UK NEQAS Respiratory Viruses Point-of-Care EQA: Assessing Diagnostic Accuracy for RSV, Influenza and SARS-CoV-2

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ISO 17043:2023 accredited!

Background

Influenza viruses, respiratory syncytial viruses (RSV) and SARS-CoV-2, known collectively as the 'big three' respiratory viruses, are the three main viruses which cause acute respiratory infections (ARIs). ARIs have strong seasonal patterns and often exhibit symptoms of influenza-like illness. These infections significantly increase the risk of morbidity and mortality in at-risk groups, the younger and older population. In 2021, 784,600 deaths worldwide in children younger than 5 years old were caused by lower respiratory infections[1]. Throughout the winter months from September 2024 to March 2025, 25,535 people of all ages were admitted to hospital with influenza, RSV or COVID-19 infections in England [2,3,4], with 16,391 (64.2%) of these being due to influenza.

Prompt and accurate diagnosis is critical for patient management. To enable this efficiency, point-of-care (POC) diagnostics have become a valuable tool in rapidly diagnosing respiratory pathogens. Their ability to be used in numerous clinical and community settings, including A&E departments, GP surgeries, paediatric wards and in care homes, is a vital feature. The increasing use of POC testing will hopefully reduce morbidity and mortality, by allowing a more focussed management, since vaccines and treatment are available for the big three respiratory viruses. Access to POC testing may also help in mitigating the severity of future respiratory virus pandemics [5].

Launched in 2024, the UK NEQAS Respiratory Viruses Point-of-Care (RV) External Quality Assessment (EQA) scheme was established in response to the growing use of POC assays. The programme aims to enhance confidence in the reliability of these assays and their role in supporting the clinical management of influenza, RSV, and SARS-CoV-2 infections worldwide.

Objectives

To evaluate the performance of participating laboratories to the ISO 17043:2023-accredited RV EQA scheme since its introduction.

The UK NEQAS for Microbiology RV EQA scheme provides specimens in liquid-format, namely viral transport medium (VTM), suitable for antigen and molecular detection of influenza A/B, RSV A/B and SARS-CoV-2. VTM has been purposefully chosen to simulate the specimens which would be used on POC assays in clinical and community settings.

Methodology

There are three distributions of the RV EQA scheme each year, consisting of four specimens prepared using cultured virus and Hep-2 cells which act as cellular controls. The specimens can contain any of the big three viruses at different concentrations, simulating different stages of infection.

Participant performance was assessed across the first four distributions (5636, 5709, 5757 and 5846) and results were evaluated based on participant concordance with the intended results.

Results

Participant results across the four distributions were classed as very good, with the lowest average accuracy of virus detection being 94.3%, for distribution 5709. There was a 100% success rate in individual virus detection on seven occasions across the four distributions. Molecular methods for virus detection proved to be more accurate than using antigen assays; for the molecular methods, participants scored 97% to 99.4% accuracy on average, compared to 94.8% to 98.5% average accuracy when antigen assays were used.

Table 1. Concordance of participants' results for the first four distributions of the RV EQA scheme, using molecular methods for the detection of the three respiratory viruses.

Virus	Concordance of result (%) by distribution			
	5636	5709	5757	5846
Influenza	95.3	99.0	97.2	100
RSV	96.5	100	97.4	97.4
SARS-CoV-2	99.2	99.1	100	100
Overall average	**97.0**	**99.4**	**98.2**	**99.1**

Table 2. Concordance of participants' results for the first four distributions of the RV EQA scheme, using antigen assays for the detection of the three respiratory viruses.

Virus	Concordance of result (%) by distribution			
	5636	5709	5757	5846
Influenza	96.0	99.0	100	100
RSV	100	98.9	90.2	97.9
SARS-CoV-2	92.9	85.1	94.1	97.7
Overall average	**96.3**	**94.3**	**94.8**	**98.5**

Antigen assays had the lowest concordance rate for SARS-CoV-2 in specimen 8855 (distribution 5709), where 40.5% of participants reported this SARS-CoV-2 positive specimen as negative (Figure 1). By comparison, 100% of participants correctly recorded this specimen as SARS-CoV-2 positive when using molecular methods.

