

# Launch of CE-IVD Marked novel coronavirus test

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Novacyt S.A.

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("Novacyt", the "Company" or the "Group")

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novel coronavirus test

Paris, France and Camberley, UK - 17 February 2020 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, is pleased to announce that its molecular diagnostics division, Primerdesign, has launched its CE-Mark molecular test for the clinical detection of the novel coronavirus (COVID-19).

The Directors believe that Primerdesign's COVID-19 test is the first CE-Mark test for the 2019 strain of novel coronavirus and follows the Company's rapid launch of its research use only (RUO) coronavirus test on 31 January 2020. As a result of the CE-Mark, the Company's COVID-19 test can be used directly by laboratories and hospitals for the testing of patients without the need for validation by clinicians. The Company anticipates increased demand for its test for COVID-19 due to this extended use for clinical diagnosis.

Primerdesign has already received requests for quotations for 288,000 CE-Mark tests since they were made available to pre-order on 14 February 2020. The Company has received orders for 40,000 RUO tests and requests for quotations for an additional 35,000 RUO tests prior to the launch of the COVID-19 clinical version. Demand for the tests has come from China, the US and the UK, as well as many other countries around the world.

The Company continues to see a high conversion rate from quotations to orders. However, it is difficult to predict how demand for the test will grow as the epidemic is still in its early stages. Since the initial reports of COVID-19, the Company has invested in manufacturing capacity to meet the current and potential future demand for its tests.

The Primerdesign test is being formally evaluated by public health authorities from five countries and the Company is in discussions with these organisations to potentially support their national screening requirements for COVID-19.

As previously announced, the Company has submitted an application to, and remains in discussion with, the US Food and Drug Administration (FDA) for Emergency Use Approval (EUA) of its test for COVID-19, which would allow laboratories in the US to use the test for clinical diagnosis on a temporary basis. The data generated from the CE-Mark approval will be used to support this application.

Graham Mullis, Chief Executive Officer of Novacyt commented.

"I am very pleased to announce the launch of our COVID-19 CE-Mark test, which we believe is the first CE-Mark approved test for clinical diagnosis of the 2019 strain of the novel coronavirus. As with our research use only test, it can produce a result in less than two hours, with the added efficiency of being able to transport the test at ambient temperatures eliminating the need for cold chain shipping. It is designed to run on multiple instrument platforms commonly used by clinical laboratories around the world, which ensures our COVID-19 test can be used by the largest possible number of clinicians. We look forward to continuing to support clinicians in the fight to contain the spread of the novel coronavirus during this public health emergency."

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

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#### Contacts

Novacyt SA

Graham Mullis, Chief Executive Officer

Anthony Dyer, Chief Financial Officer

+44 (0)1276 600081

SP Angel Corporate Finance LLP (Nominated Adviser and Broker)

Matthew Johnson / Charlie Bouverat (Corporate Finance)

Vadim Alexandre / Rob Rees (Corporate Broking)

+44 (0)20 3470 0470

FTI Consulting (International)

Victoria Foster Mitchell / Mary Whittow

+44 (0)20 3727 1000

[victoria.fostermitchell@fticonsulting.com](mailto:victoria.fostermitchell@fticonsulting.com) / [mary.whittow@fticonsulting.com](mailto:mary.whittow@fticonsulting.com)

FTI Consulting (France)

Arnaud de Cheffontaines / Astrid Villette

+33 (0)147 03 69 47 / +33 (0)147 03 69 51

arnaud.decheffontaines@fticonsulting.com / astrid.villette@fticonsulting.com

#### 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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