California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Abbott Molecular, Inc. Abbott Alinity m HPV AMP Kit

Recall Date	Product Description	Recalling Firm	Recall Reason
10/28/2024	Abbott Alinity m HPV AMP Kit, used with the Alinity m System, product codes: REF 09N15-095; REF 09N15-090; REF 09N15-091	Abbott Molecular, Inc.	Abbott has identified an increase of incidences regarding Error Code (EC) 9198 (Positive control is non-reactive) while using the Alinity m HR HPV AMP Kit and Alinity m STI AMP Kit. Certain invalidated positive assay controls can be traced to iron leaching into the Alinity m Lysis Solution from the lysis transfer pump in the Alinity m System.

Recall Class	Product Identification	Distribution	Affected Dates
II	REF 09N15-095, UDI/DI 00884999048614; REF 09N15-090, UDI/ DI 00884999047921;REF 09N15-091, UDI/DI 00884999049529; All Lots	13,318 units worldwide and nationwide including California.	September and prior.

For additional information please visit the FDA website.