BD BACTEC™ Myco/F Lytic Culture Vials

Supplemented Middlebrook 7H9 and Brain Heart Infusion Broth

FOR USE WITH BD BACTEC 9000MB R_x Only CE IVD

PP124JAA(05)
2019-08
English

INTENDED USE

BD BACTEC™ Myco/F Lytic (a modified Middlebrook 7H9 broth) when used with the BD BACTEC 9000MB instrument is a non-selective culture medium for the qualitative culture and recovery of mycobacteria from blood specimens.

SUMMARY AND EXPLANATION

Since the mid-1980s and spread of the AIDS epidemic, the incidence of septicemia caused by opportunistic mycobacteria has risen. *Mycobacterium tuberculosis* (MTB) and mycobacteria other than tuberculosis (MOTT), especially *Mycobacterium avium* complex (MAC), have become resurgent. From 1985 to 1992, the number of MTB cases reported increased 18%. 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%.

The 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 a liquid medium for mycobacterial culture.[1,2,3]

The BD BACTEC 9000MB System is designed for the rapid detection of mycobacteria in clinical specimens. BD BACTEC Myco/F Lytic Culture medium is a Middlebrook 7H9 and Brain Heart Infusion broth formulation for the recovery of mycobacteria from blood specimens. Specific modifications were made to enhance the growth and recovery of mycobacteria. These modifications include ferric ammonium citrate to provide an iron source for specific strains of mycobacteria, the addition of saponin as a blood lysing agent and the addition of specific proteins and sugars to provide nutritional supplements. Each vial contains a sensor which can detect decreases in oxygen concentration in the vial resulting from microorganism metabolism and growth. The sensor is monitored by the BD BACTEC 9000MB System for increasing fluorescence which is proportional to the decrease in oxygen. A positive determination indicates the presumptive presence of viable microorganisms in the vial.

PRINCIPLES OF THE PROCEDURE

The BD BACTEC Myco/F Lytic culture vial is designed for the rapid detection of mycobacteria in blood. Blood specimens are inoculated into the BD BACTEC Myco/F Lytic vial either with a syringe or direct draw with a needle and tubing. The vial is placed into the BD BACTEC 9000MB System and is continuously incubated at 37 °C, with agitation once every ten minutes for maximum recovery. Each vial contains a sensor which can detect decreases in oxygen concentration in the vial resulting from microorganism metabolism and growth. The sensor is monitored by the BD BACTEC 9000MB System every ten minutes. Analysis of the rate of oxygen decrease as measured by increasing fluorescence enables the BD BACTEC fluorescent series instrument to determine if the vial is instrument positive. A positive determination indicates the presumptive presence of viable microorganisms in the vial. Detection is limited to microorganisms that will grow in the medium at 37 °C. The medium is not selective and will support the growth of other aerobic organisms including yeast, fungi and bacteria which may interfere, if present, with the recovery of mycobacteria. Culture vials which remain negative for 42 days and which show no visible sign of positivity are removed from the instrument and sterilized prior to discarding.

REAGENTS

Each BD BACTEC Myco/F Lytic culture vial contains the following active ingredients prior to processing:

List of Ingredients

Processed Water	40 mL qs
7H9 Middlebrook Broth Base without phosphate salts	0.12% w/v
Brain Heart Infusion	0.5% w/v
Casein Hydrolysate	0.10% w/v
Supplement H	0.10% w/v
Inositol	0.05% w/v
Glycerol	0.10% w/v
Sodium Polyanetholsulfonate	0.025% w/v
Tween 80	0.0025% w/v
Pyridoxal HCl	0.0001% w/v
Ferric Ammonium Citrate	0.006% w/v
Potassium Phosphate	0.024% w/v
Saponin	0.24% w/v
Antifoam	0.01% w/v

This BD BACTEC media is dispensed with added CO_2 and O_2.

Composition may have been adjusted to meet specific performance requirements.

BD BACTEC Myco/F Lytic medium requires no supplement addition. Each 40 mL vial of BD BACTEC Myco/F Lytic is ready for use when received. The appearance of the media upon receipt shall be clear and light amber in color.

WARNINGS

Precautions: For *in vitro* diagnostic use.

This Product Contains Dry Natural Rubber.

POTENTIAL INFECTIOUS TEST SPECIMEN. Observe "Universal Precautions"[4,5] and institutional guidelines when handling and disposing of infectious materials.

