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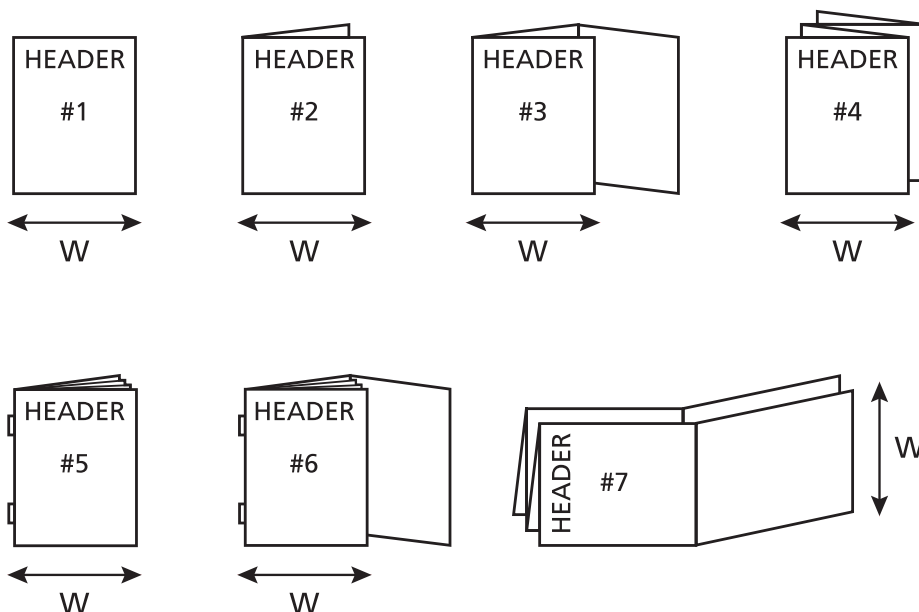
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BD BBL™ Stonebrink TB Medium + PACT



REF 220505
8011669(04)
2019-04

INTENDED USE

BD BBL™ Stonebrink TB Medium + PACT is intended for the cultivation of *Mycobacterium tuberculosis* and other mycobacterial species from specimens containing mixed flora.

SUMMARY AND EXPLANATION

BD BBL Stonebrink TB Medium + PACT is an egg-based medium containing antimicrobials. The DIN standard 58943-3 "Diagnosis of tuberculosis – Part 3: Detection of mycobacteria by culture methods" recommends the use of an egg-based medium supplemented with antimicrobials; e.g., polymyxin B 200,000 units/L, amphotericin B 10 mg/L, carbenicillin 50 mg/L, and trimethoprim 10 mg/L (PACT) for the egg-based culture media.¹

PRINCIPLES OF THE PROCEDURE

Egg yolk is a source of lipids for the metabolism of mycobacteria. Partial inhibition of bacteria is achieved by the presence of the malachite green dye. Sodium pyruvate is a growth stimulant.

The selective nature of Stonebrink TB Medium + PACT is due to the incorporation of polymyxin B, amphotericin B, carbenicillin, and trimethoprim lactate in its formula. Carbenicillin is a synthetic penicillin, which has a bactericidal effect on gram-negative bacteria, especially *Pseudomonas aeruginosa* and *Proteus* sp., by inhibiting cell wall synthesis.² Polymyxin B is a polypeptide antibiotic that is inhibitory for gram-negative bacteria due to its damaging of their plasma membranes, which affects the permeability of the cells.² Amphotericin B is a heptaene antibiotic, which is active in the inhibition of fungi by altering the permeability of cell membranes, which contain cholesterol or ergosterol, thereby allowing permeation of various micro-molecular compounds into the cell.³ Trimethoprim inhibits folic acid synthesis in gram-positive bacteria that require folic acid.⁴

REAGENTS

BD BBL Stonebrink TB Medium + PACT

Approximate Formula* per Liter Medium

Pyruvic Acid Sodium Salt.....	4.20 g
Potassium Phosphate Monobasic	2.30 g
Sodium Phosphate Dibasic	1.30 g
Malachite Green	0.27 g
Polymyxin B.....	200,000.00 I.U.
Amphotericin B	10.00 mg
Carbenicillin	100.00 mg
Trimethoprim	10.00 mg
Whole Eggs	670.00 mL
Purified Water	330.00 mL

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

Warnings and Precautions

For *in vitro* Diagnostic Use.

