

## **Certificate of Analysis**

Page: 1 of

2

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

Product Name : Bottle Plastic Bactec Lytic/10 Anaer/F

: 442021 Catalog Number Manufacture Date: 2025/01/15

: 5008910 Batch Number Expiration Date : 2025/10/13

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, Quality Assurance for Commercially Prepared Microbiological Culture Media\*, and met the following test parameters:

pH:  $7.2 \pm 0.2$ 

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

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 heat sterilization, 1994.

\*\*\*CLSI Strain

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

Creation Date: 2025/01/27 16:12:02



## **Certificate of Analysis**

2

Page: 2 of

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

Product Name : Bottle Plastic Bactec Lytic/10 Anaer/F

Catalog Number : 442021 Manufacture Date: 2025/01/15

Batch Number : 5008910 Expiration Date : 2025/10/13

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.



Jose E. Mojica Senior Quality Manager Signature Date: 2025/01/27

Creation Date: 2025/01/27 16:12:02