		Revisions	BALTSO0191 Version 7.0 Template 4
Rev from	Rev to	ECO #	
2010/07	01	6683-13	

NOTES:

1. BD Catalog Number: 297642, 298518

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

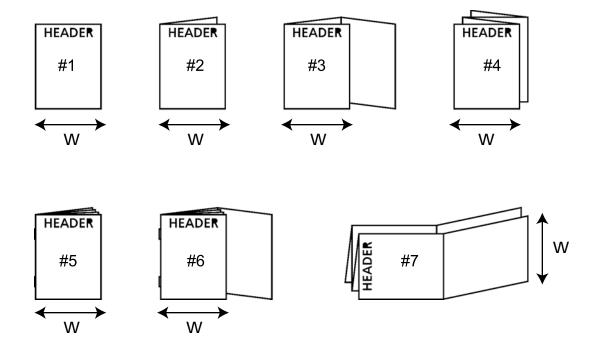
3. Number of Pages: 2 Number of Sheets: 1

4. Page Size: Length: 11" Width: 8.5" Final Folded Size: 4.25" x 1.5"

5. Ink Colors: No. of Colors: 1 PMS Standard Black

6. Printed two sides: Yes X No

7. Style (see illustrations below): # 1



- 8. See specification control number N/A for material information.
- 9. Graphics are approved by Becton, Dickinson and Company. Supplier has the responsibility for using the most current approved revision level.

Label Design	Date	COMPANY CONFIDENTAL. THIS DOCUMENT IS THE PROPERTY OF BECTON, DICKINSON AND	BECton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA			
Proofer	Date	COMPANY AND IS NOT TO BE USED OUTSIDE THE COMPANY WITHOUT WRITTEN PERMISSION.				
Checked By	Date					
спескей ву	Date	Category and Description		Sheet: 1 of 3		
Part Number: 8807191JAA		Package Insert, BBL FTM Enriched		Sileet. 1 of 5	Λ	
				Scale: N/A	A	



BD BBL™ Prepared Tubed Media for the Cultivation of **Anaerobic Microorganisms** Thioglycollate Media

8807191JAA(01) 2013-11

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 miestného zástupcu spoločnosti BD. / Kontakta lokal Becton Dickinson-representant för anvisningar. / Свържете се с местния представител на BD за инструкзии. / Contactați reprezentantul dumneavoastră local BD pentru instrucțiuni. / Talimatlar için yerel BD temsilcilerinize danișin. / Obratite se svom lokalnom predstavniku kompanije BD za uputstva. / Для получения инструкций свяжетесь с местным представителем компании BD. / Өзіңіздің жергілікті БД өкіліне жүгініп нұсқау алыңыз. / Kontaktiraj lokalnog predstavnika BD za upute.

Fluid Thioglycollate Medium Enriched is a general-purpose medium for the cultivation of a wide variety of microorganisms, particularly obligate anaerobes.

Thioglycollate Medium with Calcium Carbonate is also recommended for the maintenance of stock cultures.

SUMMARY AND EXPLANATION

Thioglycollate Medium was originally described by Brewer as a medium favoring the growth of obligately anaerobic as well as aerobic organisms. Subsequently, several versions of the

The incorporation of calcium carbonate is recommended because otherwise fastidious organisms may grow and then die off rapidly; it serves to neutralize acid produced during growth.2,3

PRINCIPLES OF THE PROCEDURE

Casein and soy peptones and L-cystine provide amino acids and other nitrogenous substances to support bacterial growth. Yeast extract provides the B-complex vitamins. Sodium chloride provides essential ions. Dextrose is an energy source.

Fluid Thioglycollate Medium, Enriched is supplemented with hemin and vitamin K₁ for enhanced growth of certain anaerobic bacteria.3-5

Calcium carbonate enhances the maintenance of stock cultures by neutralizing acids produced during growth.3

The reducing action provided by sodium thioglycollate and sodium sulfite binds molecular oxygen, thereby maintaining a low Eh.6 A small amount of agar is added to retard the absorption of oxygen by reducing convection currents in the medium.⁶

Resazurin is an indicator used for detecting changes in Eh.³ Increased oxidation raises the Eh. causing the resazurin to become pink. The indicator remains colorless if the Eh remains low.

REAGENTS

Fluid Thioglycollate Medium, Enriched

Approximate Formula* Per Liter Purified Water Pancreatic Digest of Casein15.0 g Dextrose 5.0 g

Inioglycollate Medium With Calcium Carbonate				
Approximate Formula* Per Liter Purified Water				
Pancreatic Digest of Casein	17.0 g			
Papaic Digest of Soybean Meal	3.0 g			
Dextrose	6.0 g			
Sodium Chloride	2.5 g			
Sodium Thioglycollate	0.5 g			
Agar	0.7 g			
Sodium Sulfite				
Marble Chip	1 per tube			
*Adjusted and/or supplemented as required to meet performance criteria.				

