ViroReal® Kit RSV (A & B)

Kit version 1.1

For *in vitro* diagnostic use only

ViroReal® Kit RSV (A & B)			
Order no.	**Reactions**	**Pathogen**	**Internal positive control**
DHUV02153	50	FAM channel	Cy5 channel

Kit contents:

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

Pathogen information: Human respiratory syncytial virus (RSV) is a negative-sense, single-stranded RNA virus (ss (-)RNA) of the family *Paramyxoviridae*. RSV consists of two antigenic subtypes, A and B. It causes respiratory tract infections and is a major cause of lower respiratory tract infections and hospital visits during infancy and childhood. In addition, RSV is recognized as an important cause of respiratory illness in older adults. Infection is most common during the winter and early spring e.g., in the rainy season.

Intended purpose: ViroReal® Kit RSV (A & B) 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 respiratory syncytial virus (RSV) strains lineages A and 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 RSV A or B infection and is intended as an aid in the diagnosis of RSV A or B 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 RSV 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)).

Performance data: The LoD95% (smallest number of target RNA copies which can be detected in 95% of cases) is 50.2 target copies/reaction for RSV A and 41.6 target copies/reaction for RSV B. Analytical specificity has been evaluated by BLAST analyses and by testing genomic DNA or RNA of viruses and of bacteria. This kit is specific for so far known RSV strains lineage A and B. Clinical validation was performed with samples from ring trials and nasopharyngeal swabs.

Results of clinical validation:

	Value	95% CI
Sensitivity	100.00%	82.35% to 100.00%
Specificity	100.00%	83.16% to 100.00%
NPV	100.00%	83.16% to 100.00%
PPV	100.00%	82.35% to 100.00%
Prevalence	48.72%	

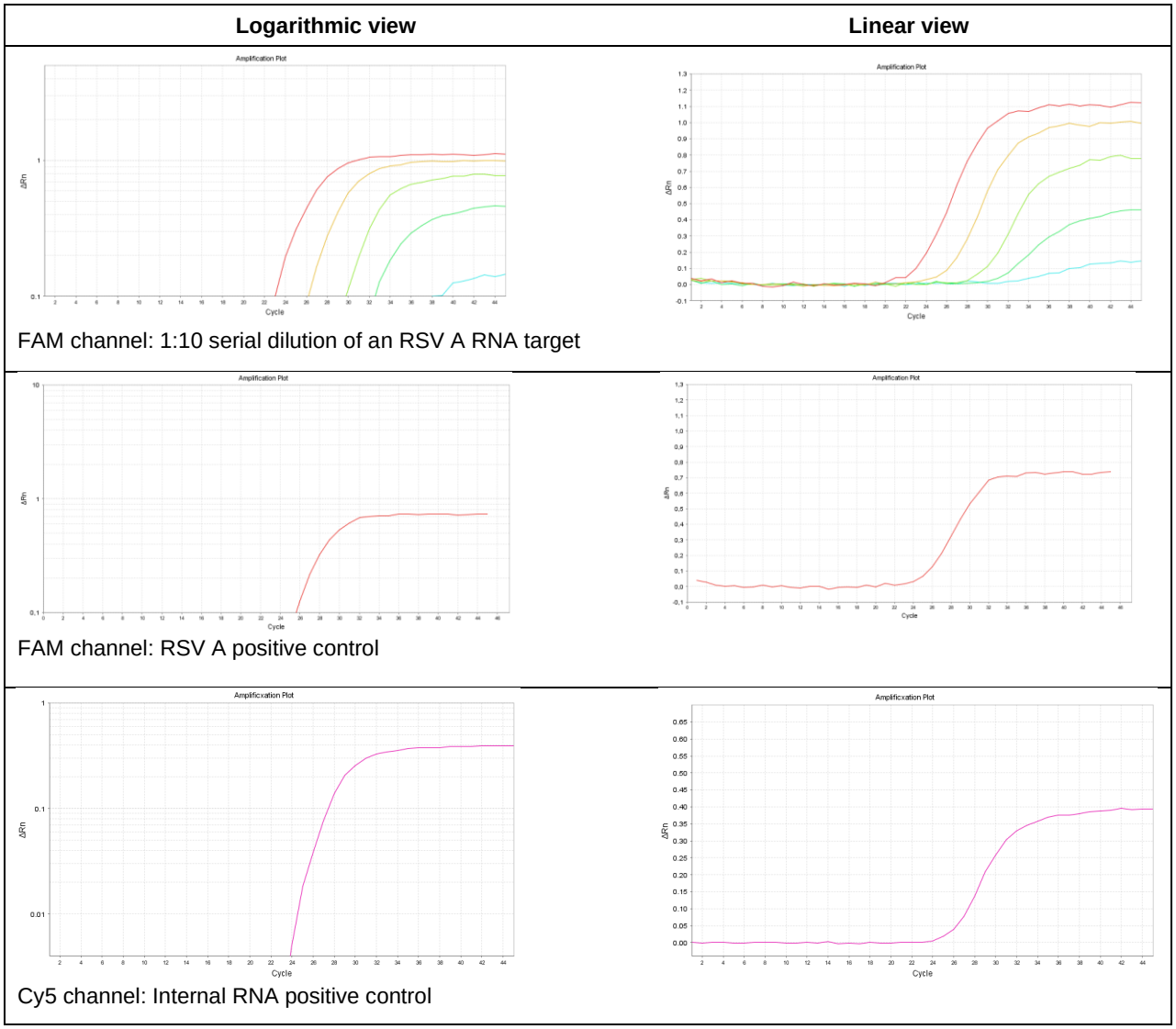

Figure 1 Performance of ViroReal® Kit RSV (A & B)