCC® 18804, 14053, 10231 or 60193). Since *Trichomonas vaginalis* and *Gardnerella vaginalis* lyse more readily than *Candida* species, it is only necessary to test *Candida* species to assure adequate sample lysis. The adequacy of the sample lysis process is confirmed if testing of *Candida albicans* results in a blue *Candida* bead, a colorless *Gardnerella* bead, a colorless *Trichomonas* bead and acceptable results for the internal controls (i.e., blue Positive Control bead and colorless Negative Control bead).

To further verify test performance, quality control testing with *C. albicans* (ATCC 10231), *T. vaginalis* (ATCC 30001) and *G. vaginalis* (ATCC 14018) may be conducted using fresh indicator cultures (18–24 h growth) or commercially prepared swabs.

If quality control (QC) testing with all three organisms, ensure that the results for the internal controls are both acceptable (i.e., blue Positive Control bead and colorless Negative Control bead) and interpret results as follows:

1. If all three organism beads turn blue, all patient results can be reported.
2. If the *Candida* bead does not turn blue, the entire QC run is invalid. The QC failure must be investigated and no patient results can be reported. Contact Technical Services for assistance.
3. If the *Candida* and *Gardnerella* beads turn blue, but the *Trichomonas* bead does not, the QC run is valid for *Candida* and *Gardnerella*. Patient results may be reported for *Candida* and *Gardnerella* only. The QC failure must be investigated. Contact Technical Services for assistance.
4. If the *Candida* and *Trichomonas* beads turn blue, but the *Gardnerella* bead does not, the QC run is valid for *Candida* and *Trichomonas*. Patient results may be reported for *Candida* and *Trichomonas* only. The QC failure must be investigated. Contact Technical Services for assistance.

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

INTERPRETATION OF RESULTS

Results are determined by the presence or absence of color on the test bead. The presence of any visible blue color on the target organism bead, when viewed against a white background, is a positive result. The absence of any visible blue color on the target organism bead is a negative result.

A positive result for *Candida*, *Gardnerella* and/or *Trichomonas* means nucleic acid for *Candida* species (*C. albicans*, *C. glabrata*, *C. kefyr*, *C. krusei*, *C. parapsilosis*, *C. tropicalis*), *G. vaginalis* and/or *T. vaginalis*, respectively, is present in the sample and indicates the patient has candidiasis, bacterial vaginosis, and/or trichomoniasis when consistent with clinical signs and symptoms. Simultaneous infections by more than one organism are common.

Negative results for *Candida*, *Gardnerella* or *Trichomonas* tests suggest the patient does not have candidiasis, bacterial vaginosis and/or trichomoniasis, respectively, when consistent with clinical signs and symptoms.

LIMITATIONS OF THE PROCEDURE

The assay is intended to be used with the BD Affirm VPIII Ambient Temperature Transport System, the BD Affirm VPIII Sample Collection Set, or the swabs provided in the BD Affirm VPIII Microbial Identification Kit. Other methods of collection have not been evaluated.

Optimal test results require appropriate specimen collection. Test results may be affected by improper specimen collection, handling and/or storage conditions. A negative test result does not exclude the possibility of vaginitis/vaginosis.

When using the BD Affirm VPIII Ambient Temperature Transport System, specimens held longer than 72 h at ambient (15 to 30 °C) or refrigerated (2 to 8 °C) conditions may cause false results. When using the BD Affirm VPIII Sample Collection Kit or the swabs provided in the BD Affirm VPIII Microbial Identification Kit, specimens held longer than 1 h at room temperature or 4 h at 2 to 8 °C prior to preparation may cause false results. Prepared specimens held longer than 24 h at room temperature prior to processing may give inaccurate results.

When performing this test, the temperature of the testing environment must be 22 to 28 °C.

A negative result for *Candida*, *Gardnerella* and/or *Trichomonas* indicates nucleic acid from less than 1 x 10^4 *Candida* cells, 2 x 10^5 CFU of *G. vaginalis* or 5 x 10^3 trichomonads, respectively, may be present in the patient sample.

The BD Affirm VPIII Microbial Identification Test detects the presence of *G. vaginalis* at concentrations of greater than 2 x 10^5 CFU per patient sample. The diagnostic value of this level of detection is not definitive.

