IFU

Instructions for Use

CRITERION™ MODIFIED LETHEEN AGAR

Cat. no. C7900	CRITERION™ Modified Letheen Agar	118.2gm
Cat. no. C7901	CRITERION™ Modified Letheen Agar	500gm
Cat. no. C7902	CRITERION™ Modified Letheen Agar	2kg
Cat. no. C7903	CRITERION™ Modified Letheen Agar	10kg
Cat. no. C7904	CRITERION™ Modified Letheen Agar	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Modified Letheen Agar is used to determine the antimicrobial activity of quaternary ammonium compounds.

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

Quaternary ammonium compounds are molecules which contain a nitrogen atom with four other atoms bonded to it. Most quaternary ammonium compounds are organic compounds and have biological activity. These compounds often work well as disinfectants, offering bactericidal and bacteriostatic effects. Modified Letheen Agar is used as a quaternary ammonium compound neutralizer for the sampling of environmental surfaces. Quaternary ammonia compounds are neutralized by lecithin while phenolic disinfectants and hexacholorphene are neutralized by Tween® 80. Together, lecithin and Tween® 80 neutralize ethanol.

Modified Letheen Agar is formulated as described in the 7th edition of the U.S. FDA Bacteriological Analytical Manual.[1] Modified Letheen Agar is recommended by the FDA for use in the microbiological testing of cosmetics.[2] The medium contains beef extract and peptone to provide a nutrient rich medium supporting the growth of a variety of microorganisms. The tryptone level was increased in the Modified Letheen Agar formula in order to provide for better growth. The yeast extract not only provides vitamins and co-factors required for growth, but also serves as an additional source of nitrogen and carbon. Sodium chloride provides for osmotic balance.

FORMULA

Gram weight per liter:	59.1gm/L
Letheen Agar	32.0gm
Proteose Peptone No. 3	10.0gm
Tryptone	5.0gm

Sodium Chloride	5.0gm
Yeast Extract	2.0gm
Sodium Bisulfite	0.1gm
Agar	5.0gm

Final pH 7.2 +/- 0.2 at 25 degrees 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 2-30ºC. 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 2-8ºC.

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 59.1gm 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 121ºC. for 15 minutes.

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. G221.

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, 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	
Staphylococcus aureus ATCC® 6538	A	24hr	35°C	Aerobic	Growth
Escherichia coli ATCC® 25922	A	24hr	35°C	Aerobic	Growth

* 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 Letheen Agar powder should appear homogenous, free-flowing, and light beige in color. The prepared media should appear clear, slightly opalescent, and light to medium amber in color.

REFERENCES

1. Tomlinson, L. (ed.). 1992. *FDA Bacteriological Analytical Manual*, 7th ed. AOAC International, Arlington, Virginia.

2. Hitchins, A.D., T.T. Tran and J.E. McCarron. *In* L.A. Tomlinson, L. (ed.). 1992. *FDA Bacteriological Analytical*

Manual, 7th ed. AOAC International, Arlington, Virginia.

3. Marshall, R.T., ed. 1992. *Standard Methods for the Examination of Dairy Products*, 16th ed. APHA, Washington, D.C.

4. Vanderzant, C. and D.F. Splittstoesser, (ed.). 1992. *Compendium of Methods for the Microbiological Examination of Foods*, 3rd ed. APHA, Washington D.C.

5. Greenberg, A.E., et al. (ed.). 1992. *Standard Methods for the Examination of Water and Wastewater*, 18th ed. APHA, Washington D.C.

6. FDA. 1995. *Bacteriological Analytical Manual*, 8th ed. FDA.

7. *U.S. Pharmacopeia*, 22nd rev. 1990. U.S. Pharmacopeial Convention, Rockville, MD.

8. MacFaddin, J.F. 1985. *Media for Isolation, Cultivation, Identification, Maintenance of Bacteria*, Vol. I. Williams & Wilkins, Baltimore, MD.

9. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

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1430 West McCoy Lane, Santa Maria, CA 93455, USA
Phone: (805) 346-2766 ext. 5658
Fax: (805) 346-2760
Website: HardyDiagnostics.com
Email: TechnicalServices@HardyDiagnostics.com
Ordering Information

Distribution Centers:
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]