

BD Tryptic Soy Agar

Partially Prepared Media



L012106(01)

2020-07

English

INTENDED USE

BD Tryptic Soy Agar, provided in bottles, is a general purpose partially prepared medium which, after pouring into Petri dishes or tubes, supports the growth of nonfastidious as well as moderately fastidious microorganisms.

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

Microbiological method.

The nutritional composition of BD Tryptic 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} The prepared medium is used for a multitude of purposes including maintenance of stock cultures, plate counting, isolation of microorganisms from a variety of materials.³⁻⁵ It is included in the compendia of methods for the examination of water, wastewater and foods.^{6,7}

The use of this medium in clinical microbiology is limited since it does not support the growth of a variety of fastidious bacteria. However, since BD Tryptic Soy Agar does not contain the X and V growth factors, it may be used in determining the requirements for these growth factors by isolates of *Haemophilus* species by the addition of X, V and XV factor strips to inoculated plates.⁸ BD Tryptic Soy Agar may also be used as a medium for maintaining or subculturing reference strains, e.g., *Enterobacteriaceae* and staphylococci. The unsupplemented medium is not used as a primary isolation medium for clinical applications. After the addition of blood (e.g., 5% sheep blood), it can be used for the isolation of bacteria from clinical specimens.^{9,10}

In BD Tryptic Soy Agar, the combination of casein and soy peptones renders the medium nutritious by supplying organic nitrogen, particularly amino acids and longer-chained peptides. Sodium chloride maintains the osmotic equilibrium. BD Tryptic Soy Agar (Bottled Media) are partially prepared media supplied in bottles from which the user can prepare a plated or tubed medium. These media are manufactured from BD Difco™ dehydrated medium.

REAGENTS

Approximate Formulas* Per Liter Purified Water

BD Tryptic Soy Agar	
Pancreatic Digest of Casein	15.0 g
Papaic Digest of Soybean Meal	5.0 g
Sodium Chloride	5.0 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.

Do not use bottles if they show evidence of microbial contamination, discoloration, drying, cracking, or other signs of deterioration. For completion of this partially prepared medium, follow the methods and observe the warnings described under

PROCEDURE—Reagent Preparation.

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.¹²

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.¹³

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.

STORAGE

On receipt, store bottles in the dark at 5–25 °C. Avoid freezing and overheating. The medium may be used up to the expiration date and incubated for the recommended incubation times. Bottles from opened packages can be used up to the expiration date. Opened bottles must be used immediately. To prepare plates or tubes from the bottled medium, it must first be liquefied (see **PROCEDURE—Reagent Preparation**). Do not liquefy leftovers for a second time.

USER QUALITY CONTROL

Unsupplemented medium: Prepare plates or tubes from the partially prepared medium (see **PROCEDURE—Reagent Preparation**), without adding supplements such as blood. Inoculate plates or tubes with the test strains indicated in the table below. For further details. Incubate the bacteria for 1 to 3 days aerobically at 30–35 °C. Incubate *Aspergillus brasiliensis* for 2 to 5 days aerobically at 30–35 °C.

Species	Strains	Growth Results
<i>Aspergillus brasiliensis</i>	ATCC® 16404	Growth
<i>Candida albicans</i>	ATCC 10231	Growth
<i>Staphylococcus aureus</i>	ATCC 6538	Growth
<i>Staphylococcus epidermidis</i>	ATCC 12228	Growth
<i>Bacillus subtilis</i>	ATCC 6633	Growth
<i>Pseudomonas aeruginosa</i>	ATCC 9027	Growth
<i>Escherichia coli</i>	ATCC 8739	Growth
<i>Salmonella</i> Typhimurium	ATCC 14028	Growth
Uninoculated		Light amber to amber, slightly opalescent

Medium supplemented with 5% defibrinated sheep blood: Prepare plates from the partially prepared medium (see **PROCEDURE—Reagent Preparation**) and supplement with 5% sheep blood after cooling to 48–50 °C. It is recommended to test the supplemented medium according to CLSI Standard M22.¹¹ Incubate strains for 20 to 24 hours in an aerobic atmosphere enriched with carbon dioxide.

