BD BBL™ MGIT™

Mycobacteria Growth Indicator Tube 7 mL With BD BACTEC™ MGIT™ 960 Supplement Kit

R_x Only CE IVD

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INTENDED USE

The BD BBL™ MGIT™ Mycobacteria Growth Indicator Tube supplemented with BD BACTEC™ MGIT™ Growth Supplement and BD BBL™ MGIT™ PANTA™ antibiotic mixture is intended for the detection and recovery of mycobacteria using the BD BACTEC™ MGIT™ 960 and BD BACTEC MGIT 320 Systems. 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 reported cases of infection with *Mycobacterium tuberculosis* (MTB) increased 18%. Tuberculosis still kills an estimated 3 million persons 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 for 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.[3,4]

The MGIT Mycobacteria Growth Indicator Tube contains 7 mL of modified Middlebrook 7H9 Broth base.[5,6] The complete medium, with OADC enrichment and 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 extrapulmonary (except blood and urine) can be processed for primary isolation in the MGIT tube using conventional methods.[4] The processed specimen is inoculated into a MGIT tube, placed into the BD BACTEC MGIT instrument for continuous monitoring until positive or the end of the testing protocol.

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 detected.

Tubes entered into the BD BACTEC MGIT instrument are continuously incubated at 37 °C and monitored every 60 min for increasing fluorescence. Analysis of the fluorescence is used to determine if the tube is instrument positive; i.e., the test sample contains viable organisms. An instrument positive tube contains approximately 10^5 to 10^6 colony forming units per milliliter (CFU/mL). Culture vials which remain negative for a minimum of 42 days (up to 56 days) and which show no visible signs of positivity are removed from the instrument as negatives and sterilized prior to discarding.

The BD BACTEC MGIT Growth Supplement is added to each MGIT tube to provide substances essential for the rapid growth of mycobacteria. Oleic acid is utilized by tubercle bacteria 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 is reduced when supplementing the BD BBL MGIT broth base with BD BACTEC MGIT Growth Supplement/ 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 7 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 of Purified Water:

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

BACTEC MGIT Growth Supplement contains 15 mL Middlebrook OADC enrichment.

Approximate Formula* Per L of Purified Water:

Bovine albumin	50.0 g	Catalase	0.03 g
Dextrose	20.0 g	Oleic acid	0.1 g
Polyoxyethylene stearate (POES)	1.1 g		

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

Approximate Formula* Per Vial Lyophilized 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.*

Storage of Reagents: BD BBL MGIT Mycobacteria Growth Indicator Tubes – On receipt, store at 2–25 °C. 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 BACTEC MGIT Growth Supplement – 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 PANTA mixture must be stored at 2–8 °C and used within 5 days.

WARNINGS AND PRECAUTIONS:

For *in vitro* Diagnostic Use.

This Product Contains Dry Natural Rubber.

Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions"[7-10] and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.

Working with *Mycobacterium tuberculosis* grown in culture requires Biosafety Level 3 practices, containment equipment and facilities.[4]

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

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

In the event of tube breakage: 1) Close the instrument drawers; 2) Turn off the instrument; 3) Vacate the area immediately; 4) Consult your facility/CDC guidelines. An inoculated leaking or broken vial may produce an aerosol of mycobacteria; appropriate handling should be observed.

Autoclave all inoculated MGIT tubes prior to disposal.

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.[11]

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*.[4] Alternatively, use the BD BBL™ MycoPrep™ kit for processing mycobacterial specimens (see "Availability").

GASTRIC ASPIRATES: Specimens should be decontaminated as for 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 to 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 contain 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*.[4]

The routine inoculation of solid media is especially important for optimal recovery of mycobacteria from tissue specimens as these specimen types are particularly susceptible to sporadic organism recovery.

STOOL: Suspend 1 g of feces in 5 mL of Middlebrook Broth. Agitate the suspension on a vortex mixer for 5 s. Proceed to the NALC-NaOH procedure as recommended by the CDC's *Public Health Mycobacteriology: A Guide for the Level III Laboratory*.[4]

NOTE: For all specimen processing methods, a phosphate buffer solution (pH 6.8) should be used to QS the sample decontaminant mixture to 50 mL prior to centrifugation. Resuspension of pellet must also be done using a fresh preparation of phosphate buffer solution (pH 6.8).

