Evaluate Vantage

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More Covid-19 tests authorised, but logistical problems remain

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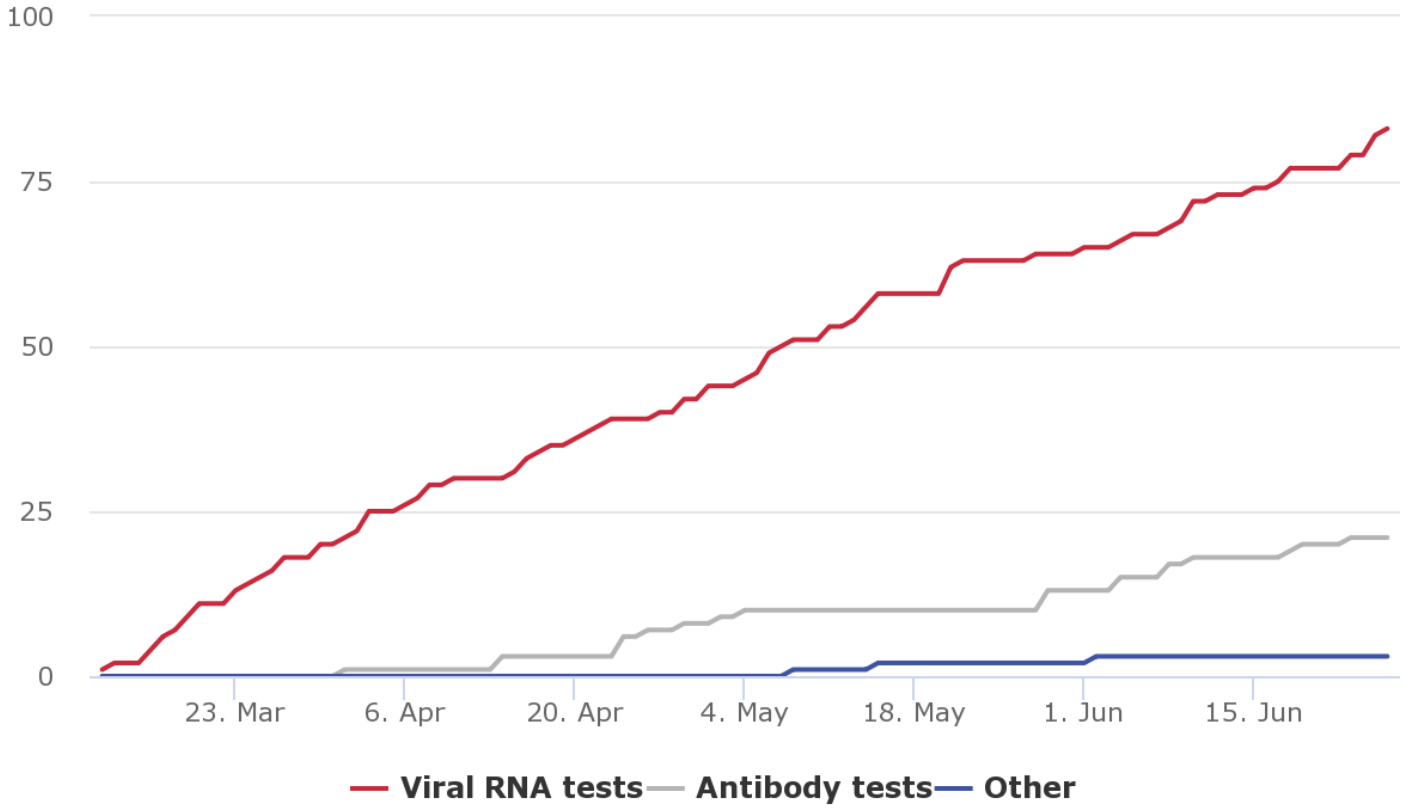
In the week that saw cases of Covid-19 rise above 10 million worldwide, the US FDA authorised a further five viral RNA tests for active infections. But only one commercial antibody test gained emergency authorisation last week: that developed by Babson Diagnostics, a small company that in March partnered with Becton Dickinson to develop a system for capillary blood sampling. Babson gained emergency use authorisation for its IgG antibody test, for which it claims 100% specificity and 100% sensitivity when performed at least 15 days after a positive result on an FDA-authorised molecular test. Antibody tests are still not being manufactured fast enough, however, with Roche – the largest diagnostics company in the world – reportedly unable to meet demand for its assay. Another factor that could affect US testing rates is new guidance from three government agencies stating, in contravention of earlier recommendations, that insurance companies need not cover the full cost of Covid-19 antibody testing when it is used to screen for general workplace health and safety. This has imperilled the programmes some groups have arranged to get their employees back to work, since it is now unclear who must pay for these tests.

EUAs granted to Covid-19 tests



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.