

Part Number:	S11931	BALTSO0191 Version 13.0 Template 4 Inserts	
Category and Description: Package Insert, Difco Oxford or Modified Oxford Antimicrobial Supplement	Rev from: 01		Rev to: 02
	Job Number:		415-18

Catalog Number: 211763

Blank (Sheet) Size: Length: 11" Width: 8.5"

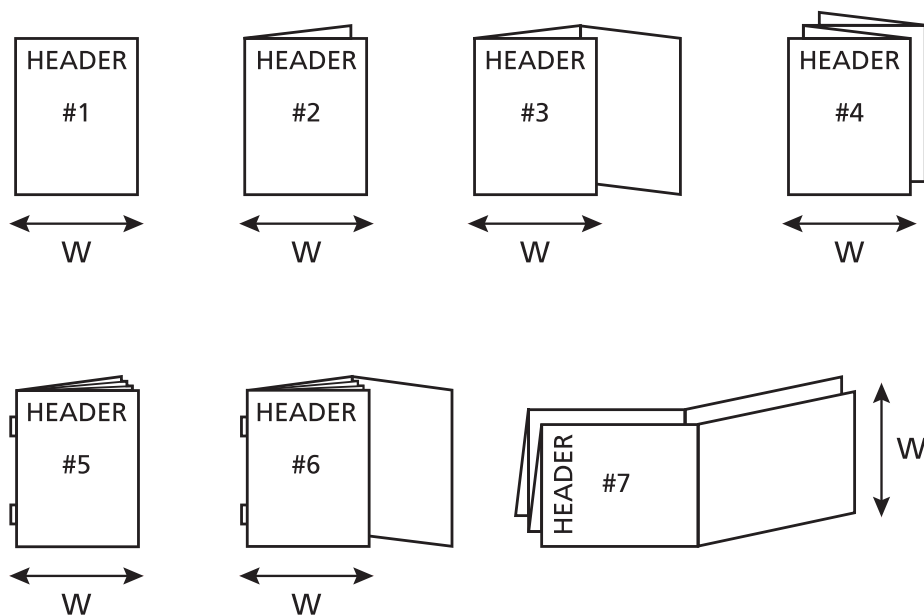
Number of Pages: 6 Number of Sheets: 6

Page Size: Length: 11" Width: 8.5" Final Folded Size: N/A

Ink Colors: Number of Colors: 1 PMS #: Standard Black

Printed Two Sides: Yes: ☐ No: ☒ Web only

Style (see illustrations below): # 1



Vendor Printed: ☐ Online / In House Printed: ☐ Web Printed: ☒

See Specification control no. N/A for material information.



BD Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152 USA

Company confidential. This document is the property of Becton, Dickinson and Company and is not to be used outside the company without written permission. Graphics are approved by Becton, Dickinson and Company. Supplier has the responsibility for using the most current approved revision level.

Revised By: **REVISED BY**
By Nancy Carlsen at 1:50 pm, Feb 19, 2019

Proofing Approved By: **PROOFING APPROVED BY**
By Nichole Graham at 1:34 pm, Mar 25, 2019

Third Eye By: **THIRD EYE BY**
By Kim Stone at 4:22 pm, Mar 25, 2019

 BD Difco™ Oxford Medium Base
Difco™ Oxford Antimicrobial Supplement
Difco™ Modified Oxford Antimicrobial Supplement

REF 211763

S11931(02)

2019-02

INTENDED USE

BD Difco™ Oxford Medium Base is a selective, solid medium used with BD Difco™ Oxford Antimicrobial Supplement or Modified BD Difco™ Oxford Antimicrobial Supplement for isolating and differentiating *Listeria monocytogenes* in foods.

SUMMARY AND EXPLANATION

First described in 1926 by Murray, Webb, and Swann,¹ *Listeria monocytogenes* is recognized as a problem of importance in public health, especially by the food and dairy industries. *L. monocytogenes* has been documented as the cause of food-associated illness in the Canadian Maritime Provinces, Boston and southern California. These outbreaks of listeriosis were notable because of the high case-fatality rate.²

The isolation and identification of *L. monocytogenes* has been difficult because of the need for a faster enrichment procedure and the lack of a suitable selective and differential medium for isolating the organism from suspected sources in mixed populations. Many common food contaminants such as the streptococci, *Bacillus* species, *Escherichia coli*, *Pseudomonas aeruginosa* and *Proteus vulgaris* interfere with the isolation of *Listeria monocytogenes*.³

The *Listeria* are short, gram-positive, non-sporeforming, motile rods. The organism can grow over a wide temperature range. It is characterized by its ability to hydrolyze esculin and by tolerance of salt, tumbling motility and beta hemolysis.

