Designing quality assurance samples suitable for point of care testing

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Background: Rapid Diagnostic Tests (RDT) in use at Point of Care (POC) are available for a range of infectious diseases. However, their use was popularised as part of Australia's public health strategy over 2021 with the emergence of SARS-CoV-2. Unfortunately, Quality Assurance (QA) programs in POC testing services are rarely used, despite the importance they hold in laboratory settings. NRL designed a fit-for-purpose QA program, with samples designed to meet the conditions at POC testing services.

Methods: Two sample types were developed to address separate projects; a dried, whole blood sample for use with a hepatitis C virus (HCV) molecular assay, and a nasal analogue for use with SARS-CoV-2 antigen RDTs. The robustness of both sample types was assessed for stability and ease of use, considering that POC testing services lack the infrastructure of diagnostic laboratories.

Results: HCV positive, dried whole blood samples were stored at three different temperatures (2-8°C, 21-25°C and 35-37°C) for a period of six months. The viral load results of these samples showed no statistically significant difference (*p*-value = 0.668) at the three storage temperatures. SARS-CoV-2 antigen positive samples were also stored at three temperatures (5°C, 25°C and 45°C). The samples stored over a 21-day period at 5°C and 25°C were consistently interpreted as "COVID-19 antigen positive". The SARS-CoV-2 materials did not require any additional equipment to test, while the dried whole blood samples required an additional transfer pipette and reconstitution buffer vial.

Conclusion: QA should be included with all POC testing services to detect and troubleshoot testing errors. The stability of the samples in NRL's POC QA program are supplied without requiring additional infrastructure. Thus, QA programs supplied to POC testing services assures confidence in the results generated at POC test sites.

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