

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

Brussels, 28th April 2026

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

Impacted products			
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.

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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 or previously used 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.

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 :

E-mail: Confidential business information

Phone: Confidential business information

Yours faithfully,
Customer Service

bioMérieux Benelux b.v.

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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

TO BE RETURNED TO YOUR *BIO-MERIEUX* CUSTOMER SERVICE BY SELECTING THE "REPLY" OPTION TO THE E-MAIL FROM *BIO-MERIEUX*

Name and Address of the laboratory	
Contact information	
Customer Account Number	

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

☐ I have implemented the required actions.

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

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 Customer Service representative.

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

IT IS IMPORTANT THAT YOU COMPLETE THIS ACKNOWLEDGMENT FORM AND RETURN IT TO YOUR *BIO-MERIEUX* CUSTOMER SERVICE BY SELECTING THE "REPLY" OPTION TO THE INITIAL E-MAIL FROM *BIO-MERIEUX*.

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