IFU

HARDY DIAGNOSTICS
A Culture of Service™

Instructions for Use

CETRIMIDE SELECTIVE AGAR

Cat. no. G18	Cetrimide Selective Agar, USP, 15x100mm Plate, 26ml	10 plates/bag
Cat. no. J330	TSA (Tryptic Soy Agar) / CET (Cetrimide Selective Agar) / MSA (Mannitol Salt Agar), 15x100mm Triplate, 7ml/section	10 plates/bag
Cat. no. J314	Cetrimide Selective Agar (CET) / MacConkey Agar (MAC) / Vogel and Johnson Agar (VJ), 15x100mm triplate, 7ml/section	10 plates/bag

INTENDED USE

Hardy Diagnostics Cetrimide Selective Agar is recommended for the selective isolation and identification of *Pseudomonas aeruginosa*.

SUMMARY

Cetrimide Selective Agar, USP is recommended by the U.S. Pharmacopeia for use in the growth promotion testing of non-sterile products tests for specified microorganisms.[8]

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

Ingredients per liter of deionized water:*

Pancreatic Digest of Gelatin	20.0gm
Potassium Sulfate	10.0gm
Magnesium Chloride	1.4gm
Cetyltrimethylammonium Bromide	0.3gm
Glycerine	10.0ml
Agar	13.6gm

Final pH 7.2 +/- 0.2 at 25ºC.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store plated media at 2-8ºC. away from direct light. 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.[2-5]

Method of Use: Consult listed references for the correct inoculation procedure.[2-5] Prior to inoculation, the medium should be brought to room temperature. Inoculate from an 18-24 hour old pure culture or directly from the specimen. Streak so as to obtain isolated colonies. Incubate aerobically at 35-37°C. for up to seven days. Observe daily for growth.

INTERPRETATION OF RESULTS

The presence of growth is indicative of a positive reaction. Examine colonies under short wavelength (254nm) ultraviolet light for the presence of fluorescein. Visual examination may also reveal the typical yellow-green to blue color which indicates the production of pyocyanin. Both pyocyanin and fluorescein are typically produced by strains of *P. aeruginosa* .

A negative reaction is denoted by no growth.

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.

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 loops, other culture media, swabs, applicator sticks, ultraviolet lights, 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® 9027 **	J	18hrs	30-35°C	Aerobic	Growth; yellow-green to blue colonies
Escherichia coli ATCC® 8739 **	B	72hrs	30-35°C	Aerobic	Partial to complete inhibition

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

* 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

Cetrimide Selective Agar should appear opalescent, with a precipitate, and light amber in color.

Pseudomonas aeruginosa (ATCC® 9027) colonies growing on Cetrimide Selective Agar (Cat. no. G18). Incubated aerobically for 18-24 hours at 35ºC.

Escherichia coli (ATCC® 8739) growth inhibited on Cetrimide Selective Agar (Cat. no. G18). Incubated aerobically for 48 hours at 35ºC.

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.

ATCC is a registered trademark of the American Type Culture Collection.

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

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