July xx, 2021

<h1 style="color:red; text-align:center">URGENT FIELD SAFETY ONTICE</h1>

<h2 style="text-align:center">FSCA 5231</h2>

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

The purpose of this letter is to inform you that the BioFire® FilmArray® Gastrointestinal (GI) Panel Pouch Module Software will need to be updated on any BioFire Instruments (i.e. BioFire® FilmArray®2.0 and/or BioFire® FilmArray® Torch) purchased after November of 2020.

In 2019, BioFire validated an updated version of the BioFire® FilmArray® GI Panel Pouch Module Software that improved temperate control during BioFire GI Panel testing on the BioFire Torch System and mitigated an increased risk of *Campylobacter* and *Cryptosporidium* false positives. This update did not affect thermocycling parameters and did not change the claimed performance of the BioFire GI Panel. The updated software made 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.

BioFire issued FSCA# 4820-2 in June of 2019; informing customers to install the updated GI Panel Pouch Module Software on their BioFire instruments. FSCA# 4280-2 was closed in July of 2020, however recent internal investigation has indicated that some BioFire Instruments purchased after November 2020 may have an outdated version of the BioFire GI Panel Pouch Module Software installed. To correct this, BioFire recommends that customers follow the actions outlined below:

Actions to be taken by customer:

1. Confirm positive BioFire GI Panel *Campylobacter* and *Cryptosporidium* results by another method prior to reporting those results when running the panel on a BioFire Instrument purchased after November of 2020.
2. Update the BioFire® GI Panel Pouch Module Software on all instruments purchased after November of 2020:

   BioFire Torch System Users
   - **Required:** Update the BioFire GI Panel Pouch Module Software.
     - o 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
     - o 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 2.0 System Users
- **Recommended**: Update the BioFire GI Panel Pouch Module Software.
    - The updated BioFire GI Panel Pouch Software Module and 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.
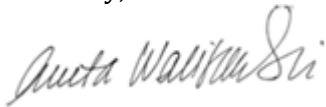

Actions to be taken by BioFire:

As part of the ongoing investigation, BioFire is currently performing corrective and preventative actions.

If you have any further questions or concerns, please do not hesitate to contact your local bioMérieux representative. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

Thank you for your understanding and patience in this matter.

Sincerely,

Aneta Waliszewski
Senior Quality Director
BioFire Diagnostics, LLC