State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Do Not Use Certain Celltrion DiaTrust COVID-19 Tests

Recall Date	Product Description	Recalling Firm	Recall Reason
12/01/2021	**Celltrion DiaTrust COVID-19 Ag Rapid Test** REF CT-P60 D-2 01. Contains 25 disposable test tubes with extraction buffer, 25 filter caps, 25 sterilized swabs per box	**CELLTRION USA INC** Jersey City, New Jersey	The European version of the DiaTrust COVID-19 Ag Rapid Test is not approved for marketing in the U.S. but was illegally distributed in the U.S. The packaging and labeling of the European test kit is different from the US test kit and is NOT authorized for distribution in the US.

Recall Class	Product Identification	Distribution	Affected Dates
II	Lot numbers: **All Lots**	162,000 Units Nationwide including California	July 2020 - August 2020

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