BD BBL™ MGIT™

Mycobacteria Growth Indicator Tube, OADC Enrichment, PANTA™ Antibiotic Mixture

R_x Only CE IVD

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INTENDED USE

The BD BBL™ MGIT™ Mycobacteria Growth Indicator Tube supplemented with BD BBL MGIT OADC enrichment and BD BBL™ MGIT™ PANTA™ antibiotic mixture, when appropriate, is intended for the detection and recovery of mycobacteria. Acceptable specimen types are digested and decontaminated clinical specimens (except urine) and sterile body fluids (except blood).

SUMMARY AND EXPLANATION

From 1985 to 1992, the number of MTB cases reported increased 18%. Tuberculosis still kills an estimated 3 million people a year worldwide, making it the leading infectious disease cause of death.[1] Between 1981 and 1987, AIDS case surveillances indicated that 5.5% of the patients with AIDS had disseminated nontuberculous mycobacterial infections, e.g., MAC. By 1990, the increased cases of disseminated nontuberculous mycobacterial infections had resulted in a cumulative incidence of 7.6%.[2] In addition to the resurgence of MTB, multidrug-resistant MTB (MDR-TB) has become an increasing concern. Laboratory delays in the growth, identification and reporting of these MDR-TB cases contributed at least in part to the spread of the disease.[3]

The U.S. Centers for Disease Control and Prevention (CDC) have recommended that every effort must be made by laboratories to use the most rapid methods available for diagnostic mycobacteria testing. These recommendations include the use of both a liquid and a solid medium for mycobacterial culture.[3]

The BD BBL MGIT Mycobacteria Growth Indicator Tube contains 4 mL of modified Middlebrook 7H9 Broth base.[4,5] The complete medium, with 0.5 mL OADC enrichment and 0.1 mL of BD BBL MGIT PANTA antibiotic mixture, is one of the most commonly used liquid media for the cultivation of mycobacteria.

All types of clinical specimens, pulmonary as well as extra-pulmonary (except blood and urine), can be processed for primary isolation in the MGIT tube using conventional methods.[6] The processed specimen is inoculated into a MGIT tube, incubated and read daily from the second day of incubation using a longwave UV light. At the time of tube positivity, there are approximately 10^4–10^7 CFU/mL of mycobacteria present.

PRINCIPLES OF THE PROCEDURE

A fluorescent compound is embedded in silicone on the bottom of 16 x 100 mm round-bottom tubes. The fluorescent compound is sensitive to the presence of oxygen dissolved in the broth. Initially, the large amount of dissolved oxygen quenches emissions from the compound and little fluorescence can be detected. Later, actively respiring microorganisms consume the oxygen and allow the fluorescence to be observed using a 365 nm UV transilluminator or longwave UV light (Wood's lamp). Growth can also be detected by the presence of a non-homogeneous turbidity or small grains or flakes in the culture medium.

The medium components are substances essential for the rapid growth of mycobacteria. Oleic acid is utilized by tubercle bacilli and plays an important role in the metabolism of mycobacteria. Albumin acts as a protective agent by binding free fatty acids, which may be toxic to *Mycobacterium* species, thereby enhancing their recovery. Dextrose is an energy source. Catalase destroys toxic peroxides that may be present in the medium.

Contamination may be reduced by supplementing the combined BD BBL MGIT base and BD BBL MGIT OADC enrichment with the BD BBL MGIT PANTA Antibiotic Mixture prior to inoculation with a clinical specimen.

REAGENTS

The BD BBL MGIT Mycobacteria Growth Indicator Tube contains: 110 µL of fluorescent indicator and 4 mL of broth. The indicator contains Tris 4, 7-diphenyl-1,10-phenanthroline ruthenium chloride pentahydrate in a silicone rubber base. The tubes are flushed with 10% CO_2 and capped with polypropylene caps.

Approximate Formula* Per L Purified Water

Modified Middlebrook 7H9 Broth Base	5.9 g
Casein peptone	1.25 g

BD BBL MGIT OADC contains 15 mL Middlebrook OADC enrichment.

