

IMPORTANT:
URGENT FIELD SAFETY NOTICE

BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel – Ref. Number: RFIT-ASY-0116 & RFIT-ASY-0104
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

Date
bMx local contact information
(to be adapted at local level)

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) RFIT-ASY-0104* (6-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 recall (correction) (FSCA 5812) involving the **BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel** (part number: **RFIT-ASY-0116** and **RFIT-ASY-0104**). The Norovirus GI/GII clinical specificity was added and the analytical specificity was revised based on recent investigations into reported false positive results.

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



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. 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
<p>Additions:</p> <ul style="list-style-type: none"> • A Clinical Performance (2023) section was added to describe the PMPF study, including change in specificity for Norovirus result <ul style="list-style-type: none"> ○ Table 16 (demographic summary) for 2023 prospective clinical evaluation ○ Table 17 (Norovirus GI/GII Clinical Performance) for 2023 clinical evaluation
<p>Updates:</p> <ul style="list-style-type: none"> • Analytical specificity (cross-reactivity) updates: <ul style="list-style-type: none"> ○ 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

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
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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.

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

Sincerely,

Customer Service

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Attachment A: Acknowledgement Form.

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

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

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 Acknowledgement Form and return it to bioMérieux

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