ViroReal® Kit SARS-CoV-2 & SARS

Kit version 1.2

For *in vitro* diagnostic use only

ViroReal® Kit SARS-CoV-2 & SARS			
Order no.	**Reactions**	**Pathogen**	**Internal positive control**
DHUV02313	100	FAM channel	Cy5 channel
DHUV02313x5	500	FAM channel	Cy5 channel
DHUV02313x50	5000	FAM channel	Cy5 channel

Kit contents:

- Assay for detection of SARS-CoV-2 / SARS-CoV and of internal RNA positive control (IPC)
- IPC-Target RNA (control of RNA extraction and of RT PCR amplification)
- 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, a beta corona virus, causes COVID-19 (corona virus disease 2019). Fever, cough, and breathing difficulties are described as the most common initial symptoms, and infection can subsequently lead to pneumonia. The coronavirus spreads mainly by droplet and contact transmission.

Intended purpose: ViroReal® Kit SARS-CoV-2 & SARS is a non-automated CE-certified IVD test, based on one-step reverse transcription real-time PCR (RT-PCR), for the qualitative detection of RNA of the N gene of SARS-CoV-2, SARS-CoV and SARS-related coronavirus (Sarbecovirus).
Proper specimens are RNA extracts of samples from the human respiratory tract (throat rinsing fluid, nasopharyngeal and oropharyngeal swabs, anterior nasal swab and mid-turbinate nasal swab specimens, nasopharyngeal wash/aspirate and nasal aspirates).
This test is suitable for patients of all ages with or without a suspected SARS-CoV-2 or SARS coronavirus infection and is intended as an aid in the diagnosis of such infections in combination with patient history and additional clinical information. The test is intended for professional use and is limited to qualified personnel instructed in the procedures of real-time PCR and *in vitro* diagnostic procedures.
A probe-specific amplification-curve in the FAM channel indicates the amplification of virus-specific RNA. The internal RNA positive control (IPC) is detected in Cy5 channel and serves as a control for RNA extraction and possible RT-PCR inhibition. The target for the RNA IPC (artificial target RNA) is added during sample extraction.

PCR-platforms: ViroReal® Kit SARS-CoV-2 & SARS was validated with the ABI® 7500 Fast Real-Time PCR System (fast cycle parameters are not supported, Thermo Fisher Scientific), and was also tested with Mx3005P® (Agilent), qTOWER^{3}G (Analytik Jena), MIC instrument (bio molecular systems), LightCycler® 480 I (Roche) and cobas Z 480 Analyzer (Roche). It

is also compatible with other real-time PCR instruments which detect and differentiate fluorescence in FAM, and Cy5 channel (eg., QuantStudio™ 5 / 6 / 7 (Thermo Fisher Scientific)).

Performance data: At least 1 target copies/reaction can be detected. The LoD95% (smallest number of copies of target RNA which can be detected in 95% of cases) is 893 target copies/ml sputum, which corresponds to approx. 21 target copies/PCR reaction.
ViroReal® Kit SARS-CoV-2 & SARS is specific for SARS-CoV-2 as well as SARS-CoV and SARS-like coronavirus. Other beta coronaviruses are not detected with this kit. Clinical validation was performed with clinical samples.

Results of clinical validation:

	Value	95% CI
Sensitivity	100 %	79.41% to 100.00%
Specificity	100 %	95.38% to 100.00%
NPV	100 %	100 %
PPV	100 %	100 %
Prevalence	17.02 %	10.05% to 26.16%

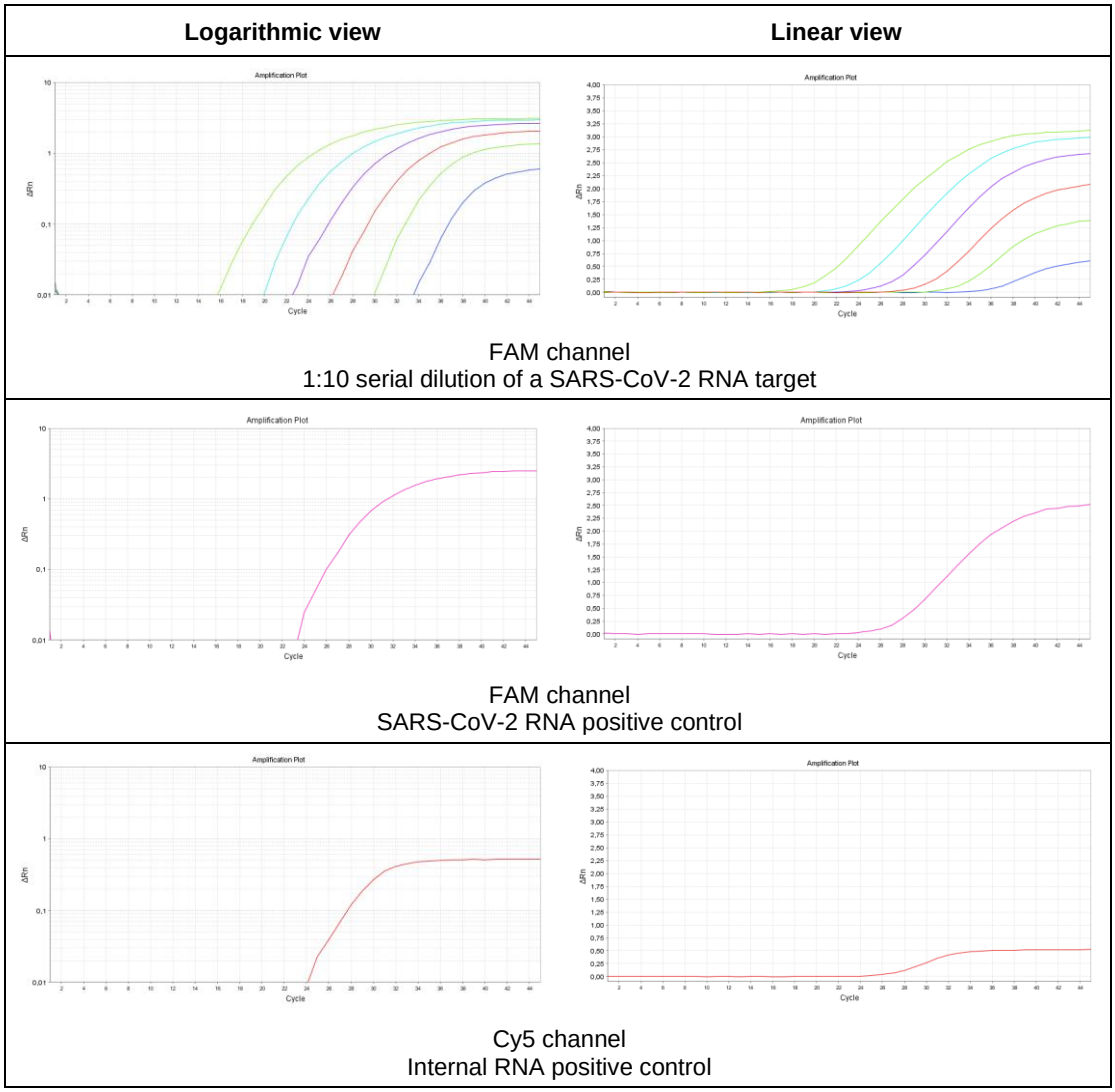

Figure 1: Performance of ViroReal® Kit SARS-CoV-2 & SARS