



# 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 Tryptic Soy Agar 500G  
**Catalog Number** : 236950 **Manufacture Date**: 2018/07/09  
**Batch Number** : 8227560  
**Expiration Date** : 2023/06/30

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. Meets USP/EP/JP Growth Promotion test performance specifications where applicable (harmonized chapter for "Microbiological/ Examination of Non-Sterile Products: Microbial Enumeration Tests"). Growth results below are representative of recovery between 50% and 200% and are comparable to that of a previously released batch.

TEST ORGANISMS	ATCC®	INOC	RECOVERY	TEMP	INCUBATION
Aspergillus brasiliensis	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. Meets ISO11133 performance specifications: plates were inoculated with approximately 100 CFUs and incubated at 30 ± 1°C and 37 ± 1°C for up to 3 days. Growth results below represent recovery of >= 70% as compared to a previously released control batch.

ORGANISMS	ATCC®	RESULT
Bacillus cereus	11778	growth
Bacillus subtilis	6633	growth
Escherichia coli	8739	growth
Listeria monocytogenes	13932	growth
Staphylococcus aureus	25923	growth

08. 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

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Characteristic	Unit	Value	Lower Limit	Upper Limit
pH at 25°C :		7.3	7.1	7.5
Bulk Lot Number :	-	8176778		

Animal source	Country of Origin	Tissue Category		
		BIC	SIC	ABC
Bovine	New Zealand	IV	IV	MLK
Porcine	USA	III	III	IB

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

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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](http://www.bd.com/ds/technicalCenter/regulatory.asp).

*Megan Reeher*

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