BD BACTEC™ Mycosis IC/F Culture Vials

Selective Medium for Yeast and Fungi in a Plastic Vial

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English

REF **442017**

INTENDED USE

BD BACTEC™ Mycosis IC/F Culture Vials are for aerobic blood cultures. The principal use is with the BD BACTEC™ fluorescent series instruments for the qualitative, selective culture and recovery of yeasts and fungi from blood. The culture vials are used as an aid to diagnosis and are automated on the BD BACTEC™ fluorescent series instruments.

SUMMARY AND EXPLANATION

The sample to be tested is inoculated into one or more vials which are inserted into the BD BACTEC™ fluorescent series instrument for incubation and periodic reading. Each vial contains a chemical sensor which can detect increases in CO_2 produced by the growth of microorganisms. The sensor is monitored by the instrument every ten minutes for an increase in its fluorescence, which is proportional to the amount of CO_2 present. A positive reading indicates the presumptive presence of viable microorganisms in the vial.

PRINCIPLES OF THE PROCEDURE

If yeast and fungi are present in the test sample inoculated into the BD BACTEC™ Mycosis IC/F Culture Vial, CO_2 will be produced when the microorganisms metabolize the substrates present in the vial. Increases in the fluorescence of the vial sensor caused by the increase of CO_2 are monitored by the BD BACTEC™ fluorescent series instrument. Analysis of the rate and amount of CO_2 increase enables the BD BACTEC™ fluorescent series instrument to determine if the vial is positive, i.e., that the test sample contains viable organisms. This qualitative culture functions as an aid to diagnosis and is automated on the BD BACTEC™ fluorescent series instrument.

BD BACTEC™ Mycosis IC/F Culture Vials are a Ready-to-Use Media.

REAGENTS

The BD BACTEC™ Mycosis IC/F Culture Vials contain the following reactive ingredients prior to processing:

List of Ingredients

Processed Water	40 mL	Ferric Ammonium Citrate	0.0001% w/v
Brain Heart Infusion Broth	1.0% w/v	Sodium Polyanetholsulfonate (SPS)	0.05% w/v
Soybean-Casein Digest Broth	0.5% w/v	Saponin	0.24% w/v
Yeast Extract	0.035% w/v	Chloramphenicol	0.0037% w/v
Sucrose	0.6% w/v	Tobramycin	0.001% w/v
Dextrose	0.1% w/v	Antifoaming Agent	0.01% w/v
m-Inositol	0.05% w/v		

All BD BACTEC™ media are dispensed with added CO_2.

WARNINGS AND PRECAUTIONS

For in vitro diagnostic use. For Use by Trained Laboratory Personnel.

This Product Contains Dry Natural Rubber.

Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions"[1-4] and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.

Prior to use, each vial should be examined for evidence of damage, contamination or deterioration. Vials displaying evidence of damage or contamination such as leakage, cloudiness, discoloration (darkening), bulging or depressed septum should not be used.

A contaminated vial could contain positive pressure. If a contaminated vial is used for direct draw, contaminated culture media could be refluxed into the patient's vein. Vial contamination may not be readily apparent. When using direct draw procedures, monitor the process closely to avoid refluxing materials into patient.

On rare occasions, a vial may not be sealed sufficiently. In both cases the contents of the vial may leak or spill. If the vial has been inoculated, treat the leak or spill with caution, as pathogenic organisms/agents may be present. Before discarding, sterilize all inoculated vials by autoclaving.

Positive culture vials for subculturing or staining, etc.: Before sampling it is necessary to release gas which often builds up due to microbial metabolism. Sampling should be performed in a biological safety cabinet if possible, and appropriate protective clothing, including gloves and masks, should be worn. See Procedure section for more information on subculturing.

To minimize the potential of leakage during inoculation of specimen into culture vials, use syringes with permanently attached needles or BD Luer-Lok™ brand tips.

Molecular tests performed on positive blood cultures will detect both viable and non-viable organisms commonly found in culture media. Therefore, molecular test results should be evaluated in conjunction with Gram stain results in accordance with standard-of-care practices as well as manufacturer's instructions for use.

Dispose of all used reagents and any other contaminated disposable materials following procedures for infectious or potentially infectious waste. It is the responsibility of each laboratory to handle solid and liquid waste according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

Storage Instructions

The BD BACTEC™ Mycosis IC/F Culture Vials are ready for use as received and require no reconstitution or dilution. Keep dry; store between 2–25 °C, keep away from light.

