HCVPOCT

National Australian Hepatitis C Point-of-Care Testing Program

Evaluation of operator training and quality management for point-of-care testing for hepatitis C infection.

Sub study funded by CRE Rapid

Corey Markus

Research Officer

International Centre for Point-of-Care Testing

Flinders University

2021: Flinders University International Centre for Point-of-Care Testing Staff

RAPID Point of Care Research Consortium for infectious disease in the Asia Pacific | ashm | UNSW AUSTRALIA | Kirby Institute | ST VINCENT'S CENTRE FOR APPLIED MEDICAL RESEARCH | Flinders University | FHMRI

Demonstration Study

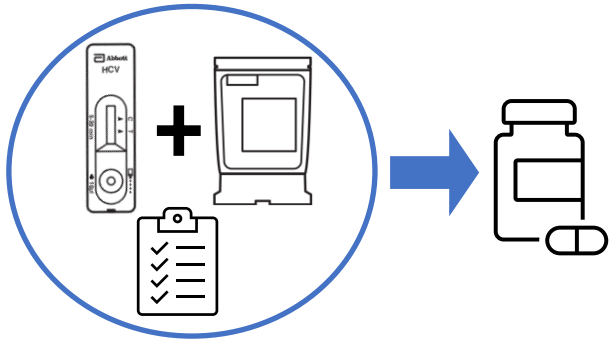
The National Australian HCV Point-of-Care Testing Program

Primary Objective

To evaluate the proportion of HCV RNA positive participants who initiate HCV treatment within 12 weeks of finger-stick point-of-care HCV RNA testing.

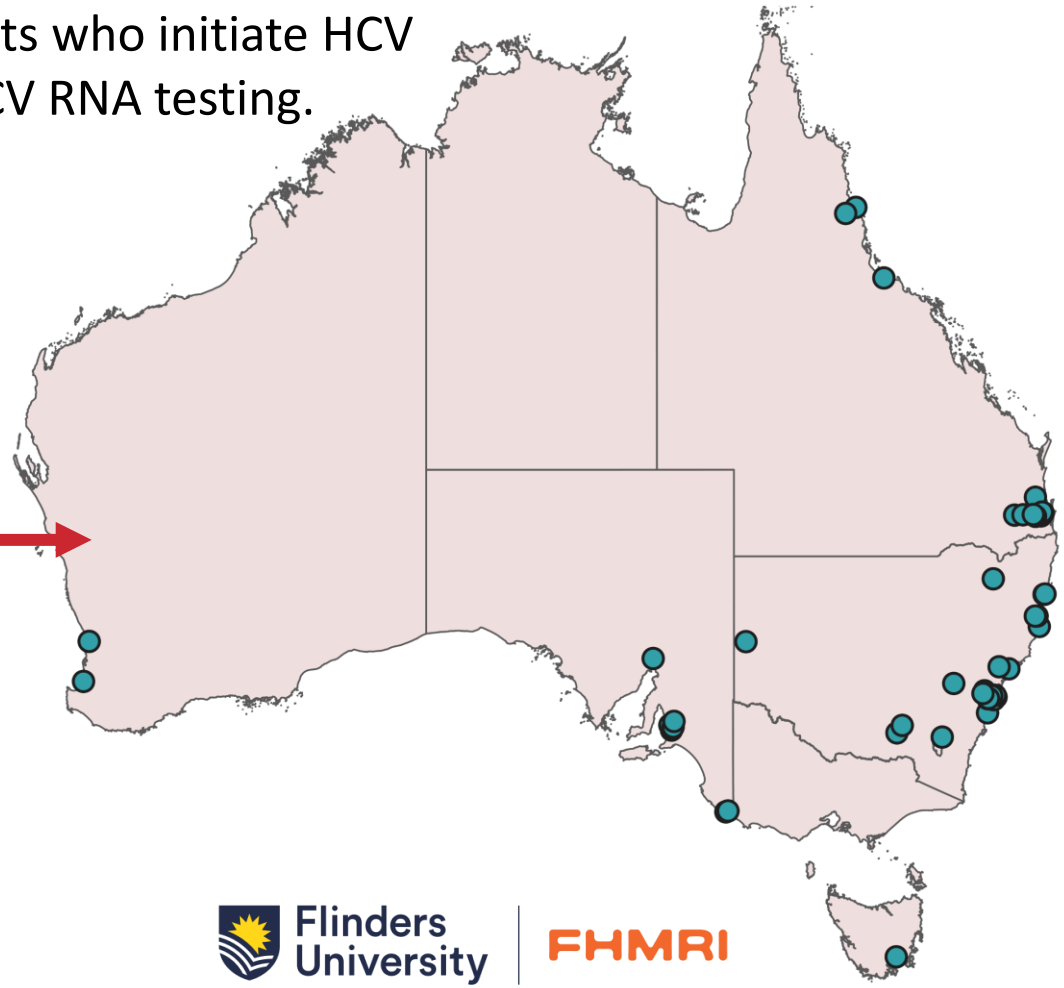
HCVPOCT

National Australian Hepatitis C Point-of-Care Testing Program



Rapid anti-HCV antibody test with reflex HCV RNA test with diagnosis (Health Care Workers)

58 Sites



Flinders University | FHMRI

Grebely *et al*, (2017) Expert Review of Molecular Diagnostics.

GeneXpert HCV VL Fingerstick Assay

- *In vitro* reverse transcription polymerase chain reaction (RT-PCR) assay for the detection and quantification of HCV RNA
- Able to detect HCV infections in capillary blood using Minivette® in 58 minutes
- Conditions of TGA certification:

a. NATA medical testing laboratories with HCV EQA participation; OR
b. organisations that:
i. **train health professionals** to perform and **supervise HCV testing**; and
ii. have established referral and testing pathways with NATA accredited lab; and
iii. **Participate in HCV External Quality Assurance (EQA)**

Low Risk	IVD Classification	Risk	Example
	Class I	No public health or low personal risk	Glucose Meter
	Class II	No public health or moderate personal risk	Pregnancy/Fertility self-test
	Class III	Moderate public health or high personal risk	Prothrombin Time test strip/cartridge
High Risk	**Class IV**	**High public health risk**	**Molecular HCV, HIV cartridge or blood bank screening tests**

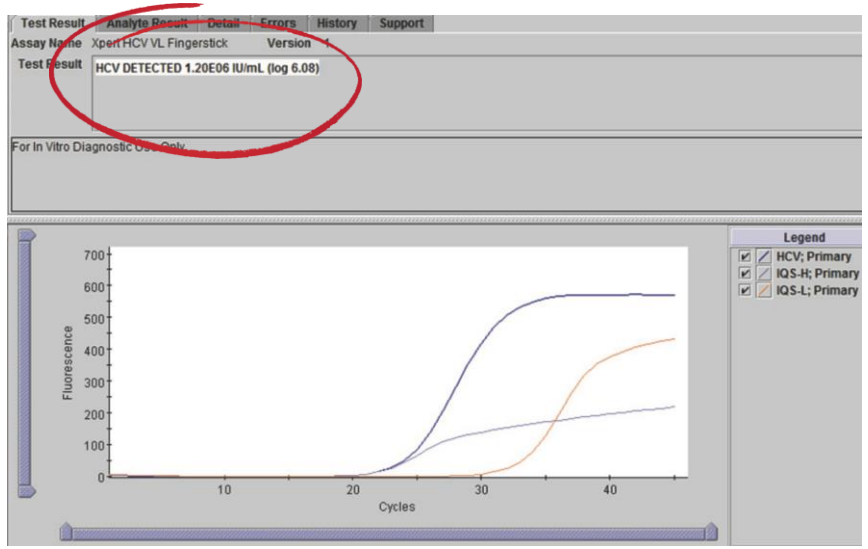
100µl fingerstick EDTA

Closed cartridge HCV VL assay

Random Access GeneXpert NAAT (RT-PCR)

58 mins

HCV RNA Detection/Quantification (IU/ml)



Development Of Training Resources

NPAAC TIER 4 DOCUMENT

REQUIREMENTS FOR POINT OF CARE TESTING

(Second Edition 2021)

3. Training and competency

PoCT operators must be competent to perform PoCT in the local healthcare setting and be able to have confidence in the test result itself. Therefore, it is critical that staff have the necessary training and skills to perform such testing.

S3.1 PoCT must only be performed by operators who have undertaken relevant approved training and demonstrated that they are competent.

C3.1(i) The organisation responsible for providing the PoCT service **must** have an approved training program.

C3.1(ii) The training program **must** include but not be limited to the following areas:

(a) procedures for safely and competently performing patient tests and interpreting the validity of PoCT results

(b) education and training that covers common sources of error, including the source of pre- and post-analytical errors

(c) conducting quality control and quality assurance to regularly assess analytical quality of the PoCT device

(d) general awareness of privacy and confidentiality of patient information

(e) workplace health and safety as it relates to PoCT.

