State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Celltrion Recalls DiaTrust COVID-19 Ag Rapid Test for Distribution Error

Recall Date	Product Description	Recalling Firm	Recall Reason
4/01/2022	**Celltrion DiaTrust COVID-19 Ag Rapid Test** Reference No. CT-P60 D-2 02	**CELLTRION USA INC** Jersey City, New Jersey	Point of Care (PoC) rapid test products were distributed to customers who did not have a valid CLIA ID.

Recall Class	Product Identification	Distribution	Affected Dates
I	All lots distributed to end users without valid CLIA ID UPC: 8 806121 763044	Nationwide including California	December 2021 – February 2022

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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