Certificate of Analysis

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

Product Name : Bottle Plastic Bactec Plus Aerob/F 50/Pk
Catalog Number : 442023 **Manufacture Date**: 2020/12/29
Batch Number : 0349852
Expiration Date : 2021/09/30

This is to certify that representative samples of
BACTEC PLUS AEROBIC 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: 7.3 ± 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 8 mL at time of manufacture.

Biological Performance:
Satisfactory growth:

CULTURE	ATCC No.
Alcaligenes faecalis	8750
Candida glabrata	66032
Escherichia coli	25922
Haemophilus influenzae	19418
Neisseria meningitidis	13090
***Pseudomonas aeruginosa	27853
Staphylococcus aureus	25923
***Streptococcus pneumoniae	6305
S. pyogenes Group A	19615

Antimicrobial Removal: Satisfactory

ATCC is a trademark of the American Type Culture Collection.

* Clinical and Laboratory Standards Institute. 2004. Approved Standard, 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

Creation Date: 2021/01/20 17:58:22

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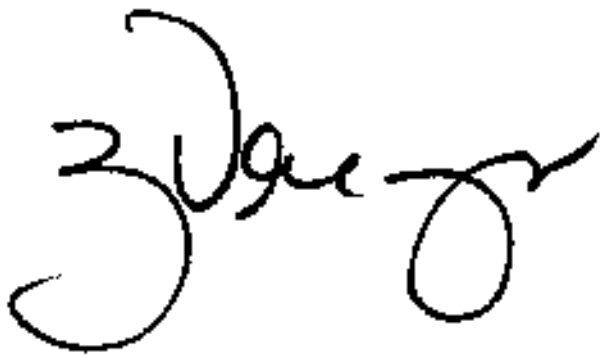
The Batch Number on this certificate is synonymous with the Lot Number shown on the product label.

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.



Zuleika Vargas
Senior Quality Manager
Signature Date:2021/01/20