C3.1(iii) Records of staff PoCT training, retraining and competency **must** be maintained.

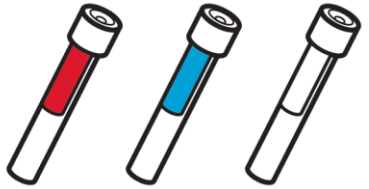
C3.1(iv) Competency **must** be reassessed after training at regular intervals and when new PoCT devices (different model or manufacturer) are deployed.

C3.1(v) PoCT operators **must** receive training updates when a competency issue with that operator is identified or where the PoCT operator performs testing infrequently.

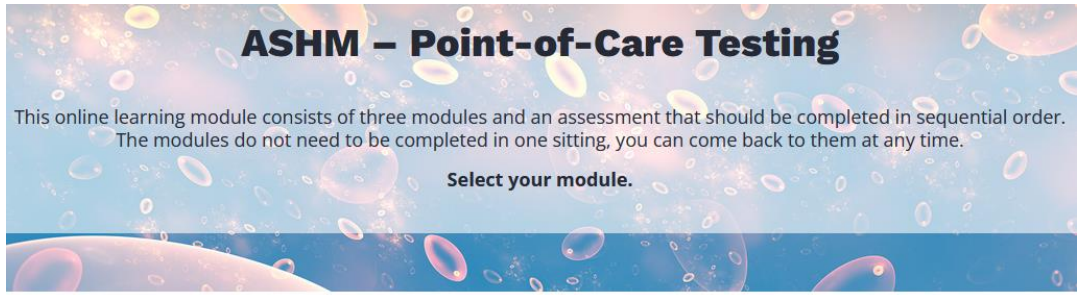
SOP Development

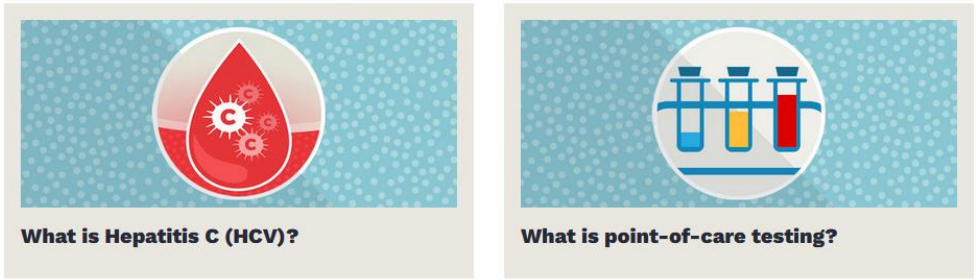
Flinders University | FHMRI

Overview Of Operator Education and Training



SOP Dev. → **ASHM OLM (30 mins)** → **Theory Sessions (2 hrs)** → **Theory Test (15 mins)** → **Practical Test (1.5 hrs)** → **Competent Operator**





Competency in performing the test + **Confidence in test results**

Flinders University | FHMRI

Study Design - Evaluation of operator training & quality

Questionnaire topics:

Ensuring people at risk are screened
Interpreting results and diagnosing HCV
Collecting capillary samples
Performing HCV POCT
Operation and maintenance of GX

Study Visit	Screening (Enrolment)	ASHM Pre-requisite OLM	GeneXpert Theoretical Training	GeneXpert Practical Session	6-month Post-training Review
Questionnaire (Screening)	X				
Questionnaire (Follow-up)		X	X	X	X
Responses (n =)	98	77	55	39	4

Qualitative data analysis

Frequency of participant responses at each stage
Self-perceived competency assessed at each stage
5-part Likert scale then dichotomised
6-month post-training review in progress

Quantitative data analysis

Data extraction from Program data base
QC and EQA participation and concordance
Valid tests and error rates

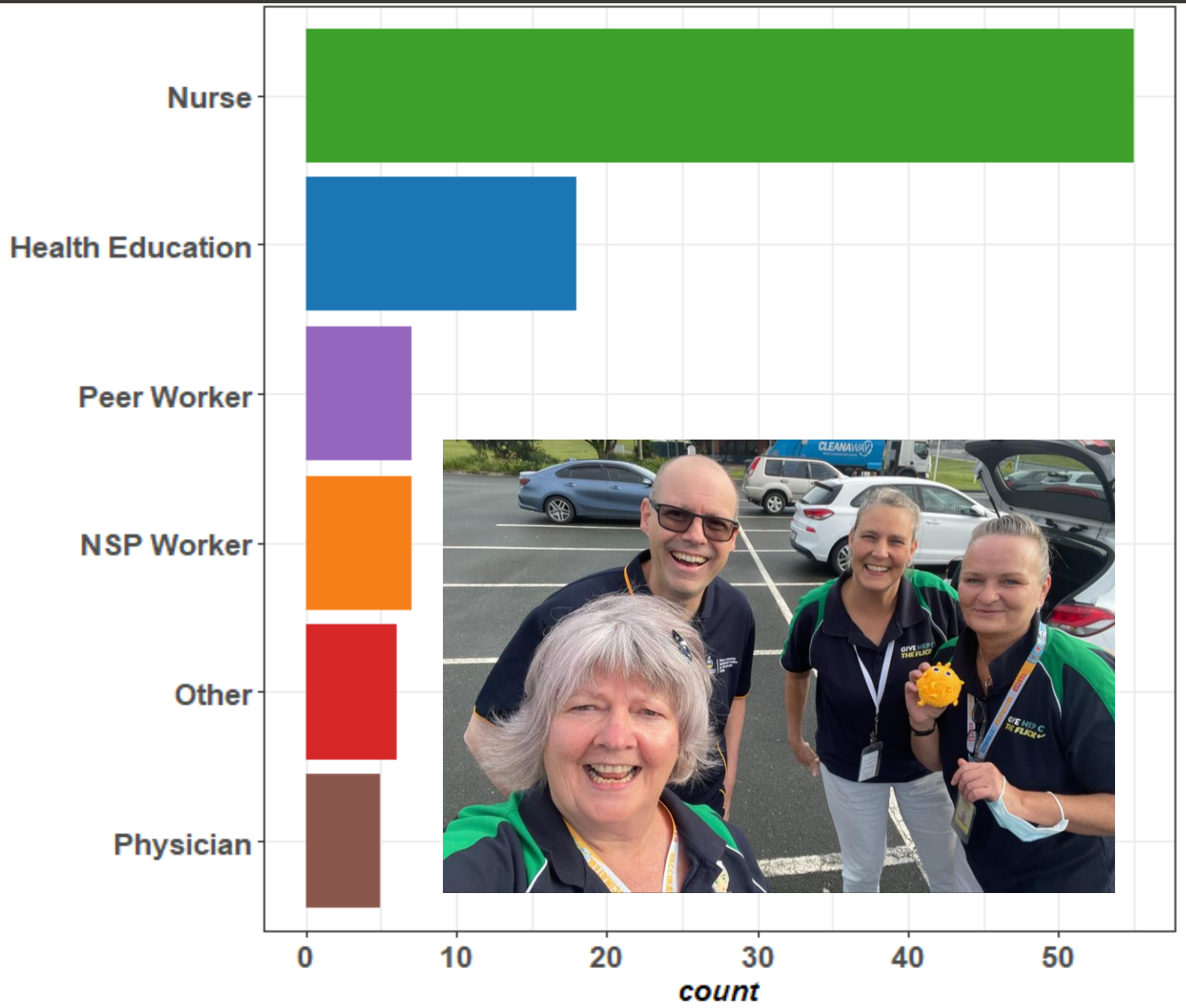
1 Not at all;
2 Have a slight knowledge, skills or confidence
3 Average competence amongst my peers
4 Confident and competent;
5 Very confident and competent

<Average Confidence

Confident & Competent

Flinders University | FHMRI

Results – Workforce and Testing Volumes



Data Extraction Overview

February 2022 to October 2022

Active sites = 31
HCV RNA tests = 3937
Patients tested = 3703
Operators (at any stage) = 104

