Evaluate Vantage

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Roche takes on Abbott in Covid-19 antibody testing

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Robust specificity data mark Roche's serological test out as a major competitor.

Roche has become the latest company to gain FDA emergency use authorisation for a Covid-19 antibody blood test, and the accuracy claims the Swiss group makes for the assay suggest it is very competitive with Abbott's rival product.

Roche claims sensitivity of 100% and specificity of more than 99.8% when an individual is tested two weeks after a PCR test has diagnosed an active Covid-19 infection. This beats – though only by the slimmest margin – the figures Abbott released for its test, which was launched in the US in mid-April, without an EUA. It finally got the FDA's buy-in last week, though it only obtained EUA last Tuesday.

The Elecsys anti-Sars-CoV-2 antibody test works on Roche's cobas e range of analysers, more than 40,000 of which are installed around the world and which can run up to 300 tests an hour. Roche has already started shipping the test, which is also CE marked, and says it can ramp up production capacity to "high double-digit millions" per month.

The Elecsys assay is the ninth serological test to have gained an EUA from the FDA, but the quality of the evidence for their accuracy – specificity is particularly important – varies (*Covid-19 antibody tests face a very specific problem, April 22, 2020*).

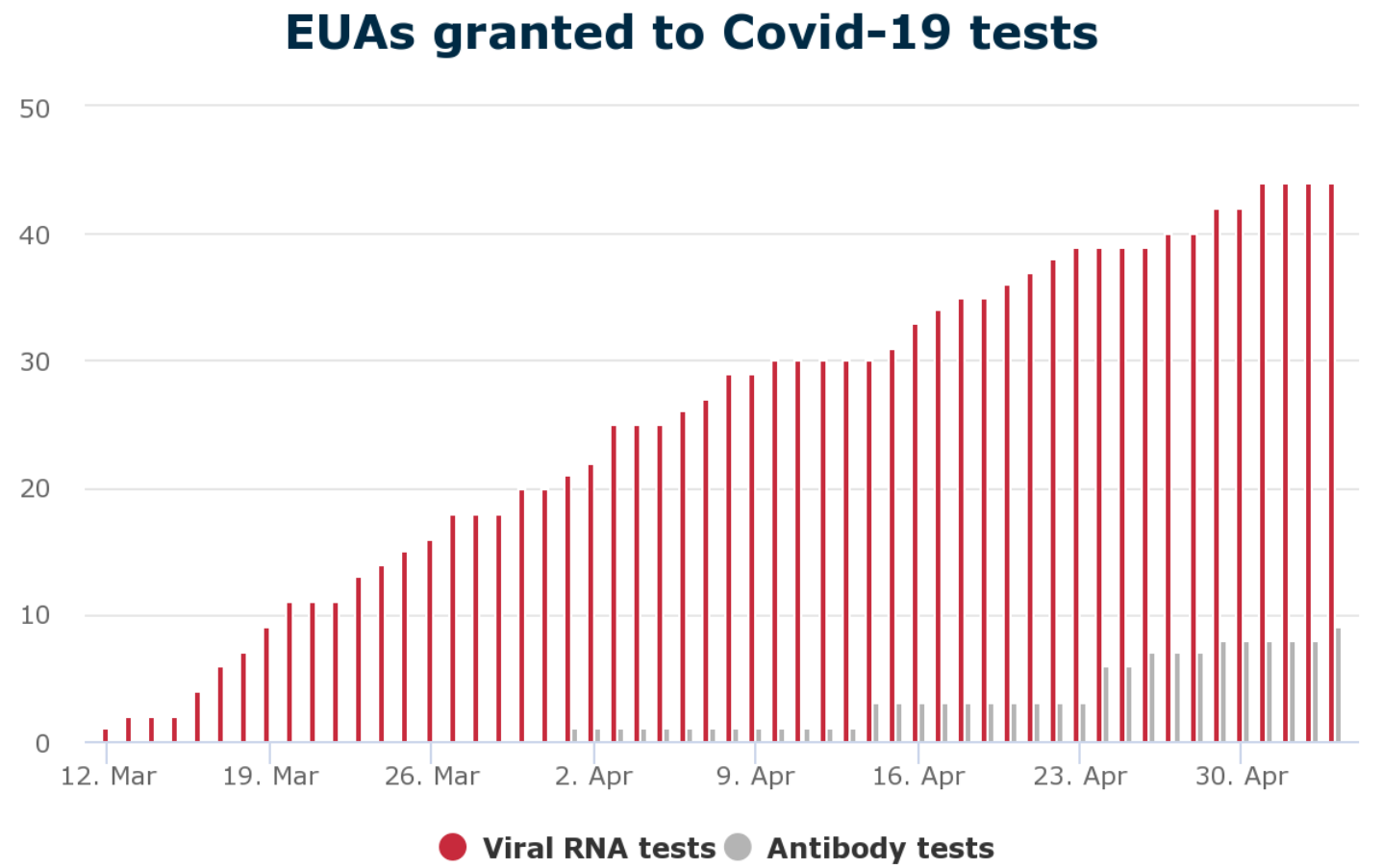
Evidence

Roche assessed its test's sensitivity on 204 samples from 69 symptomatic patients with a PCR-confirmed Covid-19 infection. But only 29 samples were from the 14-day time point, a smallish dataset, though to be fair the assay correctly flagged them all.

Still, specificity is the crucial point, and here the Elecsys test acquitted itself well, and in a much larger cohort. It was used to test 5,272 blood samples taken from routine diagnostic testing, blood donors, a common cold panel, and a coronavirus panel comprising 40 potentially cross-reactive samples from individuals with past infection with non-Covid-19 coronaviruses. All of these samples were obtained before December 2019 and thus could not carry the Covid-19 virus. 10 of the samples came back positive, giving a specificity of 99.81%.

Accuracy figures for selected Covid-19 antibody tests					
Company	**Test name**	**Date of US EUA**	**EU status**	**Sensitivity (%)**	**Specificity (%)**
Cellex	Cellex qSars-CoV-2 IgG/IgM cassette rapid test	Apr 1	Unknown	93.8	95.6
Ortho-Clinical Diagnostics	Vitros anti-Sars-CoV-2 total reagent pack	Apr 14	Unknown	83.3	100.0
Diasorin	Liaison Sars-CoV-2 S1/S2 IgG test	Apr 24	CE marked	97.4	98.5
Ortho-Clinical Diagnostics	Vitros anti-Sars-CoV-2 IgG reagent pack	Apr 24	Unknown	87.5	100.0
Autobio Diagnostics	Anti-Sars-CoV-2 rapid test (IgM and IgG)	Apr 24	Unknown	93.0	100.0
Abbott Laboratories	Abbott Sars-CoV-2 IgG test	Apr 26	CE marked	100.0	99.5
Bio-Rad Laboratories	Platelia Sars-CoV-2 total Ab assay	Apr 29	CE marked	98.0	99.0
Roche	Elecsys anti-Sars-CoV-2 antibody test	May 3	CE marked	100.0	99.8
Note: All accuracy claims made by the companies. Includes only tests with FDA emergency use authorisation.					

There is one last thing to remember, however, when considering the potential of these assays to permit the reopening of businesses, offices and schools. There is still no definite proof that the presence of antibodies to Sars-CoV-2 does in fact confer immunity to subsequent infection by this virus in humans.



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

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