IVD

## ViroReal<sup>®</sup> Kit SARS Coronavirus & Influenza A/B



ViroReal <sup>®</sup> Kit SARS Coronavirus & Influenza A/B			
Order no.	Reactions	Pathogen	Internal positive control
DHUV02513	100	FAM+VIC channel	Cy5 channel
DHUV0253x5	500	FAM+VIC channel	Cy5 channel



## Kit contents:

- Detection assay for the N gene of SARS-CoV-2 and Sarbecovirus (FAM), for the matix protein gene of influenza A virus (VIC), for the hemagglutinin gene of influenza B virus (VIC) and for the RNA IPC (Cy5)
- 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<sup>™</sup> dye (passive reference) and buffer components – additives optimized to handle RT-PCR inhibitors)
- RNA positive control for SARS-CoV-2 and influenza A virus
- 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). 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. 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%.

Influenza is an acute infectious disease caused by influenza virus A, B or, to a much lesser extent, influenza virus C. Influenza viruses are enveloped viruses with single-stranded, segmented RNA with negative polarity as genome. These viruses can be found worldwide. Epidemics and pandemics are mainly caused by influenza virus A, due to antigenic drift of the hemagglutinin and neuraminidase molecules. Type B and C influenza viruses are isolated almost exclusively from humans, while influenza A viruses infect a wide variety of warm-blooded animals.

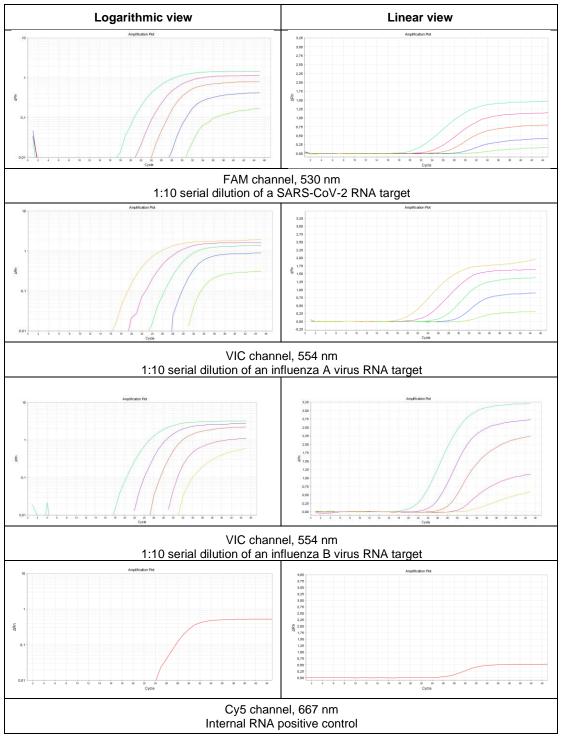
**Description:** ViroReal<sup>®</sup> Kit SARS Coronavirus & Influenza A/B is an *in vitro* diagnostic test, based on multiplex one-step reverse transcription real-time PCR, for the detection of the N gene of SARS-CoV-2, SARS-CoV and SARS-related coronavirus (Sarbecovirus), of the matix protein gene of influenza A virus (VIC) and of the hemagglutinin gene of influenza B virus of patients with or without a suspected SARS-CoV or influenza 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).

**PCR-platforms:** ViroReal<sup>®</sup> Kit SARS Coronavirus & Influenza A/B has been validated with the ABI<sup>®</sup> 7500 instrument (Thermo Fisher Scientific), LightCycler<sup>®</sup> 480 II (Roche), MIC instrument (bio molecular systems) and Mx3005P<sup>®</sup> QPCR System (Agilent), but is 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 12 copies/reaction for SARS-CoV-2, 15 copies/reaction for influenza A virus and 28 copies/reaction influenza B virus. ViroReal<sup>®</sup> Kit SARS Coronavirus & Influenza A/B is specific for SARS-CoV-2 as well as SARS-CoV and SARS-like coronavirus (Sarbecovirus) and influenza A or B virus.

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