

Launch of VariPLEX CE-Mark test

RNS Number : 2590T

Novacyt S.A.

24 March 2021

Novacyt S.A.

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

Launch of CE-Mark test to detect multiple COVID-19 variants of concern

SNPsig® VariPLEX™ is able to detect six key mutations of SARS-CoV-2 using PCR genotyping in under two hours

Paris, France and Camberley, UK - 24 March 2021 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, announces that, further to the announcement on 2 February 2021, the Company will launch SNPsig® VariPLEX™ this week as a CE-Mark approved polymerase chain reaction (PCR) assay panel able to detect the four COVID-19 variants of concern (VOC) that are currently recognised and the two most biologically significant mutations in a single kit.

VariPLEX™ is the latest addition to Novacyt's innovative and expanding PCR genotyping assay portfolio, SNPsig®, to identify mutations (single nucleotide polymorphisms (SNPs)). The VariPLEX™ panel detects the variants originally identified in the UK (20I/501Y.V1), South Africa (20H/501Y.V2), Brazil (20J/501Y.V3) and California (20C/S.452R), and mutations N501Y and E484K, which are now all prevalent globally.¹

VariPLEX™ can be deployed on-site in near-patient settings to generate results in under two hours to facilitate same-day patient and public health decision making when using the Company's q32 instruments or in any central laboratory with an open platform instrument with the ability to detect across at least four fluorescent channels. This provides a rapid alternative or could complement next generation sequencing, which typically requires up to 14 days of off-site analysis.

At present, if SARS-CoV-2 variants are considered to have 'concerning' properties, including causing higher infection rate, reduced vaccine efficacy or resistance to antibody treatment, they are raised for formal investigation and classified as a variant under investigation (VUI).² Following a risk assessment with the relevant expert committee, such as the World Health Organization, a VUI may be designated as a VOC. Due to the concerning properties, Novacyt recognises the importance and need to closely monitor VOC and significant mutations. Therefore, VariPLEX™ is a fully customisable assay panel and new mutations can be added to the panel within weeks as and when they become relevant.

Concurrently, Novacyt is also making a research use only (RUO) version of VariPLEX™ available for epidemiological application and will be pursuing emergency use authorisations in a number of countries.

Graham Mullis, Chief Executive Officer of Novacyt, commented:

"This is an important step in our response to COVID-19. As we reach a point where vaccination efforts are increasing globally, we are also seeing a worrying rise in the number of variants of the virus, all of which bring subtly different challenges to healthcare systems around the world. With VariPLEX™, we are offering an affordable, scalable and time efficient alternative to next generation sequencing which allows for reliable testing of key variants in a single test. By providing an on-site solution which reads out in less than two hours, we are ensuring that it is possible to track variants and the infections they cause on a global scale."

- End -

Contacts

Novacyt SA

Graham Mullis, 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

FTI Consulting (International)

Victoria Foster Mitchell / Alex Shaw / Mary Whittow

+44 (0)20 3727 1000

[victoria.fostermitchell@fticonsulting.com](mailto: victoria.fostermitchell@fticonsulting.com) / [Alex.Shaw@fticonsulting.com](mailto: Alex.Shaw@fticonsulting.com) / [mary.whittow@fticonsulting.com](mailto: mary.whittow@fticonsulting.com) / [Novacyt.group@fticonsulting.com](mailto: 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

About N501Y and E484K mutations

The N501Y mutation is important as it leads to an increase in ACE2 binding and therefore to increased infectivity.³ This mutation has been seen in the UK, South African, and Brazilian variants and has been correlated in epidemiological studies to increase infectivity by approximately 70% and could potentially lead to an increase in mortality.⁴⁻⁸ The E484K mutation is seen in all current VOC and is called an escape mutation because it helps the virus slip past the body's immune defences to evade host antibodies and may, as a result, diminish the efficacy of immunisation.^{4-7,9-12}

SNPsig® portfolio

The table below contains details on Novacyt's SNPsig® portfolio of products, which have been launched to date or are due to launch imminently. Novacyt's bioinformatics surveillance group remains highly vigilant and, as significant new mutations are identified, these will be added to the SNPsig® portfolio.