BD BACTEC Myco/F Lytic vials will accept more than the recommended maximum of 5 mL of specimen volume, monitoring of fill volume should be conducted.

Biosafety Level 2 practice, containment equipment and facilities are recommended for preparing acid-fast stains and for culturing clinical specimens. For activities involving the propagation and manipulation of *Mycobacterium tuberculosis* or *Mycobacterium bovis* grown in culture, Biosafety Level 3 practice, containment equipment and facilities are recommended.[5,6,7]

Prior to use, each vial should be examined for evidence of contamination such as cloudiness, bulging or depressed septum, or leakage. **DO NOT USE** any vial showing evidence of contamination, leakage or damage. Vial contamination may not be readily apparent. A contaminated vial could contain positive pressure. If a contaminated vial is used for direct draw, gas or contaminated culture media could be refluxed into the patient's vein. On rare occasions, the glass bottle neck may be cracked and the neck may break during removal of the flip-off cap or in handling. Also, on rare occasions, a vial may not be sealed sufficiently. In both cases the contents of the vials may leak or spill, especially if the vial is inverted.

To minimize the potential of leakage during inoculation by syringe of specimen into culture vials, use syringes with BD Luer-Lok™ brand tips. A one-handed inoculation technique and a suitable vial holder should be employed to prevent accidental needle stick injury.

Before discarding, sterilize all inoculated BD BACTEC Myco/F Lytic vials by autoclaving.

Before sampling **positive culture vials for subculturing or staining, etc.:** It is necessary to release gas which often builds up due to microbial metabolism. Sampling must be performed in a biological safety cabinet, and appropriate protective clothing, including gloves and masks, should be worn. See Procedure Section for more information on subculturing.

LEAKING OR BROKEN VIALS

CAUTION: Because an inoculated leaking or broken vial may produce an aerosol of mycobacteria, including *M. tuberculosis* or other bacteria, appropriate handling should be observed.

If an inoculated vial is found to be leaking or is accidentally broken during collection or transport, use the established procedure in your facility for dealing with mycobacterial spills. As a minimum, "Universal Precautions" should be employed. Vials should be discarded in an appropriate manner.

In the rare instance where a vial is found to have leaked contents into the instrument proper, or if a vial is accidentally broken, turn off the instrument immediately. Vacate the affected area. Contact your facility's Safety or Infection Control Officer(s). Determine the necessity of turning off or modifying the settings of the air handling units serving the affected area. Do not return to the area until any potential aerosols have settled or have been removed by appropriate ventilation. Becton Dickinson and Company should be notified by calling 1.800.544.7434 in the USA or the appropriate Becton Dickinson representative in your area. Guidelines for proper handling of accidental mycobacterial contamination due to breakage of culture tubes or broth suspensions have been issued by the CDC.[5,6,7]

STORAGE INSTRUCTIONS

Store at 2–25 °C in a dry location **out of direct light**.

SPECIMEN COLLECTION

NOTE: It is recommended that this procedure be reviewed with appropriate personnel prior to use of medium to insure proper specimen collection techniques as described in this section.

The specimen must be collected using sterile technique to reduce the chance of contamination. The range of blood volume which can be cultured is 1.0 mL to 5.0 mL. It is recommended that the specimen be inoculated at bedside. Most commonly, a syringe with a BD Luer-Lok brand tip is used to draw the specimen. If appropriate, a BD Vacutainer® brand Needle Holder and a BD Vacutainer brand Blood Collection Set, BD Vacutainer Safety-Lok™ Blood collection Set or other tubing "butterfly" set may be used. If using a needle and tubing (direct draw), carefully observe the direction of the blood flow when starting sample collection. Prior to inoculation, the medium fill volume should be noted on the label with a pen or marker to indicate the starting point of specimen collection. The vacuum in the bottle will usually exceed 5 mL, so the user should monitor the volume collected by means of the 5 mL graduation marks on the vial label. When the desired 1–5 mL of blood has been drawn, the flow should be stopped by crimping the tubing and removing the needle from the BD BACTEC vial. The BD BACTEC vial should be transported as quickly as possible to the laboratory and placed in the BD BACTEC instrument. A yellow-top BD Vacutainer Brand Tube containing SPS may also be used to collect the blood sample from the patient. The tube should be transported to the laboratory as quickly as possible for transfer into the BD BACTEC culture vial.