Tubes with tight caps should be opened carefully to avoid injury due to breakage of glass.

Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions" ⁵⁻⁸ and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids. Prior to discarding, sterilize specimen containers and other contaminated materials by autoclaving.

Biosafety Level 2 practices and procedures, containment equipment and facilities are required for non-aerosol-producing manipulations of clinical specimens such as preparation of acid-fast smears. All aerosol-generating activities must be conducted in a Class I or II biological safety cabinet. Biosafety Level 3 practices, containment equipment and facilities are required for laboratory activities in the propagation and manipulation of cultures of *M. tuberculosis* and *M. bovis*. Animal studies also require special procedures.⁷

Storage Instructions

On receipt, store tubes in the dark at 2–8 °C. Avoid freezing and overheating. Do not open until ready to use. Tubed media stored as labeled until just prior to use may be inoculated up to the expiration date and incubated for the recommended incubation times. Minimize exposure to light.

Product Deterioration

Do not use tubes if they show evidence of microbial contamination, discoloration, drying or other signs of deterioration.

SPECIMEN COLLECTION AND HANDLING

Specimens suitable for culture may be handled using various techniques. For detailed information, consult appropriate texts.^{9,10} Specimens should be obtained before antimicrobial agents have been administered. Provision must be made for prompt delivery to the laboratory.

PROCEDURE

Material Provided: BD BBL Stonebrink TB Medium + PACT

Materials Required But Not Provided: Ancillary culture media, reagents, quality control organisms and laboratory equipment as required for this procedure.

Test Procedure: Observe aseptic techniques.

The test procedures are those recommended by the Centers for Disease Control and Prevention (CDC) for primary isolation from specimens containing mycobacteria.¹¹ N-acetyl-L-cysteine-sodium hydroxide (NALC-NaOH) solution is recommended as a gentle but effective digesting and decontaminating agent. For detailed decontamination and culturing instructions, consult an appropriate reference.¹⁰⁻¹³

Following inoculation, keep containers shielded from light and place in a suitable system providing an aerobic atmosphere enriched with 5 to 10% carbon dioxide. Incubate at 35 ± 2 °C.

The media should be incubated in a horizontal plane until the inoculum is absorbed. Tubes should have screw caps loose for the first 3 weeks to permit the circulation of carbon dioxide for the initiation of growth. Thereafter, to prevent dehydration, tighten caps; loosen briefly once a week. Stand tubes upright if space is a problem.

NOTE: Cultures from skin lesions suspected to be *M. marinum* or *M. ulcerans* should be incubated at 25 to 33 °C for primary isolation; cultures suspected to contain *M. avium* or *M. xenopi* exhibit optimum growth at 40 to 42 °C.¹¹ Incubate a duplicate culture at 35 to 37 °C.

USER QUALITY CONTROL

1. Inoculate Lowenstein-Jensen Medium slants with stock cultures of the pertinent mycobacterial strains using sterile inoculating sticks.
2. Incubate tubes with loosened caps in an aerobic atmosphere supplemented with carbon dioxide at 35 ± 2 °C until heavy growth is obtained (usually within 2 to 3 weeks).
3. Harvest the growth with a sterile sharpened applicator stick by gently removing the cells from the surface of the medium with care being taken not to include culture medium with the cell crop.
 - A. For *Mycobacterium tuberculosis* ATCC® 25177:
 - 1) Transfer growth to 5.0 mL Middlebrook 7H9 Broth with Glycerol in a sterile screw-capped glass tube containing sterile glass beads.
 - 2) Vortex well (several minutes) until suspension is free of large clumps.
 - 3) Compare this suspension to a McFarland #1 nephelometer standard. The suspension should be more turbid than the standard.
 - 4) Place the tube in a rack for 2 to 3 h at room temperature to allow large particles to settle to the bottom.
 - 5) Transfer the supernate to a sterile container.
 - 6) Adjust the turbidity of the suspension to the McFarland #1 standard by slowly adding sterile Middlebrook 7H9 Broth with Glycerol. Shake well.
 - 7) Dilute to 10^5 CFU/mL before use. Mix well and streak-inoculate the test medium using a 0.01 mL calibrated loop.
 - B. For all other mycobacterial strains:
 - 1) Transfer the growth to a sterile 50 mL screw-capped centrifuge tube containing 8 to 12 sterile glass beads (2 mm diameter) and 5 mL of Mycobacterium Diluent prepared as follows:
 - a. Mix the following ingredients in a 1 L flask and adjust the pH, using 1N sodium hydroxide, to 6.7 to 7.0:

