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

Inglis TJJ[1,2,3,4], Paton TF[1,5], Carson CF[2,1]

1. PathWest Laboratory Medicine WA, QEII Medical Centre, WA,
2. School of Medicine, University of Western Australia, Crawley, WA,
3. School of Biomedical Sciences, UWA, Crawley, WA,
4. WA Country Health Service, Perth, WA,
5. Harry Perkins Institute of Medical Research, Nedlands, WA.

Competing interests

- Check✓IT LAMP tests provided by Lucira Health Inc.
- In vitro assessment by WA state pathology service (TJJI and TFP)
- Financial support through
  - an NH&MRC IDEAS project grant: adaptive diagnostics for emerging pandemic threats (ADEPT), managed by UWA
  - WA Country Health Service Translation Fellowship, FHRI

Australian Government
National Health and Medical Research Council

GOVERNMENT OF WESTERN AUSTRALIA
Western Australian Future Health Research & Innovation Fund

SEEK WISDOM

Problem

- Centralised molecular diagnostic service
- COVID-19 diagnosis in regional, rural & remote communities
- Poor sensitivity of 1st gen RATs

Potential solution

- Project ADEPT
- POC nucleic acid amplification
- Compact, battery-powered isothermal loop-mediated amplification (LAMP) test

Methods

- De-identified archive specimens
- Previously tested for SARS-CoV-2 by PCR assay (COBAS)
- Tested with single-use LAMP assay (Check✓IT, Lucira Health Inc, USA)

- Sample Vial inoculated with residual viral transport media specimens
- Mixed, then connected to Test Unit + left until completion
- Qualitative reaction compared with COBAS PCR afterwards

Results

- 42 specimens
- Ct values ranging from 22 to 35 by in-house COBAS protocol

- 33 PCR positives were LAMP positive
- Seven PCR negatives LAMP negative
- Two PCR positives LAMP negative.
  - Discrepancies checked by COBAS PCR: both negative
  - Likely dilution effect during transfer into fresh VTM

Overall: 42/42 conformity between COBAS PCR and LAMP

Initial	PCR +	PCR -
LAMP +	33	0
LAMP -	2	7

FE: $P < 0.0001$

Checked	PCR +	PCR -
LAMP +	33	0
LAMP -	0	9

Conclusion

- easy-to-use POC SARS-CoV-2 NAA test
- suitable for regional use outside a fixed laboratory
- where there is no current molecular diagnostic capability