



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Ortho Clinical issues Booklet Correction for Documentation of Vitros Immunodiagnostic Products Anti-HBc IgM Controls

Recall Date	Product Description	Recalling Firm	Recall Reason
10/15/2021	VITROS Immunodiagnostic Products Anti-HBc IgM Controls For use in monitoring the performance of the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems	Ortho Clinical Diagnostics Inc Rochester, New York	Ortho Clinical Diagnostics confirmed a complaint that some VITROS Immunodiagnostic Products Anti-HBc IgM Controls Lot 1690 Controls Values booklet contained information for the incorrect product. While the accuracy of patient test results is not affected by this issue, there is a potential for delayed results due to the troubleshooting of Quality Control results

Recall Class	Product Identification	Distribution	Affected Dates
III	Lot 1690 UDI 10758750001200	8 Booklets in California	October 2021 and prior

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