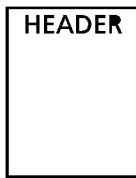


Revisions

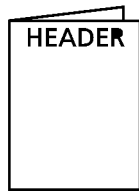
Rev from	Rev to	ECO #
0803	2010/07	5431-10

Notes:

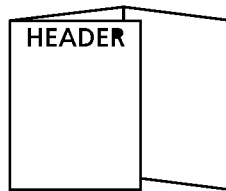
- BD Cat. Number 297684
- Blank (Sheet) Size: Length: 11" Width: 8.5"
 Number of Pages: 2 Number of Sheets: 1
 Page Size: Length 11" Width 8.5" Final Folded Size: N/A
- Style (see illustrations below): #1



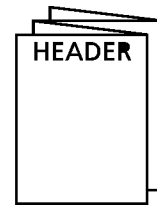
#1



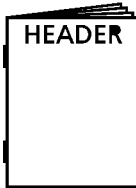
#2



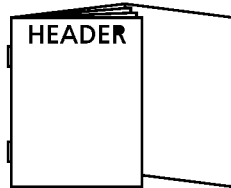
#3



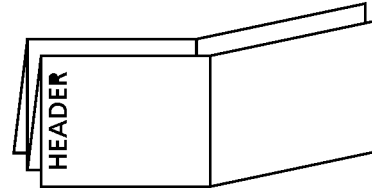
#4



#5




#6



#7

- See Specification Control Number N/A for Material Information
- Ink Colors: Printed two sides Yes No
 No. of Colors: 1 PMS# Black
- Graphics are approved by Becton, Dickinson and Company. Supplier has the responsibility for using the most current approved revision level

VS Controlled by BDDS, Madison

Label Design	Date	COMPANY CONFIDENTIAL. THIS DOCUMENT IS THE PROPERTY OF BECTON, DICKINSON AND COMPANY AND IS NOT TO BE USED OUTSIDE THE COMPANY WITHOUT WRITTEN PERMISSION	 Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA	
Proofer	Date			
Checked By	Date			
Part Number: 8808461JAA		Category and Description Package Insert, MacConkey II with Sorbitol Deeps	Sheet: 1 of 3 Scale: N/A	A

BD BBL™ Prepared Tubed Medium for Detection of *Escherichia coli* Associated with Hemorrhagic Colitis

MacConkey II Agar with Sorbitol Deeps

CE 8808461JAA
2010/07

Pokyny vám poskytne miestní zástupce spoločnosti BD. / Kontakt den lokale BD repræsentant for at få instruktioner. / Kasutusjuhiste suhtes kontakteeruge oma kohaliku BD esindajaga. / Επικοινωνήστε με τον τοπικό αντιπρόσωπο της BD για οδηγίες. / A használati utasítást kérje a BD helyi képviselőjétől. / Naudojimo instrukcijų teiraukitės vietos BD įgaliotojo atstovo. / Kontakt din lokale BD-representant for mer informasjon. / Aby uzyskać instrukcje użytkowania, skontaktuj się z lokalnym przedstawicielstwem BD. / Contacte o seu representante local da BD para obter instruções. / Instrukcije ziskate u miestneho zástupcu spoločnosti BD. / Kontakta lokal Becton Dickinson-representant för anvisningar. / Свържете се с местния представител на BD за инструкциите. / Contactați reprezentantul dumneavoastră local BD pentru instrucțiuni. / Talimatlar için yerel BD temsilcilerinize danışın. / Obratite se svom lokalnom predstavniku kompanije BD za uputstva. / Для получения инструкций свяжитесь с местным представителем компании BD. / Өзіндікді жергілікті BD өкіліне жүгініп нұсқау алыңыз. / Kontaktiraj lokalnog predstavnika BD za upute.

INTENDED USE

MacConkey II Agar with Sorbitol is used as a selective and differential medium for the detection of *Escherichia coli* serotype O157:H7 associated with hemorrhagic colitis.