Presumptive identification of *Listeria* is based on the esculin hydrolysis reaction which can be seen as a darkening of the medium after incubation in Fraser Broth⁴ or on BD Difco Oxford Medium Base.⁵ Motility can be observed as an umbrella-type growth in Motility Test Medium. A narrow zone of beta-hemolysis around and under *Listeria* colonies can be observed on blood agar (McBride *Listeria* Agar or Columbia Blood Agar Base).⁶

After successful isolation of the organism, final identification of *Listeria* is based on biochemical characterization and serological confirmation.

PRINCIPLES OF THE PROCEDURE

BD Difco Oxford Medium Base is prepared according to the formulation of Curtis et al.⁵ who originally described the medium and its use in the selective isolation of *Listeria* from mixed cultures.

Differentiation is aided by including ferric ammonium citrate in the medium. Since all *Listeria* species hydrolyze esculin, the addition of ferric ions to the medium will detect the reaction. A blackening of the colony and surrounding medium in cultures containing esculin-hydrolyzing bacteria is the result of the formation of 6,7-dihydroxycoumarin which reacts with the ferric ions.⁴

Selectivity is provided by the presence of lithium chloride in the formula. The high salt tolerance of *Listeria* is utilized as a means to markedly inhibit growth of enterococci. Selectivity is increased by adding various antimicrobial agents to the base. Incorporating these agents into BD Difco Oxford Medium Base will completely inhibit gram-negative organisms and most gram-positive organisms at 24 h incubation. The most widely recognized antimicrobial agent combinations are the Oxford Medium formulation⁵ which contains cycloheximide, colistin sulfate, acriflavine, cefotetan and fosfomycin (available as BD Difco Oxford Antimicrobial Supplement) and the Modified Oxford Medium formulation⁶ which contains moxalactam and colistin methane sulfonate or colistin sulfate (available as BD Difco Modified Oxford Antimicrobial Supplement).

In 1989, the United States Department of Agriculture⁵ recommended Modified Oxford medium for isolating and identifying *Listeria monocytogenes* from processed meat and poultry products. In 1990, the United States Food and Drug Administration⁷ recommended Oxford Medium for isolating *Listeria* from Enrichment Broth cultures.

FORMULA

BD Difco Oxford Medium Base			
Approximate Formula* Per Liter			
Pancreatic Digest of Casein	8.9 g	Sodium Chloride	4.4 g
Proteose Peptone No.3	4.4 g	Esculin	1.0 g
Yeast Extract	4.4 g	Ferric Ammonium Citrate	0.5 g
Tryptic Digest of Beef Heart	2.7 g	Lithium Chloride	15.0 g
Starch	0.9 g	Agar	15.3 g
Final pH 7.2 ± 0.2 at 25°C			

Five hundred grams will make 8.7 liters of medium.

**BD Difco Oxford
Antimicrobial Supplement**

Approximate Formula*

Per 10 mL Vial

Acriflavine	5.0 mg
Cefotetan	2.0 mg
Colistin Sulfate	20.0 mg
Cycloheximide	400.0 mg
Fosfomycin	10.0 mg

One rehydrated vial is added to
one liter of basal medium.**BD Difco Modified Oxford
Antimicrobial Supplement**

Approximate Formula*

Per 10 mL Vial

Colistin Sulfate	10.0 mg
Moxalactam	20.0 mg

One rehydrated vial is added to
one liter of basal medium.**Precautions:** For Laboratory Use.**WARNING:** BD DIFCO OXFORD MEDIUM BASE CAUSES IRRITATION.

Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

FIRST AID: IN CASE OF CONTACT, immediately flush eyes with plenty of water for at least 15 min. Call a physician. Flush skin with water. Wash clothing before reuse.**WARNING:** BD DIFCO OXFORD ANTIMICROBIC SUPPLEMENT IS HARMFUL IF SWALLOWED OR INHALED. MAY CAUSE IRRITATION. MAY CAUSE BIRTH DEFECTS. Avoid contact with eyes, skin and clothing. Do not breathe dust.**FIRST AID:** IF SWALLOWED, induce vomiting. Call a physician. Never give anything by mouth to an unconscious person. IF INHALED, remove to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. If breathing is difficult, give oxygen. Call a physician. IN CASE OF CONTACT, immediately flush eyes with plenty of water for at least 15 min. Call a physician. Flush skin with water.

