Quality assurance testing for SARS-CoV-2 RNA detection in the Aboriginal and Torres Strait Islander COVID-19 Point-of-Care Testing Program

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Background

The Aboriginal and Torres Strait Islander COVID-19 Point-of-Care Testing (POCT) Program was implemented in response to the COVID-19 pandemic. The Australian Government funded the program, which commenced in April 2020 to improve access to the rapid detection of COVID-19 in regional and remote Indigenous communities, and is managed by Kirby Institute and Flinders University International Centre for Point-of-Care Testing. The program enrolled 105 health services, approved by the (then) Aboriginal and Torres Strait Islander Advisory Group, and utilised SARS-CoV-2 RNA testing on the Cepheid GeneXpert®.

Consistent with the National Pathology Accreditation Advisory Council (NPAAC) requirements for POCT in Australia, trained and competent POCT health service operators performed external quality assurance testing (EQA) to ensure analytical performance was acceptable. A bespoke EQA program was developed collaboratively with the Royal College of Pathologists of Australasia Quality Assurance Programs (RCPAQAP) to comply with these requirements.

Methods

EQA surveys were prepared approximately every 3 months, with each survey consisting of 2 blinded samples; a SARS-CoV-2 positive (of variable viral loads) inactivated by gamma irradiation, and a negative sample. The material was suspended in 800µL of buffered saline to simulate a respiratory sample. Different SARS-CoV-2 variants were included in the positive EQA samples as they became of concern. The samples were laboratory tested prior to dispatch. Each survey was shipped from RCPAQAP to the enrolled health services for testing, with detailed instructions for sample testing and result submission.

Figure 1; Survey 7 SARS-CoV-2 EQA samples as manufactured by the RCPAQAP to participating health services. Source: Courtesy of RCPAQAP.

EQA samples were tested at participating health services by trained and competent POCT operators using the Xpert® Xpress SARS-CoV-2 assay on the Cepheid GeneXpert®.

Figure 2: GeneXpert platform and Xpert® Xpress SARS-CoV-2 cartridge. Used with permission from Cepheid.

Results were submitted via manual EQA result forms or online entry to the POCT Program Help Desk for collation, then forwarded to the RCPAQAP for analysis. Generic and individual site EQA reports, designed collaboratively by the RCPAQAP and COVID-19 POCT team, were issued and facilitated review of overall program performance and site performance. Individual site reports showed analytical performance compared to other deidentified enrolled services.

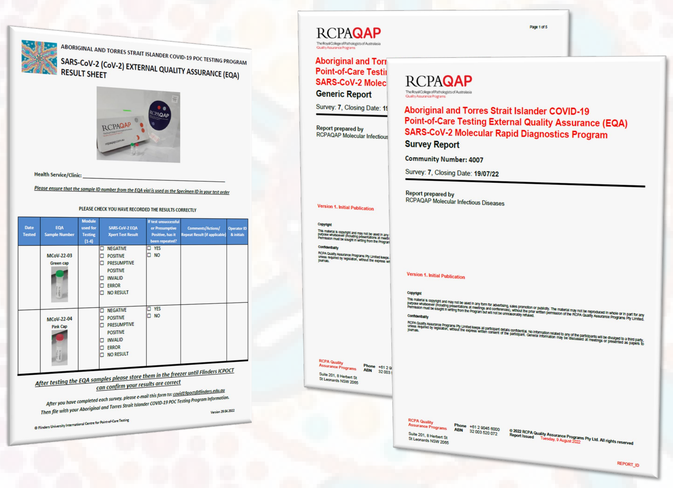

Figure 3: COVID-19 EQA result sheet (ICPOCT), generic and individual site report for Survey 7 (RCPAQAP)

Results

Seven EQA surveys were completed from mid-2020 to mid-2022. The mean participation rate of eligible health services was 93.4% and ranged from 91.0% (n=81, survey 6) to 98.9% (n=86, survey 5).

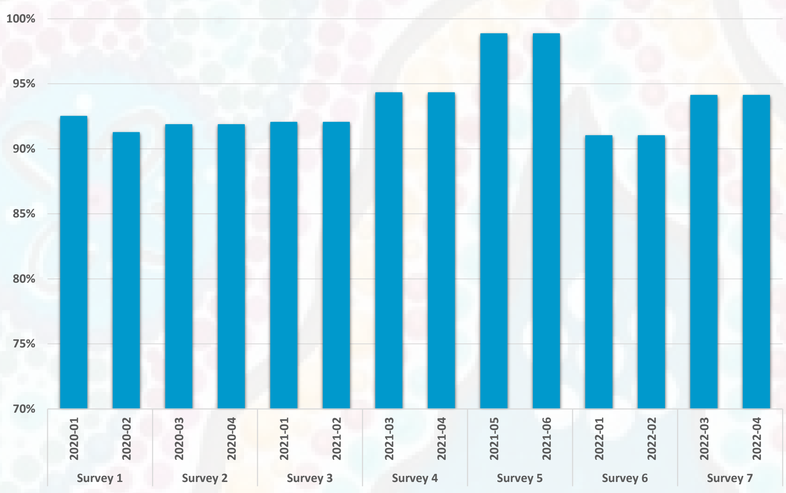

Figure 4: Percentage of eligible enrolled sites who submitted results for EQA Survey 1 to 7.

