

ENVIROTRANS™ LETHEEN BROTH

Cat. no. SRK25 EnviroTrans™ Letheen Broth, 15x75mm Polyproplyene Tube with swab, 5ml	20 vials/box
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INTENDED USE

Hardy Diagnostics EnviroTrans[™] Letheen Broth is designed for sampling surfaces as a part of HACCP (Hazard Analysis Critical Control Point) systems and other environmental monitoring. The EnviroTrans[™] Letheen Broth 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™ Letheen Broth is a self contained unit which includes a sterile dacron swab, attached to the lid, and a tube containing 5ml of Letheen Broth.

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. Letheen Broth is used in the AOAC procedure for determining the effect of these bactericidal compounds. (3)

Letheen Broth, the transport media in this unit, is formulated according to the guidelines set by the AOAC for the determination of phenol coefficient of quaternary ammonium compounds. ⁽³⁾ The medium contains beef extract and peptic digest of animal tissue to provide a nutrient rich medium supporting the growth of a variety of microorganisms. Quaternary ammonia compounds are neutralized by lecithin while phenolic disinfectants and hexachlorophene are neutralized by Tween * 80. Together, lecithin and Tween * 80 neutralize ethanol.

FORMULA

Ingredients per liter of deionized water:*

Peptic Digest of Animal Tissue	10.0gm
Beef Extract	5.0gm
Sodium Chloride	5.0gm
Tween ® 80	5.0gm
Lecithin	0.7gm

Final pH 7.0 +/- 0.2 at 25 degrees C.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt, store at 2-8 degrees C. 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 applies to the product in its intact packaging when stored as directed.

These products have the following shelf life from the date of manufacture:

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365 Days:	SRK25	EnviroTrans™ Letheen Broth
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Refer to the keyword "Storage", in the Hardy Diagnostics software program HUGO™, for more information on storing culture media.

PRECAUTIONS

This product is for laboratory use only and 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". The "Guideline for Isolation Precautions" is available from the Centers for Disease Control and Prevention at www.cdc.gov/ncidod/dhqp/gl isolation.html .

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 M-29: Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline.

Sterilize all biohazard waste before disposal.

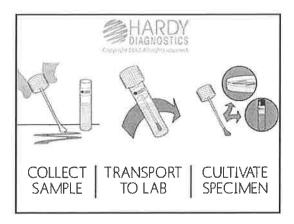
Refer to the keyword "Precautions", in the Hardy Diagnostics' software program HUGO™, for more information regarding general precautions when using culture media.

Refer to the keyword "MSDS", in the Hardy Diagnostics' software program HUGO™, for more information on handling potentially hazardous material.

PROCEDURE

Specimen Collection (1)

Aseptically collect sample. After removing the swab from its wrapper, moisten the tip in the Letheen Broth. 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 Letheen Broth 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 1.0ml and 0.1ml samples of Letheen Broth containing the sample. Incubate plates at 35 degrees C. for 48 hours, then calculate the number of colonies from, the 50cm ² sample area. ⁽²⁾ Letheen Broth can be used with 3M Petri FilmTM.

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 and/or serological tests be performed on colonies from pure culture for complete identification.

Refer to the keyword "Limitations", in the Hardy Diagnostics software program $HUGO^{TM}$, for more information regarding general limitations on culture media.

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

The following organisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			
		Time	Temperature	Atmosphere	Results
Staphylococcus aureus ATCC [®] 25923	A	18-48hr	35°C	Aerobic	Growth; turbidity
Escherichia coli ATCC [®] 25922	A	18-48hr	35°C	Aerobic	Growth; turbidity
Salmonella enterica ATCC [®] 14028	A	18-48hr	35°C	Aerobic	Growth; turbidity

USER QUALITY CONTROL

Check for signs of contamination and deterioration. Users of commercially prepared media may be required to perform quality control testing with at least one known organism to demonstrate growth or a positive reaction; and at least one organism to demonstrate inhibition or a negative reaction (where applicable). Refer to the following keywords, in the Hardy Diagnostics software program HUGOTM, for more information on QC: "Introduction to QC", and "QC of Finished Product". Also see listed references for more information.

* Refer to the keyword "Inoculation Procedures", in the Hardy Diagnostics software program HUGO™, for a description of inoculation procedures.

PHYSICAL APPEARANCE

Enviro TransTM Letheen Broth should appear clear with a slight opalescence, and light to medium amber in color,

REFERENCES

- 1. APHA Technical Committee on Microbiological Methods for Foods. 2001. *Compendium of Methods for the Microbiological Examination of Foods*, 4th ed. 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. Association of Official Analytical Chemists. 2005. Official Methods of Analysis, 18th ed. AOAC, Washington, D.C.

ATCC is a registered trademark of the American Type Culture Collection. Tween is a registered trademark of ICI Americas, Inc.

3M and Petri Film are trademarks of the 3M Corporation.

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

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