Species	Strains	Growth Results
<i>Streptococcus pyogenes</i>	ATCC 19615	Growth; beta hemolysis
<i>Streptococcus pneumoniae</i>	ATCC 6305	Growth; alpha hemolysis
<i>Staphylococcus aureus</i>	ATCC 25923	Growth; may or may not be beta-hemolytic
Uninoculated		Red (blood color)

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 10⁴ cfu per plate.¹⁴ 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.¹⁵ 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 10⁵ cfu per plate must be used for inoculation, and about 10⁴ or more cfu according to DIN EN 12322.^{14,15} 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 10³ to 10⁴ (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 10⁵ cfu according to the CLSI M22-A2 standard.¹⁴ 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

BD Tryptic Soy Agar partially prepared media.

Materials Not Provided

Autoclave (set at 100 ± 2 °C), steam cooker, or hot plate; water bath (48–50 °C); defibrinated blood (for preparation of blood plates only); sterile glassware and sterile plastic Petri dishes or tubes.

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

Reagent Preparation

Liquefy BD Tryptic Soy Agar (Bottled Media) by heating in an autoclave or steam cooker. Alternatively, the bottle may be placed into a jar containing water, which is placed on a hot plate and brought to boiling. **Slightly loosen the cap before heating to allow pressure exchange.**

Warning: It is not recommended to use microwave ovens for liquefaction of the medium. Do not place media bottles with metal closures into a microwave oven.

When using an autoclave, set the temperature to not more than $100 \pm 2^\circ\text{C}$ as excessive heating may deteriorate the ingredients, possibly leading to unsatisfactory microbiological performance. When using a hot plate and/or a water bath, boil sufficiently long to dissolve the whole medium. The time needed for complete liquefaction of the medium may vary considerably and depends on the actual temperature of the heating device before use, its wattage, size, and the volume and temperature of the medium in the container. It is recommended to test and record the time needed for liquefaction after the first use.

After complete liquefaction, remove the container from the heating device and place into a water bath set at $48\text{--}50^\circ\text{C}$.

Warning: Wear heat-protective gloves. Do not place the hot container into an ice bath or in cold water to accelerate cooling as this might cause cracks in the glass. Risk of severe scald.

Leave the container in the water bath sufficiently long to allow cooling of the complete medium to the set temperature.

If defibrinated blood (e.g., 5% sheep blood) or other heat-sensitive supplements (which must be brought to room temperature before use) are added, the temperature of the medium must not be higher than 50°C . Apply aseptic conditions during addition of the supplement and during pouring of the plates. Use sterile dishes or tubes. Mix the medium gently after addition of the supplement, but avoid formation of foam and bubbles.

Pour the medium into the dishes if surface inoculation is desired. For a normal 90 to 100 mm dish, 19 to 21 mL is an appropriate volume. Allow the completed medium to solidify, invert the plates and allow to dry at room temperature for an adequate time (for complete solidification, store overnight at $18\text{--}23^\circ\text{C}$). Wrap in fresh plastic bags and store at $2\text{--}8^\circ\text{C}$. Prepared plates of this medium may be used for 5 to 7 days.

If the pour plate method shall be applied, add the material to be tested or its dilution into the empty dish, overlay with the medium, rotate the dish gently to mix, and allow to solidify completely.

For the preparation of slants in tubes, add the appropriate amount of liquefied medium, cooled to $48\text{--}50^\circ\text{C}$, to the tubes and allow to solidify in the desired slanted position. Tubes, when closed tightly with screw caps, can be used for 2 to 3 weeks when stored in the dark at room temperature or at $2\text{--}8^\circ\text{C}$.

Before use, the medium surfaces must not be excessively wet.

Liquefy the bottled medium only once. Do not allow any leftovers to solidify and liquefy thereafter for a second time as repeated heating will damage the ingredients of the medium, leading to unsatisfactory microbiological performance.

