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 – Hemosil Synthafax Partial Thromboplastin Time Tests Recall

Recall Date	Product Description	Recalling Firm	Recall Reason
12/18/2025	**Hemosil Synthafax** An activated partial thromboplastin time (aPTT) test used to evaluate blood coagulation function in laboratory settings.	**INSTRUMENTATION LABORATORY** Bedford, MA, USA	Recalled lots were manufactured with double the intended preservative concentration due to a process control issue.

Recall Class	Product Identification	Distribution	Affected Dates
III	**Part No.** 0020007400; **UDI**: 08426950087649; **Lot Nos.:** N0542231 (Exp. 2026-06-30), N0250088 (Exp. 2027-04-30), N0452249 (Exp. 2027-06-30)	4,506 Units Internationally and California	November 2025 and prior

For additional information, please visit the FDA website

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