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Development of an External Quality Assessment (EQA) Programme for Influenza A & B and Respiratory Syncytial Virus (RSV)

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Introduction

A number of POCT devices used for rapid screening of respiratory viral infections including seasonal influenza are now widely available in the UK. The viral testing targets in POCT platforms can be single, dual or multiplex; the most common being Influenza A (and/or subtypes) and B alone, or Influenza A and B with Respiratory Syncytial Virus (RSV). Platforms tend to be based on nucleic acid amplification technologies (NAAT), which generally have improved sensitivity compared to first generation Antigen based lateral flow devices.

Studies have shown that their use in well designed and defined settings with appropriate governance arrangements can lead to improved patient triage, better use of isolation rooms during periods of winter pressure, more targeted use of antivirals, reduction in unnecessary antibiotic use and a reduced length of hospital stay.

With the increased utilisation of these platforms, in January 2021, Weqas developed an External Quality Assessment (EQA) programme to assess and monitor the performance of these tests.

Method

For the pilot study 14 sites in the UK were recruited to take part. Each month 2 – 3 samples were sent, with each site receiving 10 samples over 4 months. The following platforms were enrolled in the programme: Roche cobas Liat (n=12), Abbott ID NOW (n=1) and Cepheid GeneXpert Xpress (n=1).

Following the initial pilot another 3 samples were distributed to 23 sites over 2 months (Roche cobas Liat (n=17), Abbott ID NOW (n=5) and Cepheid GeneXpert Xpress (n=1)).

The material was prepared by the addition of inactivated Influenza A/B & RSV into a buffered solutions, dispensed into 1mL aliquots and stored at -20°C until dispatch.

For the initial pilot 5 positive samples were prepared for Influenza A, 2 samples for Influenza B, and 2 samples with RSV. Both H1N1 and H3N2 subtypes were used for Influenza A. The extra 3 samples consisted of further positive samples, 2 for Influenza B and 1 for RSV.

Stability

The material was found to be stable for 3 weeks at room temperature for Influenza A and 2 weeks at room temperature for Influenza B. The returned data suggests samples for RSV are stable for at least 2 weeks at 4°C.

Long term stability experiments showed that Influenza A and B were stable for 3.5 months at -20°C.

Long term stability of RSV will be assessed in a further study.

Results

Reported results for all samples distributed are shown in Table 1. 100% sensitivity (48/48 correctly identified as Positive) was observed for Influenza A, 88% (42/48 correctly identified as Positive) for Influenza B and 89% (32/36 correctly identified as Positive) for RSV. For RSV 100% sensitivity was observed at a high and 'normal' viral load with only 50% sensitivity at a low viral load (1 sample).

99% specificity (93/94 correctly identified as Negative) was observed for Influenza A, 100% (80/80 correctly identified as Negative) for Flu B, and 99% (99/100 correctly identified as Negative) for RSV respectively. All users correctly identified the sample with no virus present (all other samples had at least 1 virus present).

Table 1 Reported results for Influenza A/B & RSV for each sample distributed in the study

Distribution / Sample Number	Flu A	Reported Results	Flu B	Reported Results	RSV	Reported Results
FL1 S1	**Positive** (high viral load)	7/7 correct	**Negative**	7/7 correct	**Negative**	7/7 correct
FL1 S2	**Positive**	7/7 correct	**Negative**	7/7 correct	**Negative**	7/7 correct
FL2 S2	**Positive** (high viral load)	11/11 correct	**Negative**	11/11 correct	**Negative**	11/11 correct
FL3 S3	**Positive**	12/12 correct	**Negative**	12/12 correct	**Negative**	12/12 correct
IF0421 S1	**Positive**	11/11 correct	**Negative**	11/11 correct	**Negative**	11/11 correct
IF0421 S3	**Negative**	7/8 correct	**Positive**	7/8 correct	**Negative**	7/8 correct
FL2 S1	**Negative**	11/11 correct	**Positive** (high viral load)	10/11 correct	**Negative**	11/11 correct
IF0921 S2	**Negative**	15/15 Correct	**Positive**	12/15 Correct	**Negative**	15/15 Correct
IF1021 S1	**Negative**	14/14 Correct	**Positive**	13/14 Correct	**Negative**	16/16 Correct
FL3 S1	**Negative**	12/12 correct	**Negative**	12/12 correct	**Positive** (high viral load)	12/12 correct
IF0421 S2	**Negative**	8/8 correct	**Negative**	8/8 correct	**Positive** (low viral load)	4/8 correct
IF1021 S2	**Negative**	14/14 correct	**Negative**	14/14 correct	**Positive**	16/16 Correct
FL3 S2	**Negative**	12/12 correct	**Negative**	12/12 correct	**Negative**	12/12 correct

Discussion and Conclusions

The study showed excellent performance for Influenza A/B & RSV for all samples except 1 sample with low viral load RSV. The data shows excellent specificity for Influenza A/B & RSV which provides high confidence in the use of these assays as a rule in test. Only 2 false Positive results were seen in the study, 1 for Influenza A (Roche cobas Liat) and 1 for RSV (Roche cobas Liat).

The low sensitivity for RSV, particularly at lower viral load (50% false Negatives), limits the use of this assay as a rule out test for RSV. This needs further investigation and further samples with lower viral loads will be distributed to assess this anomaly.

Additional studies are ongoing to determine cross reactivity including the effects of positive SARS-CoV-2 virus on the performance of these platforms. A combined EQA programme for Influenza A & B, RSV and SARS-CoV-2 would benefit users, especially in POCT settings.

References

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