



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Ortho Clinical recalls Vitros Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Controls

Recall Date	Product Description	Recalling Firm	Recall Reason
05/12/2021	<p>VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Controls (IVD) For use in monitoring the performance of the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems when used with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Calibrator for the determination of IgG antibodies to SARS-CoV-2. Product Code: 6199966 & 50</p>	<p>Ortho Clinical Diagnostics Inc Rochester, New York</p>	<p>Quantitative Controls Outside of Expected Control Range, potential for delayed results</p>

Recall Class	Product Identification	Distribution	Affected Dates
II	<p>Lot Number: 0040(*and potentially future lots) UDI: 10758750034475 Exp. Date: 19NOV2021</p>	<p>74 Units Nationwide including California</p>	<p>May 2021 to Nov 2021</p>

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