IFU

Instructions for Use

CRITERION™ PC (PSEUDOMONAS CEPACIA) AGAR

Cat. no. C6660	CRITERION™ PC Agar	60gm
Cat. no. C6661	CRITERION™ PC Agar	500gm
Cat. no. C6662	CRITERION™ PC Agar	2kg
Cat. no. C6663	CRITERION™ PC Agar	10kg
Cat. no. C6664	CRITERION™ PC Agar	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ PC (*Pseudomonas cepacia*) Agar is recommended for the selective isolation of *Burkholderia* (*Pseudomonas*) *cepacia*.

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™ PC Agar was developed by Gilligan, et al.[1] They were able to demonstrate that *P. cepacia* could be recovered from mixed cultures of cystic fibrosis patients using this media. This formula contains bile salts and crystal violet, which inhibits gram-positive bacteria. Gram-negative bacteria can be inhibited by the addition of polymyxin B and ticarcillin. *P. cepacia* utilizes the pyruvate and produces alkaline products that turns the media bright pink to red.

FORMULA

Gram weight per liter:	30.0gm/L
Sodium Pyruvate	5.0gm
Dipotassium Phosphate	4.3gm
Monopotassium Phosphate	2.1gm
Peptic Digest of Animal Tissue	1.0gm
Ammonium Sulfate	1.0gm
Bile Salts No. 3	0.5gm
Magnesium Sulfate	0.2gm
Phenol Red	20.0mg
Ferrous Ammonium Sulfate	10.0mg

Crystal Violet	1.0mg
Agar	15.0gm

Final pH 7.1 +/- 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 light beige.

Store the prepared culture medium 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 30.0gm 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 ticarcillin (100mg) and polymyxin B (300,000 units).

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. G48.

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.

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	
Burkholderia (Pseudomonas) cepacia ATCC® 25416	A	18-72hr	35°C	Aerobic	Growth; gray-white colonies surrounded by a red zone in medium
Pseudomonas aeruginosa ATCC® 27853	B	24hr	35°C	Aerobic	Growth**
Escherichia coli ATCC® 25922	B	24hr	35°C	Aerobic	Growth**
Staphylococcus aureus ATCC® 25922	B	24hr	35°C	Aerobic	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 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.

** Inhibited (partial to complete) when prepared with antimicrobics ticarcillin (100mg) and polymyxin B (300,000 units).

PHYSICAL APPEARANCE

CRITERION™ PC Agar powder should appear homogeneous, free-flowing, and light beige in color. The prepared

media should appear clear to slightly hazy, and orange-red in color.

REFERENCES

1. Gilligan, P.H., et al. 1985. *J. Clin. Microbiol.*; 22:5.

2. 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.

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

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

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

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

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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]