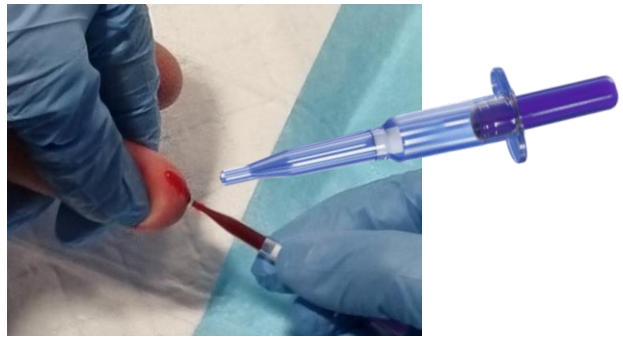
Flinders University | FHMRI

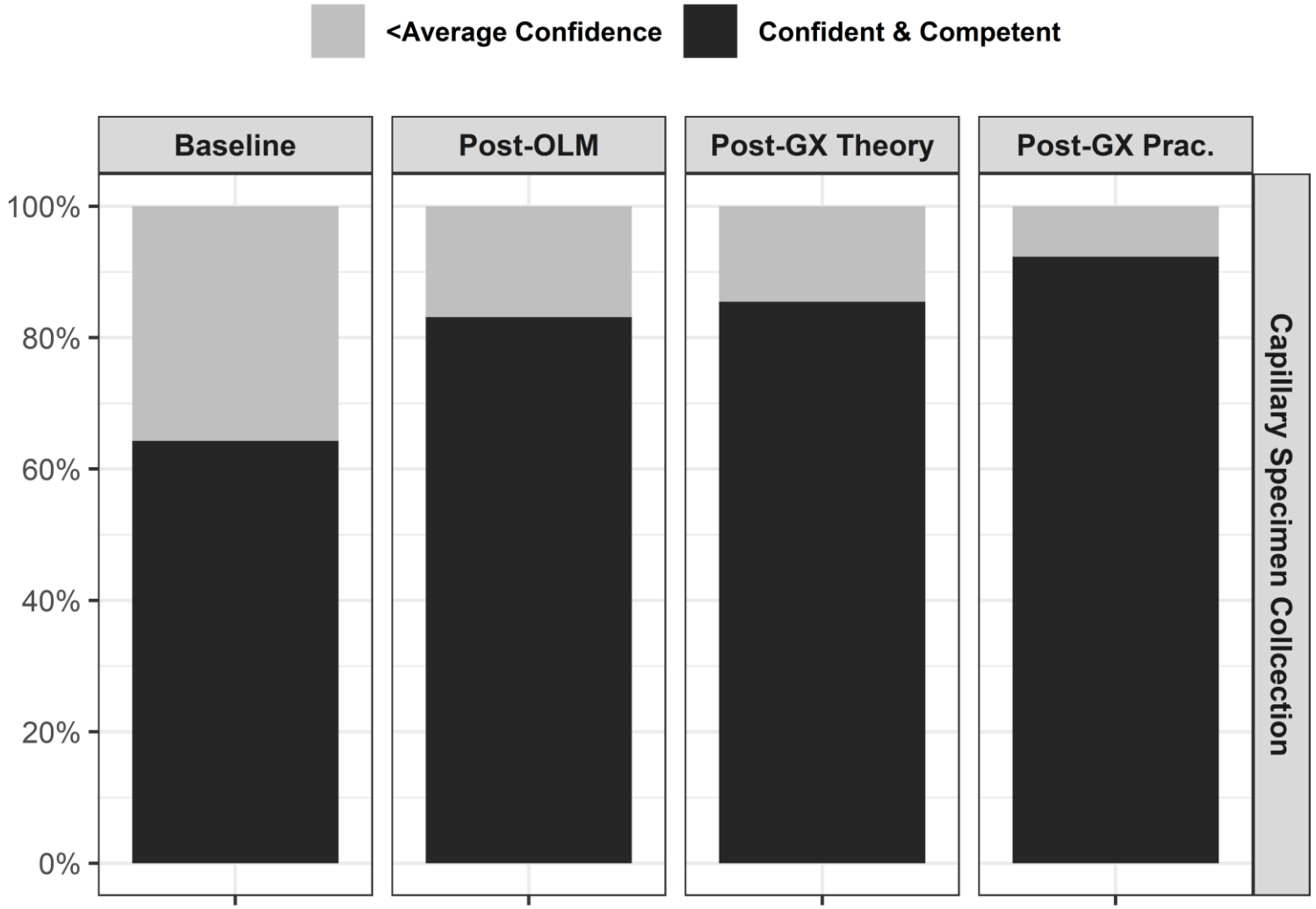
Results – Specimen Collection

How confident are you in your ability to draw a whole blood sample into a 100µL minivette?

Increasing linear trend in proportions of "*confident and competent*" across each training stage; P <0.001

Meaningful gain in "*confident and competent*" between post-GX Theory and post-GX Practical sessions (81% vs 92%); P = 0.22





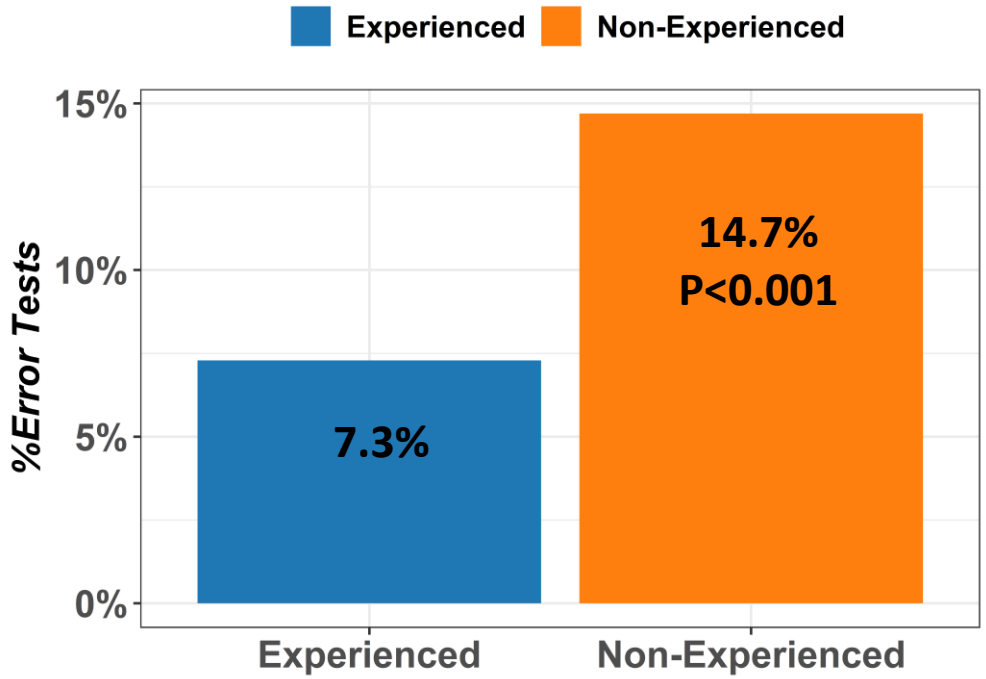
Flinders University | FHMRI

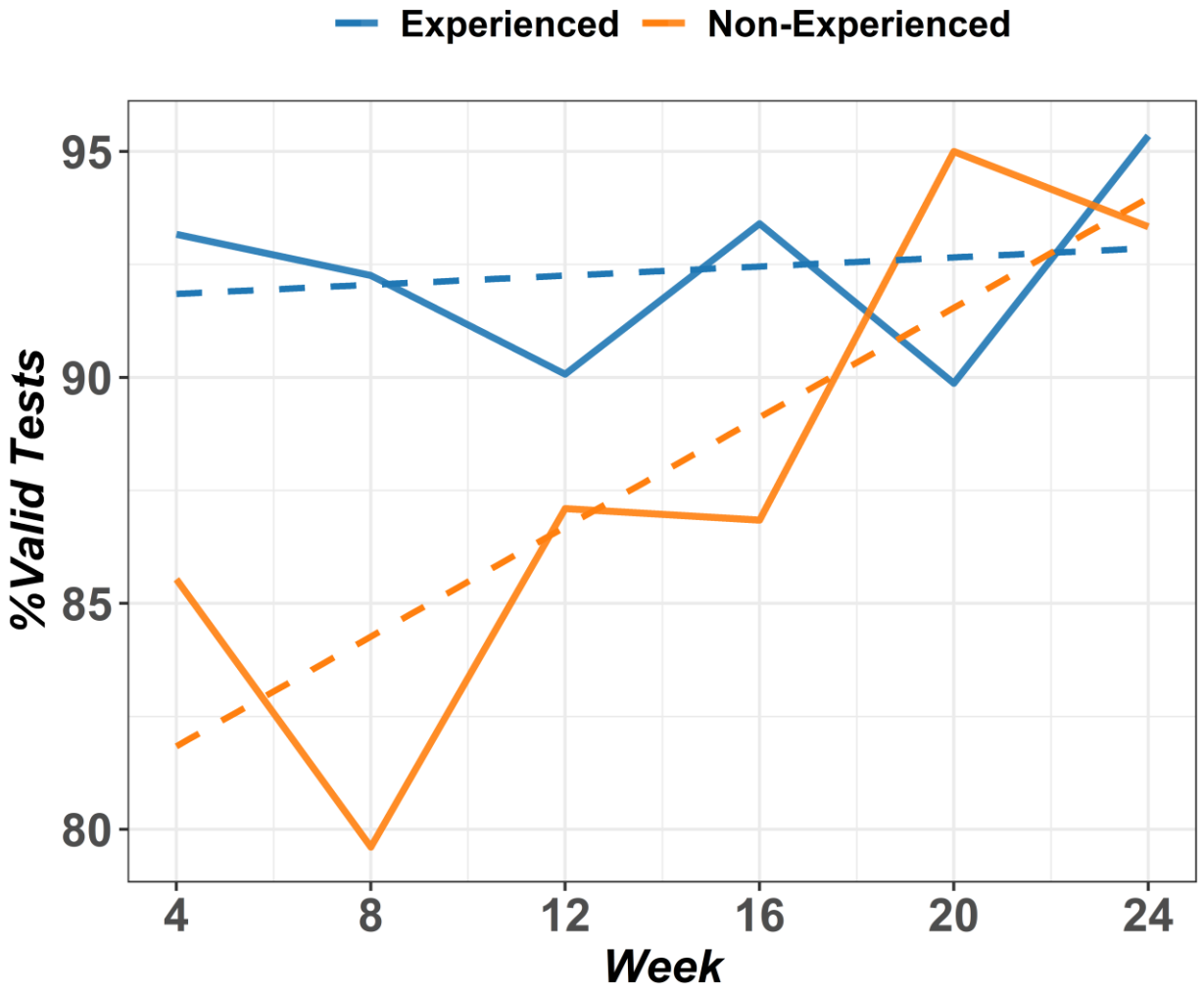
Results – Specimen Collection, Errors and Experienced Operators

