

IMPORTANT:

Update - URGENT FIELD SAFETY NOTICE

BIOFIRE® Blood Culture Identification 2 (BCID2) Panel – Ref. Number: RFIT-ASY-0147

FSCA 5884 – Update to FSCA 5788 and FSCA 5811 – Mandatory BIOFIRE® Blood Culture Identification 2 (BCID2) Panel Pouch Module Software Update

To the attention of the Laboratory Medical Director

Möln dal, Date

Our reference: FSCA 5884 – Update to FSCA 5788 and FSCA 5811

Product Name	Reference Numbers	Lot Number/Serial Number/ Product version	Product Expiration Date (if applicable)
BIOFIRE BCID2 Panel	RFIT-ASY-0147 (30-pack)	N/A – All lot numbers	N/A – All unexpired product

Dear bioMérieux Customer,

The purpose of this letter is to inform you that bioMérieux is releasing a mandatory Pouch Module software update for the **BIOFIRE® Blood Culture Identification 2 (BCID2) Panel** (part number: **RFIT-ASY-0147**) that will mitigate risk to previous field safety notices:

- FSCA 5788- ‘Not Detected’ *Candida tropicalis* results when testing the BIOFIRE BCID2 Panel with MMQCI Control Panel M416
- FSCA 5811- Increased risk of false positive *Candida tropicalis* results when the BIOFIRE® Blood Culture Identification 2 (BCID2) Panel (Part No.: RFIT-ASY-0147) is used with BD BACTEC™ Blood Culture Vials

Both false negative and false positive *C. tropicalis* risks are mitigated via the BIOFIRE BCID2 Panel pouch module software update.

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bioMérieux adjusted the Temperature melt (Tm) limit for a subset of assays of the BIOFIRE BCID2 Panel pouch module software following reanalysis of performance data to include data generated from synthetic control materials. The revised Tm limit mitigates the risk of false negative test results associated with MMQCI Control Panel M416 and no risks to clinical performance were identified with the change.

Reanalysis of the performance data (clinical and non-clinical/analytical studies) with the modified pouch module software led to a change in sensitivity for *Staphylococcus epidermidis* from 96.5% [95% CI: 93.0-98.2%] to 96.9% [95% CI: 93.8-98.5%], as documented in the updated BIOFIRE BCID2 Panel Instructions for Use. Reanalysis did not result in an overall change of the performance study conclusions.

Additionally, the pouch module revision also includes the addition of the following note to the results report:

“Note: All BIOFIRE BCID2 Panel results are intended to be interpreted in conjunction with Gram stain results. In some cases, the Gram stain result and the BIOFIRE BCID2 Panel result may be discrepant. In these cases, the BIOFIRE BCID2 Panel results should be confirmed, e.g., by culture or other laboratory, epidemiological, or clinical findings. Blood culture media may contain non-viable organisms and/or nucleic acids that may lead to false positive BIOFIRE BCID2 Panel results. Typically, these false positives present with more than one positive result from the BIOFIRE BCID2 Panel.”

The note in the pouch module results report increases visibility to the risk of false positive results due to the presence of non-viable organism/ nucleic acid in blood culture media.

In addition to the pouch module software update, the BIOFIRE BCID2 Panel Instructions for Use (IFU) have been updated, briefly outlined in the table below. Please read the BIOFIRE BCID2 Panel IFU for detailed information: <https://www.biofiredx.com/e-labeling/ITI0048>

Description of BIOFIRE BCID2 Panel IFU Changes
<p>Changes related to the field correction:</p> <ul style="list-style-type: none"> • Figure 1, BIOFIRE BCID2 Panel Example Test Report to include the note (referenced above) • Updated Limitation #9 describing non-viable organism in media • Sensitivity/PPA of <i>S. epidermidis</i> assay from 96.5% to 96.9%
<p>Changes related to general lifecycle management of product:</p> <ul style="list-style-type: none"> • Customer Technical Support phone number • Minor typographical errors throughout for clarity • Lifecycle analytical updates to Analytical and Summary of Detected Organisms sections, including organism nomenclature

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Required actions

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

- Update your BIOFIRE BCID2 Panel Pouch Module software: The updated BIOFIRE BCID2 Panel Pouch Module Software and instructions for installation can be downloaded here: <https://www.biofiredx.com/e-labeling/ITIFA20BCID210>. Please use the English version and read the technical note before installation. This technical note and installation download cannot be opened via Firefox browser; please use a different browser.
- Distribute this letter and the updated BIOFIRE BCID2 Panel IFU revision 06 (downloaded from e-labeling website: <https://www.biofiredx.com/e-labeling/ITIO048>) to all appropriate personnel in your laboratory, retain a copy in your files, 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 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.

bioMérieux is committed to providing our customers with the highest quality product possible.

We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please don't hesitate to contact customersupport.nordic@biomerieux.com.

Regards,

Customer Service Department
bioMérieux Nordic countries

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Attachment A: Acknowledgement Form.

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TO BE RETURNED TO YOUR BIOMERIEUX CUSTOMER SERVICE BY REPLYING TO THE EMAIL IN WHICH THIS LETTER WAS PROVIDED

Table with 2 columns: Field Name (Name and Address of the laboratory, Contact information, Customer Account Number) and empty space for input.

I have implemented the required actions.

Table with 5 columns: REF #, Product Name, Software Version number, Quantity impacted, Quantity corrected*. Row 1: RFIT-ASY-0147 (30-pack), BIOFIRE® Blood Culture Identification 2 Panel, V1.0 - v2.0.5, empty, empty.

DATE.....SIGNATURE.....

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

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