NRL RapidQ EQA PERIODIC REPORT

DBCR4

HCV Whole Blood Molecular PoC EQA

Reporting Period

May 2025 – June 2026

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1. INTRODUCTION

National Serology Reference Laboratory, Australia (NRL) is a division of St. Vincent's Institute of Medical Research. NRL is a WHO Collaborating Centre for Diagnostics and Laboratory Support for HIV and AIDS and other Blood-borne Infections and an accredited EQA (External Quality Assessment) Provider under ISO/IEC 17043:2023 by NATA. Aspects of this program, such as logistics, informatics and testing services may be subcontracted to competent external service providers, in a manner which is compliant with ISO/IEC 17043:2023.

Confidentiality. Participant confidentiality is strictly maintained throughout the EQA process by NRL and/or the network provider, as applicable.

Periodic Report. Results are submitted by participants using EDCNet™ software via QR code or directly via the web portal for immediate preliminary assessment. This Periodic Report presents a final summary of participant data submitted during the defined reporting period.

Program Objectives. NRL designed sample sets for this program to:

- examine the detection and/or quantification of different HCV genotypes.
- examine the detection and/or quantification of samples with low HCV viral load.
- detect instances of cross contamination.

Questions / Comments. Any questions or comments regarding this Periodic Report are welcomed by NRL via RapidQ@nrlquality.org.au.

Acknowledgements. NRL thanks all participants for their commitment to continuing quality improvement and hope that this Report advances that commitment.

2. METHODS

- The samples are manufactured and managed by NRL. It was requested that participants store and process samples in accordance with the Program Instructions.
- The samples were confirmed to be homogenous. Stability was validated for these samples.
- NRL conducted and/or organised reference testing of samples as outlined in the Results & Discussion section of this Periodic Report.
- More information on the evaluation methodology and other supplementary details relevant to this program can be found by clicking here.

3. RESULTS & DISCUSSION

3.1. EQA Sample Characterisation

The EQA samples for which results were submitted during the reporting period comprised HCV RNA-negative and HCV RNA-positive specimens, including HCV genotypes 1a, 1b, 2b, 3a and 6a.

Sample lots were consolidated under Sample Classification based on pre-release testing results as Negative, Low Positive [<3 $\log_{10}$ IU/mL], Medium Positive [3–4 $\log_{10}$ IU/mL] and High Positive [>4 $\log_{10}$ IU/mL]). The pre-release (reference) testing assay, along with the corresponding results for each Sample Lot, are summarised in Table 1.

Table 1. Composition and Characterisation of EQA Sample Lots | DBCR4 May 2025 – June 2026

Sample Classification	**HCV Genotype**	**Sample Lot**	**Cepheid Xpert HCV VL Fingerstick***	
			HCV RNA Viral Load ($\log_{10}$ IU/mL)	**Assay Interpretation**
Negative	Not Applicable	N221892	Not Detected	Not Detected
		N232861		
		N250451		
		N232021		
Low Positive **(<3 $\log_{10}$ IU/mL)**	6a	N251682	2.88	**DETECTED**
Medium Positive **(3–4 $\log_{10}$ IU/mL)**	1a	N221961	3.02	
		N232581	3.33	
		N232651	3.47	
	1b	N230381	3.84	
	6a	N231952	3.42	
High Positive **(>4 $\log_{10}$ IU/mL)**	2b	N251681	4.19	
	3a	N220421	4.13	
	6a	N231951	4.34	

Note: *This testing was performed internally at NRL and supports previous external characterisation testing performed by ISO 15189 accredited laboratories.

3.2. Participant Performance

3.2.1. Participation

This Periodic Report presents data submitted by 100 participants between May 2025 and June 2026.

3.2.2. Assays

Participants submitted results using the following assays (where 'n' = number of results):

- Cepheid Xpert HCV VL Fingerstick (n=1068)

3.2.3. Qualitative Performance

Qualitative participant data were analysed by comparing the expected (reference) assay interpretation as listed in Table 1 with qualitative detection outcomes derived from participant results. Results from Sample Lots under the same assigned Sample Classification and HCV genotype (Table 1) were grouped together to facilitate comparison of participant percentage (%) concordance against the reference result (RR) (Figure 1).

