BD BACTEC™ Standard/10 Aerobic/F Culture Vials
Soybean-Casein Digest Broth in a Plastic Vial

IVD R_X Only CE

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English

INTENDED USE

BD BACTEC™ Standard/10 Aerobic/F Culture Vials (enriched Soybean-Casein Digest broth with CO_2) are for aerobic blood cultures. Principal use is with the BD BACTEC fluorescent series instruments for the qualitative culture and recovery of aerobic microorganisms (bacteria and yeast) from blood.

SUMMARY AND EXPLANATION

The sample to be tested is inoculated into one or more vials which are inserted into the BD BACTEC fluorescent series instrument for incubation and periodic reading. Each vial contains a chemical sensor which can detect increases in CO_2 produced by the growth of microorganisms. The sensor is monitored by the instrument every ten minutes for an increase in its fluorescence, which is proportional to the amount of CO_2 present. A positive reading indicates the presumptive presence of viable microorganisms in the vial. Detection is limited to microorganisms that will grow in a particular type of medium.

PRINCIPLES OF THE PROCEDURE

If microorganisms are present in the test sample inoculated into the BD BACTEC vial, CO_2 will be produced when the organisms metabolize the substrates present in the vial. Increases in the fluorescence of the vial sensor caused by the higher amount of CO_2 are monitored by the BD BACTEC fluorescent series instrument. Analysis of the rate and amount of CO_2 increase enables the BD BACTEC fluorescent series instrument to determine if the vial is positive; i.e., that the test sample contains viable organisms.

REAGENTS

The BD BACTEC Standard/10 Aerobic/F Culture Vials contain the following active ingredients prior to processing:

List of Ingredients

(WTR) Processed Water .....40 mL
(SCB) Soybean-Casein Digest Broth .....3.0% w/v
(YEX) Yeast Extract.....0.3% w/v
(ATD) Animal Tissue Digest.....0.01% w/v
(SCR) Sucrose .....0.1% w/v
(HEM) Hemin.....0.0005% w/v
(MEN) Menadione .....0.00005% w/v
(PXH) Pyridoxal HCl (Vitamin B_6).....0.001% w/v
(SBC) Sodium Bicarbonate .....0.04% w/v
(SPS) Sodium Polyanetholsulfonate .....0.035% w/v

All BD BACTEC media are dispensed with added CO_2.

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"[1-4] and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.

Prior to use, each vial should be examined for evidence of contamination such as cloudiness, bulging or depressed stopper, or leakage. DO NOT USE any vial showing evidence of contamination. 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. Vial contamination may not be readily apparent. If a direct draw procedure is used, monitor the process closely to avoid refluxing materials into the patient.

Vials displaying turbidity, contamination, or discoloration (darkening) should not be used. On rare occasions a vial may not be sealed sufficiently; the contents of the vials may leak or spill, especially if the vials are inverted. If the vial has been inoculated, treat the leak or spill with caution, as pathogenic organisms/agents may be present. Before discarding, sterilize all inoculated vials by autoclaving.

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

To minimize the potential of leakage during inoculation of specimen into culture vials, use syringes with permanently attached needles or BD Luer-Lok™ brand tips.

Molecular tests performed on positive blood cultures will detect both viable and non-viable organisms commonly found in culture media. Therefore, Molecular test results should be evaluated in conjunction with Gram Stain results in accordance with standard-of-care practices as well as manufacturer's instructions for use.

Storage Instructions

The BD BACTEC vials are ready for use as received and require no reconstitution or dilution. Store at 2–25 °C, in a dry place **out of direct light**.

SPECIMEN COLLECTION

The specimen must be collected using sterile techniques to reduce the chance of contamination. The range of blood volume which can be cultured is 3–10 mL. It is recommended that the specimen be inoculated into the BD BACTEC vials at bedside. Most commonly, a 10 cc or 20 cc syringe with a BD Luer-Lok brand tip is used to draw the sample. 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 set (direct draw), carefully observe the direction of blood flow when starting sample collection. The vacuum in the vial will usually exceed 10 mL, so the user should monitor the volume collected by means of the 5 mL graduation marks on the vial label. When the recommended 8–10 mL has been drawn, the flow should be stopped by crimping the tubing and removing the tubing set from the BD BACTEC vial.

