Disruptions in Availability of BD BACTEC Blood Culture Media Bottles - Letter to Health Care Providers

Update: August 15, 2024

The FDA updated this communication to add additional external resources about the BD BACTEC blood culture media bottle shortage.

The FDA will continue to provide updates if new or additional information becomes available.

July 10, 2024

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. The disruption in supply of this device is expected to impact patient diagnosis, follow up patient management, and antimicrobial stewardship efforts. The FDA recommends laboratories and health care providers consider conservation strategies to prioritize the use of blood culture media bottles, preserving the supply for patients at highest risk.

Recommendations

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) (https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciae104/7619499) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
    - World Health Organization (WHO) guidelines on drawing blood: best practices in phlebotomy (https://www.who.int/publications/i/item/9789241599221) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
    - CDC resources:
        - Preventing Adult Blood Culture Contamination: A Quality Tool for Clinical Laboratory Professionals (https://www.cdc.gov/labquality/blood-culture-contamination-prevention.html)
        - Blood Culture Contamination: An Overview for Infection Control and Antibiotic Stewardship Programs Working with the Clinical Laboratory (https://www.cdc.gov/antibiotic-use/core-elements/pdfs/fs-bloodculture-508.pdf)

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

Background

On July 10, 2024, the FDA updated the Medical Device Shortages List (/medical-devices/medical-device-supply-chain-and-shortages/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. BD has previously issued a letter (https://www.medline.com/media/assets/pdf/vendor-list/June2024-BD-BACTEC-BloodCulture-MediaSupply.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) to customers identifying the product impacted.

FDA Actions

The FDA is:

- Continuing to monitor the current situation to help ensure blood culture media bottles remain available for patients when testing for bloodstream infection is medically necessary.
- Informing the public if significant new information becomes available.

The FDA reviews each notification received under section 506J of the FD&C Act and uses this information, along with any additional details about the supply of and demand for a device, to determine whether the device is in shortage.

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

Reporting Problems to the FDA

The FDA encourages health care providers to report any supply chain challenges or suspected adverse events experienced with the blood culture media bottles.

- You can submit information on potential shortages or interruptions in availability to deviceshortages@fda.hhs.gov (mailto:deviceshortages@fda.hhs.gov).
- You can submit voluntary reports through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).
- Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).
- Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

By promptly reporting device availability issues and potential shortages, you can help the FDA understand the scope of the problem and when possible, mitigate the issue.

Additional External Resources

Laboratorians and other healthcare providers should also be aware of external resources available from manufacturers and professional societies. These are independent of the FDA’s actions and recommendations and are provided here for convenience.

- Manufacturer's web page: BD BACTEC Blood Culture Vial Supply (https://bdbactec-update.com/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- American Society for Microbiology (ASM) guideline, endorsed by the Society for Healthcare Epidemiology of America (SHEA): Blood Culture Bottle Inventory Management and Clinical Conservation During Supply Shortages (https://asm.org/getmedia/8daa65e4-c141-4a0b-9d60-0ae2337505fc/Blood-Culture-shortage-FAQ_FINAL.pdf?ext=.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) published August 5, 2024 (PDF - 1039 KB)
- Informational web page from the Infectious Disease Society of America (IDSA): Blood Culture Bottle Shortage (https://www.idsociety.org/clinical-practice/blood-culture-bottle-shortage/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Contact Information

If you have questions about this letter, contact the Division of Industry and Consumer Education (DICE) (/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice).