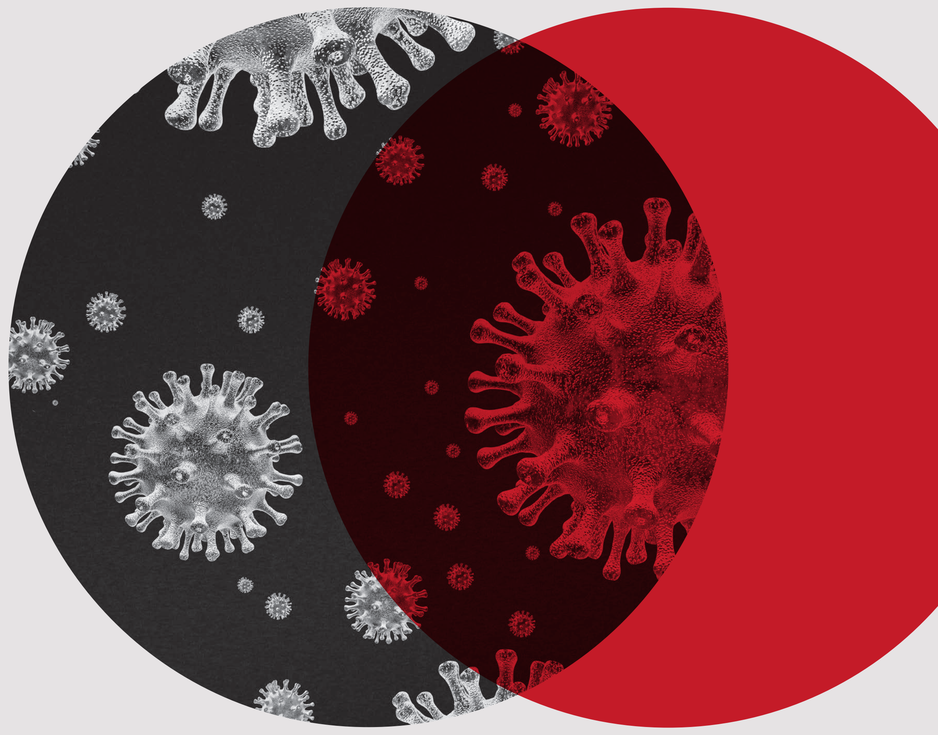
Do Point of Care Tests for Influenza & RSV Work? Four Years of Data



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Introduction

In contrast to central clinical laboratories, point of care (PoC) testing facilitates rapid results at the site of care and in resource-limited settings, supporting timely and proper treatment.[1]

However, external quality assurance (EQA) is essential to ensure PoC diagnostic assays are producing accurate and reliable results.[1]

RCPAQAP developed a program for the rapid PoC testing of influenza A & B and RSV to support molecular-based PoC assays targeting respiratory viruses.

This EQA program was first offered in 2019 and a four year review of participation and performance was performed to assess program fit for purpose.

Methods

The proficiency testing (PT) program contained three surveys per year, each with four specimens.

The PT panels consisted of inactivated influenza A & B strains and RSV types at various concentrations in addition to negative samples.

The material was suspended in buffered saline solution to simulate respiratory samples.

The data obtained between 2019–2022 was analysed with respect to participation numbers, assay usage, values reported, and overall performance.

Results

Comparing the first survey in 2019 and the latest survey in 2022 revealed a 3.3-fold increase in participation (87 to 290) and a 2.5-fold increase in the number of assays (6 to 16) **(Table 1)** used for molecular influenza/RSV PoC testing.

Across the 12 surveys issued over the four years, results were 98–100% concordant **(Figure 1)**, with discordant results often attributed to transcription errors or sample reversal. Reported Ct values were consistent within assay user groups.

Over the last two years, two samples containing SARS-CoV-2 were included, and 99% of participants determined that these samples did not contain influenza virus or RSV. However, four participants reported false positive results for influenza in these samples.

Over the four years, participants were predominantly from Australia and this same trend was still present in the last survey of 2022 **(Figure 2)**.

Table 1. Summary of Assays Used in the Final Survey of 2022.

Assay Name	Total Users (Count)
Abbott ID NOW Influenza A & B Ag	1
Becton Dickinson BD MAX ExK TNA-3	3
bioMerieux (BioFire) FilmArray Respiratory Panel 2.1 plus	1
Cepheid Xpert Flu/RSV XC	2
Cepheid Xpert Xpress CoV-2/Flu/RSV plus	2
Cepheid Xpert Xpress Flu/RSV	100
Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV	101
CerTest Biotec VIASURE Flu A; Flu B & RSV RT-PCR Detection Kit	3
CerTest Biotec VIASURE SARS-CoV-2, Flu & RSV RT-PCR Detection Kit	1
Genetic Signatures EasyScreen Respiratory Pathogen Detection Kit	1
Hologic Panther Fusion Flu A/B/RSV	2
Other	1
Roche Diagnostics Cobas LIAT Flu/RSV	25
Roche Diagnostics Cobas LIAT SARS-CoV-2/Flu	45
Seegene Allplex RV Essential Assay	1
Thermo Fisher MagMax Viral RNA Isolation Kit	1

