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Instructions for Use

PC (PSEUDOMONAS CEPACIA) AGAR

Cat. no. G48	PC Agar, 15x100mm Plate, 18ml	10 plates/bag

INTENDED USE

Hardy Diagnostics PC (*Pseudomonas cepacia*) Agar is recommended for the selective isolation of *Burkholderia* (*Pseudomonas*) *cepacia* from clinical and environmental materials.

SUMMARY

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

Ingredients per liter of deionized water:*

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
Ticarcillin	0.1gm
Phenol Red	20.0mg
Ferrous Ammonium Sulfate	10.0mg
Crystal Violet	1.0mg
Polymyxin B	300,000U
Agar	15.0gm

Final pH 7.1 +/- 0.3 at 25ºC.

* Adjusted and/or supplemented as required to meet performance criteria.

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-8ºC. Media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing.

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 Precautions for blood. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic 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.

PROCEDURE

Specimen Collection: Consult listed references for information on specimen collection.[1-3,5,6] Infectious material should be submitted directly to the laboratory without delay and protected from excessive heat and cold. If there is to be a delay in processing, the use of a buffered holding medium has been shown effective in the recovery of most microorganisms.

Method of Use: Allow the plates to warm to room temperature, and the agar surface to dry before inoculating. Inoculate and streak the specimen as soon as possible after collection. If the specimen to be cultured is on a swab, roll the swab over a small area of the agar surface. Streak for isolation with a sterile loop. Incubate plates aerobically at 35ºC. for 18-72 hours. Examine plates daily for typical colonial morphology and growth characteristics.

INTERPRETATION OF RESULTS

Growth of gray-white colonies surrounded by bright pink to red zone in medium may be presumptively identified as *Burkholderia* (*Pseudomonas*) *cepacia.*

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification of bacteria and/or fungi.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, other culture media, swabs, applicator sticks, incinerators, and incubators, etc., as well as serological and biochemical reagents, 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 bright pink to red zone in medium
Pseudomonas aeruginosa ATCC® 27853	B	24hr	35°C	Aerobic	Inhibited (partial to complete)
Escherichia coli ATCC® 25922	B	24hr	35°C	Aerobic	Inhibited (partial to complete)
Staphylococcus aureus ATCC® 25923	B	24hr	35°C	Aerobic	Inhibited (partial to complete)

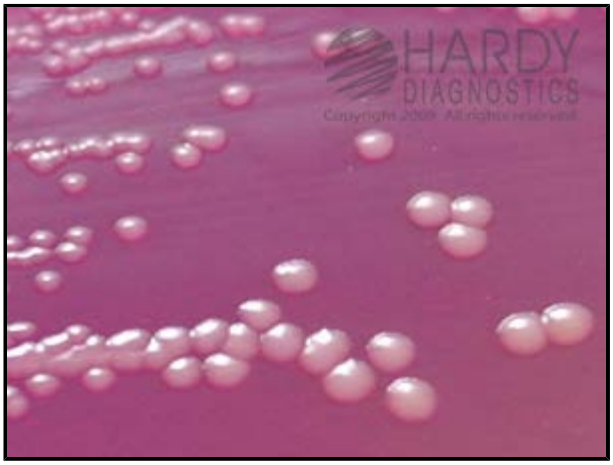
* Refer to the document "Inoculation Procedures for Media QC" for more information.

USER QUALITY CONTROL

End users of commercially prepared 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. Also refer to the document "Finished Product Quality Control Procedures," and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media* for more information on the appropriate QC procedures. See the references below.

PHYSICAL APPEARANCE

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



Burkholderia (Pseudomonas) cepacia (ATCC® 25416) colonies growing on PC Agar (Cat. no. G48). Incubated aerobically for 48 hours at 35ºC.

Uninoculated plate of PC Agar (Cat. no. G48).

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