Follow proper, established laboratory procedures in handling and disposing of infectious materials.

Storage: Store BD Difco Oxford Medium Base at 2–25°C. Store BD Difco Oxford Antimicrobial Supplement, BD Difco Modified Oxford Antimicrobial Supplement and prepared medium at 2–8°C.**Expiration Date:** The expiration date applies to the product in its intact container when stored as directed. Do not use a product if it fails to yield expected results described in "User Quality Control."**Method of Preparation:**

1. To rehydrate the medium, suspend 57.5 g of the powder in 1 L of purified water. Mix thoroughly.
2. Heat with frequent agitation and boil for 1 min to completely dissolve the powder.
3. Autoclave at 121 °C for 10 min. Cool to 45–50 °C.
4. To prepare OXFORD MEDIUM, aseptically rehydrate one vial of BD Difco Oxford Antimicrobial Supplement with 5 mL reagent grade ethanol and 5 mL sterile purified water. Rotate in an end-over-end motion to dissolve completely. Add 10 mL to 1 L of molten (45–50 °C) BD Difco Oxford Medium Base. Mix thoroughly.
To prepare MODIFIED OXFORD MEDIUM, aseptically rehydrate one vial of BD Difco Modified Oxford Antimicrobial Supplement with 10 mL sterile purified water. Rotate in an end-over-end motion to dissolve completely. Add 10 mL to 1 L of molten (45–50 °C) BD Difco Oxford Medium Base. Mix thoroughly.

PROCEDUREGrowth of *Listeria* in culture media is generally slow and delicate, especially upon primary isolation. Attempts at direct isolation from positive specimens may fail. Selective enrichment and cold enrichment have both been determined to increase isolation rates.^{8,9}Because cold enrichment procedures are lengthy and, therefore, not convenient for routine testing of food or biological specimens by microbiological laboratories, shortened enrichment procedures for isolating *Listeria* are necessary.¹⁰ UVM Modified *Listeria* Enrichment Broth,¹¹ *Listeria* Enrichment Broth¹² and Fraser Broth⁴ have been shown to be useful in isolation methods.To isolate and identify *Listeria monocytogenes*, the following procedure is recommended.⁶

1. Enrich the sample in UVM Modified *Listeria* Enrichment or *Listeria* Enrichment Broth.
2. If desired, use Fraser Broth as a secondary enrichment to increase selectivity and differentiation before plating.
3. Inoculate Oxford Medium or Modified Medium with the enriched culture to isolate *Listeria* colonies.
4. Select esculin-positive colonies and confirm their identity by further biochemical testing.
5. Use macroscopic tube and rapid slide tests for definitive serological identification. For additional information, refer to the *Manual of Clinical Microbiology*.¹³

User Quality Control:**Identity Specifications****BD DIFCO OXFORD MEDIUM BASE**

Dehydrated medium:	tan, homogeneous, free-flowing
Reaction of 5.75% solution:	pH 7.2 ± 0.2 at 25°C
Prepared plates:	light to medium amber, slightly opalescent

	BD Difco Oxford Antimicrobial Supplement	BD Difco Modified Oxford Antimicrobial Supplement
Appearance	yellow cake; yellow solution upon rehydration	white to off-white cake; upon rehydration colorless solution

Typical Cultural Response After 24–40 H at 35 °C

Test Organism	Approximate Inoculum	Recovery on Oxford Medium	Recovery on Modified Oxford Medium
<i>Enterococcus faecalis</i> ATCC® 29212	1,000–2,000 CFU	inhibited	inhibited
<i>Escherichia coli</i> ATCC® 25922	1,000– 2,000 CFU	inhibited	inhibited
<i>Listeria monocytogenes</i> ATCC® 19114	100–1,000 CFU	good, esculin + (black colonies)	good, esculin + (black colonies)

The cultures listed above are the minimum that should be used for performance testing.

LIMITATIONS

1. Since *Listeria* species other than *L. monocytogenes* can grow on these media, an identification of *Listeria monocytogenes* must be confirmed by biochemical and serological testing.¹³
2. Antimicrobial agent solutions must be freshly prepared before each use or aliquoted and stored at -20°C or below.
3. Poor growth and a weak esculin reaction may be seen after 40 h incubation for some enterococci.

