

# genesig® COVID-19 2G Real-Time PCR assay

The genesig® Real Time PCR COVID-19 2G assay is a CE marked, in vitro diagnostic, real-time, reverse transcriptase PCR (RT-PCR) multiplex assay intended for the qualitative detection of nucleic acid from SARS-CoV-2 (ORF1ab and S gene targets) in nasopharyngeal swabs, oropharyngeal swabs and sputum specimens.



## PRIMER DESIGN

This multiplex assay provides rapid screening of individuals suspected of SARS-CoV-2 and aids the diagnosis of suspected disease in patients. The assay has been designed to be used with Real Time PCR instruments capable of simultaneously detecting FAM and Cy5 fluorophores (for the SARS-CoV-2 targets) along with VIC/HEX for IEC detection.



### Product Features

- For the detection of two SARS-CoV-2 targets (ORF1ab and S gene targets)
- High priming efficiency
- Accurate controls to confirm extraction and assay validity
- Lyophilised components for ambient shipping
- 96 Reactions
- Results in under 2 hours
- Can be used to detect SARS-CoV-2 Variants of Concern (B.1.1.7 - Alpha, B.1.351 - Beta, B.1.1.28.1/P1 - Gamma, and B.1.617 - Delta/Delta Plus)

### Surveillance Programme

Surveillance programs have proved to be an indispensable tool to track how the virus mutates. With any virus, you want to have complete visibility on all variants to avoid a situation where positive cases are being missed. Sequencing technology is so much more widely accessible today than it ever has been before. This has provided the team with the opportunity to closely monitor the progression of the virus around the globe and align sequences of any new variants with our COVID-19 products to ensure complete coverage. The bioinformaticians (data scientists) here at Novacyt are aware of multiple variants, known for its substantially increased transmissibility, and continue to closely monitor new sequence data to ensure our tests continue to provide laboratories with confidence in their results.

## The Design behind the Product

Every day, our expert bioinformaticians analyse sequences from Coronavirus COVID-19 ORF1ab and S gene regions to ensure 100% detection is maintained. Each new sequence represents a potential risk of false negatives for competitors without surveillance programs. As of the 05<sup>th</sup> February 2021 our multiple target assays that include ORF1ab and S gene on genesig® COVID-19 2G (CE IVD) show 100% detection with all good quality SARS-CoV-2 sequences published on the GISAID EpiCoV database.



Assay Target	Number of Sequences Analysed	Detection Level
ORF1ab	334,213	100%
S gene	334,386	100%

**“ORF1ab is a highly conserved region of the SARS genome, so we knew this would be the same for SARS-CoV-2. Following analysis of a large number of sequences, a specific region was selected from the S gene which showed very low variation compared with the reference genome sequence.”**

### Lyophilised Components

The OneStep Lyophilised Master Mix, the primers and probes mix, COVID-19 2G positive control template and genesig® RNA IEC are all provided lyophilised so the kit does not require dry ice shipping.

Validated for use with:

- Nasopharyngeal Swabs
- Oropharyngeal Swabs
- Sputum

### Ordering Information

**Product:** genesig® COVID-19 2G  
**Real-Time PCR assay**  
**Catalogue no:** D00011  
**Kit Size:** x96 tests

