# BD BACTEC™ Lytic/10 Anaerobic/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 442021

### INTENDED USE

BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials (pre-reduced enriched Soybean-Casein Digest broth with $CO_2$) are for anaerobic blood cultures. The principal use is with the BD BACTEC™ fluorescent series instruments for the qualitative culture and recovery of anaerobic microorganisms from blood.

**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 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. Detection is limited to microorganisms that will grow in a particular type of medium.

### PRINCIPLES OF THE PROCEDURE

If microorganisms are present in the test sample inoculated into the BD BACTEC™ Lytic/10 Anaerobic/F Culture Vial, $CO_2$ 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™ Lytic/10 Anaerobic/F Culture Vials are a Ready-to-Use Media.

### REAGENTS

The BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials contain the following active ingredients prior to processing:

**List of Ingredients**

| | |
|---|---|
| Processed Water | 40 mL |
| Soybean-Casein Digest Broth | 2.75% w/v |
| Yeast Extract | 0.2% w/v |
| Animal Tissue Digest | 0.05% w/v |
| Dextrose | 0.2% w/v |
| Hemin | 0.0005% w/v |
| Menadione | 0.00005% w/v |
| Sodium Citrate | 0.02% w/v |
| Thiols | 0.1% w/v |
| Sodium Pyruvate | 0.1% w/v |
| Saponin | 0.26% w/v |
| Antifoaming Agent | 0.01% w/v |
| Sodium Polyanetholsulfonate (SPS) | 0.035% 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.

EUH208: Contains (Propanoic acid, 2-oxo-, sodium salt (1:1)). May produce an allergic reaction.

EUH210: Safety data sheet available on request.

**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 the patient.

On rare occasions, a vial may not be sealed sufficiently, which may result in the contents of the vial leaking or spilling. 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™ Lytic/10 Anaerobic/F Culture Vials are ready for use as received and require no reconstitution or dilution. Keep dry; store between 2 to 25 °C, keep away from light.

## SPECIMEN COLLECTION

The specimen must be collected using sterile techniques to reduce the chance of contamination. Published studies have shown that the recommended specimen volume is 8–10 mL.[5,6] It is recommended that the specimen be inoculated into the BD BACTEC™ Lytic/10 Anaerobic/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™ Lytic/10 Anaerobic/F Culture Vial. 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™ Lytic/10 Anaerobic/F Culture Vial should be transported as quickly as possible to the laboratory.**

## PROCEDURE

**Materials Provided**

BD BACTEC™ Lytic/10 Anaerobic/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™ Lytic/10 Anaerobic/F Culture Vial 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. If sample volumes of 3–4 mL are used, recovery will not be as great as with larger volumes (see Limitations of the Procedure). Inoculated anaerobic 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 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.

Blood will lyse immediately upon addition to the BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials. The blood will appear chocolatized or very dark initially. If at the end of the testing period a BD BACTEC™ Lytic/10 Anaerobic/F Culture Vial is observed to have a bulging septum, it should be subcultured, Gram stained or treated as presumptive positive.

Positive vials should be subcultured and a Gram stained slide prepared. In a great majority of cases, organisms will be seen and a preliminary report can be made to the physician. Subcultures to selective media and a preliminary direct antimicrobial susceptibility test may be prepared from fluid in the BD BACTEC™ Lytic/10 Anaerobic/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, *Quality Control for Commercially Prepared Microbiological Culture Media*.[7]

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:

| | | |
|---|---|---|
| *Clostridium perfringens* ATCC® 13124 | *Bacteroides fragilis** ATCC® 25285 | *Bacteroides vulgatus* ATCC® 8482 |
| *Streptococcus pneumoniae* ATCC® 6305 | *Escherichia coli* ATCC® 25922 | *Staphylococcus aureus* ATCC® 25923 |
| *Clostridium histolyticum* ATCC® 19401 | | |

*CLSI 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.

## LIMITATIONS OF THE PROCEDURE

### Contamination

Care must be taken to prevent contamination of the sample during collection and inoculation into the BD BACTEC™ Lytic/10 Anaerobic/F Culture Vial. A contaminated sample will give a positive reading, but will not indicate a relevant clinical result. 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.

### Recovery of SPS Sensitive Organisms from Blood Samples

Because blood can neutralize the toxicity of SPS toward organisms sensitive to SPS (such as *P. anaerobius*), the presence of maximum volumes of blood (i.e., up to 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 may be used as a nutritional supplement.

### 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.[8]

### General Considerations

Optimum recovery of isolates will be achieved by adding 8–10 mL of blood.[5,6] 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. The default 5 day protocol was utilized for all analytical testing with this device and protocols longer than 5 days have not been evaluated.

