



Food and Drug Branch – Device Recalls

**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Ellume Recalls COVID-19 Home Test for Potential False Positive SARS-CoV-2 Test Results**

Recall Date	Product Description	Recalling Firm	Recall Reason
11/10/2021	<b>Ellume COVID-19 Home Test</b> Cat No. I-SRS-C-01	<b>Ellume Ltd.</b> East Brisbane, Australia	higher rate of false positive test results.

Recall Class	Product Identification	Distribution	Affected Dates
I	<b>Ellume COVID-19 Home Test</b> Lot No. 21047-4; 21047-5; 21089-1; 21117-1; PF06Z-H; 21099-1; 21124-1; 21125-1; PF03X-H; PF057-H; PF05W-H; PF069-H; PF06E-H; PF06N-H; PF06Z-H; PG080-H; PG08H-H; PH08X-H	289,748 units in California 112,920 of affected units were used, of which 7,041 have been remotely deactivated	October 2021 and prior

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