



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

Certificate of Analysis

Product Name : BOTTLE MACCONKEY AGAR 500G
Catalog Number : 212123 **Manufacture Date** : 2011/04/05
Batch Number : 1108423
Expiration Date : 2016/02/29

- 01. Dehydrated Medium Appearance: Pink to pinkish beige, free-flowing, homogeneous
- 02. Solubility: 5.0% solution, soluble in distilled or deionized water on boiling
- 03. Prepared Media Appearance: Reddish-purple, slightly opalescent
- 04. Meets USP/EP/JP performance specification

CULTURE	ATCC®	INOC	TEMP	RESULT*
Escherichia coli	8739	<100 CFUs	30-35°C	growth
INCUBATION		INDICATIVE		
18 Hours		Yes		

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

- 05. Biological Performance: Medium was prepared per label instructions. Plates were inoculated with the test organisms and incubated at 35 ± 2°C for 18-24 hours (and 40-48 hours for E. coli).

TEST ORGANISMS	ATCC®	RECOVERY	COLONY COLOR
Enterococcus faecalis	29212	marked to complete inhibition	- - - - -
Escherichia coli	25922	good	pink to red with bile ppt.
Proteus mirabilis	12453	good	colorless
Salmonella typhimurium	14028	good	colorless

Characteristic	Unit	Value	LowLimit	HighLimit
pH at 25°C :		7.3	6.9	7.3
Bulk Lot Number:	-	1081484		

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



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Porcine	USA	II	II	B
Porcine	Canada	IV	IV	C
Porcine	USA	IV	IV	C
Equine	Mexico	II	II	B
Equine	Uruguay	II	II	B
Equine	Mexico	IV	IV	C
Equine	Uruguay	IV	IV	C
Bovine	Australia	IV	IV	NDF
Bovine	Brazil	IV	IV	NDF
Bovine	India	IV	IV	NDF
Bovine	New Zealand	IV	IV	NDF
Bovine	USA	IV	IV	NDF
Ovine	New Zealand	IV	IV	NDF

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



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Page: 3 of 3

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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/>.

John Gerlich
Vice President,
Quality Management and
Regulatory Compliance
Signature Date: 2011/05/11