IMPORTANT:

URGENT: MEDICAL DEVICE RECALL

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

FSCA 5812 – Increased Risk of False Positive Norovirus Results with the BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel

January 26, 2024

To the attention of the Laboratory Director

bioMérieux Reference: FSCA 5812

Table 1 - Affected Product

Product Name	Reference #	Kit Lot #	Expiration Date
BIOFIRE GI Panel	RFIT-ASY-0116 (30-pack) RFIT-ASY-0104 (6-pack)	N/A – All lot numbers	N/A – All unexpired product

Dear bioMérieux Customer,

The purpose of this letter is to inform you of a product recall (correction) involving the **BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel** (part number: **RFIT-ASY-0116** and **RFIT-ASY-0104**). bioMérieux has identified a potential signal of increased false positive Norovirus results when using the BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel. **All unexpired product is potentially impacted.**

It has been determined the overall risk of false positive Norovirus reported by the BIOFIRE GI Panel may be serious for patients at greatest risk. False positive results are typically associated with unnecessary treatment and reduced likelihood of identifying the true cause of the patient's disease. The risk is mitigated by a health care provider's evaluation of other clinical and diagnostic findings including the context of an evaluation of patient clinical history, travel history, suspicion of infection, clinical presentation, and severity of the disease.

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.

- If a positive Norovirus result is inconsistent with clinical presentation, the positive Norovirus result should be confirmed using another method.

- 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.

In addition to reporting to bioMérieux, adverse events or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report online.
- Regular Mail or Fax: Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

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.

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,

Aneta Waliszewski
Senior Director, Quality SLC Sites

Attachment A: Acknowledgement Form.

URGENT MEDICAL DEVICE RECALL

FSCA 5812 – Increased Risk of False Positive Norovirus Results with the BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel

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Please complete this form using one of the following options:

1) Fill out electronically using the following URL: https://www.biofiredx.com/recall5812

2) Scan to PDF and return completed form to: recall5812@biomerieux.com

Company Name:	
Contact Name:	
Contact Title:	
Contact Email:	
Telephone:	
Company Address:	

☐ I have read and acknowledge the receipt of FSCA 5812, regarding the increased risk of false positive *Norovirus* results when using the BIOFIRE GI Panel.

DATE…… ..... SIGNATURE……

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