**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 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)<br>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.

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.

If you require additional assistance or have any questions, please contact *your local bioMérieux Customer Service representative (to be adapted at local level*).

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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**TO BE RETURNED TO *YOUR BIOMERIEUX CUSTOMER SERVICE (TO BE ADAPTED AT LOCAL LEVEL)* AT THE FOLLOWING**
**FAX NUMBER: XXXXXXXX OR EMAIL ADDRESS: XXXXXXX**

| | |
|---|---|
| **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.

**DATE……  SIGNATURE……**

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