

15<sup>th</sup> December 2021

### Omicron Variant Update: Novacyt Group Assay Performance

At Novacyt Group, we pride ourselves on the scientific rigour we apply to all aspects of product design. As the COVID-19 pandemic continues to develop, ongoing analysis becomes increasingly crucial. Our state-of-the-art SARS-CoV-2 genomic surveillance programme allows us to monitor the virus closely as it spreads and mutates. We are pleased to report the latest findings for our solutions:

- 1. SNPsig<sup>®</sup> SARS-CoV-2 EscapePLEX** screens for 4 mutations: K417T, K417N, E484K and P681R. The mutation information provided by EscapePLEX<sup>™</sup> can be used to screen SARS-CoV-2 positive samples for presence of the Omicron variant with >98% confidence; this includes the recently identified BA.1 and BA.2 sub-lineages. We are therefore confident that EscapePLEX<sup>™</sup> can serve as an effective healthcare tool to facilitate the real time management of the Omicron variant's population spread, including supporting the research efforts investigating the potential for immune escape. That confidence is maintained even with the emergence of the BA.1 and BA.2 sub-lineages of Omicron.
- 2. PathFlow<sup>®</sup> COVID-19 Rapid Antigen Pro** targets the nucleocapsid protein (NP) of the SARS-CoV-2 virus. It therefore avoids the problematic spike (S) protein region. This is important because Omicron has more mutations than other variants, including more than 30 mutations in the Spike gene. Based on our analyses, we can report that the regions targeted by our product are not affected by the mutations associated with Omicron (BA.1 & BA.2), and other Variants of Concern (VoC).
- 3. Novacyt's other main qPCR assays** intended for primary SARS-CoV-2 testing, are unaffected by the emergence of the Omicron variant as communicated on the 1<sup>st</sup> December 2021. Additionally, these assays are similarly unaffected by the mutations associated with the BA.2 Omicron sub-lineage. Our 1-gene PCR test targets a highly conserved region within Orf1ab. The S-gene design (included in genesig<sup>®</sup> SARS-CoV-2 Winterplex and genesig<sup>®</sup> COVID-19 2G) avoids the problematic 69/70 deletion associated with the Omicron BA.1 variant and responsible for the S-gene target failure phenomenon observed with other qPCR assays.

Please refer to Appendix 1 for the updated list of our assays that are unaffected by the Omicron variant. Kindly contact your dedicated Novacyt sales personnel or us at [enquiries@primerdesign.co.uk](mailto:enquiries@primerdesign.co.uk) should you need more information.



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**Appendix 1- Novacyt's Assays That are Unaffected by the Omicron Variant**

No	Product Name	Detection Profile	Product Code
1	SNPsig® EscapePLEX (SARS-CoV-2)	E484K, K417N, K417T and P681R mutations (which are found in Beta, Gamma, Delta and Delta Plus Variants of Concern) as well as two SARS-CoV-2 targets (ORF 1ab and M gene) to confirm positivity <b><i>Suitable to be used to detect the Omicron variant as EscapePLEX™ will produce a K417N-positive, E484K-negative, K-417T-negative and P681R-negative mutation profile in the presence of the Omicron variant.</i></b>	CE IVD – D00152 RUO – R00152
2	genesig® SARS-CoV-2 Winterplex	SARS-CoV-2 (ORF1ab, S and M gene targets), Influenza A & B, RSV A&B	D00020
3	genesig® COVID-19	ORF1ab	Z-Path- COVID-19-CE
3	genesig® COVID-19 (US Only)		Z-COVID-19 (US ONLY)
4	genesig® COVID-19 2G	ORF1ab and S gene targets	D00011
5	genesig® COVID-19 3G	ORF1ab, M gene and S gene targets	D00063
6	genesig® COVID-19 3G HT		D00062
7	genesig® Real-time PCR detection kit for 2019-nCoV	ORF1ab	Z-Path-2019- nCoV
8	genesig® Standard Real-time PCR detection kit for 2019-nCoV		Z-Path-2019- nCoV-std
9	genesig® Easy kit for 2019-nCoV		Z-Path-2019- nCoV-EASY
10	PROMate® COVID-19 (q16)		D00068
11	PROMate® COVID-19 (q32)		D00070
12	PROMate® COVID-19 (q32) 2G	Two targets within ORF1ab	D00074
13	Exsig® COVID-19 Direct	OFR1ab	Z-Exsig COVID-19 Direct
14	PathFlow® COVID-19 Rapid Antigen Pro	SARS-CoV-2 IgG antigen	M600CE