Evaluate Vantage

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The importance of testing Covid-19 tests

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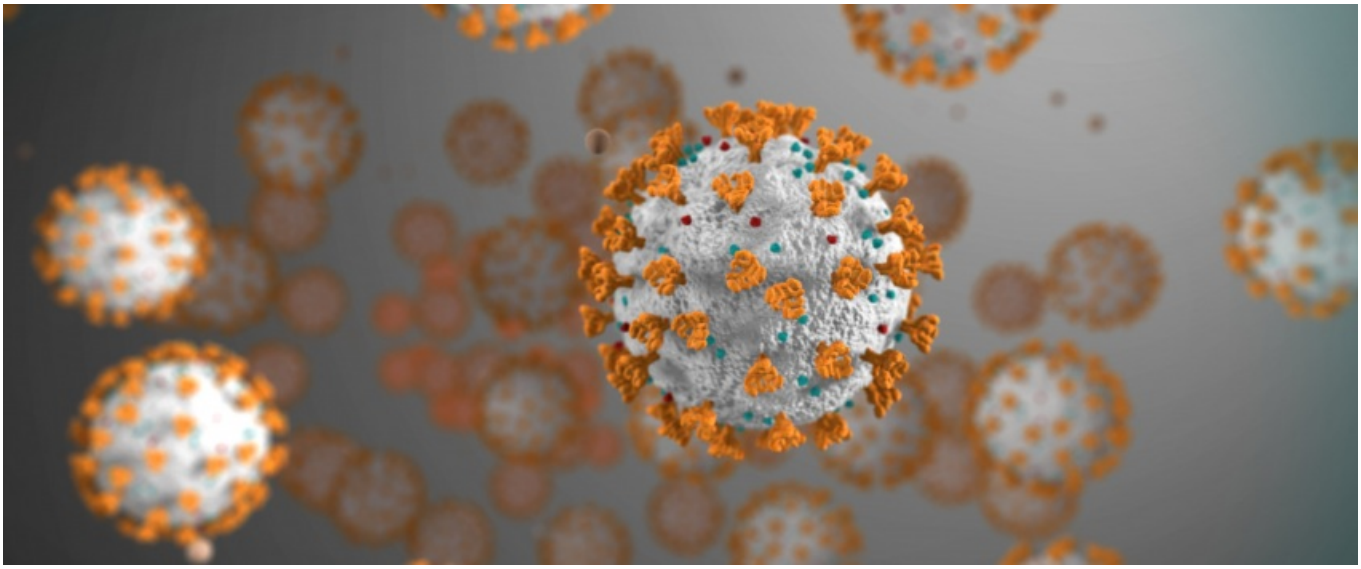


The US is authorising new Covid-19 antibody tests faster than it is checking their accuracy.

As many countries around the world begin to reopen schools and businesses in earnest, warnings of the perils of relying on antibody tests to pinpoint people with immunity to the Covid-19 virus have become louder.

It is still unclear whether antibodies confer immunity and, if they do, how long this might last. Questions over accuracy remain, with the figures claimed for marketed tests varying, and quality of the evidence on which those claims are based also showing some disparity. And the FDA continues to authorise new antibody tests rather faster than it is able to conduct their promised independent evaluations.

So far the US regulator has published independent accuracy data on two of the antibody tests to which it has issued emergency use authorisation – those from Euroimmun and Healgen. It has also published data on three tests that it has said must no longer be sold in the US, including that developed by Biomedomics, which had been distributed by Becton Dickinson.

Meanwhile the number of antibody, or serological, tests to have gained authorisation has ticked up to 15. The most recent are from Hangzhou Biotest Biotech and Vibrant America Clinical Labs. No sensitivity and specificity figures are yet available for Vibrant's test. Hangzhou Biotest's RightSign assay, meanwhile, has been independently validated at the Frederick National Laboratory for Cancer Research, with the tests being sponsored by the National Cancer Institute. This testing put sensitivity and specificity alike at 100% for IgG and IgM combined.

Interestingly the FDA's own independent accuracy testing is also taking place at the Frederick National Laboratory, under the NCI's auspices. Presumably when the FDA gets around to checking RightSign it will come up with near-identical figures.

In the meantime, 13 antibody tests have gained EUA and are on sale in the US without having gone through this independent accuracy validation step.