Testing Errors

Unsuccessful tests = 8.8% (n= 348/3937)

- Poor quality samples (errors) = 82.2%
- Cartridge related issues (invalids) = 12.9%
- Device issues (no results) = 4.8%





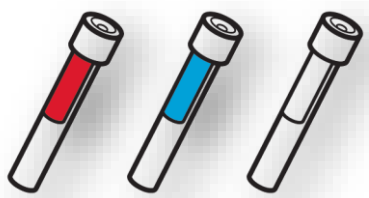
Flinders University | FHMRI

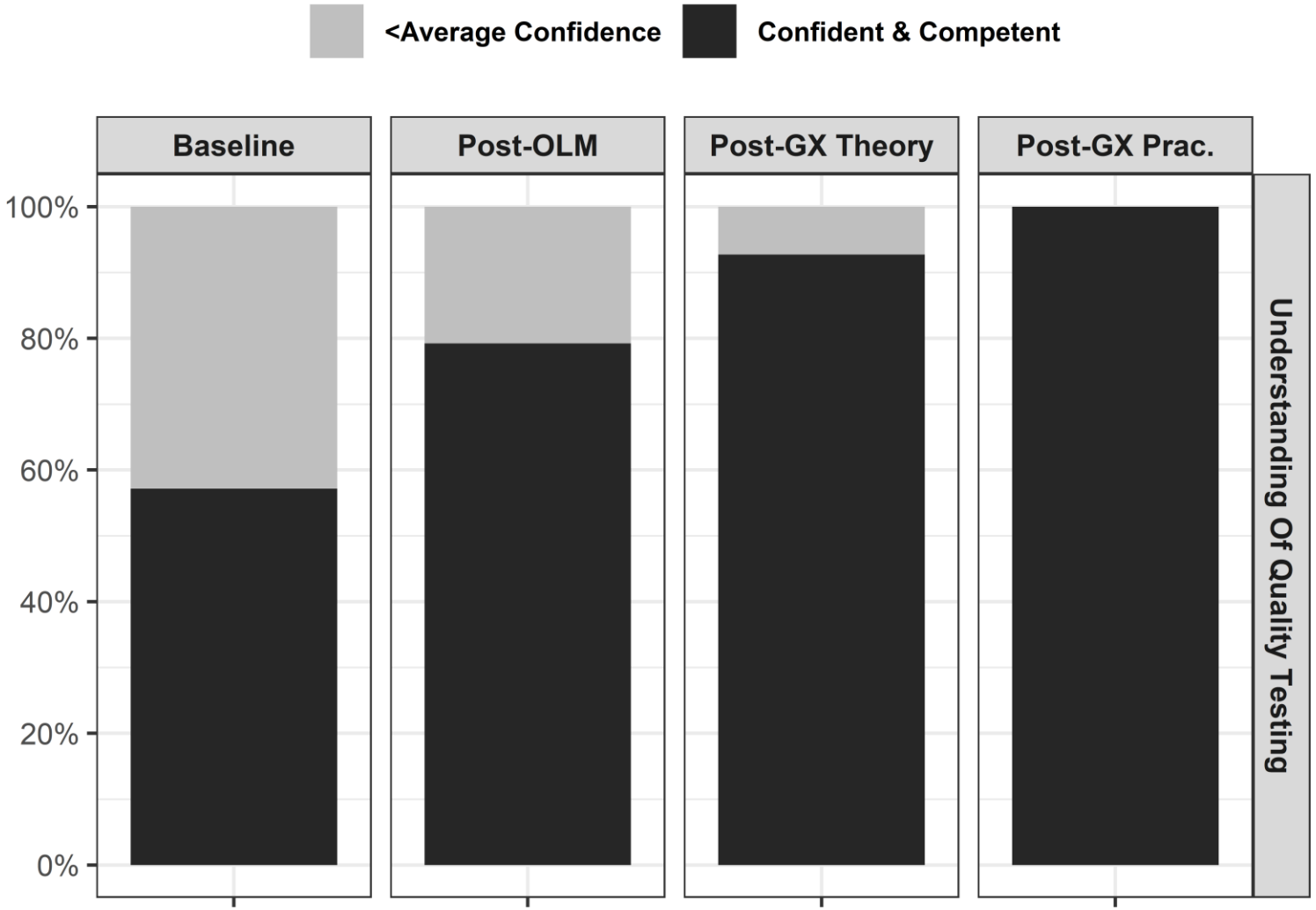
Results – Performing Tests

How confident are you in your understanding of the purpose of a quality control (QC, a known HCV positive and negative specimen) for HCV testing?

A significant increasing linear trend in proportions of "*confident and competent*" across each training stage; P <0.001

Note increase to 100% "*confident and competent*" in understanding the purposes of QC post-GX Practical session; P <0.001





Flinders University | FHMRI

Competency panel concordance

Competency Panels (Quality Controls)

Two samples with known HCV results (Negative and Positive)

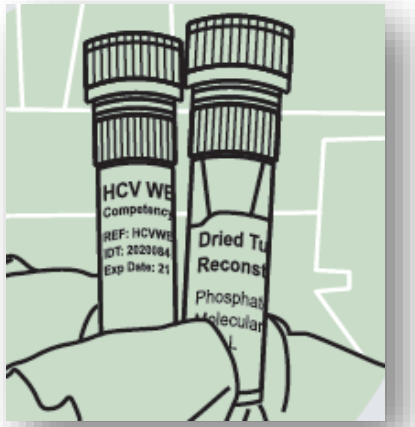
Operators must obtain expected results and viral load in target range

