BD Trypticase™ Soy Agar, Isolator Pack XT 150 mm

Prepared Plated Media

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English

INTENDED USE

BD Trypticase™ Soy Agar (TSA, Soybean-Casein Digest Agar Medium) is a general purpose medium which supports the growth of nonfastidious as well as moderately fastidious microorganisms. TSA is not the medium of choice for fastidious anaerobes. Isolator Pack "XT" products are gamma-sterilized after the aseptic fill procedure to allow monitoring of the environmental and product hygiene and the efficiency of disinfection in clean rooms of pharmaceutical production and fill rooms, and in isolators.

All products labeled "XT" are packaged in impermeable plastic films to allow an extended stability and storage at 2–25 °C throughout the shelf life.

BD does not assume responsibility if the product is used for applications, microorganisms, or procedures not recommended in the Instructions for Use.

PRINCIPLES OF THE PROCEDURE

The nutritional composition of BD Trypticase Soy Agar has made it a popular medium for many years. It is the medium specified as Soybean-Casein Digest Agar Medium in the United States Pharmacopeia and in the European Pharmacopeia for the total aerobic microbial count portion of the microbial limit testing procedures.[1,2] It is included in the compendia of methods for the examination of water, wastewater and foods.[3,4]

TSA contains peptones which provide the carbon and nitrogen sources required for growth of a wide variety of organisms. Sodium chloride provides osmotic equilibrium. Sodium pyruvate is added to absorb peroxides and radicals that develop during gamma-irradiation and during exposure to isolator air that contains residues of hydrogen peroxide.

The aseptic manufacturing processes of this medium is controlled to ensure that the bioburden of the product is reduced to a minimum. Each piece of equipment used in the manufacturing has been qualified and validated. Using a proprietary filling process, Isolator Pack media are dispensed in a controlled environment, which has been verified as ISO class 5 and is monitored during production to ensure that specifications are met. Once a medium is dispensed, the plates of all XT products are packed and sealed in a dedicated, controlled environment (ISO class 7) into three impermeable plastics bags to reduce evaporation and oxidation of the medium to a minimum. This allows storage at room temperature for the whole shelf life period.

Because the entire triple-bagged product in its carton box is subjected to a sterilizing dose of gamma-irradiation, the contents inside the outer bag are sterile. This allows the inner bags to be aseptically removed and brought into an environmental-controlled area without introducing contaminants.

The microbiological status of these products has been validated according to ISO 11137.[5,6] As a result from the validation tests, an irradiation dose of 9.6 kGray was determined to be the minimum irradiation dose necessary for achieving an SAL of 10^{-5}.[7] The media are gamma-irradiated in the packaging material as delivered with 10 to 22 kGray to ensure a reduction of the microbial load potentially present in the medium, on the dishes, and on the packaging materials. Gamma-irradiation of the product is indicated by an orange to red color of the irradiation indicator stripe on the inner label. A yellow to mustard-colored indicator indicates insufficient irradiation.

The bags (with undamaged sealing seams) of Isolator Pack XT products are impermeable to hydrogen peroxide. This applies to product packaged in one, two, or three bags.

REAGENTS

Approximate Formulas* Per Liter Purified Water

All Isolator Pack XT products with BD Trypticase Soy Agar	
Pancreatic Digest of Casein	15.0 g
Papaic Digest of Soybean Meal	5.0 g
Sodium Chloride	5.0 g
Sodium Pyruvate	3.5 g
Agar	15.0 g

pH 7.3 ± 0.2

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

WARNINGS AND PRECAUTIONS

For laboratory use only.

The contents of the unopened and undamaged bags are sterile. Do not use packages if they show evidence of microbial contamination, discoloration, drying, cracking, open or damaged bags or other signs of deterioration. The inner bag of these products contain irradiation indicator dots or stripes (dark orange to red = irradiated; yellow to mustard-colored = not irradiated). Do not use the product if the irradiation indicators are yellow to mustard-colored.

The plastic bags used for packaging of these products consist of polyethylene/ polyethylene terephthalate (=PE/PET).

Biological and Chemical Safety of the Product

This section may also contain information on specific biological and/or chemical hazards, indicated by the appropriate symbols, together with the appropriate R (risk)- and S (safety)-phrases.[11]

Biohazard Originating from Specimens and Microorganisms Cultivated on Microbiological Media

Observe established precautions against microbiological hazards. Specimens and cultures of microorganisms must be handled according to local biohazard guidelines and legislation. According to the European Directive 2000/54/EC, most bacterial and fungal pathogens are included in risk group 2. Risk group 3 has been created to include *Salmonella* Typhi, enterohemorrhagic *Escherichia coli* (EHEC; also referred to as STEC = Shiga toxin-producing *E. coli*), *Shigella dysenteriae* (type 1) and several other bacteria and fungi. Other bacterial and fungal pathogens included in risk group 3 are: all *Brucella* spp.; *Mycobacterium tuberculosis; M. bovis; M. africanum; M. ulcerans;* and *Histoplasma capsulatum*. For details, consult Annex III of Directive 2000/54/EC.[12]

Product Disposal

After use and prior to discarding, specimen containers and all contaminated material, including the used culture media and contaminated culture containers, must be autoclaved for 20 to 30 min at 121 °C or higher (if large volumes of disposed materials must be sterilized), or incinerated by validated procedures.

