State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Biofire Diagnostics LLC Medical Recalls BioFire Respiratory Panel 2.1 (RP2.1) Due to manufacturing issue, panels may result in false negative results.

Recall Date	Product Description	Recalling Firm	Recall Reason
8/30/2023	**BioFire Respiratory Panel 2.1 (RP2.1), REF: 423742, For FILMARRAY systems, 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 Respiratory Panel 2.1 **(RP2.1)** Lot # 2MRG22 - 2N0Z22- 2N1622- 2N2122- 2N2322- 2N2522- 2N2P22- 2N2T22- 2N3022- 2N3222- 2N4C22- 2N4D22- 2N4H22- 2N4Z22- 2N5K22- 2N5Y22- 2N6122- 2N6222- 2N6R22- 2N6S22- 2N6W22- 2N6X22- 2N7422 UDI-DI: UDI: 00815381020482	705 kits Nationwide including California	May 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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