Manufactured by NRL

QC data August 2022 to February 2023

QC test episodes n = 563

100% Concordance with expected results



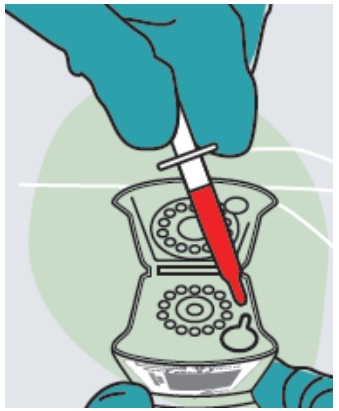
1	ICPOCT Site Identifier	Initals	Date of Test	Specimen ID Name	Cartridge Lot No.	QC Level	QC Lot No	Module	Qualitative Result	Viral Load (log10)	Qualitative Concordant	Quantitative Within Limits
324	NSW1363	JW	12/12/2022	hcv-neg-dec-qe	14301	Neg	N221963	1	NOT DETECTED		Concordant	
325	NSW1363	JW	12/12/2022	hcv-pos-dec-qe	14301	Pos	N221963	2	DETECTED	2.37	Concordant	Acceptable
326	NSW1363	JW	12/12/2022	hcv-neg-dec-ub	14301	Neg	N221963	4	NOT DETECTED		Concordant	
327	NSW1363	JW	12/12/2022	hcv-pos-dec-ub	14301	Pos	N221963	3	DETECTED	2.58	Concordant	Acceptable
328	ACT1355	JW	14/12/2022	HCV POS DEC LK	14102	Pos	N221963	2	DETECTED	2.53	Concordant	Acceptable
329	NSW1364	JW	15/12/2022	HCV-NEG-DEC-JV	14301	Neg	N221963	1	NOT DETECTED		Concordant	
330	NSW1364	JW	15/12/2022	HCV-pos-DEC-JV	14301	Pos	N221963	2	DETECTED	2.1	Concordant	Acceptable
331	NSW1351	JW	15/12/2022	HCV-Neg-Dec	14301	Neg	N221963	4	NOT DETECTED		Concordant	
332	NSW1351	JW	15/12/2022	HCV-NEG-DEC	14301	Neg	N221963	4	NOT DETECTED		Concordant	
333	NSW 1340	JW	19/12/2022	HCV-POS-December	14102	Pos	N221963	4	DETECTED	2.32	Concordant	Acceptable
334	NSW1363	JW	19/12/2022	HCV-Pos-Dec	14301	Pos	N221963	2	DETECTED	2.44	Concordant	Acceptable
335	NSW1352	JW	20/12/2022	HCV-QC-POS-DEC22	14102	Pos	N221963	2	DETECTED	2.39	Concordant	Acceptable
336	NSW1361	JW	20/12/2022	HCV-QC-POS-DEC	14102	Pos	N221963	2	DETECTED	2	Concordant	Acceptable
337	NSW1325	JW	20/12/2022	94FA-0688-5F2F	14301	Pos	N221963	2	DETECTED	2.61	Concordant	Acceptable
338	NSW1363	JW	20/12/2022	HCV_POS_DEC_PEJ	14301	Pos	N221963	2	DETECTED	2.75	Concordant	Acceptable
339	NSW1358	JW	20/12/2022	hcv_pos_dec_bl	14301	Pos	N221963	2	DETECTED	2.05	Concordant	Acceptable
340	NSW1371	JW	21/12/2022	HCV-QC-NEG-DEC	14301	Neg	N221963	4	NOT DETECTED		Concordant	
341	NSW1371	JW	21/12/2022	Xpert H 211222105840	14301	Pos	N221963	2	DETECTED	2.32	Concordant	Acceptable
342	NSW1351	JW	21/12/2022	HCV-NEG-DEC-GR	14301	Neg	N221963	2	NOT DETECTED		Concordant	
343	NSW1351	JW	21/12/2022	HCV-POS-DEC-GR	14301	Pos	N221963	4	DETECTED	2.12	Concordant	Acceptable
344	NSW1351	JW	21/12/2022	HCV-NEG-DEC-AV	14301	Neg	N221963	3	NOT DETECTED		Concordant	
345	NSW1351	JW	21/12/2022	HCV-POS-DEC-AV	14301	Pos	N221963	1	DETECTED	2	Concordant	Acceptable
346	SA1348	JW	21/12/2022	HCV-QC POS DECEMBER	14102	Pos	N221963	3	DETECTED	2	Concordant	Acceptable
347	QLD1338	JW	21/12/2022	December 22 QC	14102	Pos	N221963	2	DETECTED	2	Concordant	Acceptable
348	NSW61214	JW	21/12/2022	HCV-Pos-Dec	14301	Pos	N221963	2	DETECTED	2.35	Concordant	Acceptable
349	NSW1350	JW	21/12/2022	HCV-POS-DECEMBER	14102	Pos	N221963	2	DETECTED	2	Concordant	Acceptable
350	NSW1350	JW	21/12/2022	HCV-NEG-DEC-IC	14102	Neg	N221963	1	NOT DETECTED		Concordant	
351	NSW1350	JW	21/12/2022	HC-POS-DEC-IC	14102	Pos	N221963	2	DETECTED	2.09	Concordant	Acceptable
352	SA1337	JW	21/12/2022	29C7-0689-B477	14301	Pos	N221963	2	DETECTED	2.08	Concordant	Acceptable
353	NSW1351	JW	22/12/2022	HCV-POS-DEC-GR	14301	Pos	N223181	1	DETECTED	2.47	Concordant	Acceptable
354	NSW1327	JW	22/12/2022	CP Dec 2022	13902	Pos	N221963	2	DETECTED	2	Concordant	Acceptable
355	QLD1344	JW	23/12/2022	HCV-DEC-POS	14301	Pos	N221963	2	DETECTED	2.32	Concordant	Acceptable
356	NSW2377	JW	23/12/2022	B1FC-068C-63C4	14301	Pos	N221963	2	DETECTED	2.16	Concordant	Acceptable
357	NSW 1340	JW	9/01/2023	HCV-QC-NEG-JAN 23	14102	Neg	N221963	3	NOT DETECTED		Concordant	

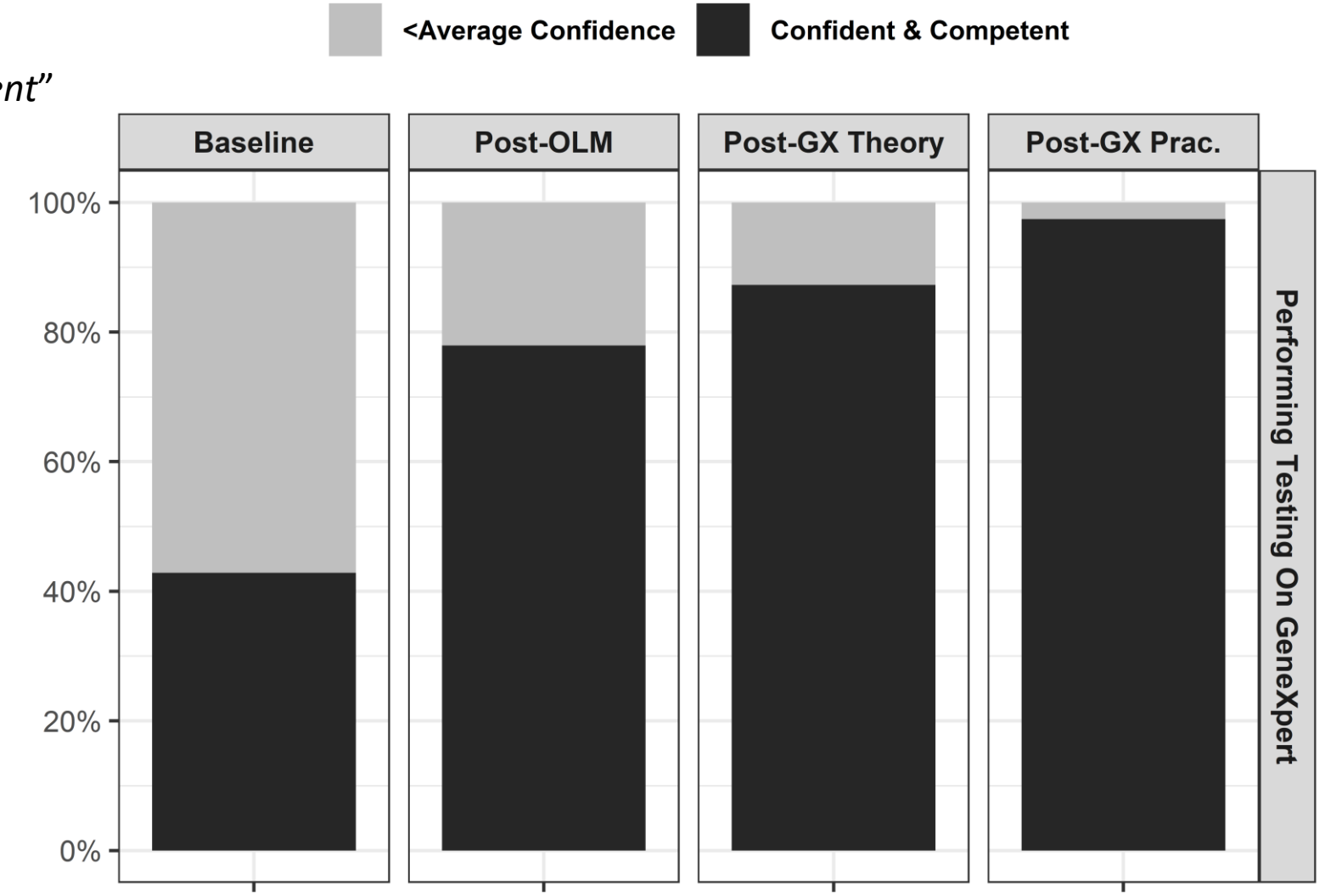
Results – Performing Tests on GeneXpert

How confident are you in your ability to perform an HCV Viral Load Fingerstick test on the GeneXpert platform?