Test Procedure

The unsupplemented medium, poured into Petri dishes is used in a variety of procedures, e.g., for pharmaceutical tests. In clinical microbiology, it must not be used as an isolation medium for pathogens from clinical specimens, unless supplemented with blood (e.g., 5% sheep blood). If supplemented with 5% blood, the plated medium can be universally used for primary isolation of pathogens from all types of specimens. Consult the references for specimen collection and processing.^{4,10} The tubed, slanted medium must not be used directly with clinical specimens but only for the growth and maintenance of bacterial cultures.

Before use, agar surfaces of the completed medium (in Petri dishes or in tubes) should be smooth and moist, but without excessive moisture because this could cause confluent growth. Consult the appropriate references for specific methods.^{2,6,7}

Plates supplemented with blood: Streak the specimen as soon as possible after it is received in the laboratory. The streak plate is used primarily to isolate pure cultures from specimens containing mixed flora. Alternatively, if material is being cultured directly from a swab, roll the swab over a small area of the surface at the edge; then streak from this inoculated area. Incubate the plates or tubes under the conditions chosen.

- If used for clinical specimens, incubate for 18 to 48 hours (or longer if necessary) at $35 \pm 2^\circ\text{C}$ or as appropriate for the organisms.
- If used for hygiene monitoring, incubate at $30\text{--}35^\circ\text{C}$, for up to 5 days.

If used for pharmaceutical materials, consult the references.^{1,2}

The slanted medium in tubes is used for the cultivation and maintenance of bacterial cultures. Streak the strain directly or after suspension in sterile water or saline onto the whole slanted surface. Incubate as appropriate for the isolate. During incubation, caps may be slightly loosened to allow venting. After incubation and during storage, close completely.

Results

After incubation, plates may show an area of confluent growth. Because the streaking procedure is, in effect, a "dilution" technique, diminishing numbers of microorganisms are deposited on the streaked areas. Consequently, one or more of these areas should exhibit isolated colonies of the organisms contained in the specimen. In addition, growth of each organism may be semi-quantitatively scored on the basis of growth in each of the streaked areas.

- Pour plate method: Consult the appropriate references.^{1,2,6,7}

If inoculated with an appropriate inoculum, slants will show growth on the whole surface. Tightly closed tubes may be stored refrigerated for several weeks without loss of viability of the culture. The survival time depends on the individual strains.

The number and types of organisms growing on the completed media prepared from BD Tryptic Soy Agar (Bottled Media) is very large. Therefore, no specific details on their appearance can be given here. Consult the references.^{4,9,10}

From the isolates obtained on the media, appropriate subcultures must be set up to allow a further differentiation and identification.

PERFORMANCE CHARACTERISTICS AND LIMITATIONS OF THE PROCEDURE

BD Tryptic Soy Agar is used in a variety of industrial microbiology procedures, e.g., in microbial limit testing and in water and food microbiology.^{1-3,6,7}

Unsupplemented BD Tryptic Soy Agar is used for cultivation of many less fastidious bacteria, e.g., *Enterobacteriaceae*, nonfermenting gram-negative rods (*Pseudomonas* and many others), enterococci, staphylococci, sporeforming bacteria (*Bacillus* and related genera), and other organisms with similar growth requirements. The medium is not suitable for the isolation and cultivation of very fastidious bacteria, such as *Neisseria* or *Haemophilus* species, or other organisms with special nutritional requirements, and it is not an optimal medium for the isolation of fastidious strict anaerobes. Therefore, the use in clinical microbiology is limited to special tests, e.g., the differentiation of *Haemophilus* with X, V, and XV factors strips.⁸

BD Tryptic Soy Agar supplemented with blood (e.g., 5% sheep blood), is frequently used as a primary isolation medium for aerobic bacteria in clinical microbiology. For details, consult the references.^{3-5,8-10}

Unsupplemented BD Tryptic 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 BD Tryptic Soy Agar with Lecithin and Polysorbate or to supplement the medium appropriately.

