

ViroReal® Kit Influenza A/B



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Order no.	Reactions	Pathogen	Internal positive control
DHUV00253	50	FAM+VIC channel	Cy5 channel

Kit contents:

- Detection assay for influenza virus A (FAM) + influenza virus B (VIC) + the internal RNA positive control (Cy5)
- Target for internal RNA positive control
- RNA reaction mix
- Nuclease-free water
- Positive control (RNA) for influenza virus A and B



Background: 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 use: ViroReal® Kit Influenza A/B is a non-automated IVD test, based on one-step reverse transcription real-time PCR (RT-PCR), for the qualitative detection of RNA of the matrix protein gene of influenza A virus and the hemagglutinin gene of influenza B virus.

Proper specimens are RNA extracts of samples from the human upper respiratory tract (nasal swabs, nasopharyngeal swabs and oropharyngeal swabs).

This test is suitable for patients of all ages with suspected influenza A or B virus infection and is intended as an aid in the diagnosis of these pathogens in combination with patient history and additional clinical information.

The test is for professional use only and the use is limited to qualified personnel instructed in real-time PCR and *in vitro* diagnostic procedures.

Influenza virus A RNA is detected in FAM channel, influenza virus B RNA in VIC channel. The internal RNA positive control (RNA IPC) is detected in Cy5 channel and is used as RNA extraction as well as RT-PCR inhibition control. The RNA IPC target is extracted with the sample.

PCR-platforms: The test is compatible with real-time PCR instruments detecting and differentiating fluorescence in FAM, VIC and Cy5 channel. Recommended are ABI® 7500 instrument (Thermo Fisher Scientific), QuantStudio™ 7 realtime PCR system (Thermo Fisher Scientific), LightCycler® 480 II (Roche Diagnostics) and Mic instrument (bio molecular systems).

Performance data: The limit of detection (LoD95 = smallest number of copies of target RNA which can be detected in 95% of cases) is 5.7 target copies/reaction for influenza A virus and 6.0 target copies/reaction for influenza B virus. This kit is specific for so far known influenza A and B strains.

For diagnostic evaluation, 24 influenza A isolates and 6 nasopharyngeal swabs positive for influenza A were tested with an Assay Mix containing primers and probe for the detection of the matrix protein gene of influenza A virus (singleplex detection). Furthermore, 9 influenza B isolates, 4 nasopharyngeal swabs positive for influenza B and 13 nasopharyngeal swabs negative for influenza B were tested with an Assay Mix containing primers and probe for the detection of the hemagglutinin gene of influenza B virus (singleplex detection).

Table 1 Summary diagnostic evaluation

	Influenza virus A		Influenza virus B	
	Value	95% CI	Value	95% CI
Sensitivity	100%	88.43% to 100%	100%	75.29% to 100.00%
Specificity	100%	85.18% to 100%	100%	88.43% to 100.00%
NPV	100%	85.18% to 100%	100%	88.43% to 100.00%
PPV	100%	88.43% to 100%	100%	75.29% to 100.00%
Prevalence	64%		30%	

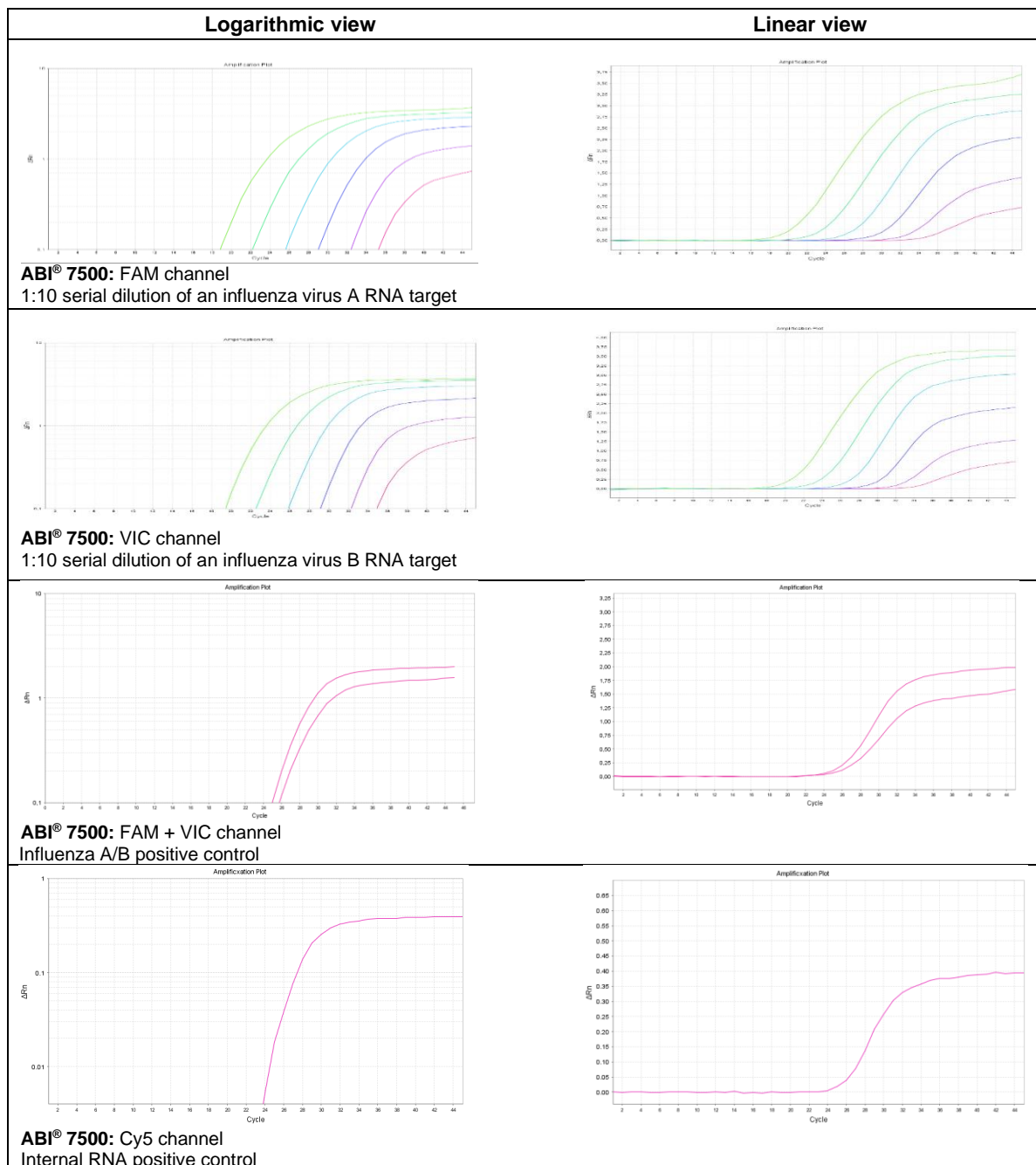


Figure 1 Performance of ViroReal® Kit Influenza A/B

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