SARS-CoV-2 Testing

One step real-time reverse transcription PCR (RT-PCR) assay for highly sensitive detection of SARS-CoV-2

Gold standard RT-PCR for rapid and sensitive SARS-CoV-2 identification

SARS-CoV-2 is a positive sense, single stranded RNA respiratory virus that emerged in late 2019. Within two months, it spread globally, and coronavirus disease 2019 (COVID-19) was declared a pandemic by the WHO in March 2020.

Although several countries have temporarily reduced the number of daily new cases, robust diagnostic tools facilitating the efficient control of new outbreaks are highly demanded. Quick and sensitive testing by using real-time reverse transcription PCR technology remains the gold standard to test for current infections.

Importantly, asymptomatic persons seem to account for approximately 40% - 45% of SARS-CoV-2 infections.[1]
Due to this silent spread, it is essential to test also individuals without clinical or subclinical symptoms who suspectedly have been exposed to SARS-CoV-2, in order to control the pandemic locally, regionally and globally.

The ViennaLab **SARS-CoV-2 RealFast™ Assay** allows for highly sensitive detection of two viral target genes (*N* and *RdRP/ORF1ab)*, specific to SARS-CoV-2, in a one-tube reaction.

Key Features

• Multiplex one-tube reaction assay (human *ACTB* gene-detecting control included)
• Two separate virus specific target genes: *N* and *RdRP/ORF1ab*
• High sensitivity (LoD: 10 copies per reaction)
• Successfully passed external quality assessment schemes
• Compatibility with a wide range of real-time PCR instruments   CE IVD

Order Information: SARS-CoV-2 RealFast™ Assay: 8-410/8-412 (100/500 reactions)

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In March 2020, the WHO stated in an interim guidance paper that the routine confirmation of cases of COVID-19 shall be based on detection of unique sequences of virus RNA (*N*, *RdRP*, *S*, and *E* genes) by real-time reverse transcription PCR.[2] An integrated control assay for the human *ACTB* gene simultaneously monitors the performance of nucleic acid extraction and RT-PCR step.

References:
[1] Oran D.P., Topol E.J. Prevalence of Asymptomatic SARS-CoV-2 Infection: A Narrative Review. Ann Intern Med. 2020;M20-3012.
[2] World Health Organization (2020). Laboratory testing for coronavirus disease (COVID-19) in suspected human cases: interim guidance, 19 March 2020. World Health Organization.

SARS-CoV-2 RealFast™ Assay: Interpretation of results

The one-tube test includes a reverse transcription step followed by three simultaneous TaqMan® fluorogenic 5' nuclease assay reactions.
(A) In SARS-CoV-2 positive clinical samples, the virus-specific assays generate fluorescence signals in the FAM (blue curve) and HEX (green curve) channels. Due to the common presence of human RNA in the extracted specimen, a signal in the Cy5 channel (red curve) is also expected to emerge. (B) In negative samples, the human *ACTB* gene-specific assay generates a fluorescence signal in the Cy5 channel while no or only a baseline signal can be observed in the FAM and HEX channels.
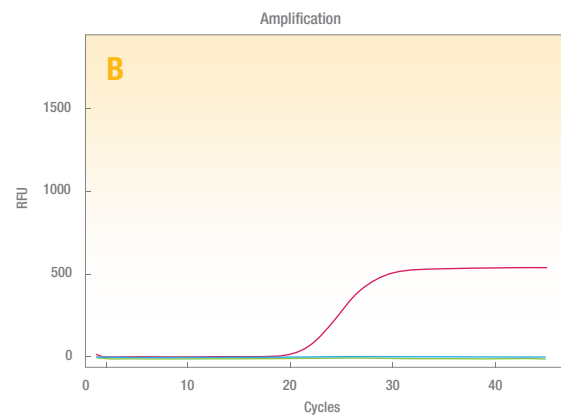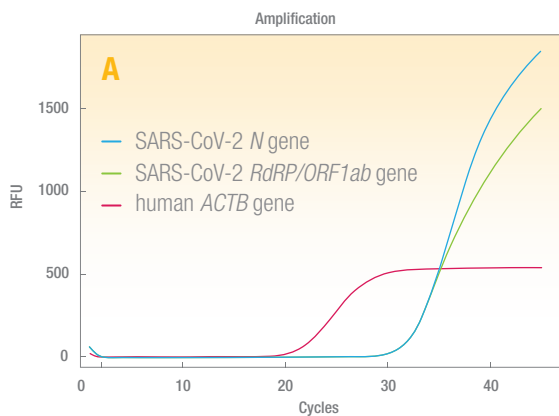
Amplification plots of the SARS-CoV-2 RealFast™ Assay. Fluorescent levels and corresponding amplification curves are automatically displayed in the real-time PCR software. Amplification curves correspond to the various assay targets as depicted in the inset legend. SARS-CoV-2 *N* gene (blue curve; FAM channel); SARS-CoV-2 *RdRP/ORF1ab* gene (green curve; HEX channel); human *ACTB* gene (red curve; Cy5 channel) **A.** Human swab sample positive for the targeted SARS-CoV-2 sequences. **B.** Human swab sample negative for the targeted SARS-CoV-2 sequences.

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