



Technical Alert

Rapid GI Panel Requires Confirmation for *Campylobacter* and *Cryptosporidium*

TO: Medical Staff and Clients

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SUBJECT: **BioFire FilmArray Gastrointestinal Panel recalled due to false positives**

BioFire Diagnostics, LLC (BioFire) has announced a recall and has stopped shipping the Gastrointestinal (GI) Panel due to false positive results for *Campylobacter* and *Cryptosporidium*. Products shipped to DLS are part of the recall.

There were 307 tests performed with recalled products between December 5, 2018 and February 14, 2019. There was 1 positive for *Cryptosporidium* and 9 positive for *Campylobacter*. These results will be amended as presumptive, but unconfirmed. Client Services will be assisting with the notifications.

In order to maintain our services, DLS will continue to perform the Stool GI Pathogen Panel, PCR (5600) using the affected product; however, any positive results for *Campylobacter* and *Cryptosporidium* will be confirmed by another method. This may impact turn-around-time (TAT):

1. If a specimen tests NEGATIVE for both these organisms, there is NO IMPACT on TAT.
2. If a specimen tests positive for *Cryptosporidium*, an antigen test will be performed. The final result (positive or negative) will be based on the antigen test. This is expected to add about 8-24 hours to the TAT.
3. If a specimen tests positive for *Campylobacter*, a culture will be performed. The final result (positive or negative) will be based on the culture results. This is expected to add 24-48 hours to the TAT.

If either *Campylobacter* or *Cryptosporidium* are suspected, consider ordering alternate tests:

Order codes: 6231 *Cryptosporidium* by IF
 622 Stool Culture w/ Shiga Toxin EIA

Please refer any questions to Terrie Koyamatsu, Manager - DLS Microbiology Laboratory at 589-5196, or DLS Client Services at 589-5101.