SUMMARY AND EXPLANATION

Escherichia coli serotype O157:H7 is a human pathogen associated with hemorrhagic colitis.¹ Unlike most *E. coli* strains, *E. coli* O157:H7 ferments sorbitol slowly or not at all. Therefore, the efficacy of MacConkey Agar containing sorbitol instead of lactose as a differential medium for the detection of *E. coli* O157:H7 in stool cultures was determined. Field trial results showed that the growth of *E. coli* O157:H7 on MacConkey Agar with Sorbitol was heavy and occurred in almost pure culture as colorless sorbitol-nonfermenting colonies. Most organisms of the fecal flora ferment sorbitol and appear pink on this medium. The MacConkey Agar with Sorbitol, therefore, permits ready recognition of *E. coli* O157:H7 in stool cultures.¹

PRINCIPLES OF THE PROCEDURE

MacConkey II Agar with Sorbitol is a modified MacConkey II Agar formula using sorbitol instead of lactose. It is a selective and differential medium, but only slightly selective since the concentration of bile salts, which inhibits gram-positive microorganisms, is low in comparison with other enteric plating media. Crystal violet also is included in the medium to inhibit the growth of gram-positive bacteria, especially enterococci and staphylococci.

Differentiation of enteric microorganisms is achieved by the combination of sorbitol and the neutral red indicator. Colorless or pink to red colonies are produced depending upon the ability of the isolate to ferment the carbohydrate.

MacConkey II Agar is also formulated to reduce swarming of *Proteus* species.

REAGENTS

MacConkey II Agar with Sorbitol

Approximate Formula* Per Liter Purified Water

Pancreatic Digest of Gelatin	17.0	g
Pancreatic Digest of Casein	1.5	g
Peptic Digest of Animal Tissue	1.5	g
D-Sorbitol	10.0	g
Bile Salts	1.5	g
Sodium Chloride	5.0	g
Neutral Red	0.03	g
Crystal Violet	0.001	g
Agar	13.5	g

*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"²⁻⁵ 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.

Storage Instructions: On receipt, store tubes in the dark at 2 to 25°C. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light. 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.

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

SPECIMEN COLLECTION AND HANDLING

Refer to appropriate texts for details of specimen collection and handling procedures.⁶⁻⁸

PROCEDURE

Material Provided: MacConkey II Agar with Sorbitol

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. To prepare plated medium, place agar deeps with loosened caps in a boiling water bath until the medium becomes liquefied (clear). Pour the molten medium into a sterile Petri dish and allow the medium to solidify before use. The agar surface should be smooth and moist, but without excessive moisture.

Inoculate the medium as soon as possible after the specimen arrives at the laboratory. To culture a specimen from a swab, inoculate the medium by rolling the swab over a small portion of the agar and streak the remainder of the agar with a sterilized inoculating loop to obtain isolated colonies. Material not being cultured directly from swabs may be streaked onto the medium with a sterilized inoculating loop. The streak plate technique is used primarily to obtain isolated colonies from specimens containing mixed flora.

Incubate plates, protected from light, in an inverted position (agar side up) at 35 ± 2°C for 18 to 24 h.

User Quality Control:

1. Examine the tubes for signs of deterioration as described under "Product Deterioration".
2. Check performance by inoculating a representative sample of plates with pure cultures of stable control organisms that give known, desired reactions. The following test strains are recommended:

TEST STRAIN	EXPECTED RESULTS
<i>Escherichia coli</i> O157:H7 ATCC™ 35150	Growth, colorless colonies (negative for sorbitol fermentation)
<i>Escherichia coli</i> ATCC 25922	Growth, rose-red colonies (positive for sorbitol fermentation)

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 NCCLS guidance and CLIA regulations for appropriate Quality Control practices.

RESULTS

After 18 to 24 h of incubation, the plates should show isolated colonies in streaked areas and confluent growth in areas of heavy inoculation.

Sorbitol fermenters produce pink to red colonies, some surrounded by zones of precipitated bile, while sorbitol nonfermenters produce colorless colonies.

Gram staining, biochemical tests and serological procedures should be performed to confirm findings.

