IFU

Instructions for Use

HARDY DIAGNOSTICS
A Culture of Service™

CRITERION™ CETRIMIDE SELECTIVE AGAR BASE

Cat. no. C5370	CRITERION™ Cetrimide Selective Agar Base	88.6gm
Cat. no. C5371	CRITERION™ Cetrimide Selective Agar Base	500gm
Cat. no. C5372	CRITERION™ Cetrimide Selective Agar Base	2kg
Cat. no. C5373	CRITERION™ Cetrimide Selective Agar Base	10kg
Cat. no. C5374	CRITERION™ Cetrimide Selective Agar Base	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Cetrimide Selective Agar Base is recommended for the selective isolation 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

Cetyltrimethylammonium bromide, a quaternary ammonium, cationic detergent, is the component of Cetrimide Agar which allows for the selective isolation of *Pseudomonas aeruginosa*. Cetyltrimethylammonium bromide, when in contact with bacteria, causes the release of nitrogen and phosphorous from the bacterial cell. Organisms other than *P. aeruginosa* are unable to withstand this germicidal activity.

Cetrimide Selective Agar employs the use of 0.03% cetrimide which follows the formulation established by Sawbury and Collins.[6] Both pyocyanin and fluorescein pigment production are enhanced on Cetrimide Agar.

FORMULA

Gram weight per liter:	44.3gm/L
Pancreatic Digest of Gelatin	20.0gm
Potassium Sulfate	10.0gm
Magnesium Chloride	1.4gm
Cetyltrimethylammonium Bromide	0.3gm
Agar	12.6gm

Final pH 7.2 +/- 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 tan.

Store the plated culture media at 2-8ºC. and tubed media at 2-30ºC.

The expiration dating 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 quality control incubation times.

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." The "Guidelines for Isolation Precautions" is available from the Centers for Disease Control and Prevention at www.cdc.gov/ncidod/dhqp/gl_isolation.html.

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 M-29: *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

Refer to the document SDS Search instructions on the Hardy Diagnostics' website for more information.

METHOD OF PREPARATION FOR DEHYDRATED CULTURE MEDIA

1. Suspend 44.3gm of the dehydrated culture media in one liter of distilled or deionized water. Add 10.0ml of glycerol and stir to mix thoroughly.

2. Boil to dissolve completely. Do not overheat.

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

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. G18.

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.

Recovery rates for ready-to-use suspensions of lyophilized or water-soluble quantitative microorganism dilutions requiring no preparation or pre-incubation may encounter performance issues with direct plating and growth promotion testing on selective media. Users are advised to refer to the specific manufacturer's package insert for potential limitations using these types of QC organisms.

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

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as autoclave, 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 Certificates of Analysis (CofA). The following organisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Pseudomonas aeruginosa ATCC® 27853	A	24-48hr	35°C	Aerobic	Growth; yellow-green to blue colonies
*Pseudomonas aeruginosa*** ATCC® 9027	J	18hr	30-35°C	Aerobic	Growth; yellow-green to blue colonies
Escherichia coli ATCC® 25922	B	24-48hr	35°C	Aerobic	Partial to complete inhibition
Escherichia coli ATCC® 8739	B	72hr	30-35°C	Aerobic	Partial to complete inhibition
Staphylococcus aureus ATCC® 25923	B	24-48hr	35°C	Aerobic	Partial to complete inhibition

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

** Tested in accordance with USP <61> and <62>.[7,8]

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 certificates of analysis (CofA) available from Hardy Diagnostics Certificates of Analysis website. In addition, refer to the following document "Finished Product Quality Control Procedures," for more information on QC or see reference(s) for more specific information.

PHYSICAL APPEARANCE

CRITERION™ Cetrimide Selective Agar Base powder should appear homogeneous, free-flowing, and tan in color. The prepared media should be opalescent, with a precipitate, and light amber 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. Versalovic, J., 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. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology,* J.B. Lippincott Company, Philadelphia, PA.

6. *J. Clin. Path.*; 8:47, 1955.

7. The Official Compendia of Standards. USP General Chapter <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD.

8. The Official Compendia of Standards. USP General Chapter <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD.

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HARDY DIAGNOSTICS

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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 [C]