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Instructions for Use

HARDY DIAGNOSTICS
A Culture of Service™

RAPPAPORT-VASSILIADIS BROTH, USP

Cat. no. K246	Rappaport-Vassiliadis Broth, USP, 16x125mm Tube, 10ml	20 tubes/box

INTENDED USE

Hardy Diagnostics' Rappaport-Vassiliadis Broth, USP is recommended for the selective enrichment of *Salmonella* spp., and conforms to the Harmonized USP/EP/JP requirements.

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

SUMMARY

Rappaport Medium was initially developed by Rappaport et al. in 1956 as an alternative to Tetrathionate Broth for the enrichment of *Salmonella* . [(1)] This formulation features magnesium chloride to inhibit *Proteus* spp. and *Escherichia coli* ; malachite green to inhibit coliforms; and a high osmotic pressure and/or low pH to inhibit accompanying microbial flora other than *Salmonella* . In 1976, Vassiliadis et al. described a modification of Rappaport Medium called R10. [(2)] This formula features a reduced concentration of malachite green and an increased incubation temperature. It was later shown in 1989 by Peterz et al. that incubation at 41.5 +/- 0.5ºC. for 24 hours significantly improved the recovery of *Salmonella* spp. [(3)]

Rappaport-Vassiliadis Broth, USP is a modification of Rappaport-Vassiliadis R10 Broth and uses soy peptone as the nitrogen and vitamin source. Studies show that soy peptone enhances the growth of *Salmonella* spp. and counteracts the risk of potential Bovine Spongiform Encephalopathy (BSE) exposure associated with bovine derived products. Rappaport-Vassiliadis Broth, USP conforms to the Harmonized United States Pharmacopoeia (USP), European Pharmacopoeia (EU), and Japanese Pharmacopoeia (JP). [(4-7)] The medium selectively enriches for *Salmonella* spp.; although, malachite green may inhibit the growth of more sensitive strains of *Salmonella* , such as *S. typhi* and *S. choleraesuis* .

FORMULA

Ingredients per liter of deionized water:*

Magnesium Chloride, Anhydrous	13.4gm
Sodium Chloride	8.0gm
Soy Peptone	4.5gm
Dipotassium Phosphate	1.26gm
Monopotassium Phosphate	0.18gm
Malachite Green	0.036gm

Final pH 5.2 +/- 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. away from direct light. Media should not be used if there are any signs of deterioration, discoloration, contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing.

The expiration dating 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 quality control incubation times.

Refer to the document "Storage" on the Hardy Diagnostics Technical Document website 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." The "Guidelines 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 document "Precautions When Using Media" on the Hardy Diagnostics Technical Document website for more information.

Refer to the document SDS Search instructions on the Hardy Diagnostics website for more information.

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification.

Certain strains of *Salmonella* , such as *S. typhi* and *S. choleraesuis* , may be inhibited on this medium. Therefore, isolation techniques should include a variety of enrichment broths and selective media.

Refer to the document "Limitations of Procedures and Warranty" on the Hardy Diagnostics Technical Document website for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, swabs, applicator sticks, 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 Certificates of Analysis (CofA). The following organisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Salmonella enterica ATCC ® 14028**	J***	18-24hr	30-35°C	Aerobic	Growth
Staphylococcus aureus ATCC ® 6538**	B	24hr	30-35°C	Aerobic	Inhibited

* Refer to the document "Inoculation Procedures for Media QC" on the Hardy Diagnostics Technical Document website for more information.

** Recommended QC strains for User Quality Control according to the CLSI document M22 and/or USP/EP, when applicable.

***Tested in accordance with USP <62>

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 certificates of analysis (CofA) available from Hardy Diagnostics Certificates of Analysis website. In addition, refer to the following documents on the Hardy Diagnostics Technical Document website for more information on QC: "Introduction to Quality Control" and "Finished Product Quality Control Procedures," or see reference(s) for more specific information.

PHYSICAL APPEARANCE

Rappaport-Vassiliadis Broth, USP should appear clear and blue in color.

REFERENCES

1. Rappaport, F., N. Konforti, and B. Navon. 1956. A New Enrichment Medium for Certain Salmonellae. *J. Clin. Pathol.* ; 9:261-266.

2. Vassiliadis, P., D. Trichoppoulos, A. Kalandidi, and E. Xirouchaki. 1978. Isolation of Salmonellae from Sewage with a New Procedure of Enrichment. *J. Appl. Bacteriol.* ; 44:233-239.

3. Peterz, M. C. Wiberg, and P. Norberg. 1989. The Effect of Incubation Temperature and Magnesium Chloride Concentration on Growth of *Salmonella* in Homemade and Commercially Available Dehydrated Rappaport-Vassiliadis Broths. *J. Appl. Bacteriol.* ; 66:523-528.

4. United States Pharmacopeial Convention. 2007. The United States Pharmacopeia, Amended Chapters 61, 62, 111. The United States Pharmacopeial Convention, Rockville, MD.

5. The Official Compendia of Standards. *USP-NF* . United States Pharmacopeial Convention, Rockville, MD.

6. Directorate for the Quality of Medicines of the Council of Europe (EDQM). 2007. The European Pharmacopoeia, Amended Chapters 2.6.12, 2.6.13, 5.1.4, Council of Europe, 67075 Strasbourg Cedex, France.

7. Japanese Pharmacopoeia. 2007. Society of Japanese Pharmacopoeia. Amended Chapters 35.1, 35.2, 7. The Minister of Health, Labor, and Welfare.

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

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

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

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

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

13. American Public Health Association. *Standard Methods for the Examination of Water and Wastewater,* APHA, Washington, D.C.

14. U.S. Food and Drug Administration. *Bacteriological Analytical Manual.* AOAC, Arlington, VA. www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm

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

16. Association of Official Analytical Chemists. 2012. *Official Methods of Analysis* , 19th ed. AOAC, Washington, D.C.

17. The Official Compendia of Standards. USP General Chapter <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms. *USP-NF* . United States Pharmacopeial Convention Inc., Rockville, MD.

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

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