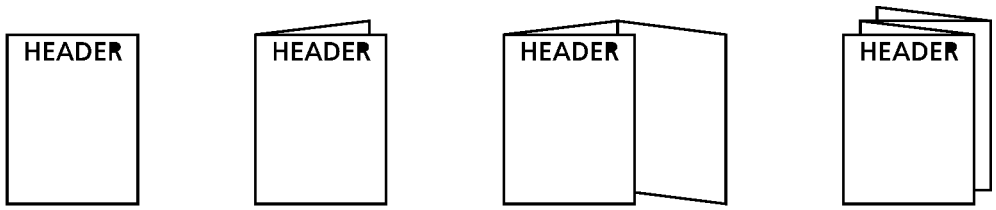
Revisions

Rev from	Rev to	ECO #
0803	**2010/07**	**5430-10**

Notes:

1. BD Cat. Number 221938
2. 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: NA
3. Style (see illustrations below): # 1



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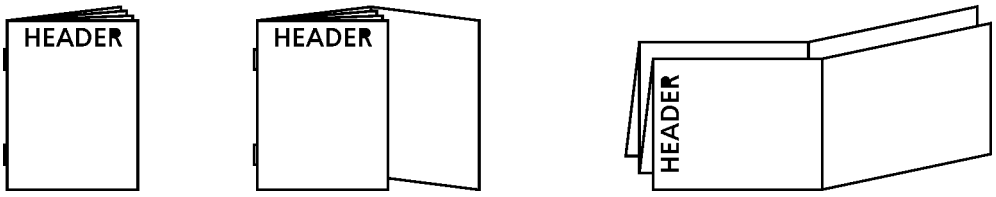

#5 #6 #7

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

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Label Design Date Proofer Date Checked By Date Part Number: 8808191JAA		BD Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA	
	Category and Description Package Insert, MacConkey II Agar with MUG	Sheet: 1 of 3 Scale: N/A	A

BD BBL™ Prepared Plated Medium for the Differentiation of *Escherichia coli*

MacConkey II Agar with MUG

CE

8808191JAA
2010/07

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INTENDED USE

MacConkey II Agar with MUG is used for the presumptive identification of *Escherichia coli.*

SUMMARY AND EXPLANATION

Trepeta and Edberg[1] modified MacConkey Agar by the incorporation of MUG (4-methylumbelliferyl-β-D-glucuronide). The resulting medium allowed the authors to presumptively identify *E. coli* from the primary plating medium within 5 min.

The **BBL** MacConkey II Agar formulation was designed to improve the inhibition of swarming *Proteus* species, to achieve more definitive differentiation of lactose fermenters and nonfermenters and for the promotion of superior growth of enteric pathogens.

PRINCIPLES OF THE PROCEDURE

Most strains (96 to 97%) of *E. coli* produce β-D-glucuronidase.[2] The enzyme hydrolyzes MUG to yield 4-methylumbelliferone, a compound which fluoresces under long-wave (366 nm) UV light. The addition of MUG to the formulation allows β-D-glucuronidase positive strains of *E. coli* to fluoresce blue-green when examined under UV light.

MacConkey II Agar is a selective and differential medium. It is 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 lactose and the neutral red indicator. Colorless or pink to red colonies are produced depending upon the ability of the isolate to ferment the carbohydrate.

REAGENTS

MacConkey II Agar with MUG

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
Lactose	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
MUG (4-methylumbelliferyl-β-D-glucuronide)	0.1	g

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

Warnings and Precautions:

For *in vitro* Diagnostic Use

If excessive moisture is observed, invert the bottom over an off-set lid and allow to air dry in order to prevent formation of a seal between the top and bottom of the plate during incubation.

Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions"[3-6] and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids. Prior to discarding, sterilize prepared plates, specimen containers and other contaminated materials by autoclaving.

Storage Instructions: On receipt, store plates in the dark at 2 to 8°C. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light. Prepared plates stored in their original sleeve wrapping at 2 to 8°C until just prior to use may be inoculated up to the expiration date and incubated for recommended incubation times. Allow the medium to warm to room temperature before inoculation.

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

SPECIMEN COLLECTION AND HANDLING

Refer to appropriate texts for details of specimen collection and handling procedures.[7-9]

PROCEDURE

Material Provided: MacConkey II Agar with MUG

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 agar surface should be smooth and moist, but without excessive moisture.

