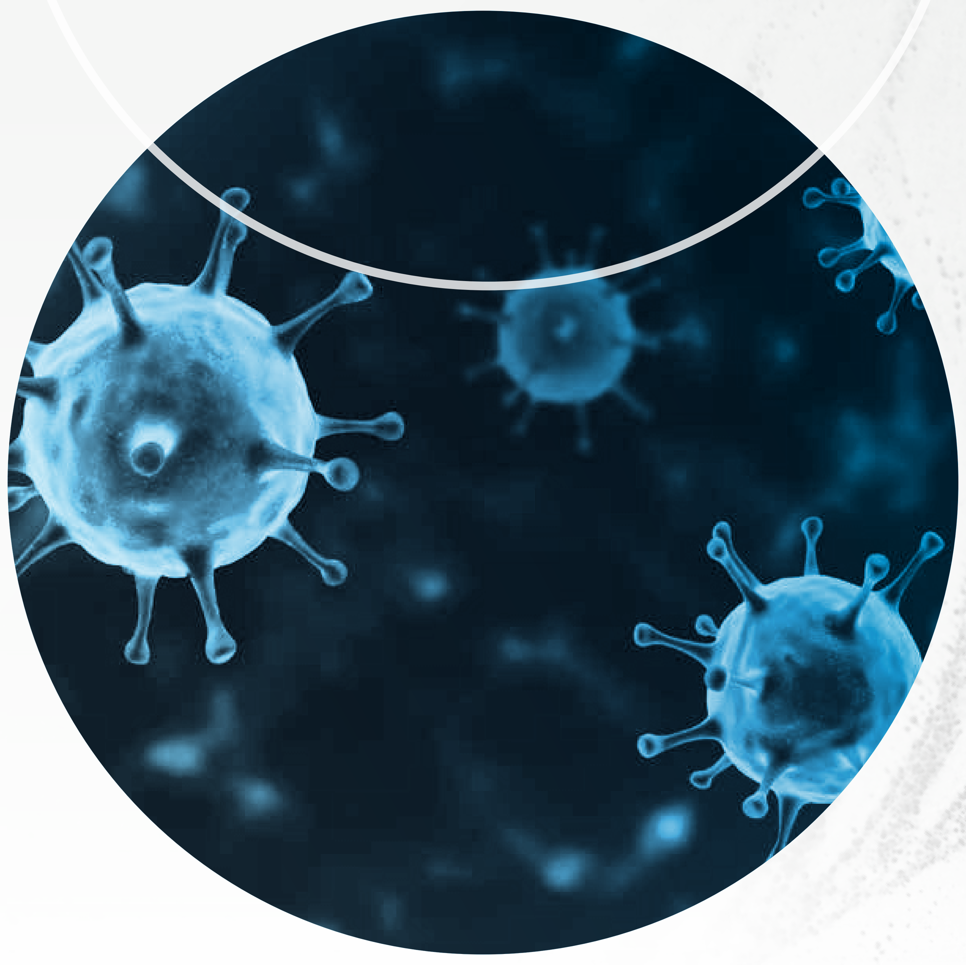
A Proficiency Testing Program for Point-of-Care Testing of Influenza A & B, RSV and SARS-CoV-2 – A 6-year Review



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Introduction

Point of care (PoC) testing is the fastest growing frontier of laboratory medicine and refers to testing performed by healthcare personnel at the site of care, which enables timely clinical decision making.[1]

As such, external quality assessment (EQA) of PoC tests is essential to ensure that these diagnostic assays are producing accurate and reliable results.[1]

In 2019, the RCPAQAP developed a program for the rapid PoC testing of influenza A & B and RSV to support molecular-based PoC assays targeting respiratory viruses. In 2023, this program was expanded to include SARS-CoV-2.

This poster presents a six-year retrospective review (2019–2024) of participation and performance trends in the RCPAQAP Molecular Rapid Diagnostics program.

Methods

The EQA program consisted of three surveys each year, with four samples per survey.

Panels included inactivated influenza A & B viruses, RSV strains, negative controls and (from 2023 onwards) SARS-CoV-2, present at varying concentrations.