Approximate Formula* Per L Purified Water

Bovine albumin	50.0 g	Catalase	0.03 g
Dextrose	20.0 g	Oleic acid	0.6 g

The BD BBL MGIT PANTA vial contains a lyophilized mixture of antimicrobial agents.

Approximate Formula* Per Vial Lyophilized BD BBL MGIT PANTA

Polymyxin B	6,000 units	Trimethoprim	600 µg
Amphotericin B	600 µg	Azlocillin	600 µg
Nalidixic acid	2,400 µg		

**Adjusted and/or supplemented as required to meet performance criteria.*

Directions for Use: Reconstitute a lyophilized vial of BD BBL MGIT PANTA antibiotic mixture with 3 mL of sterile distilled or deionized water.

Warnings and Precautions: For *in vitro* Diagnostic Use.

Pathogenic microorganisms including Hepatitis B Virus and Human Immunodeficiency Virus may be present in specimens. "Universal Precautions"[1,2] should be followed in handling all items contaminated with blood or other body fluids.

Working with *Mycobacterium tuberculosis* grown in culture requires Biosafety Level 3 practices, containment equipment and facilities.[6]

Prior to use, each MGIT tube should be examined for evidence of contamination or damage. Discard any tubes if they appear unsuitable or exhibit fluorescence prior to use.

Dropped tubes should be examined carefully. If damage is seen, the tube should be discarded.

Wear UV protective glasses when observing fluorescence and use only longwave illumination (365 nm). DO NOT USE SHORTWAVE UV LIGHT FOR READING TUBES.

Autoclave all inoculated MGIT tubes prior to disposal.

Storage of Reagents: BD BBL MGIT Mycobacteria Growth Indicator Tubes – On receipt, store at 2–25 °C (35–77 °F). DO NOT FREEZE. Minimize exposure to light. Broth should appear clear and colorless. Do not use if turbid. MGIT tubes stored as labeled prior to use may be inoculated up to the expiration date and incubated for up to eight weeks.

BD BBL MGIT OADC – On receipt, store in the dark at 2–8 °C. Avoid freezing or overheating. Do not open until ready to use. Minimize exposure to light.

BD BBL MGIT PANTA Antibiotic Mixture – On receipt, store lyophilized vials at 2–8 °C. Once reconstituted, the BD BBL MGIT PANTA mixture may be used within 72 h, provided it is stored at 2–8 °C, or up to 6 months if stored at -20 °C or colder. Once thawed, the BD BBL MGIT PANTA mixture must be used immediately. Discard unused portion.

SPECIMEN COLLECTION AND HANDLING

All specimens should be collected and transported as recommended by the CDC, the *Clinical Microbiology Procedures Handbook* or your laboratory procedure manual.[6,8]

DIGESTION, DECONTAMINATION AND CONCENTRATION

Specimens from different body sites should be processed for inoculation of MGIT tubes as follows:

SPUTUM: Specimens should be processed using the NALC-NaOH method as recommended by the CDC's *Public Health Mycobacteriology: A Guide for the Level III Laboratory*.[6] Alternatively, use the BD BBL™ MycoPrep™ kit for processing mycobacterial specimens (see "Availability").

GASTRIC ASPIRATES: Specimens should be decontaminated as in sputum. If the volume of the specimen is more than 10 mL, concentrate by centrifugation. Resuspend the sediment in about 5 mL of sterile water and then decontaminate. Add a small amount of NALC powder (50–100 mg) if the specimen is thick or mucoid. After decontamination, concentrate again prior to inoculation into MGIT tube.

BODY FLUIDS (CSF, synovial fluid, pleural fluid, etc.): Specimens which are collected aseptically and are expected to have no other bacteria can be inoculated without decontamination. If the specimen volume is more than 10 mL, concentrate by centrifugation at 3,000 *x g* for 15 min. Pour off supernatant fluid. Inoculate MGIT tube with sediment. Specimens that are expected to contain other bacteria must be decontaminated.

