



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Biofire Diagnostics Recalls Filmarray Pneumonia Panel (Pneumo), For Filmarray Systems, Due To Manufacturing Issue, Panels May Result In False Negative Results.

Recall Date	Product Description	Recalling Firm	Recall Reason
8/30/2023	BioFire Diagnostics LLC FilmArray Pneumonia Panel (Pneumo), REF: RFIT-ASY-0145, For FILMARRAY systems, CE 2797, IVD, Rx Only	BioFire Diagnostics, LLC Salt Lake City, Utah	Due to manufacturing issue, panels may result in false negative results.

Recall Class	Product Identification	Distribution	Affected Dates
II	BioFire Diagnostics LLC FilmArray Pneumonia Panel (Pneumo), Pouch Lot # 2NBT22 /Kit # 2187822 ;UDI-DI: UDI: 00815381020482	24 kits Nationwide including California	May 2023 and prior

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