PROCEDURE

Materials Provided: BD BACTEC Myco/F Lytic Culture Vials.

Materials Required But Not Provided: Biological Safety Cabinet, Autoclave, venting unit, mycobacterial disinfectant, 70% isopropyl alcohol, Quality Control Organisms (*Mycobacterium intracellulare*, ATCC® 13950; *Mycobacterium kansasii*, ATCC 12478; and *Mycobacterium fortuitum*, ATCC 6841), microscope and materials for staining slides and subculturing vials.

CAUTION: BD BACTEC Myco/F Lytic vials must be used with instrument software version 3.6 or higher.

Inoculation of BD BACTEC Myco/F Lytic Culture Vials

1. Remove the flip-off cap from the BD BACTEC vial top and inspect the vial for cracks, leaks, contamination, excessive cloudiness, and bulging or indented septuM. DO NOT USE if any defect is noted.
2. Label culture vial with specimen identification and mark medium fill graduation line on vial label.
3. Before inoculating, swab the septum with alcohol. Aseptically inject with a syringe or draw directly with the aid of the graduation lines on the vial label 1–5 mL of specimen per vial (see the section on Limitations of the Procedure). **Inoculated vials should be placed into the BD BACTEC 9000MB instrument as soon as possible** for incubation and monitoring.
4. Vials entered into the instruments will be automatically tested for the duration of the testing protocol. Positive vials will be identified by the BD BACTEC Fluorescent System (see the BD BACTEC User's Manual, MA-0092). The sensor inside the vial may not appear visibly different in positive or negative vials; however, the BD BACTEC Fluorescent System can determine a difference in sensor fluorescence.
5. Positive vials should be subcultured and an appropriate smear prepared. All positive vials should be handled using BSL III practices and containment facilities.

   Processing an instrument-positive vial

   a) Remove the vial from the instrument and transport to an area using BSL III practices and containment facilities.
   b) Invert vial to mix contents.
   c) In biological safety cabinet, vent the vial to equilibrate vial pressure with atmosphere.
   d) Remove aliquot from vial (approx. 0.1 mL) for stain preparations (AFB and Gram).
   e) Inspect smear and report preliminary results only after smear evaluation.

If at the end of six weeks incubation an instrument negative vial appears to be positive (i.e., bulging septum, or very darkened blood), it should be subcultured, AFB stained and treated as a presumptive positive, providing the stain result is positive.

Subculturing of Vial: Subculturing should be performed in a biological safety cabinet, and appropriate clothing, including gloves and masks, should be worn. Prior to subculturing, place the vial in an upright position, and place an alcohol wipe over the septum. To release any positive pressure in the vial which could be caused by growth of possible contaminants, insert a sterile 25-gauge (or smaller) needle equipped with an appropriate filter or pledget through the alcohol wipe and septum. The needle should be removed after any pressure is released and before sampling the vial for subculture. The insertion and withdrawal of the needle should be done in a straight-line motion, avoiding any side-to-side motions which could permanently damage the septum. **Do not re-cap the needle. Discard needles and syringes in a puncture-resistant biohazard container.**

QUALITY CONTROL

Quality Control Certificates are provided with each carton of media.

It is recommended that each new shipment or lot of BD BACTEC Myco/F Lytic media be tested with the ATCC control organisms identified in the chart below as a positive control, and an uninoculated vial as a negative control.

Organism	Range of Time-to-detection (days)
Mycobacterium intracellulare, ATCC 13950	8 to 16
Mycobacterium kansasii, ATCC 12478	3 to 13
Mycobacterium fortuitum, ATCC 6841	1 to 3

The positive vials should be inoculated using a 1:100 dilution of a McFarland #1 suspension grown on solid medium. Inoculate the vial with 0.1 mL of the diluted culture. The vials and an uninoculated control vial should be scanned into the instrument and tested. The inoculated vial should be detected as positive by the instrument within the test protocol. The negative control should remain negative. If expected results for Quality Control are not obtained, do not use the medium and contact Becton Dickinson Technical Services (in the U.S only: 1.800.638.8663) or your local BD representative for further assistance.

For information on quality control for the BD BACTEC System, refer to the User's Manual (MA- 0092).

REPORTING OF RESULTS

An instrument positive vial may be confirmed by acid-fast smear or Gram stain. A positive result indicates the presumptive presence of viable microorganisms in the vial.

