ViroReal® Assay Influenza A/B

Only for use in combination with ViroReal® Kit SARS-CoV-2 & SARS

CE IVD

ViroReal® Assay Influenza A/B			
Order no.	**Reactions**	**Pathogen**	**Internal positive control**
RTGM001RV	100	VIC channel	Cy5 channel
RTGM002RV	500	VIC channel	Cy5 channel

Contents:

- Detection assay for the matrix protein gene of influenza A virus (VIC) and for the hemagglutinin gene of influenza B virus (VIC)
- RNA positive control for influenza A virus

Pathogen information:
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.
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.

Description: ViroReal® Assay Influenza A/B is an *in vitro* diagnostic test which can be used in combination with ViroReal® Kit SARS-CoV-2 & SARS. Both tests combined are based on one-step reverse transcription real-time PCR and allow for the detection of the matrix protein gene of influenza A virus (VIC channel), of the hemagglutinin gene of influenza B virus (VIC channel) and of the N gene of SARS-CoV-2, SARS-CoV and SARS-related coronavirus (Sarbecovirus) (FAM channel) 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® Assay Influenza A/B has been developed for the ABI® 7500 instrument (Thermo Fisher Scientific), LightCycler® 480 I (Roche), MIC instrument (bio molecular systems) and Mx3005P® 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) of both tests combined is 12 copies/reaction for SARS-CoV-2, 15 copies/reaction for influenza A virus and 28 copies/reaction influenza B virus. ViroReal® Kit SARS-CoV-2 & SARS is specific for SARS-CoV-2 as well as SARS-CoV and SARS-like coronavirus (Sarbecovirus). ViroReal® Assay Influenza A/B is specific for influenza A and B virus.

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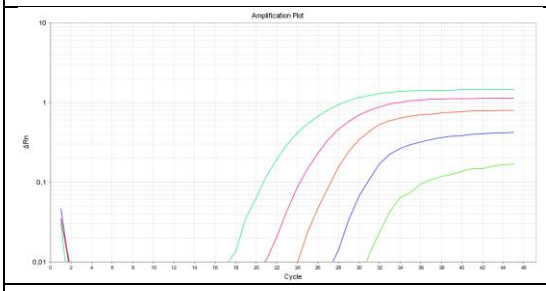
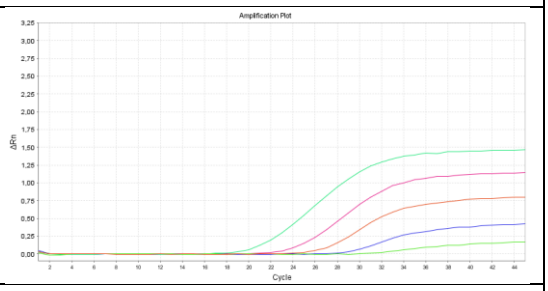
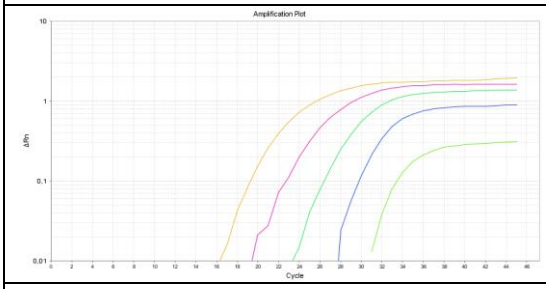
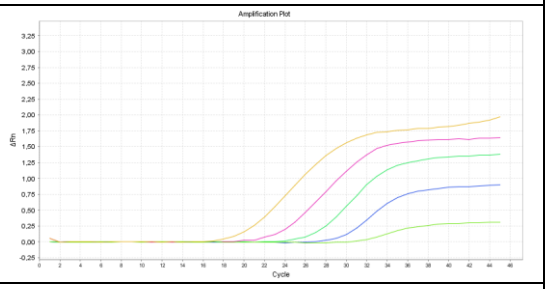
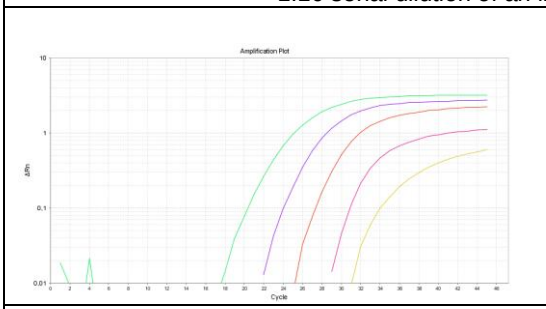
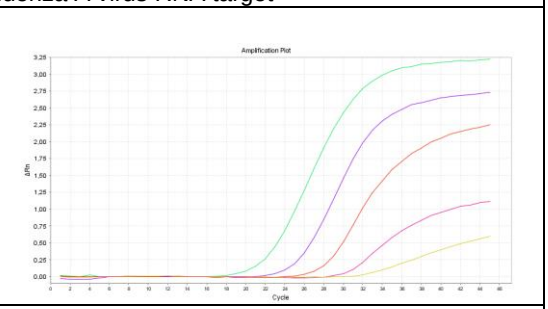
Logarithmic view	Linear view
	
FAM channel, 530 nm 1:10 serial dilution of a SARS-CoV-2 RNA target	
	
VIC channel, 554 nm 1:10 serial dilution of an influenza A virus RNA target	
	
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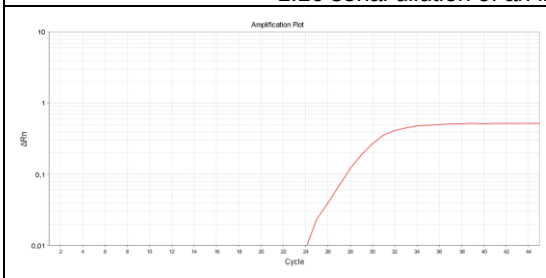	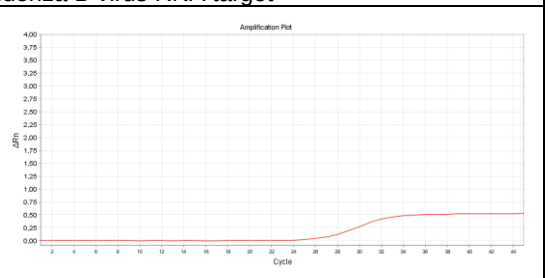
Cy5 channel, 667 nm Internal RNA positive control	

Figure 1: Performance of ViroReal® Assay Influenza A/B combined with ViroReal® Kit SARS-CoV-2 & SARS

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