



# Certificate of Analysis

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

**Product Name** : Bactec Plastic Mycosis Ic/F Medium  
**Catalog Number** : 442017 **Manufacture Date:** 2023/03/07  
**Batch Number** : 3061801  
**Expiration Date** : 2024/06/05

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



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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](http://www.bd.com/en-us/support/bd-life-sciences-diagnostic-systems-customer-regulatory-support-information).

Zuleika Vargas  
Director, Quality Management  
Signature Date:2023/03/18