

BD BBL™ IC-XT Pack CDC Anaerobe Agar Base with Penase, 90 mm LL*

BBL™ IC-XT Pack CDC Anaerobe Agar Base with Penase, BD RODAC™ Locking Lid (LL)

Prepared Plated Media

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English

INTENDED USE

BD BBL™ IC-XT Pack CDC Anaerobe Agar Base with Penase is used for the detection and enumeration of microorganism particularly obligate anaerobes in pharmaceutical clean rooms and production environments where penicillins are filled or processed. The penicillinase prevents airborne inhibitory effects through possibly existing penicillin dust.

“IC-XT Pack” (Isolator Cleanroom-Extended Temperature) products are available in different plate formats; they 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 IC-XT products are packaged in impermeable plastic films to allow an extended stability and storage at 2–25 °C throughout the shelf life. BD RODAC™ (Replicate Organism Detection and Counting) plates are particularly recommended for the use in the detection and enumeration of microorganisms present on surfaces of sanitary importance.

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

BD BBL™ CDC Anaerobe Agar Base with Penase is a nonselective medium for the isolation and cultivation of a wide variety of obligately anaerobic microorganisms. It employs BD Trypticase™ Soy Agar supplemented with additional agar and yeast extract. The addition of hemin and cystine provide essential nutrients for certain obligate anaerobes.

Penicillinase Concentrate is added to inactivate penicillin dust that may accumulate on the surface of media used for air sampling and in sedimentation procedures. The inactivation spectrum of the penicillinase when added to this medium includes penicillin G, mezlocillin, oxacillin, and first generation cephalosporins such as cefazolin when tested by the agar diffusion method using *Staphylococcus aureus* ATCC® 29737 as an indicator strain and BD Trypticase Soy Agar as a reference medium.

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 these media are controlled to ensure that the bioburden of the product is reduced to a minimum. Each piece of equipment used in the manufacturing process 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 IC-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.^{1,2} As a result from the validation tests, an irradiation dose of 9.6 kGy was determined to be the minimum irradiation dose necessary for achieving an SAL of 10⁻⁵.³ The media are gamma irradiated in the packaging material as delivered with 10 to 22 kGy 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 the IC-XT products are impermeable to hydrogen peroxide. This applies to product packaged in one, two or three bags.

* LL indicates Locking Lid

REAGENTS

Approximate Formulas* Per Liter Purified Water

All IC-XT products with BD BBL CDC Anaerobe Agar Base with Penase	
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	20.0 g
Yeast Extract	5.0 g
Hemin	0.005 g
L-Cystine	0.4 g
Penase	50 mL

pH 7.3 ± 0.2

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

BD BBL CDC Anaerobe Agar Base with Penase contains 50 mL of Penicillinase Concentrate per liter medium, added aseptically before gamma irradiation. Penicillinase Concentrate has a potency of 10 million Kershey units/mL. According to the kinetic method of Kershey *et al.*, 1 unit of benzyl penicillinase will inactivate 0.39 units of benzyl penicillin per hour in phosphate buffer at pH 7.0, at 30 °C.⁴ The penicillinase in Penicillinase Concentrate is obtained from a specific strain of *Bacillus cereus*.

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 contains 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.

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.⁸

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.⁹

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. The plastic bags used for packaging of these products consist of polyethylene/ polyethylene terephthalate (=PE/PET). The inner plastic bag contains a SORB-IT® silica gel desiccant bag. The triple-bagged stacks are packaged in white cartons.

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 (colony forming units) per plate of the strains listed in the table. Use BD Trypticase Soy Agar as a growth reference medium. See table for incubation conditions. Incubate samples anaerobically using the BD GasPak™ EZ Anaerobic System or an alternative anaerobic system. 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 (%)*
<i>Clostridium perfringens</i>	ATCC® 13124	2–4 d, 35–37 °C, anaerobic	>70
<i>Clostridium sporogenes</i>	ATCC 11437	2–4 d, 35–37 °C, anaerobic	>70
<i>Staphylococcus aureus</i>	ATCC 6538	2–4 d, 35–37 °C, anaerobic	>70
<i>Staphylococcus aureus</i>	ATCC 29737	2–4 d, 35–37 °C, anaerobic	>70
Appearance of the uninoculated medium	Light to medium tan yellow and clear to trace hazy		

* Recovery (%) = $\text{CFU}_{\text{Test medium}} / \text{CFU}_{\text{Reference medium}} \times 100$

Additionally, the penicillinase activity in BD BBL CDC Anaerobe Agar Base with Penase is tested as follows: Prepare a suspension matching the McFarland standard 0.5 (approximately 5×10^7 to 10^8 CFU/mL) of *S. aureus* ATCC 29737 from an overnight culture on BD Trypticase Soy Agar. Swab-inoculate the whole surface of the test medium with this suspension and place appropriate sensitivity test discs (e.g., BD BBL Sensi-Disc™) on the surface of BD BBL CDC Anaerobe Agar Base with Penase. BD Trypticase Soy Agar plates may be prepared in the same way as a reference medium. Incubate aerobically for 18 to 24 hours at 35–37 °C and measure the zone diameter. Zones on the medium with and without penicillinase are shown in the table below:

Test strain	Antimicrobial	BD BBL CDC Anaerobe Agar Base with Penase	BD Trypticase Soy Agar
<i>Staphylococcus aureus</i> ATCC 29737	Cefazolin CZ-30	Turbid zone <8 mm	Clear zone ≥30 mm

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 2×10^4 cfu per plate.¹⁰ 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.¹¹ 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 2×10^5 cfu per plate must be used for inoculation, and about 10^4 or more cfu according to DIN EN 12322.^{10,11} 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.¹⁰ 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 IC-XT products.