Bovine Albumin (fatty acid free)	1.0 g
Polysorbate 80	0.1 mL
Purified Water	500.0 mL
 - b. Sterilize by membrane filtration (0.2 µ filter).
 - c. Aseptically dispense in 5.5 mL amounts into sterile screw-capped tubes.
 - 2) Emulsify the mycobacterial growth on the sidewall of a screw-capped centrifuge tube using an applicator stick. Mix the growth with the diluent.
 - 3) Cap the tube and vortex approximately 10 min until the growth is well suspended and free of large clumps.
 - 4) Add 15 mL of sterile Mycobacterium Diluent and mix thoroughly.
 - 5) Compare this suspension to a McFarland #1 nephelometer standard. The suspension should be more turbid than the standard.
 - 6) Place the tube in a rack for 2 to 3 h at room temperature to allow large particles to settle to the bottom.
 - 7) Aspirate the supernate and transfer it to a sterile container. The suspension must be more turbid than a McFarland #1 standard and free of large particles. If large particles still are present, mix and allow to stand for an additional 1 h. Transfer the supernate to a sterile container.
 - 8) Adjust the turbidity of the suspension to the McFarland #1 standard by slowly adding sterile Mycobacterium Diluent. Shake well.

- 9) Dispense aliquots of the suspension into freezer vials labeled to contain organism identification and date of preparation.
- 10) Freeze the suspensions by placing the vials in a low-temperature freezer at -60 °C. The vials can be stored for up to 6 months.
- 11) For use, remove the frozen vial from the freezer and quick-thaw the contents by placing the tube in a 30 to 35 °C water bath. Dilute to 10⁵ CFU/mL before use. Mix well and streak-inoculate the test medium using a 0.01 mL calibrated loop.
4. Incubate tubes with loosened caps at 35 ± 2 °C in an aerobic atmosphere supplemented with carbon dioxide.
5. Examine tubes after 7, 14, and 21 days for growth, selectivity and pigmentation.
6. Expected Results

ORGANISM	RECOVERY
<i>Mycobacterium tuberculosis</i> H37Ra ATCC 25177	Good
<i>Mycobacterium kansasii</i> , Group I ATCC 12478	Good
<i>Mycobacterium fortuitum</i> , Group IV ATCC 6841	Good
<i>Escherichia coli</i> ATCC 25922	Partial to complete inhibition

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

RESULTS

Cultures should be read within 5 to 7 days after inoculation and once a week thereafter for up to 8 weeks.

Record Observations:¹¹

1. Number of days required for colonies to become macroscopically visible. Rapid growers have mature colonies within 7 days; slow growers require more than 7 days for mature colony forms.
2. Pigment production
White, cream or buff = Nonchromogenic (NC)
Lemon, yellow, orange, red = Chromogenic (Ch)

Stained smears may show acid-fast bacilli, which are reported only as "acid-fast bacilli" unless definitive tests are performed.