Packaging Information

Ten plates each of these products are packed in three plastic bags. White cartons are used for packaging the bagged stacks.

The sealing seams of the bags are heat-sealed. The bags allow easy opening without the use of sharp objects such as scissors or knives. Bags can be peeled open at the ends of the stacks by tearing apart both plastic films of the bag. Apply aseptic techniques. Once the outer bag is opened, appropriate measures should be used to maintain the sterility of the inner bags and the contents.

STORAGE

On receipt, store plates in the dark at 2–25 °C, in their original bags until just prior to use. Do not freeze or overheat. Avoid repeated and/or extreme variations in temperature during storage since this may cause the development of excessive moisture in the bags and plates. The ideal storage temperature of these products is 15–22 °C. Moisture appearing as a fine haze or as small droplets on the inner side of the lids, especially during or after refrigerated storage, is acceptable and is a sign for freshness of the media. Minimize exposure to light during the whole storage period.

The plates may be inoculated up to the expiration date and incubated for the recommended incubation times. The given shelf life and expiry applies to the product in unopened (completely sealed) bags.

USER QUALITY CONTROL

Inoculate representative samples of the medium with <100 CFU per plate of the strains listed in the table. Use BD Trypticase Soy Agar as a growth reference medium. See table for incubation. After the incubation, compare the CFU on both media (see table footnote). The recovery on the test medium must be >70% as compared to the reference medium.

Species	Strains	Incubation	Expected Recovery (%)*
Aspergillus niger	ATCC® 16404	2–5 d/30–35 °C	>70
Candida albicans	ATCC 10231	2–5 d/30–35 °C	>70
Bacillus subtilis	ATCC 6633	1–3 d/30–35 °C	>70
Escherichia coli	ATCC 8739	1–3 d/30–35 °C	>70
Pseudomonas aeruginosa	ATCC 9027	1–3 d/30–35 °C	>70
Salmonella Typhimurium	ATCC 14028	1–3 d/30–35 °C	>70
Staphylococcus aureus	ATCC 6538	1–3 d/30–35 °C	>70
Staphylococcus epidermidis	ATCC 12228	1–3 d/30–35 °C	>70
Appearance of the uninoculated medium	Colorless to light amber, clear to slightly hazy		

* Recovery (%) = $CFU_{Test\ medium}$ / $CFU_{Reference\ medium}$ x 100

Always use fresh test strain suspensions, prepared from overnight cultures in appropriate liquid media (e.g., Tryptic or BD Trypticase™ Soy Broth for aerobes, and Schaedler Broth with hemin and vitamin K for anaerobes). Alternatively, fresh suspensions prepared from overnight cultures on plated media can be used. Incubation times of precultures must be extended if the test strain grows slowly. For **testing the nutritive capacity of a plated medium** according to the CLSI standard M22, dilute the inoculum suspension to provide 1 to 2 x 10^4 cfu per plate.[13] A tenfold lighter inoculum should be used if this does not provide isolated colonies. According to DIN EN 12322, the growth-promoting properties are tested with 100 to 1,000 cfu or a sufficient amount of cfu to provide isolated colonies by an appropriate streaking plate technique.[14] If the strains are inoculated by a quantitative plating technique, 50 to 500 cfu per plate are usually appropriate to obtain a countable number of colonies. For **testing the inhibitory capacity of a selective plated medium**, according to CLSI M22, 1 to 2 x 10^5 cfu per plate must be used for inoculation, and about 10^4 or more cfu according to DIN EN 12322.[13,14] Very high inocula of unwanted strains may "overload" the medium, leading to "breakthrough" growth. For comparison, always include a growth reference medium which should be a nonselective medium that provides optimal growth of all test strains. For aerobic strains, Columbia Agar with 5% Sheep Blood, for fastidious strains (like *Neisseria gonorrhoeae*) Chocolate Agar, for anaerobes Schaedler Agar with Vitamin K and 5% Sheep Blood, and for fungi Sabouraud Glucose Agar are suitable for this purpose. If tested quantitatively, growth of "desired" strains on the test medium should be at least 70% of that on the reference medium. On selective media, growth of "undesired" strains must be partially to completely inhibited. The degree of inhibition depends on the medium and the strains, but growth is usually reduced by a factor of 10^3 to 10^4 (or more) as compared to the growth on the nonselective growth reference medium. For **testing the growth performance of media in vials**, comparable methods are used. Smaller tubes and vials should be inoculated with 10^5 cfu according to the CLSI M22-A2 standard.[13] Vials or bottles with fill volumes above 10 mL should first be aliquoted in 5 or 10 mL amounts in sterile tubes and tested in the same way.

