State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Ancillary reagent packs used on Atellica IM 1300 and Atellica IM 1600 analyzers may overflow when pierced while on an analyzer located at an altitude of greater than 350m (1148ft) above sea level

Recall Date	Product Description	Recalling Firm	Recall Reason
10/27/2021	**Atellica IM 1300 Analyzer, SMN 11066001** 1193 units	**Siemens Healthcare Diagnostics, Inc,** East Walpole, Massachusetts	Ancillary reagent packs used on Atellica IM 1300 analyzer may overflow when pierced while on an analyzer located at an altitude of greater than 350m (1148ft) above sea level. As a result, customers at these altitudes may observe an increased number of Reagent Volume Check Errors.
10/27/2021	**Atellica IM 1600 Analyzer, SMN 11066000** 1733 Units	**Siemens Healthcare Diagnostics, Inc,** East Walpole, Massachusetts	Ancillary reagent packs used on Atellica IM 1600 analyzer may overflow when pierced while on an analyzer located at an altitude of greater than 350m (1148ft) above sea level. As a result, customers at these altitudes may observe an increased number of Reagent Volume Check Errors.

Recall Class	Product Identification	Distribution	Affected Dates
Voluntary	**Atellica IM 1300 & 1600 Analyzers, SMN 11066001 &11066000** All units	3 Systems in California, number of ancillary packs depends on user's test mix	September 2021 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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