BD BACTEC™ Plus Aerobic/F Culture Vials

Soybean-Casein Digest Broth in a Plastic Vial

CE 2797 IVD bd.com/e-labeling Rx Only

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English

REF 442023

INTENDED USE

BD BACTEC™ Plus Aerobic/F Culture Vials are used in a qualitative procedure for the aerobic culture and recovery of microorganisms (bacteria and yeast) from blood. The principal use of this medium is with the BD BACTEC™ fluorescent series instruments.

Additional Information

The device aids in the diagnosis of disease caused by pathogenic microorganisms and is 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 10 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. Detection is limited to microorganisms that will grow in a particular type of medium.

Resins have been described for the treatment of blood specimens both prior to and after their inoculation into culture media. Resins have been incorporated into BD BACTEC™ culture media to enhance recovery of organisms without a need for special processing.[1-3]

PRINCIPLES OF THE PROCEDURE

If microorganisms are present in the test sample inoculated into the BD BACTEC™ Plus Aerobic/F Culture Vials, CO_2 will be produced when the organisms metabolize the substrates present in the vial. Increases in the fluorescence of the vial sensor caused by the higher amount 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™ Plus Aerobic/F Culture Vials are a Ready-to-Use Media.

REAGENTS

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

List of Ingredients

Processed Water	30.0 mL
Soybean-Casein Digest Broth	3.0% w/v
Yeast Extract	0.25% w/v
Amino Acids	0.05% w/v
Sugar	0.2% w/v
Sodium Polyanetholsulfonate (SPS)	0.05% w/v
Vitamins	0.006% w/v
Antioxidants/Reductants	0.005% w/v
Nonionic Adsorbing Resin	13.4% w/v
Cationic Exchange Resin	0.9% w/v

All BD BACTEC™ media are dispensed with added CO_2.

WARNINGS AND PRECAUTIONS

The prepared culture vials are 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"[4-7] and institutional guidelines should be followed in handling all items contaminated with blood.

Prior to use, each vial should be examined for evidence of contamination such as cloudiness, bulging or depressed septum, or leakage. DO NOT USE any vial showing evidence of contamination. A contaminated vial could contain positive pressure. If a contaminated vial is used for direct draw, gas or contaminated culture media could be refluxed into the patient's vein. Vial contamination may not be readily apparent. If a direct draw procedure is used, monitor the process closely to avoid refluxing materials into the patient.

Prior to use, the user should examine the vials for evidence of damage or deterioration. Vials that are cracked or leaking, or display turbidity, contamination, or discoloration (darkening) should not be used. On rare occasions, a vial neck may be cracked and the neck may break during removal of the flip-off cap or in handling. Also, on rare occasions a vial may not be sealed sufficiently. In both cases the contents of the vials may leak or spill, especially if the vial is inverted. 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™ 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™ Plus Aerobic/F Culture Vials are ready for use as received and require no reconstitution or dilution. Keep dry, store between 2 and 25 °C, and keep away from light.

SPECIMEN COLLECTION

The specimen must be collected using sterile techniques to reduce the chance of contamination. The recommended specimen volume is 8–10 mL. It is recommended that the specimen be inoculated into the BD BACTEC™ Plus Aerobic/F Culture Vials at bedside. A 10cc or 20cc syringe with a BD Luer-Lok™ brand tip is used to draw the sample, or 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. 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™ Plus Aerobic/F Culture Vials should be transported to the laboratory as quickly as possible.**

PROCEDURE

Materials Provided

BD BACTEC™ Plus Aerobic/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 the BD BACTEC™ Plus Aerobic/F Culture Vials top and inspect the vial for cracks, contamination, excessive cloudiness in medium, and bulging or indented septums. **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. If sample volumes of 3–7 mL are used, recovery will not be as great as with larger volumes (see Limitations of the Procedure). Inoculated aerobic 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, Gram stained and treated as a presumptively positive vial.

Vials entered into the instrument will be automatically tested every 10 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 vial appears visually positive (i.e., chocolatized blood, bulging septum, lysed and/or very darkened blood in BD BACTEC™ Plus Aerobic/F Culture Vials), it should be subcultured and Gram stained and treated as a presumptively positive vial.

Positive vials should be subcultured and Gram stained. In a great majority of cases, organisms will be seen and a preliminary report can be made to the physician. Subcultures to solid media and a preliminary direct antimicrobial susceptibility test may be prepared from fluid in the BD BACTEC™ Plus Aerobic/F Culture Vials.

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 list test organisms, including ATCC® cultures specified in the CLSI Standard M22, *Quality Control for Commercially Prepared Microbiological Culture Media*. 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:

- *Neisseria meningitidis* ATCC 13090
- *Haemophilus influenzae* ATCC 19418
- *Streptococcus pneumoniae** ATCC 6305
- *Streptococcus pyogenes* ATCC 19615
- *Pseudomonas aeruginosa* ATCC 27853
- *Candida glabrata* ATCC 66032
- *Staphylococcus aureus* ATCC 25923
- *Escherichia coli* ATCC 25922
- *Alcaligenes faecalis* ATCC 8750

**CLSI recommended strain*

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

RESULTS

A positive sample is determined by the BD BACTEC™ fluorescent series instrument and indicates the presumptive presence of viable microorganisms in the vial.

