



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

# Certificate of Analysis

**Product Name** : BOTTLE FLUID THIOGLYCOLLATE MED 500G  
**Catalog Number** : 225650 **Manufacture Date** : 2011/04/29  
**Batch Number** : 1166104  
**Expiration Date** : 2016/03/31

01. Dehydrated Medium Appearance: Light beige, free-flowing, homogeneous
02. Solubility: 2.98% solution, soluble in distilled or deionized water on boiling
03. Solution Appearance: Hot - light amber, clear. At room temperature - light amber, slightly opalescent, 10% or less of upper layer is medium pink. After shaking solution becomes pink throughout.
04. Mercurial neutralization test was carried out using 1% Merthiolate with Staphylococcus aureus ATCC® 6538P and Streptococcus pyogenes ATCC® 19615. Merthiolate was neutralized by this lot.
05. Cultural Response: Medium was prepared per label instructions. Tubes were inoculated with the test organisms and incubated at 30-35°C for 18-48 hours, or up to 76 hours if necessary.

\* Medium was also tested per European (EP) and United States Pharmacopeia (USP) Growth Promotion requirements. Inoculum of 10-100 CFUs were used and incubated for up to 72 hours, up to 5 days for 11437, 9341 and 8482.

TEST ORGANISMS	ATCC®	RECOVERY
Clostridium novyi	7659	good
Clostridium perfringens	13124	good
Staphylococcus aureus	25923	good

Pharmacopeia Growth Promotion:

* Bacillus subtilis	6633	growth
* Bacteroides vulgatus	8482	growth
* Clostridium sporogenes	11437	growth
* Clostridium sporogenes	19404	growth
* Micrococcus luteus	9341	growth
* Pseudomonas aeruginosa	9027	growth
* Staphylococcus aureus	6538	growth

06. Residual Solvents (CPMP/ICH/283/95): Typical Analysis for Fluid Thioglycollate medium did not detect any solvents.

Characteristic	Unit	Value	LowLimit	HighLimit
Loss on Drying :	%	1.0	0.0	5.0
pH at 25°C :		7.3	6.9	7.3
Bulk Lot Number:	-	1110951		



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Animal Source	Country of Origin	Tissue Category		
		BIC	SIC	ABC
Bovine	New Zealand	IV	IV	MLK
Porcine	Canada	III	III	IB
Porcine	USA	III	III	IB
Avian	China	IV	IV	NDF

For an avian origin ingredient used in the manufacture of this product, the BD supplier is not able to confirm animal health. The supplier has confirmed that the ingredient undergoes extensive processing that includes exposure to strong acid, filtration, crystallization, and drying.

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), 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



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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/>.

**John Gerlich**  
**Vice President,**  
**Quality Management and**  
**Regulatory Compliance**  
**Signature Date: 2011/07/12**