ViroReal® Kit SARS-CoV-2 Multiplex

CE IVD

ViroReal® Kit SARS-CoV-2 Multiplex			
Order no.	**Reactions**	**Pathogen**	**Internal positive control**
DHUV02413	100	FAM+VIC channel	Cy5 channel
DHUV02413x5	500	FAM+VIC channel	Cy5 channel

Kit contents:

- Detection assay for the N gene of SARS-CoV-2 and Sarbecovirus, for the RdRp gene of SARS-CoV-2 and for the RNA IPC
- Target for RNA internal positive control (RNA IPC, control of RT-PCR amplification and/or RNA extraction)
- RNA reaction mix for one-step reverse transcription real-time PCR (contains a thermostable MMLV Reverse Transcriptase, a RNase inhibitor, a highly purified Taq Polymerase for rapid hot-start PCR, dNTPs, ROX™ dye (passive reference) and buffer components – additives optimized to handle RT-PCR inhibitors)
- 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 coronavirus spreads mainly by droplet and contact transmission. In most cases a mild course of infection is observed, while more severe courses are observed in about 15%-20%, with a mortality rate of up to 3%.

Description: ViroReal® Kit SARS-CoV-2 Multiplex is an *in vitro* diagnostic test, based on one-step reverse transcription real-time PCR, for the detection of the N gene of SARS-CoV-2, SARS-CoV and SARS-related coronavirus (Sarbecovirus) and of the RdRp gene of SARS-CoV-2 in patients with or without a suspected SARS-CoV infection. Proper specimens are samples from the upper and lower respiratory tract (throat rinsing fluid, nasopharyngeal and oropharyngeal swabs, anterior nasal swab and mid-turbinate nasal swab specimens, nasopharyngeal wash/aspirate and nasal aspirates, sputa and BAL). The multiplex approach allows universal detection of all so far known SARS coronavirus strains (Sarbecovirus) including SARS-CoV-2, and the discrimination between SARS-CoV-2 and the other Sarbecovirus strains.

PCR-platforms: ViroReal® Kit SARS-CoV-2 Multiplex has been validated with the ABI® 7500 instrument (Thermo Fisher Scientific), qTOWER^{3}G (Analytik Jena), MIC instrument (bio molecular systems) and Mx3005P® QPCR System (Agilent), but is also compatible with other real-time PCR instruments detecting and differentiating fluorescence in FAM, VIC and Cy5 channel.

Sensitivity and specificity: The detection limit (LoD95: number of copies, which are positively detected in 95% of cases) is 13 copies/reaction for the N gene and 6 copies/reaction for the RdRp gene. ViroReal® Kit SARS-CoV-2 Multiplex is specific for SARS-CoV-2 as well as SARS-CoV and SARS-like coronavirus (Sarbecovirus).

