

US to rein in flood of virus blood tests after lax oversight

May 4 2020, by Matthew Perrone



In this April 14, 2020 file photo, a woman holds her hand out to have blood collected for COVID-19 antibodies at a drive-thru site in Hempstead, N.Y. U.S. regulators on Monday, May 4 pulled back a decision that allowed scores of coronavirus blood tests to hit the market without first providing proof that they worked. The Food and Drug Administration said it took the action because some sellers have made false claims about the tests and their accuracy. (AP Photo/Seth Wenig, File)

U.S. regulators Monday pulled back a decision that allowed scores of coronavirus blood tests to hit the market without first providing proof that they worked.

The Food and Drug Administration said it took the action because some sellers have made false claims about the tests and their accuracy. Companies will now have to show their tests work or risk having them pulled from the market.

Under pressure to increase testing options, the FDA in March essentially allowed companies to begin selling tests as long as they notified the agency of their plans and provided disclaimers, including that they were not FDA approved. The policy was intended to allow "flexibility" needed to quickly ramp up production, officials said.

"However, flexibility never meant we would allow fraud," Dr. Anand Shah, an FDA deputy commissioner, said in a statement. "We unfortunately see unscrupulous actors marketing fraudulent test kits and using the pandemic as an opportunity to take advantage of Americans."

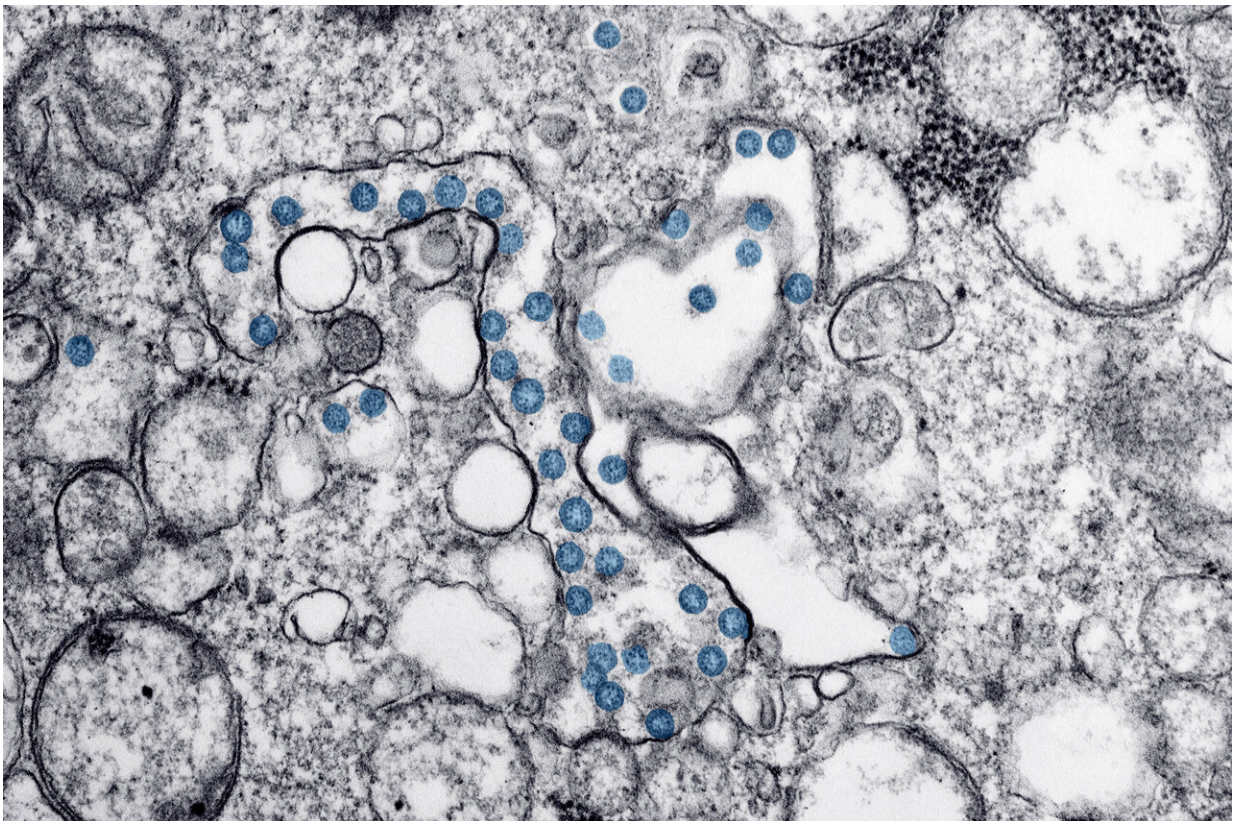
Blood tests are different from the nasal swab tests currently used to diagnose active COVID-19 infections. Instead, the tests look for blood proteins called antibodies, which the body produces days or weeks after fighting an infection. Most use a finger-prick of blood on a test strip.

