State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Kamiya Biomedical Recalls K-Assay for Performance

Recall Date	Product Description	Recalling Firm	Recall Reason
11/30/2022	**K-ASSAY** IgA Immunoturbidimetric Assay, REF: KAI-013	**Kamiya Biomedical Company, LLC** Tukwila, Washington	IgA Reagent may start showing cloudiness over time, which can affect assay performance.

Recall Class	Product Identification	Distribution	Affected Dates
II	UDI-DI: 00816426020092, Lot/ Expiration Date: H180/ 2023-01-31, K181/ 2023-03-31, N182/ 2023-06-30, D283/ 2023-09-30	99 Kits in California	September 2022 – September 2023

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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