~ CERTIFICATE OF ANALYSIS ~

PREPARED MEDIA, TEST KITS, AND REAGENTS

Product Name:	GN/GP Inoculating Fluid
Container Size:	20x150mm tube with cap
Catalog No:	72101
Lot No:	426885
Expiration Date:	10/30/2019
Certificate Date:	11/07/2018

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 quality control procedures or regulation, perform quality control testing to demonstrate positive reaction and/or a negative reaction, if applicable.

Performance Testing

This product is intended to be used as a diluent or to prepare bacterial suspensions and is not for growth promotion; therefore performance testing with microorganisms is not indicated.

Physical Characteristics

Appearance: Clear
Color: Colorless
Consistency: Liquid
Fill: 20.0 ± 1.0ml

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. *Finished Product Quality Control* is published in "Technical Documents and IFUs" under the "Technical Support" menu located at www.HardyDiagnostics.com.

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, OH. Each lot's 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-10044[A]

21124 Cabot Blvd, Hayward, CA 94545
Phone: 510-785-2564 Orders: 800-284-4949
Fax: 510-782-4639 www.biolog.com

SOP-2128S [B]