PRODUCT DISRUPTION BRIEF

BD BACTEC blood culture system (updated November 14)

BD blood culture media inventory levels show improvement; shipping at 100% of historical demand.

Current conditions

Becton Dickinson (BD) is reporting improvement blood culture media availability. Distribution inventory levels have increased to pre-shortage levels on numerous blood culture media formulations (442020, 442022, 442024, 442027, 442794). To accelerate rebuilding healthy inventory levels for BD BACTEC Plus Aerobic media (442023), BS is shifting production of BD BACTEC Lytic Anaerobic media in plastic (442021) more heavily towards glass (442265). Due to this shift, providers will see a tightening of supply of BD BACTEC Lytic Anaerobic media in plastic (442021); however, BD BACTEC Lytic Anaerobic media in glass is readily available. BD BACTEC bottle holders are available to support glass vial adoption.

Product	Description	Shelf pack size
442021 (plastic)	BD BACTEC Lytic/10 Anaerobic/F culture vials	50/ea
442265 (glass)	BD BACTEC Lytic/10 Anaerobic/F culture vials	50/ea
445771	BD BACTEC bottle holder	100/ea

Please reference the following documents related to BD BACTEC™ Lytic Anaerobic Medium in glass:

- BD BACTEC™ Lytic Anaerobic Media in Glass Communication
- BD BACTEC™ Lytic Anaerobic Medium (442265) Now Available
- BD BACTEC™ Lytic Anaerobic Media Plastic (442021) – Glass (442265) Equivalency
- Blood Culture Collectors on BD BACTEC™ Lytic Anaerobic Media in Glass (442265)
- Guidelines for Clinical Laboratory Verification of Performance of BD BACTEC™ Blood Culture Media
- Interim Shelf Life Extension for Specific Lot Numbers
- BD BACTEC™ Media Supply - Frequently Asked Questions available on www.BDBACTEC-Update.com

The above information will be made available on www.BDBACTEC-Update.com where BD will continue to provide updates as they are available. If you have additional questions, please feel free to reach out to your local representative.

Previously BD had been experiencing intermittent delays in the following BACTEC blood collection media due to reduced availability of plastic bottles:

- 442020 - BD BACTEC Peds Plus/F culture vials
- 442021 - BD BACTEC Lytic/10 Anaerobic/F culture vials
- 442022 - BD BACTEC Plus aerobic/F culture vials
- 442023 - BD BACTEC Plus aerobic/IF culture vials
- 442024 - BD BACTEC standard anaerobic/F culture vials
- 442027 - BD BACTEC standard/10 aerobic/F culture vials
- 442794 - BD BACTEC Myco/F Lytic culture vials

To learn more, please contact:
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On July 15, The BD Public Affairs team and US Centers for Disease Control and Prevention (CDC) hosted a webinar on to discuss current supply challenges with blood culture media and potential mitigation frameworks. Access the recording and meeting materials here.

On July 10, BD issued a statement on supplier issue impacting BD BACTEC™ blood culture vials. More information on BD BACTEC™ blood culture vials supply can be found at BDBACTEC-update.com. This matter is not related to BD Vacutainer blood collection tubes.

The U.S. Food and Drug Administration (FDA) is aware that the U.S. is experiencing interruptions in the supply of BD BACTEC blood culture media bottles because of recent supplier issues.

BD's blood culture media bottles only work on their blood culture instrument (BACTEC), so competitive alternatives are not compatible. BioMerieux offers alternatives; however their blood culture media bottles only work with their BACT/ALERT analyzer systems.

While inventory is forecasted to tighten in the coming weeks, BD expects that ongoing mitigation efforts will lead to increased supply to meet global demand. In the interim, BD will continue to fill customer orders regularly and as supply is available. As this is a dynamic and evolving situation, BD will provide another supply update by September 2024. The majority of products are procured through distribution; BD is working with their distribution partners to develop an allocation strategy.

Mitigation strategy

FDA recommendations

The FDA recommends The FDA recommends laboratories that may experience potential delays in supply of BD BACTEC blood culture media bottles, and health care providers who order blood cultures, develop strategies to prioritize the use of blood culture media bottles, based on clinical need, to maintain quality and safety of patient care.