The presence of *G. vaginalis*, although suggestive, is not diagnostic for bacterial vaginosis. As in many clinical situations, diagnosis should not be based on the results of a single laboratory test. Results should be interpreted in conjunction with other clinical and laboratory data available to the clinician such as pH, amine odor, clue cells and vaginal discharge characteristics.

Women with vaginal discharge should be evaluated for risk factors of cervicitis and pelvic inflammatory disease, and if present, evaluated for other organisms, including *N. gonorrhoeae* and *C. trachomatis.*

Vaginitis/Vaginosis is most frequently caused by *G. vaginalis*, *Candida* species, and *T. vaginalis*. Vaginitis symptoms may also be seen in toxic shock syndrome (caused by *Staphylococcus aureus*) or may be caused by non-specific factors or by specific organisms. Mixed infections may occur. Therefore, a test indicating the presence of *Candida* species, *G. vaginalis*, and/or *T. vaginalis*, does not rule out the presence of other organisms, including *Mobiluncus mulieris, Mycoplasma hominis,* and/or *Prevotella bivia.*

Cryptococcus neoformans at concentrations greater than 1 x 10^8 yeast/mL react with the BD Affirm VPIII Microbial Identification Test for *Candida* species. *C. neoformans* is only rarely encountered in the vagina.

M. mulieris at concentrations greater than 4 x 10^6 bacteria/mL and *Bifidobacterium dentium* at concentrations greater than 8 x 10^5 bacteria/mL may react non-specifically with the BD Affirm VPIII Microbial Identification Test for *G. vaginalis*. *B. dentium* is rarely encountered in the vagina.

The BD Affirm VPIII Microbial Identification Test method is for use with vaginal fluid specimens from patients with symptoms of vaginitis/vaginosis. Performance with other specimens or other patient populations has not been established.

The performance of this test on patient specimens collected during or immediately after antimicrobial therapy is unknown. The presence or absence of *Candida* species, *G. vaginalis* or *T. vaginalis* cannot be used as a test for therapeutic success or failure.

Adulteration of reagents or failure to follow instructions exactly as set forth in the directions for use may adversely affect performance as described in the labeling.

EXPECTED VALUES AND PERFORMANCE CHARACTERISTICS

Independent investigators evaluated the BD Affirm VPIII Microbial Identification Test for *Candida* species, *G. vaginalis* and *T. vaginalis* in vaginal samples. Specimens were from women presenting with symptoms of vaginitis/vaginosis or from women considered at high risk for infection.[21]

The investigators recorded a diagnosis of bacterial vaginosis, candidiasis or trichomoniasis. A specimen was also collected and processed for analysis by the BD Affirm VPIII Microbial Identification Test. In addition, the investigators collected specimens that were sent to the laboratory for culture isolation and identification and for preparation of a smear for analysis by Gram stain.

Candida species

The sensitivity and specificity of the BD Affirm VPIII Microbial Identification Test for *Candida* species were established by comparison to conventional microscopy methods and to culture. The performance of the BD Affirm VPIII Test for *Candida* species and microscopy was evaluated in 479 women who presented with clinical signs and symptoms of yeast vaginitis and in 261 high-risk women who were evaluated for some other reason, including pregnancy (n=186), family planning, or because they are contacts of STD-positive patients. This represents a total of 740 patients tested. A clinically significant level of yeast culture isolation (>10^4 CFU per mL vaginal fluid) was used as the comparative method since this level has been shown, in the literature, to be associated with yeast vaginitis. Approximately 15% of patients samples tested were positive for yeast by the BD Affirm VPIII test and by culture isolation at a clinically significant level.

In cases of apparent false positive results where the BD Affirm VPIII was positive and the comparative result was negative, alternate methods were used to confirm the BD Affirm VPIII result. The reconciled sensitivity/specificity for patients with an initial vaginal complaint (n=479) and for all patients (n=740) was 82%/98.4% and 81%/98.2% respectively. The BD Affirm VPIII test is more sensitive than either wet mount or Gram stain identification of yeast as compared to clinically significant culture. See Table 1.

The unreconciled sensitivity/specificity of the BD Affirm VPIII test compared to clinically significant culture for patients with an initial vaginal complaint (n=479) and for all patients (n=740) was 79%/95% and 78%/95.9% respectively. See Table 1.

