IFU

Instructions for Use

CRITERION™ PSEUDOMONAS ISOLATION AGAR BASE

Cat. no. C6680	CRITERION™ Pseudomonas Isolation Agar Base	90gm
Cat. no. C6681	CRITERION™ Pseudomonas Isolation Agar Base	500gm
Cat. no. C6682	CRITERION™ Pseudomonas Isolation Agar Base	2kg
Cat. no. C6683	CRITERION™ Pseudomonas Isolation Agar Base	10kg
Cat. no. C6684	CRITERION™ Pseudomonas Isolation Agar Base	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Pseudomonas Isolation Agar Base is recommended for the selective isolation and differentiation of *Pseudomonas aeruginosa* .

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

Non-fermentative gram-negative bacteria (NFB) can exploit the wet environments in hospitals and are often associated with nosocomial infections. For instance, non-fermentative bacteria have been implicated in the contamination of faucet aerators, respiratory therapy equipment, as well as sterile solutions and medications. Among the NFB, *Pseudomonas aeruginosa* is the most clinically significant bacteria.[8]

Hardy Diagnostics CRITERION™ Pseudomonas Isolation Agar Base is a modification of the formula developed by King, et al.[1] The medium is designed to enhance pyocyanin production, thereby improving the differentiation of pseudomonads. The modified formula contains a low phosphorous content, added glycerol, magnesium chloride and potassium sulfate, all of which promote pyocyanin production.[1] Pyocyanin production is unique to *Pseudomonas aeruginosa* and is noted as a blue-green water soluble pigment that imparts a greenish color into the media.[8]

The addition of glycerol (Cat. no. 228210) to Hardy Diagnostics CRITERION™ Pseudomonas Isolation Agar Base provides an energy source. Peptone provides nutrients necessary for bacterial growth. Irgasan® is incorporated into the medium to inhibit the growth of many gram-positive and gram-negative microorganisms other than *Pseudomonas* spp.[2]

FORMULA

Gram weight per liter:	45.0gm/L
Gelatin Peptone	20.0gm
Potassium Sulfate	10.0gm

Magnesium Chloride	1.4gm
Irgasan®	25.0mg
Agar	13.6gm

Final pH 7.0 +/- 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 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 45.0gm of the dehydrated culture media in 980ml of deionized water. Stir to mix thoroughly.

2. Add 20ml glycerol (Cat. no. 228210).

3. Boil to dissolve completely. DO NOT OVERHEAT.

4. Sterilize in the autoclave at 121ºC. for 15 minutes.

5. Cool to 45-50ºC.

6. Dispense into sterile petri dishes.

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. G219.

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.

Some pseudomonads do not grow well at 35ºC. If no growth appears after 24 hours of incubation at 35ºC., the plates should be reincubated at 25ºC. for 24 hours.

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, slides, staining supplies, other culture media, glycerol (Cat. no. 228210), microscopes, 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	
Pseudomonas aeruginosa ATCC® 27853	A	18-48hr	35°C	Aerobic	Growth; blue-green colonies
Pseudomonas aeruginosa ATCC® 9027	A	18-48hr	35°C	Aerobic	Growth; blue-green colonies
Burkholderia (Pseudomonas) cepacia ATCC® 25416	A	18-48hr	35°C	Aerobic	Growth; no pigment
Escherichia coli ATCC® 25922	B	18-48hr	35°C	Aerobic	Inhibited
Staphylococcus aureus ATCC® 25923	B	18-48hr	35°C	Aerobic	Inhibited

* 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.

PHYSICAL APPEARANCE

CRITERION™ Pseudomonas Isolation Agar Base powder should appear homogeneous, free-flowing, and light beige in color. The prepared media should appear slightly opalescent, and light amber in color.

REFERENCES

1. King, E.O., et al. 1954. *J. Lab. Clin. Med.*; 44:301.

2. Soap and Chemical Specialties, January 1968.

3. 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.

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

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

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.

8. Bodey, G.D., et al. 1989. "Infections caused by *P. aeruginosa*". *Rev. Infect. Dis.*; 5:279-313.

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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]