TISSUE: Tissue specimens should be processed as recommended by the CDC's *Public Health Mycobacteriology: A Guide for the Level III Laboratory*.[6]

STOOL: Suspend 1 g of feces in 5 mL of Middlebrook Broth. Agitate the suspension on a vortex mixer for 5 sec. Proceed to the NALC-NaOH procedure as recommended by the CDC's *Public Health Mycobacteriology: A Guide for the Level III Laboratory*.[6]

PROCEDURE

Materials Provided: BD BBL MGIT Mycobacteria Growth Indicator Tubes, 4 mL, package of 25 and 100 Tubes, or BD BBL MGIT OADC, 6 vials, 15 mL, or BD BBL MGIT PANTA Antibiotic Mixture, 6 lyophilized vials (see "Availability").

Materials Required But Not Provided: BD Falcon™ brand 50 mL centrifuge tubes, 4% sodium hydroxide, 2.9% sodium citrate solution, N-acetyl-L-cysteine powder, phosphate buffer pH 6.8, vortex mixer, 37 °C incubator, 1 mL sterile pipettes, sterile transfer pipettes, UV transilluminator (365 nm) or Wood's lamp with longwave bulb or blacklight, 0.4% sodium sulfite solution (procedure below), BD BBL™ Middlebrook and Cohn 7H10 Agar, BD BBL MycoPrep, BD BBL™ Middlebrook 7H9 Broth (see "Availability") or other mycobacterial agar or egg-based medium, tissue homogenizer or sterile swab, BD BBL™ Normal Saline (see "Availability"), microscope and materials for staining slides, pipettes 100 µL and 500 µL, corresponding pipette tips, 5% sheep blood agar plate, Eye Guard Spectacles (UVP #UVC-303, San Gabriel, CA) and tuberculocidal disinfectant.

Inoculation of MGIT Tubes:

1. Label the MGIT tube with specimen number.
2. Unscrew the cap and aseptically add 0.5 mL of BD BBL MGIT OADC.
3. Aseptically add 0.1 mL of reconstituted BD BBL MGIT PANTA antibiotic mixture. For best results, the addition of OADC enrichment and BD BBL MGIT PANTA antibiotic mixture should be made just prior to specimen inoculation.
4. Add 0.5 mL of the concentrated specimen suspension prepared above. Also add a drop (0.1mL) of specimen to a 7H10 agar plate or other mycobacterial solid agar or egg-based medium. *NOTE: Specimen volumes greater than 0.5 mL can increase contamination or otherwise adversely affect the performance of the tubes*.
5. Tightly recap the tube and mix well.

6. Tubes should be incubated at 37 °C.

   For specimens in which mycobacteria with different incubation requirements are suspected, a duplicate MGIT tube can be set up and incubated at the appropriate temperature; e.g. 30 °C or 42 °C. Inoculate and incubate at the required temperature.

   For specimens suspected of containing *Mycobacterium haemophilum*, a source of hemin must be introduced into the tube at the time of inoculation and the tube incubated at 30 °C. Aseptically place one disc of BD BBL™ Taxo™ Differentiation Discs X into each MGIT tube requiring the addition of hemin prior to inoculation of specimen (see "Availability").
7. Read tubes daily starting on the second day of incubation following the procedure "Reading the Tubes" below.

Preparation of Interpretive Negative and Positive Control Tubes: Use of the Positive and Negative Control tubes is only for the interpretation of fluorescence and is not intended as a control for the performance of the media.

Positive Control Tube:

1. Empty broth from an uninoculated MGIT tube.
2. Label tube as a Positive Control and record the date.
3. Prepare 0.4% sodium sulfite solution (0.4 g in 100 mL sterile distilled or deionized water). Discard unused portion.
4. Add 5 mL of sodium sulfite solution to the tube, replace the cap, tighten and allow the tube to stand for a minimum of 1 h at room temperature before use.
5. Positive Control tubes can be used many times. Each Positive Control tube can be used for up to four weeks when stored at room temperature.

Negative Control Tube: An unopened, uninoculated MGIT tube is used as a control.

