		Revisions	SO 0191-5
Rev from	Rev to	ECO #	
0106	2010/07	5393-10	

# **Notes:**

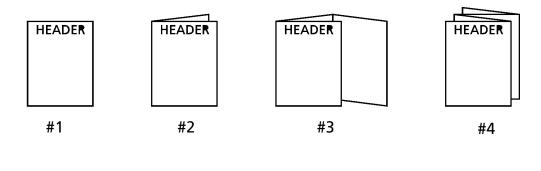
1. BD Cat. Number 295697

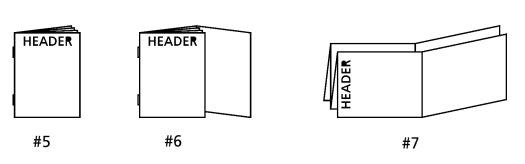
2. Blank (Sheet) Size: Length: 11" Width: 8.5"

Number of Pages: 2 Number of Sheets: 1

Page Size: Length 11" Width 8.5" Final Folded Size: 4 1/4" x 1 3/8.

3. Style (see illustrations below): # 1





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

Label Design Proofer	Date		<b>⇔</b> BD	Becton, Dickinson and Com 7 Loveton Circle	npany	
Checked By	Date  Date	COMPANY AND IS NOT TO BE USED OUTSIDE THE COMPANY WITHOUT WRITTEN PERMISSION		Sparks, MD 21152 USA		
——————————————————————————————————————	Date	Category and Description		Sheet: 1 of 3	_	
Part Number:		Package Insert	Package Insert, Dubos Broth, Enriched		<b>A</b>	
8806871JAA		Dubos Broth, Enriched				

# **❸ BD BBL™ Prepared Tubed Medium for Cultivation of Mycobacteria**

## **Dubos Broth, Enriched**

Pokyny vám poskytne místní zástupce společnosti 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 képviseletétől. / 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. / Inštrukcie získate u miestneho zástupcu spoločnosti BD. / Kontakta lokal Becton Dickinson-representant för anvisningar. / Свържете се с местния представител на BD за инструкзии. / Contactaţi reprezentantul dumneavoastrā local BD pentru instrucţiuni. / Talimatlar için yerel BD temsilcilerinize danışın. / Obratite se svom lokalnom predstavniku kompanije BD za uputstva. / Для получения

# BD za upute. INTENDED USE

Dubos Broth, Enriched, is used in the cultivation of pure cultures of mycobacteria, particularly *Mycobacterium tuberculosis*.

инструкций свяжетесь с местным представителем компании ВD. / Өзіңіздің

жергілікті БД өкіліне жүгініп нұсқау алыңыз. / Kontaktiraj lokalnog predstavnika

#### SUMMARY AND EXPLANATION

Dubos Broth, Enriched, is a modified medium based on the formulation of Dubos et al.¹ This formulation differs from the original in that it has a strong buffering system and an acid pH.²

The particular value of Dubos Broth is that it provides dispersed growth, free of excessive clumps, which can be used to prepare a relatively uniform suspension of mycobacteria for use in bacterial studies.

It is also used as a subculture and enrichment medium for the rapid cultivation of *M. tuberculosis* and other mycobacterial species from treated clinical specimens and from direct inoculation of specimens that may yield pure cultures; e.g., spinal, pleural and peritoneal fluids.<sup>3</sup>

#### PRINCIPLES OF THE PROCEDURE

Dubos Broth, Enriched, contains enzymatic digest of casein and an amino acid, L-asparagine, as sources of nutrients. A variety of inorganic salts provide ions required for the metabolism of mycobacteria. Polysorbate 80, an oleic acid ester, supplies essential fatty acids for the replication of mycobacteria. Bovine albumin acts as a protective agent by binding free fatty acids that may be toxic to mycobacteria. The albumin is heat-treated to inactivate lipase, which may release fatty acids from the polysorbate 80. Phosphate buffers maintain the pH of the medium.

#### REAGENTS

# **Dubos Broth, Enriched**

Approximate Formula\* Per 900 mL Purified Water

Pancreatic Digest of Casein	g
L-Asparagine	g
Monopotassium Phosphate 1.0	g
Disodium Phosphate 2.5	g
Ferric Ammonium Citrate 0.05 g	g
Magnesium Sulfate 0.01 g	g
Polysorbate 80	g
Calcium Chloride	mg
Zinc Sulfate	mg
Copper Sulfate0.1	mg
Bovine Albumin	mL

<sup>\*</sup>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.

