Evaluate Vantage

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Few groups have developed Covid-19 diagnostics – but this will change

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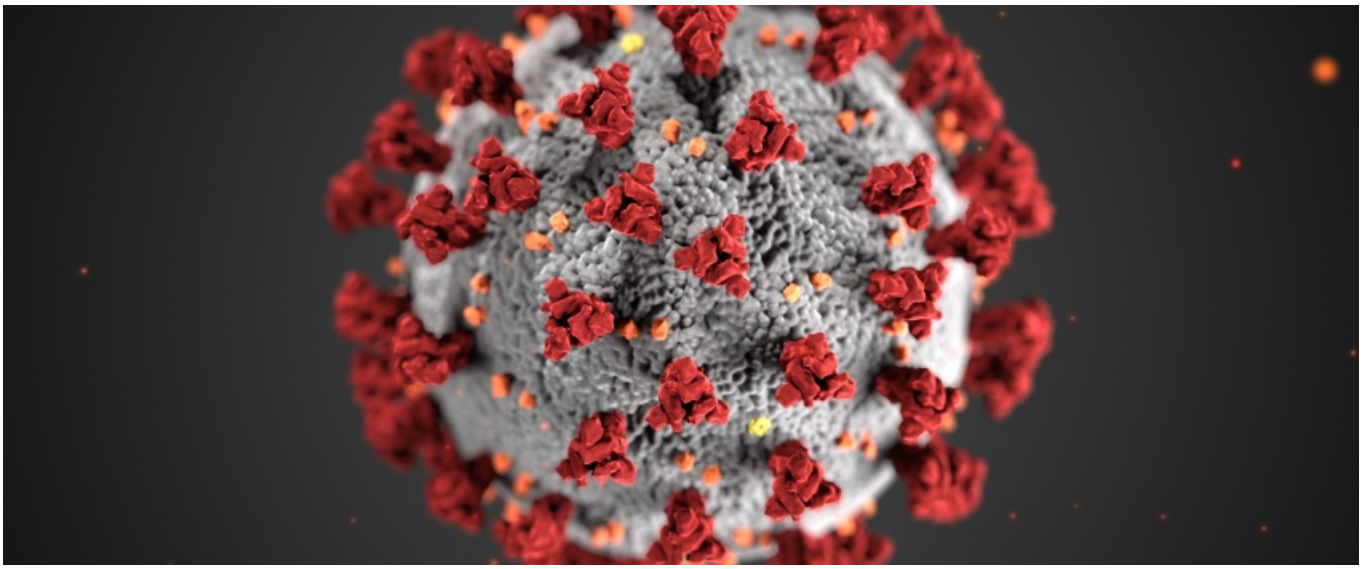

The FDA is loosening its rules on the authorisation of diagnostic tests for the new coronavirus, but it is still some way behind Europe.

The Covid-19 outbreak means medics are now turning to Western diagnostics companies for genetic tests for the virus. Five of the top 10 IVD developers have responded to the call, alongside smaller groups and independent medical centres in Europe and the US.

Roche led the charge, claiming to have put the first Covid-19 test on a commercial footing at its fourth-quarter results conference on January 30 (*Coronavirus stock hype proves infectious, February 27, 2020*). Danaher and Thermo Fisher have also both made tests available, and France's Biomérieux has two on the way.

So far no Covid-19 test has obtained FDA approval or clearance. Those that are on sale in the US have been made available under Clia waivers, whereby the facility where the tests are conducted is regulated, rather than the tests themselves.

Three tests, however, have obtained European CE mark. Most recent, announced this morning, is the Viasure Sars-CoV-2 real time PCR detection kit, developed under a partnership between Becton Dickinson and the much smaller group Certest Biotec. The micro caps Novacyt and Co-Diagnostics also have CE-marked tests.

Forthcoming

Genetic tests themselves are reasonably easy to create and deliver. The virus's genome was sequenced and published early on in the outbreak, and because of coronaviruses' propensity to mutate it has been repeatedly sequenced since.

Devising a genetic test for the virus is a case of picking parts of this genome to identify in a sequence of viral RNA taken from a patient. Thermo Fisher's test, for example, checks for three target sequences that are unique to the Covid-19 virus – the *ORF1ab* gene and regions that code for the S and N proteins.

Consequently the companies named here represent a tiny fraction of the number actually working on Covid-19 diagnostics. The FDA initially said that tests to be used in the US would have to obtain an emergency use authorisation, the means by which the agency permits use of a non-approved drug or device to respond to a declared emergency. It issued one such authorisation to a test developed by the CDC on February 4.

A few weeks later the FDA relaxed its rules. Under pressure to accelerate the availability of Covid-19 tests, it

said on February 29 that Clia-certified labs could begin using their tests without needing an EUA, though they would still have to submit an application for one 15 business days after validating their new test. The same day, the FDA awarded an EUA to a test developed by a New York-based public health facility.

In a briefing on March 7, the FDA Commissioner Stephen Hahn said that the agency had received more than 100 requests for an EUA template, adding that 36 companies had sought the FDA's assistance with development and validation of tests they plan to bring through the EUA process. Most of these companies will already be selling their tests in the US, but it is only when the EUAs are granted that it will become clear who they are.

Top 10 *in vitro* diagnostics companies' work on Covid-19				
	Annual sales ($bn)			
Company	**2019**	**2024**	**CAGR**	**Covid-19 diagnostic?**
Roche	11.1	14.2	+5%	Yes, test launched
Abbott Laboratories	7.7	10.1	+6%	No, but has donated testing instruments to China
Danaher	6.6	8.2	+5%	Yes, test launched
Siemens Healthineers	4.6	5.6	+4%	No, though has tests for other coronaviruses
Thermo Fisher Scientific	3.4	4.0*	+3%	Yes, test launched
Becton Dickinson	3.1	3.9	+5%	Yes, test CE marked
Sysmex	2.7	3.7	+6%	No, mainly cancer-focused
Exact Sciences	0.9	3.5	+32%	No, cancer-focused
Biomérieux	2.4	3.3	+6%	Yes, two tests in development, launch of first imminent
Ortho-Clinical Diagnostics	1.9	2.1	+2%	No, though has tests for other viruses including HIV
Rest of market	15.0	22.2	+8%	
Total market	59.4	81.0	+6%	
**Does not include forecasts for Qiagen, which Thermo Fisher is to acquire. Source: EvaluateMedTech.*				