Australian firm recalls over 2 million US COVID tests

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An Australian medical tech manufacturer has recalled more than two million at-home COVID-19 tests shipped to the United States after finding an increased chance of false positives.

The US Food and Drug Administration issued an alert Wednesday that the company, Ellume, had recalled 2.2 million tests since the issue was detected last month.

A false positive test result indicates that a person has coronavirus when they do not.

"The FDA has identified this as a Class I recall, the most serious type of recall," the agency said in a notice.

"Use of these tests may cause serious adverse health consequences or death."

The FDA said it had received 35 reports of false positives and no deaths to date.

In early October, Ellume announced a voluntary recall of 195,000 tests after false positive results were reported in some product batches at higher-than-expected rates.

At the time, the firm had shipped about 3.5 million tests to the US.

Ellume said Thursday the recall was expanded after additional lots were found to be affected.

"Ellume has investigated the issue, identified the root cause, implemented additional controls, and we are already producing and shipping new product to the US," it said in a statement.

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

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

receive emergency use authorisation in the US.

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