

# Launch of PCR assay portfolio

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Novacyt S.A.

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

Launch of PCR genotyping assay portfolio to detect COVID-19 variants

Paris, France and Camberley, UK - 2 February 2021 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, announces the launch of a new and innovative portfolio of assays (under the brand name SNPsig®) to aid the diagnosis of the new variants of SARS-CoV-2.

Novacyt's existing polymerase chain reaction (PCR) COVID-19 portfolio remains highly accurate in detecting all published SARS-CoV-2 variants. The launch of the new SNPsig® portfolio complements and expands the Company's offering into the rapidly evolving requirement for PCR genotyping of variants.

As noted by the US Centers for Disease Control and Prevention, multiple SARS-CoV-2 variants emerged in late 2020. The three most notable variants were originally identified by their reporting origin, the UK (20I/501Y.V1 or B.1.1.7), South Africa (20H/501Y.V2 or B.1.351) and Brazil (20J/501Y.V3 or B.1.1.28) but are now prevalent globally<sup>1</sup>. The emergence of these variants has been reported across Europe, in 32 US states<sup>2</sup>, Japan, Africa and Latin America and is expected to significantly impact the clinical care of individual patients, local community disease control and national epidemiological strategies<sup>3</sup>, due to suggested evidence that these variants are associated with an increase in mortality and transmission<sup>4</sup>.

The tracking of variants could also contribute to the effectiveness of vaccination efforts, especially if, as described in recent publications, the emergence of variants may have an impact on vaccine efficaciousness<sup>5</sup>. The SNPsig® assays offer the ability to track variants on-site and to generate a result in hours, compared to the current approach of next generation sequencing, which is typically constrained by limited capacity, cost and an off-site multi-day turnaround.

Novacyt's bioinformatics surveillance group has worked with a global network of virologists tracking variants to identify the mutations, or Single Nucleotide Polymorphisms (SNPs), critical to each variant. From this analysis, Novacyt has developed and patented the SNPsig® portfolio, which is one of the first commercially available for variant detection. The first three SNPsig® assays, launched today, enable the identification of the non-variant virus and the UK, South Africa or Brazil variants, as well as any variant carrying the N501Y mutation.

The next product in the SNPsig® portfolio, planned to launch shortly, will be an assay panel, known as VariPLEX™, to detect these three variants and two other key mutations identified by the World Health Organization<sup>6</sup> in a single test. Novacyt's bioinformatics surveillance group remains highly vigilant and, as significant new mutations are identified, these will be added to the SNPsig® portfolio.

The SNPsig® assays are designed to run on central laboratory systems and on the Company's q16 and q32 rapid PCR systems as research-use-only products. The Company expects to launch the regulatory approved clinical diagnostic assays next month.

Of note, the first three SNPsig® assays are also being deployed to an international consortium of leading academic and public health laboratories in the UK, Europe, US and Latin America<sup>7</sup>, assembled by Novacyt to support a global variant diagnostic surveillance study.

Graham Mullis, Chief Executive Officer of Novacyt, commented:

"It is clear that we must stay highly vigilant as SARS-CoV-2 continues to mutate and may, therefore, remain as a global threat for many years. Diagnostic companies have a key role to play in aiding the clinical diagnosis of the variants of greatest concern. We are therefore pleased to announce the rapid development and launch of this portfolio of PCR genotyping assays for the identification of specific new SARS-CoV-2 variants. With this launch, Novacyt continues to demonstrate its ability to remain at the forefront of this rapidly evolving field, with market-leading intelligence and expertise that allows us to support scientists and clinicians around the world in the fight against this pandemic."

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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)

[1]  
<https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/scientific-brief-emerging-variants.html>

2 <https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html>

3  
<https://www.ecdc.europa.eu/sites/default/files/documents/COVID-19-risk-related-to-spread-of-new-SARS-CoV-2-v>

ariants-EU-EEA.pdf

4 NERVTAG paper on COVID-19 variant of concern B.1.1.7 (publishing.service.gov.uk)

5 <https://jamanetwork.com/journals/jama/fullarticle/2776039>

6 <https://www.who.int/csr/don/21-december-2020-sars-cov2-variant-united-kingdom/en/>

7 UK: University of B'ham, Cambridge, Edinburgh and QMUL, Europe: Gibraltar; USA: Oklahoma, Texas; Latin America: Mexico, Colombia and / or Dominican Republic

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