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

<table>
<thead>
<tr>
<th>Recall Date</th>
<th>Product Description</th>
<th>Recalling Firm</th>
<th>Recall Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/12/2021</td>
<td>VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Controls (IVD)</td>
<td>Ortho Clinical Diagnostics Inc Rochester, New York</td>
<td>Quantitative Controls Outside of Expected Control Range, potential for delayed results</td>
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<td></td>
<td>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 &amp; 50</td>
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<tr>
<th>Recall Class</th>
<th>Product Identification</th>
<th>Distribution</th>
<th>Affected Dates</th>
</tr>
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<tbody>
<tr>
<td>II</td>
<td>Lot Number: 0040(*and potentially future lots) UDI: 10758750034475 Exp. Date: 19NOV2021</td>
<td>74 Units Nationwide including California</td>
<td>May 2021 to Nov 2021</td>
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FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](https://www.fda.gov)