California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Beckman Coulter Ireland, Inc. Apo B Reagent

Recall Date	Product Description	Recalling Firm	Recall Reason
05/23/2025	Apo B Reagent REF: OSR6143	Beckman Coulter Ireland, Inc.	The product Value Assignment Sheet (VAS) is used in calibration of the device. An erroneous value was included in the VAS which has the potential to generate an incorrect APO B patient result which could exceed the total allowable error for the APO B assay (11.6%). The error results in results with a positive bias up to 42%. However, based on the mitigating factors the risk to health is considered to be negligible or limited.

Recall Class	Product Identification	Distribution	Affected Dates
III	Lot Number: 2631 UDI: 15099590010409	8 units in California	April and prior

For additional information, please visit the FDA Website.