Reading the Tubes:

1. A Positive Control and a Negative Control are important for correctly interpreting results.
2. Remove tubes from the incubator. Place tubes on the UV light next to a Positive Control tube and an uninoculated tube (Negative Control). It is recommended that one rack at a time of tubes (4 by 10 tubes) be placed on the UV light. *NOTE: Wear UV protective glasses when observing fluorescence. Normal room light is preferred. Avoid reading tubes in a sunlit room or in a darkened room.*
3. Visually locate MGIT tubes that show bright fluorescence. Fluorescence is detected as a bright orange color in the bottom of the tube and also an orange reflection on the meniscus. The MGIT tube should then be taken out of the rack and compared to Positive Control and Negative Control tubes. The Positive Control should show a high amount of fluorescence (very bright orange color). The Negative Control should have very little or no fluorescence. If fluorescence in the MGIT tube looks more like the Positive Control, it is a positive tube. If it looks more like the Negative Control, it is a negative tube. Growth can also be detected by the presence of a non-homogeneous turbidity, small grains or flakes in the culture medium.
4. Positive tubes should be stained for acid-fast bacilli. Smear-negative tubes should be checked for bacterial contamination. Subcultures for identification and drug susceptibility testing may be performed using fluid from the MGIT tube.
5. Negative tubes should continue to be read daily for eight weeks or longer depending on the type of specimen and the past experience of the laboratory. Alternative reading schedules may be established. Failure to read the tubes for several days, such as during weekends or holidays, may delay the detection of positive tubes, but will not otherwise adversely affect the performance of the media. Tubes should be visually checked for the presence of turbidity and small grains or granules before discarding. Negative MGIT tubes cannot be reused. If mycobacterial growth is suspected, follow the "Processing a Positive MGIT Tube" procedure as stated below.

Reprocessing Contaminated MGIT Tubes: Contaminated MGIT tubes may be re-decontaminated and re-concentrated using the same procedure used to process the specimen initially.

1. Add the contents of the contaminated MGIT tube to a 50 mL plastic centrifuge tube.
2. Add 5 mL NALC-NaOH solution to the centrifuge tube. With the cap tightened, vortex the tube for 5–20 s.
3. Allow the tube to stand for 15–20 min. Do not treat for more than 20 min.
4. Add 35 mL sterile phosphate buffer pH 6.8. Replace the cap and mix the contents.
5. Concentrate the specimen in a centrifuge at a speed of 3,000 x *g* for 15 min.
6. Carefully decant the supernatant fluid from the pellet. Resuspend the pellet using a sterile Pasteur pipette with phosphate buffer pH 6.8.
7. Inoculate 0.5 mL of the suspension to a new MGIT tube.

User Quality Control: 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.

Quality Control Certificates are provided on the BD website. Quality Control Certificates list test organisms, including ATCC® cultures specified in the CLSI Approved Standard M22-A3, *Quality Control for Commercially Prepared Microbiological Culture Media*.[9]

NOTE: Middlebrook 7H9 Broth (supplemented) is exempt from User QC testing according to CLSI M22-A3.[9]

RESULTS

A culture-positive sample is identified by the observation of fluorescence or non-homogenous turbidity, small grains or flakes in an inoculated MGIT tube. Positive tubes should be subcultured and an acid-fast smear prepared. A positive acid-fast smear result indicates the presumptive presence of viable microorganisms in the tube.

Processing a positive MGIT Tube:

NOTE: All steps should be performed in a biological safety cabinet.

a) Remove MGIT tube from test rack.

b) Using a sterile transfer pipet, remove an aliquot from the bottom of the tube (approx. 0.1 mL) for stain preparations (AFB and Gram stains).

c) Inspect smear and preparations. Report preliminary results only after acid-fast stain evaluation.

If AFB positive, subculture to solid media and report as: Growth positive, AFB smear positive, ID pending.

If microorganisms other than AFB are present, report as: Growth positive, AFB smear negative, Contaminated.

If no microorganisms are present, no reportable result. Subculture broth to blood agar plate and mycobacterial culture medium; repeat smear using the addition of protein to ensure the inoculum has been adequately fixed to the slide.

LIMITATIONS OF THE PROCEDURE

Recovery of mycobacteria in the MGIT tube is dependent on the number of organisms present in the specimen, specimen collection methods, patient factors such as presence of symptoms, prior treatment and the method of processing.