Gardnerella vaginalis

The sensitivity and specificity of the BD Affirm VPIII Microbial Identification Test for *G. vaginalis* was established by comparison to a conventional microscopy method and to culture in 299 patients. The BD Affirm VPIII test was compared to clinically significant levels of *G. vaginalis*, identified as >10^5 CFU per mL of vaginal fluid.[13] Of the 299 patients evaluated for BV, 51% (152) were positive based on scored Gram stain and 56% (168) were positive based on clinically significant cultures.

In cases of apparent false positive results where the BD Affirm VPIII was positive and the comparative result was negative, alternate methods were used to confirm the BD Affirm VPIII result. The reconciled sensitivity/specificity of the BD Affirm VPIII test as compared to clinically significant culture levels and Gram stain morphology for patients with clinical BV by 3 of 4 Amstel Criteria (n=129) was 98%/100% and 95%/100% respectively. The reconciled sensitivity/specificity of the BD Affirm VPIII test as compared to clinically significant culture levels and scored Gram stain for all patients (n=299) was 89%/99% and 84%/100% respectively. When evaluated in all women, the BD Affirm VPIII test was both sensitive and specific as compared to the identification of *G. vaginalis* by either Gram stain morphology or by clinically significant culture levels. See Table 1.

The unreconciled sensitivity/specificity of the BD Affirm VPIII test as compared to clinically significant culture and Gram stain for patients with clinical BV by 3 of 4 Amstel Criteria (n= 129) was 98%/41% and 95%/83% respectively. The unreconciled sensitivity/specificity of the BD Affirm VPIII as compared to clinically significant culture and Gram stain for all patients (n=299) was 88%/82% and 84%/96% respectively. See Table 1.

Trichomonas vaginalis

The sensitivity/specificity of the BD Affirm VPIII Microbial Identification Test for *T. vaginalis* were established by comparison to conventional microscopy method and to culture in all 852 patients. Of the 852 patients evaluated 11% (98) were positive based on wet mount and 13% (111) were positive based on clinically significant culture.

In cases of apparent false positive results where the BD Affirm VPIII was positive and the comparative result was negative, alternate methods were used to confirm the BD Affirm VPIII result. The reconciled sensitivity/specificity of the BD Affirm VPIII Microbial Identification Test for *T. vaginalis* as compared to wet mount and clinically significant culture was 93%/99.9% and 90%/99.9% respectively. In this clinical evaluation, the BD Affirm VPIII Microbial Identification Test was comparable in sensitivity to 5 to 7 day culture isolation of *T. vaginalis*. See Table 1.

The unreconciled sensitivity/specificity of the BD Affirm VPIII test as compared to wet mount and clinically significant culture (5–7 days) for all patients was 92%/98% and 89%/99% respectively. See Table 1.

Mixed Infections and BV

The data in a subset of 289 patients in this clinical study was collected by having the attending clinician provide diagnoses of bacterial vaginosis, candidiasis and trichomonasis based on vaginal discharge, pH, amine odor and wet mount results. The overall ability of the attending physician to report a diagnosis of BV using 3 of 4 clinical signs and symptoms was 75% (89/118). In women who had no other cause for their vaginal symptoms except BV, the physician's ability was 82% (79/96). However, in patients who had mixed infections, i.e., candidiasis or trichomoniasis in addition to BV, the sensitivity of the attending physician to diagnose BV was 45% (10/22). Attending clinicians had greater difficulty in diagnosing BV in the presence of mixed infections, where the sensitivity of their initial diagnosis was 45%, as compared to single infections, where the sensitivity of their initial diagnosis was 82%. The diagnosis of BV was under-reported in patients with mixed infections.

Non-Clinical Results

A total of 88 isolates representing 34 different genera of microorganisms identified by Isenberg et al.[22] as clinically relevant to the genitourinary tract were tested for specificity in the BD Affirm VPIII Microbial Identification Test.

