FSCA
FIELD SAFETY CORRECTIVE ACTION

BIOMÉRIEUX

IMPORTANT:

URGENT: MEDICAL DEVICE RECALL

BIOFIRE® Blood Culture Identification 2 Panel - Ref. Number(s) RFIT-ASY-0147

5811 - FSCA - 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

January 2024

To the attention of the Laboratory Director

bioMérieux Reference: 5811 - FSCA

Table 1. Affected Media Types

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

Dear bioMérieux Customer,

The purpose of this letter 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.

Required actions:

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 in Attachment A and return it to bioMérieux so that bioMérieux may acknowledge your receipt of this notification. It is important that you return the acknowledgement form to bioMérieux even if you determine that this urgent field safety notice does not impact your facility.

bioMérieux is committed to providing our customers with the highest quality product possible and is currently coordinating efforts with BD to resolve this issue.

We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux representative. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

Sincerely,

Aneta Waliszewski
Senior Director, Quality SLC Sites

Attachment A: Acknowledgement Form.

URGENT MEDICAL DEVICE RECALL

5811 - FSCA - 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

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Customer Information:

Customer Account Number: _____ Organization Name: _____

Street Address: _____

City, State and Postal Code: _____

Contact Name: _____

Contact Title: _____

Phone Number: _____

Product Information:

Catalog Number	Description
Part Number: RFIT-ASY-0147 (30 pack)	BIOFIRE® Blood Culture Identification 2 (BCID2) Panel

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Questions:

	Yes	No
1. Did you read the enclosed Field Corrective Notice regarding the increased risk of false positive *Candida tropicalis* results when the BIOFIRE BCID2 Panel is used with BD BACTEC blood culture vials?		
2. Have you implemented the actions as indicated in this Field Corrective Notice? If yes, please check the "**Yes**" box. If no, please indicate the reason in the Comments section below.		
Comments:		

DATE…….....**SIGNATURE**……

It is important that you complete this Acknowledgement Form and return it to bioMérieux.

Please fax this form to: **[Enter Local Contact]** To the attention of: **[Enter Local Contact]**