Decontamination with the N-acetyl-L-cysteine Sodium hydroxide (NALC-NaOH) or Oxalic acid methods is recommended. Other decontamination methods have not been tested in conjunction with the MGIT medium. Digestant-decontaminant solutions may have harmful effects on mycobacteria.

Colony morphology and pigmentation can only be determined on solid media. Mycobacteria may vary in acid-fastness depending on strain, age of culture and other variables. The consistency of microscopic morphology in MGIT medium has not been established.

An AFB smear-positive MGIT tube can be subcultured, to both selective and nonselective mycobacterial media, for isolation to perform identification and susceptibility testing.

MGIT tubes which appear positive may contain other non-mycobacterial species. Non-mycobacterial species may overgrow mycobacteria present. Such MGIT tubes should be re-decontaminated and re-cultured.

MGIT tubes which appear positive may contain one or more species of mycobacteria. Faster growing mycobacteria may develop positive fluorescence prior to slower growing myocobacteria; therefore, it is important to subculture positive MGIT tubes to ensure proper identification of all mycobacteria present in the sample.

Specimen volumes greater than 0.5 mL can increase contamination or otherwise adversely affect the performance of the MGIT tubes.

Due to the richness of the MGIT broth and to the non-selective nature of the MGIT indicator, it is important follow the stated digestion/decontamination procedure to reduce the possibility of contamination. Adherence to procedural instructions is critical for optimum recovery of mycobacteria.

The use of BD BBL MGIT PANTA antibiotic mixture, although necessary for all non-sterile specimens, may have inhibitory effects on some mycobacteria.

Terminal subcultures were not routinely performed during clinical studies. Therefore, an actual false negative rate (defined as a MGIT tube that remained negative throughout the eight-week incubation period, was subcultured and grew a mycobacterial organism) cannot be determined at this time.

Seeded culture studies were performed with twenty-three species (ATCC and wild strains) of mycobacteria using inoculum levels ranging from 10^3 to 10^5 CFU/mL. The following species were detected as positive in the MGIT tube:

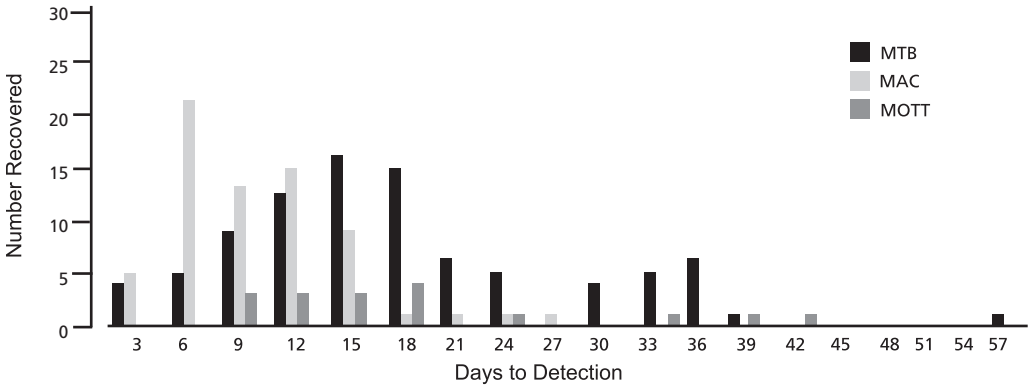
M. africanum	*M. gordonae**	*M. nonchromogenicum*	*M. terrae*
*M. avium Complex**	*M. haemophilum*	*M. phlei*	*M. triviale*
*M. chelonae**	*M. intracellulare*	*M. scrofulaceum*	*M. tuberculosis**
*M. flavescens**	*M. kansasii**	*M. simiae**	*M. vaccae*
*M. fortuitum**	*M. malmoense*	*M. smegmatis*	*M. xenopi**
M. gastri	*M. marinum*	*M. szulgai*	

*Species recovered during clinical evaluation of the MGIT tube.

Clinical studies have demonstrated recovery of mycobacteria from respiratory specimens, gastric aspirates, tissue, stool and sterile body fluids except blood; recovery of mycobacteria from other body fluids has not been established for this product.

EXPECTED VALUES

1 - Frequency distribution of recovery times for clinical trial specimens positive in the BD BBL MGIT System is illustrated in the following figure.



