



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Abbott Ireland Limited Alinity i Anti-TPO Reagent Kit for Manufacturing Fill Volume Error

Recall Date	Product Description	Recalling Firm	Recall Reason
6/14/2023	Alinity i Anti-TPO Reagent Kit List Number 09P3521	Abbott Ireland Limited Sligo, Ireland	Due to a manufacturing fill volume error, Alinity i Anti-TPO Reagent contains a marginally lower fill volume than detailed in the Kit Contents section of the Instructions for Use (IFU).

Recall Class	Product Identification	Distribution	Affected Dates
III	Alinity i Anti-TPO Reagent Kit UDI Number: (01)00380740153892(17)24072 0(10)46009FN00; List Number: 09P3521; Lot Number: 46009FN00; Expiration Date: 07/20/2024	5 Units in California	April 2023 and Prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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