SPECIMEN COLLECTION

The specimen must be collected using sterile techniques to reduce the chance of contamination. The typical specimen volume is 8–10 mL. It is recommended that the specimen be inoculated into the BD BACTEC™ Mycosis IC/F Culture Vials at bedside. Most commonly, a 10 cc or 20 cc syringe with a BD Luer-Lok™ brand tip is used to draw the sample. If appropriate, a BD Vacutainer® Brand Needle Holder and a BD Vacutainer® Brand Blood Collection Set, BD Vacutainer® Safety-Lok™ Blood Collection Set or other tubing "butterfly" set may be used. If using a needle and tubing set (direct draw), carefully observe the direction of blood flow when starting sample collection. The vacuum in the vial will usually exceed 10 mL, so the user should monitor the volume collected by means of the 5 mL graduation marks on the vial label. When the desired 8–10 mL has been drawn, the flow should be stopped by crimping the tubing and removing the tubing set from the BD BACTEC™ Mycosis IC/F Culture Vials. Sample volumes as low as 3 mL can be used, however, recovery will not be as great as with larger volumes. **The inoculated BD BACTEC™ Mycosis IC/F Culture Vials should be transported as quickly as possible to the laboratory.**

PROCEDURE

Materials Provided

BD BACTEC™ Mycosis IC/F Culture Vials

Materials Required But Not Provided

- Syringe with permanently attached needles or BD Luer-Lok™ tips or a BD Brand Needle Holder and a BD Vacutainer® Brand Blood Collection Set, BD Vacutainer® Safety-Lok™ Blood Collection set or other tubing "butterfly" set
- Alcohol
- BD BACTEC™ Fluorescent series instrument
- Microscope and materials for downstream staining of slides and subculturing of vials

Remove the flip-off cap from BD BACTEC™ Mycosis IC/F Culture Vials top and inspect the vial for cracks, contamination, excessive cloudiness, and bulging or indented stoppers. DO NOT USE if any defect is noted. Before inoculating, swab the septum with alcohol (iodine is not recommended). Aseptically inject or draw directly 8–10 mL of specimen per vial. The medium is designed for use with blood specimens ranging from
3 to 10 mL. If the sample is less than 3 mL, recovery will not be as great as with larger volumes (see Limitations of the Procedure). **Inoculated vials should be placed in the BD BACTEC™ fluorescent series instrument as soon as possible for incubation and monitoring.** If placement of an inoculated vial into the instrument has been delayed and visible growth is apparent, it should not be tested in the BD BACTEC™ fluorescent series instrument, but rather it should be subcultured, appropriately stained and treated as a presumptively positive bottle.

Vials entered into the instrument will be automatically tested every ten minutes for the duration of the testing protocol period. Positive vials will be determined by the BD BACTEC™ fluorescent series instrument and identified as such (see the appropriate BD BACTEC™ fluorescent series instrument User's Manual). The sensor inside the bottle will not appear visibly different in positive and negative vials, however the BD BACTEC™ fluorescent series instrument can determine a difference in fluorescence.

If at the end of the testing period a negative BD BACTEC™ Mycosis IC/F Culture Vial appears visually positive (i.e., bulging septum, and/or turbid), it should be subcultured, appropriately stained and treated as a presumptive positive.

Positive vials should be subcultured and stained appropriately. In a great majority of cases, organisms will be seen and a preliminary report can be made to the physician.

Subculturing

After wiping the septum of an upright vial with an alcohol wipe, a single device such as the BD BACTEC™ Subculturing/Aerobic Venting Unit, Catalog Number 249560 or equivalent, can be used to both vent and subculture the vial.

Alternatively, prior to subculturing, put the vial in an upright position, and place an alcohol wipe over the septum. To release pressure in the vial, insert a sterile needle with an appropriate filter through the alcohol wipe and septum. The needle should be removed after the pressure is released and before sampling the vial for subculture. The insertion and withdrawal of the needle should be done in a straight-line motion, avoiding any twisting motions.

For maximum yield of isolates, negative cultures may be checked by stain and/or subcultured prior to discarding as negative.

QUALITY CONTROL

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

DO NOT USE culture vials past their expiration date.

DO NOT USE culture vials that exhibit any cracks or defects; discard the vial in the appropriate manner.

