

# Coronavirus test update

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Novacyt S.A.

28 February 2020

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("Novacyt" or the "Company")

Coronavirus test update

Major distribution agreement for COVID-19 test

Paris, France and Camberley, UK - 28 February 2020 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, is pleased to provide an update regarding the novel coronavirus (COVID-19) test developed by Primerdesign, its molecular diagnostics division, and announces it has signed a major distribution agreement in Asia and an original equipment manufacturer (OEM) agreement with a US healthcare group.

As of 27 February 2020, Primerdesign has sold over £0.93m (€1.1m) of CE-Mark and research use only (RUO) tests. Since launching its CE-Mark test, the Company is experiencing high levels of interest in its product. The value of quotations has grown significantly as Novacyt is currently involved in active discussions with representatives from a number of countries which have an acute need for tests as part of their national screening programmes. Due to the high level of interest in the Primerdesign COVID-19 test and rapidly evolving nature of this outbreak, the Company cannot predict with any certainty the conversion rate of these ongoing enquiries into orders.

Primerdesign has also signed its first major distribution agreement for the COVID-19 test with a global life sciences company to supply the test to two Asian territories outside mainland China. Initial sales, which are subject to local emergency use approval, are anticipated to be £2.1m (€2.5m) during the first six months of the agreement. It is expected that the first sales under this agreement will take place in March 2020.

The Company also announces that it has signed an OEM agreement with a US healthcare group for the manufacture and sale of its RUO coronavirus tests.

In addition, as previously announced, the Primerdesign test is currently under review by the US Food and Drug Administration (FDA) for Emergency Use Approval, which would allow the test to be used for clinical diagnosis of COVID-19 in the US. The FDA and the Company are in regular contact.

Public health authorities around the world are pursuing a variety of strategies when it comes to testing for COVID-19. For example, Public Health England (PHE) has issued testing guidance to the NHS to be deployed across eight testing centres in the UK. PHE as part of its planning has also invited diagnostic manufacturers (including Primerdesign) to submit tests for a formal evaluation process, which is expected to conclude next month. It is not known at this time what conclusions or guidance the PHE will subsequently give to the NHS for COVID-19 testing.

The current COVID-19 screening procedure in France involves directing all patient samples to the Institut Pasteur in Paris. It is not known at this time whether more widespread testing will be performed and what test methods will be approved for use in these hospitals and clinics.

Other health authorities around the world have approved tests for emergency use from local manufacturers and many are also currently reviewing the Primerdesign test. The speed and processes to gain emergency approval for tests differs from country-to-country depending on their approval process and the perceived threat level of COVID-19.

The Company has put in place a number of measures to significantly increase production capacity and continues to plan for greater throughput to ensure Primerdesign can meet all current and potential demand. These measures include, if necessary, using the Company's manufacturing capacity at both its UK sites.

Graham Mullis, Chief Executive Officer of Novacyt, commented:

"I am extremely pleased with the commercial interest shown in our test to date and to be able to support the global response to monitor and contain the COVID-19 outbreak. The two contracts announced today reinforce how quickly the response to this virus is developing and shows our commitment to support these efforts anywhere in the world.

"We believe the Primerdesign test remains among the quickest and most accurate tests available for COVID-19, as well as being stable for long distance shipping without the need for specialist cold-chain shipping. It is also designed to run on multiple molecular testing platforms commonly used around the world. I am proud of the team who are working extremely hard to meet the regulatory and manufacturing challenges to make our test available to as many affected countries as possible."

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014.

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## About Novacyt Group

The Novacyt Group is an international diagnostics business generating an increasing portfolio of in vitro and molecular diagnostic tests. Its core strengths lie in diagnostics product development, commercialisation, contract design and manufacturing. The Company's lead business units comprise of Primerdesign and Lab21 Products, supplying an extensive range of high-quality assays and reagents worldwide. The Group directly serves microbiology, haematology and serology markets as do its global partners, which include major corporates.

For more information please refer to the website: [www.novacyt.com](http://www.novacyt.com)

## About COVID-19

Researchers at the Chinese Centre for Disease Control and Prevention and their collaborators have sequenced the 2019 novel coronavirus (COVID-19) pathogen from patient samples and have found it to be genetically distinct from the severe acute respiratory syndrome (SARS) virus that caused an epidemic in 2002 and 2003, as well as from the Middle East respiratory syndrome (MERS) virus that was detected in 2012.

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