

Instructions for Use

CRITERION™ D/E NEUTRALIZING AGAR

Cat. no. C5520	CRITERION™ D/E Neutralizing Agar	113.4gm
Cat. no. C5521	CRITERION™ D/E Neutralizing Agar	500gm
Cat. no. C5522	CRITERION™ D/E Neutralizing Agar	2kg
Cat. no. C5523	CRITERION™ D/E Neutralizing Agar	10kg
Cat. no. C5524	CRITERION™ D/E Neutralizing Agar	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ D/E Neutralizing Agar is used for the testing and neutralizing of antiseptics and disinfectants in order to detect organisms remaining after treatment. This agar is especially suited for environmental sampling where neutralization of the disinfectant is important to determine its bactericidal activity.

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™ D/E Neutralizing Agar, which was developed by Dey-Engley, is capable of neutralizing a broad spectrum of antiseptic and disinfectant chemicals, including ethanol, quaternary ammonium compounds, phenolics, iodine, chlorine preparations, mercurials, formaldehyde and glutaraldehyde. It can determine the bactericidal capability of disinfectants and, therefore, is well suited for environmental sampling (swab and contact plate methods). D/E Neutralizing medium can neutralize higher concentrations of residual antiseptic and disinfectant chemicals than other neutralizing agents.

D/E Neutralizing Agar contains various neutralizing agents: lecithin, Tween®, sodium thiosulfate, sodium bisulfite, and sodium thioglycollate. Lecithin neutralizes quaternary ammonia compounds while phenolic disinfectants and hexachlorophene are neutralized by Tween®. Together, lecithin and Tween® neutralize ethanol. Sodium thiosulfate neutralizes iodine and chlorine, where as sodium bisulfite neutralizes formaldehyde and glutaraldehyde. Sodium thioglycollate neutralizes mercurials.

Complete neutralization of disinfectants is important because disinfectant carryover can cause a false no-growth test result. D/E Neutralizing medium effectively neutralizes the inhibitory effects of disinfectant carryover, allowing differentiation between bacteriostasis and the true bacterocidal action of disinfectant chemicals.

In addition to neutralizing agents, this medium contains ingredients that enhance the growth of a wide variety of microorganisms. Pancreatic digest of casein provides the carbon and nitrogen sources. Yeast extract provides vitamins and cofactors required for growth. Dextrose is added as a fermentable carbohydrate source. Bromcresol purple is added to the media as a colorimetric indicator to demonstrate the production of acid from dextrose as a result of bacterial growth.

FORMULA*

Gram weight per liter:	54.02gm/L
Dextrose	10.0gm
Lecithin	7.0gm
Sodium Thiosulfate	6.0gm
Pancreatic Digest of Casein	5.0gm
Tween [®] 80	5.0gm
Yeast Extract	2.5gm
Sodium Bisulfite	2.5gm
Sodium Thioglycollate	1.0gm
Bromcresol Purple	0.02gm
Agar	15.0gm

Final pH 7.6 +/- 0.2 at 25°C.

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

STORAGE AND SHELF LIFE

Store the sealed bottle(s) containing dehydrated culture medium at 2-8°C. 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 the color has changed from its original bluish-gray.

Store the prepared culture media at 2-8°C.

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 56.7gm of the dehydrated culture medium in one liter of distilled or deionized water. Stir to mix thoroughly.
2. Heat to boiling to dissolve completely. Do not overheat.
3. Sterilize in the autoclave at 121°C. for 15 minutes.
4. Cool to 45-50°C. and aseptically pour into Petri plates.

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. G224.

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	
<i>Bacillus spizizenii</i> ATCC® 6633	A	24-48hr	35°C	Aerobic	Growth; usually no color change
<i>Escherichia coli</i> ATCC® 25922	A	24-48hr	35°C	Aerobic	Growth; yellow color change
<i>Pseudomonas aeruginosa</i> ATCC® 9027	A	24-48hr	35°C	Aerobic	Growth; no color change
<i>Salmonella enterica</i> ATCC® 14028	A	24-48hr	35°C	Aerobic	Growth; yellow color change

<i>Staphylococcus aureus</i> ATCC® 6538	A	24-48hr	35°C	Aerobic	Growth; yellow color change
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* 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™ D/E Neutralizing Agar should appear moist, lumpy, and bluish-gray in color. The prepared medium should appear opaque, with an even suspension of particulates, and gray-purple to lavender 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. Jorgensen., 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. American Public Health Association. *Standard Methods for the Examination of Water and Wastewater*, APHA, Washington, D.C.
7. Association of Official Analytical Chemists. *Official Methods of Analysissm*, AOAC, Washington, D.C.
8. The Official Compendia of Standards. 2008. *USP27-NF22*. United States Pharmacopeial Convention, Rockville, MD.

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

Tween is a registered trademark of ICI Americas, Inc.

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[Ordering Information](#)

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