State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Abbott recalls Alinity S Software for Error during Immunoassay Wash Cycle

Recall Date	Product Description	Recalling Firm	Recall Reason
02/03/2021	**Alinity s System software** version2.8.0, REF LN 06P16-01, IVD, OEI: (01)0038074-0138479 The Alinity s System is intended for In Vitro diagnostic use only. The Alinity s System is a highthroughput, fully automated immuneassay analyzer designed to determine the presence of specific antigens and antibodies by using chemiluminescent immunoassay technology.	**Abbott Laboratories** Irving, Texas	Software error associated with the immunoassay analyzer wash cycle which is using 1 mL of wash buffer instead of the intended 3 mL of wash buffer to wash the exterior of the probe.

Recall Class	Product Identification	Distribution	Affected Dates
II	Serial numbers AS1001 through AS1387 UDIs: (01)00380740138479(21)AS1002 (01)00380740138479(21)AS1005 (01)00380740138479(21)AS1009 (01)00380740138479(21)AS1012 (01)00380740138479(21)AS1013 (01)00380740138479(21)AS1016	4 Units affecting 3 Facilities	February 2022 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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