

Wade Stevenson
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Salt Lake City, UT 84108

URGENT: FIELD SAFETY NOTICE

The purpose of this letter is to inform you of a Field Safety Corrective Action (FSCA) involving the BioFire® FilmArray® Gastrointestinal (GI) Panel (part numbers: RFIT-ASY-0104 & RFIT-ASY-0116), with BioFire GI Panel kits with expiration dates ranging from 10/23/2019 through 02/20/2020. For a complete list of affected lot numbers, please use the following link: <https://www.online-ifu.com/ITIGI0281>

This FSCA has been initiated because BioFire Diagnostics, LLC (BioFire) has identified elevated rates of false positive results for *Campylobacter* and *Cryptosporidium* while using the BioFire GI Panel. **Only the BioFire GI Panel kits with expiration dates ranging from 10/23/2019 to 02/20/2020 are affected.**

If using a BioFire GI Panel kit with an expiration date that is mentioned above, positive results for *Campylobacter* and *Cryptosporidium* should be confirmed by another method prior to reporting the test results. BioFire will continue efforts to monitor the issue in the field and will notify you if additional pertinent information is uncovered, as this issue is currently still under investigation.

Actions:

- Immediately examine your inventory for product identified in this FSCA.
 - If you identify any affected BioFire GI Panel lots in your inventory, you may choose to continue using the affected product; however, positive results for *Campylobacter* and *Cryptosporidium* should be confirmed by another method prior to reporting the test results.
- For distributors: if you have further distributed this product, please identify your customers and notify them at once of this product FSCA.

As of February 26, 2019, BioFire has temporarily stopped shipments of the BioFire GI Panel (product codes: RFIT-ASY-0116 and RFIT-ASY-0104). BioFire does not yet have a definite date for resuming shipments, but is working diligently to find a solution to the existing issue and to resume shipments as quickly as possible. Please continue to submit orders for the BioFire GI Panel as you would normally so that BioFire can ensure order fulfillment as quickly as possible when shipments resume.

If you have any questions or concerns, please don't hesitate to contact your local bioMérieux representative.

Thank you for your understanding in this matter.



Wade Stevenson





Attachment A: Acknowledgement Form.

URGENT PRODUCT CORRECTION NOTICE

FSCA – 4280– Increased Risk of False Positive Results for *Campylobacter* and *Cryptosporidium* with BioFire® FilmArray® Gastrointestinal (GI) Panel (RFIT-ASY-0104 and RFIT-ASY-0116)

Customer Information:

Customer Account Number: _____ Organization Name: _____

Street Address: _____

City, State and Postal Code: _____

Contact Name: _____

Contact Title: _____

Phone Number: _____

Product Information:

Catalog Number	Description
RFIT-ASY-0104	FilmArray® Gastrointestinal (GI) Panel (6 pack)
RFIT-ASY-0116	FilmArray® Gastrointestinal (GI) Panel (30 pack)

Questions:

	Yes	No
1. Did you read the enclosed Urgent Product Correction Notice regarding increased risk of false positive <i>Campylobacter</i> and <i>Cryptosporidium</i> results using FilmArray® Gastrointestinal (GI) Panel (Part Nos.: RFIT-ASY-0104 and RFIT-ASY-0116)?		
2. Have you implemented the actions as indicated in this Urgent Product Correction Notice? If no, please indicate the reason in the Comments section below.		
3. Have you received reports of illness or injury related to the described issue?		

Comments:

Signature: _____

Date: _____

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

Please fax this form to: [\[Enter Local Contact\]](#) To the attention of: [\[Enter Local Contact\]](#)