PROCEDURE

Materials Provided: BD BBL MGIT Mycobacteria Growth Indicator Tubes and BD BACTEC MGIT 960 Supplement Kit, containing BD BACTEC MGIT Growth Supplement and BBL MGIT PANTA Antibiotic Mixture (see "Availability").

Materials Required But Not Provided: 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, BD BBL Middlebrook and Cohn 7H10 Agar, BD BBL MycoPrep Specimen Digestion / Decontamination Kit, BD BBL Middlebrook 7H9 Broth (see "Availability") or other mycobacterial agars or egg-based media. Tissue homogenizer or sterile swab, BD BBL Normal Saline (see "Availability"), microscope and materials for staining slides, adjustable 1,000 µL pipetter, corresponding sterile pipette tips, 5% sheep blood agar plates and tuberculocidal disinfectant.

INOCULATION OF MGIT TUBES:

BD BBL MGIT 7 mL Tubes must be used with a BD BACTEC MGIT instrument.

1. Reconstitute a lyophilized vial of BD BBL MGIT PANTA Antibiotic Mixture with 15 mL of BD BACTEC MGIT Growth Supplement.
2. Label the MGIT tube with the specimen number.
3. Unscrew the cap and aseptically add 0.8 mL of Growth Supplement/ BD BBL MGIT PANTA Antibiotic Mixture. For best results, the addition of Growth Supplement/ 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 (0.1 mL) of specimen to a 7H10 agar plate or other mycobacterial solid agar or egg-based medium.
5. Tightly recap the tube and mix well.
6. Tubes entered into the instrument will be automatically tested for the duration of the recommended 42 day testing protocol.

   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 or 42 °C.[13] Inoculate and incubate at the required temperature. These tubes must be manually read (refer to the BD BACTEC MGIT Instrument *User's Manual*).

   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. These tubes must be manually read (refer to the BD BACTEC MGIT Instrument *User's Manual*).
7. Positive tubes, identified by the BD BACTEC MGIT instrument should be subcultured and an acid-fast smear prepared (see "Results").

All quality control testing, reprocessing, smear preparations, sub-culturing, etc., of presumptive positive tubes must be performed using bio-safety level (BSL) III practices and containment facilities.

Processing a Positive MGIT Tube: NOTE – All steps should be performed in a biological safety cabinet.

1. Remove the MGIT tube from the instrument and transport to an area using BSL III practices and containment facilities.
2. 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).
3. Inspect smear and preparations. Report preliminary results only after acid-fast smear evaluation.

At the end of six weeks incubation, perform a visual check of all instrument negative tubes. If the tube appears visually positive (i.e., non-homogenous turbidity, small grains or clumps) it should be subcultured, acid-fast stained and treated as a presumptive positive, provided the acid-fast smear result is positive. If the tube shows no signs of positivity, it should be sterilized prior to discarding.

Reprocessing Contaminated MGIT tubes: Contaminated MGIT tubes may be re-decontaminated and re-concentrated using the procedure in Appendix E - Supplemental Procedures of the BD BACTEC MGIT Instrument *User's Manual*.

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*.[12]

NOTE: Middlebrook 7H9 Broth (supplemented) is exempt from User QC testing according to CLSI M22-A3.[12]

RESULTS

An instrument-positive sample is determined by the BD BACTEC MGIT instrument and confirmed by an acid-fast smear.

REPORTING OF RESULTS

An instrument positive tube must be confirmed by acid-fast smear. A positive AFB smear result indicates the presence of mycobacteria.

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

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

If no microorganisms are present: Reenter the tube into the instrument as an ongoing negative tube within 5 h of removal. Allow tube to complete test protocol. No reportable result.

Perform subculture from the BD BBL MGIT tube for identification and drug susceptibility testing.

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 methods of processing.

Decontamination with the N-acetyl-L-cysteine Sodium hydroxide (NALC-NaOH) method is recommended. Other decontamination methods have not been tested in conjunction with the BD BBL 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 BD BBL 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 are instrument-positive may contain other non-mycobacterial species. Non-mycobacterial species may overgrow mycobacteria present. Such MGIT tubes should be re-decontaminated and re-cultured (refer to the BD BACTEC MGIT Instrument *User's Manual*). Reprocessing is strongly recommended if the original specimen source cannot be easily recollected; e.g. tissue specimen.

