

Product Name

## Certificate of Analysis

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of

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

Catalog Number : 210950 Manufacture Date : 2016/08/08

Batch Number : 6313683
Expiration Date : 2021/06/30

01. Dehydrated Medium Appearance: Light beige, free-flowing, homogeneous

02. Solubility: 6.5% solution, soluble in distilled or deionized water on boiling

: Bottle Sabouraud Dextrose Agar 500G

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

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. Cultural Response: Medium was prepared per label instructions. Plates were inoculated with the test organisms and incubated at  $30 \pm 2^{\circ}\text{C}$  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 : Bulk Lot Number :	-	5.7 6209644	5.4	5.8

Animal source	Country of	Tissue Category				
	Origin	BIC	SIC	ABC		
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

Creation Date: 2016/11/28 16:35:25



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Becton Dickinson and Company
BD Diagnostic Systems
PO Box 999

Sparks MD 21152-0999 US Page: 2 of

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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.

Charlotte Dannenfelser

BD Life Sciences - Diagnostic Systems

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Quality Director, Microbiology

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