ViroReal® Kit Rhinovirus (A, B, C)

Kit version 1.1

For *in vitro* diagnostic use only

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Order no.	**Reactions**	**Pathogen**	**Internal positive control**
DHUV01953	50	FAM channel	Cy5 channel

Kit contents:

- Assay for detection of rhinovirus 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 rhinovirus
- Nuclease-free water

Pathogen information: Human rhinovirus (HRV) is a single-stranded positive sense RNA virus (ss(+)RNA) in the genus Enterovirus of the family *Picornaviridae*. Rhinoviruses are the most common viral infective agents in humans and are the predominant cause of the common cold. RV infections are chiefly limited to the upper respiratory tract. Although infections occur year-round, the incidence is highest during fall and spring. Most cases are mild and self-limited. Rhinovirus C, unlike the A and B species, may be able to cause sometimes more severe infections.

Intended purpose: ViroReal® Kit Rhinovirus (A, B, C) 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 (5' UTR region) of human rhinovirus species A, B, C.
Proper specimens are RNA extracts isolated from samples of the human respiratory tract.
This test is suitable for patients of all ages with suspected human rhinovirus infection and is intended as an aid in the diagnosis of human rhinovirus infection 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 rhinovirus 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: This test has been validated with the ABI® 7500 Fast instrument (fast cycle parameters are not supported, Thermo Fisher Scientific) and was also tested with QuantStudio™ 7 Pro (Thermo Fisher Scientific), Mx3005P® (Agilent), qTOWER^{3}G (Analytik Jena), MIC instrument (bio molecular systems) and LightCycler® 480 II (Roche Diagnostics). It is also compatible with other real-time PCR instruments which detect and differentiate fluorescence in FAM and Cy5 channel (e.g., QuantStudio™ 5/6/7, cobas z 480 Analyzer (Roche)).

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Performance data: ViroReal® Kit Rhinovirus (A, B, C) detects at least 10 target copies/reaction. The LoD95% (smallest number of target RNA copies which can be detected in 95% of cases) is 33 target copies/reaction. Specificity was evaluated with BLAST analyses and by testing viral and bacterial isolates. This kit shows low cross-reactivity with some strains of coxsackie-virus. Clinical validation was performed with nasopharyngeal aspirates.

Results of clinical validation:

	Value	95% CI
Sensitivity	100.00 %	80.49 % to 100.00 %
Specificity	92.59 %	75.71 % to 99.09 %
NPV	100.00 %	86.28% to 100.00%
PPV	89.47 %	66.86 % to 98.07 %
Prevalence	38.64 %	

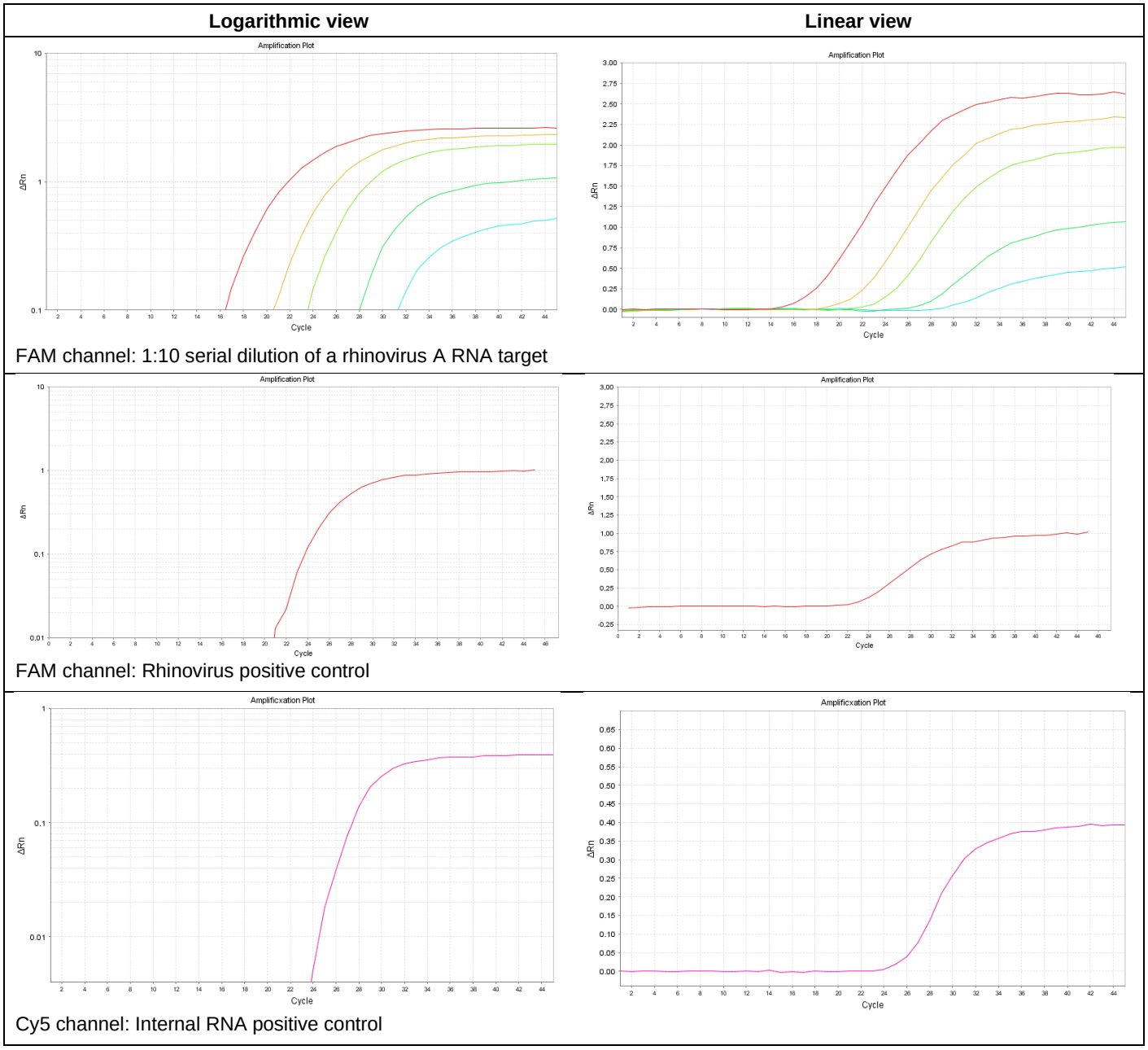

Figure 1 Performance of ViroReal® Kit Rhinovirus (A, B, C)