IFU

Instructions for Use

CRITERION™ HEART INFUSION AGAR

Cat. no. C5820	CRITERION™ Heart Infusion Agar	80gm
Cat. no. C5821	CRITERION™ Heart Infusion Agar	500gm
Cat. no. C5822	CRITERION™ Heart Infusion Agar	2kg
Cat. no. C5823	CRITERION™ Heart Infusion Agar	10kg
Cat. no. C5824	CRITERION™ Heart Infusion Agar	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Heart Infusion Agar is a general purpose growth medium. It is recommended for the cultivation of nutritionally fastidious microorganisms and as a basal medium with a variety of applications.

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

CRITERION™ Heart Infusion Agar can be used as base in various formulations. For instance, carbohydrates can be added Heart Infusion Agar to determine fermentation reactions, animal blood to evaluate hemolytic reactions, while antibiotics or other ingredients can be added for the mass cultivation of microorganisms required in biochemical testing and in the preparation of vaccines.[2,3,6] Heart Infusion Media have also been specified for the isolation of *Vibrio cholerae* and *Vibrio* species.[4,5]

A broth medium containing meat infusion was one of the first media used for the cultivation of bacteria. Huntoon prepared a "hormone" broth using fresh beef heart and peptone.[7] He found that the medium, without enrichments, could support the growth of a variety of microorganisms, including nutritionally fastidious organisms, such as, meningococci and pneumococci.[7] Hardy Diagnostics Beef Heart Infusion Media is an improved revision to this original formula. It contains beef heart infusion and peptones, which provide the nitrogen, vitamins, and carbon source to meet the nutritional growth requirements of a variety of organisms. In addition, yeast extract is added to the medium to provide additional vitamins to stimulate organism growth. Sodium chloride is added to maintain osmotic balance in the medium.

FORMULA

Gram weight per liter:	40.0gm/L
Pancreatic Digest of Casein	10.0gm
Peptic Digest of Animal Tissue	5.0gm

Sodium Chloride	5.0gm
Yeast Extract	3.0gm
Beef Heart Infusion	2.0gm
Agar	15.0gm

Final pH 7.4 +/- 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 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 40.0gm 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. Sterilize in the autoclave at 121ºC. for 15 minutes.

4. Cool to 45-50ºC.

5. Aseptically pour into the desired containers.

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. Q59.

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.

Due to the various nutritional requirements of some organisms, occasional isolates may be encountered which fail to grow or grow poorly on this medium.

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	
Escherichia coli ATCC® 25922	A	18-48hr	35°C	Aerobic	Plain: growth With 5% Sheep Blood: growth; beta-hemolysis
Staphylococcus aureus ATCC® 25923	A	18-48hr	35°C	Aerobic	Plain: growth With 5% Sheep Blood: growth; beta-hemolysis
Streptococcus pneumoniae ATCC® 6305	A	18-48hr	35°C	Aerobic	Plain: growth With 5% Sheep Blood: growth; alpha-hemolysis
Streptococcus pyogenes ATCC® 19615	A	18-48hr	35°C	Aerobic	Plain: growth With 5% Sheep Blood: growth; beta-hemolysis

* 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™ Heart Infusion Agar powder should appear homogeneous, free-flowing, and beige in color. The prepared media should appear clear, and light to medium amber in color.

REFERENCES

1. 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.

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

3. Atlas, R.M. 1997. *Handbook of Microbiological Media*, 2nd ed. CRC Press, Inc., Boca Raton, FL.

4. Vanderzant, C. PhD. and D.F. Splittstoesser, PhD. 1992. *Compendium of Methods for the Microbiological Examination of Foods*, 3rd ed. American Public Health Association, Washington, D.C.

5. U.S. Food and Drug Administration. *Bacteriological Analytical Manual.* AOAC, Arlington, VA. http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm.

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

7. Huntoon, F.M. 1918. "Hormone" Medium. A simple medium employable as a substitute for Serum Medium. *The Journal of Infectious Disease*; 23:169-172.

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

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

HDQA 2207B [D]