Designing Quality Assurance Samples suitable for Point-of-Care Testing

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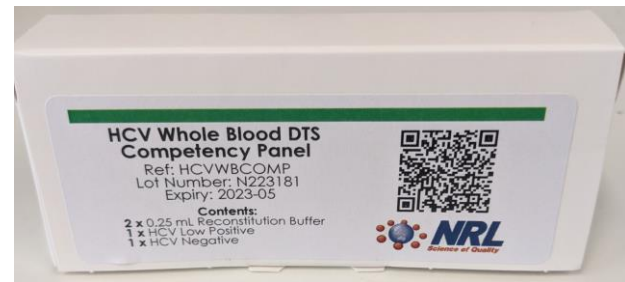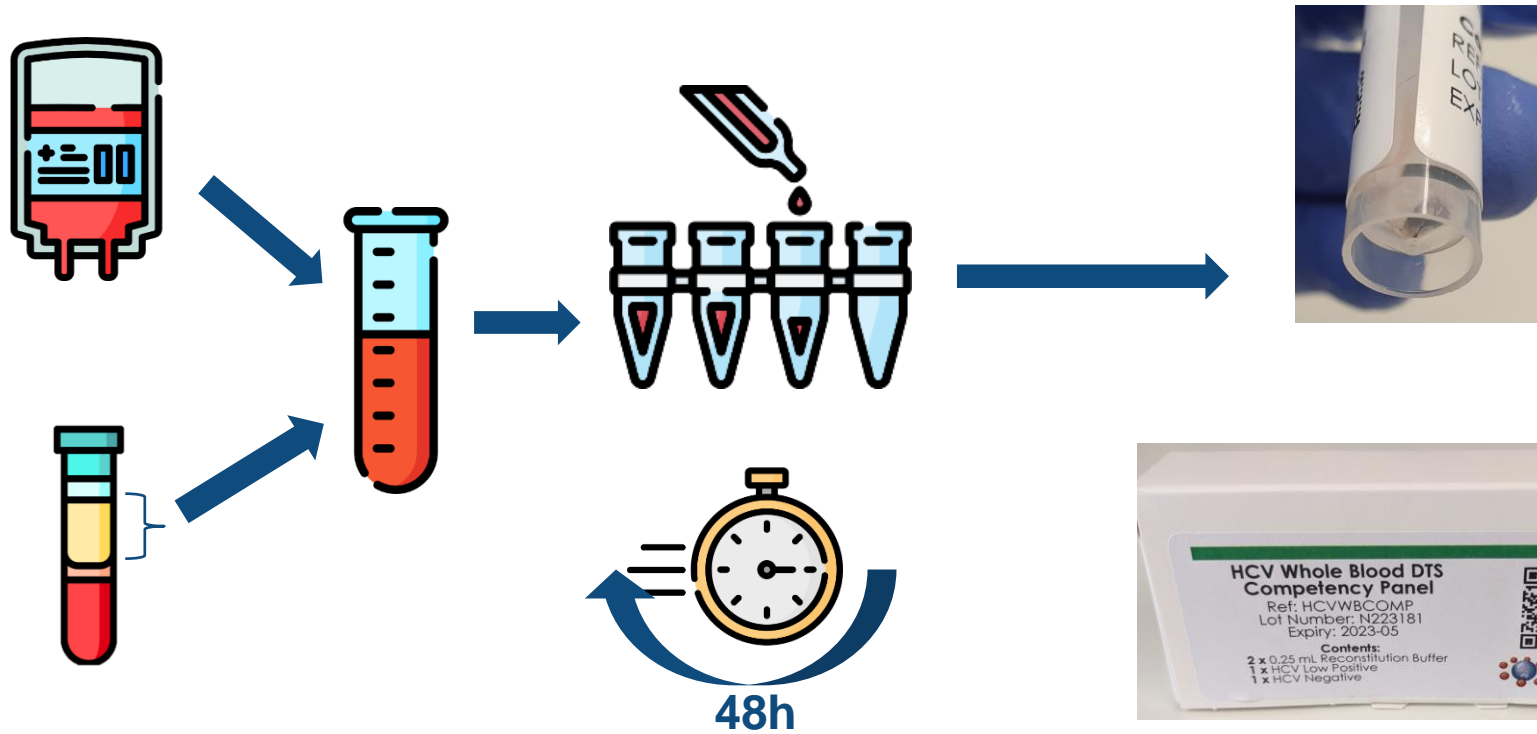
NRL
Science of Quality

What is Quality Assurance?

