ViroReal® Kit Metapneumovirus

Kit version 1.1

For *in vitro* diagnostic use only

ViroReal® Kit Metapneumovirus			
Order no.	**Reactions**	**Pathogen**	**Internal positive control**
DHUV01553	50	FAM channel	Cy5 channel

ViroReal® Kit Metapneumovirus is available in following countries: AT, CY, FI, GR, IE, LU, MC, PT, SE, TR

Kit contents:

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

Pathogen information: Human metapneumovirus (hMPV) is an enveloped negative single-stranded RNA virus (ss (-)RNA) of the family *Paramyxoviridae*. It was isolated for the first time in 2001. HMPV is present as two genetic lineages, hMPV A and hMPV B. Human metapneumovirus causes upper and lower respiratory tract infections, symptoms very similar to respiratory syncytial virus (RSV). Human metapneumovirus has a worldwide distribution and it is one of the most common causes of lower respiratory infection in young children. Reinfections appear to be common. Co-infection of human metapneumovirus with influenza virus or RSV can occur.

Intended purpose: ViroReal® Kit Metapneumovirus 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 (nucleocapsid protein gene) of human metapneumovirus (hMPV) strains lineages hMPV A and hMPV B.
Proper specimens are RNA extracts isolated from samples of the human respiratory tract.
This test is suitable for patients of all ages with suspected hMPV infection and is intended as an aid in the diagnosis of hMPV 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 metapneumovirus 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, cobas z 480 Analyzer (Roche)).

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Performance data: ViroReal® Kit Metapneumovirus detects at least 10 target copies/reaction. The LoD95% (smallest number of copies of target RNA which can be detected in 95% of cases) is 10.8 target copies/reaction for both genotypes. Validation was performed with different viral isolates, with various metapneumovirus isolates and with clinical samples. This kit is specific for so far known hMPV A or hMPV B strains.

Results of clinical validation:

	Value	95% CI
Sensitivity	100%	85.18% to 100.00%
Specificity	100%	76.84% to 100.00%
NPV	100%	76.84% to 100.00%
PPV	100%	85.18% to 100.00%
Prevalence	62%	

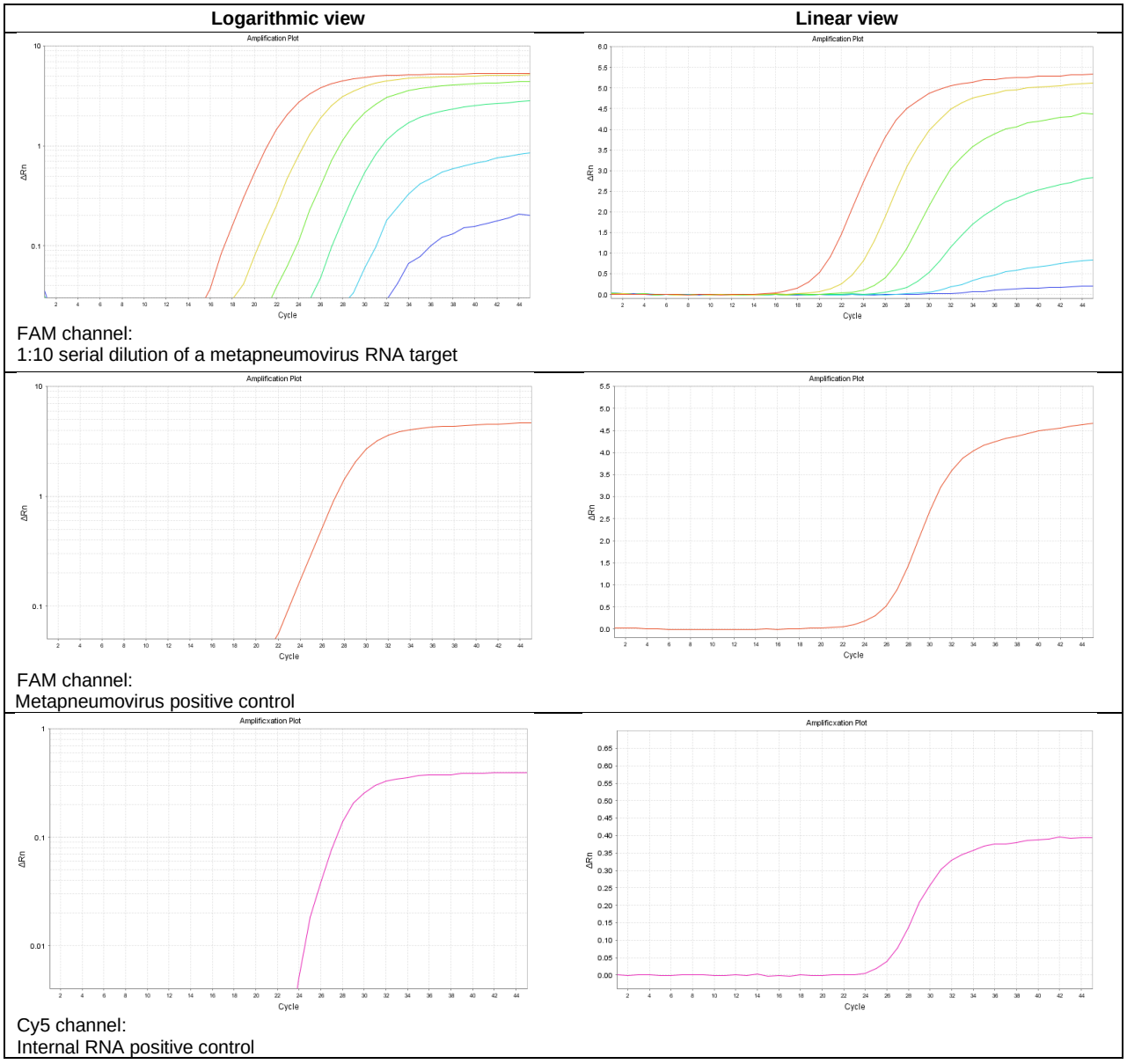

Figure 1 Performance of ViroReal® Kit Metapneumovirus