

### **Test principle of the RIDA® GENE SARS-CoV-2 Lineage RUO**

RIDA® GENE SARS-CoV-2 Lineage RUO is a multiplex real-time RT-PCR for the detection of SARS-CoV-2 mutations ((single) nucleotide polymorphisms).

Detection is done in a one-step real-time RT-PCR format: reverse transcription (RT) and subsequent PCR take place in one reaction vial. In the process, the isolated RNA is transcribed into cDNA with the help of a reverse transcriptase. Next, real-time PCR is used to amplify the specific gene fragments for the virus variants **B.1.1.7** (N gene D3L, NSP6 106/107/108del), **B.1.351** & **B.1.1.28 P.1** (NSP6 106/107/108del) and the wild-type reference (N gene, NSP6) (NCBI database). The amplified target sequences are detected using hydrolysis probes that are labeled with a quencher at one end and a fluorescent reporter dye (fluorophore) at the other. The probes hybridize to the amplicon in the presence of a target sequence. During extension, Taq-Polymerase separates the reporter from the quencher. The reporter emits a fluorescent signal that is detected by the optical unit of a real-time PCR device. The fluorescent signal increases with the quantity of formed amplicons.

### **Test principle of the Clonit COVID-19 Variant Catcher CE IVD**

COVID-19 Variant Catcher is a qualitative test that allows the identification, by means of Real Time PCR, of the S gene mutations HV 69-70del, E484K and N501Y for discrimination of SARS-CoV-2 (Wuhan strain) from SARS-CoV-2 strains **B.1.1.7 (UK variant)**, strains **B.1.351 (South African variant)** and strains **P.1 (Brazilian variant)**.

The COVID-19 Variant Catcher kit must be used with a RNA extracted from samples tested as positive for SARS-CoV-2 virus with the current validated methods on the market.

The Procedure allows the detection of the RNA target by means of a reverse-amplification reaction in reaction tubes or microplate wells.

The analysis of the results is performed by means of a Real Time PCR analyzer instrument (thermal cycler integrated with a system for fluorescence detection).