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 recalls Blood Culture Identification Panel for Risk of False Positives Against Acinetobacter Complex

Recall Date	Product Description	Recalling Firm	Recall Reason
10/11/2021	**BioFire Blood Culture Identification 2 (BCID2) Panel** Panel Part No: RFIT-ASY-0147 UDI: 00815381020338 Blood Culture Catalog No./Description: 442023	**BioFire Diagnostics, LLC** Salt Lake City, Utah	Due to an increased risk of false positive Acinetobacter calcoaceticus-baumannii complex results. The cause may be as a due to non-viable contamination in the blood culture vials.

Recall Class	Product Identification	Distribution	Affected Dates
II	**BioFire Blood Culture Identification 2 (BCID2) Panel**	12,120 pouches (404 kits) in California	November 1, 2020- October 31, 2021

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

CDPH Food and Drug Branch
MS 7602 ● P.O. Box 997435 ● Sacramento, CA 95899-7435
(916) 650-6500 ● (916) 650-6650 FAX
Internet Address: www.cdph.ca.gov