PROCEDURE

Materials Provided

See **AVAILABILITY** for the available XT products.

Materials Not Provided

Ancillary culture media, reagents, inoculating loops, spreaders, pipettors, incubators, and laboratory equipment as required.

Test Procedure

Isolator Pack XT products are used in a variety of procedures. Follow the appropriate references for sampling, inoculation, and incubation.[1-4] Isolator Pack XT products are used for monitoring the hygiene on surfaces or the microbiological quality of the air in controlled environments such as fill rooms or in isolators.

Products supplied in 150 mm dishes are generally used in air sedimentation procedures.

Incubate inoculated plates at 35–37 °C for 48 hours and at 25 °C for 7 days or as required.

Results

After the incubation, viable microorganisms will produce colonies on the surface of the medium that should be counted. Counting of plates containing a profusion of growth can lead to considerable error. A basic decision to be made is whether distinct colony margins can be observed. Spreading colonies should be counted as one but care should be taken to observe other distinct colonies intermingled in the growth around the plate periphery or along a hair line. These should also be counted as one colony, as should bi-colored colonies or halo-type spreaders.

From the isolates obtained on the media, appropriate subcultures should be set up to allow a further differentiation and identification. Refer to appropriate references and procedures.[1-3]

These media are intended for the enumeration of organisms in hygiene control. BD Trypticase Soy Agar is not suitable media for fastidious bacteria and are not the media of choice for fastidious anaerobes.

BD Trypticase Soy Agar does not contain compounds that actively neutralize disinfectants or preservatives. If materials containing such compounds or surfaces that have been previously disinfected shall be monitored, it is recommended to use media containing BD Trypticase Soy Agar with Lecithin and Polysorbate.

Extended sedimentation exposure followed by incubation in dry air may lead to cracking or splitting of the agar gel.

These media do not allow a complete identification. Further tests, made from pure cultures of the isolates, must be performed for complete identification of the isolated microorganisms. Consult the references.[8-10]

Use of these media with clinical specimens has not been validated.

AVAILABILITY

Cat. No.	Description	Number of plates per package
257377	BD Trypticase™ Soy Agar, Isolator Pack XT 150 mm	30

In addition, Sterile Transport Bags for 10 plates per bag are available for transportation of exposed or inoculated plates from the sampling site to the laboratory (Cat. No. 257405 for 55 mm plates; Cat. No. 257404 for 90 mm plates).

REFERENCES

1. U.S. Pharmacopeial Convention, Inc. The U.S. Pharmacopeia/The national formulary *Current edition*. U.S. Pharmacopeial Convention, Inc., Rockville, Maryland USA.
2. Council of Europe. European Pharmacopoeia, *current edition*. European Pharmacopoeia Secretariat. Strasbourg/France.
3. Eaton, A.D., L.S. Clesceri, and A.E. Greenberg (ed.). 1995. Standard methods for the examination of water and wastewater, 19th ed. American Public Health Association, Washington, D.C. USA.
4. Downes, F.P, and K. Ito (ed.). 2001. Compendium of methods for the microbiological examination of foods, 4th ed. American Public Health Association, Washington, D.C. USA.
5. ISO 11137-1: 2006.Sterilization of health care products—Radiation–Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
6. ISO 11137-2: 2006.Sterilization of health care products—Radiation–Part 2: Establishing the sterilization dose.
7. Data on file: Isolator Pack XT Qualification Study. BD Heidelberg, Germany, 2006.
8. Holt, J.G., N.R. Krieg, P.H.A. Sneath., J.T. Staley, and S.T. Williams (ed.). 1994. Bergey's Manual of Determinative Bacteriology, 9th ed. Williams & Wilkins, Baltimore, Maryland USA.
9. Forbes, B.A., D.F. Sahm, and A.S. Weissfeld. 1998. Bailey & Scott's diagnostic microbiology, 10th ed. Mosby, Inc., St. Louis, Missouri USA.
10. Murray, P.R., E.J. Baron, M.A. Pfaller, F.C. Tenover, and R.H. Yolken (ed.). 1995. Manual of clinical microbiology, 6th ed. American Society for Microbiology, Washington, D.C. USA.
11. Directive 67/548/EEC of the European Parliament and of the Council of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Official Journal P 196, 16.08.1967, p. 0001–0098.
12. 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 98/391/EEC). Official Journal L 262, 17.10.2000, p. 0021–0045.
13. Clinical and Laboratory Standards Institute. Standard M22. Quality assurance for commercially prepared microbiological culture media. Wayne, Pennsylvania USA. Search for latest version at clsi.org.
14. DIN EN 12322. 1999. Culture media for microbiology–performance criteria for culture media. Beuth Verlag Berlin.

