Evaluate Vantage

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A lull in FDA Covid-19 test authorisations

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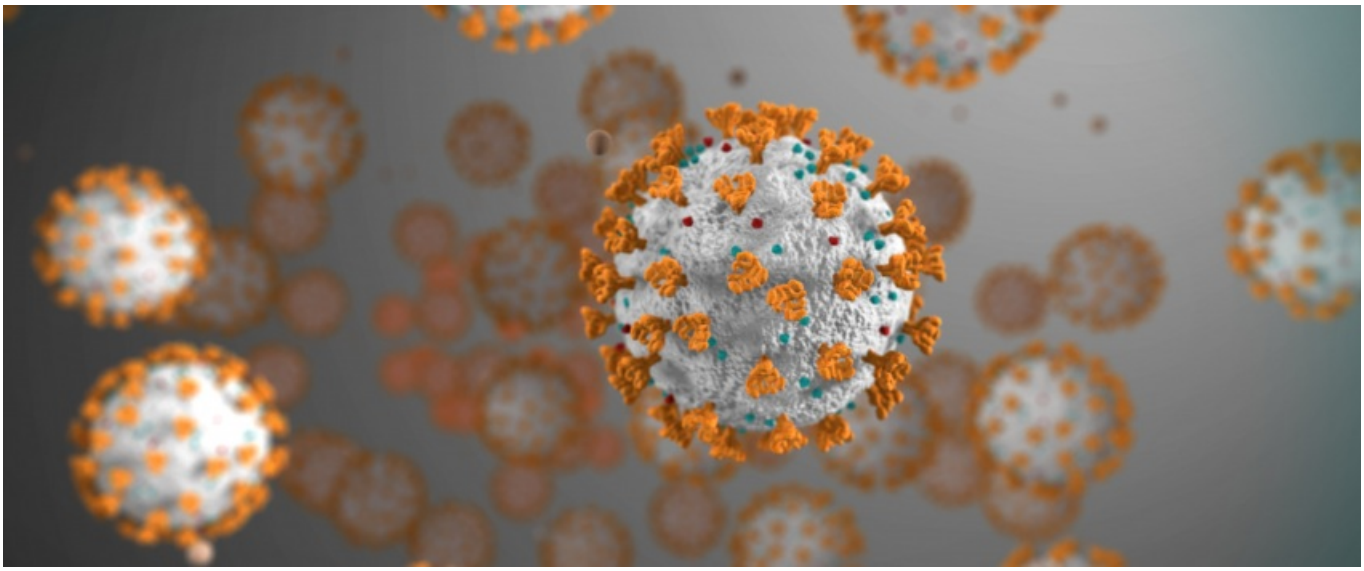


