State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Randox Laboratories Recalls Randox Liquid Urine Control Level 2- For Laboratory Testing Issues Include Vial-To-Vial Variation In Hcg Results, High Cortisol Levels, And A Transcription Error For Creatinine In The Instructions For Use, Causing Delays In Patient Results And Potential Diagnostic Inaccuracies.

Recall Date	Product Description	Recalling Firm	Recall Reason
8/30/2023	**Randox Laboratories Ltd** Randox Liquid Urine Control Level 2	**Randox Laboratories Ltd.** Crumlin, Ireland	Laboratory testing issues include vial-to-vial variation in hCG results, high cortisol levels, and a transcription error for Creatinine in the Ins-tructions For Use, causing delays in patient results and potential diagnostic inaccuracies.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Randox Laboratories Ltd** Randox Liquid Urine Control Level 2 GTIN: 05055273207569 Batch/Lot Number: 1209UC	39 Units Nationwide	June 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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