- Check correct function of tests & instruments
- Independent confirmation of staff competency
- Part of the Quality Management System

Comparison of testing conditions

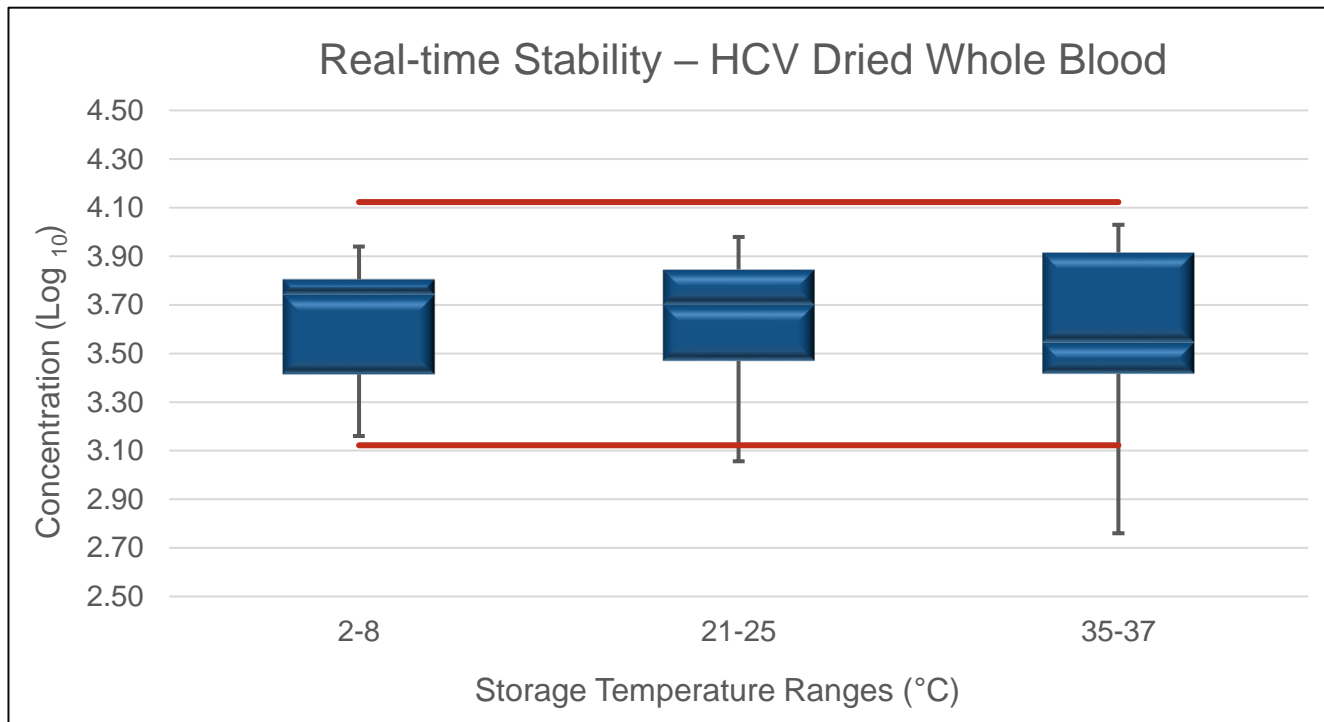|	In laboratory	At POCT site
Appropriate sample storage (e.g. freezer)	✓	±
Stable environmental conditions	✓	✗
Ease of shipping (e.g. overnight delivery)	✓	±
Specialised equipment	✓	±
Feedback loop to manufacturer on test kit performance	✓	✗

Manufacture – HCV

48h

Icons made by Freepik from www.flaticon.com

HCV Whole Blood DTS
Competency Panel
Ref: HCVWBCOMP
Lot Number: N223181
Expiry: 2023-05
Contents:
2 x 0.25 mL Reconstitution Buffer
1 x HCV Low Positive
1 x HCV Negative

