IFU

Instructions for Use

CRITERION™ MODIFIED EC MEDIUM BASE

Cat. no. C8090	CRITERION™ Modified EC Medium Base	73.2gm
Cat. no. C8091	CRITERION™ Modified EC Medium Base	500gm
Cat. no. C8092	CRITERION™ Modified EC Medium Base	2kg
Cat. no. C8093	CRITERION™ Modified EC Medium Base	10kg
Cat. no. C8094	CRITERION™ Modified EC Medium Base	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Modified EC Medium Base, used in conjunction with Novobiocin Supplement (Cat. no. SR181E), is recommended for the selective enrichment of *Escherichia coli* O157:H7 from meat and poultry products.

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

Modified EC Medium, supplemented with novobiocin, is based on the modified EC broth formula (mEC+n) described by Okrend and Rose.[8] In this modification, Okrend and Rose reduced the amount of bile salts no. 3 from 1.5 grams to 1.12 grams per liter and added 20 milligrams per liter of sodium novobiocin. When using this formulation, Okrend et. al. reported that mEC+n was helpful in the enrichment and detection of *E. coli* O157:H7 from meat and poultry products. Consequently, this formulation is currently recommended by the U.S.D.A for testing food products.[9-11]

Hardy Diagnostics Modified EC Medium Base includes peptone which provides nitrogen, vitamins and amino acids to the medium. Lactose is added as a carbon source for microorganisms that can ferment sugar like *E. coli*. Bile salts are used as a selective agent to inhibit certain gram-positive cocci and spore-forming bacteria. Buffers in the form of dipotassium phosphate and monopotassium phosphate promote the recovery of injured or damaged cells. Sodium chloride provides a suitable ionic environment to promote growth. In addition, novobiocin supplement, when added, suppresses the growth of nuisance microorganisms commonly found in food products.

The selectivity of this medium is based on the addition of bile salts no. 3 and by the further addition of novobiocin supplement to the completed medium. Both of these agents work to suppress the growth of competing microorganisms commonly found in food products. Novobiocin supplement (Cat. no. SR181E) may be purchased in a freeze-dried state that can be rehydrated with sterile purified water prior to supplementation.

FORMULA*

Gram weight per liter:	36.6gm/L

Casein Peptone	20.0gm
Bile Salts No. 3	1.12gm
Lactose	5.0gm
Dipotassium Phosphate	4.0gm
Monopotassium Phosphate	1.5gm
Sodium Chloride	5.0gm

Final pH 6.9 +/- 0.2 at 25ºC.

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

Novobiocin Supplement	
Composition per 10.0ml	
Novobiocin Supplement	20.0mg

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 beige.

Store the prepared culture media at 2-30ºC.

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

Modified EC Medium:

1. Suspend 36.6gm of the dehydrated culture media in 1 liter of distilled or deionized water. Stir to mix thoroughly.

2. Heat as necessary to dissolve completely.

3. Sterilize in the autoclave at 121ºC. for 15 minutes.

4. Cool media to room temperature.

5. Aseptically add 10ml of rehydrated Novobiocin supplement (Cat. no. SR181E) and mix well.

Novobiocin Supplement:

1. Aseptically add 10ml of sterile purified water to vial.

2. Shake to dissolve contents.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, consult listed references.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as autoclaves, incinerators, incubators, Novobiocin supplement (Cat. no. SR181E), MacConkey Sorbitol Agar plates (Cat. no. G36), and Butterfield's Phosphate Buffer (Cat. no. U290), 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	
Escherichia coli O157:H7 ATCC® 35150	A	24hr	35°C	Aerobic	Growth; turbidity with gas production (gas bubble in durham tube)
Enterococcs faecalis ATCC® 29212	B	24hr	35°C	Aerobic	Inhibited

* 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™ Modified EC Medium Base powder should appear homogeneous, free-flowing, and light beige in color. The prepared media should appear clear and light amber in color.

REFERENCES

1. *Standard Methods for the Examination of Water and Wastewater* , 20th ed. 1998. American Public Health Association, Washington, D.C.

2. *Compendium of Methods for the Microbiological Examination of Foods*, 4th ed. 2001. American Public Health Association, Washington, D.C.

3. *Standard Methods for the Examination of Dairy Products*, 16th ed. 1992. American Public Health Association, Washington, D.C.

4. *Bacteriological Analytical Manual* (BAM), 2002. Association of Official Analytical Chemists International, Gaithersburg, MD.

5. *Official Methods of Analysis of the Association of Official Analytical Chemists*, 15th ed. 1990. AOAC, Arlington, VA.

6. Hajna A.A., and C.A. Perry. 1943. Comparative study of presumptive and confirmatory media for bacteria of the coliform group and for fecal streptococci. *Am. J. Public Health.* 33:550-556.

7. Perry, C.A. and Hajna, A.A. 1944. Further evaluation of EC medium for the isolation of coliform bacteria and *Escherichia coli*. *Am. J. Public Health and Nation's Health.* 34:735-748.

8. Okrend, A.J.G., and B.E. Rose. 1989. USDA Communication No. 38, rev. 4. USDA, Washington, D. C.

9. Okrend, A.J.G., B.E. Rose and B. Bennet. 1990. A screening method for the isolation of *Escherichia coli*O157:H7 from ground beef. *J. Food Prot.* 53:249-252.

10. Okrend, A.J.G., B.E. Rose and C.P. Latuada. 1990. Use of 5-bromo-4-chloro-3-indoxyl-b-D-glucuronide in MacConkey sorbitol agar to aid in the isolation of *Escherichia coli* O157:H7 from ground beef. *J. Food Prot.* 53:941-943.

11. Okrend, A.J.G., B.E. Rose and Matner, R. 1990. An improved screening method for the detection and isolation of *Escherichia coli* O157:H7 from meat, incorporating the 3M Petrifilm test kit- HEC- for hemorrhagic *Escherichia coli* O157:H7. *J. Food. Prot.* 53:936-940.

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Ordering Information

Distribution Centers:

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