



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Randox Laboratories Immunoassay Premium Control Tri Level for Delay in Reporting

Recall Date	Product Description	Recalling Firm	Recall Reason
7/5/2023	Immunoassay Premium Control Tri Level Catalog Number: IA2633	Randox Laboratories Ltd. Crumlin, Ireland	Delay in reporting results due to Quality Controls running high outside of range. Target value and range for ACTH in Immunoassay Premium Level 3, IA2640, lot 2031EC and Immunoassay Premium Control Tri Level kit batch 583135 lot 2031EC has been reassigned on the Roche Cobas e801 due to High recovery outside range.

Recall Class	Product Identification	Distribution	Affected Dates
III	Immunoassay Premium Control Tri Level GTIN: 05055273203837 Batch/Lot Number: 583135 Exp. Date: 28th April 23	1 Units in California	May 2023 and Prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

