



~ CERTIFICATE OF ANALYSIS ~

PREPARED MEDIA, TEST KITS, AND REAGENTS


Product Name:	BUG with Blood
Container Size:	10x100mm monoplate
Catalog No:	71102
Lot No:	463288
Manufacture Date:	6/16/2020
Expiration Date:	9/14/2020
Certificate Date:	6/23/2020

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. 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-users check for signs of contamination and deterioration and, if dictated by laboratory QC procedures or regulation, perform quality control testing to demonstrate positive reaction and/or a negative reaction, if applicable.

Performance Testing

Test Organism	Strain Number	Results
<i>Streptococcus pyogenes</i>	ATCC® 19615*	Growth
<i>Streptococcus pneumoniae</i>	ATCC® 6305*	Growth
<i>Staphylococcus aureus</i>	ATCC® 25923*	Growth
<i>Escherichia coli</i>	ATCC® 25922*	Growth

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

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

Physical Characteristics

Appearance: Opaque, cherry red; with no precipitate, chips, or debris

Consistency: Firm, not soft

pH: 7.3 ± 0.1 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 both 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.



Andre Hsiung
Director of Technical Services
Hardy Diagnostics

References

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

COA-10041[A]



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