



# Certificate of Analysis

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

**Product Name** : Plate Campy Cefex Agar 100 Ea  
**Catalog Number** : 292487 **Manufacture Date**: 2018/08/13  
**Batch Number** : 8212779  
**Expiration Date** : 2018/10/19

PPM Release Testing

01. Plate Appearance: Medium red to brown and translucent to trace hazy
02. Gel Strength: Firm
03. Bioburden: Passed inspection after three days
04. Biological Performance: Samples were inoculated with 1.00E+03 to 1.00E+04 CFU (direct for ATCC 16404) of the test organisms, incubated at 40-44°C for 36-48 hours (ATCC 16404 incubated at 20-25°C for 3 days) under appropriate atmospheric conditions and gave cultural responses as indicated:

CULTURE	ATCC®	RESULT
Aspergillus brasiliensis	16404	Inhibition (partial to complete)
Campylobacter jejuni	33291	Moderate to heavy growth
Campylobacter jejuni	33292	Moderate to heavy growth
Enterococcus faecalis	29212	Inhibition (partial to complete)
Escherichia coli	25922	Inhibition (partial to complete)
Proteus mirabilis	12453	Inhibition (partial to complete)
Pseudomonas aeruginosa	10145	Inhibition (partial to complete)

Characteristic	Unit	Value	Lower Limit	Upper Limit
pH at 25°C :		7.0	6.8	7.2

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

The Batch Number on this certificate is synonymous with the Lot Number shown on the product label.



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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).

Representative samples of this lot were tested for microbial load and were found to be acceptable.

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.

Megan Reeher  
Senior Manager Quality Assurance

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