Storage Instructions: On receipt, store tubes in the dark at 2 to 8°C. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light. Tubed media stored as labelled until just prior to use may be inoculated up to the expiration date and incubated for up to 8 weeks. Allow the medium to warm to room temperature before inoculation.

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

#### SPECIMEN COLLECTION AND HANDLING

This medium is not suitable for use directly with clinical specimens, except as stated above or as a "backup" enrichment medium in addition to isolation media. Consult appropriate texts for more information.<sup>3-7</sup>

Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions" 11 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.<sup>10</sup>

#### **PROCEDURE**

Material Provided: Dubos Broth, Enriched

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

8806871JAA

2010/07

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.⁴ N-acetly-L-cysteine-sodium hydroxide (NALC-NaOH) solution is recommended as a gentle, but effective digesting and decontaminating agent. These ragents are provided in the BBL™ MycoPrep™ Specimen Digestion/Decontamination Kit. For detailed decontamination and culturing instructions, consult an appropriate text.³-7

Specimens that are less likely to be contaminated with other microorganisms (cerebrospinal fluid, pleural fluid, tissue biopsy, etc.) may be inoculated directly into the medium. Consult appropriate texts for recommended procedures.<sup>3-7</sup>

Incubate the tubes at  $35 \pm 2^{\circ}$ C in a CO<sub>2</sub>-enriched atmosphere. Keep the tube caps loosened for at least one week to permit circulation of CO<sub>2</sub>, but tighten the caps thereafter to prevent dehydration. Loosen briefly once a week to replenish CO<sub>2</sub>. Six to 8 weeks of incubation may be necessary for evidence of growth of many mycobacteria.

#### **User Ouality Control:**

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

TEST STRAIN	EXPECTED RESULTS
Mycobacterium fortuitum ATCC™ 6841 Mycobacterium tuberculosis ATCC 25177	Growth Growth
AICC 25177	

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

Growth in broth media is indicated by turbidity compared to an uninoculated control.

#### LIMITATIONS OF THE PROCEDURE

Enrichment broths should not be used as the sole isolation medium. They are to be used in conjunction with selective and nonselective plating media to increase the probability of isolating pathogens, especially when they may be present in small numbers.

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.<sup>3-7</sup>

#### PERFORMANCE CHARACTERISTICS

Since Dubos Broth provides dispersed growth, it is used to prepare a relatively uniform suspension of mycobacteria in bacterial studies. Dubos Broth was used to grow *Mycobacterium tuberculosis* to determine the enzymatic activity of alcohol dehydrogenase. After 7 days, the specific activity of the enzyme from cells grown in Dubos Broth was 2 to 3 times higher than from cells grown on Sauton medium.<sup>12</sup>

#### AVAILABILITY

Cat. No. Description

295697 BBL™ Dubos Broth, Enriched, Pkg of 10 size K tubes

#### REFERENCES

- Dubos, R.J., F. Fenner, and C.H. Pierce. 1950. Properties of a culture of BCG grown in liquid media containing Tween 80 and the filtrate of heated serum. Am. Rev. Tuberc. 61:66.
- MacFaddin, J.F. 1985. Media for isolation-cultivation-identification-maintenance of medical bacteria, vol. 1. Williams & Wilkins, Baltimore.
- Cernoch, P.L., Enns, R.K., Saubolle, M.A. and R.J. Wallace. 1994. Cumitech 16A, Laboratory diagnosis of the mycobacterioses. Coordinating ed. A.S. Weissfeld, American Society for Microbiology, Washington, D.C.
- Kent, P.T., and G.P. Kubica. 1985. Public health mycobacteriology: a guide for the level III laboratory. USDHHS. Centers for Disease Control, Atlanta.
- Forbes, B.A., D.F. Sahm, and A.S. Weissfeld. 1998. Bailey & Scott's diagnostic microbiology, 10th ed. Mosby, Inc., St. Louis.
- Metchock B.G., Nolte, F.S., and R.J. Wallace. 1999. Mycobacterium, p. 399-437. In P.R. Murray, E.J. Baron, M.A. Pfaller, F.C. Tenover, and R.H. Yolken (ed.), Manual of clinical microbiology, 7th ed. American Society for Microbiology, Washington, D.C.
- Master, R.N. 1992. Mycobacteriology, 3.0.1-3.16.4. In H.D. Isenberg (ed.), Clinical microbiology procedures handbook, vol. 1. American Society for Microbiology, Washington, D.C.
- 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.