LIMITATIONS OF THE PROCEDURE

For identification, organisms must be in pure culture. Morphological, biochemical, and/or serological tests should be performed for final identification. Consult appropriate texts for detailed information and recommended procedures.⁹⁻¹³

PERFORMANCE CHARACTERISTICS

Prior to release, all lots of **BD BBL** Stonebrink TB Medium + PACT are tested for specific product characteristics. Using a 0.01 mL calibrated loop, samples are streak-inoculated with the following cultures diluted to contain 10³ colony-forming units (CFU) per 0.01 mL of *Mycobacterium kansasii* Group I (ATCC 12478), *M. fortuitum* Group IV (ATCC 6841) and *M. tuberculosis* (ATCC 25177); *Escherichia coli* (ATCC 25922) is diluted to contain 10⁴ CFU per 0.01 mL and inoculated in the same manner. After inoculation, the tubes are incubated with loosened caps at 35 ± 2 °C in an atmosphere supplemented with 5 to 10% carbon dioxide. Tubes are read for growth and pigmentation after 7, 14 and 21 days incubation. All mycobacteria exhibit moderate to heavy growth within 21 days. Colonial morphology is as follows: *M. kansasii* exhibits smooth cream-colored colonies when grown in the dark, becoming bright lemon yellow to orange when exposed to light; and *M. tuberculosis* and *M. fortuitum* are cream-colored (*M. fortuitum* may show greening due to dye absorption). *E. coli* shows no growth to fair growth after 14 days incubation.

AVAILABILITY

Cat. No.	Description
220505	BD BBL™ Stonebrink TB Medium + PACT, Ctn. of 100 size A tubes

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	Serial number / Сериен номер / Sériové číslo / Seriennummer / Seriennummer / Σειριακός αριθμός / N° de serie / Seerianumber / Numéro de série / Serijski broj / Sorozatszám / Numero di serie / Топтамалық нөмірі / 일련 번호 / Serijos numeris / Sėrijas 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 оцінку качестве на работа на IVD / Pouze pro vyhodnocení výkonu IVD / Kun til evaluering af IVD ydelse / Nur für IVD-Leistungsbewertungszwecke / Μόνο για αξιολόγηση απόδοσης IVD / Solo para la evaluación del rendimiento en diagnóstico in vitro / Ainult IVD seadmehindamiseks / Réserve à l'évaluation des performances IVD / Само у знаяствене сврхе за IVD / Diagnostikust / Kizárólag in vitro diagnosztikához / Solo per valutazione delle prestazioni IVD / Жасанды жагдайда «пробирка ишнде» диагностикада тек жумусти бааралы ушун / IVD 성능 평가에 대해서만 사용 / Tik IVD prietaisui veikimo charakteristikoms tikrinti / Vientigi IVD darbības novērtēšanai / Uitsluitend voor doeltreffendheidsonderzoek / Kun for evaluering av IVD-ytelse / Tylko do oceny wydajności IVD / Uso esclusivo para avaliação de IVD / Numai pentru evaluarea performanței IVD / Tolyko dlya ocenki kachestva diagnostiki in vitro / Určenie iba na diagnostiku in vitro / Samo za procenu učinka in vitro dijagnostiki / Endast för utvärdering av diagnostisk användning in vitro / Yalnızca IVD performans değerlendirmesi için / Tilyki dlya otsinovaniya yakosti dijagnostiki in vitro / 仅限 IVD 性能评估

For US: "For Investigational Use Only"



Lower limit of temperature / Долен лимит на температурата / Dolni hranice teploty / Nedre temperaturgrænse / Temperaturuntergrenze / Κατώτερο όριο θερμοκρασίας / Limite inferior de temperatura / Alumine temperaturuuri / Limite inférieure de température / Najnižia dozvoljena temperatura / Alsó hőmérsékleti határ / Limite inferiore di temperatura / Температураның төменгі рұқсат шегі / 하한 온도 / Žemiausia laikymo temperatūra / Temperatūras zemākā robeža / Laagste temperatuurulimiet / Nedre temperaturgrænse / Dolna granica temperatury / Limite minimo de temperatura / Limity minima de temperatură / Нижний предел температуры / Spodná hranica teploty / Donja granica temperature / Nedre temperaturgräns / Sıcaklık alt sınırı / Мінімальна температура / 温度下限

