Australian firm recalls US COVID tests over false positives

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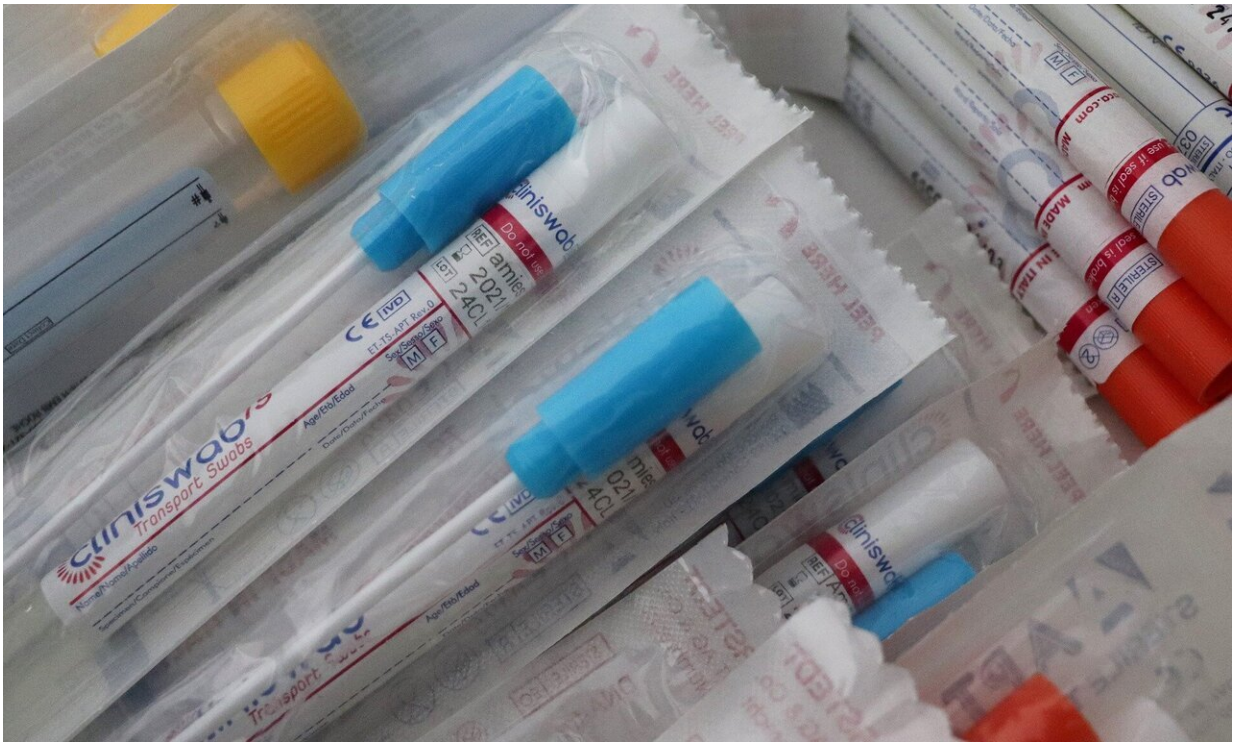

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Australian medical tech manufacturer Ellume said it had recalled almost 200,000 at-home COVID-19 tests in the United States over an increased chance of false positives.

Ellume's rapid at-home coronavirus test last year became the first to

receive emergency use authorisation in the US.

The US Food and Drug Administration issued an alert Tuesday over the "potential for false positive results with certain lots of the Ellume COVID-19 Home Test, due to a recently identified manufacturing issue".

"Negative results do not appear to be affected by the manufacturing issue," the statement said.

"The FDA is working closely with Ellume to assess the company's additional manufacturing checks and other corrective steps to help ensure that the issue is resolved."

A spokesman for Ellume told AFP on Wednesday that 195,000 of the 3.5 million tests shipped to the United States had been affected.

Among them were tests provided to the Department of Defense for distribution to community health programmes.

In a statement dated October 1, the company said the voluntary recall was ordered after false positive results were reported in some product batches at higher rates than expected.

"I offer my sincere apologies—and the apologies of our entire company—for the stress or difficulties people may have experienced due to a false positive result," founder Sean Parsons said.

The firm said it had identified the cause of the issue and implemented additional controls, and had resumed distributing the tests to US retailers.

"We have and will continue to work diligently to ensure test accuracy, in

all cases," Parsons added.