Materials Not Provided

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

Test Procedure

IC-XT products are used in a variety of procedures. Follow the appropriate references for sampling, inoculation, and incubation.¹⁻⁴

LL plates feature a locking system specifically designed to ensure higher security and convenience throughout handling while reducing the risk of accidental contamination. The LL mechanism allows for an easy locking of plates after sampling and for a safer transport from a controlled environment to the laboratory. The locked position of the plate ensures a secure fit between the lid and the base thereby minimizing unintentional opening of plates while allowing for appropriate aeration during incubation.

The BD RODAC Locking Lid (LL) plated media are used in the replicate organism detection and counting procedure to monitor the hygiene status of surfaces or in certain types of air samplers.

For surface testing, introduce the plates into the room or area to be tested or monitored. BD RODAC LL plates are provided in the unlocked position. Remove lid from the plate. Apply the plate's surface directly to the surface being tested and exert moderate pressure. Do not rub the agar surface or move laterally on the test surface! Return the lid and lock the plate by simply twisting the base and the lid of the plate into the locked position. Plates can be easily unlocked by untwisting. Areas (walls, floors, etc.) to be tested may be divided into sections or grids and samples taken from specific points within the grid.

Grid method:

1. Subdivide surface (floor or wall) into 36 equal squares per 100 square feet of area by striking five equidistant dividing lines from each of two adjacent sides.
2. These dividing lines intersect at twenty-five points.
3. Number these intersections consecutively in a serpentine configuration.
4. Use red numerals for odd numbers, black numerals for even numbers.
5. Omit number 13 which falls in the center of the total area.
6. Sample odd points at one sampling period, even points at the next sampling period.
7. For areas greater than 100 square feet, extend grid to include entire area.
8. For areas smaller than 25 square feet, divide the areas into twenty-five equal squares (sixteen intersections). Sample eight even-numbered or odd-numbered intersections at each sampling period.
9. For areas between 25 and 100 square feet, divide into 36 equal squares as in #1.
10. Mark plates with intersection numbers.

Products supplied in 90 mm LL dishes are used for monitoring the hygiene in penicillin filling rooms by the air sampling or sedimentation methods. The 90 mm LL plates contain 25 grams of medium and are used in laminar air flow cabinets. The large amount of medium reduces the evaporation and shrinkage caused by the air flow venting. Place plates with lids removed in the area under test. Exposure time must be validated internally. Avoid excessive desiccation of the media which may be enhanced by ventilation.

Incubate plates at 30–35 °C for up to 5 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

PERFORMANCE CHARACTERISTICS AND LIMITATIONS OF THE PROCEDURE

These media are intended to be used for the detection and enumeration of microorganism particularly obligate, non-fastidious anaerobes in hygiene control and on surfaces of sanitary importance. BD BBL CDC Anaerobe Agar Base with Penase is not the media of choice for fastidious anaerobes.

Extended sedimentation exposure followed by incubation in dry air may lead to cracking, splitting or other desiccation of the agar gel, especially in dry environments. Media shrinkage may also occur during extended incubation in incubators with air circulation. Provide sufficient moisture during incubation since media shrinkage may affect the fertility of the medium.

The penicillinase in BD BBL CDC Anaerobe Agar Base with Penase inactivates first generation penicillins, mezlocillin, oxacillin, and first generation cephalosporins. Newer cephalosporins, carbapenems, monobactams, and combinations of beta lactams with beta lactamase inhibitors are not necessarily inactivated. If such antimicrobials shall be inactivated, their suitability must first be validated by the user.

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.⁵⁻⁷

Use of this medium with clinical specimens has not been validated.