LIMITATIONS OF THE PROCEDURE

Contamination

Care must be taken to prevent contamination of the sample during collection and inoculation into the BD BACTEC™ 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 organism recovered, occurrence of the same organism in multiple cultures, patient history, etc.

Recovery of SPS Sensitive Organisms from Blood Samples

Because blood can neutralize the toxicity of SPS toward organisms sensitive to SPS, the presence of maximum volumes of blood (8–10 mL) can help to optimize recovery of these organisms. To enhance the growth of SPS sensitive organisms when less than 8 mL of blood is inoculated, additional whole human blood may be added.

Some fastidious organisms, such as certain *Haemophilus* species, require growth factors, such as NAD, or factor V, which are provided by the blood specimen. If the blood specimen volume is 3.0 mL or less, an appropriate supplement may be required for recovery of these organisms. BD BACTEC™ FOS™ Fastidious Organism Supplement or whole human blood may be used as nutritional supplements.

Nonviable Organisms

A Gram stained smear from a 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.

Antimicrobial Activity

Neutralization of the antimicrobial activity by resins varies depending upon dosage level and timing of specimen collection. The use of supplementary additives should be considered in appropriate situations; as an example, the addition of penicillinase when β-lactam therapy is being employed.

Recovery of *Streptococcus pneumoniae*

In aerobic media, *S. pneumoniae* will typically be visually and instrument positive, but in some cases no organism will be seen on Gram stain or recovered on routine subculture. If an anaerobic vial was also inoculated, the organism can usually be recovered by performing an aerobic subculture of the anaerobic vial, since this organism has been reported to grow well under anaerobic conditions.[11]

General Considerations

Optimum recovery of organisms will be achieved by adding maximum amounts of blood. Published clinical studies have shown that the use of lower blood volumes may adversely affect recovery and/or detection times of organisms.[12] 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 if significant growth has occurred before placing the vial into the system. In analytical studies, this device recovered 17 of 18 *Leuconostoc* spp. tested. False positivity may occur when the white blood cell count is high. The default 5 day protocol was utilized for all analytical testing with this device, and protocol lengths of >5 days have not been evaluated.

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.

EXPECTED VALUES AND SPECIFIC PERFORMANCE CHARACTERISTICS

Performance of the BD BACTEC™ Plus Aerobic/F medium in glass vials has been established by a number of external clinical studies.[1-3,8,9] Seeded laboratory studies performed by BD have shown equivalent performance of the BD BACTEC™ Plus Aerobic/F medium in plastic vials compared to the BD BACTEC™ Plus Aerobic/F medium in glass vials.[10] The yeasts *Candida albicans*, *C. glabrata*, and *Cryptococcus neoformans* were tested in the analytical testing of this device.

AVAILABILITY

Catalog Number	Description
442023	BD BACTEC™ Plus Aerobic/F Culture Vials

REFERENCES

1. Wallis, C. *et al.* 1980. Rapid isolation of bacteria from septicemic patients by use of an antimicrobial agent removal device. J. Clin. Microbiol. *11*:462–464.
2. Applebaum, P.C. *et al.* 1983. Enhanced detection of bacteremia with a new BACTEC resin blood culture medium. J. Clin. Microbiol. *17*:48–51.
3. Pohlman, J.K. *et al.* 1995. Controlled clinical comparison of Isolator and BACTEC 9240 Aerobic/F resin bottle for detection of bloodstream infections. J. Clin. Microbiol. *33*:2525–2529.
4. Clinical and Laboratory Standards Institute. 2005. Approved Guideline M29-A3. Protection of laboratory workers from occupationally acquired infections, 3rd ed. CLSI, Wayne, Pennsylvania USA.
5. 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.
6. 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.
7. 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.
8. Smith, J.A. *et al.* 1995. Comparison of BACTEC 9240 and BacT/Alert blood culture systems in an adult hospital. J. Clin. Microbiol. *33*:1905–1908.
9. Flayhart, D. *et al.* 2007. Comparison of BACTEC Plus blood culture media to BacT/Alert FA blood culture media for detection of bacterial pathogens in samples containing therapeutic levels of antibiotics. J. Clin. Microbiol. *45*:816–821.
10. Data available from BD Life Sciences.
11. Howden, R.J. 1976. Use of anaerobic culture for the improved isolation of *Streptococcus pneumoniae*. J. Clin. Pathol. *29*:50–53.
12. Ilstrup, Duane M. and John A. Washington. 1983. The importance of volume of blood cultured in the detection of bacteremia and fungemia. Diagn. Microbiol. Infect Dis. *1*:107–110.

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	2023-04	Initial Release.

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
	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
	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>
	Medical device
	Contains hazardous substances
	Ukrainian conformity mark
	Meets FCC requirements per 21 CFR Part 15
	UL product certification for US and Canada
	Unique device identifier
	Importer
	Place patient label in framed area only
	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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