REFERENCES

1. Murray, E.G.D., R.A. Webb, and M.B.R. Swann. 1926. A disease of rabbits characterized by large mononuclear leucocytosis caused by a hitherto undescribed bacillus *Bacterium monocytogenes* (n.sp.). J. Path. Bact 29:407–439.
2. Broome, C.V., C.A. Ciesielski, M.J. Linnan, and A. W. Hightower. 1986. Epidemiology of *Listeria monocytogenes* in the United States. 73rd Annual Meeting of the IAMFES.
3. Kramer, P.A., and D. Jones. 1969. Media selective for *Listeria monocytogenes*. J. Appl. Bact. 32:381–394.
4. Fraser, J. and W. Sperber. 1988. Rapid detection of *Listeria* in food and environmental samples by esculin hydrolysis. Journal of Food Protection. 51:762–765.
5. Curtis, G.D.W., R.G. Mitchell, A.F. King and E.J. Griffin. 1989. Appl. Microbiol. 8:95-98.
6. Lee, W.H., and D. McClain, 1989. Laboratory communication No. 57 (revised May 24, 1989). USDA, FSIS, Microbiology Division, Beltsville, MD.
7. Chesemore, R.G. 1990. FDA Bacteriological Analytical Manual, Chapter 29 - *Listeria* isolation; culture medium substitution in method of analysis. Federal Register. 55(183):38753–4.
8. Hayes, P.S., J.C. Feely, L.M. Graves, G.W. Ajello, and D.W. Fleming. 1986. Isolation of *Listeria monocytogenes* from raw milk. Appl. and Environ. Microb. 51:438–440.
9. Doyle, M.P., L.M. Meske, and E.H. Martha. 1985. Survival of *Listeria monocytogenes* during the manufacture and storage of nonfat dry milk. J. of Food Protection. 48:740–742
10. Doyle, M.P., and J.L. Schoeni. 1986. Selective-enrichment procedure for isolation of *Listeria monocytogenes* from fecal and biological specimens. Appl. Environ. Microbiol. 51:1127–1129.
11. Lee, W.L., and D. McClain. 1986. Improved *Listeria monocytogenes* selective agar. Appl. Environ. Microbiol. 51:1215–1217.
12. Donnelly, C.W., and G.J. Baignet. 1986. Method for flow cytometric detection of *Listeria monocytogenes* in milk. Appl. Environ. Microbiol. 52:689–695.
13. Bille, J., J. Rocourt and B. Swaminathan. 1999. *Listeria*, *Erysipelothrix* and *Kurthia*. In Murray, Baron, Pfaller, Tenover and Tenover (ed.). Manual of clinical microbiology, 7th ed. American Society for Microbiology, Washington, D.C.

AVAILABILITY

Cat. No.	Description
222530	BD Difco Oxford Medium Base, 500 g.
222510	BD Difco Oxford Medium Base, 2 kg.
211755	BD Difco Oxford Antimicrobial Supplement, 6 x 10 mL.
211763	BD Difco Modified Oxford Antimicrobial Supplement, 6 x 10 mL.
222120	LPM Agar Base, 500 g.
222110	LPM Agar Base, 2 kg.
212156	McBride <i>Listeria</i> Agar, 500 g.
222220	<i>Listeria</i> Enrichment Broth, 500 g.
222330	UVM Modified <i>Listeria</i> Enrichment Broth, 500 g.
211436	Motility Test Medium, 500 g.
223001	<i>Listeria</i> O Antiserum, Type 1, 1 mL.
223011	<i>Listeria</i> O Antiserum, Type 4, 1 mL.
223021	<i>Listeria</i> O Antiserum, Poly Types 1 & 4, 1 mL.



