In vitro performance assessment of Check✓IT LAMP assay for SARS-CoV-2

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Background: The WA state pathology service provider (PathWest) in conjunction with The University of Western Australia, is evaluating a range of novel point of care (POC) COVID tests for use in regional communities where conventional molecular diagnostic methods are difficult to implement. Rapid antigen tests used in these settings lack the sensitivity or negative predictive value of nucleic acid amplification tests. An isothermal loop mediated amplification (LAMP) test for SARS-CoV-2 presented an attractive alternative.

Methods: De-identified specimens previously tested for SARS-CoV-2 by conventional PCR assay (COBAS) were tested in the single-use LAMP assay (Check✓IT, Lucira Health Inc, USA). Residual viral transport media (VTM) specimens were sampled with a swab (COPAN) to inoculate the Sample Vial. After mixing, the Sample Vial was connected to the Test Unit and left until test completion. The qualitative reaction outcome was compared with COBAS PCR after completion of LAMP.

Results: 42 specimens were tested, with Ct values ranging from 22 to 35 by in-house COBAS two-target protocol. 33 PCR positives were LAMP positive, seven PCR negatives LAMP negative and two PCR positives LAMP negative. As these results were from the original COBAS PCR, VTM used for the LAMP swabs was checked on a separate PCR run for both LAMP discrepant results. These repeat COBAS PCR results were negative, consistent with a dilution effect during transfer of stored specimens into fresh transport medium. There was thus 42/42 conformity between COBAS PCR and LAMP outcomes.

Conclusion: In this preliminary *in vitro* assessment of a LAMP single use SARS-CoV-2 assay, LAMP test outcomes matched qualitative COBAS PCR results in all paired comparisons. If this level of conformity can be demonstrated in a clinical setting, this easy-to-use POC SARS-CoV-2 test will be suited to use in regional locations where no molecular diagnostic capability currently exists.

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