California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Beckman Coulter Laboratory Systems (Suzhou) CO., LTD. DxC 500 AU Clinical Chemistry Analyzer

Recall Date	Product Description	Recalling Firm	Recall Reason
02/25/2025	DxC 500 AU Clinical Chemistry Analyzer REF: C63519, and C63520 with affected software.	Beckman Coulter Laboratory Systems (Suzhou) CO., LTD.	Beckman Coulter has identified an issue which prevents the DxC 500 AU instrument from providing the correct onboard stability (Open Expiration) dates for assays that were loaded prior to a software upgrade (e.g. 1.3 to 1.4, 1.4 to 1.4.1, etc.). As a result, assays that have expired may still be used for sample processing, leading to inaccurate or erroneous patient test results. The issue only happens on assays loaded before instruments doing upgrades and does not impact new installation. It does not impact the assays loaded after upgrade. Beckman Coulter has determined that

			device software versions V1.3, V1.4, V1.4.1, V1.4.2, V1.4.3. have a defect due of which, when all constituent tests of a calculated result are rerun, either manually ordered by the operator at the analyzer or automatically triggered by predefined rules in System Configuration, the calculated result will not be recalculated using the constituent tests rerun results. The system will report only the calculated result using the initial constituent tests results to the operator and LIS/Remisol. The issue was identified by Beckman Coulter internal engineering testing. The defect may cause a delay in reporting patient results.

Recall Class	Product Identification	Distribution	Affected Dates
II	Software Versions: V1.4, V1.4.1, V1.4.2, V1.4.3 REF: C63519 UDI-DI: 14987666545058 Serial Numbers: 2024090170 REF: C63520 UDI-DI: 14987666545065 Serial Numbers: 2024070116 - 2024080144	5 units in California	January and prior

	Catalog Number: C63519 UDI-DI: 14987666545058 Serial Numbers: 2024060094 - 2024070118 Catalog Number: C63520 UDI-DI: 14987666545065 Serial Numbers: 2024010028 - 2024080144		February and prior

For additional information, please visit: FDA Website (1) and FDA Website (2).