California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Beckman Coulter Inc. IMMAGE Immunochemistry Systems IGM Immunoglobulin M Reagent

Recall Date	Product Description	Recalling Firm	Recall Reason
10/17/2024	IMMAGE Immunochemistry Systems IGM Immunoglobulin M Reagent REF 447610 IGM reagent, when used in conjunction with IMMAGE Immunochemistry Systems and Calibrator 1, is intended for the quantitative determination of immunoglobulin M (IGM) in human serum by rate nephelometry.	Beckman Coulter Inc.	Firm identified two lots of reagents that are not meeting the sensitivity statement in the IFU

Recall Class	Product Identification	Distribution	Affected Dates
II	Catalog Number: 447610 UDI-DI code: 15099590221195 Lot Numbers: M307362 M309410	33 distributed in California	July 2024 and Prior

For additional information, please visit the FDA Website.