



# Certificate of Analysis

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

**Product Name** : Tube Lipase Reagent 20Ml 10Pk  
**Catalog Number** : 215335 **Manufacture Date** : 2016/09/14  
**Batch Number** : 6245501  
**Expiration Date** : 2018/09/01

- 01 Appearance: White, opaque emulsion
- 02 Microbial Load: Satisfactory (Negative)
- 03 Cultural Response: Spirit Blue Agar (code 295020) was prepared per label instructions and Lipase Reagent was added. Plates were inoculated with the 30 - 300 CFUs of test organisms and incubated at 35 ± 2°C up to 72 hours.

| TEST ORGANISMS             | ATCC® | SPIRIT BLUE AGAR |                 |
|----------------------------|-------|------------------|-----------------|
|                            |       | RECOVERY         | LIPASE REACTION |
| Proteus mirabilis          | 25933 | good             | -               |
| Staphylococcus aureus      | 25923 | good             | +               |
| Staphylococcus aureus      | 6538P | good             | +               |
| Staphylococcus epidermidis | 12228 | good             | +               |

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>



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Page: 2 of 2

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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.

Charlotte Dannenfelser  
BD Life Sciences - Diagnostic Systems  
Quality Director, Microbiology  
Signature Date:2016/10/06