Manufacturer / Производител / Výrobce / Fabrikant / Hersteller / Κατασκευαστής / Fabricante / Tootja / Fabricant / Proizvođač / Gyártó / Fabbicante / Атқарушы / 제조업체 / Gamintojas / Ražotājs / Tilvirker / Producent / Producător / Производитель / Výrobca / Proizvođač / Tillverkare / Üretici / Виробник / 生产厂商



Use by / Използвайте до / Spotřebujte do / Brug før / Verwendbar bis / Χρήση έως / Usar antes de / Kasutada enne / Date de péremption / 사용 기한 / Upotrijebiti do / Felhasználhatóság dátuma / Usare entro / Дейін пайдалануға / Naudokite iki / Izlietot līdz / Houdbaar tot / Brukes for / Stosować do / Prazo de validade / A se utiliza până la / Исползовать до / Použít do / Upotrebiti do / Använd före / Son kullanma tarihi / Використати до / 使用截止日期

YYYY-MM-DD / YYYY-MM (MM = end of month)
 ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = края на месеца)
 RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
 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)
 ЖЖЖЖ-АА-КК / ЖЖЖЖ-АА / (АА = айдың соңы)
 YYYY-MM-DD/YYYY-MM (MM = 월말)
 MMMM-MM-DD / MMMM-MM (MM = menses pabaiga)
 GGGG-MM-DD/GGGG-MM (MM = menses 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)
 ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = конец месяца)
 RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
 GGGG-MM-DD / GGGG-MM (MM = kraj meseca)
 AAAA-MM-DD / AAAA-MM (MM = slutet av månaden)
 YYYY-AA-GG / YYYY-AA (AA = айın соңу)
 PPPP-MM-DD / PPPP-MM (MM = кінець місяця)
 YYYY-MM-DD / YYYY-MM (MM = 月末)



Catalog number / Каталог номер / Katalogové číslo / Katalognummer / Αριθμός καταλόγου / Número de catálogo / Katalooginumber / Numéro catalogue / Kataloški broj / Katalógusszám / Numero di catalogo / Каталог номер / 카탈로그 번호 / Katalogo / numeris / Kataloga numurs / Catalogus number / 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 Közösségben / Rappresentante autorizzato nella Comunità Europea / Европа қауымдастығындағы уәкілетті өкіл / 유럽 공동체의 위임 대표 / Igaliotasis atstovas Europos Bendrijoje / Pilnvarotais pārstāvis Eiropas Kopienā / Bevoegde vertegenwoordiger in de Europese Gemeenschap / Autoriseret representant i EU / Autoryzowane przedstawicielstwo we Wspólnocie Europejskiej / Representante autorizado na Comunidade Europeia / Reprezentantul autorizat pentru Comunitatea Europeană / Уполномоченный представитель в Европейском сообществе / Autorizovaný zástupce 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 meditsiinaparatuur / Dispositif médical de diagnostic in vitro / Medicinska pomagala za In Vitro Diagnostiku / In vitro diagnosztikai orvosi eszköz / Dispositivo medicale per diagnostica in vitro / Жасанды жағдайда жүзгізетін медициналық диагностика аспабы / In Vitro Diagnostic 의료 기기 / In vitro diagnostikos prietaisas / Medicīnas ierīces, ko lieto in vitro diagnostikā / Medisch hulpmiddel voor in-vitro diagnostiek / In vitro diagnostisk medisinsk utstyr / Urządzenie medyczne do diagnostyki in vitro / Dispositivo médico para diagnóstico in vitro / Dispositiv medical pentru diagnostic in vitro / Медицинский прибор для диагностики in vitro / Medicinska pomůcka na diagnostiku in vitro / Medicinski uređaj za in vitro dijagnostiku / Medicinteknisk produkt för in vitro-diagnostik / In Vitro Diagnostik Tibbi Cihaz / Медицинский прибор для диагностики in vitro / 体外诊断医疗设备



Temperature limitation / Температурни ограничения / Teplotní omezení / Temperaturbegrænsning / Temperaturbegrenzung / Περιορισμοί θερμοκρασίας / Limitación de temperatura / Temperaturi piirang / Limites de température / Dozvoljena temperatura / Hőmérsékleti határ / Limiti di temperatura / Температураны шектеу / 온도 제한 / Laikymo temperatūra / Temperatūras ierobežojumi / Temperaturilimiet / Temperaturbegrensning / Ograniczenie temperatury / Limites de temperatura / Limite de temperatură / Ограничение температуры / Ohraničenje teploty / Ograničenje temperature / Temperaturgräns / Sıcaklık sinirlaması / 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 (kodi) / Tétel száma (Lot) / Codice batch (lotto) / Топтама коды / 배치 코드(코트) / Partijos numeris (LOT) / Partijos kods (laidiens) / Lot number / 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 партии / 批号 (亚批)



