

Novacyt S.A.

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

## Launch of two new PCR COVID-19 assays

**Paris, France and Camberley, UK – 3 June 2021** – Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, announces the launch of two new polymerase chain reaction (PCR) assays, expanding its genesig® COVID-19 and SNPsig® SARS-CoV-2 variant detection portfolios.

- **genesig® COVID-19 3G** is a CE-Marked three-gene assay to detect the ORF1ab, M gene, and S gene targets of SARS-CoV-2, enabling fulfilment of certain international testing requirements, including Fit to Fly Certificate, Test to Release and US Food and Drug Administration regulations.
- **SNPsig® EscapePLEX SARS-CoV-2** is a first-to-market assay panel in a single kit able to detect the four most critical SARS-CoV-2 mutations currently recognised, combined with a confirmatory two-gene assay for COVID-19. The research-use-only kit detects the biologically significant 'escape' mutations E484K, K417N, K417T and P681R, present in the Alpha, Beta, Gamma and Delta Variants<sup>1</sup> of Concern (VoC), and also incorporates the two gene (ORF1ab and M) assay to provide a confirmatory detection of SARS-CoV-2.

Novacyt's genesig® portfolio is a well-established range of PCR kits for pathogen detection. The new three-gene assay for COVID-19 has been developed in recognition of rapidly changing testing needs dictated by SARS-CoV-2 mutations and complements the Company's existing one-gene, two-gene, and high-throughput tests. The Company aims to capture a wider share of the growing global travel market for COVID-19 testing with the three-gene test.

The SNPsig® portfolio is initially focused on detecting the most significant mutations, VoC and variants of SARS-CoV-2 and currently includes 13 assays. The Company believes the SNPsig® EscapePLEX SARS-CoV-2 will be crucial in helping clinicians and public healthcare centres globally identify SARS-CoV-2 mutations which can impact transmissibility, immunity, and infection severity<sup>2</sup>.

### **Graham Mullis, Chief Executive Officer of Novacyt, commented:**

*"The success of our COVID-19 PCR assays has been built around robust design principles and our real-time bioinformatics surveillance programme to monitor new SARS-CoV-2 genome sequences. As a result, our genesig® COVID-19 portfolio is highly accurate despite mutations, and we believe our SNPsig® portfolio is the world's largest for detecting SARS-CoV-2 variants. The addition of both of these new assays ensures that Novacyt's COVID-*

<sup>1</sup> <https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/>

<sup>2</sup> <https://www.ecdc.europa.eu/en/covid-19/variants-concern>

19 solutions remain robust and that pragmatic options are available to support both public health and private sector testing alike.”

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**About the genesig® COVID-19 portfolio**

The genesig® COVID-19 Real-Time PCR portfolio is a range of CE-Marked, in vitro diagnostic, reverse transcriptase PCR (RT-PCR) assays intended for the qualitative detection of nucleic acid from SARS-CoV-2. Supported by the Company’s global surveillance programme of virus monitoring, the genesig® COVID-19 Real-Time PCR range continues to evolve, bringing innovations to markets that can impact the management of patients and patient-care outcomes. The current portfolio is described below.

<b>Assay Type</b>		<b>Detection Profile</b>	<b>Pack Size</b>
genesig® COVID-19	CE-IVD	ORF1ab	96 reactions (Master Mix Included)
genesig® COVID-19 2G		ORF1ab and S gene targets	
genesig® COVID-19 3G		ORF1ab, M gene and S gene targets	

genesig <sup>®</sup> COVID-19 HT 2.0		ORF1ab	1,536 reactions (384 x 4) (Master Mix Included)
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### About the SNPsig<sup>®</sup> COVID-19 portfolio

The SNPsig<sup>®</sup> COVID-19 portfolio is able to detect the most significant mutations, VoC and variants of SARS-CoV-2. Novacyt's bioinformatics surveillance group remains highly vigilant and, as new biologically significant mutations are identified, these will continue to be added to the SNPsig<sup>®</sup> portfolio. The current portfolio is described below.

<b>SNPsig<sup>®</sup> Assays Launched</b>		
<b>Assay Type</b>		<b>Detection Profile</b>
SNPsig <sup>®</sup> SARS-CoV-2 (20I/501Y.V1)	RUO	Alpha variant also known as 20I/501Y.V1 (UK)
SNPsig <sup>®</sup> SARS-CoV-2 (20H/501Y.V2)		Beta variant also known as 20H/501Y.V2 (SA)
SNPsig <sup>®</sup> SARS-CoV-2 (N501Y)		Variants with the N501Y mutation (Alpha, Beta & Gamma variants)
SNPsig <sup>®</sup> SARS-CoV-2 (E484K)		Variants with the E484K mutation
SNPsig <sup>®</sup> SARS-CoV-2 (20J/501Y.V3)		Gamma variant also known as 20J/501Y.V3 (Brazil)
SNPsig <sup>®</sup> VariPLEX (COVID-19)	CE-IVD	Alpha, Beta, Gamma, Epsilon variants, and the key biologically significant mutations N501Y and E484K
SNPsig <sup>®</sup> VariPLEX (SARS-CoV-2)	RUO	
SNPsig <sup>®</sup> SARS-CoV-2 (20B/S.484K)	RUO	Zeta variant also known as 20B/S.484K (Brazil)
SNPsig <sup>®</sup> SARS-CoV-2 (L452R)	RUO	Variants with the L452R mutation
SNPsig <sup>®</sup> COVID-19 (20I/501Y.V1+ E484K)	CE-IVD	20I/501Y.V1, VOC-21FEB-02 and variants carrying the E484K mutation
SNPsig <sup>®</sup> SARS-CoV-2 (E484K) Easy	RUO	Variants with the E484K mutation (one-step PROMate workflow)
SNPsig <sup>®</sup> SARS-CoV-2 (VUI-21APR)		Kappa variant also known as VUI-21APR-01 and VUI-21APR-03 (India)
SNPsig <sup>®</sup> EscapePLEX (SARS-CoV-2)		E484K, K417N, K417T and P681R mutations, which are included in the Alpha, Beta, Gamma and Delta variants (also known as UK, South

		Africa, Brazil, and India Variants of Concern (VoC)
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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)