State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Beckman Coulter Recalls IVD for Lipemic Interference Failure to Meet Specification

Recall Date	Product Description	Recalling Firm	Recall Reason
9/6/2023	**Beckman Coulter, IVD** REF: OSR61171, IgA, 4 x 14 mL R1, 4 x 11 mL R2	**BECKMAN COULTER INC.** Brea, California	Lipemic interference failed to meet the performance specification listed within the IFU.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Beckman Coulter, IVD** All Lots/UDI-(01)15099590011574	12,850 Units Nationwide including California	July 12, 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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