MGIT tubes which are instrument-positive may contain one or more species of mycobacteria. Faster growing mycobacteria may be detected prior to slower growing mycobacteria; therefore, it is important to subculture positive MGIT tubes to ensure proper identification of all mycobacteria present in the sample.

Due to the richness of the MGIT broth and to the non-selective nature of the MGIT indicator, it is important to follow the stated digestion/decontamination procedure to reduce the possibility of contamination. Adherence to procedural instructions, which includes use of recommended inoculum volume (0.5 mL), is critical for optimum recovery of mycobacteria.

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

Seeded culture studies were performed with twenty-four species (ATCC and wild strains) of mycobacteria using inoculum levels ranging from 10^1 to 10^2 CFU/mL. The following species were detected as positive in the BD BACTEC MGIT 960 System:

*M. avium**	*M. gordonae**	*M. nonchromogenicum*	*M. terrae*
M. abscessus	*M. haemophilum*†	*M. phlei*	*M. trivale*
M. bovis	*M. intracellulare*	*M. simiae**	*M. tuberculosis**
M. celatum	*M. kansasii**	*M. scrofulaceum*	*M. xenopi**
*M. fortuitum**	*M. malmoense*	*M. smegmatis*	
M. gastri	*M. marinum*	*M. szulgai**	

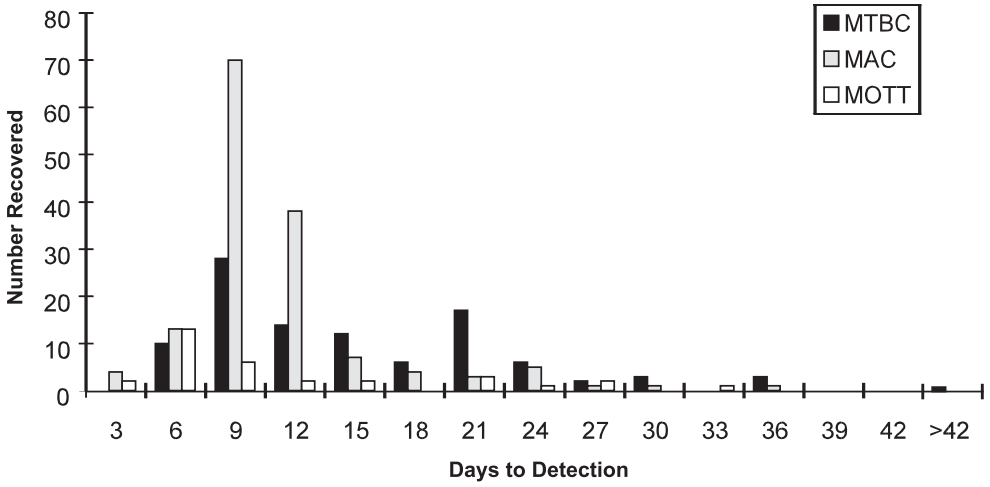
*Species recovered during clinical evaluation of the BACTEC MGIT 960 System. In addition, *M. mucogenicum* was recovered at one of the clinical sites.

†The *M. haemophilum* was recovered using the addition of a source of hemin to the MGIT tube prior to inoculation.

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

Figure 1 – Frequency distribution of recovery times for clinical trial specimens positive in the BD BACTEC MGIT 960 System



