Disruptions in Availability of Becton Dickinson (BD) BACTEC™ Blood Culture Bottles

DATE:    July 24, 2024
TO:      Health Alert Network
FROM:    Debra L. Bogen, M.D., FAAP, Secretary of Health

Disruptions in Availability of Becton Dickinson (BD) BACTEC™ Blood Culture Bottles
DISTRIBUTION: Statewide
LOCATION: N/A
STREET ADDRESS: N/A
COUNTY: N/A
MUNICIPALITY: N/A
ZIP CODE: N/A

This transmission is a “Health Advisory” provides important information for a specific incident or situation; may not require immediate action.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL; EMS COUNCILS: PLEASE DISTRIBUTE AS APPROPRIATE; FQHCs: PLEASE DISTRIBUTE AS APPROPRIATE LOCAL HEALTH JURISDICTIONS: PLEASE DISTRIBUTE AS APPROPRIATE; PROFESSIONAL ORGANIZATIONS: PLEASE DISTRIBUTE TO YOUR MEMBERSHIP; LONG-TERM CARE FACILITIES: PLEASE SHARE WITH ALL MEDICAL, INFECTION CONTROL, AND NURSING STAFF IN YOUR FACILITY

Summary
• On July 23, 2024, The Centers for Disease Control and Prevention (CDC) issued this Health Alert Network (HAN) Health Advisory to inform healthcare providers, laboratory professionals, healthcare facility administrators, and state, tribal, local, and territorial health departments of a critical shortage of Becton Dickinson (BD) BACTECTM blood culture media bottles.
• This shortage has the potential to disrupt patient care by leading to delays in diagnosis, misdiagnosis, or other challenges in the clinical management of patients with certain infectious diseases.
• Healthcare providers, laboratory professionals, healthcare facility administrators, and state, tribal, local, and territorial health departments affected by this shortage should immediately begin to assess their situations and develop plans and options to mitigate the potential impact of the shortage on patient care.
• If you have additional questions about this guidance, please contact DOH at 1-877-PA-HEALTH (1-877-724-3258) or your local health department.

Background
On July 23, 2024, the CDC issued a Health Alert Network (HAN) on a critical shortage of Becton Dickinson (BD) BACTECTM blood culture media bottles. Blood cultures are critical for assisting healthcare providers with diagnosing patients with bloodstream infections and associated conditions including endocarditis, catheter-related bloodstream infections and sepsis. Blood cultures can identify the microorganisms causing these infections, and follow-on antimicrobial susceptibility testing can be performed to help guide optimal therapy. Negative blood culture results can help to rule out certain severe infections as a cause of a patient’s illness. Repeat blood cultures may be
used for patients with certain infections, like *Staphylococcus aureus* bacteremia, to help guide treatment duration. Most blood cultures in the United States are performed using continuous-monitoring blood culture systems; the BD continuous-monitoring blood culture system is used in about half of all U.S. laboratories and is only compatible with BD BACTECTM blood culture media bottles.

Unnecessary and incorrect blood culture collection are not only detrimental to patient care but can contribute to or exacerbate shortages of blood culture media bottles. Thus, experts in laboratory utilization recommend that all facilities should implement diagnostic stewardship best practices to improve blood culture ordering and collection practices. Several studies have demonstrated that unnecessary blood cultures can be reduced without an increase in adverse events. These studies can serve as a template for collaborative efforts to reduce the number of unnecessary blood cultures performed in healthcare facilities. In addition, CDC offers a quality tool to prevent blood culture contamination and improve diagnostic accuracy.

**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). 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.

**Recommendations for State, Tribal, Local, and Territorial Health Departments**

- Contact hospitals and laboratories in your jurisdiction that serve acute care patients (i.e., patients who are hospitalized or visiting an emergency department) to determine what type of blood culture bottles they use and whether this shortage will impact them.
- Focus the following interventions on impacted facilities and laboratories:
  - Provide education on the supply shortage, optimal use of blood cultures, and mechanisms for reporting supply chain shortages or interruptions and suspected adverse events to the FDA.
Facilitate communication between laboratories and facilities willing to assist others in need, either by sharing supplies of available blood culture bottles or working out arrangements for nearby laboratories using continuous monitoring blood culture systems unaffected by the shortage to perform blood cultures on behalf of the affected laboratory or facility.

If you have additional questions about this guidance, please contact DOH at 1-877- PA-HEALTH (1-877-724-3258) or your local health department.

For More Information

- BD Update, CDC Blood Culture Quality Tools, and Blood Culture Utilization | CDC's Laboratory Outreach Communication System (LOCS)
- Disruptions in Availability of BD BACTEC Blood Culture Media Bottles - Letter to Health Care Providers | FDA
- Medical Device Shortages List | FDA
- 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 | CDC
- 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

Individuals interested in receiving further PA-HANs are encouraged to register at HAN Notification Registration (mir3.com)

Categories of Health Alert messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of July 24, 2024, but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.