Specimens were suspended in buffered saline to mimic respiratory tract samples.

Data from 2019 to 2024 was analysed to assess participation trends, assay types, reported results, and overall analytical performance.

Results

From 2019 to 2024, program participation rose 4.2-fold (87 to 366), and the number of assays used for molecular influenza/RSV/SARS-CoV-2 PoC testing increased 4.1-fold (6 to 25) (**Table 1**). Over time, participants shifted to using assays which included SARS-CoV-2 in the multiplex.

All four pathogens (influenza A, influenza B, RSV, and SARS-CoV-2) were detected at high rates with all PoC tests used (**Table 2**).

Across 17 of 18 surveys, 98–100% result concordance was observed (**Figure 1**); most discrepancies stemmed from transcription errors or sample mix-ups. Ct values were consistently reported within assay groups, supporting assay reliability.

In Survey 2 (2024), 54 participants failed to detect influenza A/H1N1pdm09 (clade 5a.2a, subclade C.1.6) due to primer/probe mismatches in two assay variants from the same manufacturer. The manufacturer deemed this detection gap as non-impacting as the influenza strain was rare in 2023.

Over the six-year period, participants were predominantly from Australia, a trend that remained consistent in the final 2024 survey (**Figure 2**).

Table 1 Summary of assays used in the final survey of 2024.

Assay Name	Total Users (Count)
Abbott ID NOW Influenza A & B 2	4
Abbott Molecular Alinity m Resp-4-Plex AMP Kit	6
AusDiagnostics Respiratory Pathogens B (16-well)	1
AusDiagnostics SARS-CoV-2 Influenza and RSV (8-Well)	1
BD Respiratory Viral Panel for BD MAX System	1
Becton Dickinson BD MAX ExK TNA-3	1
bioMerieux (BioFire) FilmArray Respiratory Panel 2.1 plus	5
Cepheid GeneXpert Xpert Xpress SARS-CoV-2	14
Cepheid Xpert Flu/RSV XC	1
Cepheid Xpert Xpress CoV-2/Flu/RSV plus	183
Cepheid Xpert Xpress Flu/RSV	29
Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV	54
CerTest Biotec VIASURE Respiratory Virus Mix I Real Time PCR Detection Kit for BD MAX System	1
CerTest Biotec VIASURE SARS-CoV-2 Flu & RSV RT-PCR Detection Kit	3
Genetic Signatures EasyScreen Respiratory Pathogen Detection Kit	1
Hologic Panther Fusion Flu A/B/RSV	2
Other (VitaPCR)	1
Roche Diagnostics Cobas LIAT Flu/RSV	7
Roche Diagnostics Cobas LIAT SARS-CoV-2	5
Roche Diagnostics Cobas LIAT SARS-CoV-2/Flu	37
SD Biosensor STANDARD M10 Flu/RSV/SARS-CoV-2	1
Seegene Allplex RV Master Assay	1
Seegene Allplex SARS-CoV-2/FluA/FluB/RSV Assay	5
SpeeDx PlexPCR RespiVirus	1
Thermo Fisher MagMax Viral RNA Isolation Kit	1

Table 2 Summary of assays used in the final survey of 2024.

Virus	Number Detected	Tests Performed	Detection Rate (%)
Influenza A	4882	4948	98.67
Influenza B	2904	2923	99.35
RSV	3315	3333	99.46
SARS-CoV-2	2255	2265	99.60

