



Becton Dickinson and Company
BD Diagnostic Systems
PO Box 999
Sparks MD 21152-0999 US

Certificate of Analysis

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Product Name : BOTTLE SABOURAUD DEXTROSE AGAR 500G
Catalog Number : 210950 **Manufacture Date** : 2011/06/21
Batch Number : 1200386
Expiration Date : 2016/04/30

01. Dehydrated Medium Appearance: Light beige, free-flowing, homogeneous
02. Solubility: 6.5% solution, soluble in distilled or deionized water on boiling
03. Solution Appearance: Light to medium amber, very slightly to slightly opalescent
04. USP/EP/JP Performance specifications where applicable

TEST ORGANISMS	ATCC®	INOCULATION	RECOVERY	TEMP	INCUBATION
Aspergillus niger	16404	<100 CFUs	growth	20-25°C	up to 5 days
Candida albicans	10231	<100 CFUs	growth	20-25°C	5 days
Candida albicans	10231	<100 CFUs	growth	30-35°C	2 days

05. Cultural Response: Medium was prepared per label instructions. Plates were inoculated with the test organisms and incubated at 30 ± 2°C for 18-48 hours (or up to 7 days for Trichophyton and Aspergillus).

TEST ORGANISMS	ATCC®	RECOVERY
Saccharomyces cerevisiae	9763	good
Trichophyton mentagrophytes	9533	good

06. Residual Solvents (CPMP/ICH/283/95): Typical Analysis for Sabouraud Dextrose Agar indicates that there is less than 5000 ppm of Acetone. No other solvents were detected during analysis.

Characteristic	Unit	Value	LowLimit	HighLimit
pH at 25°C :		5.6	5.4	5.8
Bulk Lot Number:	-	1160596		

Animal Source	Country of Origin	Tissue Category	BIC	SIC	ABC
Bovine	Australia	IV	IV	MLK	
Porcine	USA	III	III	IB	
Porcine	USA	II	II	IB	

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

Creation Date: 2011/07/29 16:02:20



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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: 2011/07/29