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URGENT: FIELD SAFETY NOTICE

Increased risk of false positive *Campylobacter* and *Cryptosporidium* results using the BioFire® FilmArray® Gastrointestinal (GI) Panel (Part No.: RFIT-ASY-0104 and RFIT-ASY-0116) – Expansion/Revision

The purpose of this letter is to inform you that BioFire Diagnostics, LLC (BioFire) has identified an increased risk of false positive results for *Campylobacter* and *Cryptosporidium* when using the BioFire GI Panel with expiration dates of 23 October 2019 onward. An investigation has determined that the false positive results are due to non-specific PCR amplification in the test, not from contamination with these two organisms. BioFire continues to investigate solutions for this ongoing problem.

This is an expansion of BioFire's previous notice (FLM1-PRT-0280) to include all BioFire GI Panel kit lots with an expiration date of 23 October 2019 onward and to provide revised recommended actions for use of the affected product.

On February 26, 2019, BioFire had temporarily stopped shipment of the BioFire GI Panel (product codes: RFIT-ASY-0116 and RFIT-ASY-0104). BioFire will now resume shipment of the product with the following limitations:

Limitations:

- Users may experience combined rates of false positive *Campylobacter* and *Cryptosporidium* results ranging from 0 – 9% while using the BioFire GI Panel. The majority of product is expected to exhibit rates below 3%.
- **For specimens that test positive for *Campylobacter* and/or *Cryptosporidium* on the BioFire GIPanel:**
    - Results should be confirmed by retesting using a new BioFire GI Panel pouch or by an alternative assay for *Campylobacter* and/or *Cryptosporidium*. Only results from confirmatory retesting for *Campylobacter* and/or *Cryptosporidium* should be reported for that analyte. This is illustrated in Figure 1 below.
- If confirmatory testing is performed with the BioFire GI Panel overall specificity is estimated to be (>99%) of both of these analytes, but may also result in a small reduction in sensitivity (by approximately 2-2.5%; from 97.1% to 94.7% for *Campylobacter* and from 100% to 98.1% for *Cryptosporidium*) as compared to the claimed performance in the Instruction Booklet (See Table 1 below).
- If *Campylobacter* and/or *Cryptosporidium* is not suspected, users may choose not to report/mask *Cryptosporidium* or *Campylobacter* results from the initial testing.
- If testing is repeated with the BioFire GI Panel, other analytes on the panel, if present at low levels (*i.e.*, at or near the assay Limit of Detection), may be discrepant between the first and second test. The testing scheme recommends reporting results from the first test; however, users should apply clinical judgement to determine the course of action and may choose to confirm these results with another method.

- Discrepant results between the initial test and second test should be reported to BioFire Customer Technical Support (contact information below).
- Results from the BioFire® FilmArray® Gastrointestinal (GI) Panel must be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient. Detection of organism targets does not imply that the corresponding organisms are infectious or are the causative agents for clinical symptoms.

