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FDA authorises Covid-19 tests from Roche and Thermo Fisher

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The race between diagnostics companies to be the first to get the FDA's authorisation for a Covid-19 assay was declared a draw on Friday, with both Roche and Thermo Fisher gaining emergency use authorisation for their respective tests. These can now be used immediately by Clia-certified laboratories in the US to detect nucleic acid from the novel coronavirus, provided that these have the right instrumentation. The machines on which Roche's test is run are widely available: the company has placed 695 Cobas 6800s and 132 8800s worldwide, and the Swiss group says it can make "millions of tests a month" available. Several companies are known to be seeking EUAs for their tests. One of the most hotly awaited Covid-19 tests is that being developed by Hologic, since like Roche's diagnostic this will run on a fully automated high-throughput machine, the Panther Fusion. But there could be trouble ahead: the RNA extraction reagents needed to run Covid-19 assays are in short supply, and Leerink analysts believe that rationing of these chemicals is a likely scenario over the next few weeks until reagent production ramps among manufacturers.

US FDA emergency use authorisations for Covid-19 tests

Date of EUA	Company	Test	Instrument	Turnaround time	1-day share price move
March 13	Thermo Fisher Scientific	TaqPath Covid-19 Combo Kit	Applied Biosystems 7500	4hr	5%
March 13	Roche Molecular Systems	Cobas Sars-CoV-2 test	Cobas 6800 and 8800	3.5hr	13%

Note: excludes non-commercially-developed tests. Source: FDA and company communications.