



# Certificate of Analysis

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

**Product Name** : Bottle Columbia Agar Base 500G  
**Catalog Number** : 211124 **Manufacture Date**: 2018/06/22  
**Batch Number** : 8206968  
**Expiration Date** : 2022/05/31

- 01. Dehydrated Medium Powder Appearance: Fine, homogeneous and free of extraneous material.
- 02. Solubility (42.5 g/L): Soluble in distilled or deionized water on boiling.
- 03. Prepared Plain Plate Appearance: hazy. Prepared Blood Plate Appearance: red; opaque.
- 04. Meets USP/EP/JP performance specifications where applicable: (harmonized chapters for "Microbiological Examination of Non-Sterile Products: Tests for Specified Organisms"). Growth results below are representative of recovery between 50% and 200% and are comparable to that of a previously released batch.

CULTURE	ATCC®	INOC	RESULT	TEMP	INCUBATION
Clostridium sporogenes	11437	<100 CFUs	growth	30-35°C	48 Hrs
Clostridium sporogenes	19404	<100 CFUs	growth	30-35°C	48 Hrs

- 05. Biological Performance: Medium was prepared per label directions. Plates were inoculated with the test organisms, incubated at 33-37°C under appropriate atmospheric conditions for 48 hours, at 40-44°C for 48-72 hours for (\*) organisms and gave cultural responses as indicated:

CULTURE	ATCC®	RESULT
Without added 5% Defibrinated Sheep Blood		
Pseudomonas aeruginosa	10145	Light to heavy growth
Shigella flexneri	12022	Light to heavy growth
Staphylococcus aureus	25923	Light to heavy growth
Streptococcus pneumoniae	6305	Light to heavy growth
With added 5% Defibrinated Sheep Blood		
*Campylobacter jejuni	33291	Light to heavy growth
*Campylobacter jejuni	33292	Light to heavy growth
Candida albicans	10231	Light to heavy growth
Escherichia coli	25922	Light to heavy growth within 24 hours
Listeria monocytogenes	19115	Light to heavy growth

Characteristic	Unit	Value	Lower Limit	Upper Limit
pH at 25°C :		7.3	7.1	7.5
Bulk Lot Number :	-	8130915		

Animal source	Country of Origin	Tissue Category		
		BIC	SIC	ABC
Bovine	New Zealand	IV	IV	IB



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Bovine	New Zealand	IV	IV	MLK
Porcine	USA	II	II	IB
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 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).

Stability data for this product is on file.

The pH stated was obtained at the time of release, and the pH may vary within the stated range depending on the age of the product and the type of pH meter and probe used.



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*Megan Reeher*

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Senior Manager Quality Assurance