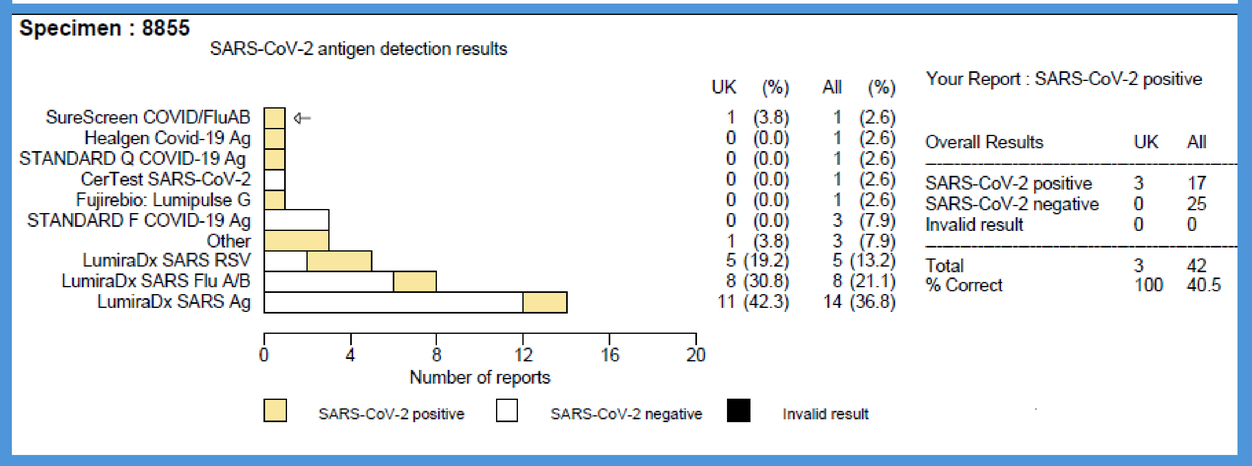

Figure 1. Participants' SARS-CoV-2 antigen assay results for specimen 8855.

One of the specimens (9011) in distribution 5757 also proved to be challenging when using antigen assays; only 39.1% of participants correctly reported the specimen as RSV positive, compared to 89.5% when using molecular methods (Figure 2).

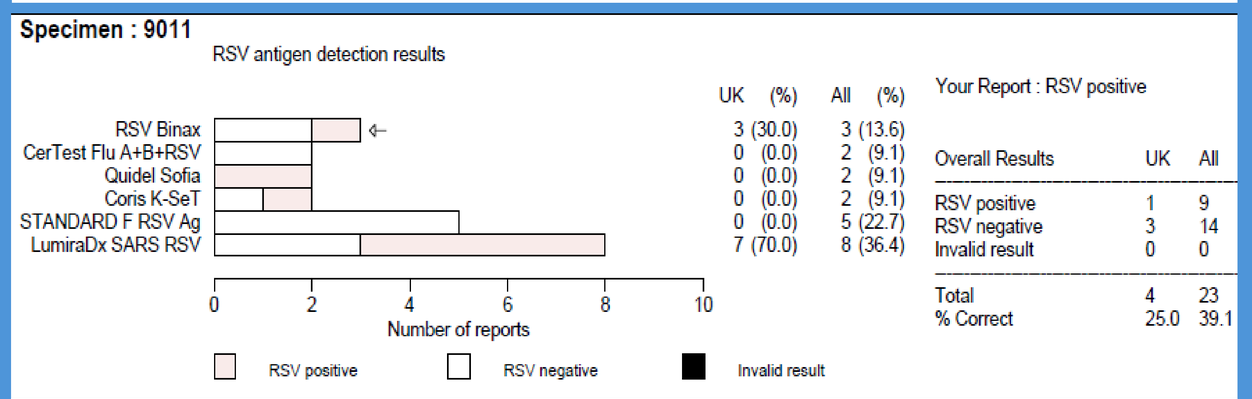

Figure 2. Participants' RSV antigen assay results for specimen 9011.

Conclusions

Participants using antigen assays reported less successful detection rates for specimens deemed more challenging, including those containing diluted viral loads or variant strains (e.g. Omicron BA.2), compared to participants using molecular methods. This was observed for SARS-CoV-2 in specimen 8855 and specimen 9011 for RSV.

The lack of sensitivity of these assays could lead to false negative results which might impact patients who have low antigen levels in a course of infection. Some antigen assays may not detect certain viral strains, which could also be a contributing factor for incorrect results. Antigen assays are qualitative, so they are not the most useful tool for surveillance and tracking disease progression.

Overall performance in the UK NEQAS Respiratory Viruses Point-of-Care EQA scheme has been very good across all distributions, demonstrating high diagnostic accuracy among participating laboratories. Molecular methods consistently outperformed antigen assays in detecting low viral load specimens. The variation in assay accuracy emphasises the importance of method selection for accurate diagnosis.

Participant numbers have been steadily increasing over the distributions as more laboratories become aware of this EQA scheme and its benefits in patient management, particularly in point-of-care settings.

Tailored support for antigen-based testing is essential to uphold high diagnostic standards. Ongoing external quality assessment plays a critical role in ensuring accuracy, reliability and consistency of results, thereby providing clinicians and patients with confidence in diagnostic decision-making.

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