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

If microorganisms other than acid-fast bacilli are present, subculture to solid media and report as: instrument positive, AFB smear negative, ID pending.

If no microorganisms are present on the smears, subculture to solid media, re-enter the vial into the instrument as an ongoing negative vial and allow to complete test protocol. No reportable result.

Perform subcultures from the BD BACTEC Myco/F Lytic vial for identification and susceptibility testing.

LIMITATIONS OF THE PROCEDURE

Detection of mycobacterial species in blood specimens is dependent on the number of organisms present in the specimen, specimen collection methods, and patient factors such as presence of symptoms and prior treatment.

Mycobacteria may vary in acid-fastness depending on strain, age of culture and other variables.

Care must be taken to prevent contamination of the sample during collection and inoculation into the BD BACTEC vial. A contaminated vial will give a positive instrument reading, but will not indicate a relevant clinical result. Such a determination must be made by the user, based on such factors as, stain results, type of organism recovered, occurrence of the same organism in multiple cultures, patient history, etc.

BD BACTEC Myco/F Lytic vials are not selective and will support the growth of other aerobic organisms besides mycobacteria. Positive vials may contain one or more species of mycobacteria and/or other non-mycobacterial species. If present, fast growing organisms may mask the detection of slower growing mycobacteria. Subculture and additional procedures are required. The consistency of microscopic morphology in BD BACTEC Myco/F Lytic has not been established.

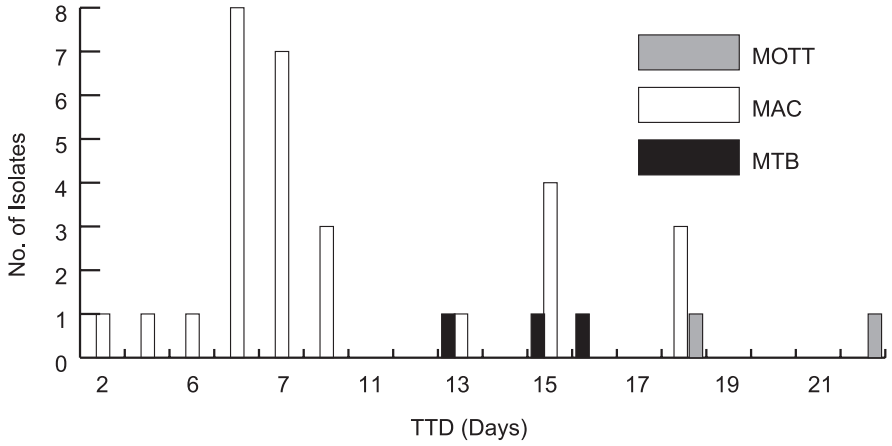
Optimum recovery of isolates will be achieved by adding 1–5 mL of blood to each vial. Use of lower or higher volumes may adversely affect recovery, detection times and/or specificity. False positivity most likely will increase when the blood volume is above 5 mL.

Blood may contain antimicrobials or other inhibitors which may slow or prevent the growth of microorganisms.

BD BACTEC Myco/F Lytic vials are incubated at 37 °C potentially precluding the recovery of mycobacteria requiring other incubation temperatures (e.g., *M. marinum*, *M. ulcerans*, *M. haemophilum*). Recovery of such organisms requires additional culture methods. The following isolates were detected as positive in the BD BACTEC 9000MB instrument using BD BACTEC Myco/F Lytic medium during internal studies and/or clinical trials: *M. tuberculosis*, *M. kansasii*, *M. fortuitum*, *M. avium*, *M. intracellulare*, *M. bovis*, *M. terrae*, *M. simiae*, *M. gordonae*, *M. celatum*, *M. abscessu*s, *M. malmoense*. During internal studies, *M. xenopi* and *M. szulgai* exhibited unsatisfactory recovery with BD BACTEC Myco/F Lytic culture medium.

EXPECTED RESULTS

Frequency distribution of recovery times (TTD) for clinical trial blood specimens positive with the BD BACTEC Myco/F Lytic Culture medium is illustrated in the following figure.