In developing strategies to preserve the supply for patients at highest risk, please consider the following:

- Performing blood culture collections when medically necessary, following clinical guidelines, such as those provided below.
- Prioritizing use for patients with clinical signs and symptoms of a bloodstream infection.
- Performing routine disinfection of skin protocols prior to collection to minimize the risk of contamination of the blood culture.
- Ensuring proper blood volume collection to avoid a need to recollect additional samples.
- Utilizing safe blood collection and transfer devices to minimize the risk of damage to blood culture media bottles.
- Referring to the following guidelines for best practices for blood collection and potential considerations for prioritization for use of blood culture media bottles:
  - Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2024 Update by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM)
  - World Health Organization (WHO) guidelines on drawing blood: best practices in phlebotomyExternal Link Disclaimer
  - CDC resources:
    - Preventing Adult Blood Culture Contamination: A Quality Tool for Clinical Laboratory Professionals
    - Blood Culture Contamination: An Overview for Infection Control and Antibiotic Stewardship Programs Working with the Clinical Laboratory

On July 10, the FDA updated the Medical Device Shortages List to include blood culture media bottles (product code MDB). Section 506J of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires the FDA to maintain a publicly available, up-to-date list of the devices the FDA has determined to be in shortage.

The FDA will continue to keep health care providers and the public informed if new or additional information becomes available.

Centers for Disease Control and Prevention (CDC) recommendations

On July 23, the CDC released a health alert, Disruptions in Availability of Becton Dickinson (BD) BACTEC™ Blood Culture Bottles Blood Culture Bottles, to inform healthcare providers, laboratory professionals and healthcare facility administrators, and of a critical shortage of Becton Dickinson (BD) BACTEC™ blood culture media bottles. In addition, CDC offers a quality tool to prevent blood culture contamination and improve diagnostic accuracy. The health alert included the following recommendations:

Recommendations for Healthcare Providers and Phlebotomists

- Implement practices to optimize the use of blood cultures at your facility.
- Take steps to prevent blood culture contamination.
- Ensure that the appropriate volume is collected when collecting blood for culture.

Recommendations for Laboratory Professionals and Healthcare Facility Administrators

- Determine the type of blood culture bottles your laboratory or facility uses and whether this shortage will impact you.
- Implement practices to optimize the use of blood cultures at your facility. Doing so may be helpful even for facilities not affected by the shortage.
- Take steps to prevent blood culture contamination. Contamination can negatively affect patient care and may require the collection of more blood cultures to help determine whether contamination has occurred.
- Ensure that the appropriate volume is collected when collecting blood for culture. Underfilling bottles decreases the sensitivity to detect bacteremia/fungemia and may require additional blood cultures to be drawn to diagnose an infection.
- If your laboratory or facility will be impacted by the bottle shortage, determine whether you have alternative options for blood cultures (e.g., working with a nearby facility or sending samples out to a laboratory not affected by the shortage).
- Monitor current and future supplies of blood culture bottles at your laboratory or facility and report any potential shortages or interruptions to the Food and Drug Administration (FDA) at deviceshortages@fda.hhs.gov.
- If your facility will be impacted by the bottle shortage, convene a group of local laboratory and clinical experts to determine how a limited supply of blood culture bottles will be prioritized for use in your facility.

BD recommendations

BD is working with the U.S. Food and Drug Administration (FDA) to review all options to resolve this challenge as quickly as possible. In the interim, they recommend providers take the following actions:

- Access the current inventory levels of BD BACTEC blood culture media within your system warehouse, laboratory, unit and nursing stations.
- Prioritize the use of blood culture media based on clinical need and following guidelines of local oversight committees, such as the most recent update from the Infectious Disease Society of America (IDSA) and/or the World Health Organization (WHO) as applicable for your region.
- Partner with your internal clinical teams to align and implement a BD BACTEC blood culture media utilization strategies.
- Emphasize the importance of proper blood volume collection and disinfection of skin protocols with collectors to optimize recovery and minimize false positive results, respectively.

Additional resources

- Journal of Clinical Microbiology: A diagnostic stewardship intervention to improve blood culture use among adult nonneutropenic inpatients: the DISTRIBUTE study
- Clinical Microbiology and Infection (CMI): A simplified blood culture sampling protocol for reducing contamination and costs: a randomized controlled trial

- National Library of Medicine: Improving blood culture quality with a medical staff educational program: a prospective cohort study
- CDC: Blood Culture Contamination (BCC) Prevention
- CDC: Preventing Adult Blood Culture Contamination: A Quality Tool for Clinical Laboratory Professionals
- CDC: Blood Culture Contamination: An Overview for Infection Control and Antibiotic Stewardship Programs Working with the Clinical Laboratory
- Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2024 Update by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM)
- Blood Culture Stewardship | Johns Hopkins Medicine

Additional resources

Supply assurance webpage; Vizient Newsroom

Want to receive weekly Supply Assurance updates?
Update your preferences through our Subscription Manager by selecting Supply Assurance Weekly Digest.

Questions? Contact disasterresponse@vizientinc.com, pharmacyquestions@vizientinc.com, novaplus@vizientinc.com.