**IMPORTANT:**

**URGENT FIELD SAFETY NOTICE**

False Positive Staphylococcus aureus on the BIOFIRE Joint Infection (JI) Panel lots 0878825 and 0883425

Please distribute the attached customer letter.
To the Laboratory Manager
To the attention of the Laboratory Medical Director

**Date**

**bMx local contact information**

***(to be adapted at local level)***

Our reference: FSCA - FIELD SAFETY CORRECTIVE ACTION - FA-TWD-000074

**Impacted products** ***(to be adapted at local level if necessary including for names and ref #, local license #, name and address of manufacturer)***

| Product Name | Reference Number | Lot Number/Serial Number/ Product version | Product Expiration Date (if applicable) |
|---|---|---|---|
| BIOFIRE JI Panel | RFIT-ASY-0138 | 0878825 | 2026-05-10 |
| BIOFIRE JI Panel | RFIT-ASY-0138 | 0883425 | 2026-05-11 |

Dear bioMérieux Customer,

Our records indicate that you may be using the product listed in the table above.

The purpose of this letter is to inform you that bioMérieux has identified an increased risk of false positive *S. aureus* on kit lot 0878825 (pouch lot 3RXZ25) and kit lot 0883425 (pouch lot 3RZB25) of the BIOFIRE® JI Panel.

**Required actions**

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

- Examine your inventory for the lot identified in this field safety notice.
- Discontinue use and discard any remaining product from this lot in your possession.
- Please confirm the quantity of kits that have been destroyed, previously used, or returned on the attached Acknowledgement of Receipt Form.
- If you have further distributed this product, please identify any recipients and notify them at once.
- Please complete the accompanying Acknowledgement of Receipt Form and return to bioMérieux so that bioMérieux may acknowledge your receipt of this notification.

**Description of the issue**

This field safety notice is issued due to contamination that occurred during the manufacturing of BIOFIRE JI Panel kit lots 0878825 and 0883425, which based on investigation, led to an elevated risk of false positive *S. aureus*. The risk assessment determined the potential risk was remote for false positive methicillin-resistant *S. aureus* (MRSA) results, however, the risk of a false positive MRSA result cannot be completely excluded because a false positive *S. aureus* result related to the contamination event could contribute to an erroneous MRSA interpretation.

**Impact to User/Customer/Patients**

False positive *S. aureus* and MRSA results on the BIOFIRE JI Panel could lead to inappropriate patient management.

*Local legal mentions to be added if necessary at local level (e.g. in case of recall, reporting to NCA, recall methods)*

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 contact *your local bioMérieux Customer Service representative (to be adapted at local level)*.

Sincerely,

Customer Service

**Attachment A: Acknowledgement Form.**

# URGENT FIELD SAFETY NOTICE

## FSCA - FIELD SAFETY CORRECTIVE ACTION FA-TWD-000074
## False Positive Staphylococcus aureus on the BIOFIRE Joint Infection (JI) Panel lots 0878825 and 0883425

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**TO BE RETURNED TO *YOUR BIOMERIEUX CUSTOMER SERVICE (TO BE ADAPTED AT LOCAL LEVEL)***
**AT THE FOLLOWING**
**FAX NUMBER: XXXXXXXX OR EMAIL ADDRESS: XXXXXXX**

| | |
|---|---|
| **Name and Address of the laboratory** | |
| **Contact information** | |
| **Customer Account Number** | |

*Local legal mentions to be added if necessary at local level)*

☐ I am not impacted by the issue. Please provide rationale: ……

☐ I have implemented the required actions.

*Table to be added and adapted if necessary to monitor quantities received/discarded (products names and ref.# to be adapted at local level if necessary) depending on the required actions.*

| REF # | Product Name | Batch # | Quantity received | Quantity used | Quantity destroyed | Quantity returned* |
|---|---|---|---|---|---|---|
| RFIT-ASY-0138 | BIOFIRE JI | 0878825 | | | | |
| RFIT-ASY-0138 | BIOFIRE JI | 0883425 | | | | |

** Quantity returned to bioMérieux or distributor*

If you have encountered impact on patients' results, or reports of illness or injury related to the identified issue and have not yet reported to bioMérieux, please contact your local bioMérieux representative.

**DATE…….....SIGNATURE……**

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



Company address / Adresse de la société émettrice - Zip Code City / Code postal Ville - Country / Pays
Phone / Tél.: + 33 (0)0 00 00 00 00 - Fax: + 33 (0)0 00 00 00 00 - www.biomerieux.com
Legal notice / Mentions légales de la société émettrice