



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

Certificate of Analysis

Product Name : BOTTLE LEVINE EMB AGAR BBL 500G
Catalog Number : 211221 **Manufacture Date** : 2010/12/07
Batch Number : 1059567
Expiration Date : 2014/10/31

01. Dehydrate Medium Powder Appearance: Fine, homogeneous and may contain up to a large amount of minute to small dark red purple particles.
02. Solubility (37.4g/L): Soluble in distilled or deionized water upon boiling.
03. Prepared Medium Appearance: Medium to dark, green orange brown; hazy.
04. Biological Performance: Media was prepared per label directions. Plates were inoculated with the test organisms, incubated at 33-37°C for 24 hours and gave cultural responses as indicated:

CULTURE	ATCC®	RESULT
Enterococcus faecalis	29212	Partial inhibition
Escherichia coli	25922	Light to heavy growth
Klebsiella pneumoniae	33495	Light to heavy growth
Salmonella typhi	19430	Light to heavy growth
Salmonella typhimurium	14028	Light to heavy growth
Shigella dysenteriae	9361	Light to heavy growth
Shigella flexneri	12022	Light to heavy growth

Characteristic	Unit	Value	LowLimit	HighLimit
pH at 25°C :		7.1	6.9	7.3
Bulk Lot Number :	-	0328097		

Animal Source	Country of Origin	Tissue Category		
		BIC	SIC	ABC
Bovine	USA	IV	IV	C
Porcine	USA	III	III	B
Bovine	USA	III	IV	C
Bovine	USA	I	IV	C
Bovine	USA	IV	IV	NDF
Porcine	USA	II	II	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),



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

Certificate of Analysis

Page: 2 of 3

Product Name : BOTTLE LEVINE EMB AGAR BBL 500G
Catalog Number : 211221 **Manufacture Date** : 2010/12/07
Batch Number : 1059567
Expiration Date : 2014/10/31

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.

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/>.

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.



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

Certificate of Analysis

Product Name : BOTTLE LEVINE EMB AGAR BBL 500G
Catalog Number : 211221 **Manufacture Date** : 2010/12/07
Batch Number : 1059567
Expiration Date : 2014/10/31

John Gerlich
Vice President,
Quality Management and
Regulatory Compliance
Signature Date: 2011/03/15