



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Abbott Recalls Hemoglobin Reagent for Architect and Alinity

Recall Date	Product Description	Recalling Firm	Recall Reason
6/09/2022	Hemoglobin A1c for use with Architect IVD, CE, R1 1 x 52 mL, R2 1 x 20 mL, A1cDL 2 x 35 mL REF: 4P52-20	Abbott Laboratories Irving, Texas	There is a potential for falsely elevated Hemoglobin %A1c and Hemoglobin A1c results to be generated
6/09/2022	Alinity c Hemoglobin Reagent Kit IVD, CE, R1 5 x 46.0 mL, R2 5 x 18.3 mL, A1cDL 5 x 67.6 mL REF: 08P4320	Abbott Laboratories Irving, Texas	There is a potential for falsely elevated Hemoglobin %A1c and Hemoglobin A1c

Recall Class	Product Identification	Distribution	Affected Dates
II	Hemoglobin A1c for use with Architect UDI/DI: 00380740102746/ Lots: 59588UQ04, 59868UQ05, 59900UQ06, 60138UQ07, 60237UQ08, 60535UQ08, 60698UQ09, 60880UQ10, 61066UQ11, 61246UQ01	13,546 units in California	June 2022 and prior
II	Alinity c Hemoglobin Reagent Kit UDI/DI: 00380740135591/ Lots: 59561UQ04, 59779UQ05, 60229UQ07, 60540UQ09, 61011UQ10, 61349UQ01	77 units in California	June 2022 and prior

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