

# **Instructions for Use**

# CRITERION<sup>™</sup> MACCONKEY AGAR WITH SORBITOL

Cat. no. C6170	CRITERION <sup>™</sup> MacConkey Agar with Sorbitol	111.5gm
Cat. no. C6171	CRITERION <sup>™</sup> MacConkey Agar with Sorbitol	500gm
Cat. no. C6172	CRITERION <sup>™</sup> MacConkey Agar with Sorbitol	2kg
<u>Cat. no. C6173</u>	CRITERION <sup>™</sup> MacConkey Agar with Sorbitol	10kg
Cat. no. C6174	CRITERION™ MacConkey Agar with Sorbitol	50kg

# **INTENDED USE**

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Hardy Diagnostics CRITERION<sup>™</sup> MacConkey Agar with Sorbitol is to be used as a selective and differential medium for the detection of enterohemorrhagic *Escherichia coli*O157:H7.

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**

*E. coli* O157:H7 is an enteric pathogen that typically causes hemorrhagic colitis and bloody diarrheal illnesses. It may be followed by hemolytic uremic syndrome, especially in young children. MacConkey Agar with Sorbitol is recommended for isolation of this organism. Rappaport and Henig first described the formulation of the medium, and it was later confirmed by March and Ratnam who reported MacConkey Agar with Sorbitol to have a sensitivity of 100% and a specificity of 85%. This medium has proved to be an inexpensive, rapid, simple yet reliable means for the detection of *E. coli* O157:H7.

# FORMULA

Gram weight per liter:	58.0gm/L
Pancreatic Digest of Gelatin	18.0gm
Sorbitol	10.0gm
Sodium Chloride	5.0gm
Pancreatic Digest of Casein	4.5gm
Peptic Digest of Animal Tissue	4.0gm
Bile Salts Mixture	1.5gm
Neutral Red	30.0mg

Crystal Violet	1.0mg
Agar	15.0gm

Final pH 7.1 +/- 0.2 at 25°C.

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

# STORAGE AND SHELF LIFE

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

Store the prepared culture media at 2-8°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 "<u>Guidelines for Isolation</u> <u>Precautions</u>" 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 55.75gm of the dehydrated culture media in 1 liter of distilled or deionized water.
- 2. Heat to boiling and mix to dissolve completely.
- 3. Sterilize in the autoclave at 121°C. for 15 minutes. Avoid overheating.
- 4. Cool to 50-55°C. and dispense approximately 20ml into sterile petri dishes.

#### **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. G36.

# LIMITATIONS

Reading of MacConkey Agar with Sorbitol beyond 24 hours should be avoided since the pink color fades in sorbitol-fermenting colonies. Likewise, an extremely heavy inoculum of sorbitol-fermenters may prematurely exhaust the sorbitol and yield white to off-white colonies.

Other gram-negative organisms are able to grow on MacConkey Agar with Sorbitol, however, colony appearance is generally enough to differentiate these organisms from *E. coli* O157:H7.

The MacConkey Agar with Sorbitol may be used as an aid in the identification of bacteria.

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.

Sorbitol-negative colonies may be presumptively identified as *E. coli* O157 using our E. coliPRO<sup>TM</sup> O157 Kit (Cat. no. PL070HD). Further serotyping with H7 antiserum is necessary for definitive identification (Cat. no. 221591).

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

# MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as autoclave, 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			Bossilta
	Method*	Time	Temperature	Atmosphere	Results
Escherichia coli O157:H7 ATCC <sup>®</sup> 35150	А	24hr	35°C	Aerobic	Clear colonies seen; no fermentation of sorbitol
Escherichia coli ATCC <sup>®</sup> 25922	А	24hr	35°C	Aerobic	Pink colonies seen; fermentation of sorbitol

\* 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 <u>Certificate of Analysis</u> website. In addition, refer to the following document "<u>Finished Product</u> <u>Quality Control Procedures</u>," for more information on QC or see the reference(s) for more specific information.

# PHYSICAL APPEARANCE

CRITERION<sup>TM</sup> MacConkey Agar with Sorbitol powder should appear homogeneous, free-flowing, and light pinkishbeige in color. The prepared media should appear slightly opalescent, and reddish-purple in color.

#### REFERENCES

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

2. 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.

3. Rappaport, F., E. Henig. 1952. J. Clin. Path.; 5:361.

4. March, S.B., S. Ratnam, et al. 1986. Sorbitol-MacConkey Medium for detection of *Escherichia coli* O157:H7 associated with hemorrhagic colitis. *J. Clin Microbiol.*; 23:869-872.

5. March, S.B., S. Ratnam, et al. 1988. Characterization of *Escherichia coli* serotype O157:H7. *J. Clin. Microbiol.*; 26:2006-2012.

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

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

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