IFU

Instructions for Use

CRITERION™ PHENYLETHANOL AGAR (PEA)

Cat. no. C6610	CRITERION™ PEA Agar	84.8gm
Cat. no. C6611	CRITERION™ PEA Agar	500gm
Cat. no. C6612	CRITERION™ PEA Agar	2kg
Cat. no. C6613	CRITERION™ PEA Agar	10kg
Cat. no. C6614	CRITERION™ PEA Agar	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Phenylethanol Agar (PEA) is recommended for use in the cultivation and selective isolation of gram-positive bacteria.

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

Brewer and Lilley reported that the addition of phenylethanol to a nutritive medium will permit growth of gram-positive organisms but markedly to completely inhibit growth of gram-negative organisms found in the same specimen.[10,11] PEA Agar is used for the isolation of enterococci, coagulase-positive staphylococci and most other gram-positive cocci from clinical specimens of mixed gram-positive and gram-negative flora, particularly when specimens are contaminated with swarming *Proteus* spp.[7]

FORMULA

Gram weight per liter:	42.5gm/L
Casein Peptone	15.0gm
Sodium Chloride	5.0gm
Soy Peptone	5.0gm
Phenylethanol	2.5gm
Agar	15.0gm

Final pH 7.3 +/- 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 2-8ºC. 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 homogeneous with soft clumps 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 42.4gm 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.

4. Cool to 45-50ºC. and aseptically add blood and enrichments, if desired.

5. Prepare 5 to 10% blood agar by adding the appropriate volume of sterile defibrinated blood to melted sterile agar medium.

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. A90.

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.

A "brown-sugar" appearance is characteristic of dehydrated product and not an indication of deterioration.[3]

Do not store dehydrated medium at room temperature; store in refrigerator, 2- 8ºC.[7]

Medium cannot be depended upon to determine hemolytic patterns; hemolytic reactions are atypical. Recommended that Sheep Blood Agar (SBA) plates by inoculated simultaneously to determine degree of hemolysis, if any.[7]

Some gram-positive cocci may be slightly inhibited on initial incubation (24hr) and may require further incubation to 48 hours for sufficient growth to be evident.[7]

Many gram-negative bacilli may exhibit visible colonies on PEA; however, their size and numbers are smaller than on other selective enteric isolation media.[7]

Avoid over-heating or prolonged heating of medium base which could destroy the capacity of PEA substrate to inhibit gram-negative bacilli.[11]

Pseudomonas aeruginosa is not inhibited on this medium.[7]

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, incubators, blood, and supplements, 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	
Streptococcus pyogenes ATCC® 19615	A	24hr	35°C	CO_2**	Growth; beta-hemolysis may appear atypical
Streptococcus pneumoniae ATCC® 6305	A	24hr	35°C	CO_2**	Growth; alpha-hemolysis may appear atypical
Staphylococcus aureus ATCC® 25923	A	24hr	35°C	CO_2**	Growth
Proteus mirabilis ATCC® 12453	B	18-24hr	35°C	Aerobic	Partial to complete inhibition; slight growth without swarming

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

USER QUALITY CONTROL

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

PHYSICAL APPEARANCE

CRITERION™ PEA Agar powder should appear homogeneous with soft clumps, and beige in color. The prepared media with sheep blood should appear opaque, and dark red 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. Ellner, et al. 1966. *Am. Journ. Clin. Path.*; 45:502.

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

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

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

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

10. Brewer, J.H., et al. 1949. Paper presented at the December meeting of the Maryland Association of Medical and Public Health Laboratories.

11. Lilley, B.D., et al. 1953. The selective antibacterial action of phenylethylalcohol. *J. Pharm. Assoc.*; 42:6.

IFU-10224[B]

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Ordering Information

management system is certified to ISO 13485.