



August 2024

BD BACTEC™ Blood Culture Vial Supply FAQ

Supply Management:

What is the cause of the BD BACTEC™ Media shortage?

Our vial supplier began to experience technical challenges with production that constrained our ability to produce BD BACTEC™ blood culture vials during peak demand periods starting in early 2024. BD immediately began working with the blood culture vial supplier through the ensuing months to ensure corrective actions were taken to improve production efficiency and increase vial output.

When will the supply improve?

We now expect to get production levels back to meeting 100% of historic demand levels by end of September for the U.S. market. And by the end of 2024, we expect to produce 125% of historical weekly demand to enable distributors and customers in the U.S. to begin rebuilding inventory and safety stock.

How much allocation will I receive until supply improves?

Because of the complexities associated with our manufacturing and shipping process, we cannot provide universal guidance on allocation that would be accurate for all labs. Please contact our dedicated BD BACTEC hotline at 1.888.834.4332 or your BD Account Executive using the "[Contact Us](#)" form at [BDBACTEC-update.com](https://www.bd.com/BDBACTEC-update.com) for the latest and most accurate information about your open orders.

What BD products are affected by this vial shortage?

These plastic vials are only used in the production of BD BACTEC™ blood culture vials and do not impact production of other BD products. Please see list of impacted products below.

SKU	Product Name
442023	BD BACTEC™ Plus Aerobic/F Culture Vials
442021	BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials
442020	BD BACTEC™ Peds Plus™/F Culture Vials
442022	BD BACTEC™ Plus Anaerobic/F 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
442265 (Glass)	BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials in glass

Has BD considered extending expiration dates on blood culture media?

Yes. Based on internal stability data, BD has issued an interim shelf-life extension for specific lots of BD BACTEC™ Plus Aerobic, Plus Anaerobic, Lytic Anaerobic, and Peds Plus SKUs in the United States. Details of specific products included in this communication, can be found on the [resources](#) tab.

(NEW) Why can't BD BACTEC™ media be extended beyond an additional month for specific lots and media types?

BD uses strict testing standards in line with product and design requirements to assign shelf-life for each of its products. As a global manufacturer, careful consideration is required to account for broad coverage of targeted organisms, the environments where our products may be used, and variations in logistic pathways. The current process for establishing shelf-life for regulated devices includes obtaining a successful time point beyond the claimed expiry time-period and recently this data has been used as supporting evidence to grant an interim extension to 10 months for [specific lots](#). While we are aware of published data that suggests that some blood culture media may, under certain conditions and for certain pathogens, meet requirements beyond the stated shelf-life, products in the market are expected to meet all design input requirements. BD has looked at expanding shelf-life for BACTEC™ media as it has many positive benefits for both BD and our customers, however our internal data does not support broad extensions beyond what we have determined for each specific lot at this time.

How does BD determine what media to manufacture with the limited vial supply?

Production schedules for blood culture media are regularly updated to ensure optimal product mixes based on regional demands.

Who is my BD Account Executive and how do I reach them for additional information?

Please use the "[Contact Us](#)" form at BDBACTEC-update.com and we will route your question to the appropriate BD representative. We have also established a dedicated BD BACTEC™ support team to help answer both supply chain and clinical questions. Call 1-888.834.4332 to connect to the BD BACTEC™ support team.

Laboratory and Clinical Management:

Is CMS considering relaxing some of the current requirements around blood culture collection during this supply crisis?

The CMS Division of Clinical Improvement and Quality (DCLIQ) is responsible for the oversight of clinical laboratories and laboratory testing. DCLIQ is aware of the BD BACTEC™ blood culture media vial supply challenges. For hospital sepsis quality metric questions, please contact MeaningfulMeasuresQA@cms.hhs.gov for assistance.

How are anaerobic and aerobic media different?

The formulation for each BD BACTEC™ blood culture vial is carefully determined to best meet the intended use of each product (e.g., optimal growth environment for anaerobic or aerobic organisms). In addition to different media formulations, anaerobic and aerobic media types differ in the composition of the vials' atmospheric headspace to optimize growth of targeted organisms.

Who is my BD Account Executive and how do I reach them for additional information?

Please use the "[Contact Us](#)" form at BDBACTEC-update.com and we will route your question to the appropriate BD representative. We have also established a dedicated BD BACTEC™ to help answer both supply chain and clinical questions. Call 1-888.834.4332 to connect to the BD BACTEC™ support team.

Lytic Glass:

(UPDATED) Is BD bringing back glass vials?

Yes. As an additional mitigation measure, we are launching the BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials (SKU #442265) in glass **only** in the **United States** and **select countries in Europe**¹ based on registration status. This was a product we previously discontinued but are now reintroducing to supplement and improve the overall supply of media worldwide until our plastic supplier can resolve their challenges. Availability is expected at the beginning of September for the US and the beginning of October for Europe. Please see the [Now Available](#) letter for communication in the USA. Additional communication on glass can be found on the “Resources” tab.

