

# Approval of COVID-19 test under CTDA legislation

RNS Number : 6637T

Novacyt S.A.

26 November 2021

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

Approval of COVID-19 test in the UK under CTDA legislation

Paris, France and Camberley, UK - 26 November 2021 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, announces that, further to the announcement on 2 November 2021, the Company's genesig® COVID-19 Real-Time PCR test has been approved in the UK under the UK Health Security Agency's Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 ("CTDA"). The genesig® COVID-19 test is Novacyt's first test to be added to the CTDA register and the Company will now work to resume the sale of the product in the UK.

Novacyt's genesig® COVID-19 assay was launched on 31 January 2020 and was one of the world's first commercially available tests for COVID-19. To date, the genesig® COVID-19 test, which targets the ORF1ab gene, continues to be able to detect all known variants and mutations of COVID 19, with over 4.5 million sequences analysed, as documented in Novacyt's latest weekly bioinformatic surveillance report.

As announced on 2 November 2021, the Company submitted 11 products for review under the CTDA to meet the original submission deadline of 1 September 2021. Further to the validation of its genesig® COVID-19 test, Novacyt's Primerdesign Ltd PROMate® COVID-19 test (encompassing both the PROMate® 1 Gene q16 and q32 products) remains on the temporary protocol and continues to be supplied to the NHS under the PHE National Microbiology Framework. The Company awaits updates on the additional eight products submitted to the CTDA across its COVID-19 testing portfolio. To note, only validated products, or products on the temporary protocol, can be sold in the UK after 31 October 2021.

On 2 November 2021, Novacyt also stated that if no further products were added to the CTDA register, the impact on full year revenues for 2021 would be circa £3 million. With this approval, the financial impact on 2021 will be significantly lower as the genesig® COVID-19 test accounts for approximately 30% of the circa £3 million revenue shortfall.

David Allmond, Group CEO of Novacyt, commented:

"I am delighted to announce that our genesig® COVID-19 test has become the seventh product to be approved and

added to the CTDA register. With the associated resumption of the sale of this product in the UK, we look forward to ensuring our customers continue to have access to this market leading test during the winter season. Our genesig® COVID-19 test was launched in late January 2020 and is recognised globally by leading public health bodies, including the US FDA<sup>1</sup>, alongside long term agreements with both UNICEF and the World Health Organization. We continue to engage with the UK Health Security Agency and look forward to further updates on our tests still under review."

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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)

#### References:

1. <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2>

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