

Supplier: Becton Dickinson (BD) International

Subject: Supply Interruption of BD BACTEC MGIT 960 PZA Kits and BD BACTEC MGIT 960 PZA Tubes.

Cause of supply interruption: In mid-2024, BD initiated a field action for the BD BACTEC MGIT 960 PZA Kits following the detection of performance issues. After implementing corrective action that included raw material modification based on positive results from expanded performance testing, production resumed alongside additional stability testing.

However, BD has since received new complaints concerning intermittent false resistance results for pyrazinamide (PZA) in susceptibility testing of *Mycobacterium tuberculosis* isolates using the affected product. Concurrently, additional stability testing conducted by BD indicates that the corrective action implemented may not fully resolve the issue, and further investigation is ongoing.

As the PZA Kits are used in combination with the BD BACTEC MGIT 960 PZA Tubes, the supply of the PZA Tubes will also be interrupted until the PZA Kits become available again.

Extent of supply interruption: Until further notice. GDF will update this notice as soon as new information regarding the duration of the supply delay becomes available.

GDF Mitigation Actions:

- GDF is working closely with BD to identify all affected orders and is prioritizing efforts to split and fast-track shipments.
- GDF will assess potential alternative suppliers or diagnostic options for PZA testing, with the aim of identifying feasible alternatives that could be introduced in the short to medium term if the current supply interruption persists.
- GDF is in continuous communication with BD to receive regular updates on the status of the investigation and the expected timelines for resolution and resumption of supply.
- GDF will notify clients as soon as the affected products become available again to enable rapid procurement and minimize further disruption to programmatic activities.

Contact Information: For additional information, or if you need support with order planning, please contact either the GDF Country Supply Officer for your programme or gdf@stoptb.org

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Date of last update: N/A

Status: Open