AVAILABILITY

Cat. No.	Description	Number of plates per package
257614	BD BBL™ IC-XT Pack CDC Anaerobe Agar Base with Penase, 90 mm LL	100
257615	BD BBL™ IC-XT Pack CDC Anaerobe Agar Base with Penase, BD RODAC™ Locking Lid (LL)	100

REFERENCES

1. ISO 11137-1:2006 + Amd 1:2013. Sterilization of health care products—Radiation—Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
2. ISO 11137-2:2013. Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose.
3. Data on file: Isolator Pack XT Qualification Study. BD Heidelberg, Germany, 2006.
4. Kershney *et al.* 1955. Antibiotics Annual, 1954-55. Medical Encyclopedia, Inc., New York USA.
5. 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.
6. Forbes, B.A., D.F. Sahm, and A.S. Weissfeld. 1998. Bailey & Scott's diagnostic microbiology, 10th ed. Mosby, Inc., St. Louis, Missouri, USA.
7. Murray, P.R., E.J. Baron, M.A. Pfaller, F.C. Tenover, and R.H. Tenover (ed.) 1995. Manual of clinical microbiology, 6th ed. American Society for Microbiology, Washington, D.C. USA.
8. 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.
9. 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.
10. 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.
11. 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 / Fabbicante / Атқарушы / 제조업체 / Gamintojas / Ražotājs / Tilviker / 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 / Дейин 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 kullanna 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 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)
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 / Dispozitiv 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 / Περιορισμό θερμοκρασίας / Limitación de temperatura / Temperatuuri piirang / Limites de température / Dozvoljena temperatura / Hőmérsékleti határ / Limiti di temperatura / Температураны шектеу / 온도 제한 / Laikymo temperatūra / Temperatūras ierobežojumi / Temperaturlimit / Temperaturbegrensing / 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



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	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 kontrolé / Pozitívá kontrolé / 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 kontrolé / Negatívá kontrolé / 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 / Steriliseringmetode: ethylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / Método de esterilización: óxido de etileno / Steriliseerimismetode: 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 / Steriliseringmetode: etylenoksid / Metoda sterylizacji: tlenek etylu / Método de esterilização: óxido de etileno / Metodă de sterilizare: oxid de etilenă / Metod sterilizacji: этиленоксид / Metóda sterilizacji: etylenoxid / Metoda sterilizacije: etilen oksid / Steriliseringsmetod: etenoxid / Sterilizasyon yöntemi: etilen oksit / Metod sterilizacji: этиленоксидом / 灭菌方法: 环氧乙烷
	Method of sterilization: irradiation / Метод на стерилизация: ирадиация / Způsob sterilizace: záření / Steriliseringmetode: bestråling / Sterilisationsmethode: Bestrahlung / Μέθοδος αποστείρωσης: ακτινοβολία / Método de esterilización: irradiación / Steriliseerimismetode: kiirgus / Méthode de stérilisation : irradiation / Metoda sterilizacije: zračenje / Sterilizálás módszere: besugárzás / Metodo di sterilizzazione: irradiazione / Стерилизация адісі – сәулелік тәуекелдер / 생물의학 위험 / Sterilizavimo būdas: radiacija / Sterilizēšanas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Steriliseringmetode: bestråling / Metoda sterylizacji: napromienianie / Método de esterilização: irradiação / Metodă de sterilizare: iradiere / Metod sterilizacji: облучение / Metóda sterilizacji: ożarzenie / Metoda sterilizacije: ozračevanje / Steriliseringsmetod: strålning / Sterilizasyon yöntemi: ırradyasyon / Metod sterilizacji: 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 / Биологический тәуекелдер / 생물학적 위험 / Sterilizavimo būdas: biologinis pavojus / Sterilizēšanas risks / Biologiskie riski / Biologisch risico / Biologisk risiko / Zagrożenia biologiczne / Perigo biológico / Riscuri biologice / Биологическая опасность / Biologické riziko / Biološki rizici / Biologisk risk / Biyojoklik Riskler / Биологічна 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 priedamam 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 / Trockengalen / 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 / Uchovávejte 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 / Opsamlingsstidspunkt / 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 / Uppsamlingsstid / Toplama zamanı / Нас забору / 采集时间
	Peel / Оберте / Otevěte zde / Abn / Abziehen / Αποκολλήστε / Desprendre / Koord / Décoller / Otvoriti skini / Húzza le / Staccare / Ўстіңгі қабатын алып таста / 벗기기 / Plešti čia / Atīmēt / Schillen / Trekk av / Oderwać / Destacar / Se dezlipeste / Отклеить / Odrhňte / Oljušiti / Dra isår / Ayırma / Відклеїти / 撕下
	Perforation / Перфорация / Perforace / Perforering / Διότρηση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Tecik тесу / 절취선 / Perforacija / Perforácia / Perforatie / Perforacja / Perfuração / Perforare / Перфорация / Perforacia / Perforasyon / Перфорация / 穿孔
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	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 / Óvja a melegdtől / Tenere lontano dal calore / Сапқын жерде сақтау / 열을 피해야 함 / Laikykite atokiau nuo šilumos šaltinių / Sargàt 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 / Uchovávejte mimo zdroja tepla / Držite dalje od toplote / Får ej utsättas för värme / Isidan uzak tutun / Беретти від дії тепла / 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 / Pozpizati / 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 / 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/檢測

Keep away from light / Пазете от светлина / Nevystavujte svétlu / 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 svetla / 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 źródła światła / Manter ao abrigo da luz / Feriți de lumină / Хранить в темноте / Uchovávať 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 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 / Газтөктес 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 / Vyrobene 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 / Идентифікатор пацієнта / 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



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