State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Potential for False Positive Results with Abbott Molecular Inc. Alinity m SARS-CoV-2 AMP and Alinity m Resp-4-Plex AMP Kits

Recall Date	Product Description	Recalling Firm	Recall Reason
9/2/2021	**Alinity m SARS-CoV-2 AMP Kit** 51,897 units **4 trays** AMP, ACT List Number 09N78-095	**Abbott Molecular Inc,** Des Plaines, Illinois	False positive likely resulting from software mixing parameters of chemicals with patient sample causing overflow between wells.
9/2/2021	**Alinity m Resp-4-Plex AMP Kit** PCR Test panel for Infl A & B, RSV, SARS-CoV-2 251 Units **4 trays** AMP, ACT List Number 09N79-096	**Abbott Molecular Inc,** Des Plaines, Illinois	False positive likely resulting from software mixing parameters of chemicals with patient sample causing overflow from one well to another.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Software for automated molecular analyzer**	187 Software Installs nationwide,	May 2020 – August 2021

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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