The inoculated BD BACTEC vial should be transported as quickly as possible to the laboratory.

PROCEDURE

Remove the flip-off cap from BD BACTEC vial top and inspect the vial for cracks, contamination, excessive cloudiness, and bulging or indented septums. **DO NOT USE** if any defect is noted. Before inoculating, swab the septum with alcohol (iodine is **NOT** recommended). Aseptically inject or draw directly 3–10 mL of specimen per vial. **Inoculated aerobic vials should be placed in the BD BACTEC fluorescent series instrument as soon as possible** for incubation and monitoring. If placement of an inoculated vial into the instrument has been delayed and visible growth is apparent, it should not be tested in the BD BACTEC fluorescent series instrument, but rather it should be subcultured, Gram-stained and treated as a presumptively positive bottle.

Vials entered into the instrument will be automatically tested every ten minutes for the duration of the testing protocol period. Positive vials will be determined by the BD BACTEC fluorescent series instrument and identified as such (see the appropriate BD BACTEC fluorescent series instrument User's Manual). The sensor inside the bottle will not appear visibly different in positive and negative vials, however the BD BACTEC fluorescent series instrument can determine a difference in fluorescence.

If at the end of the testing period a negative BD BACTEC Standard/10 Aerobic/F vial appears visually positive (i.e., chocolatized blood, bulging septum, lysed and/or very darkened blood), it should be subcultured, Gram-stained and treated as a presumptive positive.

Positive vials should be subcultured and a Gram-stained slide prepared. In a great majority of cases, organisms will be seen and a preliminary report can be made to the physician. Subcultures to selective media and a preliminary direct antimicrobial susceptibility test may be prepared from fluid in the BD BACTEC vials.

Subculturing: Prior to subculturing, put the vial in an upright position, and place an alcohol wipe over the septum. To release pressure in the vial, insert a sterile needle with an appropriate filter or pledget through the alcohol wipe and septum. The needle should be removed after the 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 twisting motions.

For maximum yield of isolates, negative cultures may be checked by stain and/or subcultured at some point prior to discarding as negative.

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.

DO NOT USE culture vials past their expiration date.

DO NOT USE culture vials that exhibit any cracks or defects; discard the vial in the appropriate manner.

Quality Control Certificates are provided with each carton of media. Quality Control Certificates list test organisms, including ATCC® cultures specified in the CLSI Standard, *Quality Control for Commercially Prepared Microbiological Culture Media*.

The range of time-to-detection in hours was ≤ 72 hours for each of the organisms listed on the Quality Control Certificate for this medium:

Streptococcus pyogenes ATCC 19615	*Escherichia coli* ATCC 25922	*Streptococcus pneumoniae** ATCC 6305
Pseudomonas aeruginosa ATCC 27853	*Candida albicans* ATCC 18804	*Neisseria meningitidis* ATCC 13090
Alcaligenes faecalis ATCC 8750	*Haemophilus influenzae* ATCC 19418	*Staphylococcus aureus* ATCC 25923

*CLSI Strain

For information on Quality Control for the BD BACTEC fluorescent series instrument, refer to the appropriate BD BACTEC fluorescent series instrument User's Manual.

LIMITATIONS OF THE PROCEDURE

Contamination

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

Recovery of SPS Sensitive Organisms from Blood Samples

Because blood can neutralize the toxicity of SPS toward organisms sensitive to SPS, the recommendation of maximum volumes of blood (8–10 mL) can help to optimize recovery of these organisms.

Some fastidious organisms, such as certain *Haemophilus* species, require growth factors, such as NAD, or factor V, which are provided by the blood specimen. If the blood specimen volume is 3.0 mL or less, an appropriate supplement may be required for recovery of these organisms. BD BACTEC FOS™, Fastidious Organism Supplement, may be used as a nutritional supplement. Recovery of *Haemophilus parainfluenzae* is strain dependent.

