IMPORTANT:

URGENT FIELD SAFETY NOTICE

BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel – Ref. Number: RFIT-ASY-0116

FSCA 5812 – Update to BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel Labeling - Norovirus GI/GII Clinical and Analytical Specificity

To the attention of the Laboratory Medical Director

Mölndal, 2025-02-XX

Our reference: FSCA 5812 Update

Product Name	Reference Numbers	Lot Number/Serial Number/ Product version	Product Expiration Date (if applicable)
BIOFIRE GI Panel	RFIT-ASY-0116* (30-pack)	N/A – All lot numbers	N/A – All unexpired product

*At time of FSCA 5812 Update issuance remaining BIOFIRE GI Panel kit inventory (expiration date on or prior to January 14, 2026) may contain the initial FSCA 5812 Letter regarding risk of norovirus false positives. This FSCA 5812 Update letter supersedes the initial letter contained in the kit box. bioMérieux has stopped including the initial FSCA 5812 Letter in the BIOFIRE GI Panel kit boxes as of January 15, 2025.

Dear bioMérieux Customer,

The purpose of this letter is to inform you of a product literature revision to resolve the previous correction (FSCA 5812) involving the **BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel** (part number: **RFIT-ASY-0116**). The Norovirus GI/GII clinical specificity was addended and the analytical specificity was revised based on recent investigations into reported false positive results.

An internal investigation was initiated in response to an increase in false positive Norovirus complaints from customers using the BIOFIRE GI Panel. A controlled Postmarket Performance Follow-up (PMPF) clinical study was conducted to assess the GI Panel Norovirus GI/GII performance. Similar to the original 2013 clinical evaluation of the BIOFIRE GI Panel, the PMPF clinical study evaluated prospectively collected specimens.

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In this new study, the clinical sensitivity (PPA) was consistent with the findings of the original clinical study while the clinical specificity (NPA) for the Norovirus assays was found to be outside the original labeling claims. This letter is to inform you that product labeling has been updated to include the clinical specificity found in the 2023 PMPF clinical study (see Table 1 below).

Table 1: ***BIOFIRE GI Panel Norovirus GI/GII Clinical Performance***

Study	Positive Percent Agreement (PPA)			Negative Percent Agreement (NPA)		
	TP/(TP + FN)	%	95% CI	TN/(TN + FP)	%	95% CI
Original Clinical Study (May-Sept 2013)	52/55	94.5	84.9-98.9%	1483/1501	98.8	98.1-99.3%
PMPF Study (April – July 2023)	34/35	97.1	85.1-99.9%	808/837	96.5	95.1-97.7%

Additionally, the analytical specificity of the Norovirus assays has been updated to include the risk of cross-reactivity with additional organisms that were identified via investigation of false positive results.

Please read the GI Panel IFU for detailed information: https://www.biofiredx.com/e-labeling/ITI0030

Briefly, the following changes have been made to the BIOFIRE FILMARRAY GI Panel IFU (Revision 08):

Description of Changes

Additions:
• A Clinical Performance (2023) section was added to describe the PMPF study, including change in specificity for Norovirus result
  ○ Table 16 (demographic summary) for 2023 prospective clinical evaluation
  ○ Table 17 (Norovirus GI/GII Clinical Performance) for 2023 clinical evaluation

Updates:
• Analytical specificity (cross-reactivity) updates:
  ○ Table 43 update select sequences as cross reactive with Noro 1 assay
  ○ Table 44 updated to include all Off-panel testing and indicate which test species had cross-reactivity confirmed in analytical testing (in bold).
• Limitation #24 language updated to include false positive results
• Updated General Laboratory Precaution #3 to include more information for false positive test results

Required actions

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

- Distribute this letter and 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 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.

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 do not hesitate to contact us at customersupport.nordic@biomerieux.com

Regards,

Customer Service Department
bioMérieux Nordic countries

Attachment A: Acknowledgement Form

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

Name and Address of the laboratory	
Contact information	
Customer Account Number	

☐ I have read and acknowledge the receipt of FSCA 5812 Update, regarding the updated BIOFIRE GI Panel Norovirus GI/GII performance.

DATE……SIGNATURE……

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