The revised policy follows weeks of criticism from doctors, lab specialists and members of Congress who said the FDA's lack of oversight created a Wild West of unregulated tests.

The agency acknowledged Monday that there have been problems with deceptive, false marketing among the 160 tests that have been launched in the U.S. Some companies have claimed their tests can be used at home, although FDA has not allowed that use. Others make

unsubstantiated claims about their accuracy. Some U.S. hospitals and [local governments](#) have reported buying tests that turned out to be inaccurate or frauds.

So far, the FDA has granted authorization to 12 antibody tests, meaning their methods, materials and accuracy passed muster with agency regulators. Companies with [test](#) kits currently on the market without FDA authorization will now be required to submit formal applications to regulators within 10 business days. Companies that launch at a later date will have 10 days to turn over their applications after validating their tests.



This 2020 electron microscope image made available by the U.S. Centers for Disease Control and Prevention shows the spherical particles of the new coronavirus, colored blue, from the first U.S. case of COVID-19. U.S.

regulators on Monday, May 4 pulled back a decision that allowed scores of coronavirus blood tests to hit the market without first providing proof that they worked. The Food and Drug Administration said it took the action because some sellers have made false claims about the tests and their accuracy. (Hannah A. Bullock, Azaibi Tamin/CDC via AP, File)

Health officials in the U.S. and around the world have suggested the tests could be helpful in identifying people who have previously had the virus—with or without getting sick—and developed some immunity to it. But researchers haven't yet been able to answer key questions that are essential to their practical use: what level of antibodies does it take to be immune and how long does that protection last?

"We're spending a lot of time and resources on something that is not really a panacea for reopening," said Kamran Kadkhoda, a lab director at the Cleveland Clinic.

For now, the tests are mainly a [research tool](#) for scientists trying to determine how widely the [coronavirus](#) has spread among the U.S. population. Those studies are underway but have produced widely different preliminary results, in part, due to variations between tests. Even high-performing tests can produce skewed results when used in a large population where few people have had the virus.

The National Institutes of Health and other federal agencies are also reviewing tests and conducting research into whether they can successfully predict immunity.

FDA Commissioner Stephen Hahn told reporters Monday that his agency's "careful balancing of risks and benefits shifted to the approach we've outlined today," based on new data from FDA and NIH reviews.

Hahn said more than 200 companies are in the process of submitting testing data to the FDA.

Experts who criticized the government's previous policy welcomed the new evidence requirement.

"We want to make sure that testing in the U.S. is of high quality and that those using the tests understand how the results should or should not be used," said Dr. Robin Patel of the Mayo Clinic.

Monday's move is the latest in the Trump administration's fitful attempt to roll out an effective, comprehensive testing strategy. While testing has ramped up since the outset of the outbreak, state and local governments continue to report shortages of testing supplies needed to screen for the virus and safely ease social distancing measures. A "testing blueprint" released last week by the White House emphasized that states are responsible for developing their own testing plans.

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