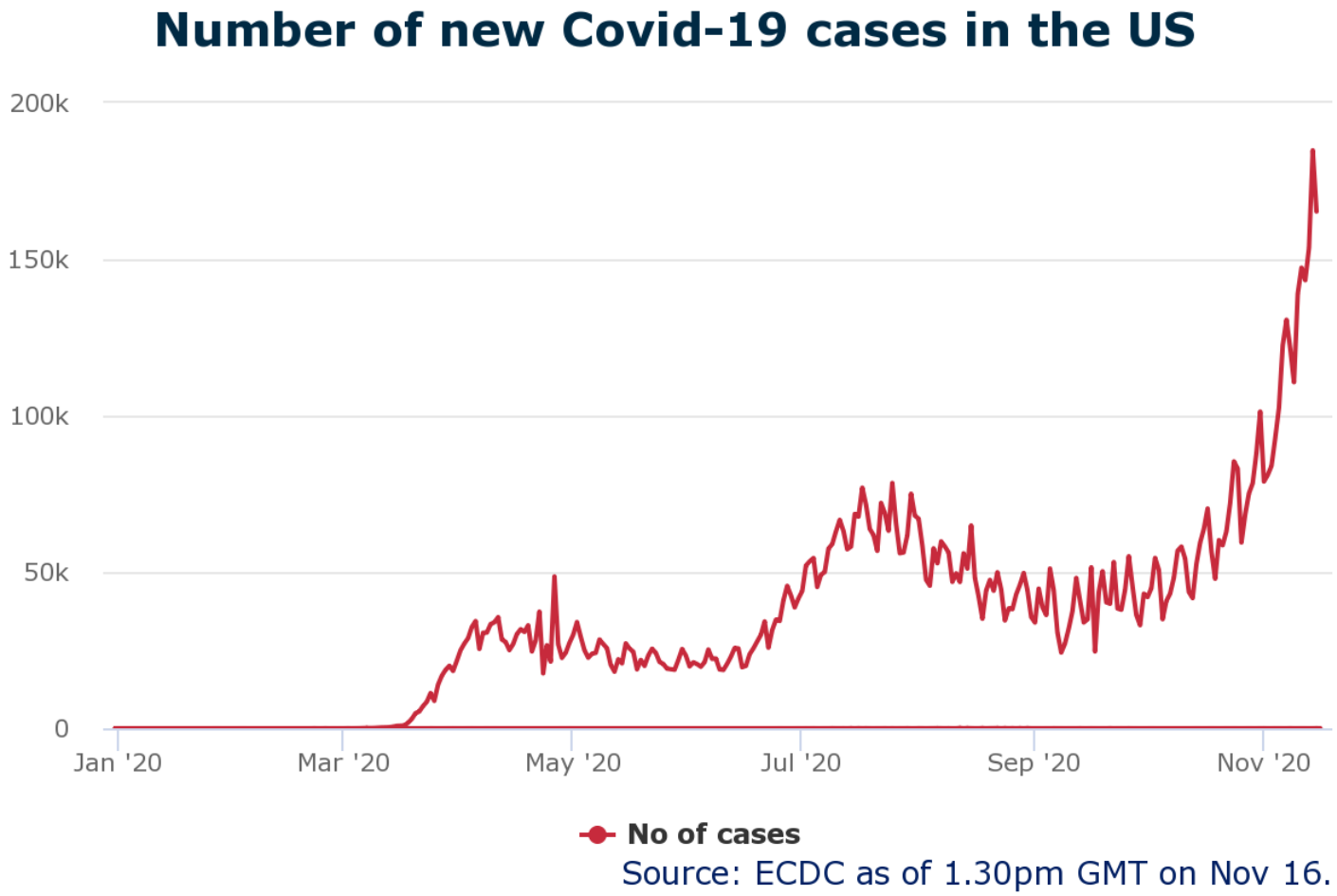
Just as demand for coronavirus tests is peaking, the US regulator has a quiet week.

For the first time since early March, a week has passed without the FDA granting any emergency use authorisations for individual coronavirus tests. Whether this is the agency dragging its feet or the result of a drop in the number of EUA applications is not known.

Hundreds of different tests are already authorised, of course. But many US labs are close to capacity. Following peaks in new Covid-19 cases in late March and mid-July, the US is now in the grip of a deadly third wave. It is unlikely that new labs can be built quickly enough for currently available tests to be able to deal with the current surge.

To be fair to the FDA, it has already authorised 180 viral RNA tests, 57 antibody tests and seven antigen tests capable of detecting the virus or identifying people who have been infected with it in the past. It has also given its blessing to a number of peripheral technologies, and there are an additional 34 high complexity molecular lab-developed tests for the virus authorised under an umbrella EUA.

Still, the last peak in infections in the summer resulted in bottlenecks at some testing facilities, with companies including Quest Diagnostics and Labcorp reporting backlogs. In mid-July Quest was reporting an average turnaround time of just over a day for top-priority patients including those in hospital and symptomatic healthcare workers, and seven days or more for everyone else.



This prompted the Centers for Medicare and Medicaid Services to announce that it would be cutting the reimbursement price for labs that take more than two days to return test results (*US cuts fees for Covid-19 tests, October 19, 2020*). This new pricing structure does not take effect until the start of next year, but there is no guarantee that the current level of demand for testing will have slackened by then.

