



Technical Alert

UPDATE: Medical Device Recall: BIOFIRE FILMARRAY Pneumonia Panel

TO: Medical Staff and Clients

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SUBJECT: UPDATE: Medical Device Recall: False Positive Coronavirus on BF FA Pneumonia Panel

As of 2/27/2025 DLS will resume reporting seasonal Coronavirus positives on the BioFire Film Array Pneumonia Panel.

This alert supersedes the 12/21/23 medical device recall applying to DLS ordering code #7212, Pneumonia Panel by BioFire FilmArray, which is only available to emergency departments and inpatients.

Initial Notice communicated 12/21/23:

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

Update – Medical Device Correction:

BioMerieux initiated a mandatory software update in response to the increase in false positive seasonal Coronavirus results. The software update excludes most instances of cross-reactivity with human genomic DNA. Reanalysis of the seasonal Coronavirus clinical performance data with the updated software slightly alters the clinical specificity/NPA for the seasonal Coronavirus from 98.4% to 98.7% in BAL-like specimens and from 99.3% to 99.5% in sputum-like specimens from the prospective evaluation. Clinical performance data has been updated in the Instructions for Use found [here](https://www.biofire.com/e-labeling/ITI0075). <https://www.biofire.com/e-labeling/ITI0075> See Tables 22 and 23 below.

Table 22. BIOFIRE Pneumonia Panel Clinical Performance Summary for BAL Specimens^a

BAL							
Analyte	Reference Method	Sensitivity/PPA			Specificity/NPA		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Coronavirus ^a	PCR/Seq	18/21	85.7	65.4-95.0%	812/823	98.7	97.6-99.3%

Table 23. BIOFIRE Pneumonia Panel Clinical Performance Summary for Sputum Specimens^a

Sputum							
Analyte	Reference Method	Sensitivity/PPA			Specificity/NPA		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Coronavirus ^t	PCR/Seq	28/32	87.5	71.9-95.0%	798/802	99.5	98.7-99.8%

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

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