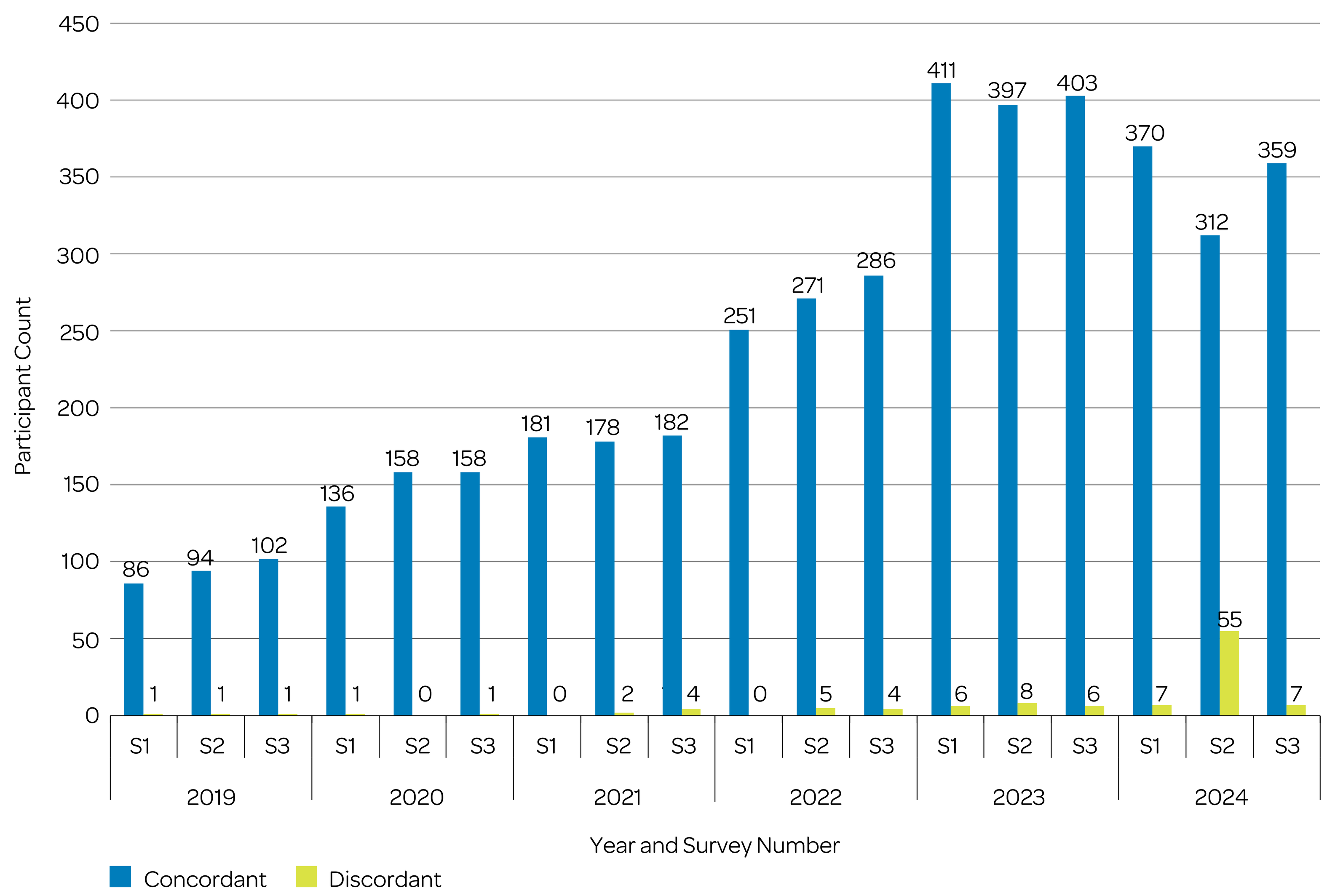

Figure 1 Participant performance from 2019–2024. Concordant refers to a participant returning correct results for all tested samples in a survey, while discordant refers to a participant that returned at least one incorrect result in a survey.