Contains sufficient for <n> tests / Съдържанието е достатъчно за <n> теста / Dostatečné množství pro <n> testů / Indeholder tilstrækkeligt til <n> tests / Ausreichend für <n> Tests / Περιέχει επαρκή ποσότητα για <n> εξετάσεις / Contenido suficiente para <n> pruebas / Küllaldane <n> testide jaoks / Contenu suffisant pour <n> tests / Sadržaj za <n> testova / <n> teszthez elegendő / Contenido suficiente per <n> test / <n> тестрегі үшін жеткінікті / <n> 테스트가 충분한 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 / Lugeda 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 / Consultați instrucțiunile de utilizare / См. руководство по эксплуатации / Pozri Pokyny na používanie / Pogledajte uputstvo za upotrebu / Se bruksanvisningen / Kullanım Talimatları'na başvurun / Див. інструкції за 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 / Nepoužívajte opakovane / Ne upotrebljavajte ponovo / Får ej återanvändas / Tekrar kullannamayi / He використовувати повторно / 请勿重复使用



Serial number / Серийн 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 / Sērijas numurs / Serie nummer / Numer seryjny / Número 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 работа на IVD / Pouze pro vyhodnocení výkonu IVD / Kun til evaluering af IVD ydelse / Nur für IVD-Leistungsbewertungszwecke / Móvo 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 / Kizárolag in vitro diagnosztikához / Solo per valutazione delle prestazioni IVD / Жасанды жағдайда «пробирка ішінде» диагностикада тек жұмысты бағалау үшін / IVD 성능 평가에 대해서만 사용 / Tik IVD prietaisų veikimo charakteristikoms tikrinti / Vienīgi IVD darbības novērtēšanai / Uitsluitend voor doeltreffendheidsonderzoek / Kun for evaluering av IVD-yltelse / Tylko 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 рұқсат шегі / 하한 온도 / Žemiausia laikymo temperatūra / Temperatūros žemākā robeža / Laagste temperatuurlimiet / Nedre temperaturgrænse / Dolna granica temperatury / Limite minimo de temperatura / Limită minimă de temperatură / Нижний предел температуры / Spodná hranica teploty / Donja granica temperature / Nedre temperaturgräns / Sıcaklık alt sınırı / Мінімальна температура / 温度下限



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



Positive control / Положителен контрол / Pozitivní kontrola / Positiv kontrol / Positive Kontrolle / Θετικός μάρτυρας / Control positivo / Positiivne kontroll / Contrôle positif / Pozitivna kontrola / Pozitiv kontrol / Controllo positivo / Оң бақылау / 양성 컨트롤 / Teigiama kontrolė / Pozitívna kontrola / Positieve controle / Kontrola dodatnia / Controllo positivo / Kontrol pozitiv / Положительный контрол / Pozitif kontrol / Позитивный контрол / 阳性对照试剂



Negative control / Отрицателен контрол / Negativní kontrola / Negativ kontrol / Negative Kontrolle / Αρνητικός μάρτυρας / Control negativo / Negatiivne kontroll / Contrôle négatif / Negativna kontrola / Negativ kontroll / Controllo negativo / Негативтік бақылау / 음성 컨트롤 / Neigiama kontrolė / Negatívna kontrola / Negatieve controle / Kontrola ujemna / Controllo negativo / Control negativ / Отрицательный контрол / Negatif kontrol / Негативный контрол / 阴性对照试剂



Method of sterilization: ethylene oxide / Метод на стерилизация: этиленов оксид / Způsob sterilizace: etylenoxid / Steriliseringmetode: ethylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / Método de esterilización: óxido de etileno / Steriliseerimismeetod: etüleenoksiid / Méthode de stérilisation : oxyde d'éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszere: etilén-oxid / Metodo di sterilizzazione: ossido di etilene / Sterilizacija edici – этилен тотығы / 소독 방법: 에틸렌옥사이드 / Sterilizavimo būdas: etileno oksidas / Sterilizēšanas metode: etilēnoksiids / Gesteriliseerd met behulp van ethyleenoxide / Steriliseringsmetode: etylenoksid / Metoda sterilizacji: tlenek etylu / Método de esterilização: óxido de etileno / Metoda de sterilizare: oxid de etilenă / Метод стерилизации: этиленоксид / Metóda sterilizácie: etylenoxid / 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 / Steriliseerimismeetod: kiirgus / Méthode de stérilisation : irradiation / Metoda sterilizacije: zračenje / Sterilizálás módszere: besugárzás / Metodo di sterilizzazione: irradiazione / Стерилизация edici – сәуле тисі / 소독 방법: 방사 / Sterilizavimo būdas: radiacija / Sterilizēšanas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Steriliseringsmetode: bestrålning / Metoda sterylizacji: napromienianie / Método de esterilização: irradiação / Metoda de sterilizare: iradiere / Метод стерилизации: облучение / Metóda sterilizácie: ožiarenie / Metoda sterilizacije: ozračevanje / Steriliseringsmetod: strålning / Sterilizasyon yöntemi: irdayasyon / Метод стерилизації: опроміннення / 灭菌方法: 辐射



