

Certificate of Analysis

Becton Dickinson and Company BD Diagnostic Systems PO Box 999

Sparks MD 21152-0999 US Page: 1 of 3

Product Name : BOTTLE MUELLER HINTON AGAR 500G

Catalog Number : 225250 Manufacture Date : 2011/02/24

Batch Number : 1124453
Expiration Date : 2016/01/31

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

- 02. Solubility: 3.8% solution, soluble in distilled or deionized water on boiling
- 03. Solution Appearance: Light to medium amber, slightly opalescent, may have a slight precipitate
- 04. Certificate of Suitability issued by the European Directorate for the Quality of Medicines (EDQM): CEP 2000-317
- 05. Cultural Response: Medium was prepared per label instructions. Plates were inoculated and antibiotic disks were tested as recommended by current CLSI. The diameters of the zones around designated disks with the appropriate test culture fell within the CLSI recommended zone ranges.

TEST ORGANISMS	ATCC®
Enterococcus faecalis	33186
Escherichia coli	25922
Pseudomonas aeruginosa	27853
Staphylococcus aureus	25923

Characteristic	Unit	Value	LowLimit	HighLimit
pH at 25°C : Bulk Lot Number:	-	7.3 1048947	7.2	7.4

Animal Source	Country of	Tissue Category		
	Origin	BIC	SIC	ABC
Avian	Taiwan	IV	IV	NDF
Porcine	USA	III	III	В
Bovine	New Zealand	IV	IV	С
Bovine	USA	III	IV	С
Bovine	USA	IV	IV	С

For an avian origin ingredient used in the manufacture of this product, the BD supplier is not able to confirm animal health. The supplier has confirmed that the ingredient undergoes extensive processing that includes exposure to strong acid, filtration, crystallization, and drying.

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

Creation Date: 2011/05/27 15:24:55



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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 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/.

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John Gerlich Vice President,

Quality Management and Regulatory Compliance

Signature Date: 2011/05/27

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