Evaluate Vantage

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US pursues pooled testing for Covid-19, and Quest benefits

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Batch testing could allow large numbers of people to be ruled out as having Covid-19, but accuracy concerns remain.

In a tacit admission that demand for Covid-19 testing in the US is so vast that it cannot be met by testing suspected patients individually, the US FDA on Saturday reissued the emergency use authorisation for an RNA test from Quest Diagnostics to allow its use with pooled samples. This technique allows for rapid testing of large numbers of people, but is imprecise, and requires retesting to pinpoint infected patients.

FDA Commissioner Stephen Hahn said this batch testing approach “becomes especially important as infection rates decline and we begin testing larger portions of the population.” Currently, however, infection rates appear to be spiralling out of control in many parts of the US, and Quest itself said that demand is outpacing its current capacity to perform up to 125,000 Covid-19 RNA tests per day.

The Quest Sars-CoV-2 rRT-PCR test gained its initial EUA in mid-March, permitting its use to diagnose active Covid-19 infections in individual people – and this authorisation remains in place. It may now also be used to test nasal swab samples from up to four people, with the samples being mixed together before testing. If the test comes back negative, all four subjects can be eliminated as Covid-19 patients.

If RNA from the coronavirus is detected in the pooled sample, however, this means that at least one of the four people sampled has Covid-19 – but in order to pinpoint the positive patients all four will have to be re-tested individually.

Accuracy

In areas with low Covid-19 prevalence this could be a sensible strategy, allowing large numbers of potential patients to be ruled out more quickly and cheaply than would be possible with one-at-a-time testing. In high-prevalence areas it would clearly have less utility.

And even in low-prevalence regions there are concerns. If, for example, one positive sample is mixed with three negative, the viral RNA will be diluted, making its presence harder to detect. Still, according to the data Quest submitted to the FDA and which is quoted in the test’s instructions for use, this ought not to be a problem.

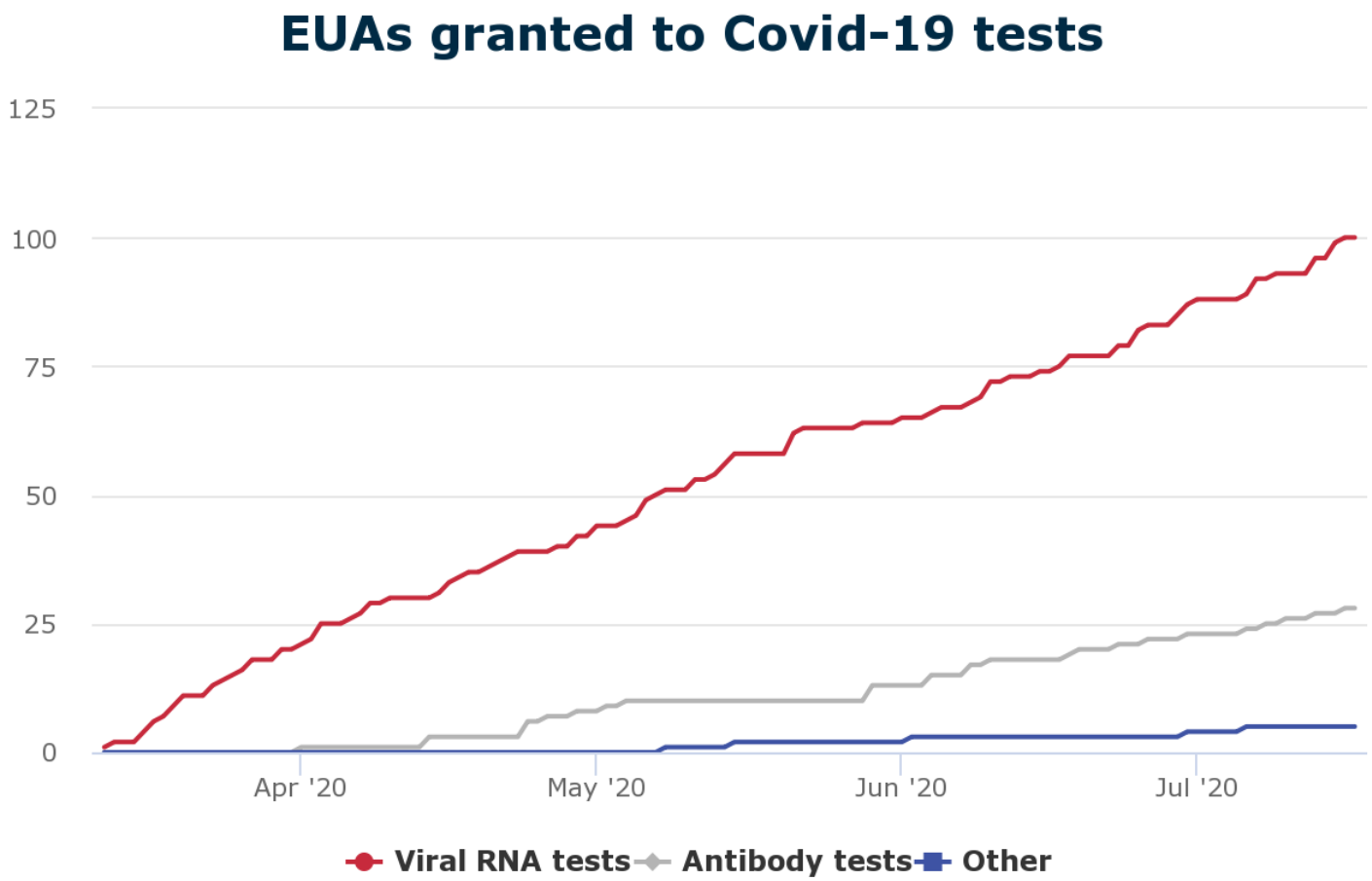
The assay was used to test 101 pooled samples, each made up of one known positive – detected with the same test, but on an individual basis – and three known negatives. Of these, 99 came out as positive and two were

returned as “inconclusive”. Since an inconclusive pooled test would lead to the four contributors all being re-tested individually, Quest regards this outcome as yielding a positive percent agreement of 100%.

When tested on wholly negative pooled samples, 245 of 247 were correctly identified as negative, while two were tagged as inconclusive, suggesting a negative percent agreement of 99.2%.

More tests are likely to gain authorisation for use with pooled samples in the coming weeks. But the US might have to get infection rates under control via other means if this technique is to be truly useful.

Separately, Quest received three other EUAs covering a kit to enable people with suspected Covid-19 to take nasal samples themselves, under the supervision of a healthcare professional via video link. The EUAs cover the tests being run on the Hologic Panther Fusion, Hologic Aptima and Roche cobas molecular platforms. The self collection kit itself originally received EUA for use with Quest’s own test back in May. Four other molecular tests and two antibody tests have also gained EUA over the past week.



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