



April 25, 2023

FIELD CORRECTIVE NOTICE
FCA 5747

BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel (Part No.: RFIT-ASY-0104 & RFIT-ASY-0116) Pouch Module Software Update

Dear valued BIOFIRE® FILMARRAY® Customer,

The purpose of this letter is to inform you that bioMérieux has issued a Field Corrective Action, FCA 5747, for a mandatory BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel pouch module software update to ensure that all BIOFIRE GI Panel customers are using the most up-to-date software version (FLM2-SFW-0040 v2.0.3.1).

Customer Service Notification CSN-2022-167-0 described an increased number of instances of unconfirmed *Cryptosporidium* results (i.e., “false positive” results) from customers using the BIOFIRE GI Panel. The BIOFIRE GI Panel contains two assays for the detection of *Cryptosporidium*: Crypt 1 and Crypt 2. A subset of the unconfirmed *Cryptosporidium* results appear to be caused by a previously unknown non-specific product that is being generated by the Crypt 2 assay. This amplification product is being erroneously interpreted as “positive” by the current software, leading to a *Cryptosporidium* Detected result. To date, this rare and non-specific product has been primarily observed in a small fraction of patient samples and there has been no correlation to specific reagent lots, FILMARRAY instruments, or Cary Blair media.

The update to the pouch module software (FLM2-SFW-0040 v2.0.3.1) covered by this FCA mitigates this erroneous interpretation of the non-specific Crypt 2 assay amplification that could generate false positive *Cryptosporidium* results. This pouch module software update does not otherwise impact *Cryptosporidium* assay detection nor the performance of the BIOFIRE GI Panel.

Required actions to be taken by customer:

- Update the BIOFIRE GI Pouch Module Software
 - The updated BIOFIRE GI Pouch Module Software and instructions for installation can be downloaded here: <https://www.biofiredx.com/e-labeling/ITIFA20GI21>. Please use the English (USA) version and read the technical note **before** installation.
 - This technical note and download cannot be opened via Firefox browser; please use a different browser.
- Once the pouch module software has been updated, please fill out the webform located at <https://www.biofiredx.com/gissoftware-5747> or complete the accompanying Acknowledgment of Receipt Form and return to FCA5747@biomerieux.com. This will acknowledge that you've updated your BIOFIRE GI Panel's Software to the latest version.

If you have any questions or concerns, 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,

Mari Hoidal,
Vice President, Global Marketing BioFire