



Certificate of Analysis

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

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Product Name : Bottle Fluid Thioglycollate Med 500G
Catalog Number : 225650 **Manufacture Date** : 2016/10/20
Batch Number : 7045539
Expiration Date : 2021/09/30

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.
- | TEST ORGANISMS | ATCC® | RECOVERY |
|-------------------------|-------|----------|
| Clostridium novyi | 7659 | good |
| Clostridium perfringens | 13124 | good |
| Staphylococcus aureus | 25923 | good |
06. Medium was also tested per European (EP), Japanese (JP) and United States Pharmacopeia (USP) Growth Promotion requirements. Inoculum of < 100 CFUs was used and tubes were incubated for up to 3 days.
- Pharmacopeia Growth Promotion:
- | | | |
|------------------------|-------|--------|
| Bacillus subtilis | 6633 | growth |
| Bacteroides vulgatus | 8482 | growth |
| Clostridium sporogenes | 11437 | growth |
| Clostridium sporogenes | 19404 | growth |
| Kocuria rhizophila | 9341 | growth |
| Pseudomonas aeruginosa | 9027 | growth |
| Staphylococcus aureus | 6538 | growth |
07. Residual Solvents (CPMP/ICH/283/95): Typical Analysis for Fluid Thioglycollate medium did not detect any solvents.

Characteristic	Unit	Value	Lower Limit	Upper Limit
Loss on Drying :	%	3.0	0.0	5.0
pH at 25°C :		7.2	6.9	7.3
Bulk Lot Number:	-	6278807		

Animal source	Country of Origin	Tissue Category		
		BIC	SIC	ABC
Avian	China	IV	IV	NDF

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Bovine	New Zealand	IV	IV	MLK
Porcine	USA	III	III	IB

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 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.

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Charlotte Dannenfelser
BD Life Sciences - Diagnostic Systems
Quality Director, Microbiology
Signature Date: 2017/03/22