Nonviable Organisms

A Gram-stained smear from culture medium may contain small numbers of nonviable organisms derived from media constituents, staining reagents, immersion oil, glass slides, and specimens used for inoculation. In addition, the patient specimen may contain organisms that will not grow in the culture medium or in media used for subculture. Such specimens should be subcultured to special media as appropriate.[5]

Recovery of *Streptococcus pneumoniae*

In aerobic media, *S. pneumoniae* will typically be visually and instrument positive, but in some cases no organism will be seen on Gram stain or recovered on routine subculture. If an anaerobic vial was also inoculated, the organism can usually be recovered by performing an aerobic subculture of the anaerobic vial, since this organism has been reported to grow well under anaerobic conditions.[6]

General Considerations

Recovery of isolates will be achieved by adding 3–10 mL of blood. Blood may contain antimicrobials or other inhibitors which may slow or prevent the growth of microorganisms. False negative readings may result when certain organisms are present which do not produce enough CO_2 to be detected by the system or significant growth has occurred before placing the vial into the system. False positivity may occur when the white blood cell count is high.

Due to the nature of biological materials in media products and inherent organism variability, the user should be cognizant of potential variable results in the recovery of certain microorganisms.

The default 5-day (120 hours) protocol was utilized for all analytical testing with the BD BACTEC Standard/10 Aerobic/F culture media and protocol lengths of >5 days have not been evaluated.

EXPECTED VALUES AND PERFORMANCE CHARACTERISTICS

Performance of the BD BACTEC Standard/10 Aerobic /F medium contained in glass vials has been established by a number of external clinical studies.[7] Seeded laboratory studies performed by BD have shown equivalent performance of the BD BACTEC Standard/10 Aerobic /F medium contained in plastic vials to the BD BACTEC Standard/10 Aerobic /F medium contained in glass vials.[8]

A total of 984 paired sets at 10–100 CFU per vial were evaluated across the four instruments comprising the BD BACTEC fluorescent-series instrument family: BD BACTEC 9050, BD BACTEC 9240, BD BACTEC FX and the BD BACTEC FX40. Of the 984 paired sets 948 sets recovered organisms within the instrument series in both the BD BACTEC Standard/10 Aerobic/F medium contained in a plastic vial and the BD BACTEC Standard/10 Aerobic/F medium contained in a glass vial.

The BD BACTEC Standard/10 Aerobic/F medium contained in a plastic vial did not recover organisms in four instances: *Candida glabrata* (1), *Pediococcus acidilactici* (1), *Haemophilus influenzae* type a (1), and *Haemophilus parainfluenzae* (1). The BD BACTEC Standard/10 Aerobic/F medium contained in a glass vial did not recover organisms in nine instances: *Cryptococcus neoformans* (1), *Pediococcus acidilactici* (4), *Haemophilus influenzae* biotype I (1), and *Neisseria gonorrhoeae* (3). Twenty - three paired sets of *Haemophilus parainfluenzae* inoculated at 82 CFU per vial did not detect in either the BD BACTEC Standard/10 Aerobic/F medium contained in a plastic vial or the BD BACTEC Standard/10 Aerobic/F medium contained in a glass vial. The median time to detection difference between the paired sets across all inoculum levels (0–1 CFU, 1–10 CFU and 10–100 CFU per bottle) was approximately 1 hour, in favor of the BD BACTEC Standard/10 Aerobic/F medium contained in a plastic vial. There were thirty four false negative observations (i.e., end of protocol, instrument negative vials with a positive terminal subculture); eighteen false negatives across all inoculum levels were identified within the BD BACTEC Standard/10 Aerobic/F medium contained in a glass vial. Sixteen false negatives across all inoculum levels were identified within the BD BACTEC Standard/10 Aerobic/F medium contained in a plastic vial: *Candida glabrata* (1) *Cryptococcus neoformans* (2), *Haemophilus influenzae* (1), *Haemophilus parainfluenzae* biotype I (11), and *Pediococcus acidilactici* (1). Of the eleven *Haemophilus parainfluezae* biotype I, six inoculated at 82 CFU and five inoculated at 2 CFU. In an additional seeded study with five *Haemophilus parainfluenzae* strains tested with blood volumes 3, 5, and 10 mL at target inoculum 10–100 CFU, recovery rate was strain dependent and varies from 0% to 94% for plastic vial and from 6% to 100% for glass vial. Four additional yeast species (i.e., two strains each for *Candida parapsilosis, Candida tropicalis,* and one strain each for *Candida glabrata, Cryptococcus neoformans*) were tested and detected in both glass and plastic vials; median time to detection favored the plastic vial in this study.

