Evaluate Vantage

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US cuts fees for Covid-19 tests

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Slower labs are to be paid less for Covid-19 tests, but will the move actually speed things up?

Last week was quiet at the US FDA when it came to Covid-19 tests. Only three new coronavirus tests obtained emergency authorisation from the regulator, one of which was not really a test at all but a tube for collecting saliva from patients suspected to have Covid-19.

Instead the action was at the other Maryland-based regulatory institution, the Centers for Medicare and Medicaid Services. From the start of next year, the CMS will cut the rate it pays for high-throughput Covid-19 tests to labs that take more than two days to return results. The move is aimed at speeding up testing following reports of hefty backlogs, but one laboratory organisation claims that it risks making the situation worse.

The CMS currently pays $100 per test to labs running high-throughput Covid-19 tests – the kind that detect viral RNA and are run on the large lab-based instruments produced by companies including Abbott, Roche and Hologic, among others. To count as high-throughput, the machines must allow the automated processing of more than 200 samples per day.

Selected high-throughput Covid-19 test providers		
Company	**Instrument**	**Approximate turnaround time**
Abbott Laboratories	m2000 & Alinity m	3hr
Danaher	GeneXpert & Biomek	45 mins
Hologic	Panther	3hr
Perkinelmer	Explorer	1hr
Qiagen	NeuMoDx 288	1.5hr
Roche	Cobas	3hr
Thermo Fisher Scientific	Amplitude	4hr
Source: Stifel.		

From January, the base rate is to be reduced to $75. A top-up payment of $25 will be made to labs that provide test results within two days of sample collection, and which have taken less than two days to conduct the majority of their high-throughput Covid-19 assays – not just those covered by Medicare – over the past month.

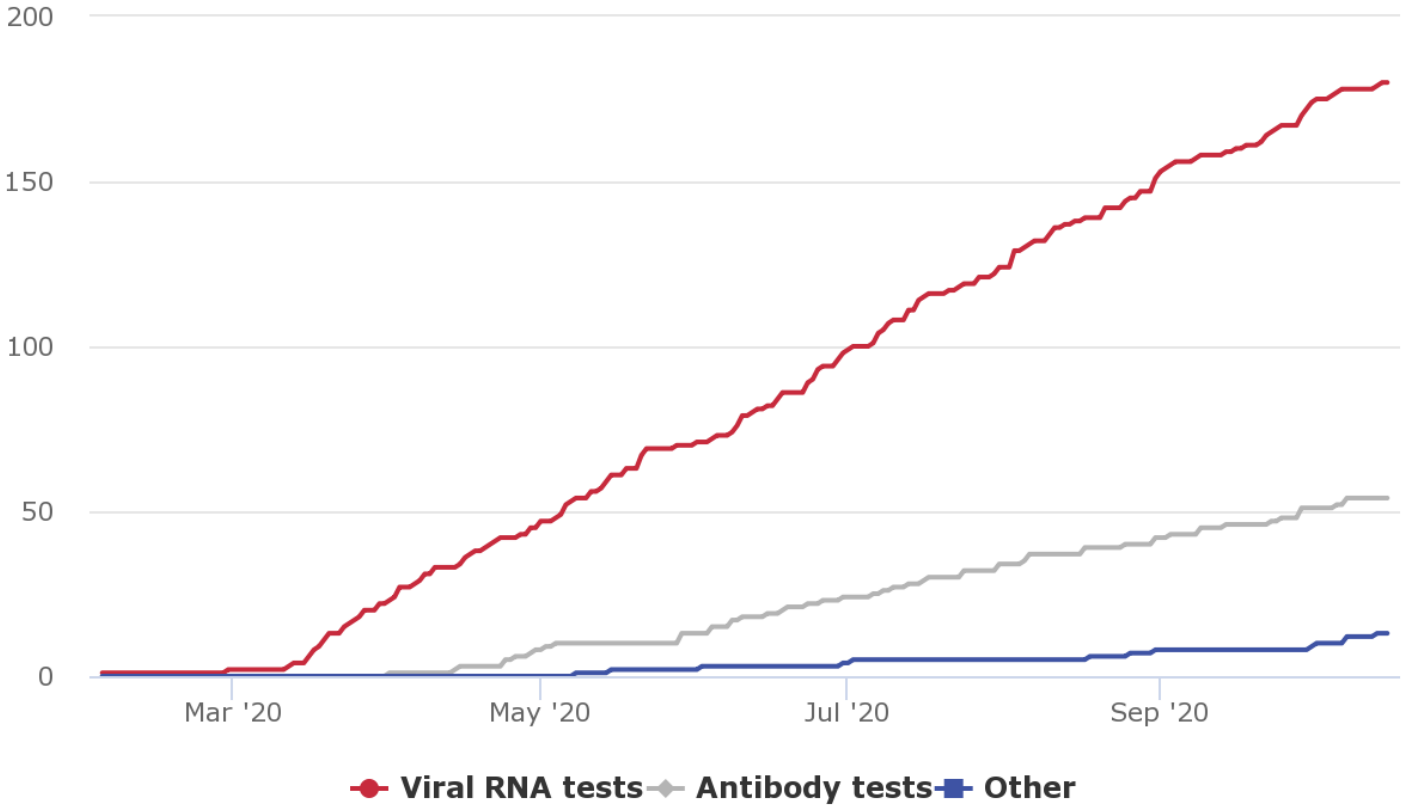
Objection

The American Clinical Laboratory Association, which counts many of the largest diagnostics groups among its members, objected to the CMS's decision, saying that it would do nothing to address the underlying causes of testing delays. The ACLA says turnaround times are caused largely by fluctuations in demand and access to the consumables and reagents used in the tests. The implication is that penalising the slower labs is unfair.

The ACLA also says that the CMS's new policy could "create a domino effect where patient access to testing is severely reduced". If labs hasten to bulk-buy the consumables and chemicals they need, a new bottleneck could be created. Alternatively, should the reduced payments drive some labs out of business there will be fewer sites at which Covid-19 tests can be processed, slowing things further.

And anyone who has worked in a lab knows that rushing things is an effective way to introduce errors. It is vital that the threat of reduced payments does not lead to faster turnaround at the price of diminished accuracy.

EUAs granted to Covid-19 tests



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

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