[illegible]

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

CONTROL	+
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Positive control / Положительный контроль / Pozitivní kontrola / Positiv kontrol / Positive Kontrolle / Θετικός μάρτυρας / Control positivo / Positiivne kontroll / Contrôle positif / Pozitivná kontrola / Pozitiv kontrol / Controlo positivo / Оң бақылау / 양성 컨트롤 / Teigiama kontrolė / Pozitivna kontrol / Positive controle / Kontrola dodatna / Controlo positivo / Control pozitiv / Положительный контроль / Pozitif kontrol / Позитивный контроль / 阳性对照试剂

CONTROL	-
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Negative control / Отрицательный контроль / Negativní kontrola / Negativ kontrol / Negative Kontrolle / Αρνητικός μάρτυρας / Control negativo / Negatiivne kontroll / Contrôle négatif / Negativna kontrola / Negativí kontrol / Controlo negativo / Негативтік бақылау / 음성 컨트롤 / Neigiama kontrolė / Negativá kontrola / Negatieve controle / Kontrola ujemna / Controlo negativo / Control negativ / Отрицательный контроль / Negatív kontrol / Негативний контроль / 阴性对照试剂

STERILE	EO
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Method of sterilization: ethylene oxide / Метод на стерилизација: етиленов оксид / Způsob sterilizace: ethylenoxid / Steriliseringsmetode: ethylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / Método de esterilización: óxido de etileno / Sterilisieringsmethode: etyleenoksidi / Méthode de stérilisation : oxyde d'éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszere: etilén-oxid / Metodo di sterilizzazione: ossido di etilene / Sterilizacija edici – этилен тотыгы / 소독 방법: 에틸렌옥사이드 / Sterilizavimo būdas: etileno oksidas / Sterilizācijas metode: etilēnoksīds / Gesteriliseerd met behulp van ethyleenoxide / Steriliseringsmetode: etyleenoxid / Metoda sterilizacji: tlenek etylu / Método de esterilização: óxido de etileno / Metodă de sterilizare: oxid de etilă / Metod steriliziranja: etilenoeksid / Metóda sterilizácie: etylenoxid / Metoda sterilizacije: etilen oksid / Steriliseringsmetode: etenoxid / Sterilizasyon yöntemi: etilen oksit / Metod sterilizácii: etilenoeksidom / 灭菌方法: 环氧乙烷

STERILE	R
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Method of sterilization: irradiation / Метод на стерилизация: ирадиация / Způsob sterilizace: záření / Steriliseringmetode: bestråling / Sterilisationsmethode: Bestrahlung / Μέθοδος στεινώσεως: ακτινοβολία / Método de esterilización: irradiación / Steriliseringmismeetod: kiirgus / Méthode de stérilisation : irradiation / Metoda sterilizacije: zračenje / Sterilizācijas līdzeklis: besugāzārs / Metodo di sterilizzazione: irradiazione / Стерилизаційна аґісія – сәуле түсімі / 소독 방법: 방사 / Sterilizavimo būdas: radiacija / Sterilizēšanas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Steriliseringsmetode: bestråling / Metoda sterylizacji: napromienianie / Método de esterilização: irradiação / Metoda de sterilizare: iradiere / Метод стерилизации: облучение / Metoda sterilizacije: ozračevanje / Steriliseringsmetod: strålning / Sterilizasyon yöntemi: irradyasyon / Метод стерилизації: опромінення / 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 / Biológiallag veszélyes / Rischio biologico / Биологиялык тәуекелдер / 생물학적 위험 / Biologinis pavojus / Biologiskie riski / Biologisk risiko / Biologisk risiko / Zagrożenia biologiczne / Perigo biológico / Riscuri biologice / Биологическая опасность / Biologické riziko / Biološki rizici / Biologisk risk / Biyolojik Riskler / Биологічна небезпека / 生物学风险