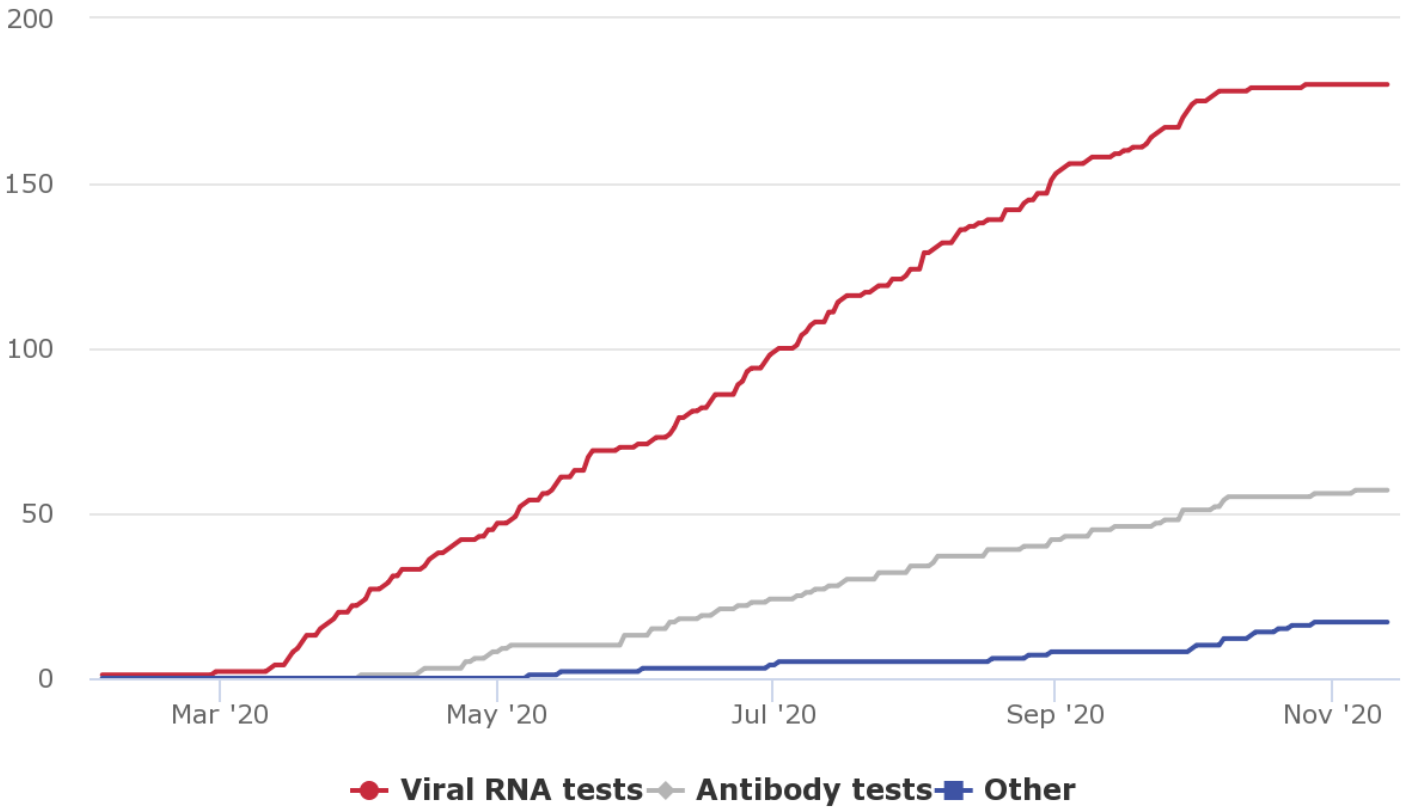
On November 9 Quest said its turnaround times remained within two days. But it added that over the prior three weeks, it had seen a steady increase in demand and in positivity rates. And in the week since then there have been nearly a million more cases of Covid-19 in the US.

The American Clinical Laboratory Association (ACLA) has warned that testing groups could soon be overwhelmed once more – and fast. Thanks to the new CMS pricing, diagnostics companies could be in for a hard winter.

Fortunately the lull at the FDA is unlikely to last much longer. Last week Qiagen submitted a new antigen test, Qiareach, for EUA and European approval. The assay, developed in partnership with the Australian diagnostics company Ellume, is a portable digital test that is run on a battery powered instrument which can run up to eight samples at once, yielding results within 15 minutes. Qiagen claims sensitivity of 90% and a specificity of 100% for the Qiareach assay.

This assay and others may well gain authorisation in the coming weeks. But unless manufacturers and the FDA work to get testing volumes up fast, a crunch could be coming.

EUAs granted to Covid-19 tests



EUA = emergency use authorisation. Cumulative figures. Source: FDA.

Note: "Other" includes seven antigen tests, five home sampling kits, three saliva collection devices and two IL-6 tests.