PERFORMANCE CHARACTERISTICS

The BD BACTEC Myco/F Lytic culture medium was evaluated with the BD BACTEC 9000MB instrument at two clinical sites considered large tertiary care teaching hospitals in geographically diverse areas. The site populations included patients suspected of a mycobacterial infection, immunocompromised patients and transplant patients. The BD BACTEC Myco/F Lytic culture medium was compared to the BD BACTEC 13A culture medium for the recovery and detection of mycobacteria from blood specimens. A total of 284 compliant blood specimens were tested during the study. The total number of pathogenic mycobacterial isolates recovered in the study was 39 (See TABLE 1). Of these positives, five (13%) were recovered in the BD BACTEC Myco/F Lytic culture medium only and two (5%) were recovered by BD BACTEC 13A culture medium only. A total of 28 BD BACTEC Myco/F Lytic vials were over filled with specimen (between 6 to 20 mL) during the clinical evaluation and were not included in this study since they were above the maximum fill volume (not compliant). Of these 28 BD BACTEC Myco/F Lytic vials, 16 (57%) were identified as false positive.

Of the 284 blood specimens tested in the clinical study, one BD BACTEC Myco/F Lytic vial (0.4%) was determined to be false positive (instrument-positive, smear and/or subculture-negative). Of the 38 instrument positive Myco/F Lytic vials, 1 (2.6%) was determined to be false positive. The false negative rate (instrument-negative, smear and/or subculture-positive) was determined to be 0% based on terminal subcultures of ≥ 50% of negative vials. The contamination rate during this evaluation was determination to be 0.9%.

TABLE 1: Summary of Myco/F Lytic Culture Medium Isolate Recovery During Clinical Trials

Organism	Total Isolates	Myco/F Lytic Medium Only	13A Medium Only	Both
All Pathogenic Mycobacteria:				
Mycobacterium avium	30	3	1	26
Mycobacterium tuberculosis	6	0	0	6
Mycobacterium kansasii	3	2	1	0
Total	39	5	2	32

AVAILABILITY

Cat. No.	Description
442288	BD BACTEC™ Myco/F Lytic Culture Vials, case of 50 vials

REFERENCES

1. Horsburg Jr., C.R. 1991. *Mycobacterium Avium* Complex Infection in the acquired immunodeficiency syndrome. New England Journal of Medicine *324:*1332–1338.
2. Tenover, F.C., et al, 1993. The resurgence of Tuberculosis: Is Your Laboratory Ready? Journal of Clinical Microbiology *31:*767–770
3. Isolation and Identification of *Mycobacterium tuberculosis*: A Guide for the Level II Laboratory. U.S. Department of Health and Human Services, Atlanta, GA, 1981.
4. Kent, P.T., and G.P. Kubica. 1985. Public Health Mycobacteriology: A Guide for the Level III Laboratory. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta, GA.
5. Recommendations for preventing transmission of Human Immunodeficiency Virus and Hepatitis B Virus to patients during exposure-prone invasive procedures. MMWR 1991, Vol. 40, No. RR-8.
6. Bloodborne pathogens. Code of Federal Regulations, Title 29, Part 1910.1030, Federal Register 1991, *56:*64175–64182.
7. Biosafety in Microbiogical and Biomedical Laboratories. U.S. Department of Health and Human Services Public Health Service/ Centers for Disease Control and Prevention, Atlanta, GA, May, 1993.

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)	2019-08	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

Authorized Representative in the European Community / Оторизиран представител в Европейската общност / Autorizovaný zástupce pro Evropském společenství / Autoriseret repræsentant i De Europæiske Fællesskaber / Autorisierter Vertreter in der Europäischen Gemeinschaft / Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα / Representante autorizado en la Comunidad Europea / Volitatud esindaja Euroopa Nõukogus / Représentant autorisé pour la Communauté européenne / Autorizuirani predstavnik u Europskoj uniji / Meghatalmazott képviselő az Európai Közösségben / Rappresentante autorizzato nella Comunità Europea / Европа қауымдастығындағы уәкілетті өкіл /유럽 공동체의 위임 대표 / Įgaliotasis atstovas Europos Bendrijoje / Pilnvarotais pārstāvis Eiropas Kopienā / Bevoegde vertegenwoordiger in de Europese Gemeenschap / Autorisert representant i EU / Autoryzowane przedstawicielstwo we Wspólnocie Europejskiej / Representante autorizado na Comunidade Europeia / Reprezentantul autorizat pentru Comunitatea Europeană / Уполномоченный представитель в Европейском сообществе / Autorizovaný zástupca v Európskom spoločenstve / Autorizovano predstavništvo u Evropskoj uniji / Auktoriserad representant i Europeiska gemenskapen / Avrupa Topluluğu Yetkili Temsilcisi / Уповноважений представник у країнах ЄС / 欧洲共同体授权代表