A significant increasing linear trend in proportions of "*confident and competent*" across each training stage; P <0.001

Significant gain in "*confident and competent*" between post-GX Theory and post-GX Practical sessions (83% vs 97%); P <0.001



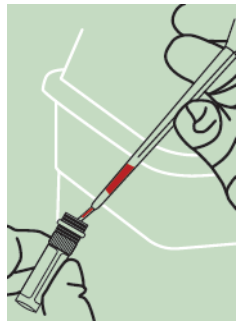


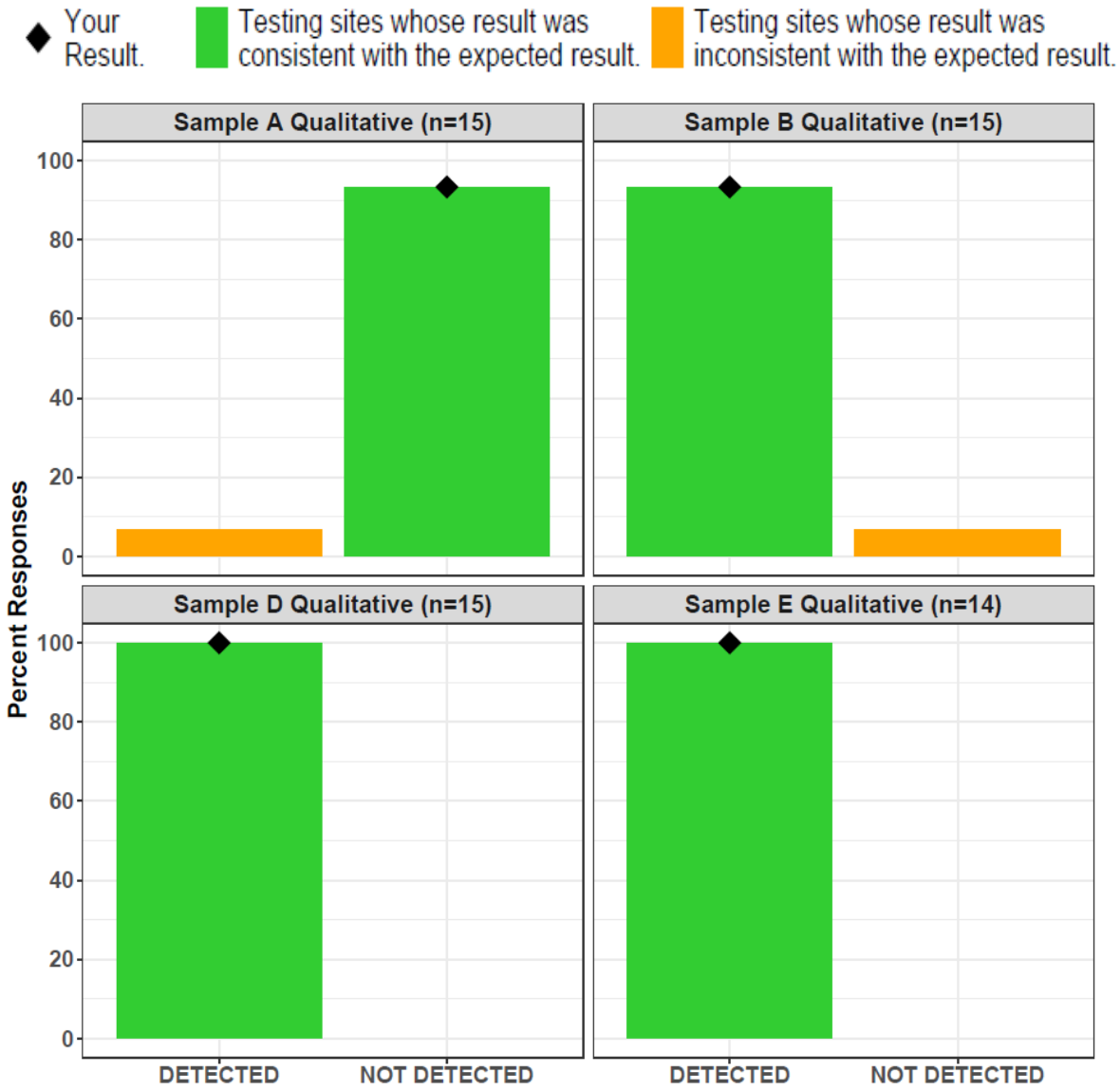
Flinders University | FHMRI

Results – External Quality Assurance (EQA) October 2022

External Quality Assurance (EQA) Program
Simulates patient samples with unknown HCV status
Five blinded samples (unknown HCV status)
Two challenges per year
Manufactured by NRL

October 2022
15/15 Sites
100% Participation Rate
One transcription error- initiated a retraining event





Flinders University | FHMRI

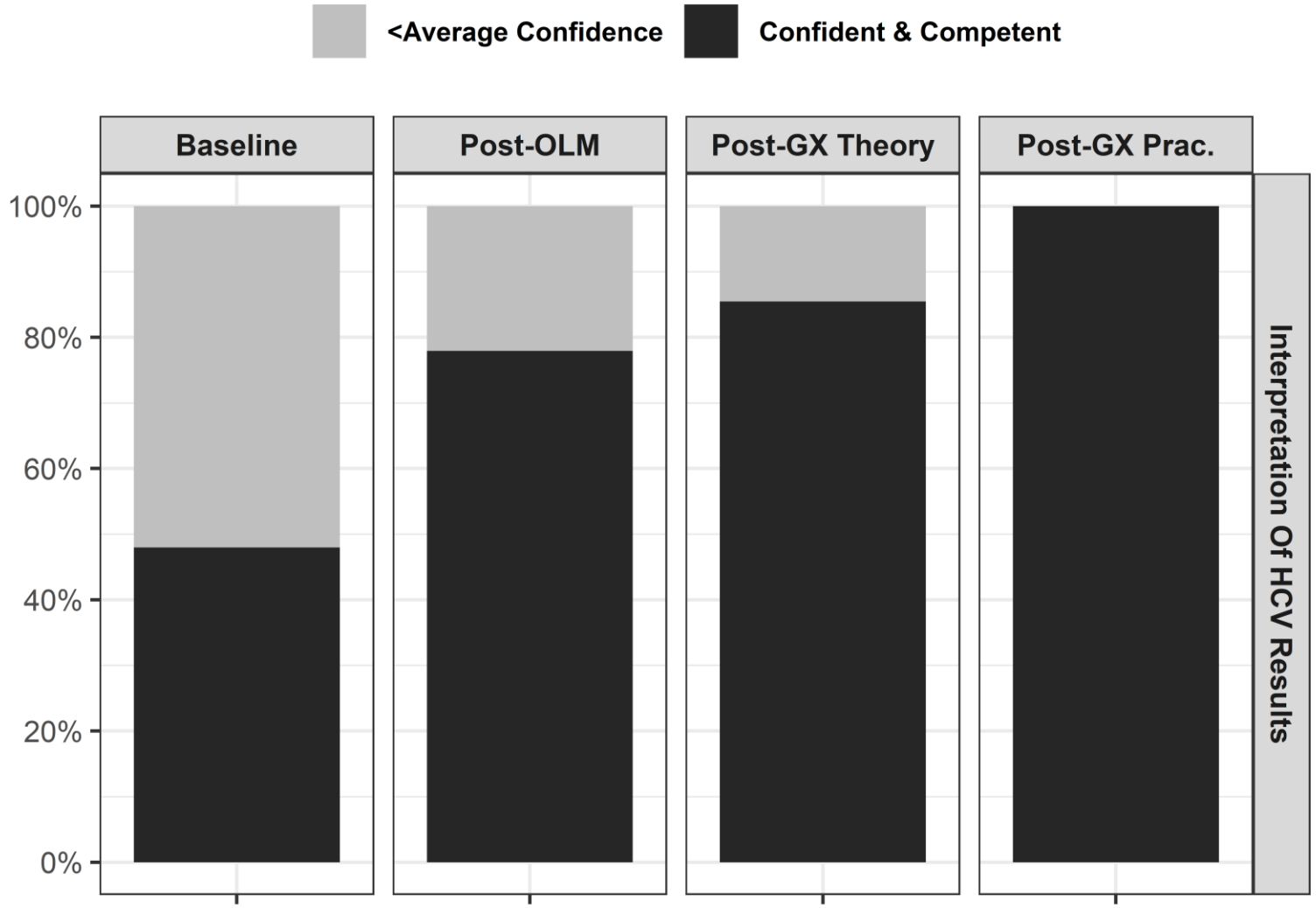
Results – Interpretation of HCV results

How confident are you in your ability to interpret the HCV viral load result from the GeneXpert platform?

