IFU

Instructions for Use

CRITERION™ A-1 MEDIUM

Cat. no. C7570	CRITERION™ A-1 Medium	63gm
Cat. no. C7571	CRITERION™ A-1 Medium	500gm
Cat. no. C7572	CRITERION™ A-1 Medium	2kg
Cat. no. C7573	CRITERION™ A-1 Medium	10kg
Cat. no. C7574	CRITERION™ A-1 Medium	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ A-1 Medium is recommended for the detection of fecal coliforms in foods, treated wastewater, and seawater.

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

Enumeration of coliform organisms, specifically *E. coli*, has been used since the early 1900's to determine water purity. Rapid detection is of great importance from a public health standpoint. One of the limiting factors in using *E. coli* is the length of time required for complete identification. In 1972, Andrews and Presnell reported on the development of A-1 Medium, which was capable of *E. coli* recovery from estuarine water in 24 hours instead of 72 hours. *E. coli* was recovered in greater numbers and the broth did not require a preenrichment step.[1] They were able to confirm its productivity and determined that recovery was faster and the occurrence of false-positives was substantially reduced when compared to the APHA method.[2,3]

FORMULA

Gram weight per liter:	31.5gm/L
Pancreatic Digest of Casein	20.0gm
Lactose	5.0gm
Sodium Chloride	5.0gm
Salicin	0.5gm
Triton® X-100	1.0ml

Final pH 6.9 +/- 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 the color has changed from its original light beige.

Store the prepared media at 2-30ºC. away from light.

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 31.5gm 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. Dispense into tubes containing inverted durham tubes.

4. Autoclave at 121ºC for 10 minutes.

PROCEDURE AND INTERPRETATION OF RESULTS

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

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.

Some strains may fail to grow or grow poorly on this medium due to varying nutritional requirements.

Fecal coliform counts are usually greater than *E. coli* counts.

Interpretation of test procedure using A-1 Medium requires understanding of the microflora of the specimen.

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	
Klebsiella aerogenes ATCC® 13048	A	24hr	35°C	Aerobic	Growth with gas production
Escherichia coli ATCC® 25922	A	24hr	35°C	Aerobic	Growth with gas production
Bacillus spizizenii ATCC® 6633	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™ A-1 Medium powder should appear non-free-flowing, and light beige in color. The prepared media should appear clear, and light to medium amber in color. Flocculent precipitate may be present.

REFERENCES

1. Andrews, W.H. and M.W. Presnell. 1972. Rapid recovery of *Escherichia coli* from estuarine water. *Appl. Microbiol.*; 23:521-523.

2. Eaton, A.D., L.S. Clesceri, and A.E. Greenberg. 1995. *Standard Methods for the Examination of Water and*

Wastewater, 19th ed. American Public Health Association Inc., Washington, D.C.

3. Andrews, W.H., C.D. Diggs, and C.R. Wilson. 1975. Evaluation of a medium for the rapid recovery of *Escherichia coli* from shellfish. *Appl. Microbiol.*; 29:130-131.

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.

8. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology*, J.B. Lippincott Company, Philadelphia, PA.

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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]