

Certificate of Analysis

Becton Dickinson and Company BD Diagnostic Systems PO Box 999

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Product Name : BOTTLE NUTRIENT BROTH 500G

Catalog Number : 234000 Manufacture Date : 2011/06/29

Batch Number : 1180366
Expiration Date : 2016/06/17

01. Dehydrated Medium Appearance: Medium tan, free-flowing, homogeneous

02. Solubility: 0.8% solution, soluble in distilled or deionized water

03. Solution Appearance: Light to medium amber, clear

04. Certificate of Suitability issued by the European Directorate for the Quality of Medicines (EDQM): CEP 2000-248

05. Cultural Response: Medium was prepared per label instructions. Tubes were inoculated with the test organisms and incubated at $35 \pm 2^{\circ}\text{C}$ for 18-24 hours.

TEST ORGANISMS ATCC® RECOVERY Escherichia coli 25922 good Staphylococcus aureus 25923 good

| Characteristic | Unit | Value | LowLimit | HighLimit |
|-----------------------------------|------|----------------|----------|-----------|
| pH at 25°C : Bulk Lot Number : | _ | 6.9 1116732 | 6.6 | 7.0 |

| Animal Source | Country of | Tissue Category | | |
|---------------|------------|-----------------|-----|-----|
| | Origin | BIC | SIC | ABC |
| Porcine | USA | III | III | IB |
| Bovine | Australia | IV | IV | IB |
| Bovine | USA | IV | IV | IC |
| Bovine | USA | III | IV | IC |
| Bovine | USA | I | IV | IC |

The Batch Number on this certificate is synonymous with the Lot Number shown on the product label.

BD Diagnostic Systems (BDDS) is an ISO 13485:2003 and ISO 9001:2008 Registered facility. BDDS products are manufactured in facilities registered with the United States Food and Drug Administration (FDA), and are regulated by the FDA's Quality System Regulations (QSRs). This product met BDDS stringent quality standards at time of batch/lot release. Any test results reported on this certificate were obtained at time of release.

BD Diagnostic Systems' Certificates of Analysis (COA) typically are set up to contain animal origin information for finished products manufactured using materials of animal origin. The animal origin

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information may be contained in the animal source table and/or in one or more of the additional paragraphs found on the COA. This information is a compilation of animal origin data from the individual lots of raw materials used to manufacture the batch of BD Diagnostic Systems (BDDS) finished product for which the COA was created.

At the time the BDDS Certificate of Analysis is created and sent to the Internet website address at http://www.bd.com/regdocs/, the animal origin information as provided to BDDS by its suppliers is pulled into the certificate as it is created by the BDDS automated certificate system.

At times, suppliers notify BDDS of new and/or additional information they have received from their raw material suppliers that modifies the animal origin information for lots previously provided to BDDS. When this situation occurs, BDDS updates the animal origin information in the automated certificate system, recreates the affected finished product COAs for batches within expiration date, and sends them to the Internet website where they replace the prior certificate and are immediately available to customers.

Customers enrolled in BD Diagnostic Systems' Automated Change Notification Program will be notified of the changes described above.

For complete details refer to "BD Position Statement - BD Diagnostic-Diagnostic Systems, COA Animal Origin Information Position Statement", located on the Internet website address at http://www.bd.com/regdocs/.

John Gerlich Vice President,

Quality Management and Regulatory Compliance

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