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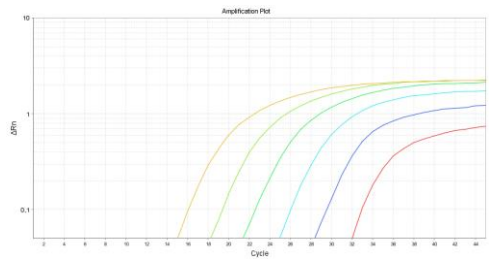
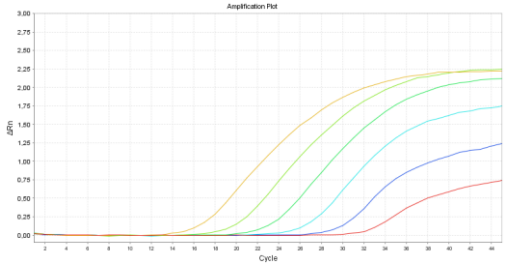
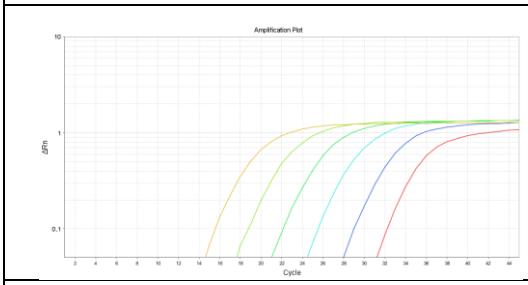
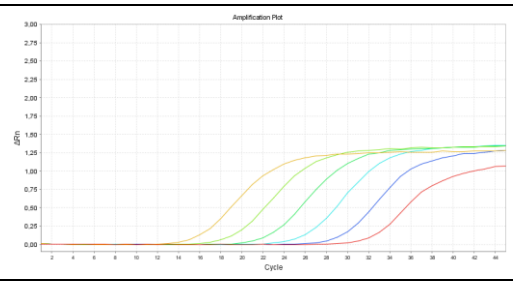
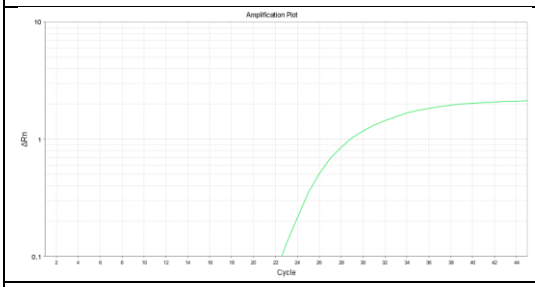
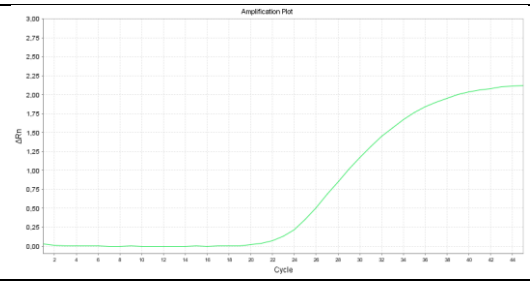
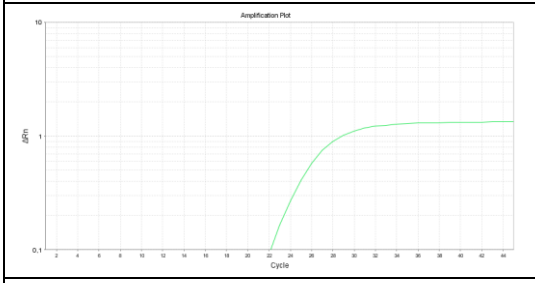
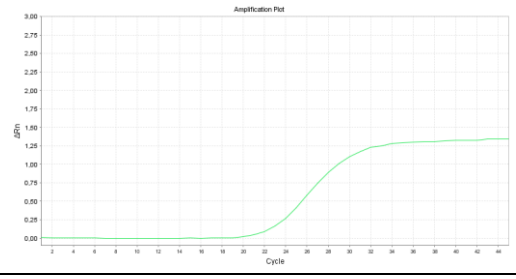
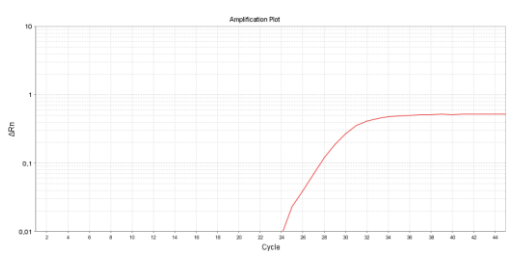
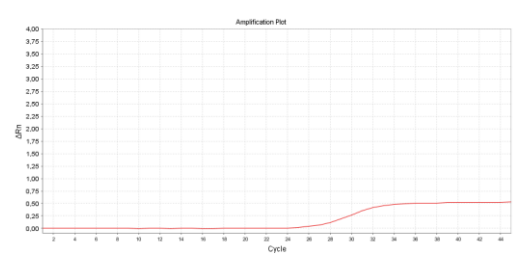
Logarithmic view	Linear view
	
FAM channel, 1:10 serial dilution of a SARS-CoV-2 RNA target (N gene)	
	
VIC channel, 1:10 serial dilution of a SARS-CoV-2 RNA target (RdRp gene)	
	
FAM channel, SARS-CoV-2 RNA positive control (N gene)	
	
VIC channel, SARS-CoV-2 RNA positive control (RdRp gene)	
	
Cy5 channel, Internal RNA positive control	

Figure 1: Performance of ViroReal® Kit SARS-CoV-2 Multiplex

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