

URGENT: FIELD SAFETY NOTICE

Investigation Update and Required and Recommended Customer Actions:

Modification to the BioFire® FilmArray® Gastrointestinal (GI) Panel (Part No.: RFIT-ASY-0104 and RFIT-ASY-0116) BioFire® FilmArray® Gastrointestinal (GI) Panel Pouch Module Software

Investigation Update

An increased incidence of non-specific chemistry interactions in BioFire GI Panels performed on the BioFire® FilmArray® Torch System combined with a recent change in reagent manufacturing is leading to a rate of false positive *Campylobacter* and *Cryptosporidium* results that exceeds BioFire's published product claims.

The rates of false positive results for BioFire GI Panels performed on the BioFire® FilmArray® 1.5 or the BioFire® FilmArray® 2.0 Systems were found to be within BioFire's published product claims. BioFire GI Panels performed on either of these systems no longer require previously recommended confirmatory testing for *Campylobacter* and *Cryptosporidium* (customer letter issued March 2019, <https://www.online-ifu.com/ITIGI2357>).

Action Taken by BioFire

BioFire has validated an updated version of the BioFire GI Panel Pouch Module Software that improves temperature control during BioFire GI Panel testing on the BioFire Torch System and mitigates the increased risk of related false positives. *This update does **not** affect thermocycling parameters and does **not** change the claimed performance of the BioFire GI Panel.* The updated software makes the BioFire Torch System less susceptible to non-specific chemistry interactions by maintaining high temperatures between nested PCR steps that occur within the BioFire GI Panel reagents.

Actions to Be Taken By BioFire GI Panel Users

BioFire Torch System Users

- **Required:** Update the BioFire GI Panel Pouch Module Software.
 - The updated BioFire GI Panel Pouch Module Software and a technical note with important information and instructions for installation can be downloaded here: <https://www.online-ifu.com/ITIFA20GI21>. Please read this technical note *before* installation.
- Once the software has been updated, previously recommended confirmatory testing for *Campylobacter* and *Cryptosporidium* may be stopped and results may be reported normally.

BioFire FilmArray 2.0 System Users

- **Recommended:** Update the BioFire GI Panel Pouch Module Software.
 - The updated BioFire GI Panel Pouch Module Software and a technical note with important information and instructions for installation can be downloaded here: <https://www.online-ifu.com/ITIFA20GI21>. Please read this technical note before installation.



- Previously recommended confirmatory testing for *Campylobacter* and *Cryptosporidium* may be stopped and results may be reported normally.

BioFire® FilmArray® 1.5 System Users

- No action related to the BioFire® FilmArray® Gastrointestinal (GI) Panel Pouch Module Software is required. BioFire has not updated BioFire GI Panel Pouch Module Software for the BioFire 1.5 System.
- Previously recommended confirmatory testing for *Campylobacter* and *Cryptosporidium* may be stopped and results may be reported normally.

Additional Information

BioFire will continue to provide credit to BioFire® FilmArray® Torch System users for the BioFire® FilmArray® Gastrointestinal (GI) Panel retesting to confirm positive *Campylobacter* and *Cryptosporidium* results through July 15, 2019. This is to provide ample time for BioFire Torch System users to install the updated BioFire GI Panel Pouch Module Software.

BioFire will not continue to provide credit to BioFire FilmArray 1.5 or BioFire® FilmArray® 2.0 System users as previously recommended confirmatory testing for *Campylobacter* and *Cryptosporidium* is no longer required for BioFire GI Panels performed on either of these systems.

The countdown timer displayed for the BioFire GI Panel run time, which was originally set at 65 minutes, has been updated to display 75 minutes with the updated pouch module software. This display change was made to better reflect observed run times for BioFire Torch and BioFire 2.0 System users.

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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