Acinetobacter sp. (1)	*Corynebacterium* spp.(1)	*Listeria monocytogenes* (1)	*Porphyromonas* sp. (1)
Actinomyces sp. (1)	*Cryptococcus neoformans* (1)	*Mobiluncus* spp. (3)	*Propionibacterium* sp. (1)
Bacteroides spp. (4)	*Entamoeba* sp. (1)	*Mycobacterium* sp. (1)	*Pseudomonas* sp. (1)
Branhamella sp. (1)	*Enterobacteriaceae* (5)	*Mycoplasma hominis* (1)	*Staphylococcus* spp. (3)
Bifidobacterium sp. (1)	*Enterococcus* sp. (1)	*Neisseria* spp. (2)	*Streptococcus* spp. (3)
Campylobacter sp. (1)	*Fusobacterium* sp. (1)	*Neisseria gonorrhoeae* (1)	*Trichomonas vaginalis* (9)
Candida spp. (16)	*Gardnerella vaginalis* (10)	*Peptococcus* sp. (1)	*Ureaplasma urealyticum* (1)
Chlamydia trachomatis (2)	*Haemophilus ducreyi* (1)	*Peptostreptococcus* spp. (3)	*Veillonella* sp.(1)
Clostridium spp. (2)	*Lactobacillus* spp. (3)	*Prevotella* spp.(2)	

All of the organisms, except *Cryptococcus neoformans* and *Candida* species, were nonreactive in the BD Affirm VPIII Microbial Identification Test for *Candida* species at a concentration of 10^8 organisms/mL.

All of the organisms, except *M. mulieris, B. dentium* and *G. vaginalis* were nonreactive in the BD Affirm VPIII Microbial Identification Test for *G. vaginalis* at a concentration of 10^8 organisms/mL. *M. mulieris* was nonreactive at a concentration of 4×10^6 bacteria/mL, and *B. dentium* was non-reactive at 8×10^5 bacteria/mL. *B. dentium* is only very rarely recovered from the vagina.[23] Most *Bifidobacterium* sp. and strains of *B. dentium* are recovered from body sites other than the vagina or urogenital tract.

All of the organisms except *T. vaginalis* were nonreactive in the BD Affirm VPIII Microbial Identification Test for *T. vaginalis* at a concentration of 10^8 organisms/mL.

Analytical Sensitivity

The BD Affirm VPIII Microbial Identification Test for *Candida* species can detect 1×10^4 CFU of *Candida* species in log phase per assay, 2×10^5 CFU of *G. vaginalis* in log phase per assay and 5×10^3 trichomonads per assay.

Interfering Substances

In clinical studies, no evidence of interference was determined for vaginal lubricants, douches, menses or spermicides.

In analytical studies, there was no evidence of interference with water-based vaginal lubricants.

Reproducibility

The BD Affirm System was evaluated at three typical clinics by three different first time users (nurse practitioners) for reproducibility within and between runs. Each site evaluated 24 coded samples consisting of 12 positives and 12 negative samples. Four runs of six samples per run were performed at each site. Complete agreement of results was obtained on every sample by each of the three sites, demonstrating the reproducibility and ease-of-use of the BD Affirm System within and between runs, and between sites.

AVAILABILITY

Cat. No.	Description
446252	BD Affirm™ VPIII Microbial Identification Test, 24 tests
446257	BD Affirm™ VPIII Microbial Identification Test, 120 tests
446251	BD Affirm™ VPIII Bulk Sample Collection Swabs, 100 swabs
446250	BD Affirm™ VPIII Sample Collection Sets, 24 sets
446255	BD Affirm™ VPIII Ambient Temperature Transport System (72 h transport system), 100 systems
250100	BD MicroProbe™ Processor (120 volt)
211918	BD MicroProbe™ Processor, (220/240 volt)

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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.

TABLE 1
RECONCILED

Symptomatic Patients			**BD Affirm VPIII**			**Wet Mount**			**Gram Stain**	
ORGANISM	**Ref Method**	Sensitivity	Specificity	Accuracy	Sensitivity	Specificity	Accuracy	Sensitivity	Specificity	Accuracy
Candida sp.	**Culture**	82.3% 79/96	98.4% 377/383	95.2% 456/479	71.9% 69/96	92.2% 353/383	88.1% 422/479	45.6% 26/57	99.6% 271/272	90.3% 297/329
G. vaginalis	**Gram Stain**	95.2% 118/124	100% 5/5	95.3% 123/129	— —	— —	— —	— —	— —	— —
	Culture	98.3% 118/120	100% 9/9	98.4% 127/129	— —	— —	— —	— —	— —	— —
All Patients			**BD Affirm VPIII**			**Wet Mount**			**Gram Stain**	
ORGANISM	**Ref Method**	Sensitivity	Specificity	Accuracy	Sensitivity	Specificity	Accuracy	Sensitivity	Specificity	Accuracy
Candida sp.	**Culture**	80.6% 100/124	98.2% 605/616	95.3% 705/740	60% 74/124	94.0% 579/616	88.2% 653/740	44.4% 28/63	99.3% 418/421	92.1% 446/484
G. vaginalis	**Gram Stain**	83.8% 171/204	100% 95/95	89.0% 266/299	— —	— —	— —	— —	— —	— —
	Culture	89.0% 170/191	99.1% 107/108	92.6% 277/299	— —	— —	— —	— —	— —	— —
T. vaginalis	**Wet Mount**	92.8% 103/111	99.9% 740/741	98.9% 843/852	— —	— —	— —	— —	— —	— —
	5-7 Day Culture	89.6% 103/115	99.9% 736/737	98.5% 839/852	82.6% 95/115	99.6% 734/737	97.3% 829/852	— —	— —	— —

