



# Technical Alert

## BIOFIRE FILMARRAY GI Panel Update: *Vibrio* targets

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**TO:** Medical Staff and Clients

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**SUBJECT:** BioFire FilmArray GI Panel Instructions for Use update on false positive *Vibrio* targets

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This alert applies to DLS ordering code #5600, Gastrointestinal (GI) Panel by BioFire FilmArray, which is only available to emergency departments and inpatients.

BioMerieux, the manufacturer of BioFire FilmArray multiplex panels, has updated the Instructions for Use (IFU) in response to Field Safety corrective action FSFA FA-TWD-000007 and the associated internal Corrective and Preventive Actions (CAPA) investigation, finding an **increased risk of false-positive *Vibrio/Vibrio cholerae* results on the BIOFIRE GI Panel while using certain Cary-Blair media.**

Cary Blair media may contain non-viable organisms and/or nucleic acids at levels that can be detected by the BIOFIRE GI Panel. The presence of non-viable organisms and/or nucleic acids in Cary Blair may lead to false positive test results. False positive results due to non-viable *Yersinia enterocolitica* and *Vibrio* species have been previously identified in various media types; the organism involved, and frequency of such occurrences may change in the future. In cases where results from the BIOFIRE GI Panel are not concordant with other clinical, laboratory, and epidemiological data, the BIOFIRE GI Panel results should be confirmed. Stool culture for *Vibrio* can be added using ordering code #308.

All-cause potential sources of false positive *Vibrio* BioFire GI Panel results include:

- PCR detection of low level *Vibrio*
  - Unknown weak cross reactivity
- Misidentification of *Vibrio* species carrying *toxR* homology
- Unrecognized cross-reactivity with other organisms present in specimens
- Contamination of sample or reagents with *Vibrio* organisms or nucleic acid
  - Presence of low-levels of background nucleic acid in Cary Blair media

To review the full BIOFIRE FILMARRAY GI Panel *Vibrio* Detection Technical Note, see:  
<http://www.online-ifu.com/ITIGI0239>

Please refer any questions to Jason Pon, Manager - DLS Molecular Laboratories at 808-441-5469 or DLS Client Services at 808-589-5101.