Technical Alert

Medical Device Recall: BIOFIRE FILMARRAY GI Panel

TO: Medical Staff and Clients

FROM: Dr. Amy Woron, PhD, MPH
V.P. - Technical Director (Microbiology & Molecular Labs)

Jason Pon MB(ASCP), CHS(ABHI)
Manager, DLS Molecular Labs

Dr. Wesley Kim, MD
Medical Director DLS and QMC West

Dr. Ana Ortega-Lopez, MD
Medical Director QMC Punchbowl, North Hawaii and Molokai

DATE: April 10, 2024

SUBJECT: **Medical Device Recall: False Positive Norovirus on BioFire FilmArray Gastrointestinal Panel**

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 issued an urgent medical device recall of the GI Panel because of an increased risk of false positive **norovirus** results.

IMPORTANT:

URGENT: MEDICAL DEVICE RECALL

BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel – Ref. Number: RFIT-ASY-0116 & RFIT-ASY-0104

FSCA 5812 – Increased Risk of False Positive Norovirus Results with the BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel

In the recall notice, BioMerieux recommends health care providers evaluate other clinical and diagnostic findings, including patient clinical history, travel history, suspicion of infection, clinical presentation and severity of the disease.

Although the notice indicates a recall, it does not appear that the manufacturer is pulling any product off the shelves. Consequently**, we are still able to offer the GI Panel** with some reporting restrictions. The manufacturer has advised customers that positive results for norovirus should NOT BE REPORTED unless they can be confirmed by another method. Presently, DLS does not have an alternative method, so positive norovirus results will not be reported. Negative results for norovirus and results for all other pathogen targets will be reported as usual.

We do not have a timeframe in which the manufacturer expects to resolve this problem. We plan to update this alert as more information becomes available.

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