(UPDATED) Where will lytic anaerobic media in glass be available?

BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials (SKU #442265) in glass will **only** be available in the **United States** and **select countries in Europe**¹. Please see the [Now Available](#) letter for communication in the USA. Additional communication on glass can be found on the “Resources” tab.

How can I order lytic anaerobic media in glass?

Customers who live in the United States and select countries in Europe¹ where lytic anaerobic media in glass is available, must place separate orders for these products under SKU #442265.

Will lytic anaerobic media in glass replace lytic anaerobic media in plastic?

No. Lytic anaerobic media in both glass (SKU #442265) and plastic (SKU #442021) will continue to be offered. We are reintroducing lytic anaerobic media in glass to improve overall media availability, allowing for more manufacturing of plastic vials for other SKUs. When we are able to return to full plastic supply and healthy customer inventories we plan to discontinue the manufacturing of glass.

What CLIA complexity category do glass vials have, is it the same as plastic?

The CLIA categorization for the BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials (SKU #442265) in glass is moderate complexity and is the same complexity as the BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials (SKU #442021) in plastic.

Why is BD only manufacturing lytic anaerobic media in glass?

Based on our current manufacturing capabilities, we can most quickly launch the BD BACTEC™ Lytic Anaerobic media in glass (SKU #442265). Other media types require more specialized manufacturing processes which would take longer to deploy and given the urgent nature of the current supply situation we are looking to expedite product availability. By re-launching BD BACTEC™ Lytic Anaerobic media in glass (SKU #442265), we expect to improve overall quantities of all products including our BD BACTEC™ Plus Aerobic media (SKU #442023) and BD BACTEC™ Peds Plus media (SKU #442020).

What is different about the BD BACTEC™ Lytic Anaerobic Media in glass?

Although the glass vial is a different SKU (#442265), there are no changes in the intended use of the product when compared to plastic. The glass vial is slightly taller but otherwise has the same dimensions to fit into BD BACTEC™ instruments. BD BACTEC™ instruments can run both plastic and glass vials simultaneously with no software configurations necessary. Users will have to consider the implications of glass vial when using their pneumatic tube system. BD offers a bottle holder (SKU #445771) to help protect glass vials during transport. For a copy of the IFU, please see the “[Resources](#)” tab on BDBACTEC-update.com.

Are there plans to launch other media types in glass?

No. There are no plans to launch other BD BACTEC™ blood culture media types in glass as we expect this to be a short-term measure while we resolve the issues with our plastic vial supplier. We will return to 100% plastic vials at the earliest opportunity based on consistent supply of plastic vials from our supplier. We will provide clear timelines as they become available. Please check [BDBACTEC-update.com](https://bdbactec-update.com) for the latest information.

Do we need to perform verification for glass vials?

As a manufacturer, we cannot make recommendations on the need for verification and instead would defer to your laboratory's specific Standard Operating Procedure (SOP). For additional questions regarding verification requirements please contact CMS at labexcellence@cms.hhs.gov. For our suggested verification protocols, please visit the "[Resources](#)" tab at [BDBACTEC-update.com](https://bdbactec-update.com).

(NEW) Does lytic anaerobic media in glass have similar performance to lytic anaerobic media in plastic?

Yes. Performance data including time to detection and percent recovery between glass and plastic lytic anaerobic media are available in the [Glass Equivalency](#) letter.

(NEW) Can glass vials be sent through pneumatic tube systems?

Users will have to consider the implications of glass vials when using pneumatic tube systems, however BD offers a bottle holder (SKU #445771) to help protect glass vials during transport.

Considering the shortage in plastic, is BD going to continue manufacturing BD BACTEC™ Myco F Lytic in glass?

BD BACTEC™ Myco F Lytic in glass (SKU #442288) will be discontinued in markets where Myco F Lytic media in plastic (SKU #442794) is available. Discontinuing Myco F Lytic in glass will enable us to streamline our operations and focus manufacturing on improving overall media production. Laboratories with access to Myco F Lytic media in plastic should plan appropriately for this transition by ensuring that any verification requirements have been completed.

Who is my BD Account Executive and how do I reach them for additional information?

Please use the "[Contact Us](#)" form at [BDBACTEC-update.com](https://bdbactec-update.com) and we will route your question to the appropriate BD representative. We have also established a dedicated BD BACTEC™ support team to help answer both supply chain and clinical questions. Call 1-888.834.4332 to connect to the BD BACTEC™ support team.

¹European countries include Spain, Denmark, United Kingdom, Austria, Belgium, Bulgaria, Czech Republic, Estonia, Finland, France, Germany, Greece, Guadeloupe, Hungary, Ireland, Italy, Martinique, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Sweden