

FDA STATEMENT

Coronavirus (COVID-19) Update: FDA Alerts Consumers About Unauthorized Fraudulent COVID-19 Test Kits

Subject: please help alert consumers in your area about unauthorized fraudulent COVID-19 home test kits

The U.S. Food & Drug Administration (FDA) released an announcement last Friday March 20th, that warns consumers about unauthorized fraudulent coronavirus tests. Please help us get the word out to consumers.

Briefly, the agency is beginning to see unauthorized fraudulent test kits that are being marketed to test for COVID-19 in the home. **We want to alert the American public that, at this time, the FDA has not authorized any test that is available to purchase for testing at home for COVID-19.** The FDA sees the public health value in expanding the availability of COVID-19 testing through safe and accurate tests that may include home collection, and we are actively working with test developers to bring this to fruition.

Fraudulent health claims, tests, and products can pose serious health risks. They may keep some patients from seeking care or delay necessary medical treatment. The FDA will take appropriate action to protect consumers from bad actors who take advantage of a crisis to deceive the public by marketing tests that pose risks to patient health.

We have already identified and issued warning letters to companies found selling and promoting fraudulent items, and we expect additional such actions will be forthcoming. Additionally, we are stepping up enforcement at ports of entry, including International Mail Facilities, to ensure these fraudulent products that originate outside the country do not enter through our borders.

If you are aware of fraudulent test kits for COVID-19, please report them to the FDA. Reports may be sent via email to: FDA-COVID-19-Fraudulent-Products@fda.hhs.gov. We will continue to aggressively pursue those who place the public health at risk and hold bad actors accountable. Actions may include issuing warning letters, seizures or injunctions. The FDA will continue to pursue those who place the public health at risk.

The link to the press release is as follows: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-alerts-consumers-about-unauthorized-fraudulent-covid-19-test-kits>.