AVAILABILITY

Cat. No.	Description
256665	BD Tryptic Soy Agar, cpu 10, 100 mL fill volume; in 250 mL sirup bottle
257105	BD Tryptic Soy Agar, cpu 12, 250 mL fill volume; in 500 mL flat bottle
257106	BD Tryptic Soy Agar, cpu 10, 500 mL fill volume; in 500 mL sirup bottle
257240	BD Tryptic Soy Agar, cpu 4, 400 mL fill volume; in 500 mL laboratory bottle

REFERENCES

1. U.S. Pharmacopeial Convention, Inc. The U.S. Pharmacopeia /The national formulary. U.S. Pharmacopeial Convention, Inc., Rockville, Maryland USA (*Refer to the latest edition*).
2. Council of Europe. European Pharmacopoeia. European Pharmacopoeia Secretariat. Strasbourg/France. (*Refer to the latest edition*).
3. MacFaddin, J.F. 1985. Media for isolation-cultivation-identification-maintenance of medical bacteria, vol. 1, Williams & Wilkins, Baltimore, Maryland USA.
4. Baron, E.J., L.R. Peterson, and S.M. Finegold. 1994. Bailey & Scott's diagnostic microbiology, 9th ed. Mosby-Year Book, Inc., St. Louis, Missouri, USA.
5. Nash, P., and M.M. Krenz. 1991. Culture media. In: A. Balows, W.J. Hausler, Jr., K.L. Herrmann, H.D. Isenberg, and H.J. Shadomy (ed.), Manual of clinical microbiology, 5th ed. American Society for Microbiology, Washington, D.C. USA.
6. 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.
7. 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.
8. Campos, J.M. 1995. Haemophilus. In: P.R. Murray, E.J. Baron, M.A. Pfaller, F.C. Tenover, and R.H. Tenover (ed.), Manual of clinical microbiology, 6th ed. American Society for Microbiology, Washington, D.C. USA.
9. Chapin, K.C., and T.-L. Lauderdale. 2003. Reagents, stains, and media: bacteriology. In: Murray, P. R., E. J. Baron, J.H. Jorgensen, M. A. Pfaller, and R. H. Tenover (ed.). Manual of clinical microbiology, 8th ed. American Society for Microbiology, Washington, D.C. USA.
10. Murray, P. R., E. J. Baron, J.H. Jorgensen, M. A. Pfaller, and R. H. Tenover (ed.). 2003. Manual of clinical microbiology, 8th ed. American Society for Microbiology, Washington, D.C. USA.
11. CLSI (formerly NCCLS) Document M22. Quality assurance for commercially prepared microbiological culture media (Refer to latest version) Clinical Laboratory Standards Institute. Wayne, Pennsylvania USA.
12. 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.
13. 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.
14. 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.
15. DIN EN 12322. 1999. Culture media for microbiology—performance criteria for culture media. Beuth Verlag Berlin.

Technical Service and Support: contact your local BD representative or bd.com.