PERFORMANCE CHARACTERISTICS

The BD BACTEC MGIT 960 System was evaluated at six clinical sites including one non-US site, which represented 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 BD BACTEC MGIT 960 System was compared to the BD BACTEC 460TB radiometric system and conventional solid growth media for the detection and recovery of mycobacteria from clinical specimens, except blood. A total of 3,330 specimens were tested during the study. A total of 353 specimens were positive which represented 362 isolates recovered during the study. The distribution of positives by specimen type is: respiratory (90%), tissue (7%), body fluids (1%), stool (0.85%) and bone marrow (0.65%). Of the 362 isolates, 289 (80%) were recovered by the BD BACTEC MGIT 960 System, 271 (75%) were recovered by the BD BACTEC 460TB System and 250 (69%) were recovered by conventional solid media. Of the 3,330 specimens tested in the clinical study, 27 (0.8%) MGIT 960 tubes were determined to be false positive (instrument-positive, smear and/or subculture-negative). Of the 313 MGIT 960 instrument positive tubes, 27 (8.6%) were determined to be false positive. The false negative rate (instrument-negative, smear and/or subculture-positive) was determined to be 0.5% based on terminal subcultures of 15% of instrument negative vials. The average breakthrough contamination rate for the BD BACTEC MGIT 960 System was 8.1% with a range of 1.8–14.6%.

Table 1: Detection of Mycobacteria Positive Isolates in Clinical Evaluations

Isolates	Total isolates	Total MGIT 960	MGIT Only	Total BD BACTEC 460TB	BD BACTEC 460TB Only	Total CONV	CONV Only
MTB	132	102	4	119	11	105	3
MAC	172	147	36	123	12	106	3
M. asiaticum	1	0	0	0	0	1	1
M. fortuitum/chelonae	22	18	6	13	1	15	1
M. genavense	1	0	0	1	0	1	0
M. kansasii	5	5	1	4	0	4	0
M. malmoense	1	0	0	1	0	1	0
M. marinum	1	0	0	0	0	1	1
M. mucogenicum	1	1	1	0	0	0	0
M. simiae	1	1	0	1	0	1	0
M. szulgai	2	2	0	2	0	2	0
M. xenopi	2	2	1	1	0	0	0
MOTT	2	1	1	1	1	0	0
Mycobacteria spp.	2	2	1	1	0	1	0
M. gordonae	11	6	3	3	2	6	3
M. nonchromogenicum	6	2	0	1	0	6	4
All MYCO	362	289	54	271	27	250	16

AVAILABILITY

Cat. No.	Description
245122	BD BBL™ MGIT™ Mycobacteria Growth Indicator Tubes, 7 mL, carton of 100 tubes.
245124	BD BACTEC™ MGIT™ 960 Supplement Kit, 6 vials, 15 mL, BD BACTEC™ MGIT™ Growth Supplement and 6 vials, lyophilized, BD BBL™ MGIT™ PANTA™ Antibiotic Mixture. Each Growth Supplement/BD PANTA™ vial sufficient for 15–18 BD 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.
221174	BD BBL™ Middlebrook and Cohn 7H10 Agar, package of 20.
221819	BD BBL™ Normal Saline, 5 mL, carton of 100.

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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

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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)

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Temperature limitation / Температурни ограничения / Teplotní omezení / Temperaturbegrænsning / Temperaturbegrenzung / Περιορισμοί θερμοκρασίας / Limitación de temperatura / Temperatuuri piirang / Limites de température / Dozvoljena temperatura / Hőmérsékleti határ / Limiti di temperatura / Температураны шектеу /온도 제한 / Laikymo temperatūra / Temperatūras ierobežojumi / Temperatuurlimiet / Temperaturbegrensning / Ograniczenie temperatury / Limites de temperatura / Limite de temperatură / Ограничение температуры / Ohraničenie teploty / Ograničenje temperature / Temperaturgräns / Sıcaklık sınırlaması / Обмеження температури / 温度限制

Batch Code (Lot) / Код на партидата / Kód (číslo) šarže / Batch-kode (lot) / Batch-Code (Charge) / Κωδικός παρτίδας (παρτίδα) / Código de lote (lote) / Partii kood / Numéro de lot / Lot (kod) / Tétel száma (Lot) / Codice batch (lotto) / Топтама коды / 배치 코드(로트) / Partijos numeris (LOT) / Partijas kods (laidiens) / Lot nummer / Batch-kode (parti) / Kod partii (seria) / Código do lote / Cod de serie (Lot) / Код партии (лот) / Kód série (šarža) / Kod serije / Partinummer (Lot) / Parti Kodu (Lot) / Код партії / 批号（亚批）

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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 әдici – 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 әдici – сәуле түсipy / 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 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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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 / 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/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 / Feriți 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 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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