State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Instrumentation Laboratory Recalls HemosIL ReadiPlasTin for Erroneous Result Potential

Recall Date	Product Description	Recalling Firm	Recall Reason
11/3/2021	**HemosIL ReadiPlasti 20mL** Part number 0020301400	**Instrumentation Laboratory/Werfren** Bedford, Massachusetts	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.

Recall Class	Product Identification	Distribution	Affected Dates
II	**HemosIL ReadiPlasti 20mL** Lot N0705526 UDI 08426950632887	8 units in California	October 2021 and prior.

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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