A significant increasing linear trend in proportions of "*confident and competent*" across each training stage; P <0.001

Note significant increase to 100% "*confident and competent*" for post-GX Practical session; P <0.001

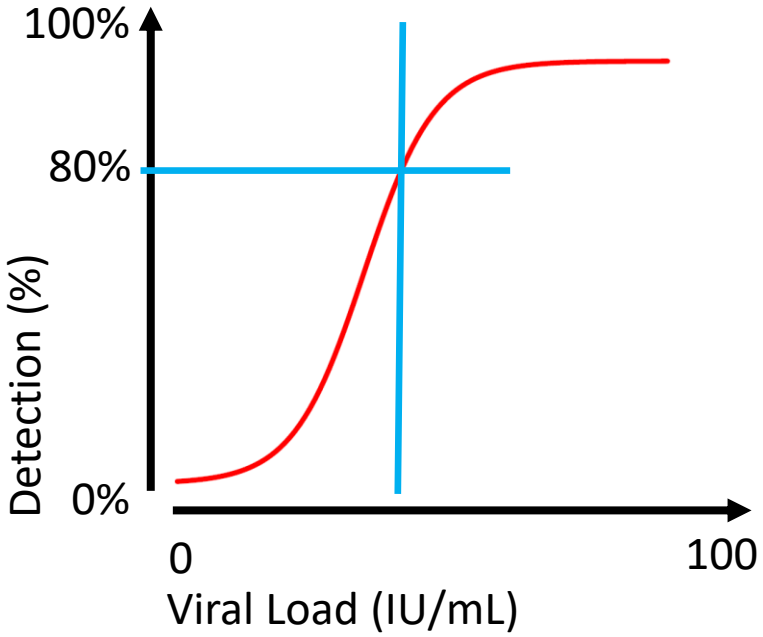
Xpert® HCV VL test result	Interpretation	Action
HCV NOT DETECTED	HCV RNA is not detected	Follow local protocols for a non-detectable HCV RNA result.
HCV DETECTED <100 IU/mL	HCV RNA is detected below the quantitative range of the assay.	Alert clinician to the presence of DETECTED HCV RNA at a level too low to be quantified by the GeneXpert. Notify public health regarding DETECTED HCV RNA by GeneXpert method. Arrange for venous sample to be collected for confirmatory HCV RNA testing at a referral laboratory. The laboratory will notify jurisdictional public health notification of a confirmed positive result.
HCV DETECTED XX IU/mL (log X.XX)	HCV RNA is detected at XX IU/mL	Follow local and/or National protocols for DETECTABLE HCV RNA and jurisdictional mandatory notification.
HCV DETECTED >1.00E08 IU/mL	HCV RNA is detected above the quantitative range of the assay.	Follow local and/or National protocols for DETECTABLE HCV RNA and jurisdictional mandatory notification.
INVALID	Test was unsuccessful	Repeat the test using a new minivette and new reagent cartridge.
ERROR	Test was unsuccessful	Repeat the test using a new minivette and new reagent cartridge.
NO RESULT	Test was unsuccessful	Repeat the test using a new minivette and new reagent cartridge.

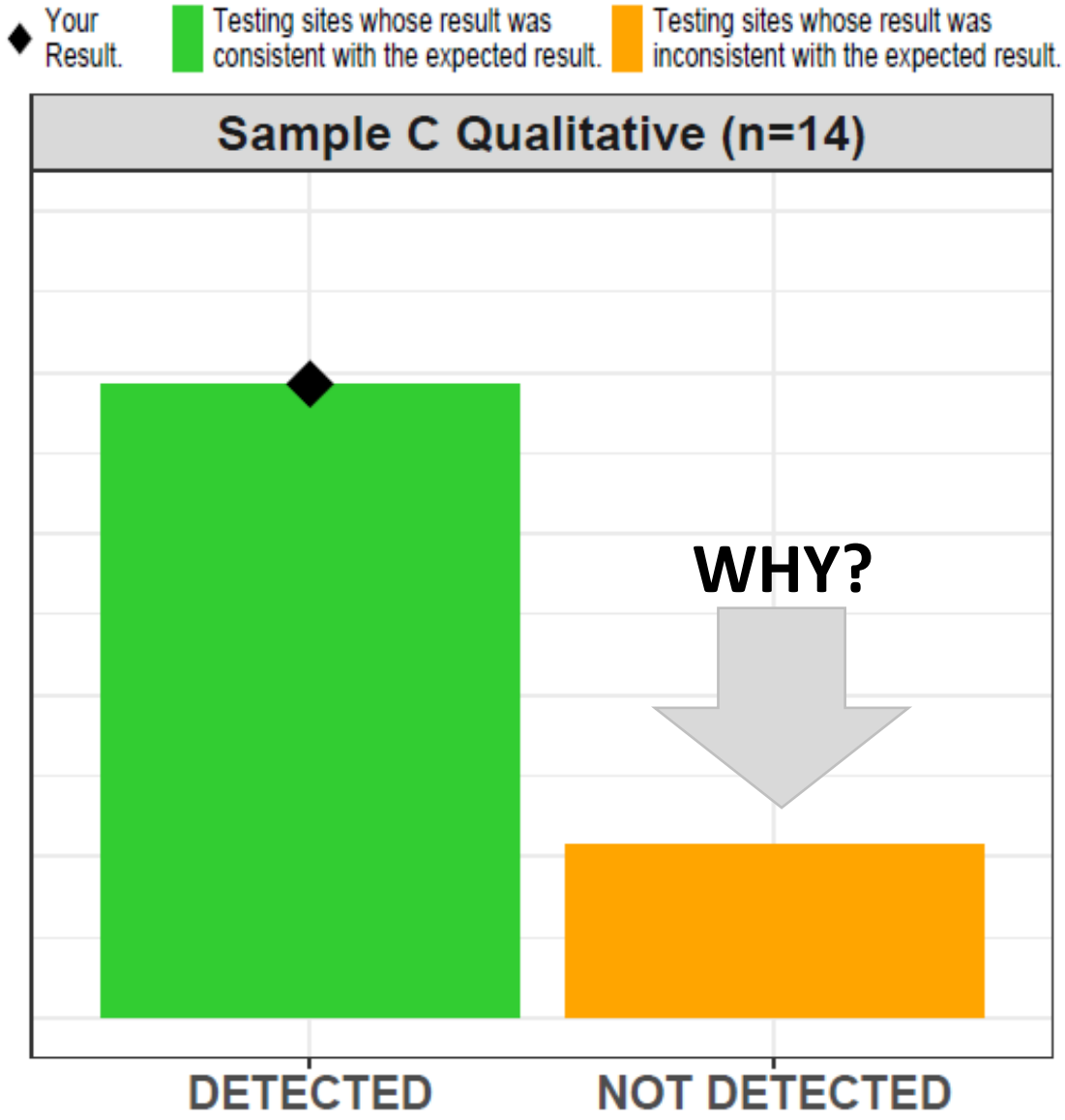


Results – EQA October 2022 – Sample C

Sample C - External Quality Assurance (EQA)
Viral load at Limit of Detection (LoD) small proportion of "Not Detected" results expected

Generates confusion around perceived discordances?





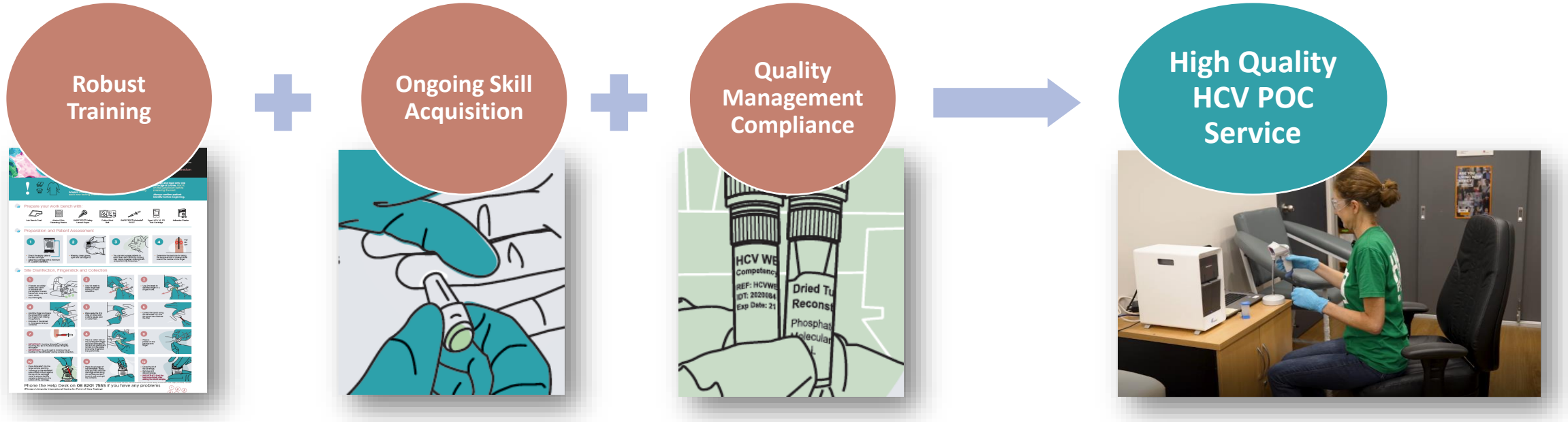
Flinders University | FHMRI

Conclusions

Risk management of POCT services is imperative to ensure recognition and elimination of errors, that can jeopardise test results and patient safety.

