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Influenza and respiratory viruses

Sensitive and reliable detection of influenza A (H1N1), influenza A (H3N2) and influenza B by commercial real-time PCR assays: RIDA®GENE Flu and RIDA®GENE Flu LC2.0 real-time PCR

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Background: Influenza is worldwide disease which affects 3-5 million people of which 250,000-500,000 die from this disease each year. Influenza viruses are divided into the subtypes A, B and C. Due to their high mutational variation (antigenic drift) of the surface antigens, hemagglutinin (HA) and neuraminidase (NA), infleunza viruses present an economic burden and a major annual threat to public health. This study evaluated the RIDA®GENE real-time RT-PCR assays for the detection of influenza A and influenza B

Material/methods: In a retrospective study, a total of 141 positive and negative clinical respiratory samples (nose/throat swabs) were extracted using the MagNAPure 96 (Roche). Extracted nucleic acids were analysed with the RIDA®GENE Flu assay on the LightCycler® 480II (Roche). Results were compared to a standard reference in-house real-time PCR assay. The analytical reactivity and analytical specificity of the RIDA®GENE Flu and RIDA®GENE Flu LC2.0 assays was tested using known quality control standards and reference materials. The RIDA®GENE Flu assay was validated on six real-time PCR instruments.

Results: Overall, 141 throat and nose swabs were tested. 31 samples were positive for Influenza A (H1N1, H3N2, H7N9, H5N1) and 24 samples were Influenza B-positive using the RIDA®GENE Flu assay. 85 samples negative for Influenza A or Influenza B were found with the RIDA®GENE Flu assay. The RIDAGENE Flu assay showed a sensitivity of 96.9%, 94.1% and 96.0% for Influenza A, Influenza A (H1N1v) and Influenza B. Overall, the specificity for Influenza A, Influenza A (H1N1v) and Influenza B was 100%, 100% and 100%. Currently circulating Influenza A and Influenza B strains were used for evaluation of the analytical reactivity of the two assays. This included the new variants of Influenza A (H3N2) from the 2014/2015 season. No cross-reactivity to non-Influenza strains was detected with the RIDA®GENE Flu and RIDA®GENE Flu LC2.0 assays. An analytical sensitivity of 50 copies/reaction was achieved with the LightCycler® 480II/LC2.0, Mx3005P, Rotor-Gene Q, ABI7500, CFX96 and SmartCycler II real-time PCR instruments.

Conclusions: The RIDA®GENE real-time RT-PCR assays are sensitive and reliable assays for the detection and differentiation of influenza A, influenza A (H1N1v) and influenza B, including all currently circulating strains and avian strains. The validation of different common real-time PCR instruments provides broad flexibility for use in the routine diagnostics laboratory.