IFU

Instructions for Use

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 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.

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.

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" 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 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	
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" 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 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

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

REFERENCES

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

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

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

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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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