

Certificate of Analysis

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

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Product Name : Bottle Mannitol Salt Agar BBL 500G

Catalog Number : 211407 Manufacture Date: 2018/12/20

Batch Number : 9038791
Expiration Date : 2022/12/31

01. Dehydrated Medium Powder Appearance: Fine, homogeneous, free of extraneous material and may contain many light to dark red flecks

02. Solubility (111g/L): Soluble in distilled or deionized water on boiling.

On DOILING.

03. Prepared Plate Appearance: Medium to dark, red to rose; clear to slightly hazy

04. Meets USP/EP/JP performance specifications where applicable: (harmonized chapters for "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.

CULTURE ATCC® INOC RESULT TEMP INCUBATION Staphylococcus aureus 6538 <100 CFUs growth* 30-35°C 18 Hrs yellow zones* 30-35°C 48-72 Hrs

Escherichia coli 8739 >100 CFUs no growth* 30-35°C 72 Hrs

05. Biological Performance: Medium was prepared per label directions. Plates were inoculated with the test organisms, incubated at 33-37°C for 42-48 hours and gave cultural responses as indicated:

CULTURE ATCC® RESULT

Proteus mirabilis 12453 Partial to complete inhibition

Staphylococcus aureus 25923 Light to heavy growth,

yellow zones at 48 hours

Staphylococcus epidermidis 12228 Light to heavy growth, red zones at 48 hours

Characteristic	Unit	Value	Lower Limit	Upper Limit
pH at 25°C : Bulk Lot Number :	_	7.5 8351728	7.2	7.6

Animal source	Country of	Tissue Category		
	Origin	BIC	SIC	ABC
Bovine	New Zealand	IV	IV	MLK
Bovine	USA	II	II	IB
Bovine	USA	III	III	IB
Bovine	USA	III	IV	IC
Bovine	USA	IV	IV	IB
Equine	Mexico	II	II	IB
Equine	Mexico	IV	IV	IB
Porcine	Canada	IV	IV	IB
Porcine	USA	II	II	IB

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Porcine USA III III IB
Porcine USA IV IV 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 13485:2016 Registered facilities. In addition, BD Diagnostics - Diagnostic Systems facilities are 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. 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 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 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 Diagnostics - Diagnostic Systems, Animal Origin Position Statement", at 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/en-us/support/bd-life-sciences-diagnostic-systems-customer-regulatory-support-information.

Stability data for this product is on file.

The pH stated was obtained at the time of release, and the pH may vary within the stated range depending on the age of the product and the type of pH meter and probe used.

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Senior Manager Quality Assurance

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