

To whom it may concern,

1<sup>st</sup> December 2021

**Update on Novacyt's qPCR assays against the Omicron variant**

Novacyt prides itself on its highly scientific approach to our product design.

Our 1 gene PCR test designed to detect COVID 19, targets a region within Orf1ab which remains unaffected by the currently published Omicron mutations.


In addition, our 2 gene and 3 gene genesig® products add S & M gene targets which are also unaffected by the published Omicron mutations.

- COVID-19 = Target within Orf1ab
- COVID-19 2G = Target within Orf1ab & S-gene
- COVID-19 3G = Target within Orf1ab, S-gene & M-gene

The S-gene design, present in our COVID-19 products, avoids the problematic 69/70 deletion responsible for the S-gene target failure.

Therefore, based on the currently available analysis of the sequences, as of 29th November 2021, we are confident that the performance of all Novacyt products, intended for primary SARS-CoV-2 testing, are unaffected by the emergence of the Omicron variant.

Please refer to Appendix 1 for the full 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.



Navin Nauth-Misir  
Group RA QA Director  
[navin.nauth-misir@novacyt.com](mailto:navin.nauth-misir@novacyt.com)

UK Company Reg: 5228545

**PrimerDesign Ltd**

[www.primerdesign.co.uk](http://www.primerdesign.co.uk)

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

No	Product Name	Detection Profile	Product Code
1	genesig® SARS-CoV-2 Winterplex	SARS-CoV-2 (ORF1ab, S and M gene targets), Influenza A & B, RSV A&B	D00020
2	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	ORF1ab	Z-Exsig COVID-19 Direct
14	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	CE IVD – D00152 RUO-R00152

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