Caution, consult accompanying documents / Внимание, направте справка в придружаващите документи / Pozor! Pristudujte si příloženou dokumentaci! / Forsigtig, se ledsagende dokumenter / Achtung, Begleitdokumente beachten / Προσοχή, συμβουλευτείτε τα συνοδευτικά έγγραφα / Precaución, consultar la documentación adjunta / Ettevaustus! Lugea kaasnavat dokumentatsiooni / Attention, consulter les documents joints / Uopozorenje, koristite prateću dokumentaciju / Fügelem! Olvassa el a mellékelt tájékoztatást / Attenzione: consultare la documentazione allegata / Абайлаңыз, тиісті құжаттармен танысыңыз / 주의, 동봉된 설명서 참조 / Dmesio, žiūrėkite pridėjamus dokumentus / Piesardzība, skatīt pavaddokumentus / Voorzichtig, raadpleeg bijgevoegde documenten / Forsiktig, se vedlagt dokumentasjon / Należy zapoznać się z dołączonymi dokumentami / Cuidado, consulte a documentação fornecida / Atentie, consultați documentele însoțitoare / Внимание: см. прилагаемую документацию / Vystřaħa, pozri sprievodné dokumenty / Pažnja! Pogledajte priložena dokumenta / Obs! Se medfølgende dokumentation / Dikkat, birlikte verilen belgeler başvurun / Увага: див. супутню документацию / 小心, 请参阅附带文档。



Upper limit of temperature / Горен љиме температура / Horní hranice teploty / Øvre temperaturgrænse / Temperaturobergrenze / Άνωτερο όριο θερμοκρασίας / Limite superior de temperatura / Limite temperaturapiiri / Limite supérieure de température / Gornja dozvoljena temperatura / Felső hőmérsékleti határ / Limite superiore di temperatura / Температураның руқсат етілген жоғары шегі / 상한 온도 / Aukščiausia laikymo temperatūra / Aukščia temperatūros ribeža / 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 / Sicaklık üst sınırı / Максимальна температура / 温度上限



Keep dry / Παзете сухо / Skladiujte v suchem prostredí / Opbevaras tørt / Trocklagern / Φυλάξτε το στεγνό / Mantener seco / Hoida kuivas / Conserver au sec / Držati na suhom / Száraz helyen tartandó / Tenere all'asciutto / Құрақ күйінде ұста / 건조 상태 유지 / Laiykite 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 / Fövaras tørt / Kuru bir şekilde muhafaza edin / Берегти від вологості / 請保持干燥



Collection time / Време на събиране / Čas odběru / Opsamlingstidspunkt / Entnahmeurzeit / Ώρα συλλογής / Hora de recogida / Kogumisaeg / Heure de prélèvement / Sati prikupljanja / Mintavétel időpontja / Ora di raccolta / Жинау уакыты / 수집 시간 / Paemimo laikas / Savākšanas laiks / Verzameltijd / Tid prøvetaking / Godzina pobrania / Hora de colheita / Ora colectării / Время сбора / Doba odboru / Vreme prikupljanja / Uppsamlingstid / Toploma zamani / Час забору / 采集时间



Peel / Обелете / Otevířete zde / Åbn / Abziehen / Αποκολλήστε / Desprender / Koorida / Décoller / Otvoriti skini / Húzza le / Staccare / Үстіңгі қабатын алып таста / 벗기 / Plešti čia / Atīmēt / Schillen / Trekk av / Oderwać / Destacar / Se dezlipeste / Отклеить / Odrhните / Oljuštiti / Dra isår / Ayırma / Відклеїти / 撕下



Perforation / Перфорация / Perforace / Perforering / Διήτρηση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Тесик тесу / 질취선
Perforacija / Perforácia / Perforatie / Perforacja / Perforação / Perforare / Перфорация / Perforácia / Perforasyon / Перфорация / 穿孔



