

## **Certificate of Analysis**

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

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Product Name : Bottle Bacto TSB Casein Med 500G

Catalog Number : 211825 Manufacture Date :2016/09/07

Batch Number : 6271720 Expiration Date : 2021/07/31

- 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), Japan (JP), 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	<b>ATCC®</b>	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	<b>ATCC®</b>	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	Lower Limit	Upper Limit
Loss on Drying : pH at 25°C : Bulk Lot Number :	%	2 7.3 6224918	0 7.1	5 7.5

Animal source	Country of	Tis	ssue Catego	ory	
	Origin	BIC	SIC	ABC	
Bovine Porcine	New Zealand USA	IV III	IV III	MLK IB	

Creation Date: 2016/10/14 15:06:30



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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 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.

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