



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 : Mycosis I/Cbactec F 50/Pk F/G
Catalog Number : 442206 **Manufacture Date**: 2021/07/06
Batch Number : 1184161
Expiration Date : 2022/10/31

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 10 ml at time of manufacture.

Biological Performance:

Satisfactory growth:

CULTURE	ATCC No.
Candida albicans	10231
C. albicans	14053
C. tropicalis	750
C. parapsilosis	10232
C. krusei	34135
Torulopsis 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 11134, Sterilization of health care products -
Requirements for validation and routine control - Industrial moist
heat sterilization, 1994.

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

Creation Date: 2021/07/21 20:53:59



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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:2021/07/21