



Instructions for Use

CRITERION™ EC MEDIUM

Cat. no. C5690	CRITERION™ EC Medium	79gm
Cat. no. C5691	CRITERION™ EC Medium	500gm
Cat. no. C5692	CRITERION™ EC Medium	2kg
Cat. no. C5693	CRITERION™ EC Medium	10kg
Cat. no. C5694	CRITERION™ EC Medium	50kg

INTENDED USE

Hardy Diagnostics CRITERIONTM EC Medium is recommended for the detection of fecal coliforms at 44.5 and 45.5°C.

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

Hajna and Perry formulated EC Media for use in the examination of waters, milk, shellfish and other material for evidence of fecal pollution⁽¹²⁾ The medium consists of a buffered lactose broth with casein peptone and bile salts.

Lactose in the medium serves as a source of fermentable carbohydrate for the growth of coliforms. Casein peptone provide a source of nutrients. The bile salts serve as inhibitory agents toward gram-positive cocci and spore formers, particularly fecal streptococci and bacilli. The pH of the medium is maintained by the presence of a strong potassium buffering system.

Lactose-fermenting microorganisms capable of growing in the presence of the bile salts will ferment lactose resulting in gas production. Gas production is noted by the appearance of bubbles within the durham tube. For the testing of water, wastewater and shellfish, the development of turbidity and gas production within 24 hours at 44.5°C. indicates the presence of fecal coliforms.⁽¹⁾ When testing food other than shellfish, the development of turbidity and gas production within 48 hours at 45.5°C. indicates the presence of fecal coliforms.⁽⁴⁾ All shellfish isolates require an incubation temperature of 44.5°C. (rather than 45.5).⁽⁴⁾

The American Public Health Association (APHA) recommends that EC Medium be used in the fecal coliform Most Probable Number (MPN) procedure for the examination of water, wastewater, and foods. (1-3)

FORMULA

Gram weight per liter:	37.0gm/L
Pancreatic Digest of Casein	20.0gm

Lactose	5.0gm
Sodium Chloride	5.0gm
Dipotassium Phosphate	4.0gm
Monopotassium Phosphate	1.5gm
Bile Salts No. 3	1.5gm

Final pH 6.9 +/- 0.2 at 25°C.

STORAGE AND SHELF LIFE

Store the sealed bottle(s) containing dehydrated culture medium at 2-30°C. 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 beige.

Store the prepared culture media at 2-30°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 39.5gm of the dehydrated culture media in 1 liter of distilled or deionized water.
- 2. Warm slightly to dissolve completely.
- 3. Dispense into tubes containing inverted durham tubes.
- 4. Sterilize in the autoclave at 121°C, for 15 minutes.

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

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. K13.

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.

It may be required that further testing be performed for confirmed results.

EC Medium should not be used for the direct isolation of coliforms.

Prior enrichment in a presumptive medium is required for optimal recovery of fecal coliforms when using EC Medium.

It may be necessary to invert the tube prior to inoculation if bubbles are trapped in the durham tube. Trapped bubbles that are not released may lead to false-positive results.

Turbidity alone is not indicative of a positive test for the presence of coliforms; turbidity with gas production is considered a positive test.

Incubation in a waterbath at 44.5 +/- 0.2°C. is recommended for the detection of fecal coliforms in water and wastewater.

Incubation in a waterbath at 45.5 +/- 0.2°C. is recommended for the detection of fecal coliforms in foods other than shellfish.

All shellfish isolates require an incubation temperature of 44.5°C. (rather than 45.5°). (4)

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, 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	Incubation			Results
Test Organisms	Method*	Time	Temperature	Atmosphere	Results
Escherichia coli ATCC® 25922	A	24hr	35°C	Aerobic	Growth; turbidity with gas production (bubble in durham tube)
Enterococcus faecalis	В	24hr	35°C	Aerobic	Inhibited

ATCC 29212

* 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

CRITERIONTM EC Medium powder should appear homogeneous, free-flowing, and beige in color. The prepared media should appear clear, and colorless to light amber in color.

REFERENCES

- 1. American Public Health Association. *Standard Methods for the Examination of Water and Wastewater*, APHA, Washington, D.C.
- 2. Compendium of Methods for the Microbiological Examination of Foods, 4th ed. 2001. American Public Health Association, Washington, D.C.
- 3. American Public Health Association. *Standard Methods for the Examination of Dairy Products*, APHA, 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.

ATCC is a registered trademark of the American Type Culture Collection.

IFU-10154[B]



1430 West McCoy Lane, Santa Maria, CA 93455, USA

Phone: (805) 346-2766 ext. 5658 Fax: (805) 346-2760

Website: <u>HardyDiagnostics.com</u>

Email: TechnicalServices@HardyDiagnostics.com

Ordering Information

Distribution Centers:

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

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