PERFORMANCE CHARACTERISTICS

The BD BBL MGIT Mycobacteria Growth Indicator Tube was evaluated at six clinical sites, which included public health laboratories as well as large acute care hospitals in geographically diverse areas. The site population included patients infected with HIV, immunocompromised patients and transplant patients. The MGIT tubes were compared to the BD BACTEC 460TB radiometric system, the BD BBL SEPTI-CHEK AFB Mycobacteria Culture System and conventional solid growth media for the detection and recovery of mycobacteria from clinical specimens (except blood and urine). A total of 2,801 specimens were tested during the study. The distribution of specimens tested by source was: respiratory (78%), gastric (0.4%), body fluid (9.8%), tissue (7.0%), stool (2.5%) and other (2.4%). A total of 318 specimens were positive which represented 330 isolates recovered during the study. Of these 330 isolates, 253 (77%) were recovered by the MGIT tubes, 260 (79%) were recovered by the BD BACTEC 460TB and the BD BBL SEPTI-CHEK AFB and 219 (66%) were recovered by conventional solid media. The MGIT tubes demonstrated a 0.5% false positive rate (MGIT fluorescent, no AFB present). The MGIT tubes failed to recover 3.7% of the isolates which were recovered in one or more of the reference systems (BD BACTEC 460TB, BD BBL SEPTI-CHEK AFB or conventional solid media). While this percentage represents a potential loss of recovery, it is not indicative of an actual false negative determination (refer to “Limitations of the Procedure” section). Use of a second medium, as recommended, will increase the probability of recovery of mycobacterial organisms. The average breakthrough contamination rate for the MGIT tubes was 9.7%.

BD BACTEC SITES

Table 2 – Detection of Mycobacteria Positive Isolates in Clinical Evaluations

Isolate	Total Isolates	Total MGIT	MGIT Only	Total BD BACTEC	BD BACTEC Only	Total CONV	CONV Only
MTB	113	91	2	98	7	92	6
MAC	99	76	9	86	13	57	3
M. kansasii	5	2	0	5	1	4	0
M. fortuitum	9	5	3	3	1	5	3
M. chelonae	2	0	0	2	1	1	0
M. xenopi	2	0	0	2	2	0	0
M. simiae	1	1	0	1	0	0	0
M. gordonae	11	4	1	4	1	9	5
M. flavescens	2	1	0	2	1	0	0
All MYCO	244*	180*	15*	203	27	168	17

*__NOTE:__ Fourteen MGIT ONLY isolates are not included in this data. Presumptive identification was performed with no final confirmation of ID.

SEPTI-CHEK SITES

Table 3 – Detection of Mycobacteria Positive Isolates in Clinical Evaluations

Isolate	Total Isolates	Total MGIT	MGIT Only	Total BD BBL SEPTI-CHEK	BD BBL SEPTI-CHEK Only	Total CONV	CONV Only
MTB	30	25	1	29	2	26	0
MAC	34	26	5	28	2	25	0
M. kansasii	1	1	1	0	0	0	0
M. gordonae	2	2	2	0	0	0	0
ALL MYCO	67*	54*	9*	57	4	51	0

***NOTE:** Five MGIT ONLY isolates are not included in this data. Presumptive identification was performed with no final confirmation of ID.

