State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

LuSys Recalls COVID-19 Viral Antigen Tests

Recall Date	Product Description	Recalling Firm	Recall Reason
1/13/2022	**LuSys 2nd Generation of COVID-19 Viral Antigen Test** For all mutant variety Cat: I-114(Saliva Test)	**LuSys Laboratories, Inc.** San Diego, California	COVID-19 test kits (Antibody Rapid Test kit and Antigen Rapid Test Kit) are not authorized, cleared, or approved for marketing and/or distribution in the U.S.
1/13/2022	**Luscient Diagnostics 2nd Generation of COVID-19 Viral Antigen Test** For Detection of COVID-19 IgG and IgM antibodies Catalog No: I-111	**LuSys Laboratories, Inc.** San Diego, California	COVID-19 test kits are not authorized, cleared, or approved for marketing and/or distribution in the U.S.

Recall	Product Identification	Distribution	Affected Dates
II	**LuSys 2nd Generation of COVID-19 Viral Antigen Test** Part Number: I-114(S) Lot Numbers: All Lots due to not having an authorized Emergency Use Authorization (EUA)	14,745 kits Nationwide including California	January 2022 and prior
II	**Luscient Diagnostics 2nd Generation of COVID-19 Viral Antigen Test** Part Number: I-114(N) Lot Numbers: All Lots due to not having an authorized	90,849 kits Nationwide including California	January 2022 and prior

	Emergency Use Authorization (EUA) UDI#(01)00630414611747(10)60408003(17)20211112		

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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