LIMITATIONS OF THE PROCEDURE

Some diagnostic tests may be performed with the primary plate. However, a pure culture is recommended for biochemical tests and serological procedures. Consult appropriate texts for further information.^{7,9}

Prolonged incubation of the culture may result in colonies of *E. coli* serotype O157:H7 losing their characteristic colorless appearance.

There are additional species of facultatively anaerobic gram-negative rods that do not ferment sorbitol.

It has been reported that some *Enterobacteriaceae* and *Pseudomonas aeruginosa* are inhibited on MacConkey Agar when incubated in a CO₂-enriched atmosphere (G. Mazura-Reetz, T.R. Neblett, and J.M. Galperin. Abstr. Annu. Meet. Am. Soc. Microbiol. 1979, C179, p. 339).

A single medium is rarely adequate for detecting all organisms of potential significance in a specimen. The agents in selective media may inhibit some strains of the desired species or permit the growth of a species they were designed to inhibit, especially if the species is present in large numbers in the specimen. Specimens cultured on selective media should also be cultured on nonselective media to obtain additional information and help ensure recovery of potential pathogens.

PERFORMANCE CHARACTERISTICS

A study was conducted at a public health laboratory involving detection of *Escherichia coli* O157:H7 in stool cultures by using SMAC (MacConkey Agar with Sorbitol) as a primary isolation medium in comparison to MacConkey Agar. A total of 1,043 diarrheal stools were tested of which 99 were from patients with bloody diarrhea. SMAC medium produced a sensitivity of 100%, detecting all 18 stools positive for *E. coli* O157:H7.¹ In addition, SMAC medium had a sensitivity of 100% (14/14), a specificity of 85% (204/240) and an accuracy of 86% (218/254) in a separate evaluation of seeded and unseeded stool specimens.¹


AVAILABILITY


Cat. No.	Description
297684	BBL™ MacConkey II Agar with Sorbitol, Pkg. of 10 size A tubes (pour tubes)

REFERENCES

1. March, S.B., and S. Ratnam. 1986. Sorbitol-MacConkey medium for detection of *Escherichia coli* O157:H7 associated with hemorrhagic colitis. J. Clin. Microbiol. 23:869-872.
2. National Committee for Clinical Laboratory Standards. 2001. Approved Guideline M29-A2. Protection of laboratory workers from occupationally acquired infections, 2nd ed. NCCLS, Wayne, Pa.

- Garner, J.S. 1996. Hospital Infection Control Practices Advisory Committee, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Guideline for isolation precautions in hospitals. *Infect. Control Hospital Epidemiol* 17:53-80.
- U.S. Department of Health and Human Services. 1999. Biosafety in microbiological and biomedical laboratories, HHS Publication (CDC), 4th ed. U.S. Government Printing Office, Washington, D.C.
- 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 89/391/EEC). *Official Journal L262, 17/10/2000, p. 0021-0045.*
- Isenberg, H.D., F.D. Schoenknecht, and A. von Graevenitz. 1979. Cumitech 9, Collection and processing of bacteriological specimens. Coordinating ed., S.J. Rubin. American Society for Microbiology, Washington, D.C.
- Forbes, B.A., D.F. Sahm, and A.S. Weissfeld. 1998. *Bailey & Scott's diagnostic microbiology*, 10th ed. Mosby, Inc., St. Louis.
- Miller, J.M., and H.T. Holmes. 1999. Specimen collection, transport, and storage, p. 30-63. *In P.R. Murray, E.J. Baron, M.A. Pfaller, F.C. Tenover, and R.H. Tenover (ed.), Manual of clinical microbiology*, 7th ed. American Society for Microbiology, Washington, D.C.
- Farmer, J.J., III. 1999. *Enterobacteriaceae: Introduction and identification*, p. 442-458. *In P.R. Murray, E.J. Baron, M.A. Pfaller, F.C. Tenover, and R.H. Tenover (ed.), Manual of clinical microbiology*, 7th ed. American Society for Microbiology, Washington, D.C.


