



Food and Drug Branch – Device Recalls

**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Universal Meditech Recalls Ventilators due to Distribution without FDA Market Approval**

Recall Date	Product Description	Recalling Firm	Recall Reason
02/08/2023	<b>Skippack Medical Lab SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) 20 TESTS/1 KIT</b> 56,300 kits	<b>Universal Meditech Inc.</b> Fresno, California	Distribution of SARS-CoV-2 Antigen Rapid Test Kits without FDA market approval, clearance or Emergency Use Authorization.

Recall Class	Product Identification	Distribution	Affected Dates
I	<b>Skippack Medical Lab SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)</b> <b>Model Number: 550-10</b> <b>Lot Numbers: UL-AG-2111-01-Q</b> <b>UL-AG-2111-02-Q UL-AG-2110-05-Q UL-AG-2112-02-Q UL-AG-2110-03-Q UL-AG-2110-04-Q</b>	US Nationwide Distribution in California and Texas	February 2023 and prior

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