

IMPORTANT:

URGENT: MEDICAL DEVICE RECALL

BIOFIRE® FILMARRAY® Pneumonia Panel – Ref. Numbers RFIT-ASY-0144 (30-pack) & RFIT-ASY-0145 (6-pack)

BIOFIRE® FILMARRAY® Pneumonia (PNplus) Panel plus – Ref. Numbers RFIT-ASY-0143 (30-pack) & RFIT-ASY-0142 (6 pack)

Increased risk of false positive seasonal Coronavirus results using the BIOFIRE® PN & PNplus Panel

December 2023

bMx local contact information

(to be adapted at local level)

To the attention of the Laboratory Medical Director

bioMérieux Reference: FSCA 5790

Impacted products			
Product Name	Reference Number	Lot Number	Product Expiration Date
BIOFIRE® FILMARRAY® Pneumonia Panel	RFIT-ASY-0144 (30-pack) RFIT-ASY-0145 (6-pack)	N/A – all unexpired lot numbers	N/A – all unexpired product
BIOFIRE® FILMARRAY® Pneumonia Panel <i>plus</i>	RFIT-ASY-0143 (30-pack) RFIT-ASY-0142 (6-pack)	N/A – all unexpired lot numbers	N/A – all unexpired product

Dear valued BIOFIRE® FILMARRAY® Customer,

The purpose of this letter is to inform you that bioMérieux has identified a potential for false positive seasonal Coronavirus results when using the BIOFIRE® FILMARRAY® Pneumonia Panel (part numbers: RFIT-ASY-0144 and RFIT-ASY-0145) and BIOFIRE® FILMARRAY® Pneumonia (PNplus) Panel *plus* (part numbers: RFIT-ASY-0142 and RFIT-ASY-0143).

Investigations of false results reported from the field has identified a risk for false positive detection of seasonal Coronavirus due to non-specific amplification or cross-reactivity with high concentrations of human genomic DNA (hgDNA) that could be present in clinical specimens.

Clinically, false positive test results for seasonal Coronavirus may reduce the likelihood of identifying the true cause of the patient's disease and affect decisions related to appropriate



treatment. Incorrect diagnosis could lead to a modification in treatment that might be inappropriate and a failure to determine the true cause of the infection.

Required actions

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

- Distribute this information 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.
- Use another method to confirm positive results for seasonal Coronavirus from the BIOFIRE Pneumonia Panel or BIOFIRE Pneumonia Panel *plus* prior to reporting the result (e.g., consider results from testing a nasopharyngeal swab with a different BIOFIRE respiratory panel such as the BIOFIRE® Respiratory Panel 2.1). Alternatively, the BIOFIRE® Pneumonia Panel or BIOFIRE Pneumonia Panel *plus* seasonal Coronavirus positive result should not be reported.

Complete the Acknowledgement Form in Attachment A (on the following page) 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]

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 and is currently performing Corrective and Preventive Actions (CAPA) as part of the ongoing investigation. Additional information and notification will be distributed when a solution is identified and can be implemented.

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 the BIOFIRE Technical Support team at biofiresupport@biomerieux.com or via telephone by dialing 1.800.735.6544 and selecting option 5 for Product Technical Support.

Sincerely,

A handwritten signature in grey ink that reads "Aneta Waliszewski".

Aneta Waliszewski
Senior Director, Quality SLC Sites



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY/CORRECTIVE NOTICE

URGENT FIELD SAFETY NOTICE

FSCA 5790 – BIOFIRE® PN & PN_{plus} Panels – RFIT-ASY-0144, RFIT-ASY-0145, RFIT-ASY-0143, & RFIT-ASY-0142
Increased risk of false positive seasonal Coronavirus

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.

REF #	Product Name	Batch #
RFIT-ASY-0144 & RFIT-ASY-0145	BIOFIRE® FILMARRAY® Pneumonia Panel	N/A – all unexpired Lot numbers
RFIT-ASY-0143 & RFIT-ASY-0142	BIOFIRE® FILMARRAY® Pneumonia <i>plus</i> Panel	N/A – all unexpired Lot numbers

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

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