Revised Abstract

Background: Seasonal epidemics of Influenza (Flu) and respiratory syncytial virus (RSV) are responsible for significant morbidity and mortality worldwide. The ability to efficiently and accurately detect and differentiate respiratory viruses is paramount for effective treatment, infection control, and epidemiological surveillance. At present, nucleic acid amplification testing is preferred for rapid, sensitive, and accurate detection of viral respiratory infections. In this study we compared the performance characteristics of two FDA-cleared nucleic acid-based tests, Simplex™ Flu A/B & RSV Direct assay (SIRD; Focus Diagnostics Inc., Cypress, CA), and Prodesse ProFlu+™ (ProFlu+; Hologic, Bedford, MA) in detecting Flu A, B and RSV viruses from clinical nasopharyngeal (NP) swab specimens.

Methods: A total of 188 NP swab specimens (FLU A=90, FLU B=22, RSV=26, INVALID=50) were analyzed and compared by both SIRD and ProFlu+. The SIRD assay was performed from clinical specimens that have not undergone nucleic acid extraction on the 3M Integrated Cycler (with Integrated Cycler Studio Software), the Direct Amplification Disc and associated accessories. For the Prodesse assay, the nucleic acid was extracted from 200 µl of specimen using the NucliSENS easyMAG (bioMerieux, Durham, NC) and the assay was performed on the SmartCycler (Cepheid, Sunnyvale, CA) according to the package insert.

Results: Out of 90 FLU A positive, 22 FLU B positive, 26 RSV positive results detected by the Prodesse ProFlu+ Assay, the SIRD Assay detected 83 Influenza A (Fig. 1), 21 Influenza B (Fig. 2), and 26 RSV (Fig. 3) positive samples. In addition, of the 50 invalid results by ProFlu+ assay, the SIRD Assay detected 34 negative results and 16 invalid results. The observed average Ct with ProFlu+ assay for FLU A was 29.29 (20.7 – 37.9), FLU B = 25.54 (15.7 – 33.3), RSV = 24.13 (19.5 – 31.4) and with SIRD assay for FLU A = 32.51 (22.7 – 39.6), FLU B = 31.35 (23.2 – 36.3), RSV = 27.75 (21.3 – 35.1). (Fig. 4)

Accuracy and Sensitivity: Out of 90 Influenza A positive, 22 Influenza B positive, 26 RSV positive swab samples detected by the Prodesse ProFlu+ Assay, the SIRD Assay detected 83 Influenza A (Fig. 1), 21 Influenza B (Fig. 2), and 26 RSV (Fig. 3) positive samples. In addition, of the 50 invalid results by ProFlu+ assay, the SIRD Assay detected 34 negative results and 16 invalid results. The observed average Ct with ProFlu+ assay for FLU A was 29.29 (20.7 – 37.9), FLU B = 25.54 (15.7 – 33.3), RSV = 24.13 (19.5 – 31.4) and with SIRD assay for FLU A = 32.51 (22.7 – 39.6), FLU B = 31.35 (23.2 – 36.3), RSV = 27.75 (21.3 – 35.1). (Fig. 4)

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