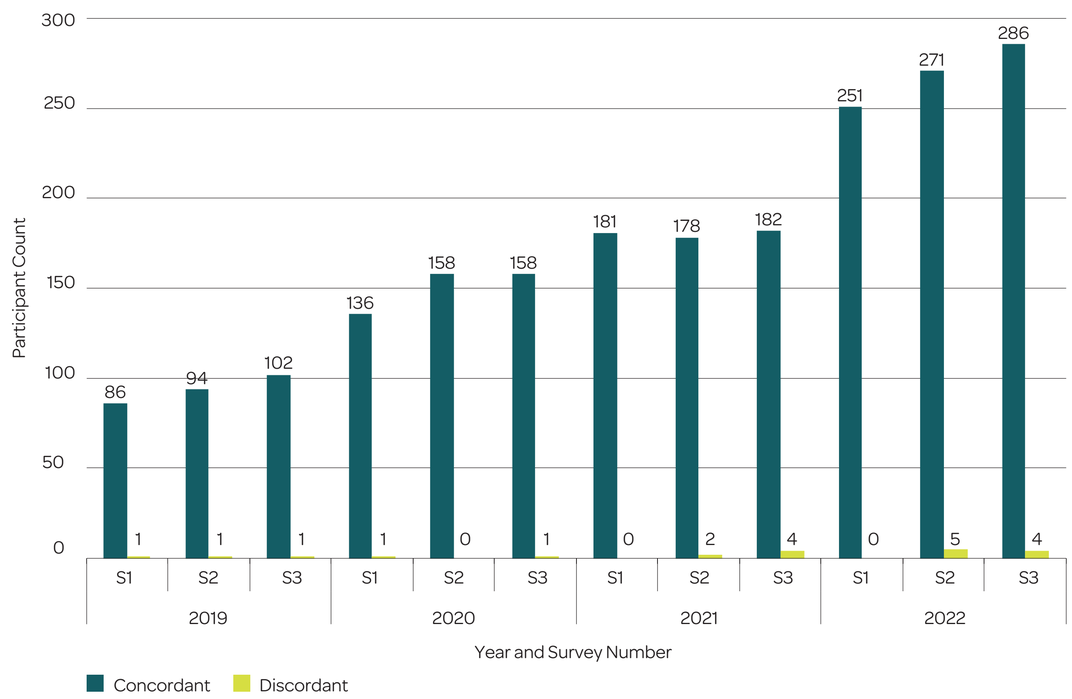

Figure 1. Participant performance from 2019–2022. Concordant refers to a participant returning correct results for all tested specimens in a survey while discordant refers to a participant having at least one incorrect results in a survey.

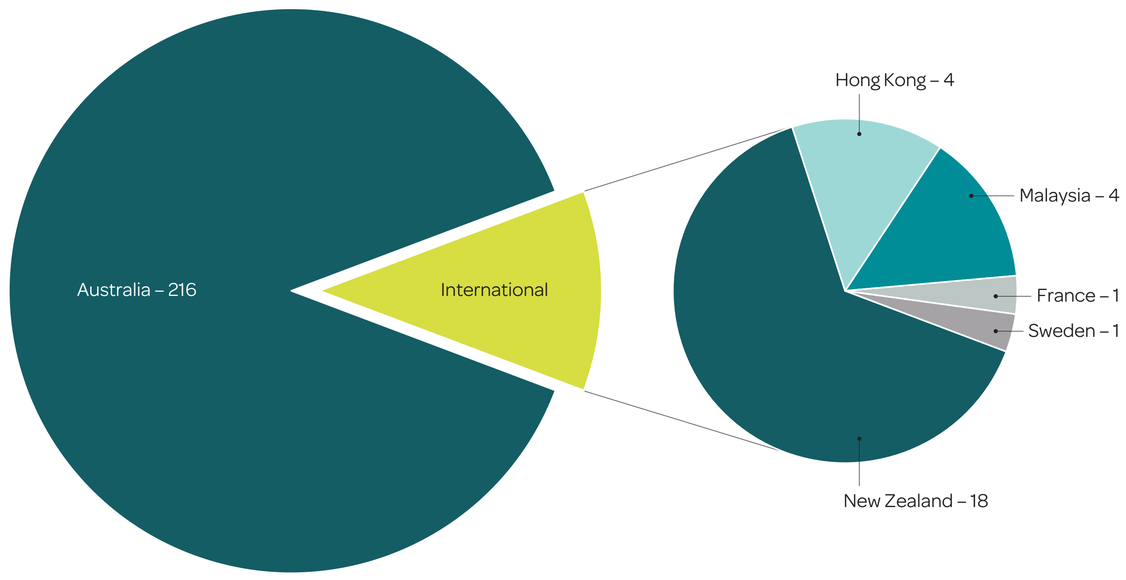

Figure 2. Breakdown of participant country in the last survey in 2022.

Conclusion

Increasing participation and assay diversity in this program suggests routine PoC testing for influenza/RSV has increased over the past four years.

Participants' overall performance was excellent, providing confidence in the results produced by these PoC assays.

Furthermore, the few discordant results that were returned were not correlated with any specific assay assuring that none of the assays encountered in this program feature systemic sensitivity or specificity issues.

As expected, the majority of participants enrolling in this program are from Australia however RCPAQAP is striving to support healthcare systems internationally.

In 2023, RCPAQAP has expanded this program to include SARS-CoV-2 as many of these PoC assays now test for influenza A, B, RSV and SARS-COV-2.

References:

1. Lisby, J. G., & Schneider, U. V. (2021). Point of care testing for infectious disease: ownership and quality. *Journal of Antimicrobial Chemotherapy, 76*(Supplement_3), iii28-iii32.