Technical Alert

UPDATE: Medical Device Recall: BIOFIRE FILMARRAY GI Panel

TO: Medical Staff and Clients

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

As of 2/18/25 DLS will resume reporting Norovirus positives on the BioFire FilmArray Gastrointestinal Panel.

This alert supersedes the 4/10/24 medical device recall applying to DLS ordering code #5600, Gastrointestinal (GI) Panel by BioFire FilmArray, which is only available to emergency departments and inpatients.

Initial Notice communicated 4/10/24:

- The manufacturer has advised customers that positive results for norovirus should NOT BE REPORTED unless they can be confirmed by another method.
- Negative results for norovirus and results for all other pathogen targets will be reported as usual.

Update – Medical Device Correction:

BioMerieux initiated an investigation in response to the increase in false positive Norovirus complaints from customers. This prompted a controlled Postmarket Performance Follow-up (PMPF) clinical study to assess the performance characteristics of the Norovirus GI/GII targets. While the clinical sensitivity (PPA) was consistent with the original study, the clinical specificity (NPA) was found to be outside of the original labeling claims.

- BioMerieux updated their observed or predicted cross reactivity tables 43 and 44 in the Instructions for Use found here. https://www.biofiredx.com/e-labeling/ITI0030
- The Norovirus GI/GII clinical specificity was addended and the analytical specificity was revised based on the PMPF clinical study to reassess performance characteristics. See Table 1 below.

Table 1: BIOFIRE GI Panel Norovirus GI/GII Clinical Performance

Study	Positive Percent Agreement (PPA)			Negative Percent Agreement (NPA)		
	TP/(TP + FN)	%	95% CI	TN/(TN + FP)	%	95% CI
Original Clinical Study (May-Sept 2013)	52/55	94.5	84.9-98.9%	1483/1501	98.8	98.1-99.3%
PMPF Study (April – July 2023)	34/35	97.1	85.1-99.9%	808/837	96.5	95.1-97.7%

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