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: 2022/12/04 Batch Number : 2333833 **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: 7.2 ± 0.2 pН: 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.



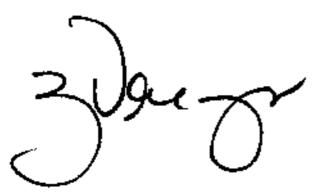
Becton Dickinson Caribe LTD. BD Diagnostics Systems 6 Vicks Drive, Lot # 6 Cayey PR 00737-2860 PR

Page: 2 of 2

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-customerregulatory-support-information.



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