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## **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.



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