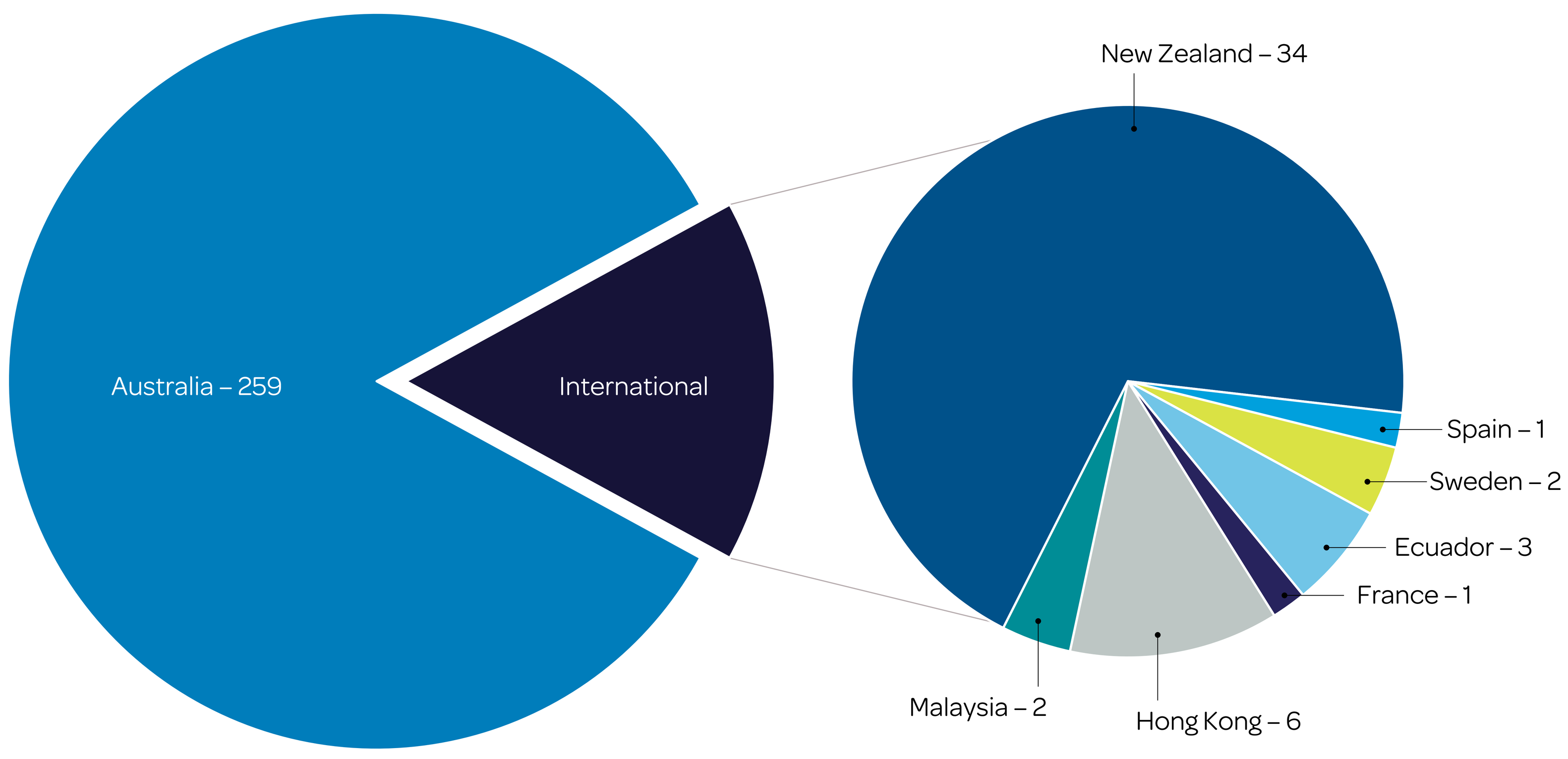

Figure 2 Participant country of origin in the last survey of 2024.

Conclusion

Increasing participation and assay diversity (with greater prevalence of assays including SARS-CoV-2) in this program suggests routine PoC testing for influenza/RSV/SARS-CoV-2 has increased over the past six years.

Participant performance was consistently high, supporting the reliability of PoC assays used in clinical settings.

Apart from Survey 2 (2024), discordant results were rare and not associated with specific assays, indicating no widespread issues with assay sensitivity or specificity.

Survey 2 (2024) underscored the need for ongoing vigilance regarding viral mutations, which may compromise assay detection and lead to false negatives.

While most participants were from Australia, the RCPAQAP continues to expand its support for international healthcare systems.

References:

1. Stavelin A, Sandberg S. Analytical performance specifications and quality assurance of point-of-care testing in primary healthcare. *Crit Rev Clin Lab Sci.* 2024;61(3):164-177.

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