Standardised POC operator training

- Develops a greater understanding of quality management procedures
- Improves self-assessed GeneXpert competency
- Facilitates a high rate of valid tests on first attempt
- Unsuccessful tests are largely attributed poor quality samples



Acknowledgements

Program managed by the Kirby Institute (PI: Prof. Jason Grebely & team) and
Flinders University International Centre for Point-of-Care Testing (AI: Dr. Susan Matthews & team)
Funded by the Australian Government Department of Health
This operator training evaluation was funded by the RAPID CRE

National HCV Operational Team

Kirby Institute

- Jason Grebely
- David Silk
- Simon Comben
- Stephanie Davies
- Elise Tu
- Maria Martinez
- Jessie Payne
- Samira Hosseini-Hooshyar
- Rebecca Henry

Flinders University

- Susan Matthews
- Mark Shephard
- Corey Markus
- Jae Williams
- Kirsty Emery
- Larissa Kahl

St Vincent's Hospital

- Phillip Cunningham
- Mitchell Starr
- Beth Catlett

Industry Partners

- Cepheid
- Gilead
- National Referral Laboratory
- Clinical Universe

Flinders University | FHMRI

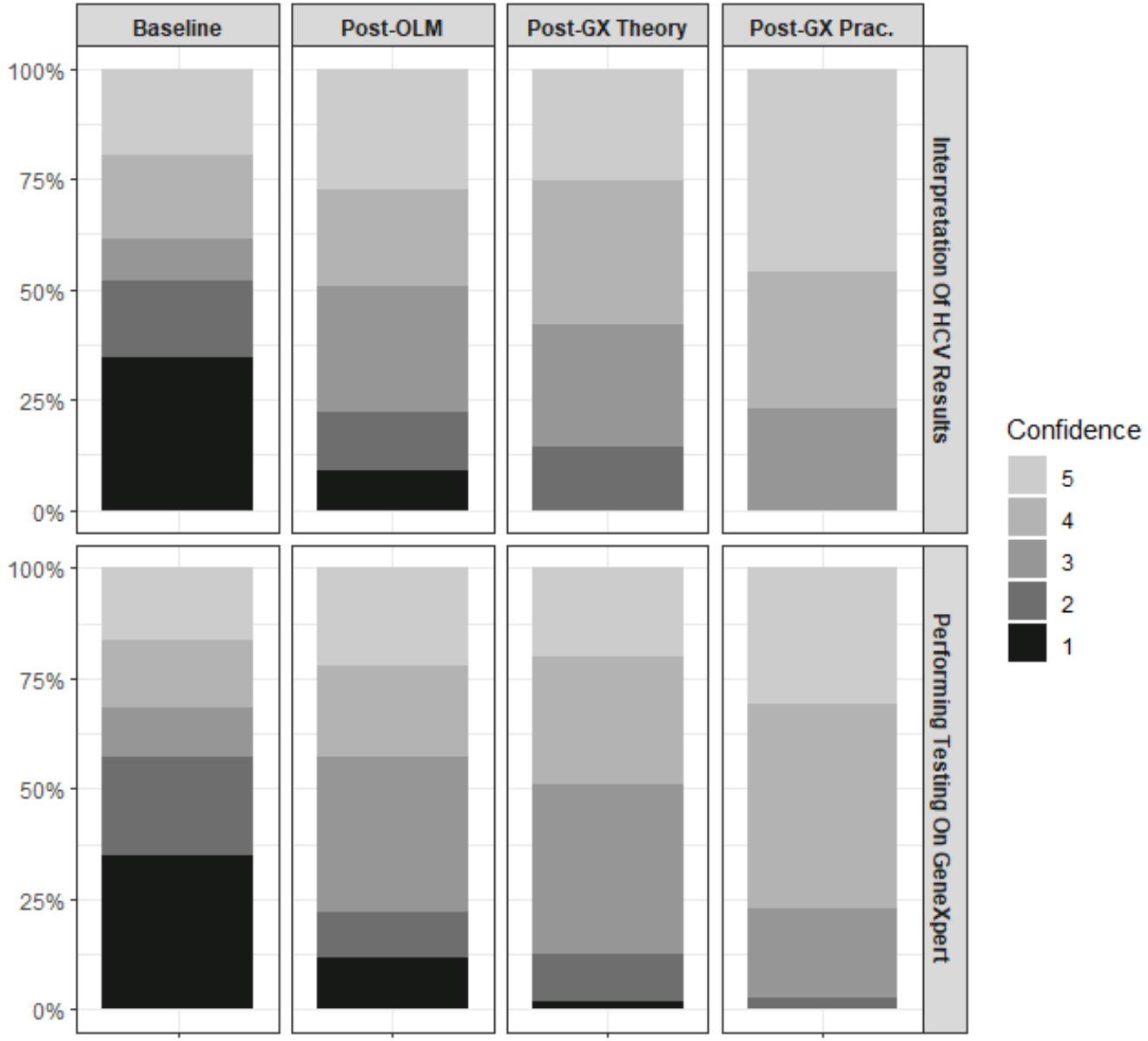
Acknowledgements

This program is funded by the Australian Government Department of Health

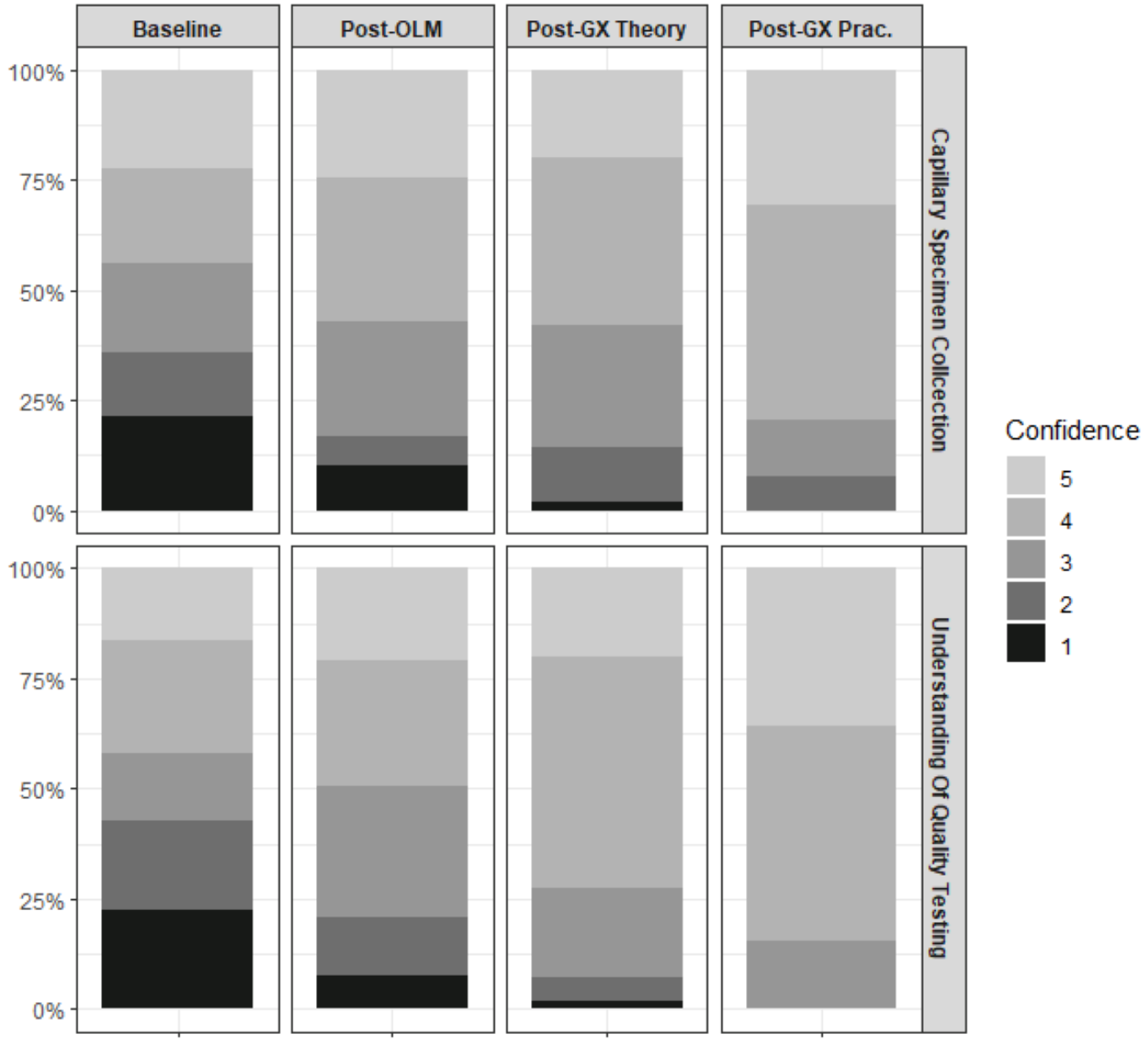
Questions?

Flinders University | FHMRI

Results –


Baseline
Post-OLM
Post-GX Theory
Post-GX Prac.
Interpretation Of HCV Results
Performing Testing On GeneXpert
100%
75%
50%
25%
0%
Confidence
5
4
3
2
1

Results –


Baseline
Post-OLM
Post-GX Theory
Post-GX Prac.
Capillary Specimen Collection
Understanding Of Quality Testing
100%
75%
50%
25%
0%
Confidence
5
4
3
2
1