California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Beckman Coulter Inc. DxC 500 AU Clinical Chemistry Analyzer

Recall Date	Product Description	Recalling Firm	Recall Reason
04/25/2025	DxC 500 AU Clinical Chemistry Analyzer Catalog Number:C63519 UDI-DI: 14987666545058 Catalog Number: C63520 UDI-DI: 14987666545065 Software versions: V1.3, V1.4, V1.4.1, V1.4.2, V1.4.3 The Beckman Coulter DxC 500 AU Clinical Chemistry Analyzer is an automated chemistry analyzer that measures analytes in samples, in combination with appropriate reagents, calibrators, quality control (QC) material and other accessories. This system is for in vitro diagnostic use only.	Beckman Coulter Inc.	The reason for the recall is incorrect sample barcode identification and processing errors that result in the reporting of erroneous and delayed results.

Recall Class	Product Identification	Distribution	Affected Dates
II	Catalog Number: C63519 UDI-DI code: 14987666545058 Serial Numbers: 2024090170	5 systems in California	March and prior

	Catalog Number: C63520 UDI-DI code: 14987666545065 Serial Numbers: 2023060005 - 2025010248		

For additional information, please visit the FDA Website.