



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

Certificate of Analysis

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Product Name : BOTTLE BACTO TSB CASEIN MED 500G
Catalog Number : 211825 **Manufacture Date** : 2011/05/16
Batch Number : 1153875
Expiration Date : 2016/04/30

01. Dehydrated Medium Appearance: Light beige, free-flowing, homogeneous
02. Solubility: 3% solution, soluble in distilled or deionized water
03. Solution Appearance: Light amber, clear
04. Medium was tested per European (EP) and United States Pharmacopeia (USP) Growth Promotion requirements. Tubes were inoculated with < 100 CFUs. Tubes were incubated aerobically for 3 days and up to 5 days for (*) organisms and gave cultural responses as indicated.

TEST ORGANISMS	ATCC®	RECOVERY	TEMPERATURE	INCUBATION
*Asperigillus brasiliensis	16404	growth	20-25°C	Up to 5 days
Bacillus subtilis	6633	growth	30-35°C, 20-25°C	Up to 3 days
*Candida albicans	10231	growth	20-25°C	Up to 5 days
Escherichia coli	8739	growth	30-35°C	Up to 3 days
Pseudomonas aeruginosa	9027	growth	30-35°C	Up to 3 days
Salmonella typhimurium	14028	growth	30-35°C	Up to 3 days
Staphylococcus aureus	6538	growth	30-35°C	Up to 3 days

05. Cultural Response: Medium was prepared per label instructions. Tubes were inoculated with the test organisms and incubated at the temperatures specified for 18-48 hours, or up to 72 hours if necessary.

TEST ORGANISMS	ATCC®	TEMPERATURE	RECOVERY
Neisseria meningitidis	13090	30-35°C	fair to good
Staphylococcus epidermidis	12228	30-35°C	good
Streptococcus pneumoniae	6305	30-35°C	good
Streptococcus pyogenes	19615	30-35°C	good

06. Residual Solvents (CPMP/ICH/283/95): Typical Analysis for Tryptic Soy Broth indicates that there is less than 5000 ppm of Acetone. No other solvents were detected during analysis.

Characteristic	Unit	Value	LowLimit	HighLimit
Loss on Drying :	%	1	0	5
pH at 25°C :		7.4	7.1	7.5
Bulk Lot Number :	-	1125333		



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

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.

Creation Date: 2011/06/21 17:20:12



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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: 2011/06/21