Quality Control Certificates are provided with each carton of media. Quality Control Certificates show test organisms, including ATCC® cultures specified in the CLSI Standard, *Quality Control for Commercially Prepared Microbiological Culture Media*.[5]

The range of time-to-detection in hours was ≤72 hours for each of the organisms listed on the Quality Control Certificate for this medium:

Organism

Candida albicans ATCC 14053	*Candida krusei* ATCC 34135	*Cryptococcus neoformans* ATCC 13690
Candida tropicalis ATCC 750	*Candida auris* CDC-AR-0387	
Candida parapsilosis ATCC 10232	*Candida (Torulopsis) glabrata* ATCC 15545	

It is recommended that each shipment of media be tested for performance through the use of a positive and negative vial test. The positive vial should be inoculated with 0.1 mL of a 0.5 McFarland Standard of either *Candida albicans* (ATCC 14053) or *Candida (Torulopsis) glabrata*. This vial and an uninoculated vial should be logged into the instrument and tested. The inoculated vial should be detected as positive by the instrument within 72 hours. The negative control vial should remain negative. This verifies that the media were not subject to adverse storage or shipping conditions prior to receipt in your laboratory. If either of these vials do not give the expected results, do not use the media until you have contacted Technical Services at 1.800.638.8663, or your BD representative.

For information on Quality Control for the BD BACTEC™ fluorescent series instrument, refer to the appropriate BD BACTEC™ fluorescent series instrument User's Manual.

LIMITATIONS OF THE PROCEDURE

Contamination

Care must be taken to prevent contamination of the sample during collection and inoculation into the BD BACTEC™ Mycosis IC/F Culture Vial. A contaminated sample will give a positive reading, but will not indicate a relevant clinical sample. Such a determination must be made by the user based on such factors as type of organisms recovered, occurrence of the same organism in multiple cultures, patient history, etc.

Nonviable Organisms

A Gram stained smear from culture medium may contain small numbers of nonviable organisms derived from media constituents, staining reagents, immersion oil, glass slides, and specimens used for inoculation. In addition, the patient specimen may contain organisms that will not grow in the culture medium or in media used for subculture. Such specimens should be subcultured to special media as appropriate.[6]

Dimorphic fungi

BD BACTEC™ Mycosis IC/F Culture Vial has been optimized for the recovery of yeast. The medium has not been proven effective for the recovery of dimorphic fungi.

General Considerations

Optimum recovery of isolates will be achieved by adding 8–10 mL of blood. Use of lower or higher volumes may adversely affect recovery and/or detection times. Blood may contain antimicrobials or other inhibitors which may slow or prevent the growth of microorganisms. False negative readings may result when certain organisms are present which do not produce enough CO_2 to be detected by the system or significant growth has occurred before placing the vial into the system. False positivity may occur when the white blood cell count is high.

Due to the nature of biological materials in media products and inherent organism variability, the user should be cognizant of potential variable results in the recovery of certain microorganisms.

Recovery of *C. albicans* (ATCC 10231) had longer TTDs with blood versus blood-free cultures in both glass and plastic bottles, these differences were generally greater in plastic bottles. This is a strain-specific and not species-specific phenomenon as the differences were not evident in *C. albicans* (ATCC 14053).

EXPECTED VALUES AND SPECIFIC PERFORMANCE CHARACTERISTICS

Performance in Seeded Blood Culture Studies

Seeded blood culture studies were performed using whole human blood and inoculum levels of 10 to 100 CFU. The following is a list of the organisms which grew in BD BACTEC™ Mycosis IC/F Culture Vials and were detected in the BD BACTEC™ fluorescent series instruments.

List of Yeast & Fungi Detected in BD BACTEC™ Mycosis IC/F Culture Vials in Seeded Blood Culture Studies

Aspergillus brasiliensis	*Candida krusei*	*Candida rugosa*	*Saccharomyces cerevisiae*
Candida albicans	*Candida auris*	*Candida tropicalis*	*Rhizopus oryzae*
Candida glabrata	*Candida parapsilosis*	*Cryptococcus neoformans*	

The performance of BD BACTEC™ Culture Vials for the recovery of yeast and fungi has been previously established with BD BACTEC™ Mycosis IC/F in glass. Seeded laboratory studies performed by BD have shown equivalent performance of the Mycosis IC/F medium to glass.

