



Certificate of Analysis

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

Page: 1 of 2

Product Name : Bottle Sabouraud Dextrose Agar 500G
Catalog Number : 210950 **Manufacture Date**: 2018/04/19
Batch Number : 8141573
Expiration Date : 2023/02/28

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. Meets USP/EP/JP performance specifications where applicable (harmonized chapters for "Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests" and "Microbiological Examination of Non-Sterile Products: Tests for Specified Organisms"). Growth results below are representative of recovery between 50% and 200% and are comparable to that of a previously released batch.

TEST ORGANISMS	ATCC®	INOCULATION	RECOVERY	TEMP	INCUBATION
Aspergillus brasiliensis	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. Meets ISO11133 performance specifications: plates were inoculated with approximately 100 CFUs and incubated at 25 ± 1°C for up to 5 days for A. brasiliensis and 2 days for S. cerevisiae. Growth results below represent recovery of ≥ 70% as compared to a previously released control batch.

ORGANISMS	ATCC®	RESULT
Aspergillus brasiliensis	16404	growth
Saccharomyces cerevisiae	9763	growth

06. 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

Characteristic	Unit	Value	Lower Limit	Upper Limit
pH at 25°C :		5.7	5.4	5.8
Bulk Lot Number :	-	8102621		

Animal source	Country of Origin	Tissue Category
		BIC SIC ABC

Creation Date: 2018/06/06 16:37:33



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Bovine	New Zealand	IV	IV	MLK
Porcine	USA	II	II	IB
Porcine	USA	III	III	IB

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

BD Diagnostics - Diagnostic Systems products are manufactured in ISO 9001:2008 Registered facilities. In addition, BD Diagnostics - Diagnostic Systems facilities are registered with the United States Food and Drug Administration (FDA), are regulated by the FDA's Quality System Regulations (QSRs), and are also ISO 13485:2003 Registered. 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. This material is not for human or animal consumption.

BD Diagnostics - Diagnostic Systems' Certificates of Analysis (COA) typically contain animal origin information when products are manufactured using materials of animal origin. This information may be contained in the animal source table and/or in one or more of the additional paragraphs found on the COA. Following Quality Control release, the COA is created and published at <http://www.bd.com/regdocs>. For each batch of finished product that contains animal origin raw materials, the COA shows the animal origin data from the individual lots of animal origin raw materials used, as provided by the raw material suppliers.

At times, suppliers notify BD Diagnostics - Diagnostic Systems 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 BD. See "COA Animal Origin Information Position Statement" located at <http://www.bd.com/regdocs> under "Position Statements" for the impact that retrospective information has on COAs and on customers enrolled in the BDDS and BDAB Automated Change Notification Program.

For complete details on animal origin information, refer to "BD Position Statement - BD Diagnostic-Diagnostic Systems, COA Animal Origin Information Position Statement", at <http://www.bd.com/regdocs> under "Position Statements".

Manufacturer is Becton Dickinson and Company, 7 Loveton Circle, Sparks, MD 21152 USA. To determine location of manufacturing for this product, please see www.bd.com/ds/technicalCenter/regulatory.asp.

Megan Reeher
Senior Manager Quality Assurance

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