Biological Risks / Биологични рискове / Biologická rizika / Biologisk fare / Biogefährdung / Βιολογικοί κίνδυνοι / Riesgos biológicos / Biologiskised riskid / Risques biologiques / Biološki rizik / Biológiai veszélyes / Rischio biologico / Биологические тәуекелдер / 생물학적 위험 / Biologinis pavojus / Biologisches Risiko / Biologisk risiko / Zagrożenia biologiczne / Perigo biológico / Riscuri biologice / Biologické nebezpečnost / Biologická riziko / Biološki rizici / Biologisk risk / Biyolojik Riskler / Біологічна небезпека / 生物学风险



Caution, consult accompanying documents / Внимание, направете справка в придружаващите документи / Pozor! Prostudujte si příloženou dokumentaci! / Forsigtig, se ledsagende dokumenter / Achtung, Begleitdokumente beachten / Προσοχή, συμβουλευτείτε τα συνοδευτικά έγγραφα / Precaución, consultar la documentación adjunta / Ettevaatust! Lugeda kaasnevat dokumentatsiooni / Attention, consulter les documents joints / Urozorenje, koristi prateću dokumentaciju / Figyelem! Olvassa el a mellékelt tájékoztatót / Attenzione: consultare la documentazione allegata / Абайлаңыз, тиісті құжаттармен танысыңыз / 주의, 동봉된 설명서 참조 / Dėmesio, žiūrėkite priedamus dokumentus / Piesardzība, skatīt pavaddokumentus / Voorzichtig, raadpleeg 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 / Vystraha, pozri sprievodné dokumenty / Pažnja! Pogledajte priložena dokumenta / Obs! Se medföljande dokumentation / Dikkat, birlikte verilen belgelere başvurun / Увага: див. супутню документацію / 小心, 请参阅附带文档。



Upper limit of temperature / Горен лимит на температурата / Horní hranice teploty / Øvre temperaturgrænse / Temperaturobergrenze / Ανώτερο όριο θερμοκρασίας / Limite superior de temperatura / Ülemine temperatuuripiir / Limite supérieure de température / Gornja dozvoljena temperatura / Felső hőmérsékleti határ / Limite superiore di temperatura / Температураның рұқсат етілген жоғарғы шегі / 상한 온도 / Aukščiausia laikymo temperatūra / Ausgējā temperatūras robeža / Hoogste temperatuurlimiet / Øvre temperaturgrænse / 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 / Міксимальна температура / 温度上限



Keep dry / Пазете сухо / Skladujte v suchém prostředí / Opbevaras tørt / Trocklagern / Φυλάξτε το στεγνό / Mantener seco / Hoida kuivaks / Conservar au sec / Držati na suhom / Száraz helyen tartandó / Tenere all'asciutto / Құрғақ күйінде ұста / 건조 상태 유지 / Laikykite sausiai / Uzglabāt sausu / Droog houden / Holdes tørt / Przechowywać w stanie suchym / Manter seco / A se feri de umezeală / Не допускать попадания влаги / Uchovávať v suchu / Držite na suvom mestu / Förvaras tork / Kuru bir şekilde muhafaza edin / Бергити від вологості / 请保持干燥



Collection time / Време на събиране / Cas odběru / Opsamlingsstidspunkt / Entnahmeuhrzeit / Ώρα συλλογής / Hora de recogida / Kogumisaeg / Heure de prélèvement / Sati prikupljanja / Mintavétel időpontja / Ora di raccolta / Жинау уақыты / 수집 시간 / Paėmimo laikas / Savākšanas laiks / Verzameltijd / Tid prøvetaking / Godzina pobrania / Hora de colheita / Ora colectării / Време сбора / Doba odboru / Vreme prikupljanja / Uppsamlingsstid / Toplama zamanı / Час забору / 采集时间



