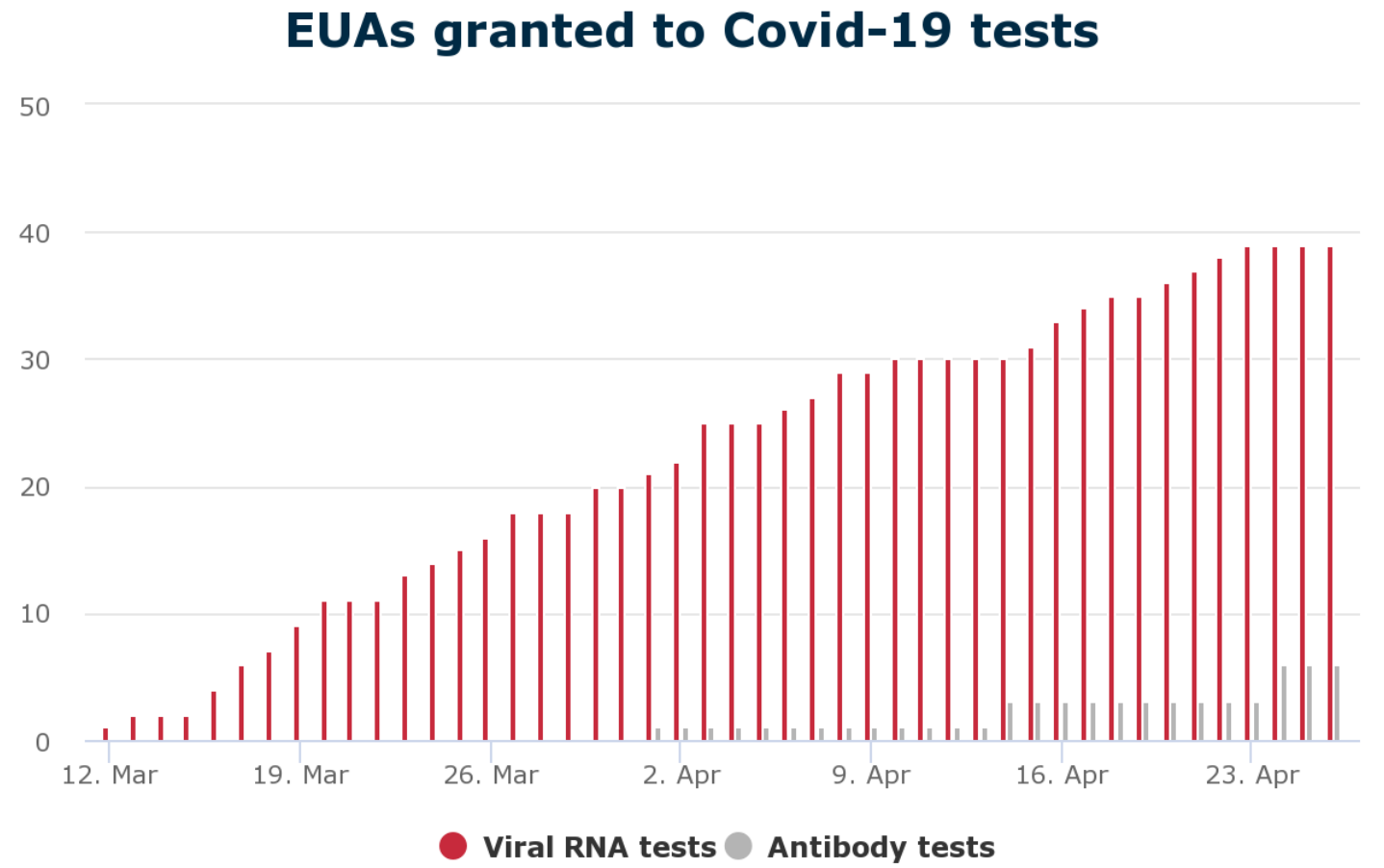
Evaluate Vantage

April 27, 2020

The FDA waves through more antibody tests

Elizabeth Cairns

The past week has seen the FDA grant emergency use authorisation to four tests to diagnose active Covid-19 infections and three that could be used to try to identify people who have had a coronavirus infection in the past, and who therefore might be immune to future infections. Diasorin's Liaison Sars-CoV-2 S1/S2 test, which detects IgG, is one of the latter; the Italian group claims sensitivity and specificity of 97.4% and 98.5%, respectively. The specificity is particularly important as a high level – ideally in excess of 99% – will be crucial in guarding against incorrect positive results (*Covid-19 antibody tests face a very specific problem, April 22, 2020*). One hotly awaited antibody test is that from Siemens Healthineers: the company says that its assay has demonstrated sensitivity and specificity of more than 99%. Healthineers is working towards an EUA as well as European CE mark, but its test is not expected to reach the market before the end of May. The FDA's plans to analyse the accuracy of these tests are not yet in place, however, so governments and other buyers are reliant on the companies' own claims when choosing which one to employ.



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

More from Evaluate Vantage

Evaluate HQ
44-(0)20-7377-0800

Evaluate Americas
+1-617-573-9450

Evaluate APAC
+81-(0)80-1164-4754

© Copyright 2023 Evaluate Ltd.