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 / Fabbicante / Атқарушы / 제조업체 / Gamintojas / Ražotājs / Tilvirker / Producent / Producător / Производителъ / Výrobca / Proizvođač / Tillverkare / Üretici / Виробник / 生产厂商
	Use by / Използвайте до / Spotbeuhte 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 / Izljetot līdz / Houdbaar tot / Brukes for / Stosować do / Prazo de validade / A se utiliza până la / Изпользовать до / Použite do / Upotrebiti do / Använd före / Son kulanma tarihi / Використати до / 使用截止日期 YYYY-MM-DD / YYYY-MM (MM = end of month) TTTT-MM-DD / TTTT-MM (MM = края на месеца) RRRR-MM-DD / RRRR-MM (MM = konec měsíce) AAAA-MM-DD / AAAA-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 lopp) 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) ЖОЖОЖ-АА-КК / ЖОЖОЖ-АА / (АА = айдың соңы) YYYY-MM-DD/YYYY-MM (MM = 월말) MMMM-MM-DD / MMMM-MM (MM = mensesio pabaiga) GGGG-MM-DD/GGGG-MM (MM = mēneša beigas) JJJJ-MM-DD / JJJJ-MM (MM = einde maand) AAAA-MM-DD / AAAA-MM (MM = sluten 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 = sfârșitul lunii) TTTT-MM-DD / TTTT-MM (MM = конец месяца) RRRR-MM-DD / RRRR-MM (MM = koniec mesiacu) GGGG-MM-DD / GGGG-MM (MM = kraj meseca) AAAA-MM-DD / AAAA-MM (MM = slutet av månaden) YYYY-AA-GG / YYYY-AA (AA = ayın sonu) PPPP-MM-DD / PPPP-MM (MM = кінець місяця) YYYY-MM-DD / YYYY-MM (MM = 月末)
	Catalog number / Каталоген 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 / Katalogové číslo / Kataloški broj / Katalog numarası / Номер за каталогом / 目录号
	Authorized Representative in the European Community / Оторизирани 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 Közösségekben / Rappresentante autorizzato nella Comunità Europea / Европа қауымдастығындағы уәкілетті өкіл / 유럽 공동체의 위임 대표 / Įgaliojasis 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 prietaisai / Medicinas ierices, 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 / Dispositiv medical pentru diagnostic in vitro / Медицинский прибор для диагностики in vitro / Medicinska pomôcka na diagnostiku in vitro / Medicinski uređaj za in vitro dijagnostiku / Medicinteknisk produkt för in vitro-diagnostik / In Vitro Diyagnostik Tibbi Cihaz / Медицинский прибор для диагностики in vitro / 体外诊断医疗设备
	Temperature limitation / Температурни ограничения / Temperaturbegrænsning / Temperaturbegrenzung / Περιορισμός θερμοκρασίας / Limitación de temperatura / Temperatuuri piirang / Limites de température / Dozvoljena temperatura / Hőmérsékleti határ / Limiti di temperatura / Температураны шектеу / 온도 제한 / Laikymo temperatūra / Temperatūras ierobežojumi / Temperaturulimiet / Temperaturbegrensning / Ograniczenie temperatury / Limites de temperatura / Limite de temperatură / Ограничение температуры / Ograničenje 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 / Съдържа много 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 충분함 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 / Conținut 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 / Lugeada 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 / Consultati instrucțiunile 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 refolositi / Не использовать повторно / Nepoužívejte opakovane / Ne upotrebļavajate ponovo / Får ej återanvändas / Tekrar kulanmayin / Не використовувати повторно / 请勿重复使用
	Serial number / Серийн номер / Sériové číslo / Seriennummer / Seriennummer / Σειριακός αριθμός / N° de serie / Seerianummer / Numéro de série / Serijski broj / Sorozatszám / Numero di serie / Топтамалық нөмірі / 일련 번호 / Serijos numeris / Sērijas numurs / Serie nummer / Numer seryjny / Numéro 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- Leistungsbeurteilungszwecke / Μόνο για αξιολόγηση απόδοσης IVD / Sólo para la evaluación del rendimiento en diagnóstico in vitro / Ainult IVD seadme hindamiseks / Réserve à l'évaluation des performances IVD / Samo u znanstvene svrhe za In Vitro Dijagnostiku / Kizárlag in vitro diagnosztikához / Solo per valutazione delle prestazioni IVD / Жасаңды жағдайда «пробирка ішінде» диагностикада тек жұмысты бағалау үшін / IVD 성능 평가에 대해서만 사용 / Tik IVD prietaisų veikimo charakteristikoms tikrinti / Vienigi IVD darības novērtēšanai / Uitsluitend voor doeltreffendheidsonderzoek / Kun for evaluering av IVD-ytelse / Tytko do oceny wydajności