Peel / Обелете / Otevřete zde / Abn / Abziehen / Αποκολλήστε / Desprender / Koorida / Décoller / Otvoriti skini / Húzza le / Staccare / Үстіңгі қабатын алып таста / 벗기기 / Pléști ăia / Atfîmîț / Schillen / Trekk av / Oderwać / Destacar / Se dezlipеște / Отклеить / Odrhните / Oljuštiti / Dra isår / Ayırma / Відклеїти / 撕下



Perforation / Перфорация / Perforace / Perforering / Διδίρηση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Тесик тесу / 절취선 / Perforacija / Perforacija / Perforatie / Perforacia / Perfuração / Perforare / Перфорация / Perforácia / Perforasyon / Перфорация / 穿孔



Do not use if package damaged / Не използвайте, ако опаковката е повредена / Nepoužívejte, je-li obal poškozený / Må ikke anvendes hvis emballagen er beskadiget / Inhal beschädigter Packung nicht verwenden / Μη χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά. / No usar si el paquete está dañado / Mitte kasutada, kui pakend on kahjustatud / Ne pas l'utiliser si l'emballage est endommagé / Ne koristiti ako je oštećeno pakiranje / Ne használja, ha a csomagolás sérült / Non usare se la confezione è danneggiata / Ереп пакет бүзылган болса, пайдаланба / 패키지가 손상된 경우 사용 금지 / Jei pakuotė pažeista, nenaudoti / Nelietot, ja iepakojums bojāts / Niet gebruiken indien de verpakking beschadigd is / Må ikke brukes hvis pakke er skadet / Nie używać, jeśli opakowanie jest uszkodzone / Não usar se a embalagem estiver danificada / A nu se folosi dacă pachetul este deteriorat / Не использовать при повреждении упаковки / 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 / 如果包裝破損, 請勿使用



Keep away from heat / Παзете от топлина / Nevystavujte přilišnému teplu / Må ikke udsættes for varme / Vor Wärme schützen / Κρατήστε το μακριά από τη θερμότητα / Mantener alejado de fuentes de calor / Hoida eemal valgusest / Protéger de la chaleur / Držati dalje od izvora topline / Övja a melegtől / Tenere lontano dal calore / Салқын жерде сақта / 열을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt no karstuma / Beschermen tegen warmte / Må ikke utsettes for varme / Przechowywać z dala od źródła 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 / Беретти від дії тепла / 请远离热源



Cut / Срежете / Odstřihněte / Klip / Schneiden / Κόψτε / Cortar / Lõigata / Découper / Reži / Vágja ki / Tagliare / Keciñiz / 잘라내기 / Kirpti / Nogriezť / Knippen / Kutt / Odciać / Cortar / Decupați / Отрезать / Odstrihnite / Iseći / Klipp / Kesme / Розрізати / 剪下



Collection date / Дата на събиране / Datum odběru / Opsamlingsdato / Entnahmedatum / Ημερομηνία συλλογής / Fecha de recogida / Kogumiskuupeäev / 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 / Datum 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/检测



Keep away from light / Παзете от светлина / Nevystavujte světlu / Må ikke udsættes for lys / Vor Licht schützen / Κρατήστε το μακριά από το φως / Mantener alejado de la luz / Hoida eemal valgusest / Conserver à l'abri de la lumière / Držati dalje od 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 / Ізідтан узак тутун / Беретти від дії світла / 请远离光线



Hydrogen gas generated / Образован 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 fejleszt / Produzione di gas idrogeno / Газтөктес сутері пайда болды / 수소 가스 생성됨 / Išskiria vandenilio dujas / Rodas vandenilis / 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 / Identificationnummer 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, vorsichtig handhaben. / Εύθραστο. 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. / Сыныш, абайлап пайдаланыңыз. / 조심 깨지기 쉬운 처리 / Trapu, elkitės atsargiai. / Trausls; rikoties 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 Taşın. / Тендітна, звертатися з обережністю / 易碎, 小心轻放

Change History

Revision/Date	Section	Change Summary
(02) 2019-02	All	Updated branding. Converted to standard 8 1/2 x 11" template. Added Change Table and Symbol Glossary



Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152 USA

ATCC is a trademark of the American Type Culture Collection.

Difco is a trademark of Difco Laboratories, a subsidiary of Becton, Dickinson and Company.

© 2019 BD. BD, the BD Logo and all other trademarks are property of Becton, Dickinson and Company.