

CRITERION™ GC AGAR BASE

<u>Cat. no. C5790</u>	CRITERION™ GC Agar Base	83gm
Cat. no. C5791	CRITERION™ GC Agar Base	500gm
Cat. no. C5792	CRITERION™ GC Agar Base	2kg
<u>Cat. no. C5793</u>	CRITERION™ GC Agar Base	10kg
Cat. no. C5794	CRITERION™ GC Agar Base	50kg

INTENDED USE

Hardy Diagnostics CRITERIONTM GC Agar Base is used in the preparation of media for the cultivation and selective isolation of fastidious organisms such as *Neisseria* and *Haemophilus* species.

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

Chocolate, Thayer Martin, Modified Thayer Martin, and Martin Lewis Agars are all used in the cultivation and isolation of *Neisseria* and *Haemophilus* species. All four media are formulated by adding supplements to CRITERIONTM GC Agar Base.

Hemoglobin and coenzyme enrichments provide growth factors necessary for the cultivation of *Haemophilus* spp. Antibiotics may also be added to inhibit growth of normal flora microorganisms.

FORMULA

Gram weight per liter:	36.0gm/L
Pancreatic Digest of Casein	7.5gm
Peptic Digest of Animal Tissue	7.5gm
Sodium Chloride	5.0gm
Dipotassium Phosphate	4.0gm
Corn Starch	1.0gm
Monopotassium Phosphate	1.0gm
Agar	10.0gm

Final pH 7.2 +/- 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 off-white.

Store the prepared culture medium at 2-8°C.

The expiration dating 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 quality control incubation times.

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." The "Guidelines for Isolation Precautions" is available from the Centers for Disease Control and Prevention at www.cdc.gov/ncidod/dhqp/gl_isolation.html.

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 M-29: *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

Refer to the document SDS Search instructions on the Hardy Diagnostics' website for more information.

METHOD OF PREPARATION FOR DEHYDRATED CULTURE MEDIA

Note: To prepare chocolate agar base, see Instructions for Use for CriterionTM Hemoglobin Powder, which is prepared separately and added to GC Agar Base along with necessary supplements and/or antibiotics.

1. Suspend 41.5gm of the dehydrated culture media in 1 liter of distilled or deionized water. To prepare Chocolate Agar, suspend 41.5g of powder in 500ml of distilled or deionized water (500ml of separately autoclaved Hemoglobin Solution will be added after autoclaving for a final volume of 1 liter).

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

- 3. Sterilize in the autoclave at 121°C. for 15 minutes.
- 4. Cool to 45-50°C. and add 2% hemoglobin, enrichments, and selective ingredients as desired.

ENRICHED AND SELECTIVE FORMULAS

Chocolate Agar: CRITERION™ GC Agar Base, 2% hemoglobin, and coenzyme enrichments.

Thayer Martin Agar: CRITERION[™] GC Agar Base, 2% hemoglobin, coenzyme enrichments, vancomycin (3.0mg/L), colistin (7.5mg/L), and nystatin (1250units/L).

Modified Thayer Martin Agar: CRITERION[™] GC Agar Base, 2% hemoglobin, coenzyme enrichments, vancomycin (3.0mg/L), colistin (7.5mg/L), nystatin (1250units/L), trimethoprim (5.0mg/L), and dextrose (1.5gm/L).

Martin Lewis Agar: CRITERION[™] GC Agar Base, 2% hemoglobin, coenzyme enrichments, vancomycin (4.0mg/L), colistin (7.5mg/L), lincomycin (1.0mg/L), trimethoprim (5.0mg/L), and dextrose (1.5gm/L).

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. E14 (Chocolate Agar), E130 (Thayer Martin), E30 (MTM), or E31 (Martin Lewis).

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.

Enrichments including hemoglobin and coenzymes, must be added to CRITERION[™] GC Agar Base in order to obtain growth of *Neisseria* and *Haemophilus* species.

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 Certificates of Analysis (CofA). The following organisms are routinely used for testing at Hardy Diagnostics:

Typical results with hemoglobin and coenzyme enrichments added.

Test Organisms	Inoculation Method*	Incubation			Results			
		Time	Temperature	Atmosphere	Results			
Chocolate Agar:								
<i>Neisseria gonorrhoeae</i> ATCC [®] 43069	А	24hr	35°C	CO ₂ **	Growth			
<i>Neisseria meningitidis</i> ATCC [®] 13090	A	24hr	35°C	CO ₂ **	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 certificates of analysis (CofA) available from Hardy Diagnostics <u>Certificates of Analysis</u> website. In addition, refer to the following document "<u>Finished</u> <u>Product Quality Control Procedures</u>," for more information on QC or see reference(s) for more specific information.

PHYSICAL APPEARANCE

CRITERION[™] GC Agar Base powder should appear homogeneous, free-flowing, and off-white in color, with or without black specks. The prepared media without hemoglobin should appear opaque, 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. Tille, P., et al. Bailey and Scott's Diagnostic Microbiology, C.V. Mosby Company, St. Louis, MO.

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

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

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

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

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

IFU-10165[B]



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

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management system is certified to ISO 13485.

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