## EXPECTED RESULTS

Performance of the BD BACTEC™ Lytic/10 Anaerobic/F medium in glass vials has been established by a number of published external clinical studies.[9,10] Seeded laboratory studies performed by BD have shown equivalent performance of the BD BACTEC™ Lytic/10 Anaerobic/F medium in plastic vials compared to BD BACTEC™ Lytic/10 Anaerobic/F medium in glass vials.[11]

A total of 342 paired sets at 10 to 100 CFU per vial were evaluated for recovery, with 100% recovering in both the BD BACTEC™ Lytic/10 Anaerobic/F medium contained in a plastic vial and the BD BACTEC™ Lytic/10 Anaerobic/F medium contained in a glass vial. This study included a diverse set of anaerobic and aerobic microorganisms frequently isolated in blood. The median time to detection (TTD) difference between the paired sets was 10 minutes, in favor of the BD BACTEC™ Lytic/10 Anaerobic/F medium contained in a plastic vial. Ninety-five percent of the TTD differences between the paired sets were between -1.68 hours faster for the glass vial and 3 hours faster for the plastic vial.

The following anaerobes were evaluated in the analytical studies: *Bacteroides fragilis*, *B. ovatus*, *B. thetaiotaomicron*, *B. vulgatus*, *Clostridium histolyticum*, *C. novyi*, *C. perfringens*, *Fusobacterium nucleatum*, *Porphyromonas asaccharolytica* (formerly *Bacteroides melaninogenicus* subsp. *asaccharolyticus*) and *Veilonella parvula*. The facultative anaerobe *S. pneumoniae* was also tested.

A subset of organisms, including *Finegoldia magna* (formerly *Peptostreptococcus magnus*) and *Peptoniphilus asaccharolyticus* (formerly *Peptostreptococcus asaccharolyticus*) were evaluated on the BD BACTEC™ FX instrument at 10 to 100 CFU per vial and demonstrated 100% recovery in both the BD BACTEC™ Lytic/10 Anaerobic/F medium contained in a plastic vial and the BD BACTEC™ Lytic/10 Anaerobic/F medium contained in a glass vial.

In microbial detection limit testing, a total of 312 paired sets at inoculum levels of 0 to 1 and 1 to 10 CFU per vial were evaluated. This study was designed to assess the capability of the BD BACTEC™ blood culture media tested to detect one CFU, when present. Of the 312 paired sets tested, 191 grew and detected in both devices and 44 did not detect in either. Twenty-nine (29) cultures grew and detected only in the BD BACTEC™ Lytic/10 Anaerobic/F medium contained in a glass vial. Forty-eight (48) cultures grew and detected only in BD BACTEC™ Lytic/10 Anaerobic/F medium contained in a plastic vial. One of 12 replicates of *Porphyromonas asaccharolytica* (ATCC® 25260, 4 CFU per bottle) failed to detect in the BD BACTEC™ Lytic/10 Anaerobic/F medium contained in a plastic vial. Signal analysis demonstrated no evidence of growth in the replicate and a terminal subculture yielded no growth; indicating that there were likely no viable organisms inoculated into the vial.

## AVAILABILITY

| Catalog Number | Description |
|---|---|
| 442021 | BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials |

**REFERENCES**


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7. Clinical and Laboratory Standards Institute. 2004. Approved Standard M22-A3. Quality control of commercially prepared microbiological culture media, 3rd ed., CLSI, Wayne, Pa.
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10. Rohner, P., *et al.* 1997. Advantage of combining resin with Lytic BACTEC blood culture media. J. Clin. Micro. *35*:2634–2638.
11. Data available from BD Life Sciences.


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 |
|---|---|---|
| 08 | 2019-09 | Converted printed instructions for use to electronic format and added access information to obtain the document from bd.com/e-labeling.<br>In Warnings and Precautions section, added recommendation to perform molecular testings on positive blood cultures according to standard-of-care practices and manufacturer's instructions for use. |
| 09 | 2023-03 | Added CE notified body number (2797) for IVDR 2017/746.<br>Added Do not reuse, Keep Dry, Keep away from light and Do not Use if Package is Damaged symbols.<br>Updated Intented Use statement and Warning and Precautions - added Intended User, Supplemental information per SDS and Safe Disposal statement.<br>Updated PRINCIPLES OF THE PROCEDURE section.<br>Added Materials Provided and Materials Required But Not Provided sections.<br>Updated Subculturing section.<br>Added Serious Incident statement and Eudamed link statement.<br>Updated Symbols Glossary, Removed eIFU key code and phone number.<br>Updated EC REP address, added CH REP symbol with address, added Australian and New Zealand sponsor addresses.<br>Updated Trademark and Copyright.<br>Replaced Culture vials with 'medium' in Performance characteristics section.<br>Removed hyphen between Gram and stain and other minor typos for consistency.<br>Updated Reagents section.<br>Added EU and Swiss Importer addresses with symbol.<br>Added U.S. Patent statement.<br>Updated "vial" to "Culture Vial" in PROCEDURE section. |

## 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<br>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<br>"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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