



Certificate of Analysis

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

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Product Name : Bactec Plastic Mycosis Ic/F Medium
Catalog Number : 442017 **Manufacture Date**: 2021/12/09
Batch Number : 1335395
Expiration Date : 2023/03/31

This is to certify that representative samples of
BACTEC MYCOSIS-IC/F MEDIUM
were tested in the Quality Control Laboratory by procedures
conventionally utilized for this type of product and met the following
test parameters:

pH: 6.8 ± 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 14 ml at time of manufacture.

Biological Performance:
Satisfactory growth:

CULTURE	ATCC No.
C. auris	CDC-AR-0387
C. albicans	14053
C. tropicalis	750
C. parapsilosis	10232
C. krusei	34135
C. glabrata	15545
Cryptococcus neoformans	13690

Bacterial Inhibition:
No growth:
Escherichia coli 25922
Staphylococcus aureus 25923

ATCC is a trademark of the American Type Culture Collection.

* ISO 17665, Sterilization of health care products -
Moist heat - Requirements for the development, validation and routine
control of a sterilization process for Medical Devices.

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

Creation Date: 2021/12/30 16:50:38



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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: 2021/12/30