IFU

Instructions for Use

D/E NEUTRALIZING AGAR

Cat. no. P99	D/E Neutralizing Agar, Contact Plate, 14.5ml	10 plates/bag
Cat. no. G224	D/E Neutralizing Agar, 15x100mm Plate, 18ml	10 plates/bag
Cat. no. P580*	D/E Neutralizing Agar, Irradiated, Triple Bagged, Contact Plate, Lok-Tight™, 14.5ml	10 plates/bag
* A fourth sterile sample bag is included for packaging after the sample is collected.		

INTENDED USE

Hardy Diagnostics D/E Neutralizing Agar is used for the testing efficacy and neutralizing of antiseptics and disinfectants based on neutralizing the chemical and detecting organisms remaining after treatment.

This product is not intended to be used for the diagnosis of human disease.

SUMMARY

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 media 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 gluteraldehyde. Sodium thioglycollate neutralizes mercurials.

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

In addition to neutralizing agents, this media 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 growth factors required for growth. Dextrose is added as a fermentable carbohydrate source. Bromcresol purple is added to the media as a colormetric indicator to demonstrate the production of acid from dextrose.

Irradiated plates are triple bagged and sterilized by irradiation to promote a higher sterility assurance level.

FORMULA

Ingredients per liter of deionized water:*

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 +/- 0.3 at 25°C

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-8°C 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. Do not use irradiated media if there is any damage to the packaging prior to use. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing.

For irradiated media: Inspect each bag prior to opening and using the product.

Do not use irradiated media if there is any damage to the packaging prior to use.

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.

PROCEDURE

Before Use of Plates: For irradiated media, it is possible that variation in temperature and pressure during shipping and storage may cause condensation on the innermost bag surrounding the plates. If condensation of the packaging or plates is observed, remove the plates from the innermost packaging in a sterile environment and allow them to dry for 10-15 minutes before use.

Contact Plate Method: Allow plates to warm to room temperature, and agar surface to dry. Select a surface to test. Sample the surface by firmly pressing the agar against the test area, using the thumb and second finger to hold the plate, and the first finger to press firmly and evenly on the base. The same amount of pressure should be used for each sample. Do not move the plate laterally, as this spreads contaminants across the agar surface. A rolling motion may be used when slightly curved surfaces are sampled. Areas to be assayed may by divided into grids or sections, and days, as required. Observe for growth and/or a zone of color change from purple to yellow which occurs when the dextrose is fermented.

INTERPRETATION OF RESULTS

Colonies of dextrose fermenting microorganisms will be surrounded by a yellow zone.

Consult listed references for information pertaining to colony morphology and biochemical tests required for identification.[1-3,5,6]

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.

Avoid repeated and/or extreme variations in temperatures during storage, as this can cause the release of excessive moisture from the media in the bags and plates.

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	
Bacillus spizizenii ATCC® 6633	A	24-48hr	35°C	Aerobic	Growth; usually no color change
Escherichia coli ATCC® 25922	A	24-48hr	35°C	Aerobic	Growth; yellow color change

Pseudomonas aeruginosa ATCC® 9027	A	24-48hr	35°C	Aerobic	Growth; no color change
Salmonella enterica ATCC® 14028	A	24-48hr	35°C	Aerobic	Growth; yellow color change
Staphylococcus aureus ATCC® 6538	A	24-48hr	35°C	Aerobic	Growth; yellow color change

For Cat. no. P580: Representative samples from each lot of irradiated media are held for seven days to confirm the media meet the validated sterilization process sterility assurance level (SAL) of 10^{-6} for contact plates following ANSI/AAMI/ISO 11137.

* 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

D/E Neutralizing Agar should appear opaque, with an even suspension of particulates, and lavender in color.

Uninoculated plate of D/E Neutralizing Agar (Cat. no. P99).

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

3. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology.* J.B. Lippincott Company, Philadelphia, PA.

4. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

5. Tille, P.M., et al. *Bailey and Scott's Diagnostic Microbiology*, C.V. Mosby Company, St. Louis, MO.

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

7. Centers for Medicare & Medicaid Services (CMS). Individualized Quality Control Plan (IQCP)

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

HDQA 2207D [D]