Product names	Detection profile	Format	Product code
---------------	-------------------	--------	--------------

SNPsig® VariPLEX™ SARS-CoV-2#	20I/501Y.V1, 20H/501Y.V2, 20J/501Y.V3, 20C/S.452R, N501Y, E484K	CE-IVD, RUO	D00060 R00137
SNPsig® SARS-CoV-2 PLUS (20I/501Y.V1)#	20I/501Y.V1 and E484K	CE-IVD	D00066
SNPsig® SARS-CoV-2 (20I/501Y.V1)	20I/501Y.V1		R00130
SNPsig® SARS-CoV-2 (20H/501Y.V2)	20H/501Y.V2		R00135
SNPsig® SARS-CoV-2 (20J/501Y.V3)	20J/501Y.V3		R00134
SNPsig® SARS-CoV-2 (20B/S.484K)*	20B/S.484K	RUO	R00147
SNPsig® SARS-CoV-2 (N501Y)	Variants with the N501Y mutation (20I/501Y.V1, 20H/501Y.V2, 20J/501Y.V3)		R00131
SNPsig® SARS-CoV-2 (E484K)	Variants with the E484K mutation (20I/501Y.V1, 20H/501Y.V2, 20J/501Y.V3, 20C/S.452R)		R00132

#Will be launched w/c 22 March 2021

*Will be launched w/c 29 March 2021

References:

1. World Health Organization. COVID-19 Weekly Epidemiological Update. World Health Organization 1-3. Available from: <https://www.who.int/publications/m/item/weekly-epidemiological-update--16-march-2021> (2021).
2. World Health Organization. Weekly epidemiological update - 25 February 2021. World Health Organization 1-3 Available from: <https://www.who.int/publications/m/item/covid-19-weekly-epidemiological-update> (2021).
3. Starr TN, Greaney AJ, Hilton SK, Ellis D, Crawford KHD, Dingens AS, et al. Deep Mutational Scanning of SARS-CoV-2 Receptor Binding Domain Reveals Constraints on Folding and ACE2 Binding. Cell [Internet]. 2020;182(5):1295-1310.e20. Available from: <http://dx.doi.org/10.1016/j.cell.2020.08.012>
4. Wang Z, Schmidt F, Weisblum Y, Muecksch F, Finkin S, Schaefer-Babajew D, et al. mRNA vaccine-elicited antibodies to SARS-CoV-2 and circulating variants 2 3. bioRxiv [Internet]. 2021 [cited 2021 Jan 25]; Available from: <https://doi.org/10.1101/2021.01.15.426911>
5. Novavax Inc. - IR Site. Novavax COVID-19 Vaccine Demonstrates 89.3% Efficacy in UK Phase 3 Trial [Internet]. [cited 2021 Feb 1]. Available from:

<https://ir.novavax.com/news-releases/news-release-details/novavax-covid-19-vaccine-demonstrates-893-efficacy-uk-phase-3>

6. Johnson | Johnson & Johnson. Johnson & Johnson Announces Single-Shot Janssen COVID-19 Vaccine Candidate Met Primary Endpoints in Interim Analysis of its Phase 3 ENSEMBLE Trial [Internet]. [cited 2021 Feb 1]. Available from:

<https://www.jnj.com/johnson-johnson-announces-single-shot-janssen-covid-19-vaccine-candidate-met-primary-end-points-in-interim-analysis-of-its-phase-3-ensemble-trial>

7. Andreano E, Piccini G, Licastro D, Casalino L, Johnson N V, Paciello I, et al. SARS-CoV-2 escape in vitro from a highly neutralizing COVID-19 convalescent plasma. bioRxiv [Internet]. 2020;2020.12.28.424451. Available from: <http://biorxiv.org/content/early/2020/12/28/2020.12.28.424451.abstract>

8. Horby, A. P. et al. NERVTAG - Presented to SAGE on 21/1/21.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/961037/NERVTAG_note_on_B.1.1.7_severity_for_SAGE_77__1_.pdf (2021)

9. Greaney AJ, Loes AN, Crawford KH, Starr TN, Malone KD, Chu HY, et al. Comprehensive mapping of mutations to the SARS-CoV-2 receptor-binding domain that affect recognition by polyclonal human serum antibodies. [cited 2021 Jan 19]; Available from: <https://doi.org/10.1101/2020.12.31.425021>

10. Cele S, Gazy I, Jackson L, Hwa S-H, Tegally H, Lustig G, et al. Escape of SARS-CoV-2 501Y.V2 variants from neutralization by convalescent plasma. medRxiv [Internet]. 2021 [cited 2021 Jan 25];1-19. Available from: <https://www.medrxiv.org/content/10.1101/2021.01.26.21250224v1>

11. COG-UK. COG-UK report on SARS-CoV-2 Spike mutations of interest in the UK [Internet]. Vol. 1. 2021. Available from: https://cov-lineages.org/global_report.html

12. Wu K, Werner AP, Moliva JI, Koch M, Choi A, Stewart-Jones GBE, et al. mRNA-1273 vaccine induces neutralizing antibodies against spike mutants from global SARS-CoV-2 variants. bioRxiv [Internet]. 2021 [cited 2021 Jan 29]; Available from: <https://doi.org/10.1101/2021.01.25.427948>

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 or visit 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

MSCFFFVFFVIVFIL