Ellume: 91%+ accurate at-home COVID test given first emergency authorization in the US

The Food and Drug Administration on [December 15] issued an emergency authorization for the country's first coronavirus test that can run from start to finish at home without the need for a prescription.

People as young as 2 years old are cleared to use the test, which takes just 15 to 20 minutes to deliver a result. Unlike many similar products, which are only supposed to be used by people with symptoms of Covid-19, this test is authorized for people with or without symptoms.

The test, developed by the Australian company Ellume, detects bits of coronavirus proteins called antigens. It's slightly less accurate than gold standard laboratory tests designed to look for coronavirus genetic material with a technique called polymerase chain reaction, or P.C.R. But in a clinical study of nearly 200 people, Ellume's product was able to detect 95 percent of the coronavirus infections found by P.C.R., regardless of whether the infected people felt sick. It also correctly identified 97 percent of the people who received negative laboratory test results.

Ellume, which was awarded a $30 million grant from the National Institutes of Health, said it planned to manufacture and deliver about 20 million home coronavirus tests to the United States within the first half of 2021. Each kit, which tests a single swab sample, is expected to cost about $30 or less.

Read the original post