IFU

Instructions for Use

CRITERION™ EE BROTH, MOSSEL

Cat. no. C8710	CRITERION™ EE Broth, Mossel	90gm
Cat. no. C8711	CRITERION™ EE Broth, Mossel	500gm
Cat. no. C8712	CRITERION™ EE Broth, Mossel	2kg
Cat. no. C8713	CRITERION™ EE Broth, Mossel	10kg
Cat. no. C8714	CRITERION™ EE Broth, Mossel	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ EE Broth, Mossel is recommended for the selective enrichment and isolation of *Enterobacteriaceae* from foods. This medium meets the harmonized United States Pharmacopeia (USP), European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP) standards for use as an enrichment medium for the microbial examination of nonsterile products.[5,6]

This dehydrated culture medium is a raw material intended to be used in the making of prepared media products, which will require further processing, additional ingredients, or supplements.

SUMMARY

The enumeration of *Enterobacteriaceae* is of great concern in monitoring the sanitary quality of foods. Most *Enterobacteriaceae* are easily injured during food-processing procedures, especially by exposure to low temperatures, sub-marginal heat, drying, radiation, preservatives or sanitizers.[2] The ability to successfully recover these organisms depends upon the proper resuscitation of damaged or sub-lethally injured cells.

CRITERION™ EE Broth, Mossel is made according to the formula developed by Mossel, Visser and Cornelissen.[3] The formula contains dextrose to facilitate the growth of most *Enterobacteriaceae*, thus promoting the detection of *Salmonella* and other non-lactose fermenting bacteria. CRITERION™ EE Broth, Mossel should be used as an enrichment broth, followed by plating to a selective medium such as Violet Red Bile Agar or Violet Red Bile Agar with Glucose. In addition, the medium conforms to the harmonized USP/EP/JP requirements for the detection of bile-tolerant, gram-negative microorganisms.[5,6]

CRITERION™ EE Broth, Mossel contains peptones as a source of nitrogen, vitamins and amino acids. Dextrose provides a carbon source. Disodium phosphate and monopotassium phosphate are included as buffering agents, while brilliant green and oxbile (oxgall) are included as selective agents.

FORMULA*

Gram weight per liter:	45.0gm/L
Oxbile (Oxgall)	20.0gm

Gelatin Peptone	10.0gm
Disodium Phosphate	8.0gm
Dextrose	5.0gm
Monopotassium Phosphate	2.0gm
Brilliant Green	0.015gm

Final pH 7.2 +/- 0.2 at 25ºC.

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

STORAGE AND SHELF LIFE

Store the sealed bottle(s) containing dehydrated culture medium at 2-30ºC. Dehydrated culture medium is very hygroscopic. Keep lid tightly sealed. Protect dehydrated culture media from moisture and light. The dehydrated culture media should be discarded if it is not free-flowing or if the color has changed from its original light green.

Store the prepared culture media at 2-30 degrees C.

The expiration date on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times as stated below.

Refer to the document "Storage" for more information.

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual universal blood precautions. Do not ingest, inhale, or allow to come into contact with skin.

This product is for laboratory use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "Guidelines for Isolation Precautions" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers from Occupationally Acquired Infections.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

METHOD OF PREPARATION FOR DEHYDRATED CULTURE MEDIA

1. Suspend 45.0gm of the dehydrated culture media in one liter of distilled or deionized water. Stir to mix thoroughly.

2. Heat as necessary to dissolve completely.

3. Heat at 100ºC. for 30 minutes. Cool immediately.

4. DO NOT AUTOCLAVE.

5. Aseptically dispense desired volume into sterile containers.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, consult listed references or refer to the prepared media Instructions for Use (IFU) for Cat. No. K191 or U391.

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification.

Some formulations may require a settling period before pH testing of the prepared medium. If the pH is tested immediately after preparation and is out of specification, retest the medium after 24 hours to obtain final pH results. Always take pH reading at room temperature.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as autoclaves, incinerators, other culture media such as Violet Red Bile Agar (Cat. no. G78) or Violet Red Bile Agar with Glucose (Cat. no. G178), and incubators, etc., are not provided.

QUALITY CONTROL

Hardy Diagnostics tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificate of Analysis (CofA) and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media*. The following microorganisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Pseudomonas aeruginosa ATCC® 9027	J	24-48hr	35°C	Aerobic	Growth; no color change
Escherichia coli ATCC® 8739	J	24-48hr	35°C	Aerobic	Growth; color change to yellow
Staphylococcus aureus ATCC® 6538	B	48hr	35°C	Aerobic	Inhibited; no color change

* Refer to the document "Inoculation Procedures for Media QC" for more information.

USER QUALITY CONTROL

Users of dehydrated culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificate of analysis (CofA) available from Hardy Diagnostics Certificate of Analysis website. In addition, refer to the following document "Finished Product Quality Control Procedures," for more information on QC or see the reference(s) for more specific information.

PHYSICAL APPEARANCE

CRITERION™ EE Broth, Mossel powder should appear homogeneous, free-flowing, and light green in color. The prepared medium should appear clear, and emerald green in color.

REFERENCES

1. Downes and Ito (ed.). 2001. *Compendium of Methods for the Microbiological Examination of Foods*, 4th ed. American Public Health Association, Washington, D.C.

2. Hartman and Minnich. 1981. Automation for Rapid Detection of Salmonellae in Foods. *J. Food Prot.* 44:385.

3. Mossel, D.A.A., M. Visser and A.M.R. Cornelissen. 1963. The Examination of Foods for Enterobacteriaceae using a Test of the Type Generally Adopted for the Detection of Salmonellae. *J. Appl. Bacteriol.*; 26:444.

4. U.S. Food and Drug Administration. *Bacteriological Analytical Manual.* AOAC, Arlington, VA. http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm.

5. The Official Compendia of Standards. USP General Chapter <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD.

6. The Official Compendia of Standards. USP General Chapter <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD.

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California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

HDQA 2207B [D]