In Vitro Diagnostic Medical Device / Медицински уред за диагностика ин витро / Lékařské zařízení určené pro diagnostiku in vitro / In vitro diagnostisk medicinsk anordning / Medizinisches In-vitro-Diagnostikum / In vitro διαγνωστική ιατρική συσκευή / Dispositivo médico para diagnóstico in vitro / In vitro diagnostika meditsiiniaparatuur / Dispositif médical de diagnostic in vitro / Medicinska pomagala za In Vitro Dijagnostiku / In vitro diagnosztikai orvosi eszköz / Dispositivo medicale per diagnostica in vitro / Жасанды жағдайда жүргізетін медициналық диагностика аспабы / In Vitro Diagnostic 의료 기기 / In vitro diagnostikos prietaisas / Medicīnas ierīces, ko lieto in vitro diagnostikā / Medisch hulpmiddel voor in-vitro diagnostiek / In vitro diagnostisk medisinsk utstyr / Urządzenie medyczne do diagnostyki in vitro / Dispositivo médico para diagnóstico in vitro / Dispozitiv medical pentru diagnostic in vitro / Медицинский прибор для диагностики in vitro / Medicínska pomôcka na diagnostiku in vitro / Medicinski uređaj za in vitro dijagnostiku / Medicinteknisk produkt för in vitro-diagnostik / İn Vitro Diyagnostik Tıbbi Cihaz / Медичний пристрій для діагностики in vitro / 体外诊断医疗设备

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）

Contains sufficient for <n> tests / Съдържанието е достатъчно за <n> теста / Dostatečné množství pro <n> testů / Indeholder tilstrækkeligt til <n> tests / Ausreichend für <n> Tests / Περιέχει επαρκή ποσότητα για <n> εξετάσεις / Contenido suficiente para <n> pruebas / Küllaldane <n> testide jaoks / Contenu suffisant pour <n> tests / Sadržaj za <n> testova / <n> teszthez elegendő / Contenuto sufficiente per <n> test / <n> тесттері үшін жеткілікті / <n> 테스트가 충분히 포함됨 / Pakankamas kiekis atlikti <n> testų / Satur pietiekami <n> pārbaudēm / Inhoud voldoende voor “n” testen / Innholder tilstrekkelig til <n> tester / Zawiera ilość wystarczającą do <n> testów / Conteúdo suficiente para <n> testes / Conţinut suficient pentru <n> teste / Достаточно для <n> тестов(а) / Obsah vystačí na <n> testov / Sadržaj dovoljan za <n> testova / Innehåller tillräckligt för <n> analyser / <n> test için yeterli malzeme içerir / Вистачить для аналізів: <n> / 足够进行 <n> 次检测

Consult Instructions for Use / Направете справка в инструкциите за употреба / Prostudujte pokyny k použití / Se brugsanvisningen / Gebrauchsanweisung beachten / Συμβουλευτείτε τις οδηγίες χρήσης / Consultar las instrucciones de uso / Lugeda kasutusjuhendit / Consulter la notice d’emploi / Koristi upute za upotrebu / Olvassa el a használati utasítást / Consultare le istruzioni per l’uso / Пайдалану нұсқаулығымен танысып алыңыз / 사용 지침 참조 / Skaitykite naudojimo instrukcijas / Skatīt lietošanas pamācību / Raadpleeg de gebruiksaanwijzing / Se i bruksanvisningen / Zobacz instrukcja użytkowania / Consultar as instruções de utilização / Consultaţi instrucţiunile de utilizare / См. руководство по эксплуатации / Pozri Pokyny na používanie / Pogledajte uputstvo za upotrebu / Se bruksanvisningen / Kullanım Talimatları’na başvurun / Див. інструкції з використання / 请参阅使用说明