 Manufacturer / Výrobce / Producent / Fabrikant / Tootja / Valmistaja / Fabricant / Hersteller / Κατασκευαστής / Gyártó / Ditta produttrice / Gamintojas / Producent / Fabricante / Výrobca / Tillverkare / Производител / Producător / Üretici / Proizvođač / Производител / Атқарушы

 Use by / Spotføjte do / Anvendes for / Houdbaar tot / Kasutada enne / Viimeinkäyttöpäivä / A utiliser avant / Verwendbar bis / Ημερομηνία λήξης / Felhasználhatóság dátuma / Usare entro / Naudokite iki / Brukes for / Stosować do / Utilizar em / Použít do / Usar antes de / Använd före / Исползуйте до / А se utiliza până la / Son kullanna tarini / Upotrebti do / Исползовать до / дейін пайдалануға / Upotrijebiti do / YYYY-MM-DD / YYYY-MM (MM = end of month) / RRRR-MM-DD / RRRR-MM (MM = konec měsíce) / ÁÁÁÁ-MM-DD / ÁÁÁÁ-MM (MM = slutning af måned) / JJJJ-MM-DD / JJJJ-MM (MM = einde maand) / AAAA-KK-PP / AAAA-KK (KK = kuu lõpp) / VVVV-KK-PP / VVVV-KK (kukaukuden loppuun mennessä) / AAAA-MM-JJ / AAAA-MM (MM = fin du mois) / JJJJ-MM-TT / JJJJ-MM (MM = Monatsende) / EEEE-MM-HH / EEEE-MM (MM = τέλος του μήνα) / ÉÉÉÉ-HH-NH / ÉÉÉÉ-HH (HH = hónap utolsó napja) / AAAA-MM-GG / AAAA-MM (MM = fine mese) / MMMM-MM-DD / MMMM-MM (MM = mensesio pabaiga) / ÁÁÁÁ-MM-DD / ÁÁÁÁ-MM (MM = slutten av måneden) / RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca) / AAAA-MM-DD / AAAA-MM (MM = fim do mês) / RRRR-MM-DD / RRRR-MM (MM = koniec mesiacu) / aaaa-mm-dd / aaaa-mm (mm = fin del mes) / ÁÁÁÁ-MM-DD / ÁÁÁÁ-MM (MM = slutet på månaden) / ГГГГ-MM-ДД / ГГГГ-MM (MM = края на месеца) / AAAA-LL-ZZ / AAAA-LL (LL = sfârșitul lunii) / YYYY-AA-GG / YYYY-AA (AA = ayın sonu) / GGGG-MM-DD / GGGG-MM (MM = kraj meseca) / ГГГГ-MM-ДД / ГГГГ-MM (MM = конец месяца) / ЖЖЖЖ-АА-КК / ЖЖЖЖ-АА (АА = айдың соңы) / GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)


REF Catalog number / Katalogové číslo / Katalognummer / Catalognummer / Kataloogi number / Tuotenumero / Numéro catalogue / Bestellnummer / Αριθμός καταλόγου / Katalógusszám / Numero di catalogo / Katalogo numeris / Numer katalogowy / Número do catálogo / Katalogové číslo / Número de catálogo / Каталоген номер / Număr de catalog / Katalog numarası / Kataloški broj / Номер по каталогу / Каталог нөмірі


EC REP Authorized Representative in the European Community / Autorizovaný zástupce pro Evropskou unii / Autoriseret repræsentant i EU / Erkend vertegenwoordiger in de Europese Unie / Volitatud esindaja Euroopa Nõukogus / Valtuutettu edustaja Euroopan yhteisössä / Représentant agréé pour la C.E.E. / Autorisierte EG-Vertretung / Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα / Hivatalos képviselő az Európai Unióban / Rappresentante autorizzato nella Comunità europea / Įgaliotasis atstovas Europos Bendrijoje / Autorisert representant i EU / Autoryzowane przedstawicielstwo w Unii Europejskiej / Reprezentante autorizado na União Europeia / Autorizovaný zástupca v Európskom spoločenstve / Reprezentante autorizado en la Comunidad Europea / Auktoriserad representant i EU / Оторизиран представител в EU / Reprezentant autorizat în Uniunea Europeană / Avrupa Topluluğu Yetkili Temsilcisi / Ovlašteni predstavnik u Evropskoj zajednici / Уполномоченный представитель в Европейском сообществе / Европа қауымдастығындағы уәкілетті өкіл / Autorizirani predstavnik u EU

