FSCA
FIELD SAFETY CORRECTIVE ACTION

BIOMÉRIEUX

IMPORTANT:

URGENT FIELD SAFETY NOTICE

False positive Serratia marcescens results on the BIOFIRE® BCID2 Panel when used in conjunction with specific lots of BACT/ALERT® Blood Culture Bottle

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-000040

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® Blood Culture Identification 2 (BCID2) Panel	RFIT-ASY-0147	All unexpired lots when used with specific BACT/ALERT® Blood Culture Bottles.	

Dear bioMérieux Customer,

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

The purpose of this letter is to inform you that bioMérieux has identified an increased risk of false positive *Serratia marcescens* results when the BIOFIRE BCID2 Panel is used with certain lots of BACT/ALERT Culture Bottles (see Appendix A - Affected BACT/ALERT Lot).

Required actions

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

- If the BIOFIRE BCID2 Panel is used to test certain lots of BACT/ALERT Culture Bottles (BACT/ALERT Lots# 0004102964, 0004102996, 0004102946, 0004102956, and 0004102998), positive results for *Serratia marcescens* 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 this urgent field safety notice does not impact your facility.

Description of the issue

The cause for this risk is the presence of an increased level of non-viable organism from *Serratia marcescens* targets in BACT/ALERT Culture Bottles. The presence of non-viable organism does not compromise the intended function of the blood culture bottles (culturing viable microorganisms). However, the BIOFIRE BCID2 Panel detects nucleic acid from viable and non-viable organisms alike.

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.

Impact to User/Customer/Patients

A false positive result (incorrect ID) could lead to an inappropriate change in therapy. The patient may remain on inappropriate therapy until the *Serratia marcescens* is confirmed or not.

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)*.

Yours faithfully,

Customer Service

Attachment A: Acknowledgement Form.

URGENT: Field Safety Notice

FSCA - FIELD SAFETY CORRECTIVE ACTION FA-TWD-000040 False positive Serratia marcescens results on the BIOFIRE® BCID2 Panel when used in conjunction with specific lots of BACT/ALERT® Blood Culture Bottle

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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.

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

Appendix A – Affected BACT/ALERT Lots

Product Name	Product Reference	Lot #	Expiration Date
BACT/ALERT ® PF Plus	410853	0004102964	9/19/2025
BACT/ALERT ® FA Plus	410851	0004102996	9/24/2025
BACT/ALERT ® FA Plus	410851	0004102946	8/29/2025
BACT/ALERT ® FA Plus	410851	0004102956	9/17/2025
BACT/ALERT ® FA Plus	410851	0004102998	9/24/2025