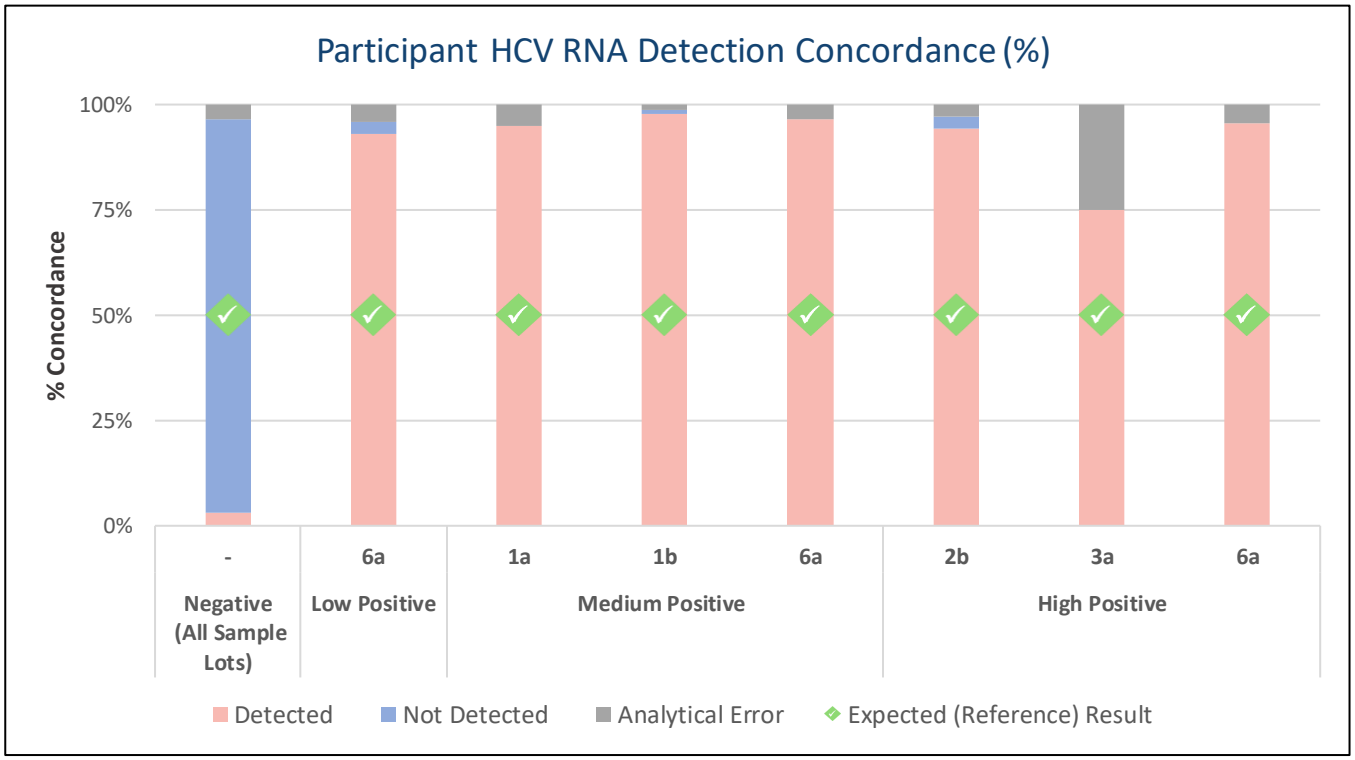

Figure 1. Participant Concordance (%) for Qualitative HCV RNA Detection by Sample Classification and HCV Genotype | DBCR4 May 2025 – June 2026.

3.2.4. Quantitative Performance

Quantitative participant data were analysed by comparing results submitted by participants within each Peer Group (PG), defined as participants using the same test method, for each Sample Lot. Table 2 presents the PG quantitative statistics, while Table 3 summarises overall PG performance.