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Change History

Revision	Date	Change Summary
01	2020-07	Document number changed, version reset to revision 01 for BD branding updates. Updated access information to obtain the document from bd.com/e-labeling.

Some symbols listed below may not apply to this product.

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)
РРРР-ММ-ДД / РРРР-ММ (ММ = кінець місяця)
YYYY-MM-DD / YYYY-MM (MM = 月末)

Catalog number / Каталожен номер / Katalogové číslo / Katalognummer / Αριθμός καταλόγου / Número de catálogo / Kataloognumber / 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)

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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 рұқсат шегі / 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 әдісі – этилен тотығы / 소독 방법: 에틸렌옥사이드 / Sterilizavimo būdas: etileno oksidas / Sterilizēšanas metode: etilēnoksīds / Gesteriliseerd met behulp van ethyleenoxide / Steriliseringsmetode: etylenoksid/ Metoda sterylizacji: tlenek etylu / Método de esterilização: óxido de etileno / Metodă de sterilizare: oxid de etilenă / Метод стерилизации: этиленоксид / Metóda sterilizácie: etylénoxid / Metoda sterilizacije: etilen oksid / Steriliseringsmetod: etenoxid / Sterilizasyon yöntemi: etilen oksit / Метод стерилізації: етиленоксидом / 灭菌方法：环氧乙烷

STERILE R

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

Biological Risks / Биологични рискове / Biologická rizika / Biologisk fare / Biogefährdung / Βιολογικοί κίνδυνοι / Riesgos biológicos / Bioloogilised riskid / Risques biologiques / 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 mellékelttájékoztatót / 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 рұқсат етілген жоғарғы шегі / 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

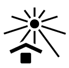
Keep dry / Пазете сухо / Skladujte v suchém prostředí / Opbevares tørt / Trocklagern / Φυλάξτε το στεγνό / Mantener seco / Hoida kuivas / Conserver au sec / Držati na suhom/ Száraz helyen tartandó / Tenere all'asciutto / Құрғақ күйінде ұста / 건조 상태 유지 / Laikykite sausai / Uzglabāt sausu / Droog houden / 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 / Үстіңгі 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/ Егер 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 / Feriţi de lumină / Хранить в темноте / Uchovávajte mimo dosahu svetla / Držite dalje od svetlosti / Får ej utsättas för ljus / Işıktan uzak tutun / Берегти від дії світла / 请远离光线

Hydrogen gas generated / Образуван е водород газ / Možnost úniku plynného vodíku / Frembringer hydrogengas / Wasserstoffgas erzeugt / Δημιουργία αερίου υδρογόνου / Producción de gas de hidrógeno / Vesinikgaasi tekitatud / Produit de l'hydrogène gazeux / Sadrži hydrogen vodik / Hidrogén gázt fejleszt / Produzione di gas idrogeno / Гаэтектес сутеги пайда болды / 수소 가스 생성됨 / Išskiria vandenilio dujas / Rodas ūdeņradis / Waterstofgas gegenereerd / Hydrogengass generert / Powoduje powstawanie wodoru / Produção de gás de hidrogénio / Generare gaz de hidrogen / Выделение водорода / Vyrobené použitím vodíka / Oslobađa se vodonik / Genererad vätgas / Açığa çıkan hidrojen gazı / Реакція з виділенням водню / 会产生氢气

Patient ID number / ИД номер на пациента / ID pacienta / Patientens ID-nummer / Patienten-ID / Αριθμός αναγνώρισης ασθενούς / Número de ID del paciente / Patsiendi ID/ No d'identification du patient / Identifikacijski broj pacijenta / Beteg azonosító száma / Numero ID paziente / Пациенттің идентификациялық нөмірі / 환자 ID 번호 / Paciento identifikavimo numeris / Pacienta ID numurs / Identificatienummer van de patiënt / Pasientens ID-nummer / Numer ID pacjenta / Número da ID do doente / Număr ID pacient / Идентификационный номер пациента / Identifikačné číslo pacienta / ID broj pacijenta / Patientnummer / Hasta kimlik numarası / Ідентифікатор пацієнта / 患者标识号

Fragile, Handle with Care / Чупливо, Работете с необходимото внимание. / Křehké. Při manipulaci postupujte opatrně. / Forsigtig, kan gå i stykker. / Zerbrechlich, vorsichtighandhaben. / 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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