



FINAL – release date: 01/05

QuantuMDx Launches Rapid, Sensitive SARS-CoV-2 Test

- Manufacturing in place to produce 2 million tests per week with millions of tests ready to ship
 - EUA application submitted to FDA
- Clinical testing is being performed with two NHS hospitals
 - CE-IVD to follow in mid-May
- Validating the test for direct from swabs

NEWCASTLE UPON TYNE, UK, 30 April 2020. QuantuMDx Group Limited, a UK-based life sciences company developing transformational point-of-care molecular diagnostics, today announces the launch of its sensitive SARS-CoV-2 assay for laboratory use, which delivers a result in approximately 70 minutes.

Working with British manufacturing partner Biofortuna Limited, QuantuMDx has scaled up production capability to to initially 2M tests per week and with the potential to scale up to 3M tests per week by introducing further automation within the manufacturing process. The company is ready to start shipping assays from today. In addition, QuantuMDx has rigorously stress tested its supply chains and is confident in its ability to supply significant volumes of tests worldwide.

QuantuMDx's SARS-CoV-2 assay is a real-time reverse transcriptase rtRT-PCR test that has been developed using advanced bioinformatics to maximise performance. The assay has been designed with the most up-to-date sequence information to ensure 100% coverage of all known SARS-CoV-2 sequences. The company's assay has been evaluated using 90 pre-extracted residual samples from The Newcastle upon Tyne Hospitals NHS Foundation Trust, UK, to assess clinical performance against tests currently in use. It has been shown to be clinically equivalent to the comparator assay presently used in NHS hospitals, with 100% concordance with all positive and negative SARS-CoV-2 classifications.

An application has been made to the U.S FDA for use under Emergency Use Authorisation and QuantuMDx expects to attain CE-IVD mark by mid-May. In addition, QuantumDx will apply for World Health Organization 'Emergency Use Listing' listing.

The sensitive test targets three SARS-Cov-2 genomic loci; the S, N and Orf1 genes and can run on multiple high- and low-throughput PCR platforms that can be calibrated for the fluorophores FAM and HEX. As all the assay reagents

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are lyophilised in a single tube, the assay is more convenient for shipping than liquid based assay kits. Moreover, lyophilised reagents have a longer shelf life and don't require stringent cold chain shipping.

In silico analysis of QuantuMDx' SARS-CoV-2 assay shows 100% specificity and 0% cross reactivity with common commensal or potentially interfering organisms. QuantuMDx is now working with St George's, University of London to undertake CE-IVD reproducibility evaluations.

In response to the shortage of extraction kits in the current market, QuantuMDx is also validating the use of the test without the need for RNA extraction, running the RT-PCR test direct from swabs. Furthermore, the company is validating the test on other specimen types, such as saliva samples.

Sanjeev Krishna, Professor of Molecular Parasitology and Medicine at St George's, University of London, said: "It's universally acknowledged that one of the most urgent needs to help us control and hopefully eliminate the COVID-19 pandemic are good diagnostic tests. We need a test that can diagnose the disease quickly and accurately, while being available and affordable for all healthcare systems. This test is very much aiming to address those needs so we can control the infection with greater precision."

Jonathan O'Halloran, Co-founder and Chief Executive Officer of QuantuMDx said: "It is clear that tackling the COVID-19 pandemic requires the widespread availability of accurate and appropriate diagnostics. It's a privilege for us at QuantuMDx to have been able to use our expertise in diagnostics to develop a SARS-CoV-2 Detection assay and contribute to the national and international efforts to tackle this disease. By securing the supply chain early, we have been able to achieve massive scale for our assay to supply the testing needs of countries around the world."

In addition to developing a SARS-CoV-2 test for laboratories, QuantuMDx continues preparations for scale-up and manufacture of its Q-POC™ rapid point-of-care testing device. The company is currently translating both its SARS-CoV-2 detection assay and its proprietary respiratory panel on to the Q-POC™ platform. Using swab samples, a Q-POC™ test could provide a result in a targeted 15-20 minutes at the patient's side whether in a hospital, pharmacy, care home, school or even immigration zones.

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About QuantuMDx

QuantuMDx Group is an ambitious company with a global vision of empowering the world to control and eradicate disease by making transformative, quality point-of-care diagnostic technologies universally accessible. QuantuMDx has operations and strategic partnerships in the United States, Asia, Australasia, Europe and Africa – keeping it at the forefront of molecular diagnostics. For more information go to: www.quantumdx.com

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