Warnings and Precautions: For in vitro Diagnostic Use.

Caution should be exercised in reporting direct Gram stain and/or other direct microbiological stain results on tissue specimens processed with this medium due to the possible presence of nonviable organisms in the culture medium.

Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions"⁷⁻¹⁰ and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.

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 according to label directions. 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 recommended incubation times. Allow the medium to warm to room temperature before inoculation.

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

For Fluid Thioglycollate Medium, Enriched, discard tubes if greater than one-third of the medium becomes oxidized, as indicated by the formation of pink discoloration.

SPECIMEN COLLECTION AND HANDLING

These media are not intended for use directly with specimens, except as a "back up" enrichment broth in addition to primary plating media. Consult appropriate texts for information.4,11,12

PROCEDURE

Material Provided: as ordered (see "AVAILABILITY").

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.

Media for anaerobic incubation should be reduced prior to inoculation by placing the tubes, with caps loosened, under anaerobic condition for 18 to 24 h prior to use. An efficient and easy way to obtain suitable anaerobic conditions is through the use of the GasPak™ EZ anaerobic system. Alternatively liquid media may be reduced immediately prior to use by boiling, with caps loosened, and cooling, with tightened caps, to room temperature before inoculation. NOTE: For optimum performance, do not boil tubes more than once.

Inoculate the specimen into the media of choice as soon as it arrives in the laboratory. With liquid specimens, tubed media should be inoculated with one or two drops of the specimen Tissue specimens should be minced and ground in sterile, reduced broth such as Enriched Thioglycollate Medium for the cultivation of microorganisms. Inoculation is then performed as for liquid specimens. Swab specimens may be inserted into the broth after inoculation of plated media. Alternatively, the swab may be "scrubbed" in a small volume of sterile, reduced broth such as Enriched Thioglycollate Medium and the broth used to inoculate media as performed with liquid specimens.

Specimens known or suspected to contain obligate anaerobes should be inoculated near the bottom of the tube. Incubate at 35 ± 2 °C or other appropriate temperature, preferably under

Broth cultures should be held at least 1 week before discarding as negative.

User Quality Control:

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

Medium	Test Strain	Expected Results
All media	Bacteroides vulgatus ATCC™ 8482	Growth
	Clostridium perfringens ATCC 13124	Growth

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.

Growth is indicated by the presence of turbidity compared to an uninoculated control. Examine growth by Gram staining. Subculture onto appropriate selective and nonselective plating media.

LIMITATIONS OF THE PROCEDURE

Enrichment broths should not be used as the sole isolation medium. They are intended 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. 4,11,13-16

PERFORMANCE CHARACTERISTICS

Prior to release, all lots of Fluid Thioglycollate Medium, Enriched are tested for performance characteristics. Before inoculation, representative samples of the lot are reduced by boiling in a water bath for a minimum of 10 min and cooled. Using a 0.01 mL calibrated loop, tubes are inoculated with cultures that have been adjusted to a 0.5 McFarland turbidity standard. The inocula for *Clostridium perfringens* (ATCC 13124) and *Peptostreptococcus anaerobius* (ATCC 27337) are prepared from colonies grown on CDC Anaerobe 5% Sheep Blood Agar plates and adjusted to the correct inoculum concentration in pre-reduced Thioglycollate Medium, Enriched. The inoculum for Bacteroides vulgatus (ATCC 8482) is taken from Thioglycollate Medium, Enriched and the inoculum for C. novyi (ATCC 7659) is taken from Chopped Meat Glucose Broth, PR II. Tubes are inoculated below the surface of the broths as deeply into the medium as possible. The caps are tightened immediately after inoculation and the tubes are incubated aerobically at 35 \pm 2 °C. Tubes are read for the amount of growth after 18 to 24 h and 42 to 48 h. All organisms show light to heavy growth after 48 h.

