CRITERION DEHYDRATED CULTURE MEDIA

~ CERTIFICATE OF ANALYSIS ~

Product Name:	Dextros Tryptone Agar
Container Size:	500gm
Catalog No:	C5621
Lot No:	510593
Expiration Date:	11/30/2023
Certificate Date:	7/25/2022

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 the powder 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.

Dehydrated culture media requires further preparation and/or supplementation in order to meet the performance characteristics indicated below. Unless otherwise listed, this product is not labeled as sterile and requires additional processing to achieve the user desired sterility assurance level.

Performance Testing

Test Organism	Strain Number	Results
Bacillus stearothermophilus	ATCC® 12980*	Growth; color change from purple to yellow

* 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 of the powder lot.

Physical Characteristics

Consistency: Homogeneous and free flowing

Solubility: Soluble in distilled or deionized water; may require heat to dissolve completely

Appearance of powder: Light green

Appearance of product after re-hydration: Clear, purple; with no precipitate, chips or debris

pH: 6.7 ± 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.

Ingredient Origin

All ingredients of animal origin in this lot have been sourced from Bovine Spongiform Encephalopathy (BSE)-free and other 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.

Paul Richmond

QC Manager
Hardy Diagnostics

References

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

2. *United States Pharmacopoeia - National Formulary* (USP-NF). General Chapters: <61> and <62>. Rockville, MD: United States Pharmacopeial Convention.

COA-10327[A]

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