

Novacyt S.A.

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

Inclusion of SNPsig[®] SARS-CoV-2 PCR genotyping portfolio in the NHS England Framework and expansion of SNPsig[®] product range

Paris, France and Camberley, UK – 17 May 2021 – Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, announces that the Company's SNPsig[®] SARS-CoV-2 polymerase chain reaction (PCR) genotyping portfolio has been included in the NHS England Framework for detecting Variants of Concern (VoC). Novacyt also announces the launch of two new PCR assays to detect SARS-CoV-2 VoC.

- **Detecting known VoC Framework**, announced by NHS England on 14 May 2021, includes the Company's SNPsig[®] SARS-CoV-2 PCR genotyping portfolio as one of the four companies selected by NHS England. This national framework is for testing of all positive SARS-CoV-2 samples from NHS (pillar 1) and high throughput Lighthouse (pillar 2) laboratories in England.
- **SNPsig[®] COVID-19 (20I/501Y.V1 + E484K)** is a CE Marked assay to detect 20I/501Y.V1, the VoC originally identified in the UK, VOC-21FEB-02 and all SARS-CoV-2 variants carrying the E484K escape mutation.
- **SNPsig[®] SARS-CoV-2 (E484K) Easy** is a research-use-only, streamlined workflow solution for the detection of SARS-CoV-2 variants carrying the E484K escape mutation for use with the Company's q32 rapid-PCR instrument. This assay comes with pre-filled cassettes and includes only one pipetting step to decrease operator complexity and improve cycle times.

Graham Mullis, Chief Executive Officer of Novacyt, commented:

"We are very pleased to be included in NHS England's VoC Framework, which allows our SNPsig[®] range of products to be used at any NHS and Lighthouse laboratories, subject to local verification, as we continue to support diagnostic testing across the UK, and globally, through our extensive portfolio. We remain committed to developing new tests to match the rapid evolution of the SARS-CoV-2 virus with our real-time bioinformatics surveillance programme and accelerated product development. Our SNPsig[®] portfolio for detecting Variants of Interest and Variants of Concern now includes 12 individual assays to support scientists and clinicians in the ongoing fight against COVID-19."

About the E484K mutation

The E484K mutation has appeared independently in several VoC, indicating an evolutionary advantage for SARS-CoV-2¹. Multiple studies have shown an association with reduced antibody neutralisation in both natural and vaccine-elicited human sera²⁻⁴. Early detection of the E484K mutation is critical to ensure a rapid public health response.

About SNPsig[®] COVID-19 (20I/501Y.V1 + E484K)

The subpopulation of 20I/501Y.V1 carrying the E484K mutation was first detected in the Southwest of England and was first known as the Bristol Variant. This VoC, now named as VOC-21FEB-02, has been detected predominantly in the UK. In addition to the observed increase in transmissibility detected for 20I/501Y.V1, the E484K mutation provides this

VoC with potential for antibody escape. SNPsig® COVID-19 (20I/501Y.V1 + E484K) is a product that combines the detection of both the VoC 20I/501Y.V1 and the clinically significant mutation E484K, allowing the identification of not only 20I/501Y.V1 and VOC-21FEB-02 positive cases, but also the presence of E484K in one assay.

About SNPsig® SARS-CoV-2 (E484K) Easy

SNPsig® SARS-CoV-2 (E484K) Easy is a rapid direct solution based on the Company's simplified PROMate workflow, to detect the E484K mutation in SARS-CoV-2 variants in less than 90 minutes using the Company's q32 instrument.

About the SNPsig® portfolio

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® portfolio. A recent study reported in the medRxiv⁵, the preprint server for health sciences, demonstrates the high potential of the SNPsig® portfolio to detect the most significant mutations, VoCs and variants. The portfolio is described below:

SNPsig® Assays launched		
Assay Type		Detection Profile
SNPsig® SARS-CoV-2 (20I/501Y.V1)	RUO	20I/501Y.V1 (UK)
SNPsig® SARS-CoV-2 (20H/501Y.V2)		20H/501Y.V2 (SA)
SNPsig® SARS-CoV-2 (N501Y)		Variants with the N501Y mutation (UK, SA & Brazil)
SNPsig® SARS-CoV-2 (E484K)		Variants with the E484K mutation
SNPsig® SARS-CoV-2 (20J/501Y.V3)		20J/501Y.V3 (Brazil)
SNPsig® VariPLEX (COVID-19)	CE-IVD	Variants originally identified in the UK (20I/501Y.V1), South Africa (20H/501Y.V2), Brazil (20J/501Y.V3) and California (20C/S:452R), and the key biologically significant mutations N501Y and E484K
SNPsig® VariPLEX (SARS-CoV-2)	RUO	
SNPsig® SARS-CoV-2 (20B/S.484K)	RUO	20B/S.484K (Brazil)
SNPsig® SARS-CoV-2 (L452R)	RUO	Variants with the L452R mutation
SNPsig® COVID-19 (20I/501Y.V1+ E484K)	CE-IVD	20I/501Y.V1, VOC-21FEB-02 and variants carrying the E484K mutation
SNPsig® SARS-CoV-2 (E484K) Easy	RUO	Variants with the E484K mutation (one-step PROMate workflow)
SNPsig® SARS-CoV-2 (VUI-21APR)		VUI-21APR-01 and VUI-21APR-03 (India)
SNPsig® Assays in development		
Assay Type		Detection Profile
SNPsig® EscapePLEX (SARS-CoV-2)	RUO	Variants with the E484K, K417N/T and P681R

		mutations including the India, SA and BR VOCs
SNPsig® SARS-CoV-2 (VUI-21MAR-02)		VUI-21MAR-02 (Brazil)
SNPsig® SARS-CoV-2 (B.1.1.519)		B.1.1.519 (Mexico)

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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

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