Prior to release, all lots of Thioglycollate Medium with Calcium Carbonate, are tested for performance characteristics. Before inoculation, representative samples of the lot are reduced by boiling in a water bath for a minimum of 10 min and cooled. Using a 0.01 mL calibrated loop, tubes are inoculated with cultures that have been adjusted to a 0.5 McFarland turbidity standard. The inocula for Clostridium perfringens (ATCC 13124) is prepared from colonies grown on CDC Anaerobe 5% Sheep Blood Agar plates and adjusted to the correct inoculum concentration in pre-reduced Thioglycollate Medium, Enriched. The inoculum for Bacteroides vulgatus (ATCC 8482) is taken from Thioglycollate Medium, Enriched and the inoculum for C. novyi (ATCC 7659) is taken from Chopped Meat Glucose Broth, PR II. Tubes are inoculated below the surface of the broths as deeply into the medium as possible. The caps are tightened immediately after inoculation and the tubes are incubated aerobically at 35 \pm 2 °C. Tubes are read for the amount of growth after 18 to 24 h and 42 to 48 h. All organisms show light to heavy growth after 48 h.

AVAILABILITY

Cat. No. Description

BBL™ Fluid Thioglycollate Medium, Enriched, Ctn. of 100 size K tubes. C € 297642

BBL™ Thioglycollate Medium with Calcium Carbonate, Ctn. of 100 size K tubes. C € 298518

REFERENCES

- 1. Brewer, J.H. 1940. A clear liquid medium for the "aerobic" cultivation of anaerobes.
- Vera, H.D. 1944. A comparative study of materials suitable for the cultivation of clostridia. J. Bacteriol. 47:59-70
- Reischelderfer, C., and J.I. Mangels. 1992. Culture media for anaerobes, p.2.3.1-2.3.8. In H.D. Isenberg (ed.), Clinical microbiology procedures handbook, vol. 1. American Society for Microbiology, Washington, D.C.
- Forbes, B.A., D.F. Sahm, and A.S. Weissfeld. 2007. Bailey & Scott's diagnostic microbiology, 12th ed. Mosby, Inc., St. Louis.
- Gibbons, R.J., and J.B. MacDonald. 1960. Hemin and vitamin K compounds as required factors for the cultivation of certain strains of Bacteroides melaninogenicus. J. Bacteriol. 80:164-170.
- MacFaddin, J.F. 1985. Media for isolation-cultivation-identification-maintenance of medical bacteria, vol. 1. Williams & Wilkins, Baltimore.
- Clinical and Laboratory Standards Institute. 2005. Approved Guideline M29-A3. Protection of laboratory workers from occupationally acquired infections, 3rd ed. CLSI, 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. 2007. Biosafety in microbiological and biomedical laboratories, HHS Publication (CDC), 5th ed. U.S. Government Printing Office, Washington, D.C.
- 10. 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.
- 11. Rodloff, A.C., P.C. Applebaum, and R.J. Zabransky. 1991. Cumitech 5A, Practical anaerobic bacteriology. Coordinating ed., A.C. Rodloff. American Society of Microbiology, Washington, D.C.
- 12. Miller, J.M., and H.T. Holmes. 1999. Specimen collection, transport, and storage, p. 33-63. 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.
- 13. Holdeman, L.V., E.P. Cato, and W.E.C. Moore (ed.). 1977. Anaerobe laboratory manual, 4th ed. Virginia Polytechnic Institute and State University, Blacksburg.
- 14. Engelkirk, P.G., J. Duben-Engelkirk, and V.R. Dowell, Jr. 1992. Principles and practice of clinical anaerobic bacteriology. Star Publishing Co., Belmont, Calif.
- Summanen, P., E.J. Baron, D.M. Citron, C.A. Strong, H.M. Wexler, and S.M. Finegold. 1993. Wadsworth anaerobic bacteriology manual, 5th ed. Star Publishing Co., Belmont, Calif.
- 16. Holt, J.G., N.R. Krieg, P.H.A. Sneath, J.T. Staley, and S.T. Williams (ed.). 1994. Bergey's Manual of determinate bacteriology, 9th ed. Williams & Wilkins, Baltimore.



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



Use by / Spotřebujte do / Anvendes 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) / RRRR-MM-DD / RRRR-MM (MM = konec měsíce) ÁÁÁ-MM-DD / AŘÁÁ-MM (MM = slutning af måned) / JJJJ-MM-DD / JJJJ-MM (MM = einde maand) AAAA-KK-PP / AAAA-KK (KK = kuu löpp) VVVV-KK-PP / VVVV-KK (kuukauden 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-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) / ГГГГ-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 = айдың соңы) /

GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)



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 / Ñumar de catalog / Katalog numarası / Kataloški broj / Номер по каталогу / Каталог немірі



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 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 Tibbi 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



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 нұсқаулығымен танысып алыңыз / Koristi upute za upotrebu

Technical Information: In the United States, contact BD Technical Service and Support: 800-638-8663 or www.bd.com/ds



EC REP Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland

ATCC is a trademark of the American Type Culture Collection.

BD, BD Logo, BBL and GasPak are trademarks of Becton, Dickinson and Company. © 2013 BD.