State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

North American Diagnostics Recalls Oral Rapid SARS-CoV-2 Rapid Antigen Test Kits That Are Not Authorized, Cleared, or Approved by the FDA

Recall Date	Product Description	Recalling Firm	Recall Reason
6/15/2022	**Oral Rapid SARS CoV 2 rapid antigen test** packaged under the following brands: Oral Rapid Test Oral Rapid Antigen Test SML LDT Kits SML Brand Finished Kits SML Brand BT Test Kits SML Brand BT Antigen Test Kit LDT	**North American Diagnostics** Holly Hill, Florida	Various brands of SARS CoV 2 Antigen Rapid Test kits were offered for sale and distribution to consumers in the United States without marketing approval, clearance, or authorization from FDA.

Recall Class	Product Identification	Distribution	Affected Dates
I	Lot: FLUSA 1020-1, Batches 8, 10, and 12	122,366 units Nationwide including California	June 2022 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

CDPH Food and Drug Branch
MS 7602 ● P.O. Box 997435 ● Sacramento, CA 95899-7435
(916) 650-6500 ● (916) 650-6650 FAX
Internet Address: www.cdph.ca.gov