~ CERTIFICATE OF ANALYSIS ~

PREPARED CULTURE MEDIA, USP

Product Name:	Rappaport Vassiliadis, 10ml, USP
Container Size:	16x125mm tube with cap
Catalog No:	K246
Lot No:	481015
Manufacture Date:	3/12/2021
Expiration Date:	12/7/2021
Certificate Date:	3/18/2021

This product lot is supplied by Hardy Diagnostics in accordance with its quality management system, which complies with the U.S. Food and Drug Administration's (FDA's) Quality Systems Regulation (QSR) and current Good Manufacturing Practices (cGMP) contained in Title 21 Part 820 of the Code of Federal Regulations (CFR). The company's manufacturing establishments are registered, and its medical devices are listed with the FDA. Hardy Diagnostics' quality management system is certified to ISO 13485 for medical devices.

Representative samples of this lot were tested and found to meet the specifications listed on this certificate and published on the Instructions for Use (IFU) for this product as located on the Hardy Diagnostics website, where applicable. In addition, this lot conforms to the quality control standards listed in the reference document, where indicated. End-users of commercially prepared culture media and reagents should perform QC testing in accordance with applicable government regulatory agencies and in compliance with accreditation requirements. Hardy Diagnostics recommends end-user to check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform QC testing to demonstrate a positive reaction and/or a negative reaction, if applicable.

Performance Testing

Test Organism	Strain Number	Results
Salmonella enterica	ATCC®14028*	Growth
Staphylococcus aureus	ATCC®6538*	Inhibited

* ATCC® is a registered trademark of the American Type Culture Collection, Manassas, VA 20108, USA.

Acceptable growth and/or inhibitory specifications with appropriate organisms as described in this document were verified at the time of release.

Physical Characteristics

Appearance: Clear, blue; with no precipitate or debris

Consistency: Liquid

Fill: 10.0 ± 0.2ml

pH: 5.2 ± 0.2 at room temperature.

Note: The pH stated was determined at room temperature shortly after the date of manufacture. The pH may vary within the stated range depending on the age of the product, the probe used, and the type of pH meter used by the end user.

Microbial Load Testing

Acceptable microbial load (as described in the "Test for Microbial Load" section of the *Finished Product Quality Control*) was verified at the time of release. Please view the *Finished Product Quality Control* document for more information.

Ingredient Origin

All ingredients of animal origin in this lot have been sourced from Bovine Spongiform Encephalopathy (BSE)-free and Transmissible Spongiform Encephalopathy (TSE)-free countries as identified by the United States Department of Agriculture (USDA). This product complies with 9 CFR 94.18 *"Restrictions on importation of meat and edible products from ruminants due to bovine spongiform encephalopathy."*

Manufacturing Facility

Hardy Diagnostics maintains manufacturing facilities in Santa Maria, California and Springboro, Ohio. The

manufacturing location can be determined from the lot number. If the lot number begins with the number 1, 2, or 3, the product was manufactured in Springboro, Ohio; if the lot number begins with the number 4 or higher, the product was manufactured in Santa Maria, California.

Sue Pruett, RAC
Director of Quality
Hardy Diagnostics

References

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

COA-11464[B]

1430 West McCoy Lane, Santa Maria, CA 93455, USA
429 South Pioneer, Springboro, OH 45066, USA
Phone: (800) 266-2222

Distribution Centers:
California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

Website: www.HardyDiagnostics.com Email: Sales@HardyDiagnostics.com

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