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FDA Sets Standards for Coronavirus Antibody Tests in Crackdown on Fraud

More than 200 antibody tests for Covid-19 entered the U.S. without prior FDA scrutiny

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A physician administered a Covid-19 swab test at a mobile testing site in Seattle.

The Food and Drug Administration, under fire for allowing hundreds of antibody tests for the new coronavirus on the U.S. market without prior review, has imposed rigorous precision standards on commercial test companies and said it is cracking down on fraudulent actors.

More than 200 antibody tests for Covid-19 entered the U.S. without previous FDA scrutiny on March 16, because the agency felt then that it was most important to get them to the public quickly. Accurate antibody testing is a potentially important tool for public-health officials assessing how extensively the coronavirus has swept through a region or state.

Now, the FDA will require test companies to submit an application for emergency-use authorization and require them to meet standards for accuracy. Tests will need to be found 90% "sensitive," or able to detect coronavirus antibodies, and 95% "specific," or able to avoid false positive results.

The tests, also called serology tests or simply blood tests, can potentially tell hospitals which health-care workers and which patients have already been exposed to the disease and recovered. Such use is under way, for example, at Partners HealthCare in the Boston area, to help Massachusetts General and other Harvard-affiliated hospitals know whether doctors and nurses have built up sufficient antibodies to the virus and can return to work.

Apart from fraud and inaccuracy, the tests also are of limited usefulness because researchers are still working to determine the precise level of antibodies sufficient to result in immunity. The hope has been that certain levels might create a kind of immunity passport, safely allowing health-care workers to return to the fray of treating severely ill coronavirus patients.

Antibody tests gauge the presence in the body of disease-fighting bodies that linger long after a patient has been sick or exposed. By contrast, polymerase chain reaction tests, generally done using swabs, test for whether a patient has the disease at the time of testing.

The FDA acted quickly in March because it had undergone criticism as early as February for not freely allowing leading academic laboratories and commercial developers to produce tests, after early assays from the federal Centers for Disease Control and Prevention had failed. As a result, the U.S. was flying blind earlier this year as to how many asymptomatic people might already be infectious and spreading the virus. Thousands of cases and deaths have followed.

Many of the antibody tests originated in China and elsewhere in Asia. Some antibody tests falsely claim they are FDA-approved, can diagnose current cases of Covid-19 or can be used at home.

FDA officials said they would take action against such violators, and will seize fraudulent tests at the U.S. border in the case of imports. In the case of any test with poor performance or misleading statements, the FDA now is requiring those failures be fixed or the tests pulled from the market.

Jeffrey Shuren, director of the FDA's medical-device center, said criminal investigations are under way over tests believed to be fraudulent.

In a statement Monday, FDA Deputy Commissioner Anand Shah and Mr. Shuren said high-quality antibody tests are necessary to assess a population's exposure to the virus, and to potentially identify recovered Covid-19 patients to collect blood plasma to be used in treating other patients. The officials pointedly noted that antibody tests aren't used to diagnose current infection.

Currently, 13 tests on the market have received FDA emergency-use authorizations, meaning that they meet the agency's standards. The FDA has been working with scientists at the National Cancer Institute to validate tests and have found "multiple good kits," said one senior government official. One such test with high validation scores is from Mt. Sinai Hospital in New York, according to the government official. The hospital didn't immediately comment.

On Sunday, Roche Diagnostics AG said it won FDA clearance for its antibody test, and that its test is 100% accurate at detecting coronavirus antibodies in the blood and 98.8% accurate in ruling out those antibodies.

The FDA acknowledged has been flexible but stated, "Flexibility never meant we would allow fraud. We unfortunately see unscrupulous actors marketing test kits and using the pandemic as an opportunity to take advantage of Americans' anxiety."

One of those improper activities involves promoting the antibody tests for diagnostic purposes. "These tests are intended to be non-diagnostic," said one senior FDA official. "A serology test should not be a stand-alone decision point." Rather, he said, the tests are designed to "understand sero-prevalence [how widely the virus has spread] in the population."

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