



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

Certificate of Analysis

Product Name : BOTTLE MANNITOL SALT AGAR BBL 500G
Catalog Number : 211407 **Manufacture Date** : 2011/03/29
Batch Number : 1171001
Expiration Date : 2015/03/31

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.
03. Prepared Medium Appearance: Medium to dark, red to rose; clear to slightly hazy
04. USP/JP/EP performance specifications where applicable

CULTURE	ATCC®	INOC	RESULT*	TEMP	INCUBATION
Staphylococcus aureus	6538	<100 CFUs	growth	30-35°C	18 Hrs
Escherichia coli	8739	>100 CFUs	no growth	30-35°C	72 Hrs

* Growth results above are comparable to a previously released batch.

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	LowLimit	HighLimit
pH at 25°C :		7.4	7.2	7.6
Bulk Lot Number :	-	1082700		

Animal Source	Country of Origin	Tissue Category		
		BIC	SIC	ABC
Bovine	Australia	IV	IV	C
Bovine	New Zealand	IV	IV	C
Porcine	USA	III	III	B
Porcine	USA	IV	IV	C
Bovine	USA	II	II	B
Bovine	USA	IV	IV	C
Porcine	Canada	III	III	B
Porcine	Canada	II	II	B
Porcine	USA	II	II	B



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Porcine	Canada	IV	IV	C
Equine	Mexico	II	II	B
Equine	Mexico	IV	IV	C
Bovine	USA	III	IV	C

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

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



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<http://www.bd.com/regdocs/>.

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.

John Gerlich
Vice President,
Quality Management and
Regulatory Compliance
Signature Date: 2011/06/30