IFU

Instructions for Use

NEUTRALIZING BUFFER

Cat. no. K105	Neutralizing Buffer, 16x125mm Tube, 10ml	20 tubes/box

INTENDED USE

Hardy Diagnostics Neutralizing Buffer is used in environmental monitoring procedures for the sterility testing of equipment and surfaces.

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

SUMMARY

Neutralizing Buffer is used for the sampling of equipment and surfaces because it has the ability to neutralize the bactericidal and bacteriostatic effects of quaternary ammonium compounds. *Standard Methods for the Examination of Dairy Products* contains a procedure for the sterility testing of equipment.[3] *Compendium of Methods for the Microbiological Examination of Foods* details a procedure for the sterility testing of surfaces and utensils.[1]

Neutralizing Buffer contains potassium phosphate to maintain the pH. Sodium thiosulfate and aryl sulfonate complex act to neutralize chlorine and quaternary ammonium compounds. Neutralizing Buffer is not toxic to microorganisms, even when used in procedures that call for concentrations up to 10 times the single strength buffer.

FORMULA

Ingredients per liter of deionized water:*

Aryl Sulfonate Complex	5.0gm
Sodium Thiosulfate	160.0mg
Potassium Phosphate	42.5mg
Sodium Hydroxide	8.0mg

Final pH 7.2 +/- 0.3 at 25°C

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-30°C away from direct light. Media should not be used if there are any signs of contamination, deterioration, discoloration, 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 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

Sample 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 Buffer 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 pour plates, using Standard Methods Agar or other appropriate media, plating 1.0ml and 0.1ml samples of Neutralizing Buffer containing the sample. Incubate plates at 35°C for 48 hours, then calculate the number of colonies from 50cm^2 sample area.[2]

Refer to listed references for more information on procedures involving Neutralizing Buffer.[1,2,4]

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.

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.

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

Neutralizing Buffer is routinely tested at Hardy Diagnostics using the following procedure:

Dilute a disinfectant containing a quaternary ammonium compound such as Roccal with Neutralizing Buffer from 1:2,500 to 1:100,000. Inoculate the tubes with *Staphylococcus aureus* ATCC® 6538. Prepare pour plates by transferring 1.0ml from each dilution to Standard Methods Agar. Incubate the plates for 40-48 hours at 35°C. Record growth. Neutralizing Buffer inactivates the bactericidal activity which the growth pattern should reflect.

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	Incubation			Results
	Time	Temperature	Atmosphere	
Staphylococcus aureus ATCC® 6538	24-48hr	35°C	Aerobic	Recovered

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

Neutralizing Buffer should appear clear and colorless to light amber.

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. *Technique for the Bacteriological Examination of Food Utensils*. Committee Report. American Journal of Public Health Yearbook.

3. American Public Health Association. *Standard Methods for the Examination of Dairy Products*, APHA, Washington, D.C.

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

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1430 West McCoy Lane, Santa Maria, CA 93455, USA
Phone: (805) 346-2766 ext. 5658
Fax: (805) 346-2760
Website: HardyDiagnostics.com
Email: TechnicalServices@HardyDiagnostics.com
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.

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