Medical Device Correction - FSCA 5811: BIOFIRE BCID2 Panel

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MEDICAL DEVICE CORRECTIVE ACTION: FSCA 5811

BIOFIRE® Blood Culture Identification 2 Panel – Ref. Number(s) RFIT-ASY-0147
Increased Risk of False Positive *Candida tropicalis* Results using BIOFIRE® Blood Culture Identification 2 (BCID2) Panel (Part No.: RFIT-ASY-0147) with BD BACTEC™ Blood Culture Vials

The purpose of this email is to inform you that bioMérieux has identified an increased risk of false positive *Candida tropicalis* results when the BIOFIRE BCID2 Panel is used with BD BACTEC blood culture vials including, but not limited to, the bottle types in Table 1.

The cause for this risk is the presence of an increased level of DNA fragments from non-viable *Candida tropicalis* targets in BD BACTEC™ blood culture vials (Table 1). The presence of DNA fragments does not compromise the intended function of the blood culture vials (culturing viable microorganisms). However, the BIOFIRE BCID2 Panel detects nucleic acid from viable and non-viable organisms alike. A false positive result (incorrect ID) could lead to an inappropriate change in therapy. The patient may remain on inappropriate therapy until the *Candida tropicalis* is confirmed or not.

BIOFIRE BCID2 Panel product literature includes the following limitations:

- *"Blood culture media may contain non-viable organisms and/or nucleic acid at levels that can be detected by the BIOFIRE BCID2 Panel, leading to false positive test results. Typically, these false positives will be present with one or more additional true positive results because the BIOFIRE BCID2 Panel will also detect the organism that is growing in the culture bottle."*

- *"In some cases, the Gram stain result and results of the BIOFIRE BCID2 Panel may be discrepant (for example, detection of gram-positive cocci by the BIOFIRE BCID2 Panel when gram-positive cocci were not observed in the Gram stain). In these cases, the BIOFIRE BCID2 Panel results should be confirmed (e.g., by culture) before reporting, unless the result is concordant with other laboratory, epidemiological, or clinical findings."*

The BIOFIRE BCID2 Panel is intended as an aid in diagnosis and results should be used in conjunction with other clinical and laboratory findings. Results are intended

to be interpreted in conjunction with Gram stain results.

Table 1. Affected Media Type

Blood Culture Media Description
BD BACTEC™ Lytic Anaerobic medium
BD BACTEC™ Peds Plus medium
BD BACTEC™ Plus Aerobic medium
BD BACTEC™ Plus Anaerobic medium
BD BACTEC™ Standard Aerobic medium
BD BACTEC™ Standard Anaerobic medium

Actions to be taken by customer:

In this context, we request you to take the following actions:

- If the BIOFIRE BCID2 Panel is used to test BD BACTEC™ blood culture vials (examples in Table 1), positive results for *Candida tropicalis* should be confirmed by another method prior to reporting the test results.
- Distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, post this letter in or near the laboratory, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.
- Complete the Acknowledgement Form by clicking the button below and submitting the form to bioMérieux to confirm receipt of this notice. It is important that you return the acknowledgement form to bioMérieux even if you determine that this urgent product correction notice does not impact your facility.

ACKNOWLEDGEMENT FORM

Actions to be taken by bioMérieux:

In addition to reporting to bioMérieux, adverse events or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report online.
- Regular Mail or Fax: Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

bioMérieux is committed to providing our customers with the highest quality product possible and is communicating with BD regarding this issue.

We sincerely apologize for any inconvenience that this may have caused you.

Please contact customer support at **biofiresupport@biomerieux.com** or via telephone by dialing 1-800-682-2666, selecting option 3, and selecting option 7 for Product Technical Support with any questions or concerns.

Sincerely,

Aneta Waliszewski
Senior Director, Quality SLC Sites
bioMérieux

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