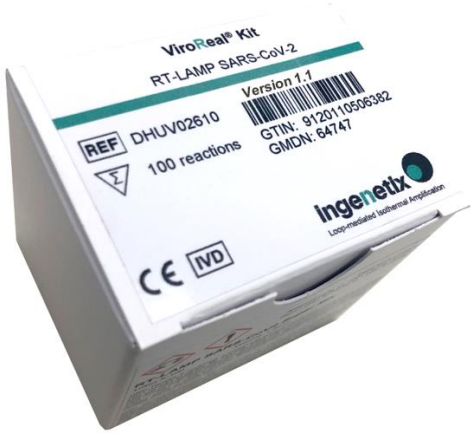
ViroReal® Kit RT-LAMP SARS-CoV-2 (Version 1.1)



CE IVD

ViroReal® Kit RT-LAMP SARS-CoV-2		
Order no.	**Reactions**	**Pathogen**
DHUV02610	100	SYBR Green / FAM channel
DHUV02610x5	500	SYBR Green / FAM channel

Kit contents:

- RT-LAMP SARS-CoV-2 Super Mix containing a pH indicator dye, Triton X-100 and an intercalating fluorescent dye
- RT-LAMP SARS-CoV-2 Primer Mix containing primers for virus RNA detection (ORF1ab region of SARS-CoV-2)
- RT-LAMP RNA/DNA reaction mix for one-step reverse transcription LAMP PCR with a reverse transcriptase and a strand displacing DNA polymerase
- RNA Positive control for SARS-CoV-2
- Nuclease-free water

Pathogen information: Coronaviruses are positive single-stranded RNA viruses of the family *Coronaviridae*. Several different strains of coronaviruses are currently known to infect humans (HCoV-229E, HCoV-NL63, HCoV-OC43, HCoV-HKU1, MERS-CoV, SARS-CoV, SARS-CoV-2, NCoV and HCoV-EMC). Strains HCoV-229E, HCoV-NL63, HCoV-OC43, MERS-CoV and HCoV-HKU1 cause cold, upper respiratory infection, bronchiolitis and pneumonia in humans. SARS-CoV, a beta coronavirus, causes the Severe Acute Respiratory Syndrome (SARS).
SARS-CoV-2 is a beta coronavirus that emerged in Wuhan, China in December 2019. The virus is responsible for the disease COVID-19 (corona virus disease 2019). Fever, cough and breathing difficulties are described as the most frequent initial symptoms, later on it can lead to pneumonia. The main route of SARS-CoV-2 transmission is via respiratory uptake of virus particles (droplets or smaller aerosols).

Test Description: ViroReal® Kit RT-LAMP SARS-CoV-2 is an *in vitro* diagnostic test for the detection of RNA of SARS-CoV-2 in patients with or without a suspected SARS-CoV infection. The test is based on one-step RT-LAMP technology (reverse transcription loop-mediated isothermal DNA amplification) and detects RNA of a part of the ORF1ab region of SARS-CoV-2. The test takes between 30-53 minutes, depending on the (real-time) PCR device used.
The test is suitable for the detection of SARS-CoV-2 of persons who are in an infectious stage. Samples with an RNA concentration of approximately 20,000 copies per ml or more (equivalent to approximately 100 copies per RT-LAMP reaction, which corresponds to a real-time PCR Cq value of approx. 31) can be reliably detected with a sensitivity of 95% and a specificity of 99%.
The results of ViroReal® Kit RT-LAMP SARS-CoV-2 represent a snapshot of the infection status of the tested person and should not be used as the sole basis for patient management decisions. Persons with a positive or questionably positive test result should be retested by real-time PCR (gold standard).

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For oropharyngeal swabs in isotonic saline solution (NaCl 0.9%) there is no need for RNA extraction, because virus inactivation and lysis occur during the isothermal amplification step. Other native specimens or transport media are not suitable. It is however possible to also use extracted RNA. In this case, proper specimens are samples from the upper respiratory tract (throat rinsing fluid, nasopharyngeal and oropharyngeal swabs, nasopharyngeal wash/aspirate and nasal aspirates).

Sensitivity and specificity: The detection limit (LoD95: number of copies, which are positively detected in 95% of cases) is 100 copies/reaction (20,000 copies per ml). The test is specific for SARS-CoV-2.

PCR-platforms: This test is compatible with real-time PCR instruments detecting fluorescence in SYBR Green / FAM channel and with conventional block-PCR instruments. The use of a real-time PCR instrument is recommended. ViroReal® Kit RT-LAMP SARS-CoV-2 has been validated with the Applied Biosystems® (ABI) 7500 instrument (Thermo Fisher Scientific), Mx3005P® (Agilent), MIC instrument (bio molecular systems) and GeneAmp® PCR System 9700 (Thermo Fisher Scientific).

The generated DNA amplicon is be detected by means of the intercalating fluorescent dye via amplification curves and melting curves when using a real-time PCR instrument. After amplification, a visual check of the reaction tubes can be performed (colorimetric detection of amplification by change of color from red to yellow, based on the pH indicator dye used in the LAMP reaction). The drop in pH value is due to the large amount of generated DNA.

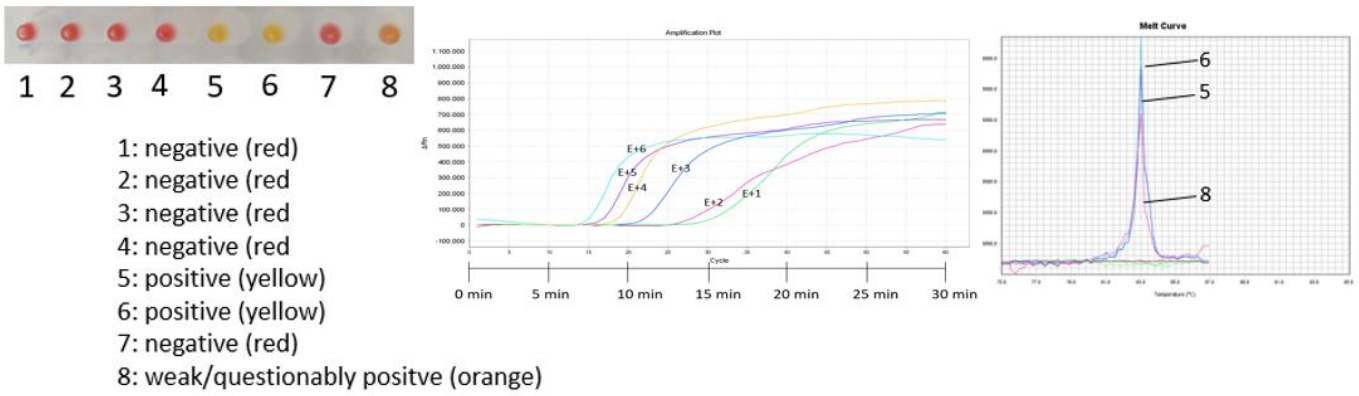

Figure 1 Visual endpoint control of the color change in the reaction tube. In a real-time PCR instrument, the amplification and melting curves are recorded in the fluorescence channel for SYBR Green / FAM.

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