P0125
Paper Poster Session
Respiratory virus diagnostics

Clinical evaluation of Seegene allplex respiratory panel 1 assay for the detection of seasonal influenza and human respiratory syncytial viruses

Laura Gimferrer*[1], Cristina Andrés[2], María Gema Codina[3], Juliana Esperalba[3], María del Carmen Martín[2], Francisco Fuentes[2], Tomás Pumarola Sole[4], Andres Anton[2]

[1]*Hospital Universitari Vall D'hebron, Barcelona, Spain*

[2]*Hospital Universitari Vall D'hebron, Microbiology, Barcelona, Spain*

[3]*Hospital Universitari Vall D'hebron, Microbiology, Barcelona, Spain*

[4]*Hospital Universitari Vall D'hebron, Microbioloogy, Microbiology, Barcelona, Spain*

Background: Influenza (Flu) and human respiratory syncytial (HRSV) viruses are etiological agents of respiratory infections that cause a significant morbidity and mortality worldwide. Rapid and accurate diagnosis of these respiratory viruses is essential for an appropriate patient management. Molecular tests are the best detection option due to their high sensitivity and specificity.

Seegene's Allplex™ Respiratory Panel 1 (Allplex RP1) is a real-time one-step RT-PCR assay for the simultaneous detection of Flu A, Flu B, HRSV-A and HRSV-B from respiratory specimens. In addition, it allows the determination of Flu A subtype (H1, H3 and H1pdm09). Based on Seegene's proprietary MuDT™ technology, this assay can detect individual C_t values of multiple targets for the quantification of viruses. This study aims to evaluate Allplex RP1 in comparison with other two commercial molecular assays, Prodesse ProFlu+ and ProFAST+ (Hologic, Madison, WI, USA), and GeneXpert Flu/RSV XC (Cepheid, USA), for the detection of influenza and respiratory syncytial viruses.

Material/methods: A total of 305 upper respiratory tract specimens, that were previously laboratory-confirmed during the 2014-2015 season as part of diagnosis routine, were used for this clinical evaluation. Seegene's assay requires prior RNA extraction from 350 μL of respiratory samples eluting in a final volume of 50 μL by using Seegene's automation extraction protocol in MICROLAB Nimbus IVD platform, which also performed PCR setup. For Hologic's assay, nucleic acids were extracted from 200 μL of respiratory specimens and eluted in 100 μL using NucliSense easyMAG (BioMérieux, Marcy l´Etoile, France) according to manufacturer's instructions. On the other hand, Cepheid's assay fully integrates and automates sample extraction, amplification and detection from 300 μL of sample.

Results: Out of the 305 samples analysed, 219 (71.8%) were concordantly screened by both Allplex RP1 and Hologic assays as Flu A, Flu B or HRSV positive, and 77 (25.2%) as negative for any

respiratory virus. Nine (3%) samples showed discrepant results by using these two assays. On the other hand, 220 (72.1%) were concordantly screened by both Allplex RP1 and Cepheid assays as Flu A, Flu B or HRSV positive, and 77 (25.2%) as negative for any respiratory virus. Results from 8 (2.7%) specimens showed discrepancy between these two methods. Overall the agreement between Allplex RP1 and Hologic was 97% (κ value=0.932, substantial) and 97.4% (κ value=0.937, substantial) between Allplex RP1 and Cepheid. Regarding the sensitivity and the specificity, of Allplex RP1 were 96% and 100% respectively.

Conclusions: In this study, Allplex RP1 assay showed to be highly sensitive, specific, and suitable for full influenza and HRSV respiratory virus detection, including influenza subtyping. In addition, it was also a hands-on-time saving assay due to the automated nucleic acid extraction and PCR setup.