IFU

HARDY DIAGNOSTICS
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Instructions for Use

ENVIROTRANS™ NEUTRALIZING SALINE

Cat. no. SRK55	EnviroTrans™ Neutralizing Saline, 15x75mm Polyproplyene Tube with swab, 5ml	20 vials/box

INTENDED USE

Hardy Diagnostics EnviroTrans™ Neutralizing Saline is designed for sampling surfaces as a part of HACCP (Hazard Analysis Critical Control Point) systems and other environmental monitoring testing. The EnviroTrans™ Neutralizing Saline packages everything needed to collect samples from work surfaces, utensils or other industrial apparatuses (i.e. pump impellers, gaskets, etc.).

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

SUMMARY

Hardy Diagnostics EnviroTrans™ Neutralizing Saline is a self-contained unit which includes a sterile dacron swab, attached to the lid, and a tube containing 5ml of Neutralizing Saline.

Quaternary ammonium compounds are molecules which contain a nitrogen atom with four other atoms bonded to it. Most quaternary ammonium compounds are organic compounds and have biological activity. These compounds often work well as disinfectants, offering bactericidal and bacteriostatic effects.

Neutralizing Saline, as the transport media in this unit, has the ability to neutralize a broad spectrum of antiseptic and disinfectant chemicals including quaternary ammonium compounds, phenolics, iodine, chlorine preparations, mercurials, formaldehyde, ethanol and glutaraldehyde (see Chart 1). This media, however, does not promote growth. It is solely intended to facilitate survival of organisms in the sample during transport to the lab.

FORMULA

Ingredients per liter of deionized water:*

Sodium Chloride	8.5gm
Lecithin	7.0gm
Sodium Thiosulfate	6.0gm
Tween® 80	5.0gm
Sodium Bisulfite	2.5gm
Sodium Thioglycollate	1.0gm

Final pH 6.9 +/- 0.2 at 25ºC.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt, store at 2-8ºC. Always keep away from direct light. Media should not be used if there are any signs of deterioration, contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat 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 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.*

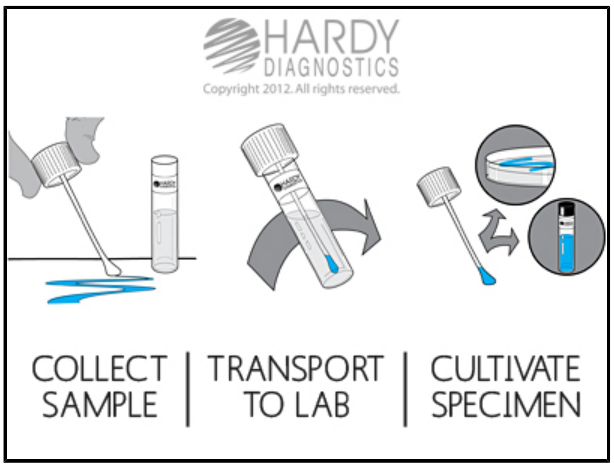
Sterilize all biohazard waste before disposal.

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

PROCEDURE

Specimen Collection[(1)]

Aseptically collect sample. Collect sample by rubbing the swab over the sample area (approximately 50cm^2), reversing directions between strokes. Repeat the collection procedure three more times, returning the swab head to the Neutralizing Saline after swabbing each area. When sampling utensils such as knives or ladles, run the swab over the entire surface of the instrument three times, as described above. If sample is not immediately taken to the lab the sample can be refrigerated for up to 24 hours prior to analysis.



Plating[1]

Prior to plating, shake the tube vigorously (50 cycles of 15cm in 10 seconds). Prepare plates, using Standard Methods Agar, or other appropriate media, plating 1ml and 0.1ml samples of Neutralizing Saline containing the sample. Incubate plates at 35ºC. for 48 hours, then calculate the number of colonies from 50cm^2 sample area.[2]

INTERPRETATION OF RESULTS

Generally, the U.S. Public Health Service states that cleaned and sterilized food service equipment should not have more than 100 colonies per utensil or surface area sampled.[1] More often, the type of organism, rather than numbers is more critical in an HACCP system. It could be that more stringent specifications need to be made based on the type of surface sampled and the nature of the finished product that is being produced.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, other culture media, 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	
Staphylococcus aureus **without** Roccal D ATCC® 6539	Control	48hr	35°C	Aerobic	Growth
Staphylococcus aureus **with** Roccal D ATCC® 6539	10^{-3}	48hr	35°C	Aerobic	Growth
Staphylococcus aureus **with** Roccal D ATCC® 6539	10^{-4}	48hr	35°C	Aerobic	Growth

Staphylococcus aureus **with** Roccal D ATCC® 6539	10^{-5}	48hr	35°C	Aerobic	Growth

* 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

EnviroTrans™ Neutralizing Saline should appear as a colloidal suspension, and white in color.

REFERENCES

1. APHA Technical Committee on Microbiological Methods for Foods. *Compendium of Methods for the Microbiological Examination of Foods*, APHA, Washington, D.C.

2. Tiedman, W.D., Chairman. 1948. *Technic for the Bacteriological Examination of Food Utensils.* Committee Report. American Journal of Public Health Yearbook.

3. Block, S.S. 1991. *Disinfection, Sterilization, and Preservation*, 4th ed. Lea & Febiger, Philadelphia, London.

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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 2207D [D]