Challenges in External Quality Assessment for Infectious Diseases Point-of-Care Testing

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Introduction

The recent SARS-CoV-2 pandemic drove point-of-care (PoC) assay development for the detection of infectious diseases, while also increasing the acceptance of molecular based PoC testing results.

To ensure reliable and accurate test results, testing sites must ensure assays are operated correctly and that the entire process including patient identification, result interpretation and reporting is correct.

Consequently, the Royal College of Pathologists of Australasia Quality Assurance Programs (RCPAQAP) provides external quality assessment (EQA) for pathology laboratories worldwide. EQA enables a comprehensive assessment of the entire testing process, although PoC-based assays and instrumentation offers a unique set of challenges.

Method

Conventional EQA involves sending a panel of samples to a laboratory to test within a routine run, with results being reported in a routine way. PoC testing is performed 'at patient side' and includes remote and non-laboratory settings. The testing is inherently less routine and encounters varying sensitivities. Therefore, EQA for PoC assays must consider these specific challenges to produce a useful program.

To ensure the appropriateness of EQA programs made for PoC testing, a review of the considerations required to develop a PoC EQA was undertaken.

Results & Discussion

A collaborative EQA program, delivered to regional and remote areas, served as a case study to highlight challenges of a PoC EQA program[1].

Four areas were identified as challenges, each containing multiple points for consideration. The main areas include samples, logistics, testing, and reports (**Figure 1**). Each area was expanded to suggest mitigation strategies for each challenge (**Table 1**).

Samples

- Simulate clinical samples
- Number/Frequency/Volume
- Pathogens/Strains
- Pathogen concentration
- Safety (infectious material)
- Survey design (neg/pos)

Logistics

- Remote site delivery
- Site contact information
- Time frame/Delivery delays
- Sample stability
- Site sample storage

Testing

- Importance of EQA
- Clear test instructions
- Simulate routine procedures
- Trained operator/availability
- Result interpretation/reporting
- Safe handling

Reports

- Simple vs comprehensive
- Generic vs individual
- Access/delivery of report
- Educational component
- Troubleshooting guide

Figure 1 Challenges for EQA Providers.

Table 1 Mitigating Challenges in developing PoC EQA.

Challenge Type	Challenge	Mitigate Challenge
Sample		
Concentration	PoC assay sensitivity possibly lower than laboratory-based tests[2]	Clinically relevant concentrations, (too weak – erode operator confidence/ too strong potential contamination)
Content	Cater for different PoC assay testing methods	Sample includes whole virus, designed to mimic clinical specimen
Matrix/Format	Simulate clinical samples	Liquid samples (eluted swab)
Number	Too much/not enough	Review number of samples
Pathogens	Meet current community needs, circulating strains	Include current/relevant strains included in tests
Safety	Infectious material	Inactivation/removal of infectious components
Survey design	Contamination detection	Include negative samples
Survey frequency	Too much/not enough	Review how often required
Volumes	Repeat/multiple testing	Sufficient volumes
Logistics		
Delays	Periodic delivery	Allow for delivery delays in survey testing period
Remote sites	Difficult to determine	Correct address/contact details
Stability	Ensure sample stability	Confirm stability at transit temperatures
Storage	Correct storage of material, No access to -70°C freezer	Clear labelling and instructions; Test immediately/store in fridge
Testing		
Assay Capacity	Single site might have multiple PoC devices to provide higher throughput	Allow participants to enrol multiple devices under the same site
Control	Ensure internal controls are triggered	Build into sample design
Operator	May not be fully trained	Ongoing education, training, retesting
Operator	Accountability in multi-user sites	Result submission keeps track of the submitting operator
Operator	EQA perceived as non-mandatory	Convince EQA is important
Operator	High staff turnover	Clear instructions, delivered with samples
Operator	Not used to performing regular EQA	Clear instructions and due dates delivered with samples
Result interpretation & reporting	Report results in a different format than usual (ie not directly to patient)	Clear instructions, checking steps
Safe handling	Consider safe handling and disposal of samples	Clear instructions
Reports		
Return/access	Reach PoC operator	Correct site contacts
Style	Simple vs comprehensive, Generic vs individual	Ability to customise reports to requirements. Include historic results for reference, troubleshooting guidance

Conclusion

Developing appropriate EQA for PoC assays is fundamental for ensuring PoC testing sites produce accurate results.

It is important that testing sites understand the importance of EQA and the challenges that are considered in providing suitable programs.

References:

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2. Iglesias-Ussel, M. D., Bowie, A., Anderson, J. G., Li, Y., Park, L. P., Cardona, J. F., ... & Woods, C. W. (2025). Clinical performance of Abbott ID NOW™ COVID-19 2.0 rapid molecular point-of-care test compared to three real-time RT-PCR assays. Microbiology Spectrum, e02033-24.

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