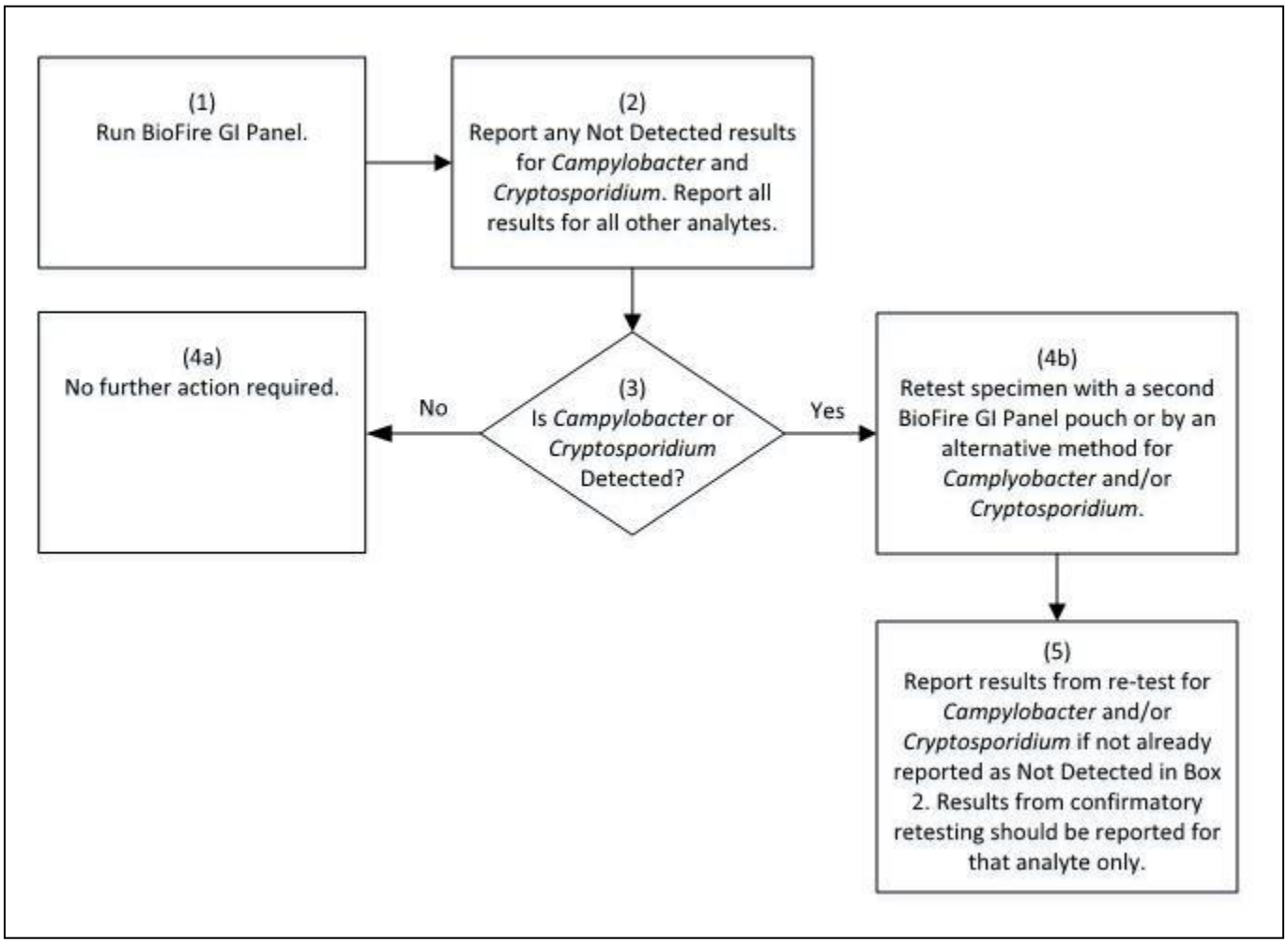

Figure 1. Recommended Testing Scheme

Table 1. Estimated Product Performance Effects of False Positive Errors and Correction (i.e., using second pouch for retest)

Analyte	Performance Estimates	Sensitivity	Specificity
Campylobacter	Claimed Product Performance (Clinical Evaluation Data)	97.1%	98.4%
	Estimated Performance with Maximum False Positive Rate [affected product]	97.2%	92.4%
	Estimated Performance after Correction (i.e., using second pouch for retest)	**94.7%**	**99.4%**
Cryptosporidium	Claimed Product Performance (Clinical Evaluation Data)	99-100%	99.6%
	Estimated Performance with Maximum False Positive Rate [affected product]	99.1%	93.6%
	Estimated Performance after Correction (i.e., using second pouch for retest)	**98.1%**	**99.6%**

Actions to be taken by customer/user:

- Immediately examine your inventory for products identified in this field safety corrective action (FSCA).
    - If you identify any affected BioFire® FilmArray® Gastrointestinal (GI) Panel lots in your inventory, or will order new lots (all new lots are currently affected by this issue) of the BioFire GI Panel, use the affected product according to the limitations as described above.
    - Track the number of retests you perform, as well as the lot numbers consumed for retest, and report this to your local bioMérieux representative to receive credits for these additional pouches.

- If you have further distributed this product, please identify your customers and inform them at once of this FSCA.

Actions to be taken by BioFire:

- BioFire will continue to investigate solutions to this product issue.

- BioFire will communicate to customers when the issue has been resolved, the above limitations can be removed, and the retesting scheme can be discontinued.

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