Do not reuse / Не използвайте отново / Nepoužívejte opakovaně / Ikke til genbrug / Nicht wiederverwenden / Μην επαναχρησιμοποιείτε / No reutilizar / Mitte kasutada korduvalt / Ne pas réutiliser / Ne koristiti ponovo / Egyszer használatos / Non riutilizzare / Пайдаланбаңыз / 재사용 금지 / Tik vienkartiniam naudojimui / Nelietot atkārtoti / Niet opnieuw gebruiken / Kun til engangsbruk / Nie stosować powtórnie / Não reutilize / Nu refolosiţi / Не использовать повторно / Nepoužívajte opakovane / Ne upotrebljavajte ponovo / Får ej återanvändas / Tekrar kullanmayın / Не використовувати повторно / 请勿重复使用

Serial number / Сериен номер / Sériové číslo / Serienummer / Seriennummer / Σειριακός αριθμός / Nº de serie / Seerianumber / Numéro de série / Serijski broj / Sorozatszám / Numero di serie / Топтамалық нөмірі / 일련 번호 / Serijos numeris / Sērijas numurs / Serie nummer / Numer seryjny /Número de série / Număr de serie / Серийный номер / Seri numarası / Номер серії / 序列号

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

For US: "For Investigational Use Only"

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

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

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

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

STERILE EO Method of sterilization: ethylene oxide / Метод на стерилизация: етиленов оксид / Způsob sterilizace: etylenoxid / Steriliseringsmetode: ethylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / Método de esterilización: óxido de etileno / Steriliseerimismeetod: etüleenoksiid / Méthode de stérilisation : oxyde d'éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszere: etilén-oxid / Metodo di sterilizzazione: ossido di etilene / Стерилизация 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 түсіру / 소독 방법: 방사 / Sterilizavimo būdas: radiacija / Sterilizēšanas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Steriliseringsmetode: bestråling / Metoda sterylizacji: napromienianie / Método de esterilização: irradiação / Metodă de sterilizare: iradiere / Метод стерилизации: облучение / Metóda sterilizácie: ožiarenie / Metoda sterilizacije: ozračavanje / Steriliseringsmetod: strålning / Sterilizasyon yöntemi: irradyasyon / Метод стерилізації: опроміненням / 灭菌方法：辐射

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

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

Upper limit of temperature / Горен лимит на температурата / Horní hranice teploty / Øvre temperaturgrænse / Temperaturobergrenze / Ανώτερο όριο θερμοκρασίας / Límite superior de temperatura / Ülemine temperatuuripiir / Limite supérieure de température / Gornja dozvoljena temperatura / Felső hőmérsékleti határ / Limite superiore di temperatura / Температураның руқсат етілген жоғарғы 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

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

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

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

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

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

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

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

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

Keep away from light / Пазете от светлина / Nevystavujte světlu / Må ikke udsættes for lys / Vor Licht schützen / Κρατήστε το μακριά από το φως / Mantener alejado de la luz / Hoida eemal valgusest / Conserver à l'abri de la lumière / Držati dalje od svjetla / Fény nem érheti / Tenere al riparo dalla luce / Қараңғыланған жерде ұста / 빛을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt no gaismas / Niet blootstellen aan zonlicht / Må ikke utsettes for lys / Przechowywać z dala od źródeł światła / Manter ao abrigo da luz / 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

R_X Only This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner." / S'applique uniquement aux États-Unis: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner." / Vale solo per gli Stati Uniti: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner." / Gilt nur für die USA: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner." / Sólo se aplica a los EE.UU.: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."

bd.com/e-labeling
KEY-CODE: PP124JAA

Europe, CH, GB, NO: International:	+800 135 79 135 +31 20 794 7071		
AR	+800 135 79 135	LT	8800 30728
AU	+800 135 79 135	MT	+31 20 796 5693
BR	0800 591 1055	NZ	+800 135 79 135
CA	+1 855 805 8539	RO	0800 895 084
CO	+800 135 79 135	RU	+800 135 79 135
EE	0800 0100567	SG	800 101 3366
GR	00800 161 22015 7799	SK	0800 606 287
HR	0800 804 804	TR	00800 142 064 866
IL	+800 135 79 135	US	+1 855 236 0910
IS	800 8996	UY	+800 135 79 135
LI	+31 20 796 5692	VN	122 80297

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

EC REP Benex Limited
Pottery Road, Dun Laoghaire
Co. Dublin, Ireland

Australian Sponsor:
Becton Dickinson Pty Ltd.
4 Research Park Drive
Macquarie University Research Park
North Ryde, NSW 2113
Australia