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

Certificate of Analysis

Product Name : BOTTLE TRYPTIC SOY AGAR 500G
Catalog Number : 236950 **Manufacture Date :** 2011/02/16
Batch Number : 1074969
Expiration Date : 2015/12/31

---

01. Dehydrated Medium Appearance: Light beige, free-flowing, homogeneous
02. Solubility: 4.0% solution, soluble in distilled or deionized water on boiling
03. Solution Appearance: Light amber, slightly to moderately opalescent
04. Plate Appearance: Clear to slightly opalescent, without precipitate
05. CAMP Test: Streptococcus agalactiae ATCC® 12386 gave a + reaction and Streptococcus pyogenes ATCC® 19615 gave a - reaction when tested with Staphylococcus aureus ATCC® 33862.
06. USP/EP/JP Growth Promotion test performance specification where applicable.

TEST ORGANISMS	ATCC®	INOC	RECOVERY	TEMP	INCUBATION
Aspergillus niger	16404	<100 CFUs	growth	30-35˚C	Up to 5 days
Bacillus subtilis	6633	<100 CFUs	growth	30-35˚C	Up to 3 days
Candida albicans	10231	<100 CFUs	growth	30-35˚C	Up to 5 days
Escherichia coli	8739	<100 CFUs	growth	30-35˚C	Up to 3 days
Pseudomonas aeruginosa	9027	<100 CFUs	growth	30-35˚C	Up to 3 days
Salmonella typhimurium	14028	<100 CFUs	growth	30-35˚C	Up to 3 days
Staphylococcus aureus	6538	<100 CFUs	growth	30-35˚C	Up to 3 days

07. Cultural Response: Medium was prepared per label instructions. Plates with and without 5% sheep blood (SB) were inoculated with the test organisms and incubated under 5-10% CO2 at 35 ± 2˚C for 18-48 hours.

TEST ORGANISMS	ATCC®	RECOVERY		HEMOLYSIS
		PLAIN	w/SB	
Escherichia coli	25922	good	good	beta
Neisseria meningitidis	13090	good	good	none
Staphylococcus aureus	25923	good	good	beta
Streptococcus pneumoniae	6305	good	good	alpha
Streptococcus pyogenes	19615	good	good	beta

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

Characteristic	Unit	Value	LowLimit	HighLimit
pH at 25˚C :		7.3	7.1	7.5
Bulk Lot Number :	-	1033722		

Creation Date: 2011/03/31 14:33:49

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

Certificate of Analysis

Product Name : BOTTLE TRYPTIC SOY AGAR 500G
Catalog Number : 236950 **Manufacture Date :** 2011/02/16
Batch Number : 1074969
Expiration Date : 2015/12/31

Animal Source	Country of Origin	Tissue Category BIC	SIC	ABC
Porcine	USA	III	III	B
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.

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

Certificate of Analysis

Product Name	: BOTTLE TRYPTIC SOY AGAR 500G		
Catalog Number	: 236950	**Manufacture Date :**	2011/02/16
Batch Number	: 1074969		
Expiration Date	: 2015/12/31		

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: 2011/03/31