IVD / Uso exclusivo para avaliação de IVD / Numai pentru evaluarea performanței 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 / Limite inferior de temperatura / Alumine temperatuuripiir / Limite inférieure de température / Najniža dozvoljena temperatura / Alsó hőmérsékleti határ / Limite inferiore di temperatura / Температураның төменгі руқсат 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 / Контрольно / Kontrola / Kontrol / Kontrolle / Μάρτυρας / Kontroll / Contrôle / Controllo / Бақылау / 컨트롤 / Kontrolé / Kontrole / Controle / Controllo / Контроль / kontrol / 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 / Teigama kontrolė / Pozitīvā kontrole / Positieve controle / Kontrola dodatnia / Controllo positivo / Control pozitiv / Положительный контроль / Pozitif kontrol / Позитивный 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 / Negatívna kontrola / Negatív kontroll / Controllo negativo / Негативтік бақылау / 음성 컨트롤 / Neigama kontrolė / Negatīvā kontrole / Negatieve controle / Kontrola ujemna / Controllo negativo / Control negativ / Отрицательный контроль / Negatif kontrol / Негативный контроль / 阴性对照试剂
	Method of sterilization: ethylene oxide / Метод на стерилизация: этиленов оксид / Způsob sterilizace: ethylenoxid / Steriliseringsmetode: ethylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / Método de esterilización: óxido de etileno / Steriliseerimismetod: etüleenoksiid / Méthode de stérilisation : oxyde d'éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszere: etilén-oxid / Metodo di sterilizzazione: ossido di etilene / Стерилизация адісі – 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 / Metod sterilizaciji: этиленоксид / Metóda sterilizácie: etylénoxid / Metoda sterilizacije: etilen oksid / Steriliseringsmetod: etenoxid / Sterilizasyon yöntemi: etilen oksit / Метод стерилизації: этиленоксидом / 灭菌方法: 环氧乙烷
	Method of sterilization: irradiation / Метод на стерилизация: ирадиация / Způsob sterilizace: záření / Steriliseringsmetode: bestrålning / Sterilisationsmethode: Bestrahlung / Μέθοδος αποστείρωσης: ακτινοβολία / Método de esterilización: irradiación / Steriliseerimismetod: kiirgus / Méthode de stérilisation : irradiation / Metoda sterilizacije: zračenje / Sterilizálás módszere: besugárzás / Metodo di sterilizzazione: irradiazione / Стерилизация адісі – сәуле тықы / 소독 방법: 방사 / Sterilizavimo būdas: radiacija / Sterilizēšanas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Steriliseringsmetode: bestrålning / Metoda sterylizacji: napromienianie / Método de esterilização: irradiação / Metodă de sterilizare: iradiere / Метод стерилизации: облучение / Metóda sterilizácie: ožiarenie / Metoda sterilizacije: ozračevanje / Steriliseringsmetod: strålning / Sterilizasyon yöntemi: iradyasyon / Метод стерилизації: опромінення / 灭菌方法: 辐射 Biological Risks / Биологични рискове / Biologická rizika / Biologisk fare / Biogefährdung / Βιολογικοί κίνδυνοι / Riesgos biológicos / Biologilised riskid / Risques biologiques / Biološki rizik / Biológiaiilag veszélyes / Rischio biologico / Биологичный тәуекелдер / 생물학적 위험 / Biologinis pavojus / Biologiskie riski / Biologisch risico / Biologisk risiko / Zagrożenia biologiczne / Perigo biológico / Riscuri biologice / Биологическая опасность / Biologické riziko / Biološki rizici / Biologisk risk / Biyojoklik Riskler / Біологічна небезпека / 生物学风险 Caution, consult accompanying documents / Внимание, направте справка на придружаващите документи / Pozor! Prostudujte si příloženou dokumentaci! / Forsigtig, se ledsagende dokumenter / Achtung, Begleitdokumente beachten / Προσοχή, συμβουλευτείτε τα συνοδευτικά έγγραφα / Precaución, consultar la documentación adjunta / Ettevaatus! Lugeka kaasnevat dokumentatsiooni / Attention, consulter les documents joints / Upozorenje, koristite prateću dokumentaciju / Figyelem! Olvassa el a mellékelt tájékoztatót / Attenzione: consultare la documentazione allegata / Абайлаңыз, тиісті құжаттармен танысыңыз / 주의, 동봉된 설명서 참조 / Dmesio, žiūrėkite pridėdamus dokumentus / Piesardzība, skatīt pavaddokumentus / Voorzichtig, gaadpleeg bijgevoegde documenten / Forsiktig, se vedlagt dokumentasjon / Należy zapoznać się z dołączonymi dokumentami / Cuidado, consulte a documentação fornecida / Atenție, consultați documentele însoțitoare / Внимание: см. прилагаемую документацию / Výstraha, pozří spríevodné dokumenty / Pažňaj! Pogledajte priložena dokumenta / Obs! Se medföljande dokumentation / Dikkat, bilirlike 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 / Limite superior de temperatura / Ülemine temperatuuripiir / Limite supérieure de température / Gornja dozvoljena temperatura / Felső hőmérsékleti határ / Limite superiore di temperatura / Температураның руқсат етілген жоғарғы шегі / 상한 온도 / Aukščiausia laikymo temperatūra / Augšējā temperatūras robeža / Hoogste temperatuurlimiet / Øvre temperaturgrense / Górná granica temperatury / Limite máximo de temperatura / Limită maximă de temperatură / Верхний предел температуры / Horná hranica teploty / Gornja granica temperature / Øvre temperaturgräns / Sıcaklık üst sınırı / Максимальна температура / 温度上限
	Keep dry / Пазете сухо / Skladujte v suchém prostředí / Opbevarer tørt / Trocknen / 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 / Hoides tørt / Przechowywać w stanie suchym / Manter seco / A se feri de umezeală / Не допускать попадания влаги / Uchovávať v suchu / Držite na suvom mestu / Förvaras tørt / Kuru bir şekilde muhafaza edin / Беретти від вологи / 请保持干燥
	Collection time / Време на събиране / Čas odběru / Opsamlingsdidspunkt / Entnahmehzeit / Ωρα συλλογής / Hora de recogida / Kogumisaeg / Heure de prélèvement / Sati prikupljanja / Mintavétel időpontja / Ora di raccolta / Жынау уақыты / 수집 시간 / Paėmimo laikas / Savākšanas laiks / Verzameltijd / Tid prøvetaking / Godzina pobrania / Hora de colheita / Ora colectării / Время сбора / Doba odboru / Vreme prikupljanja / Uppsamlingsdtd / Toplama zamanı / Нас забору / 采集时间
	Peel / Оберте / Otevřete zde / Abn / Abziehen / Αποκολλήστε / Desprendre / Koord / Décoller / Otvoriti skini / Húzza le / Staccare / Ўстіңкі қабатын алып таста / 벗기기 / Plešti čia / Atīmēt / Schillen / Trekk av / Oderwać / Destacar / Se dezlipeste / Отклеить / Odrhňte / Oljuštiti / Dra isår / Ayırma / Відклеїти / 撕下
	Perforation / Перфорация / Perforace / Perforering / Διότρηση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Tecik тесу / 절취선 / Perforacija / Perforância / Perforatie / Perforacja / Perfuração / Perfore / Перфорация / Perforacia / Perforasyon / Перфорация / 穿孔
	Do not use if package damaged / Не използвайте, ако опаковката е повредена / Nepoužívejte, je-li obal poškozený / Má ikke anvendes hvis emballagen er beskadiget / Inlhal beschädigt / Packingnicht 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 használni, ha a csomagolás sérült / Non usare se la confezione è danneggiata / Ереп пакет бұзылған болса, пайдаланба / 패키지가 손상된 경우 사용 금지 / Jei pakuotė pažeista, nenaudoti / Nelietoti, ja iepakojums bojāts / Niet gebruiken indien de verpakking beschadigd is / Má 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 / Nepoužívejte, ak je obal poškozený / 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 / Nevstavujte přitísnému teplu / Má ikke udsættes for varme / Vor Wärme schützen / Κρατήστε το μακριά από τη θερμότητα / Mantener alejado de fuentes de calor / Hoida eemal valgest / Protéger de la chaleur / Držati dalje od izvora topline / Övja a melegtől / Tenere lontano dal calore / Сапқын жерде сақтау / 열을 피해야 함 / Laikykite atokiau nuo šilumos šaltinių / Sargát no karstuma / Beschermen tegen warmte / Má ikke utsettes for varme / Przechowywać z dala od źródeł ciepła / Manter ao abrigo do calor / A se feri de căldură / Не нагревать / Uchovávať mimo zdroja tepla / Držite dalje od toplote / Får ej utsättas för värme / Isidan uzak tutun / 请远离热源
	Cut / Срежете / Odstřihněte / Klip / Schneiden / Κόψτε / Cortar / Lõigata / Découper / Reži / Vágja ki / Tagliare / Keciңіз / 잘라내기 / Kirpti / Nogriez / Knippen / Kutt / Odciać / Cortar / Decupați / Отрезать / Odstřihněte / Iseći / Klippi / Kesme / Pozpřizati / 剪下
	Collection date / Дата на събиране / Datum odběru / Opsamlingsdato / Entnahmdatum / Ημερομηνία συλλογής / Fecha de recogida / Kogumiskuupäev / Date de prélèvement / Dani prikupljanja / Mintavétel dátuma / Data di raccolta / Жынаған күні / 수집 날짜 / Paėmimo data / Savākšanas datums / Verzameldatum / Dato prøvetaking / Data pobrania / Data de colheita / Data colectării / Дата сбора / Datum odboru / 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/pärbaude / μL/teste / мкн/анализ / μL/检测