The following organisms were evaluated in the analytical studies:

Abiotrophia defectiva	*Acinetobacter lwoffii*	*Aerococcus viridans*
Aggregatibacter actinomycetemcomitans	*Alcaligenes faecalis*	*Bacillus subtilis*
Candida albicans	*Candida glabrata*	*Candida tropicalis*
Candida parapsilosis	*Cardiobacterium hominis*	*Corynebacterium jeikeium*
Cryptococcus neoformans	*Eikenella corrodens*	*Enterobacter cloacae*
Enterococcus faecalis	*Escherichia coli*	*Granulicatella adiacens*
Haemophilus influenzae	*Haemophilus influenzae* type a	*Haemophilus influenzae* type b
Haemophilus parainfluenzae biotype I	*Kingella kingae*	*Klebsiella pneumoniae*
Leuconostoc citreum	*Micrococcus luteus*	*Neisseria gonorrhoeae*
Neisseria meningitidis	*Pediococcus acidilactici*	*Proteus mirabilis*
Providencia stuartii	*Pseudomonas aeruginosa*	*Rothia mucilaginosa*
Staphylococcus aureus	*Staphylococcus epidermidis*	*Stenotrophomonas maltophilia*
Streptococcus agalactiae	*Streptococcus pneumoniae*	*Streptococcus pyogenes*
Streptococcus sanguinis		

In the microbial detection limit testing, a total of 360 paired sets at target inoculum levels of 0 to1 and 1 to 10 CFU per vial were evaluated. This study was designed to assess the capability of the BD BACTEC Standard/10 Aerobic/F blood culture media to detect one CFU, when present. Of the 360 paired sets tested, 207 paired sets were instrument positive (grew and detected) and 68 paired sets were instrument negative (did not grow and detect). There were 37 instances when only the predicate device was instrument positive and 48 instances when only the modified device was instrument positive.

AVAILABILITY

Cat. No.	**Description**
442027	BD BACTEC™ Standard/10 Aerobic/F Culture Vials, case of 50 vials.

REFERENCES:

1. Clinical and Laboratory Standards Institute. 2014. Approved Guideline M29-A4. Protection of laboratory workers from occupationally acquired infections, 4th ed. CLSI, Wayne, Pa.
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3. U.S. Department of Health and Human Services. 2007. Biosafety in microbiological and biomedical laboratories, HHS Publication (CDC), 5th ed. U.S. Government Printing Office, Washington, D.C.
4. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC). Official Journal L262, 17/10/2000, p. 0021–0045.
5. Murray, P.R., E.J. Baron, J.H. Jorgensen, M.L. Landry and M.A. Pfaller (ed.). 2007. Manual of clinical microbiology, 9th ed. American Society for Microbiology, Washington, D.C.
6. Howden, R.J., J. Clin. Path. 1976, *29:*50–53.
7. Frederick S. Nolte, *et al.,* 1993. Multicenter Clinical Evaluation of a Continuous Monitoring Blood Culture System Using Fluorescent –Sensor Technology (BACTEC 9240), Journal of Clinical Microbiology, 31:552–557.
8. Data available from BD Diagnostics.

Technical Information: In the United States contact BD Technical Service and Support at 1.800.638.8663 or 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. In Warnings and Precautions section, added recommendation to perform molecular testings on positive blood cultures according to standard-of-care practices and manufacturer's instructions for use.

US Customers only: For symbol glossary, refer to 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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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

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

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

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

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

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

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

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

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

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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

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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, manipulați cu atenție. / 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

℞ 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."

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