IFU

Instructions for Use

CRITERION™ PHENYLALANINE AGAR

Cat. no. C6600	CRITERION™ Phenylalanine Agar	46gm
Cat. no. C6601	CRITERION™ Phenylalanine Agar	500gm
Cat. no. C6602	CRITERION™ Phenylalanine Agar	2kg
Cat. no. C6603	CRITERION™ Phenylalanine Agar	10kg
Cat. no. C6604	CRITERION™ Phenylalanine Agar	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Phenylalanine Agar is recommended for use in the differentiation of gram-negative enteric bacilli based on the ability of microorganisms to produce phenylpyruvic acid by oxidative deamination.

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

In 1950, Hendriksen demonstrated that *Proteus* spp. were able to convert the amino acid phenylalanine to phenylpyruvic acid. Later, Buttiaux et al. developed a culture medium for detecting the formation of *Proteus*, *Providencia*, and *Morganella* groups.[1] This medium was modified by Bynae and further modified by Ewing et al. who simplified Bynae's formula by omitting proteose peptone.[2,3] Hardy Diagnostics CRITERION™ Phenylalanine Agar follows the formulation established by Ewing.

The deamination of phenylalanine by oxidative enzymes results in the formation of phenylpyruvic acid. After incubation, an aqueous solution of ferric chloride is added. If phenylpyruvic acid is present, a light to deep green color is produced. Of the *Enterobacteriaceae*, only *Proteus*, *Providencia*, and *Morganella* species possess enzymes capable of deaminating phenylalanine.[4]

FORMULA*

Gram weight per liter:	23.0gm/L
Sodium Chloride	5.0gm
Yeast Extract	3.0gm
Phenylalanine	2.0gm
Dipotassium Phosphate	1.0gm
Agar	12.0gm

Final pH 7.3 +/- 0.2 at 25ºCC.

* 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 tan.

Store the prepared culture media at 15-30ºC.

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 23gm of the dehydrated culture media in one liter of distilled or deionized water. Stir to mix thoroughly.

2. Heat to boiling to dissolve completely. **Do not overheat.**

3. Pour desired volume into tubes and sterilize in the autoclave at 121ºC. for 15 minutes.

4. Slant tubes after autoclaving.

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. L21.

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.

The green color reaction of a positive test fades rapidly. Test results must be interpreted within 5 minutes following the application of ferric chloride or false-negative results may occur.

Slight agitation of the medium flooded with ferric chloride will dislodge surface colonies and produce a faster more pronounced color reaction.

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, ferric chloride reagent (Cat. no. Z63), other culture media, 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	
Proteus mirabilis ATCC® 12453**	A	18-24hr	35°C	Aerobic	Growth; turns green after the addition of 4-5 drops of ferric chloride with agitation, may take 1-5 minutes
Escherichia coli ATCC® 25922**	A	18-24hr	35°C	Aerobic	Growth; ferric chloride remains yellow

* Refer to the document "Inoculation Procedures for Media QC" for more information.

** Recommended QC strains for User Quality Control according to the CLSI document M22 when applicable.

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™ Phenylalanine Agar powder should appear homogeneous, free-flowing, and light tan in color. The prepared medium should appear slightly opalescent, and light amber in color.

REFERENCES

1. Buttiaux, et al. 1954. *Ann. Inst. Pasteur*; 87:375-386.

2. Ewing, et al. 1957. *Pub Hlth Lab.*; 15:153.

3. Hendriksen. 1950. *J. Bacteriol.*; 60:225.

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

5. Tille, P., et al. *Bailey and Scott's Diagnostic Microbiology*, C.V. Mosby Company, St. Louis, MO.

6. 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.

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

8. Jorgensen., et al. *Manual of Clinical Microbiology*, 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:
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]