



# Certificate of Analysis

Becton Dickinson Caribe LTD.  
BD Diagnostics Systems  
6 Vicks Drive, Lot # 6  
Cayey PR 00737-2860 PR

Page: 1 of 2

**Product Name** : Bottle Plastic Bactec Lytic/10 Anaer/F  
**Catalog Number** : 442021 **Manufacture Date**: 2022/12/05  
**Batch Number** : 2333836  
**Expiration Date** : 2023/09/30

This is to certify that representative samples of  
BACTEC LYTIC/10 ANAEROBIC/F MEDIUM  
were tested in the Quality Control Laboratory by procedures  
conventionally utilized for this type of product, including  
methodology  
and control ATCC cultures specified in the CLSI standard, Qu  
ality Assurance for Commercially Prepared  
Microbiological Culture Media\*, and met the following test  
parameters:

pH: 7.2 ± 0.2

#### Autoclaving:

The product was exposed to a moist heat sterilization  
process(previously validated following an ISO Standard\*\*).

#### Vacuum draw:

greater than or equal to 10 ml at time of manufacture.

#### Biological Performance:

Satisfactory growth:

CULTURE	ATCC No.
***Bacteroides fragilis	25285
B. vulgatus	8482
Clostridium histolyticum	19401
C. perfringens	13124
Escherichia coli	25922
Staphylococcus aureus	25923
***Streptococcus pneumoniae	6305

ATCC is a trademark of the American Type Culture Collection.

\* Clinical and Laboratory Standards Institute. 2004. Approved Sta  
ndard, M22-A3. Quality assurance for commercially prepared  
microbiological culture media, 3rd ed. CLSI, Wayne, PA.

\*\* ISO 11134, Sterilization of health care products -  
Requirements for validation and routine control - Industrial moist hea  
t sterilization, 1994.

\*\*\*CLSI Strain

The Batch Number on this certificate is synonymous with the Lot Number  
shown on the product label.

Creation Date: 2022/12/28 12:14:49



# Certificate of Analysis

Becton Dickinson Caribe LTD.  
BD Diagnostics Systems  
6 Vicks Drive, Lot # 6  
Cayey PR 00737-2860 PR

Page: 2 of 2

**Product Name** : Bottle Plastic Bactec Lytic/10 Anaer/F  
**Catalog Number** : 442021 **Manufacture Date**: 2022/12/05  
**Batch Number** : 2333836  
**Expiration Date** : 2023/09/30

BD Diagnostic Systems is an ISO 13485:2016 Registered facility. BD Diagnostics - Diagnostic Systems 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 BD Diagnostics - Diagnostic Systems 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.

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/en-us/support/bd-life-sciences-diagnostic-systems-customer-regulatory-support-information](http://www.bd.com/en-us/support/bd-life-sciences-diagnostic-systems-customer-regulatory-support-information).

Zuleika Vargas  
Director, Quality Management  
Signature Date: 2022/12/28