- 10. 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.
- 11. 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.
- 12. De Bruyn, J., A. Johannes, M. Weckx, and M.P. Beumer-Jochmans. 1980. Partial purification and characterization of an alcohol dehydrogenase of Mycobacterium tuberculosis var. bovis (BCG). J. of Gen. Microbiol. 124: 359-363.



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

Use by / Spotřebuite do / Anyendes før / Houdbaar tot / Kasutada enne /



Viimeinkäyttöpäivä / A utiliser avant / Verwendbar bis / Ημερομηία λήξης / Felhasználhatóság dátuma / Usare entro / Naudokite iki / Brukes før / Stosować do / Utilizar em / Použite do / Usar antes de / Använd före / Използвайте до / A se utiliza până la / Son kullanma tarihi / Upotrebiti do / Использовать до / дейін пайдалануға / Upotrijebiti do / YYYY-MM-DD / YYYY-MM (MM = end of month) / YYYY-MM-DD / YYYY-MM (MM = end of month) /
RRRR-MM-DD / RRRR-MM (MM = konec měsíce)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-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 (kuukauden loppuun mennessä) AAAA-MM-JJ / AAAA-MM (MM = fin du mois) / - LILI-MM-TT / JJJ-MM (MM = Monatsende) / EEEE-MM-HH / EEEE-MM (MM = τέλος του μήνα) / ÉÉÉÉ-HH-NN / ÉÉÉÉ-HH (HH = hónap utolsó napja) AAAA-MM-GG / AAAA-MM (MM = fine mese) MMMM-MM-DD / MMMM-MM (MM = menesio pabaiga) ÅÅÅÅ-MM-DD / ÅÅÅÅ-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 mesiaca) aaaa-mm-dd / aaaa-mm (mm = fin del mes) / ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutet på månaden) / ГГГ-ММ-ДД / ГГГГ-ММ (ММ = 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-ММ-ДД / ГГГГ-ММ (ММ = конец месяца) / ЖЖЖЖ-АА-КК / ЖЖЖЖ-АА (АА = айдын соны) / GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)

Catalog number / Katalogové číslo / Katalognummer / Catalogusnummer / Kataloogi number / Tuotenumero / Numéro catalogue / Bestellnummer / Αριθμός καταλόγου / Katalogusszám / 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 немірі



ECREP 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 képviselet az Európai Unióban / Rappresentante autorizzato nella Comunità europea / Įgaliotasis atstovas Europos Bendrijoje / Autorisert representant i EU / Autoryzowane przedstawicielstwo w Unii Europejskiej / Representante autorizado na União Europeia / Autorizovaný zástupca v Európskom spoločenstve / Representante autorizado en la Comunidad Europea / Auktoriserad representant i EU / Оторизиран представител в EU / Reprezentant autorizat în Uniunea Europeană / Avrupa Topluluğu Yetkili Temsilcisi / Ovlašćeni predstavnik u Evropskoj zajednici / Уполномоченный представитель в Европейском сообществе / Европа қауымдастығындағы уәкілетті өкіл / Autorizuirani predstavnik u EU



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 Invitro-Diagnostikum / In vitro διαγνωστική ιστρική 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 diagnostico 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 / Temperatuurilmiet / 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



Batch Code (Lot) / Kód (číslo) šarže / Batch kode (Lot) / Chargenummer (lot) / Partii kood / Eräkoodi (LOT) / Code de lot (Lot) / Chargencode (Chargenbezeichnung) / Κωδικός 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 οσηγίες 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 нұсқаўлығымен танысып алыңыз / Koristi upute za upotrebu



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

ECREP Benex Limited Rineanna House Shannon Free Zone Shannon, County Clare, Ireland

ATCC is a trademark of the American Type Culture Collection. BD, BD Logo, BBL and MycoPrep are trademarks of Becton, Dickinson and Company. @2010 RD