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Establishing deployable, flexible diagnostic PCR capacity in remote and rural settings:

A pilot project for SARS CoV-2 diagnosis in the Kimberley region

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31 August 2022

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Western Australia: It's a big state

- 2,525,500 km²
- 2,400 km north to south
- Population 2,760,000
- 79% reside in the metropolitan area
- Tropical north, arid central regions, temperate south

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Background

- Western Australia is unique within Australia in geography, size and demographics
- This presents significant challenges in delivering high quality, timely diagnostic services
- The COVID 19 pandemic presented challenges to clinical laboratory services
- COVID-19 diagnosis heavily reliant on centralized molecular diagnostic services in Perth
  - Vast distances
  - Extended turnaround time may delay patient management and limit public health response
- Rapid GeneXpert had been rolled out to the regions – limited to urgent testing in situ, low throughput, limited range of pathogens, expensive, logistics of support is tricky
- Needed a different approach to provide a robust and sustainable service

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Rationale – Mobile Laboratory

- We sought to develop mobile molecular diagnostics capability for deployment to the regions in times of high demand
- Decentralisation of molecular diagnostics capability
- Medium throughput, high flexibility, open (non-proprietary) assay compatibility
  - Bridges the gap between GeneXpert and high-throughput centralised testing
  - More readily adaptable to changes in viral genome that reduces reliability
- Portable – simplifies logistics: anywhere in the state within 48 hours
- Energy efficient – for use in austere contexts
- Simple workflow – simplifies training and operations
- Value – ongoing utility post-pandemic

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The equipment

Liquid handling → Myra (Biomolecular Systems) chosen → Small footprint, fast and accurate, light, robust

Nucleic acid extraction → Tested several extraction chemistries that were one or two-step. Claims of 5 minutes processing not sustained. Poor at removing inhibitors. Reverted to more conventional process using Kurabo QuickGene-mini-480

Small footprint, semi-automatic, low current draw (no centrifugation), 48 samples per run, low cost

Thermal cycling → Magnetic Induction Cycler (Biomolecular Systems) chosen

Small footprint, fast and accurate, light, robust

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Selecting the test kit

- Due to COVID-19 pandemic, only one potentially suitable kit was available
  - Co-diagnostics Logix Smart SARS-CoV-2 (USA)
- Sensitive, specific and robust:
  - Co-primer tech increases specificity
  - Dual target and internal control
  - Stable at room temperature for up to two days, refrigerated 2 weeks
  - Claimed high sensitivity and specificity

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Within laboratory validation in Broome

- Analytical Sensitivity
  - 1.01 copies / µL, 5.05 copies per reaction (95% LLoD)
  - Exceeded manufacturer claims by almost 1 order of magnitude
- Specificity
  - 56 non-SARS-CoV-2 targets, including commensals / pathogens
  - No cross reactivity with endemic coronaviruses
  - Cross reactivity with SARS-CoV (low efficiency)
- Clinical samples: 100% sens / 100% spec vs. in-house PCR (PathWest) on 103 positive and 104 negative URT samples

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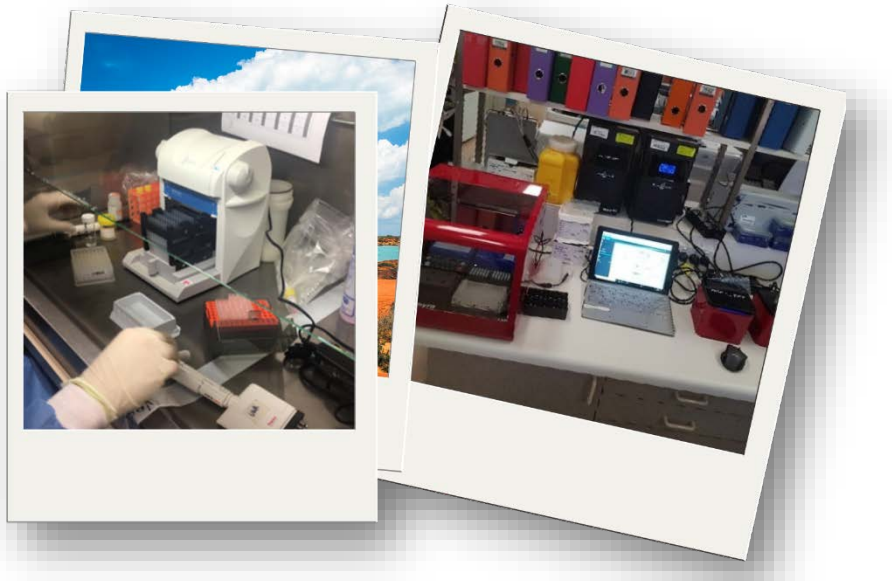
Field evaluations

Field trial 1

Conducted in June 2020 in Broome and Derby

- Parallel testing with routine workflow
- 2 days in each site
- The equipment was transport between Broome and Derby by road



Field trial 2

Conducted with the Department of Defence

- August 2020 – fly in-fly out Perth to Broome and Derby
- Depart Perth 04:30
- Arrive Broome, deploy equipment and perform calibration check
- Drive to test site (two hours), collected and register 30 samples, return to PathWest Broome, conduct testing
- Dep Broome 19:30
- Samples retested in Perth

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Lessons learned

- Climate is a hindrance!
  - Ambient temp 33°-36°C. Difficult to maintain refrigeration. Dry ice scarce
  - Investigating sub-zero phase change materials for better temperature stability
- Human RNA poor inhibition control for assay – affected by quality of collect
  - All samples retested in Perth in the Co-diagnostics assay and Smart SARS-CoV-2 kit and in-house using MS-2 phage inhibitor control

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Conclusion

- Efficient moderate-high throughput PCR testing for SARS-COV-2 can be established in small regional laboratories to support services to rural and remote communities
- Similar technology can be deployed to remote areas to assist outbreak investigation.
- Decrease TATs by up 1+ days – improves patient and public health management, especially in time critical scenarios
- Service can be provided anywhere in the state in 48 hours

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What's next?

- Further development of QC infrastructure
- Training for additional staff
- Pandemic
  - Outbreak investigation
  - Faster PH response
- Regional deployment
  - Military
  - Maritime
  - High-risk communities
- Post-pandemic
  - Open-platform system – expansion to other pathogens – respiratory viruses, group A Streptococci, AMRO
  - Easy validation
  - Future epidemic response

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Acknowledgements

- Tegan Paton – PathWest QEII
- Tim Inglis – PathWest QEII
- David Speers – PathWest QEII
- Zoe O'Keefe – PathWest QEII
- Mark Steicke – PathWest Derby
- Ray Brockenshire – PathWest Broome
- Ian Marr – Menzies School of Health
- Lab Without Walls
- Northern Star Resources
- Dept of Premier and Cabinet

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Q & A