

# Approval of COVID-19 test under CTDA legislation

RNS Number : 9324B

Novacyt S.A.

17 February 2022

Novacyt S.A.

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

Approval of the first direct-to-PCR COVID-19 test in the UK under CTDA legislation

Paris, France and Camberley, UK - 17 February 2022 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, announces that the Company's PROmate® COVID-19 2G 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 PROmate® COVID-19 2G test is the first direct-to-PCR product to be added to the CTDA register of approved products and is designed to detect two SARS-CoV-2 targets within ORF1ab in response to an increasing shift from single-gene to multi-gene testing solutions. Direct-to-PCR products remove the need for complex, manual or automated extraction solutions and are designed to significantly improve laboratory workflow and reduce costs. It also allows testing to take place away from traditional, laboratory-based settings due to simplicity and ease of use. Therefore, the PROmate® COVID-19 2G PCR test is well suited for industries such as travel, sport, film, media, and workplace settings.

The validation of the PROmate® COVID-19 2G test follows the UK approval of the Company's COVID-19 genesig® Real-Time PCR test under the CTDA, as announced on 26 November 2021. In addition, as previously announced, Novacyt's PROmate® COVID-19 1G Real-Time PCR test, currently being supplied to the NHS under a National Microbiology Framework, remains on the temporary protocol list (due to expire on 28 February 2022) and the Company awaits further updates on an additional seven products submitted to the CTDA across its COVID-19 testing portfolio.

David Allmond, Group CEO of Novacyt, commented:

"Our PROmate® COVID-19 range offers a unique combination of workflow efficiency, results in as little as 80 minutes and exceptional clinical performance, optimised for both our genesig® q16 and q32 instruments. It provides total viral inactivation, with a ready-prepared mix containing internal control for run validity, meaning there is no need for a category 2 laboratory to handle the live virus, thereby removing handling risk and bringing the test nearer to patients. With this approval from the CTDA, we can continue to meet the demand for high quality COVID-19 testing in the UK."

- End -

## Contacts

Novacyt SA

David Allmond, Chief Executive Officer

James McCarthy, 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

Numis Securities Limited (Joint Broker)

Freddie Barnfield / James Black

+44 (0)20 7260 1000

Allegra Finance (French Listing Sponsor)

Rémi Durgetto / Yannick Petit

+33 (1) 42 22 10 10

r.durgetto@allegrafinance.com/ y.petit@allegrafinance.com

FTI Consulting (International)

Victoria Foster Mitchell / Alex Shaw

+44 (0)20 3727 1000

victoria.fostermitchell@fticonsulting.com / Alex.Shaw@fticonsulting.com / Novacyt.group@fticonsulting.com

FTI Consulting (France)

Arnaud de Cheffontaines

+33 (0)147 03 69 48

arnaud.decheffontaines@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)

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact [rns@lseg.com](mailto:rns@lseg.com) or visit [www.rns.com](http://www.rns.com). RNS may use your IP address to confirm compliance with the terms and conditions, to analyse how you engage with the information contained in this communication, and to share such analysis on an anonymised basis with others as part of our commercial services. For further information about how RNS and the London Stock Exchange use the personal data you provide us, please see our Privacy Policy.

END

REATFMBTMTJBTTT