

IMPORTANT:
URGENT FIELD SAFETY NOTICE
Control Failures on the BIOFIRE® FILMARRAY® Pneumonia Panel and BIOFIRE® FILMARRAY® Pneumonia Panel plus

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-000004

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® FILMARRAY® Pneumonia Panel	RFIT-ASY-0144	2147623	28-Aug-2024
BIOFIRE® FILMARRAY® Pneumonia Panel	RFIT-ASY-0144	2147523	27-Aug-2024
BIOFIRE® FILMARRAY® Pneumonia Panel plus	RFIT-ASY-0143	2147723	27-Aug-2024

Dear bioMérieux Customer,

Subsidiary name (if applicable) / Nom de la filiale (si approprié)



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 control failures on specific lots of the BIOFIRE® FILMARRAY® Pneumonia Panel and BIOFIRE® FILMARRAY® Pneumonia Panel *plus*.

Required actions

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

- Immediately examine your inventory for product identified in this field safety notice.
- Discontinue use and discard any remaining product in your possession. bioMérieux will replace the product at no charge in accordance with our standard limited warranty.
- Confirm the amount of pouches scrapped (if any) 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

Preliminary investigation identified an issue in the manufacturing process which may contribute to elevated control failures. bioMérieux is currently investigating the issue and taking appropriate corrective and preventive actions.

Impact to User/Customer/Patients

An increase in control failures could lead to delayed results for the customer.

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.

Subsidiary name (if applicable) / Nom de la filiale (si approprié)



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

Subsidiary name (if applicable) / Nom de la filiale (si approprié)

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



Attachment A: Acknowledgement Form.

Urgent: Field Safety Notice

**FSCA - FIELD SAFETY CORRECTIVE ACTION FA-TWD-000004
Control Failures on the BIOFIRE® FILMARRAY® Pneumonia Panel and
BIOFIRE® FILMARRAY® Pneumonia Panel plus**

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

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-0144	BIOFIRE® FILMARRAY® Pneumonia Panel	2147623				
RFIT-ASY-0144	BIOFIRE® FILMARRAY® Pneumonia Panel	2147523				
RFIT-ASY-0143	BIOFIRE® FILMARRAY® Pneumonia Panel plus	2147723				

* Quantity returned to bioMérieux or distributor

Subsidiary name (if applicable) / Nom de la filiale (si approprié)



Have you encountered impact on patients' results, or reports of illness or injury related to the identified issue ? *(to be completed based on FCA/FSCA issue)*

Yes No

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

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

Subsidiary name (if applicable) / Nom de la filiale (si approprié)