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Validation of clinical throat specimens from hospitalized patients on Focus Diagnostics Simplexa Flu A/B & RSV Direct assay using the 3M Integrated Cycler instrument

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Background: Healthcare-associated influenza infections are most common when Influenza is circulating in the community. Rapid and cost effective laboratory diagnosis of respiratory infections is therefore essential to prevent the transmission and spread of Influenza helping to aid bed management in a health-care setting.

Here we undertake a retrospective study and validate Focus Diagnostics Simplexa™ Flu A/B & RSV Direct assay (supplied by Launch Diagnostics) using the 3M Integrated Cycler instrument. This is a real-time RT-PCR assay intended for the *in vitro* qualitative detection and differentiation of Influenza A, B & Respiratory Syncytial Virus viral RNA.

Material/methods: Throat swabs collected from clinically presenting hospitalised patients were expressed into Remel M4RT multi-microbe media and tested on Cepheid GeneXpert using Xpert® Flu/RSV XC assay. Specimens were stored at -20°C for between 7 – 252days before comparative testing was performed using Focus Diagnostics Simplexa™ Flu A/B & RSV Direct assay. 50µL of Direct Reaction Mix (RM) and 50µL of specimen are added to a Direct Amplification Disc, which is run on the 3M Integrated Cycler with Integrated Cycler Studio Software.

Any discrepant results would be re-run on Cepheid GeneXpert to assess whether this was due to sample degradation and inconsistencies referred to a PHE.

Results: A total of 108 clinical samples were included in the study, all were screened using the Cepheid GeneXpert. Of the samples testing positive for Flu A target on the GeneXpert, 3 were excluded due to sample degradation. The remaining 105 included: 62 negative and 43 positive samples (30 Flu A, 5 Flu B and 8 RSV).

Table 1: In-house results of Focus Diagnostics Simplexa™ Flu A/B & RSV Direct Assay Performance

Target	n	Total Positive Focus	False Positive	Total Negative	False Negative	PPV % (95 CI)	NPV % (95 CI)	Sensitivity % (95 CI)	Specificity % (95 CI)
Flu A	105	29*	0	75	1*	100 88.06-100.0	98.65 92.70-99.97	96.67 82.78-99.92	100 95.07-100.0
Flu B	105	5	0	100	0	100 47.87-100.0	100 96.38-100.0	100 47.82-100.0	100 96.38-100.0
RSV	105	6*	0	98	1**	100 54.07-100.0	98.99 94.50-99.97	85.71 42.13-99.64	100 96.31-100.0

*Reference laboratory result: Influenza A virus RNA Not detected by RT-PCR, Swine H1 RNA DETECTED by RT-PCR

**Reference laboratory result: Respiratory Syncytial Virus RNA DETECTED by RT-PCR

Conclusions: In an age where NHS laboratories are being put under more financial burden and hospital beds are at a premium, rapid diagnostic Influenza tests are increasingly being used in a clinical setting. A negative result, meaning patients do not have to be in expensive isolation rooms can be just as useful as a positive helping to guide patient management.

The Focus Diagnostics Simplexa™ Flu A/B & RSV Direct assay offers excellent performance with results being available in approximately 75 minutes.