IFU

Instructions for Use

CRITERION™ M TEC AGAR

Cat. no. C7740	CRITERION™ m TEC Agar	90.6gm
Cat. no. C7741	CRITERION™ m TEC Agar	500gm
Cat. no. C7742	CRITERION™ m TEC Agar	2kg
Cat. no. C7743	CRITERION™ m TEC Agar	10kg
Cat. no. C7744	CRITERION™ m TEC Agar	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ m TEC Agar is recommended for use in the enumeration and differentiation of *Escherichia coli* in water using membrane filtration.

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 density of *Escherichia coli* in water samples has proven to accurately represent the degree of pollution and therefore sanitary quality of ambient, drinking and waste water.[1] Hardy Diagnostics CRITERION™ m TEC (membrane Thermotolerant *E. coli*) Agar utilizes the nature of coliform bacteria to grow at 44.5ºC (+/- 0.2 degrees).[1] While previous methods of enumerating*E. coli* required the use of multiple media types and longer incubation, Dufour et al. produced a membrane filter procedure in 1981 that did not require subculture or further identification of isolates.[2]

This medium selects for and differentiates gram-negative, lactose-fermenting bacteria and allows for the resuscitation of weakened organisms by incubation for 2 hours at 35ºC., before incubation at 44.5ºC. for 18 to 22 hours.[2] If *E. coli* is present, this results in confirmatory growth at 44.5ºC. suggested by the *Standard Methods for the Examination of Water and Wastewater*.[1] Since many coliforms may be found occurring naturally from environmental sources, it is recommended that *E. coli* be used as the indicator for freshwater and marine water testing since it is a known fecal contaminant.[3]

m TEC Agar contains peptones as a source of carbon, nitrogen, vitamins and minerals. Yeast extract supplies complex B vitamins, trace elements and amino acids that help stimulate bacterial growth. Lactose is a carbohydrate that can be fermented by *E. coli* at elevated temperatures. The buffers in this formula are monopotassium phosphate and dipotassium phosphate. Sodium lauryl sulfate and sodium deoxycholate serve to inhibit gram-positive bacteria. Color indicators are bromcresol purple and bromophenol red; while agar is used to solidify the media.

FORMULA*

Gram weight per liter:	45.3gm/L

Lactose	10.0gm
Sodium Chloride	7.5gm
Proteose Peptone No. 3	5.0gm
Potassium Phosphate, dibasic	3.3gm
Yeast Extract	3.0gm
Monopotassium Phosphate	1.0gm
Sodium Lauryl Sulfate	0.2gm
Sodium Deoxycholate	0.1gm
Bromcresol Purple	0.08gm
Bromophenol Red	0.08gm
Agar	15.0gm

Final pH 7.3 +/- 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 grayish-green tan.

Store the prepared culture media at 2-8ºC.

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

2. Heat to boiling to dissolve completely. Do not overheat.

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

4. Cool to 45-50ºC and aseptically dispense into petri dishes.

PROCEDURE AND INTERPRETATION OF RESULTS

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

LIMITATIONS

Consult references for appropriate water sample size choice to ensure countable plates (20 to 80 colonies per filter) and accurate urea test results.[1]

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, membrane filters, forceps, 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 Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Escherichia coli ATCC® 25922	MF	20-24 hr	44.5°C	Aerobic	Growth; yellow to yellow-brown colonies
Enterobacter aerogenes ATCC® 13048	MF	20-24 hr	44.5°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™ m TEC Agar powder should appear homogeneous, free-flowing, and grayish-green tan in color. The prepared media should appear slightly opalescent, deep purple with a red cast, and no precipitates, chips or debris.

REFERENCES

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

2. Dufour, A.P. et al. 1981. Membrane filter method for enumerating *Escherichia coli*. *Appl. Environ. Microbiol.*; 41(5):1152-1158

3. Geldreich E.E., et al. 1965. Fecal coliform organism medium for the membrane filter technique. *J. Am. Water Works Assoc.*; 57:208-214.

4. Anderson, N.L., et al. *Cumitech 3B; Quality Systems in the Clinical Microbiology Laboratory*, Coordinating ed., A.S. Weissfeld. American Society for Microbiology, Washington, D.C.

5. Jorgensen., et al. *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, D.C.

6. Tille, P., et al. *Bailey and Scott's Diagnostic Microbiology*, C.V. Mosby Company, St. Louis, MO.

7. Isenberg, H.D. *Clinical Microbiology Procedures Handbook*, Vol. I, II & III. American Society for Microbiology, Washington, D.C.

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

HDQA 2207B [D]