# ViroReal® Kit SARS Coronavirus & Influenza A/B

**Kit version 1.1**

**For *in vitro* diagnostic use only**

| ViroReal® 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:**

- Assay for detection of the N gene of SARS-CoV-2 and Sarbecovirus (FAM), and of internal RNA positive control (IPC) (Cy5)
- Assay for detection of the matix protein gene of influenza A virus (VIC), and of the hemagglutinin gene of influenza B virus (VIC)
- 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 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). 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.
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.

**Intended purpose:** ViroReal® Kit SARS Coronavirus & Influenza A/B is a CE-certified non-automated 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), of the matrix protein gene of influenza A virus and of the hemagglutinin gene of influenza B virus.
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, SARS coronavirus or influenza virus infection and is intended as an aid in the diagnosis of these 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.

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RNA of the nucleocapsid protein gene (N gene) of SARS-CoV-2, SARS-CoV and SARS-related coronavirus (Sarbecovirus) is detected in FAM channel. RNA of the matrix protein gene of influenza A virus and of the hemagglutinin gene of influenza B virus is detected in VIC channel. Other beta coronaviruses or influenza viruses are not detected with this kit.
An internal RNA positive control (IPC) is detected in Cy5 channel and is used as RNA extraction as well as RT-PCR inhibition control. The target for the RNA IPC (artificial target RNA) is added during extraction of the sample.

**PCR-platforms:** This test has been validated with the ABI® 7500 Fast Real-time PCR System (fast cycle parameters are not supported, Thermo Fisher Scientific) and was also tested with LightCycler® 480 II (Roche Diagnostics), MIC instrument (bio molecular systems) and Mx3005P® (Agilent). It is also compatible with other real-time PCR instruments which detect and differentiate fluorescence in FAM, VIC and Cy5 channel (eg., cobas z 480 Analyzer (Roche), QuantStudio™ 5 and QuantStudio™ 7 Pro (Thermo Fisher Scientific) and qTOWER$^3$G (Analytik Jena).

**Performance data:** The LoD95% (smallest number of copies of target RNA which can be 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. The test is specific for SARS-CoV-2 as well as SARS-CoV and SARS-like coronavirus (Sarbecovirus) and influenza A or B virus. Clinical validation was performed with clinical samples.

**Results of clinical validation:**

| | Value |
|---|---|
| **Sensitivity** | 91.5 % |
| **Specificity** | 100 % |
| **NPV** | 92.2 % |
| **PPV** | 100 % |

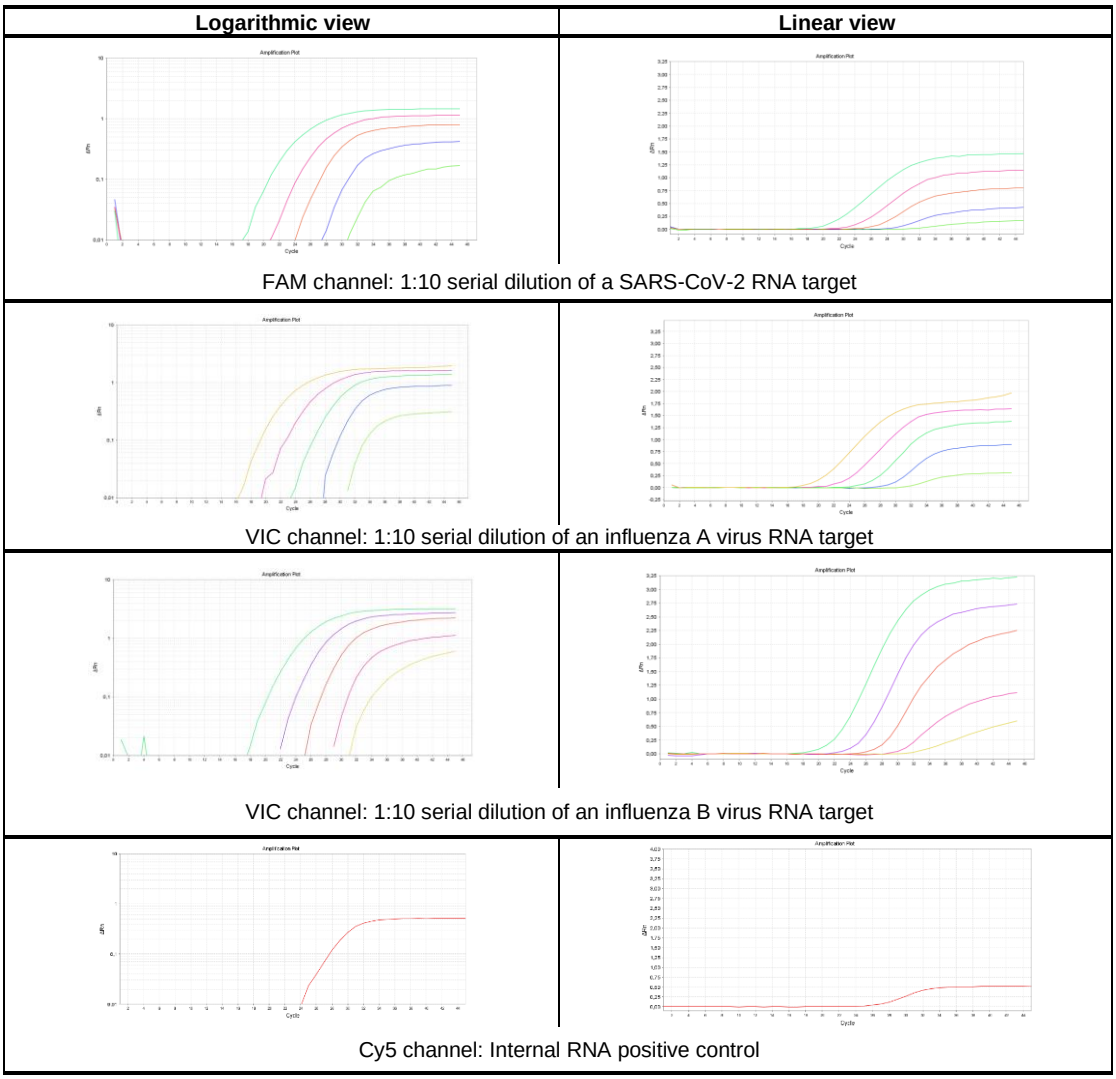


**Figure 1** Performance of ViroReal® Kit SARS Coronavirus & Influenza A/B