California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Abbott Laboratories – Alinity ci-series System Control Module Recall

Recall Date	Product Description	Recalling Firm	Recall Reason
12/18/2025	Alinity ci-series System Control Module (SCM), a chemistry/immunoassay analyzer used for clinical diagnostic testing.	Abbott Laboratories Irving, TX, USA	Potential performance issues in software versions 3.6.1 and lower may lead to erroneous results for multiple analytes.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Lot Code:** N/A **Model No.:** REF 03R70-01, 03R70-20 **UDI-DI**: 00380740137410 **S/N range:** Multiple serial numbers (see full list in recall data).	11,653 Units; Nationwide including California (138 units in CA)	November 2025 and prior.

For additional information, please visit the FDA Website.