Severe inflammatory response

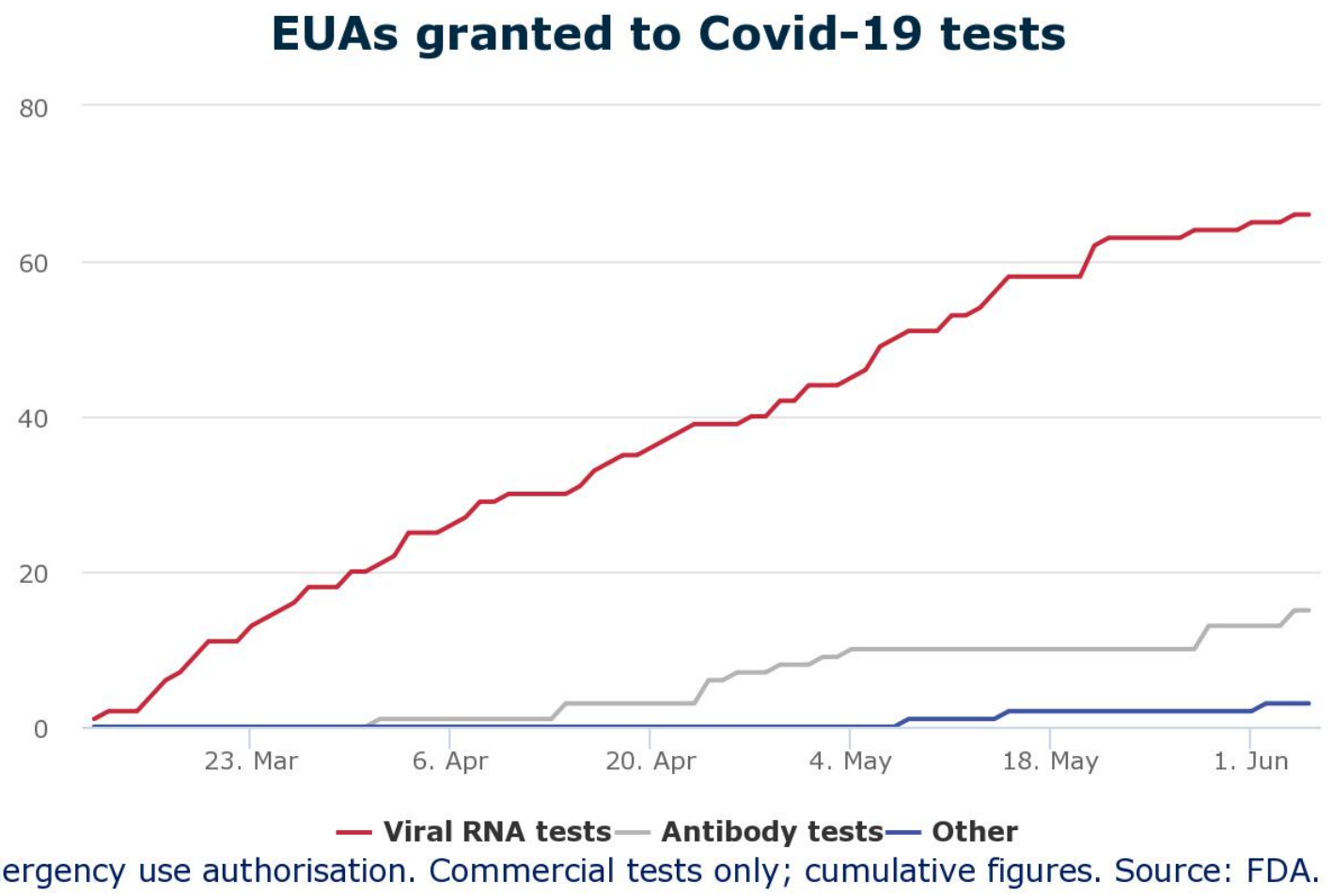
Separately, another innovative kind of Covid-19 test gained EUA this week. Roche has launched a test that measures levels of the cytokine IL-6 as a way of identifying Covid-19 patients who could be at high risk of needing mechanical ventilation.

IL-6 is released once they are activated by a pathogen such as the novel coronavirus. Roche's Elecsys IL-6

blood test, which is also CE marked and on sale in Europe, can be used for early identification of severe inflammatory response in patients with confirmed Covid-19, the Swiss group says. It runs on Roche's cobas e instrument, which can return results in less than 20 minutes, with a throughput of up to 300 tests per hour.

Research published in early March suggested that Covid-19 viral load was associated with elevated IL-6 levels in severely ill patients, spurring several biotechs to start trialling anti-IL-6 therapies in the disease. Roche's own Actemra had already been added to Chinese treatment guidelines (*Tiziana takes a deep breath and targets Covid-19, March 11, 2020*).

How large a demand there is for such an assay is not clear, but Roche has certainly had a better week than Hologic. That company obtained EUA for a molecular test for the presence of the coronavirus, to be run on its Panther Fusion analyser, in mid-March, But on Thursday the FDA warned that certain types of liquid used to preserve samples could, when used with the Panther Fusion system, produce cyanide gas.



ıergency use authorisation. Commercial tests only; cumulative figures. Source: FDA.

Note: "Other" includes one antigen test, one home sampling kit and one IL-6 test.

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