Evaluate Vantage

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Covid-19 test EUAs could fall as FDA stripped of powers

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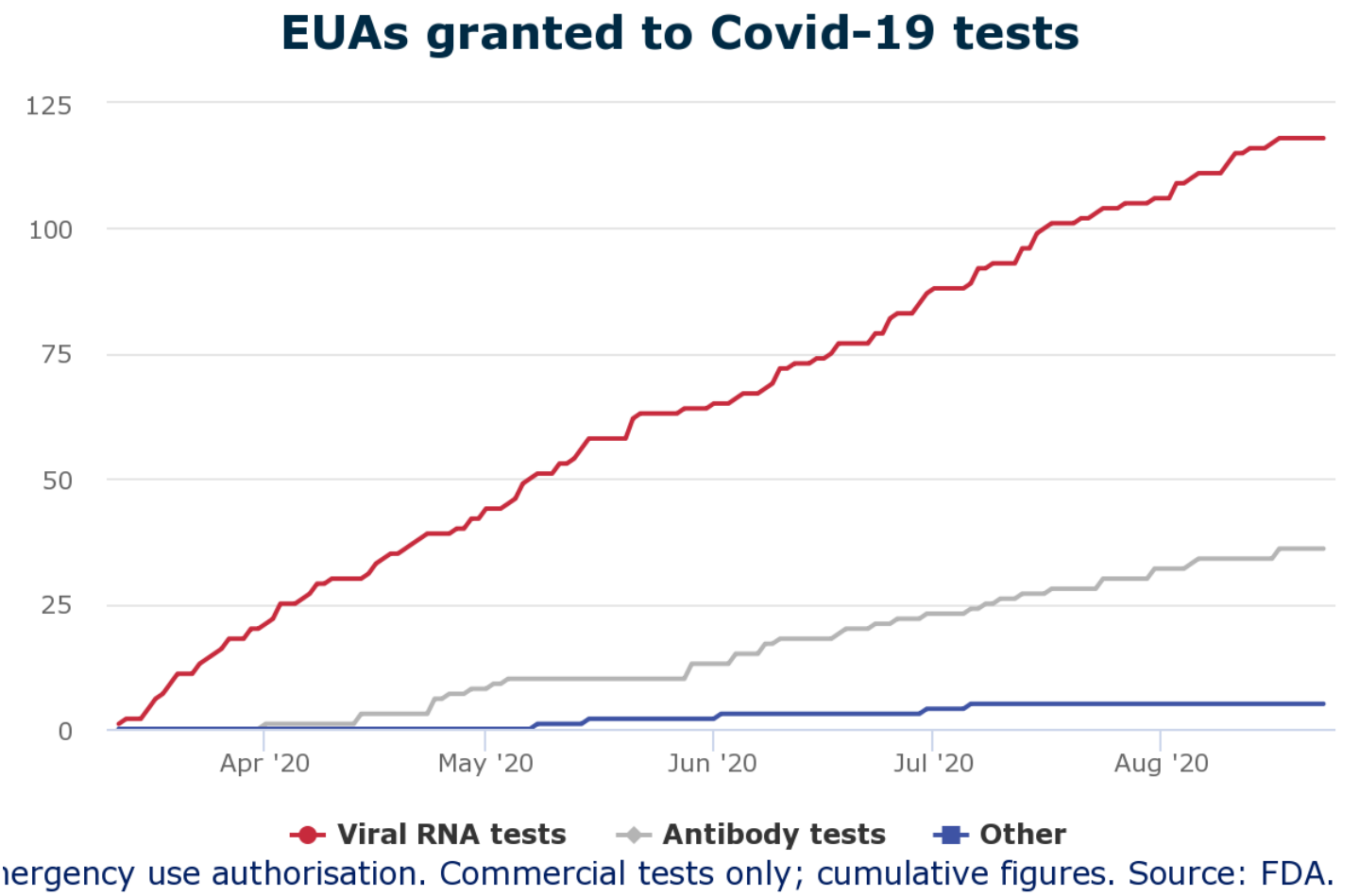
FDA approval of three new Covid-19 tests in the past week has been overshadowed by US government changes to a large section of testing. On August 19 the Department of Health and Human Services announced the FDA would no longer require any premarket review of laboratory developed tests (LDTs). The move, part of a President Trump executive order to reduce red tape, has ripples far beyond the current crop of Covid-19 tests, upending 30 plus years of the agency's oversight of LDTs. While the biggest selling Covid-19 tests used in the US have largely been developed by big medical device groups who have sought emergency use authorisation (EUA), there are fears that with no FDA oversight the US could see flawed, lab-developed Covid-19 tests reaching the market. More worryingly the ruling has implications for all LDTs, including so called high-risk applications, which cover companion diagnostics, cancer and prenatal screening. Given the high stakes, this is the area in which the agency had been most active with enforcement. While the FDA can still pull tests over accuracy, and in recent weeks has withdrawn EUAs from a number of antibody test kits, the new changes make keeping tabs on new LDTs of any variety much harder.



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

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