



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Stop Using Empowered Diagnostics COVID-19 Tests

Recall Date	Product Description	Recalling Firm	Recall Reason
12/22/2021	CovClear COVID-19 Rapid Antigen Test ATG 900-031	Empowered Diagnostics LLC Pompano Beach, Florida	COVID test kits were offered for sale and distributed to consumers in the United States without marketing approval, clearance, or authorization from FDA.
12/22/2021	ImmunoPass , COVID-19 Neutralizing Antibody Test NAB 900-60	Empowered Diagnostics LLC Pompano Beach, Florida	COVID test kits were offered for sale without FDA Approval.

Recall Class	Product Identification	Distribution	Affected Dates
I	CovClear COVID-19 Rapid Antigen Test All Lots	Nationwide	December 2021 and prior
I	ImmunoPass , COVID-19 Neutralizing Antibody Test All lots	Nationwide	December 2021 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

