State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Jiangsu Well Biotech Co., Ltd. Recalls COVID-19 Ag Rapid Test Devices That Are Not Authorized, Cleared, or Approved by the FDA

Recall Date	Product Description	Recalling Firm	Recall Reason
10/08/2022	**COVID-19 Ag Rapid Test Device** Jiangsu Well Biotech Co.,Ltd. AND SDI LABS - Cat#: CO-02	**Jiangsu Well Biotech Co.,Ltd.** Changzhou, China	Distribution of COVID-19 Ag Rapid Test kits in the U.S. without an Emergency Use Authorization, or a Pre-Market Approval or Clearance.

Recall Class	Product Identification	Distribution	Affected Dates
I	Catalog Number: CO-02 UDI-DI Code: No UDI Codes provided Lot Numbers: 202107192, 202108231, 202109231, 202111082, 202110111, 202201102	620,000 Tests (110,000 Devices) in California	August 2022 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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