AVAILABILITY

Cat. No.	Description
245111	BD BBL™ MGIT™ Mycobacteria Growth Indicator Tubes, 4 mL, carton of 25 tubes.
245113	BD BBL™ MGIT™ Mycobacteria Growth Indicator Tubes, 4 mL, carton of 100 tubes.
245116	BD BBL™ MGIT™ OADC, 15 mL, carton of 6 vials. Each vial sufficient for 25 MGIT tubes.
220908	BD BBL™ Lowenstein-Jensen Medium Slants, package of 10 (20 x 148 mm tubes with cap).
220909	BD BBL™ Lowenstein-Jensen Medium Slants, carton of 100 (20 x 148 mm tubes with cap).
240862	BD BBL™ MycoPrep™ Specimen Digestion/Decontamination Kit, ten 75 mL bottles of NALC-NaOH solution and 5 packages of phosphate buffer.
240863	BD BBL™ MycoPrep™ Specimen Digestion/Decontamination Kit, ten 150 mL bottles of NALC-NaOH solution and 10 packages of phosphate buffer.
245114	BD BBL™ MGIT™ PANTA™ Antibiotic Mixture, lyophilized, carton of 6 vials. Each vial sufficient for 25 MGIT tubes.
220959	BD BBL™ Middlebrook and Cohn 7H10 Agar Slants, carton of 100.
295939	BD BBL™ Middlebrook 7H9 Broth, 8 mL, package of 10 tubes.
221818	BD BBL™ Normal Saline, 5 mL, package of 10.
221819	BD BBL™ Normal Saline, 5 mL, carton of 100.
231729	BD BBL™ Taxo™ Differentiation Discs X, 50 discs/cartridge.

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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.

Change History

Revision	Date	Change Summary
(05)	2019-09	Converted printed instructions for use to electronic format and added access information to obtain the document from BD.com/e-labeling.

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

Manufacturer / Производител / Výrobce / Fabrikant / Hersteller / Κατασκευαστής / Fabricante / Tootja / Fabricant / Proizvođač / Gyártó / Fabbricante / Атқарушы / 제조업체 / Gamintojas / Ražotājs / Tilvirker / Producent / Producător / Производитель / Výrobca / Proizvođač / Tillverkare / Üretici / Виробник / 生产厂商

Use by / Използвайте до / Spotřebujte do / Brug før / Verwendbar bis / Χρήση έως / Usar antes de / Kasutada enne / Date de péremption / 사용 기한 / Upotrijebiti do / Felhasználhatóság dátuma / Usare entro / Дейін пайдалануға / Naudokite iki / Izlietot līdz / Houdbaar tot / Brukes for / Stosować do / Prazo de validade / A se utiliza până la / Использовать до / Použite do / Upotrebiti do / Använd före / Son kullanma tarihi / Використати до\line / 使用截止日期
YYYY-MM-DD / YYYY-MM (MM = end of month)
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = края на месеца)
RRRR-MM-DD / RRRR-MM (MM = konec měsíce)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutning af måned)
JJJJ-MM-TT / JJJJ-MM (MM = Monatsende)
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)
ÉÉÉÉ-HH-NN / ÉÉÉÉ-HH (HH = hónap utolsó napja)
AAAA-MM-GG / AAAA-MM (MM = fine mese)
ЖЖЖЖ-АА-КК / ЖЖЖЖ-АА / (АА = айдың соңы)
YYYY-MM-DD/YYYY-MM(MM = 월말)
MMMM-MM-DD / MMMM-MM (MM = mėnesio pabaiga)
GGGG-MM-DD/GGGG-MM (MM = mēneša beigas)
JJJJ-MM-DD / JJJJ-MM (MM = einde maand)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutten av måneden)
RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
AAAA-MM-DD / AAAA-MM (MM = fim do mês)
AAAA-LL-ZZ / AAAA-LL (LL = sfârşitul lunii)
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = конец месяца)
RRRR-MM-DD / RRRR-MM (MM = koniec mesiaca)
GGGG-MM-DD / GGGG-MM (MM = kraj meseca)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutet av månaden)
YYYY-AA-GG / YYYY-AA (AA = ayın sonu)
PPPP-MM-ДД / PPPP-MM (MM = кінець місяця)
YYYY-MM-DD / YYYY-MM (MM = 月末)

Catalog number / Каталожен номер / Katalogové číslo / Katalognummer / Αριθμός καταλόγου / Número de catálogo / Katalooginumber / Numéro catalogue / Kataloški broj / Katalógusszám / Numero di catalogo / Каталог нөмірі / 카탈로그 번호 / Katalogo / numeris / Kataloga numurs / Catalogus nummer / Numer katalogowy / Număr de catalog / Номер по каталогу / Katalógové číslo / Kataloški broj / Katalog numarası / Номер за каталогом / 目录号

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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 / Bioloski 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 / Bioloski 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 шеri / 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

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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 / Кесіңіз / 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/εξέτασση / 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 сутеги 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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