



Certificate of Analysis

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

Product Name : Plate MacConkey I Agar 20Ea
Catalog Number : 215197 **Manufacture Date**: 2018/10/23
Batch Number : 8288584
Expiration Date : 2019/01/30

01. Plate Appearance: Medium-Dark rose tan and 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 of the test organisms (10 - 100 CFU of ATCC 8739 and 1.00E+04 to 1.00E+05 CFU of ATCC 29212), incubated at 33-37°C for 18-24 hours (ATCC 8739 incubated at 30-35°C for 18 hours) under appropriate atmospheric conditions and gave cultural responses as indicated:

CULTURE	ATCC®	RESULT
Enterococcus faecalis	29212	Inhibition (partial to complete)
Escherichia coli	25922	Fair to heavy growth
*Escherichia coli	8739	Fair to heavy growth
Pseudomonas aeruginosa	10145	Fair to heavy growth
Salmonella enterica subspecies enterica serotype Typhimurium	14028	Fair to heavy growth
Shigella dysenteriae	9361	Fair to heavy growth

* USP/EP/JP required test organisms

05. Meets USP/EP/JP performance specifications and CLSI performance specifications, where applicable.

Characteristic	Unit	Value	Lower Limit	Upper Limit
pH at 25°C :		7.3	6.9	7.3

Animal source	Country of Origin	Tissue Category		
		BIC	SIC	ABC
Bovine	Australia	IV	IV	IC
Bovine	Brazil	IV	IV	IC
Bovine	India	IV	IV	IC
Bovine	New Zealand	IV	IV	IC
Bovine	New Zealand	IV	IV	MLK
Bovine	USA	II	II	IB
Bovine	USA	IV	IV	IB



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Bovine	USA	IV	IV	IC
Bovine	USA	IV	IV	MLK
Equine	Mexico	II	II	IB
Equine	Mexico	IV	IV	IB
Ovine	New Zealand	IV	IV	IC
Porcine	Austria	IV	IV	IB
Porcine	Belgium	IV	IV	IB
Porcine	France	III	III	IB
Porcine	Germany	IV	IV	IB
Porcine	Ireland	IV	IV	IB
Porcine	Italy	IV	IV	IB
Porcine	Lithuania	IV	IV	IB
Porcine	Netherlands	IV	IV	IB
Porcine	Poland	IV	IV	IB
Porcine	USA	II	II	IB
Porcine	USA	III	III	IB
Porcine	USA	IV	IV	IB
Porcine	United Kingdom	IV	IV	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



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Page: 3 of 3

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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.

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.

Samples meet CLSI(NCCLS) requirements for recovery, where applicable.

Megan Reeher
Senior Manager Quality Assurance