Do not use if package damaged / Не използвайте, ако опаковката е повредена / Неползуйте, је-ли обал пошкоћен / Ma ikke anvendes hvis emballagen er beskadiget / Inhal beschädigter Packungsnicht verwenden / Μη χρησιμοποιεіτε εάν η συσκευασία έχει υποστεί ζημιά. / Non 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 használnia, ha a csomagolás sérült / Non usare se la confezione è danneggiata / Ереп пакеі бузылан болса, пайдаланба / 패키지가 손상된 경우 사용 금지 / Ji pakoutě pazejsta, nenaodit / Nelietoti, ja iepakojums bojāts / Niet gebruiken indien de verpakking beschadigd is / Ma 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 / Неползуйте, ак је обал пошкоћен / Ne koristite ako je pakovanje oštećeno / Använd ej om förpackningen är skadad / Ambalaj hasar görmüşse kullanmayın / Не використовувати за пошкодженої упаковки / 如果包裝破損，請勿使用



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 / Laida eemal valgeste / Protégée de la chaleur / Držati dalje od izvora topline / Övja a melegtől / Tenere lontano dal calore / Салкын жерде сакта / 열을 피하여 함 / Hoikyti atokiau nuo šilumos šaltinių / Sargat no karstuma / Beschermen tegen warmte / Må ikke utsettes for varme / Przechowywać z dala od źródła ciepła / Manter ao abrigo do calor / A se feri de căldură / Не награвать / Uchovávať mimo zdroja tepla / Držite dalje od toplote / Far away from heat / Исдан узак толун / Берегти від тепла / 请远离热源



Cut / Crejere / Odstrînnète / Klip / Schneiden / Κόψτε / Cortar / Lõigata / Découper / Reži / Vágja ki / Tagliare / Keciñiz / 잘라내기 / Kirpti / Nogriez / Knippen / Kutt / Odciać / Cortar / Decupati / Отрезать / Odstrînnite / Iseći / Klip / Kesme / Розрізати / 剪下



Collection date / Дата на събиране / Datum odběru / Opsamlingsdato / Entnahmedatum / Ημερομηνία συλλογής / Fecha de recogida / Kogumiskuuupäev / 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/анализ / μL/검測



Keep away from light / Пазете от светлина / Nevystavujte svētlu / 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 źródła światła / Manter ao abrigo da luz / Feriți de lumină / Хранить в темноте / Uchovávajte mimo dosahu svetla / Držite dalje od svetlosti / Får ej utsättas för ljus / Işıktan uzak tutun / Берегти від дії світла / 请远离光线



Hydrogen gas generated / Образуван е водород газ / Možnost úniku plynného vodíku / Frembringer hydrogengas / Wasserstoffgas erzeugt / Δημιουργία αερίου υδρογόνου / Producción de gas de hidrógeno / Vesinikgaasi tekitatud / Produit de l'hydrogène gazeux / Sadrží hydrogen vodik / Hidrogén gázt fejeleszt / Produzione di gas idrogeno / Газтекес сутери 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 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 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, vorsichtig handhaben. / Ευθραusto. Χειριστείτε το με προσοχή. / Frágil. Manipular con cuidado. / Öm, käsitsege ettevaatlikult. / Fragile. Manipuler avec précaution. / Lomljivo, rukujte pažljivo. / Törékeny! Óvatosan kezelendő. / Fragile, maneggiare con cura. / Сынгыш, абайлап пайдаланыңыз. / 조심 깨지기 쉬운 처리 / Trapu, elkites atsargiai. / Trausls; rīkoties uzmanīgi / Breekbaar, voorzichtig behandelen. / Ømtålig, håndter forsigtig. / Krucha zawartość, przenosić ostrożnie. / Frágil, Manuseie com Cuidado. / Frágil, manipulați cu atenție. / Хрупкое! Обращаться с осторожностью. / Krehké, vyžaduje sa opatrná manipulácia. / Lomljivo - rukujte pažljivo. / Bräckligt. Hantera försiktigt. / Kolay Kırılır, Dikkatli Taşıyın. / Тендітна, звертатися з обережністю / 易碎，小心轻放

Change History

Revision	Date	Change Summary
(03)	2018-06	Updated BD logo Removed discontinued catalog number 220504 Included entire Symbol Glossary with FDA url
(04)	2019-04	Fixed typo to table in User Quality Control section. Added ATCC trademark statement.



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