Instrumentation Laboratory Recalls HemosIL ReadiPlasTin for Erroneous Result Potential

<table>
<thead>
<tr>
<th>Recall Date</th>
<th>Product Description</th>
<th>Recalling Firm</th>
<th>Recall Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/3/2021</td>
<td>HemosIL ReadiPlasTin 20mL Part number 0020301400</td>
<td>Instrumentation Laboratory/Werfen Bedford, Massachusetts</td>
<td>The firm has received customer reports of performance issues with the affected lot, including increased imprecision, out of range quality controls, and prolonged sample results. If quality controls are not performed or do not pass for each vial of reagent, there is a potential risk of reporting an erroneous result.</td>
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</tbody>
</table>

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<tr>
<th>Recall Class</th>
<th>Product Identification</th>
<th>Distribution</th>
<th>Affected Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>II</td>
<td>HemosIL ReadiPlasTin 20mL Lot N0705526 UDI 08426950632887</td>
<td>8 units in California</td>
<td>October 2021 and prior.</td>
</tr>
</tbody>
</table>

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](https://www.fda.gov)