UNRECONCILED

Symptomatic Patients			**BD Affirm VPIII**			**Wet Mount**			**Gram Stain**	
ORGANISM	**Ref Method**	Sensitivity	Specificity	Accuracy	Sensitivity	Specificity	Accuracy	Sensitivity	Specificity	Accuracy
Candida sp.	**Culture**	79.3% 65/82	95.0% 377/397	92.3% 442/479	67.1% 55/82	88.9% 353/397	85.2% 408/479	42.6% 23/54	98.5% 271/275	89.4% 294/329
G. vaginalis	**Gram Stain**	95.1% 117/123	83.3% 5/6	94.6% 122/129	— —	— —	— —	— —	— —	— —
	Culture	98.1% 105/107	40.9% 9/22	88.4% 114/129	— —	— —	— —	— —	— —	— —
All Patients			**BD Affirm VPIII**			**Wet Mount**			**Gram Stain**	
ORGANISM	**Ref Method**	Sensitivity	Specificity	Accuracy	Sensitivity	Specificity	Accuracy	Sensitivity	Specificity	Accuracy
Candida sp.	**Culture**	78.0% 85/109	95.9% 605/631	93.2% 690/740	54.1% 59/109	91.8% 579/631	86.2% 638/740	41.7% 25/60	98.6% 418/424	91.5% 443/484
G. vaginalis	**Gram Stain**	83.5% 167/200	96.0% 95/99	87.6% 262/299	— —	— —	— —	— —	— —	— —
	Culture	87.5% 147/168	81.7% 107/131	84.9% 254/299	— —	— —	— —	— —	— —	— —
T. vaginalis	**Wet Mount**	91.8% 90/98	98.1% 740/754	97.4% 830/852	— —	— —	— —	— —	— —	— —
	5-7 Day Culture	89.2% 99/111	99.3% 736/741	98.0% 835/852	82.0% 91/111	99.1% 734/741	96.8% 825/852	— —	— —	— —

*Sensitivity = TP/(TP+FN); Specificity = TN/(TN+FP); Accuracy (TP+TN)/(TP+FP+FN+TN)

Change History

Revision	Date	Change Summary
(04)	2019-06	Converted printed package insert to electronic insert. Additional languages can be found at bd.com/e-labeling. Added access information to obtain instructions for use electronically.

US Customers only: For symbol glossary, refer to www.bd.com/symbols-glossary

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ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutning af måned)
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EEEE-MM-HH / EEEE-MM (MM = τέλος του μήνα)
AAAA-MM-DD / AAAA-MM (MM = fin del mes)
AAAA-KK-PP / AAAA-KK (KK = kuu lõpp)
AAAA-MM-JJ / AAAA-MM (MM = fin du mois)
GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)
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RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
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RRRR-MM-DD / RRRR-MM (MM = koniec mesiaca)
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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 руқсат 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 / Контролно / Kontrola / Kontrol / Kontrolle / Μάρτυρας / Kontroll / Contrôle / Controllo / Бақылау / 컨트롤 / Kontrolė / Kontrole / Controle / Controlo / Контроль / kontroll / Контроль / 对照

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

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

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

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

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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

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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 / Kesiņiз / 잘라내기 / Kirpti / Nogriezt / Knippen / Kutt / Odciąć / Cortar / Decupaţi / Отрезать / Odstrihnite / Iseći / Klipp / Kesme / Розрізати / 剪下

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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 / Газтектес сутеri 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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