For positive EQA samples, mean concordance was 98.3% (range 91.9-100%); while for negative samples, the mean concordance was 98.4% (range 94.5-100%). Concordance of each EQA survey improved from Survey 1 (93.2%) to Survey 2 (98.8%) and remained consistent across Surveys 3 to 7 (99%, range 98.8-100%).

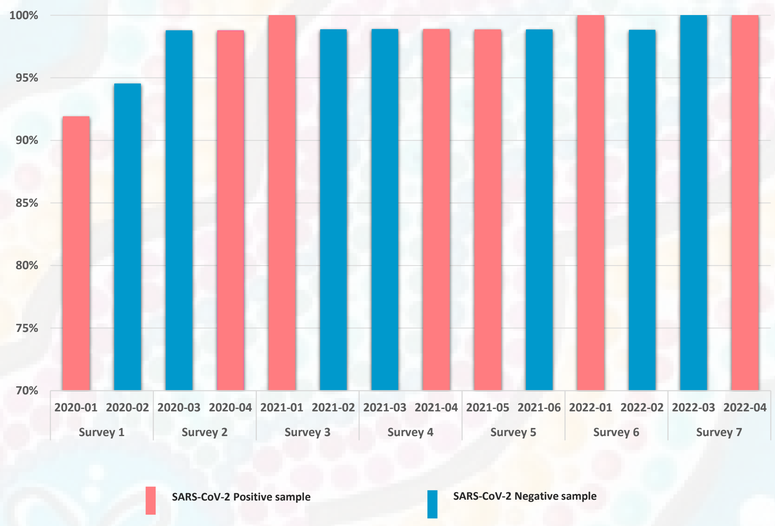

Figure 5: Concordance of first-run results returned from eligible participating health services for Surveys 1 to 7.

While the Xpert® Xpress SARS-CoV-2 assay has been approved as a qualitative test, cycle threshold (Ct) values for positive EQA samples were also submitted to RCPAQAP for analysis. Comparison of single positive Ct values for the envelope (E) or nucleocapsid (N2) gene targets across eligible health services were generally consistent. This data was reported in the generic report only, provided internally to the COVID-19 POCT Program.

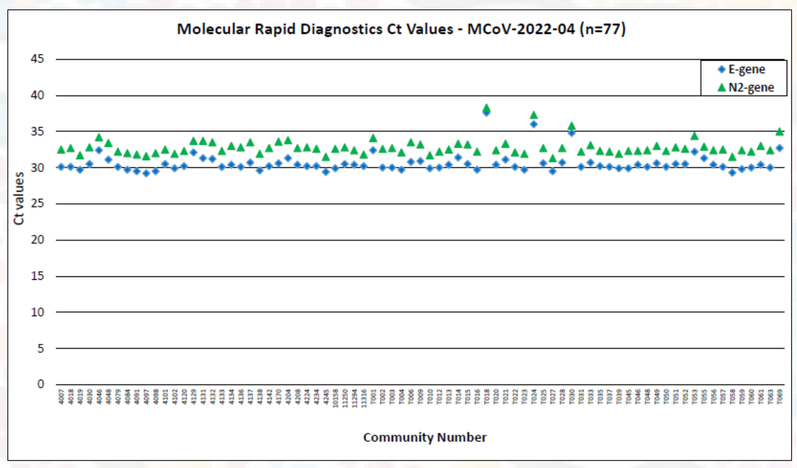

Figure 6: SARS-CoV-2 cycle threshold (Ct) values for Envelope (E) and Nucleocapsid (N2) positive EQA sample (MCoV-2022-04) across deidentified community numbers (Survey 7 RCPAQAP generic report).

Conclusion

This customised EQA program demonstrated that trained and competent, non-laboratory POCT operators can perform SARS-CoV-2 RNA testing in primary care settings to a high analytical standard.

From Survey 8 2022, the EQA material has been modified to include four samples per survey, with mixed positive and negative respiratory virus panel consisting of influenza A, influenza B and respiratory syncytial virus (RSV) in addition to SARS-CoV-2. The change in EQA material coincided with transition of the program to the use of Cepheid Xpert® Xpress SARS-CoV-2/Flu/RSV assay and program name change to Respiratory Infection POCT Program, following COVID-19 POCT operator training and re-certification.

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