AVAILABILITY

Catalog Number	Description
442017	BD BACTEC™ Mycosis IC/F Culture Vials

REFERENCES

1. Clinical and Laboratory Standards Institute. 2005. Approved Guideline M29-A3. Protection of laboratory workers from occupationally acquired infections, 3rd ed. CLSI, Wayne, Pennsylvania USA.
2. Garner, J.S. 1996. Hospital Infection Control Practices Advisory Committee, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Guideline for isolation precautions in hospitals. Infect. Control Hospital Epidemiol. *17*: 53–80.
3. U.S. Department of Health and Human Services. 2007. Biosafety in microbiological and biomedical laboratories, HHS Publication (CDC), 5th ed. U.S. Government Printing Office, Washington, D.C. USA.
4. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC). Official Journal L262, 17/10/2000, p. 0021–0045.
5. Clinical and Laboratory Standards Institute. 2004. Approved Standard M22-A3, Quality control for commercially prepared microbiological culture media, 3rd ed., CLSI, Wayne, Pennsylvania USA.
6. Murray, P.R., E.J. Baron, J.H. Jorgensen, M.L. Landry and M.A. Pfaller (ed.). 2007. Manual of clinical microbiology, 9th ed. American Society for Microbiology, Washington, D.C. USA.

Technical Service and Support: In the United States contact BD at 1.800.638.8663 or bd.com.

For regions outside of the United States, contact your local BD representative or bd.com.

EU Only: Users shall report any serious incident related to the device to the Manufacturer and National Competent Authority.

Outside EU: Contact your local BD representative for any incident or inquiry related to this device.

Refer to the Eudamed website: https://ec.europa.eu/tools/eudamed for Summary of Safety and Performance.

Change History

Revision	Date	Change Summary
01	2019-07	Initial release.
02	2022-07	Minor typographical correction: Updated Antifoaming Agent concentration under List of Ingredients.
03	2023-03	Added CE notified body number (2797) for IVDR 2017/746. Added eIFU with URL, Do not reuse, Keep Dry, Keep away from light, and Do not use if package is damaged symbols. Updated Intended Use statement and PRINCIPLES OF THE PROCEDURE section. Updated Reagents section. Updated Warnings and Precautions section. Added Intended User and Safe Disposal statements. Added Materials Provided and Materials Required But Not Provided sections. Updated Subculturing section. Removed hyphen between Gram and stain and other minor typos for consistency. Updated EXPECTED VALUES AND SPECIFIC PERFORMANCE CHARACTERISTICS section. Updated Technical Service and Support statement. Added Serious Incident statement and Eudamed link statement. Updated Symbols Glossary. Updated EC REP address. Added CH REP symbol and address. Added New Zealand sponsor address. Added EU and Swiss Importer addresses with symbol. Added U.S. Patent statement.

SYMBOLS GLOSSARY

Please refer to product labeling for applicable symbols.

Symbol	Meaning
	Manufacturer
	Authorized representative in the European Community
	Authorised representative in Switzerland
	Date of manufacture
	Use-by date
	Batch code
	Catalogue number
	Serial number
	Sterile
	Sterilized using aseptic processing techniques
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Sterilized using steam or dry heat
	Do not resterilize
	Non-sterile
	Do not use if package is damaged and consult *instructions for use*
	Sterile fluid path
	Sterile fluid path (ethylene oxide)
	Sterile fluid path (irradiation)
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Lower limit of temperature
	Upper limit of temperature
	Temperature limit
	Humidity limitation
	Biological risks
	Do not re-use
	Consult *instructions for use* or consult electronic *instructions for use*
	Caution
	Contains or presence of natural rubber latex
	In vitro diagnostic medical device
	Negative control
	Positive control
	Contains sufficient for *<n>* tests
	For IVD performance evaluation only
	Non-pyrogenic
	Patient number
	This way up
	Do not stack

Symbol	Meaning
	Single sterile barrier system
	Contains or presence of phthalate: combination of bis(2-ethylhexyl) phthalate (DEHP) and benzyl butyl phthalate (BBP)
	Collect separately Indicates separate collection for waste of electrical and electronic equipment required.
	CE marking; Signifies European technical conformity
	Device for near-patient testing
	Device for self-testing
R_x Only	This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."
	Country of manufacture "CC" shall be replaced by either the two letter or the three letter country code.
	Collection time
	Cut
	Peel here
	Collection date
	Keep away from light
	Hydrogen gas is generated
	Perforation
	Start panel sequence number
	End panel sequence number
	Internal sequence number
	<Box #> / <Total Boxes>
MD	Medical device
	Contains hazardous substances
	Ukrainian conformity mark
	Meets FCC requirements per 21 CFR Part 15
	UL product certification for US and Canada
UDI	Unique device identifier
	Importer
	Place patient label in framed area only
MR	Magnetic resonance (MR) safe
	Magnetic resonance (MR) conditional
	Magnetic resonance (MR) unsafe
For use with	For use with
This Product Contains Dry Natural Rubber	This Product Contains Dry Natural Rubber
For Export Only	For Export Only
Instruments	Instruments

Note: Text layout in symbols is determined by label design.

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