ViroReal® Kit Adenovirus

Kit version 1.1

For *in vitro* diagnostic use only

ViroReal® Kit Adenovirus			
Order no.	**Reactions**	**Pathogen**	**Internal positive control**
DHUV00153	50	FAM channel	Cy5 channel

Kit contents

- Assay for detection of adenovirus and of internal DNA positive control (IPC)
- IPC-Target DNA (control of DNA extraction and of PCR amplification)
- DNA reaction mix (contains a highly purified Taq Polymerase for rapid hot-start PCR, dNTPs with dUTP and Uracil-N glycosylase (UNG) to eliminate amplicon carryover, ROX™ dye (passive reference) and buffer components – additives optimized to handle PCR inhibitors)
- DNA positive control for adenovirus
- Nuclease-free water

Pathogen information: Adenoviruses are non-enveloped, double-stranded, linear DNA viruses (dsDNA) belonging to the family Adenoviridae, genus *Mastadenovirus*. At present seven human adenovirus species are known (A-G) which are divided in more than 50 serotypes. They can cause diseases of the respiratory tract, but also gastroenteritis, conjunctivitis, cystitis, rhinitis, pharyngitis or diarrhoea. Human adenoviruses have a worldwide distribution.

Intended purpose: ViroReal® Kit Adenovirus is a non-automated CE-certified IVD real-time PCR test for the qualitative detection of DNA (hexon gene) of adenovirus (species A-G).
Proper specimens are DNA extracts isolated from of samples of the respiratory tract. This test is suitable for patients of all ages with suspected infection with adenovirus and is intended as an aid in the diagnosis of infection with this pathogen 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 amplification of adenovirus specific DNA. The internal DNA positive control (IPC) is detected in the fluorescence channel Cy5 and serves as a control for DNA extraction and possible real-time PCR inhibition. The target for the DNA IPC (artificial target DNA) is added during sample extraction.

PCR-platforms: This test has been validated with the ABI® 7500 Fast Real-time PCR System (fast cycle parameters are not supported, Thermo Fisher Scientific) and tested with a LightCycler® 480 Instrument II (Roche Diagnostics) and Mx3005P® QPCR System (Agilent). It is also compatible with other real-time PCR instruments which detect and differentiate fluorescence in FAM and Cy5 channel (e.g., QuantStudio™ 5, QuantStudio™ 7 real-time PCR system (Thermo Fisher Scientific), qTOWER^{3}G (Analytik Jena), Mic instrument (bio molecular systems), cobas z 480 Analyzer (Roche)).

Performance data: ViroReal® Kit Adenovirus detects at least 10 target copies/reaction of adenovirus species B, C, D, E and G, at least 100 target copies/reaction of adenovirus species F and at least 1000 target copies/reaction of adenovirus species A. The LoD95% (smallest number of target DNA copies which can be detected in 95% of cases) is 137

copies/reaction for adenovirus B, 120 copies/reaction for adenovirus C and 40 copies/reaction for adenovirus G. The LOD95% for adenovirus species F and A was not determined. This kit is specific for so far known adenovirus species A-G. Validation was performed with viral isolates and clinical samples. A total of 24 adenovirus-positive samples and 15 adenovirus-negative samples were tested.

Results of clinical validation:

	Value	95% CI
Sensitivity	100%	85.75% to 100%
Specificity	100%	78.20% to 100%
NPV	100%	78.20% to 100%
PPV	100%	85.75% to 100%
Prevalence	62%	

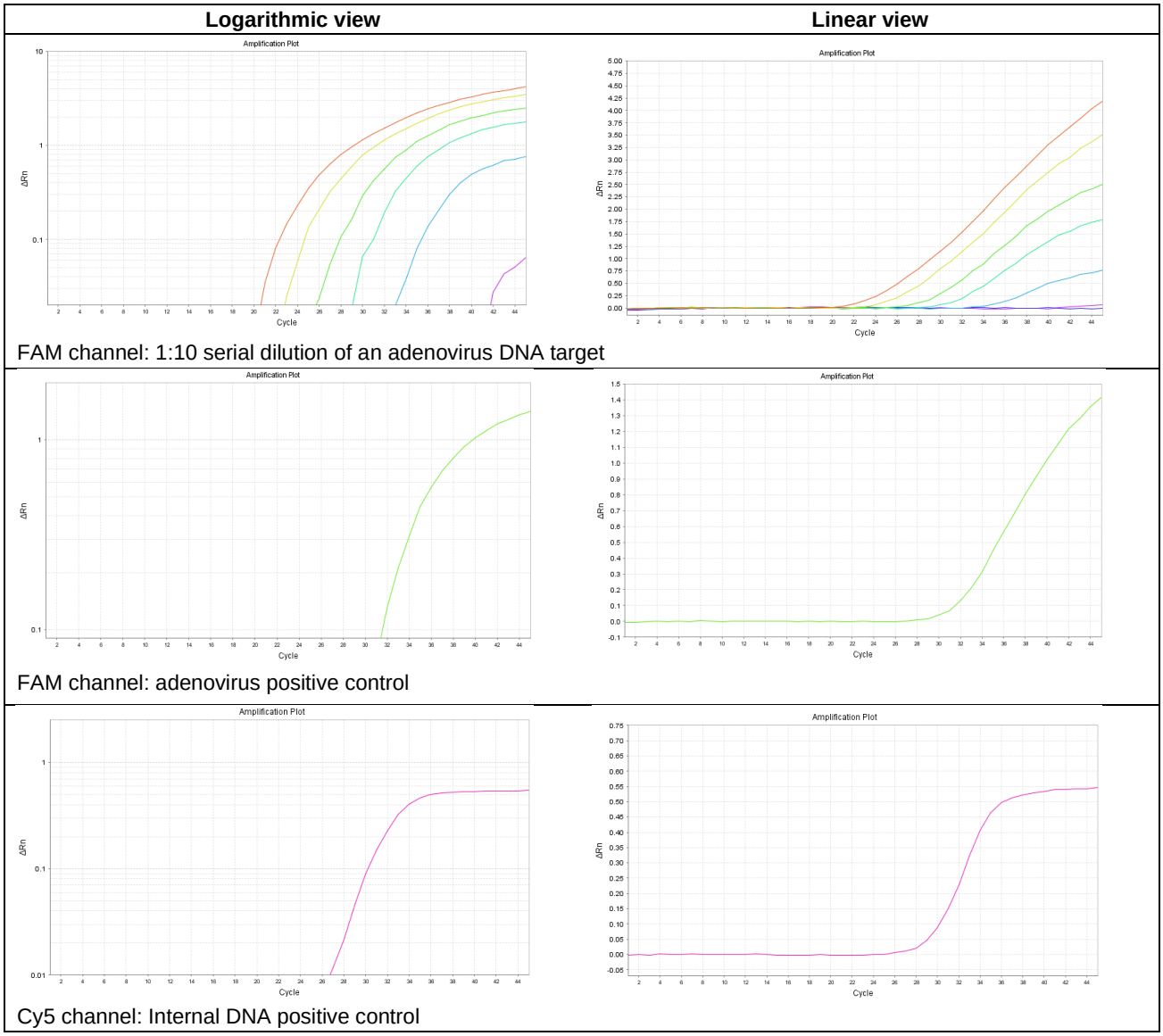

Figure 1 Performance of ViroReal® Kit Adenovirus