IVD In Vitro Diagnostic Medical Device / Lékařské zařízení určené pro diagnostiku in vitro / In vitro diagnostisk medicinsk anordning / Medisch hulpmiddel voor in vitro diagnose / In vitro diagnostika meditsiiniaparatuur / Lääkinnällinen in vitro -diagnostiikkalaitte / Dispositif médical de diagnostic in vitro / Medizinisches In-vitro-Diagnostikum / In vitro διαγνωστική ιατρική συσκευή / In vitro diagnostikai orvosi eszköz / Dispositivo medico diagnostico in vitro. / In vitro diagnostikos prietais / In vitro diagnostisk medisinsk utstyr / Urządzenie medyczne do diagnostyki in vitro / Dispositivo médico para diagnóstico in vitro / Medicínska pomôcka na diagnostiku in vitro / Dispositivo médico de diagnóstico in vitro / Medicinsk anordning för in vitro-diagnostik / Медицински уред за диагностика ин витро / Aparatură medicală de diagnosticare in vitro / In Vitro Diagnostik Tibbi Cihaz / Medicinski uređaj za in vitro dijagnostiku / Медицинский прибор для диагностики in vitro / Жасанды жағдайда жүргізілетін медициналық диагностика аспабы / Medicínska pomagala za In Vitro Dijagnostiku

 Temperature limitation / Teplotní omezení / Temperaturbegrænsning / Temperatuurlimiet / Temperatuuri piirang / Lämpötilarajoitus / Température limite / Zulässiger Temperaturenbereich / Οριο θερμοκρασίας / Hölmérsékleti határ / Temperatura limite / Laikymo temperatūra / Temperaturbegrænsning / Ograniczenie temperatury / Limitação da temperatura / Ohraničenje teploty / Limitación de temperatura / Temperaturbegrænsning / Температурни ограничения / Limitare de temperatură / Sıcaklık sınırlaması / Ograničenje temperature / Ограничение температуры / Температураны шектеу / Dozvoljena temperatura

LOT Batch Code (Lot) / Kód (číslo) šarže / Batch kode (Lot) / Chargennummer (lot) / Partii kood / Eräkoodi (LOT) / Code de lot (Lot) / Chargencode (Chargenbezeichnung) / Κυβικός παρτίδας (Παρτίδα) / Tétel száma (Lot) / Codice del lotto (partita) / Partijos numeris (Lot) / Batch-kode (Serie) / Kod partii (seria) / Código do lote (Lote) / Kód série (šarža) / Código de lote (Lote) / Satskod (parti) / Код (Партида) / Număr lot (Lotul) / Parti Kodu (Lot) / Kod serije / Код партии (лот) / Топтама коды / Lot (kod)

 Consult instructions for Use / Prostudujte pokyny k použití / Læs brugsanvisningen / Raadpleeg gebruiksaanwijzing / Lugeda kasutusjuhendit / Tarkista käyttöohjeista / Consulter la notice d'emploi / Gebrauchsanweisung beachten / Συμβουλευτείτε τις οδηγίες χρήσης / Olvassa el a használati utasítást / Consultare le istruzioni per l'uso / Skaitykite naudojimo instrukcijas / Se i bruksanvisningen / Zobacz instrukcja użytkowania / Consulte as instruções de utilização / Pozri Pokyny na používanie / Consultar las instrucciones de uso / Se bruksanvisningen / Направете справка в инструкциите за употреба / Consultați instrucțiunile de utilizare / Kullanım Talimatları'na başvurun / Pogledajte uputstvo za upotrebu / См. руководство по эксплуатации / Пайдалану нұсқаулығымен танысып алыңыз / Koristi upute za upotrebu

 Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152 USA
800-638-8663
www.bd.com/ds

EC REP Benex Limited
Rineanna House
Shannon Free Zone
Shannon, County Clare, Ireland