Table 2. Quantitative Peer Group Statistics for 'Cepheid Xpert HCV VL Fingerstick' | DBCR4 May 2025 – June 2026

Sample Classification	HCV Genotype	Sample Lot	Peer Group Statistics			
			Total Results (n)	Statistical (n)*	Median (log_{10} IU/mL)	Range^ (Median ± 0.5)
Negative	Not Applicable	N221892	2	2	Not Detected	
		N232861	80	80		
		N250451	253	253		
		N232021	14	14		
Low Positive (<3 log_{10} IU/mL)	6a	N251682	180	128	2.24	2.00 - 2.74
Medium Positive (3–4 log_{10} IU/mL)	1a	N221961	86	82	3.4	2.90 - 3.90
		N232581	3	1		
		N232651	8	8	2.98	2.48 - 3.48
	1b	N230381	89	87	3.71	3.21 - 4.21
	6a	N231952	85	82	3.55	3.05 - 4.05
High Positive (>4 log_{10} IU/mL)	2b	N251681	171	161	3.71	3.21 - 4.21
	3a	N220421	4	3	4.01	3.51 - 4.51
	6a	N231951	93	89	4.29	3.79 - 4.79

Note: *Minimum of three valid results required for meaningful statistics.
^Where applicable, peer group range is adjusted to reflect values within the assay's quantifiable range.

Table 3. Peer Group Performance Summary for 'Cepheid Xpert HCV VL Fingerstick' |DBCR4 May 2025 – June 2026

Sample Classification	HCV Genotype	Total Results (n)*	Peer Group Performance Outcomes				
			Within PG Range n (%)	Outside PG Range n (%)	Detected – Not Quantified n (%)	Not Detected n (%)	Analytical Errors n (%)
Negative (All Sample Lots)	Not Applicable	349	0	11 (3)	0	326 (93)	12 (4)
Positive (All Sample Lots)	All	719	602 (84)	39 (5)	41 (6)	11 (1)	26 (4)
Low Positive **(<3 log_{10} IU/mL)**	6a	180	126 (70)	2 (1)	39 (22)	5 (3)	8 (4)
Medium Positive **(3–4 log_{10} IU/mL)**	1a	97	84 (87)	7 (6)	2 (2)	0	4 (5)
	1b	89	84 (95)	3 (3)	0	1 (1)	1 (1)
	6a	85	78 (92)	4 (5)	0	0	3 (3)
High Positive **(>4 log_{10} IU/mL)**	2b	171	157 (92)	4 (2)	0	5 (3)	5 (3)
	3a	4	2 (50)	1 (25)	0	0	1 (25)
	6a	93	71 (76)	18 (20)	0	0	4 (4)

Note: *Performance summaries based on small datasets should be interpreted carefully due to limited statistical reliability

3.3. Troubleshooting

Review of participant results identified several factors that may have contributed to 'Discordant' preliminary feedback, as per below. Participants are encouraged to promptly investigate any unexpected outcomes by reviewing instrument error logs, the assay manufacturer's troubleshooting guidance, and supporting documentation provided by NRL which can be found by clicking here.

3.3.1. Not Evaluated Results

a) Analytical Error Reported

A total of 38 submissions (4% of all submitted results) were classified as 'Not Evaluated' due to analytical errors. These comprised 17 instrument error results, two invalid results, and 19 unevaluable submissions where no explanatory comment was provided.

Within the Cepheid Xpert HCV VL Fingerstick peer group, 14 instrument error codes were reported. These were associated with instrument hardware or communication failures, possible cartridge integrity issues, sample loading or processing errors. Error codes indicative of sample loading or processing issues accounted for the majority of reported instrument errors.

b) Low Concentration Samples

Low Positive samples with an assigned viral load of <3 $\log_{10}$ IU/mL are included for educational purposes to assess assay sensitivity and facilitate inter-assay comparison where peer group data are available. In this reporting period, all submitted results were from the Cepheid Xpert HCV VL Fingerstick peer group.

Preliminary feedback at time of result submission is based on the assigned viral load evaluation criteria via reference testing. However, participant results submitted as '*Detected – Not Quantified*' or '*Not Detected*' were classified as 'Not Evaluated', as they were consistent with expected assay performance variation when testing low concentration samples under routine point-of-care testing conditions.

3.3.2. Unacceptable Results

a) False Positive Results

A total of 11 false-positive results (3% of total results) were submitted for HCV RNA-Negative samples and were classified as 'Unacceptable'. Possible causes may include but are not limited to cross contamination during sample processing, sample mix-up during testing or data entry errors.

b) Quantitative Outliers & False Negative Results

Quantitative results outside the peer group range (Median ± 0.5 $\log_{10}$ IU/mL) and false-negative results were classified as 'Unacceptable'. These results may indicate sample processing or analytical issues, such as incomplete or inconsistent reconstitution of the dried blood samples, although other site-specific analytical factors cannot be excluded.