State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Siemens-Health Declares Insufficient Data on EUA for SARS-CoV-2 Antigen Assays

Recall Date	Product Description	Recalling Firm	Recall Reason
11/10/2021	**Atellica IM SARS-CoV-2 Antigen Assay** 100 Test kit SMN # 11207861	**Siemens Healthcare Diagnostics, Inc,** East Walpole, Massachusetts	Data provided in the Emergency Use Authorization (EUA) submission was insufficient to determine that the assays were adequately validated for the intended use.
11/10/2021	**ADVIA Centaur SARS-CoV-2 Antigen Assay** 100 Test kit SMN # 11207866	**Siemens Healthcare Diagnostics, Inc,** East Walpole, Massachusetts	Data provided in the Emergency Use Authorization (EUA) submission was insufficient to determine that the assays were adequately validated for the intended use.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Atellica IM SARS-CoV-2 Antigen Assay** Lot # 44989001 Exp. Date 2021-10-07 UDI#(01)00630414611846(10)44989001(17)20211007 Lot # 60407003 Exp. Date 2021-03-22 UDI#(01)00630414611846(10)60407003(17)20211112	3 kits in California	September 2021 and prior

II	**ADVIA Centaur SARS-CoV-2 Antigen Assay** Lot # 44990001 Exp. Date 2021-10-07 UDI#(01)00630414611747(10)44990001(17)20211007 Lot # 60408003 Exp. Date 2021-11-12 UDI#(01)00630414611747(10)60408003(17)20211112	214 kits in California	September 2021 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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