FDA tightens scrutiny of coronavirus antibody tests

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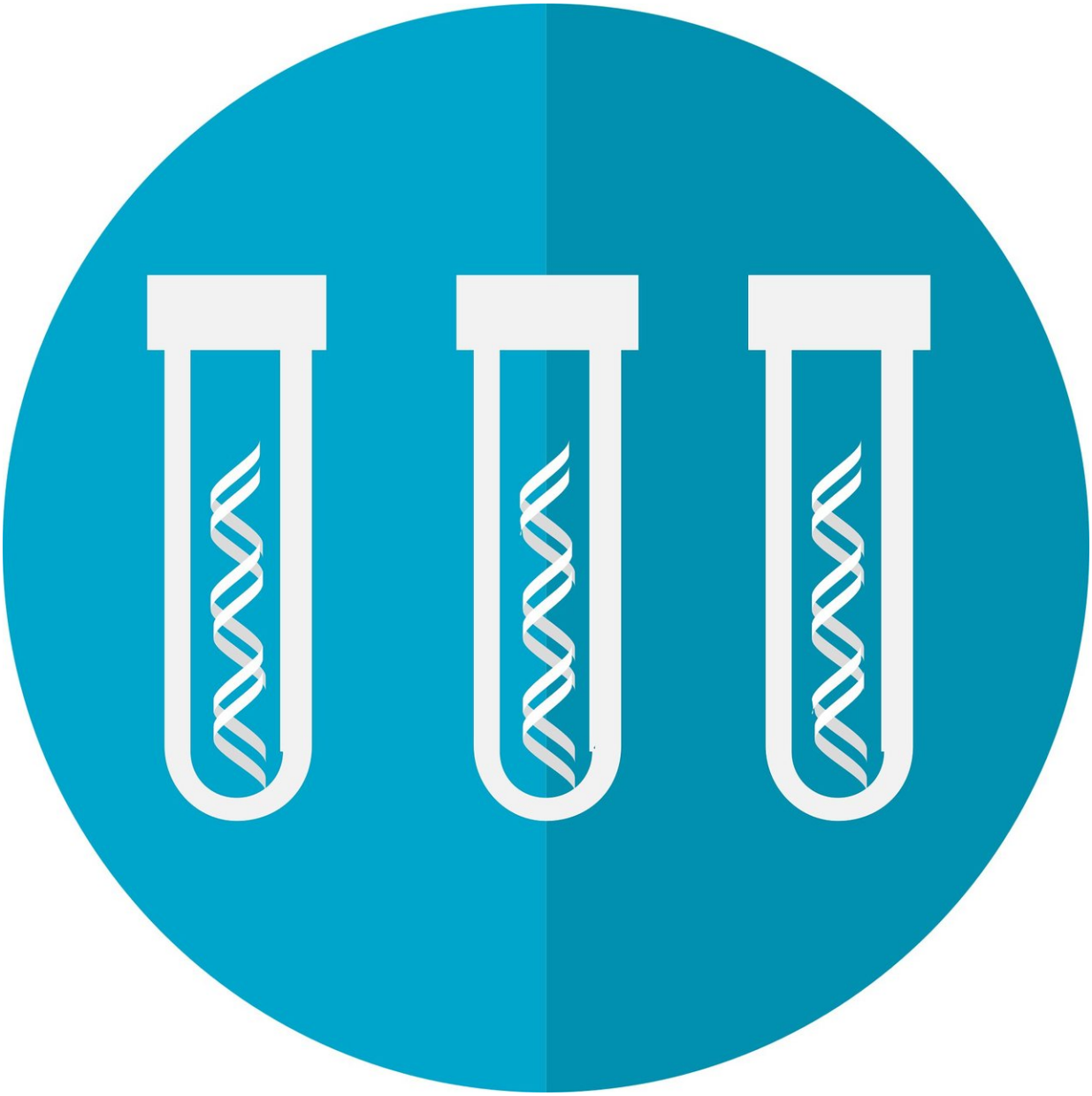

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The US Food and Drug Administration (FDA) on Monday tightened its oversight of coronavirus antibody tests after the market was flooded with dubious tests.

Companies selling antibody tests, which determine whether someone has been infected with COVID-19, must submit data to prove their accuracy, the FDA said.

The agency had previously allowed companies to validate their own data from antibody tests, also known as serology tests.

"We unfortunately see unscrupulous actors marketing fraudulent test kits and using the pandemic as an opportunity to take advantage of Americans' anxiety," the FDA said in a statement.

"Some test developers have falsely claimed their serological tests are FDA approved or authorized."

The FDA said test manufacturers will have 10 days to submit performance data and request an emergency use authorization (EUA).

"To date, 12 antibody tests have been authorized under an individual EUA, most within just the past few days, and over 200 antibody tests are currently the subject of a pre-EUA or EUA review," the FDA said.

A serology test detects the presence of antibodies to the new coronavirus in the blood of someone who has recovered from COVID-19, the disease it causes.

"These tests may be important for guiding our next steps in the fight against this pandemic, such as by providing information on disease prevalence and the frequency of asymptomatic infection," the FDA said.

It said the tests could also help identify potential donors of "convalescent plasma," which involves using blood plasma from a recovered individual as therapy for an infected patient.