Technical Alert

Medical Device Recall: BIOFIRE FILMARRAY Pneumonia Panel

TO: Medical Staff and Clients

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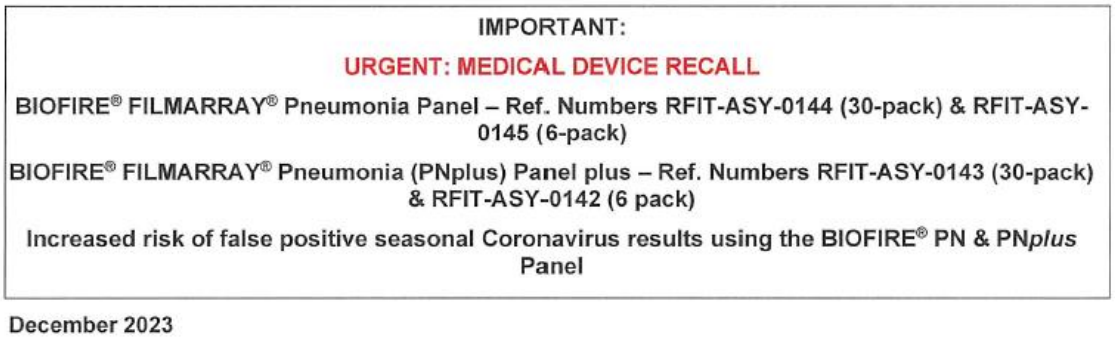
DATE: December 21, 2023

SUBJECT: **Medical Device Recall: False Positive Coronavirus on Biofire Filmarray Pneumonia Panel**

This alert applies to DLS ordering code #7212, Pneumonia Panel by 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 Pneumonia Panel because of an increased risk of false positive **seasonal** coronavirus results. This panel does not test for SARS-CoV-2 (COVID-19).



In the recall notice, bioMerieux reported that investigations indicated that the false positives appear to be as a result of non-specific amplification or cross-reactivity with high concentrations of human genomic DNA (hgDNA) that could be present in clinical specimens.

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 Pneumonia Panel** with some reporting restrictions. The manufacturer has advised customers that positive results for seasonal coronavirus should NOT BE REPORTED unless they can be confirmed. There is no confirmatory testing available, so positive results will not be reported. Negative results for seasonal coronavirus and 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 589-5101.