Streak the specimen as soon as possible after it is received in the laboratory. The streak plate is used primarily to isolate pure cultures from specimens containing mixed flora. A nonselective medium should also be streaked to increase the chance of recovery when the population of gram-negative organisms is low and to provide an indication of other organisms present in the specimen.

Alternatively, if material is being cultured directly from a swab, roll the swab over a small area of the surface at the edge; then streak away from this inoculated area.

Incubate plates, protected from light, at 35 ± 2°C (do not use CO_2-enriched atmosphere with MacConkey II Agar) or other appropriate temperature for 18 to 24 h; if negative after 24 h, reincubate an additional 24 h.

User Quality Control:

1. Examine plates 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
Escherichia coli ATCC™ 25922	Growth, rose-red colonies, fluorescence
Proteus mirabilis ATCC 12453	Growth, colorless colonies, inhibition of swarming, no fluorescence
Salmonella choleraesuis subsp. *choleraesuis* serotype Typhimurium ATCC 14028	Growth, colorless colonies, no fluorescence
Enterococcus faecalis ATCC 29212	Inhibition (partial to complete), no fluorescence

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 incubation, the medium is examined macroscopically for typical colonies.

Colonies of lactose-fermenting bacteria appear pink to rose-red in color and may be surrounded by a zone of bile precipitation while lactose-nonfermenting colonies are colorless. Examine the medium under long-wavelength UV light (366 nm). β-D-glucuronidase positive colonies have a blue-green fluorescence; β-D-glucuronidase negative colonies do not fluoresce.

LIMITATIONS OF THE PROCEDURE

Not all strains of *E. coli* ferment lactose or produce β-D-glucuronidase. Some strains of *Salmonella* and *Shigella* produce β-D-glucuronidase and will fluoresce.[10] A small percentage of *Yersinia* and streptococci have been reported to fluoresce.[11] Additional biochemical or serological tests are necessary for definitive identification.[9,12,13]

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 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, therefore, also be cultured on nonselective media to obtain additional information and help ensure recovery of potential pathogens.

PERFORMANCE CHARACTERISTICS

In a clinical study performed at a hospital and university school of medicine, MUG was incorporated into **BBL** MacConkey II Agar to detect the presence of β-glucuronidase. It was found that the time to identify *E.coli* strains was reduced from 1 h to 5 min and the ability to identify this organism in mixed specimens was enhanced.[1]

AVAILABILITY

Cat. No.	Description
221938	**BBL™** MacConkey II Agar with MUG, Pkg. of 20 Plates

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EEEE-MM-HH / EEEE-MM (MM = τέλος του μήνα) /
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ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutet på månaden) /
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = края на месеца) /
AAAA-LL-ZZ / AAAA-LL (LL = sfârşitul lunii) /
YYYY-AA-GG / YYYY-AA (AA = ayın sonu) /
GGGG-MM-DD / GGGG-MM (MM = kraj meseca) /
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = конец месяца) /
ЖЖЖЖ-АА-КК / ЖЖЖЖ-АА (АА = айдың соңы) /
GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)

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

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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 -diagnostiikkalaite / Dispositif médical de diagnostic in vitro / Medizinisches In-vitro-Diagnostikum / In vitro διαγνωστική ιατρική συσκευή / In vitro diagnosztikai orvosi eszköz / Dispositivo medico diagnostico in vitro. / In vitro diagnostikos prietaisas / 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 Diyagnostik Tıbbi Cihaz / Medicinski uređaj za in vitro dijagnostiku / Медицинский прибор для диагностики in vitro / Жасанды жағдайда жүргізетін медициналық диагностика аспабы / Medicinska pomagala za In Vitro Dijagnostiku

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

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Keep away from light / Nevystavujte světlu / Må ikke udsættes for lys / Weghoudvan licht / Hoida eemal valgusest / Suojattava valolta / Conserver à l'abri de la lumière / Vor Licht schützen / Φυλάξτε το μακριά από φως / Fény nem érheti / Tenere al riparo dalla luce / Laikyti atokiau nuo šilumos šaltinių / Må ikke utsettes for lys / Przechowywać z dala od źródeł światła / Manter ao abrigo da luz / Uchovávajte mimo dosahu svetla / Mantener alejado de la luz / Får ej utsättas för ljus / Пазете от светлина / A se feri de lumină / Işıktan uzak tutun / Držite dalje od svetlosti / Хранить в темноте / Қараңғыланған жерде ұста / Držati dalje od svjetla