IMPORTANT:

URGENT FIELD SAFETY NOTICE

Mandatory Pouch Module Software Update to Mitigate Risk of False Positive Coronavirus Results using the BIOFIRE® PN & PNplus Panels

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

BIOFIRE® FILMARRAY® Pneumonia (PNplus) Panel Plus – Ref Number RFIT-ASY-0143 (30-pack) & RFIT-ASY-0142 (6-pack)

To the attention of the Laboratory Medical Director

Date: 06.03.2025

Our reference: FSCA 5790 Update

Product Name	Reference Number	Lot Number	Previous Software Version	Updated Software Version
BIOFIRE® FILMARRAY® Pneumonia Panel	RFIT-ASY-0144* (30-pack) RFIT-ASY-0145* (6-pack)	N/A – all unexpired lot numbers	v2.0 - v2.1.3.12	v2.0 - v2.1.4.10
BIOFIRE® FILMARRAY® Pneumonia Panel *plus*	RFIT-ASY-0143* (30-pack) RFIT-ASY-0142* (6-pack)	N/A – all unexpired lot numbers	v2.0 - v2.1.0.5	v2.0 - v2.1.1.2

*At the time of FSCA 5790 Update issuance remaining BIOFIRE PN and PNplus Panel kit inventory (expiration date on or prior to January 14, 2026) may contain the initial FSCA 5790 Letter regarding risk of coronavirus false positives. This FSCA 5790 Update letter supersedes the initial letter contained in the kit box. bioMérieux has stopped including the initial FSCA 5790 Letter in the BIOFIRE PN and PNplus Panel kit boxes as of January 15, 2025.

Dear bioMérieux Customer,

The purpose of this letter is to inform you that bioMérieux is releasing a mandatory Pouch Module software update for **the BIOFIRE® FILMARRAY® Pneumonia Panel** (part number: **RFIT-ASY-0144** and **RFIT-ASY-0145**) and **BIOFIRE® FILMARRAY® Pneumonia Panel plus** (part number: **RFIT-ASY-0142** and

RFIT-ASY-0143) that will mitigate the risk of false positive Coronavirus results previously communicated in FSCA 5790.

The update to the Pouch Module software modifies the melt range of the Coronavirus assay to exclude most instances of a non-specific amplicon generated by cross-reactivity with human genomic DNA (hgDNA) and reports a 'Not Detected' Coronavirus result. The update to the Pouch Module software also includes a modification of the CTX-M assay analysis rule to prevent risk of false assay results linked to cross-reactivity with hgDNA that was also identified during the coronavirus root cause investigation (Note, CTX-M analysis rule modification is to prevent, not correct, a risk of CTX-M false assay results).

Reanalysis of the Coronavirus clinical performance data with the updated software slightly alters the clinical specificity/NPA for Coronavirus from 98.4% to 98.7% in BAL-like specimens and from 99.3% to 99.5% in sputum-like specimens from the prospective evaluation. CTX-M performance is unchanged. (Refer to the Pneumonia IFU https://www.biofiredx.com/e-labeling/ITI0075 and PNplus IFU https://www.biofiredx.com/e-labeling/ITI0038 for product literature changes)

Required actions.

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

- Update your BIOFIRE PN and/or PNplus Panel Pouch Module software: The updated BIOFIRE PN and PNplus Pouch Module Software and instructions for installation can be downloaded here: https://www.biofiredx.com/e-labeling/ITIFA20PNEUMO20 (PN Panel); https://biofiredx.com/e-labeling/ITIFA20PNEUMOplus20 (PNplus Panel) The PN and PNplus installation technical note is only available in English. Please read and use the English installation technical note to install the PN and/or the PNplus panel software. The technical note and installation download cannot be opened via Firefox browser; please use a different browser.
- Distribute this information and the updated IFU 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.
- Complete the Acknowledgement Form in Attachment A and return it to bioMerieux 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.

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 don't hesitate to contact *your local bioMerieux Customer Service Representative (to be adapted at local level).*

Sincerely,

Customer Service

A&B d.o.o.

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Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5790 Update – Mandatory Software Update to Mitigate Risk of False Positive Coronavirus Results using the BIOFIRE® PN & PNplus Panels

TO BE RETURNED TO *YOUR BIOMERIEUX CUSTOMER SERVICE* AT THE FOLLOWING FAX NUMBER: XXXXXXXX OR EMAIL ADDRESS: XXXXXXX

Name and Address of the laboratory	
Contact information	

☐ I have implemented the required actions.

REF #	Product Name	Software Version number	Quantity impacted	Quantity corrected*
RFIT-ASY-0144 (30-pack) RFIT-ASY-0145 (6-pack)	BIOFIRE® FILMARRAY® Pneumonia Panel	v2.0 - v2.1.4.10	0	0
RFIT-ASY-0143 (30-pack) RFIT-ASY-0142 (6-pack)	BIOFIRE® FILMARRAY® Pneumonia Panel *plus*	v2.0 - v2.1.1.2	1	1

** Quantity corrected include software updates or instruments corrections.*

DATE……SIGNATURE……

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

A&B d.o.o.

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