Liat Influenza A/B and RSV Assay was evaluated with 24 Influenza A, 13 Influenza B, 6 Influenza A, H1N1 non 2009, 4 Influenza A, H3N2, and 10 RSV strains. All tested influenza and RSV strains were detected by the Liat Influenza A/B and RSV assay, except one Influenza A strain. The Liat Influenza A/B and RSV assay detected all strains of influenza A, influenza B, and respiratory syncytial viruses (RSV) in nasal swab specimens.

Clinical Performance using Repeatedly Collected Samples.

Historically collected nasopharyngeal samples from both children and adults were tested at a physician clinic. Samples were collected and placed in a universal transport medium.

The samples were tested using the Liat Influenza A/B and RSV assay (Figure 1A) and results were compared to that obtained with an FDA-cleared/CE-marked nucleic acid test, the Proflu+® assay.

Statistical analysis. Positive and negative agreement of the assay were determined by comparing results retested with the Proflu+® assay.

Analytical Performance.

Limit of Detection.

The LOD was determined as the lowest log virus concentration that was detected with a 95% CI.

Analytical Reactivity

The Liat Influenza A/B and RSV assay was evaluated with 2 Influenza A strains, 2 Influenza B strains, and 2 RSV strains at 3x LOD.

The panel comprising human origin strains included 2 influenza A strains (including 1 H1N1 variant strain, 1 H3N2 variant strain), 11 influenza A/H3 strains (including 1 H3N2 variant strain), and 1 avian origin H7N9 strain.

Cross Reactivity: The Liat Influenza A/B and RSV assay was evaluated against a panel comprising human respiratory virus DNA and RNA microarrays.

Interfering Substances: The Liat Influenza A/B and RSV assay was evaluated with 13 potentially interfering substances that may be encountered in respiratory specimens including endogenous RNA (such as, Measles virus, Varicella-Zoster virus, Human Rhinovirus Type 1A, Human Parainfluenza Type 3, Human Metapneumovirus, Human Coronavirus 229E, Herpes Simplex virus, Cytomegalovirus, Adenovirus Type 1), and human microbiota (such as, Neisseria meningitidis, Neisseria elongata, Mycobacterium tuberculosis, Haemophilus influenzae, Staphylococcus aureus, Mycoplasma pneumoniae, Pseudomonas aeruginosa, Enterococcus faecalis, Enterobacter aerogenes, Enterobacter cloacae, Escherichia coli, Staphylococcus aureus, Streptococcus pyogenes, Staphylococcus epidermidis, Lactobacillus casei, and Haemophilus parainfluenzae).

1. Methods

1.1. Sample Collection

Infected cell cultures, simulated clinical samples of respiratory tract origin, and other microorganisms tested, and none of these interfered with detection of influenza A, influenza B, and RSV.

1.2. Liat Influenza A/B and RSV Assay

The Liat Influenza A/B and RSV assay was evaluated with 24 Influenza A, 13 Influenza B, 6 Influenza A, H1N1 non 2009, 4 Influenza A, H3N2, and 10 RSV strains. All tested influenza and RSV strains were detected by the Liat Influenza A/B and RSV assay.

1.3. Methods

Proflu+ assay.

The performance of the Liat Influenza A/B and RSV assay was determined using 3x LOD serologically collected nasal swab specimens. Samples were collected and placed in universal transport medium. Results were compared to the Proflu+® assay. Dilution studies with multiple strains of each virus were conducted to determine the limit of detection. Analytical studies were done with 3 strains of influenza A, 10 strains of influenza B, 6 strains of RSV in nasal swabs. 13 of 14 strains of influenza A, 9 strains of influenza B, and 8 strains of RSV were detected. The Liat Influenza A/B and RSV assay detected all strains of influenza A, influenza B, and respiratory syncytial viruses (RSV) in nasal swab specimens.

Clinical Performance using Repeatedly Collected Samples.

Historically collected nasopharyngeal samples from both children and adults were tested at a physician clinic.

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Statistical analysis. Positive and negative agreement of the assay were determined by comparing results retested with the Proflu+® assay.

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The Liat Influenza A/B and RSV assay was evaluated with 2 Influenza A strains, 2 Influenza B strains, and 2 RSV strains at 3x LOD.

The panel comprising human origin strains included 2 influenza A strains (including 1 H1N1 variant strain, 1 H3N2 variant strain), 11 influenza A/H3 strains (including 1 H3N2 variant strain), and 1 avian origin H7N9 strain.

Cross Reactivity: The Liat Influenza A/B and RSV assay was evaluated against a panel comprising human genetic DNA and RNA microarrays.

Interfering Substances: The Liat Influenza A/B and RSV assay was evaluated with 13 potentially interfering substances that may be encountered in respiratory specimens including endogenous RNA (such as, Measles virus, Varicella-Zoster virus, Human Rhinovirus Type 1A, Human Parainfluenza Type 3, Human Metapneumovirus, Human Coronavirus 229E, Herpes Simplex virus, Cytomegalovirus, Adenovirus Type 1), and human microbiota (such as, Neisseria meningitidis, Neisseria elongata, Mycobacterium tuberculosis, Haemophilus influenzae, Staphylococcus aureus, Mycoplasma pneumoniae, Pseudomonas aeruginosa, Enterococcus faecalis, Enterobacter aerogenes, Enterobacter cloacae, Escherichia coli, Staphylococcus aureus, Streptococcus pyogenes, Staphylococcus epidermidis, Lactobacillus casei, and Haemophilus parainfluenzae).

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