Hydrogen gas generated / Образуван е водород газ / Možnost úniku plyného vodíku / Frembringer hydrogengas / Wasserstoffgas erzeugt / Δημιουργία αερίου υδρογόνου / Producción de gas de hidrógeno / Vesinikgaasi tekitatud / Produit de l'hydrogène gazeux / Sadržaji hydrogen vodik / Hidrogén gázt fejleszt / Produzione di gas idrogeno / Газтекес 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 / Oslobada se vodonik / Genererad vätegas / 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 / Patsienti 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 pacienta / Número da ID do doente / Număr ID pacient / Идентификационный номер пациента / Identifikačné číslo pacienta / ID broj pacijenta / Patientnummer / Hasta kimlik numarası / Идентификатор пациента / 患者标识号



Fragile, Handle with Care / Чупливо, Роботете с необходимото внимание. / Křehké. Při manipulaci postupujte opatrně. / Forsigtig, kan gå i stykker. / Zerbrechlich, vorsichtighandhaben. / Ευθραusto. Χειριστείτε το με προσοχή. / Frágil. Manipular con cuidado. / Örn, 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; rūkotiis uzmanīgi / Breekbaar, voorzichtig behandelen. / Ømtålig, håndter forsigtig. / Krucha zawartość, przenosić ostrożnie. / Frágil, Manuseie com Cuidado. / Fragil, manipulați cu atenție. / Хрупкое! Обращаться с осторожностью. / Křehké, vyžaduje sa opatrná manipulácia. / Lomljivo - rukujte pažljivo. / Bräckligt. Hantera försiktigt. / Kolay Kırılır, Dikkatli Taşıyın. / Тендітна, звертатися з обережністю / 易碎，小心轻放



bd.com/e-labeling



Becton Dickinson GmbH
Tullastrasse 8-12
69126 Heidelberg/Germany
Phone: +49-62 21-30 50; Fax: +49-62 21-30 52 16
Reception_Germany@bd.com

ATCC® is a trademark of American Type Culture Collection.

BD, the BD Logo, Difco, and Trypticase are trademarks of Becton, Dickinson and Company or its affiliates. © 2020 BD.
All rights reserved.