4

Manufacture – SARS-CoV-2

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Real-time Stability – HCV
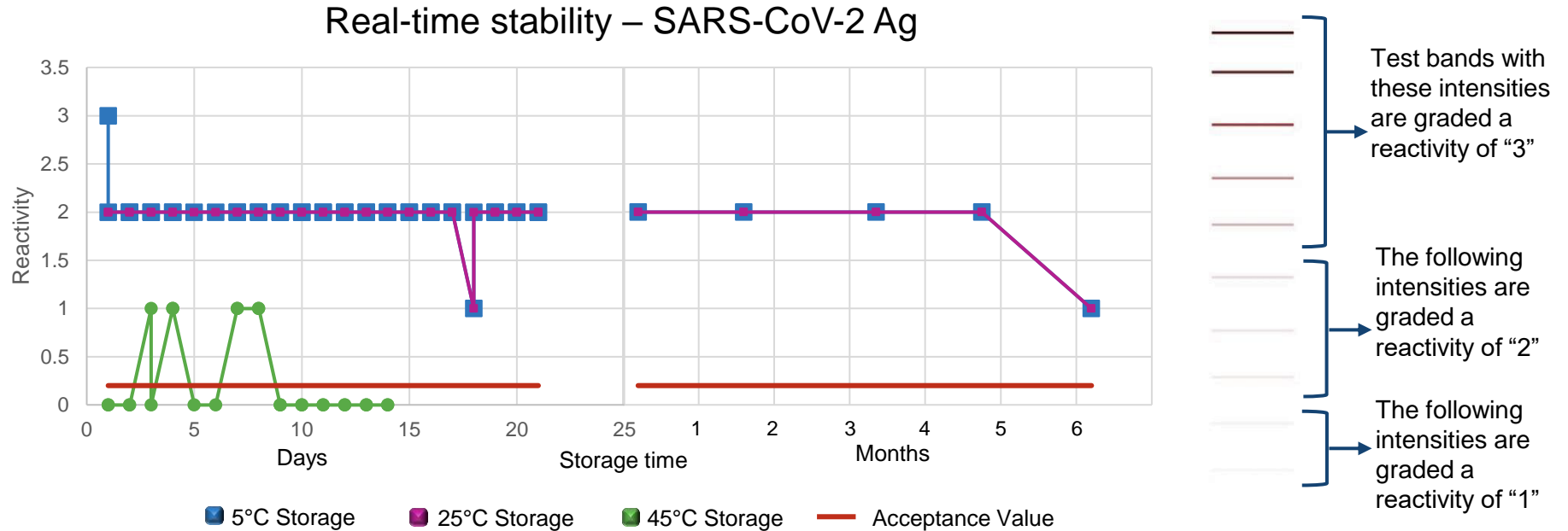

Real-time Stability – HCV Dried Whole Blood

Data was collected over a period of six months.

Whiskers represent the highest and lowest values recorded for each storage condition.

Red reference lines denote upper and lower acceptance values.

Real-time Stability – SARS-CoV-2

Real-time stability – SARS-CoV-2 Ag

Note: any point ABOVE the red line is interpreted as "COVID-19 Positive"

Conclusions

- Material stability allows POCT sites to participate in QA activities

- Participation in QA activities provides:
  - assurance of the quality of POCT
  - evidence of competence in the individuals performing testing
  - access to technical knowledge

- Contributes to **Confidence** and **Trust** in results from POCT sites

Acknowledgements

- National Australian HCV Point-of-Care Testing Program
  - International Centre for Point-of-Care Testing (Flinders University, South Australia)
  - The Kirby Institute (UNSW, New South Wales)
- Access to COVID-19 Tools Accelerator
  - Foundation for Innovative New Diagnostics (Geneva, Switzerland)
- Technology Partners
  - Cepheid (Sunnyvale, USA)
  - Abbott Rapid Diagnostics (Jena, Germany)

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- Check out Poster Number 4 *Implementation of a fit-for-purpose point of care Quality Assurance Program* for more features