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
05/15/2025	DxC 500 AU Clinical Chemistry Analyzer Catalog Numbers/UDI codes: C63519 / 14987666545058 C63520 / 14987666545065. 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.	Beckman Coulter is recalling their DxC 500 AU Clinical Chemistry Analyzer because a software error causes the analyzer to not run a requested calibration order in the following scenario: when a reagent blank or calibration is ordered during sample processing and then any of the components (R1 and/or R2) depletes to zero tests, the analyzer will not be able to complete the calibration request, and the calibration order will remain pending. No further calibration orders can be processed for any assays, and the instrument refuses to accept further sample processing order after the existing calibration curves are

			expired. Although in-process tests will be completed, this error can cause a delay in reporting subsequent test results. No further calibration orders can be processed for any assays which may cause a delay in reporting test results.

Recall Class	Product Identification	Distribution	Affected Dates
II	Catalog Number: C63519 UDI-DI code: 14987666545058 Catalog Number: C63520 UDI-DI code: 14987666545065	1 unit in California	March and prior

For additional information, please visit the FDA Website.