

HCVPOCT

Australian Hepatitis C Point-of-Care Testing Program

Detection and clinical management of low-level Hepatitis C RNA following point-of-care HCV RNA testing

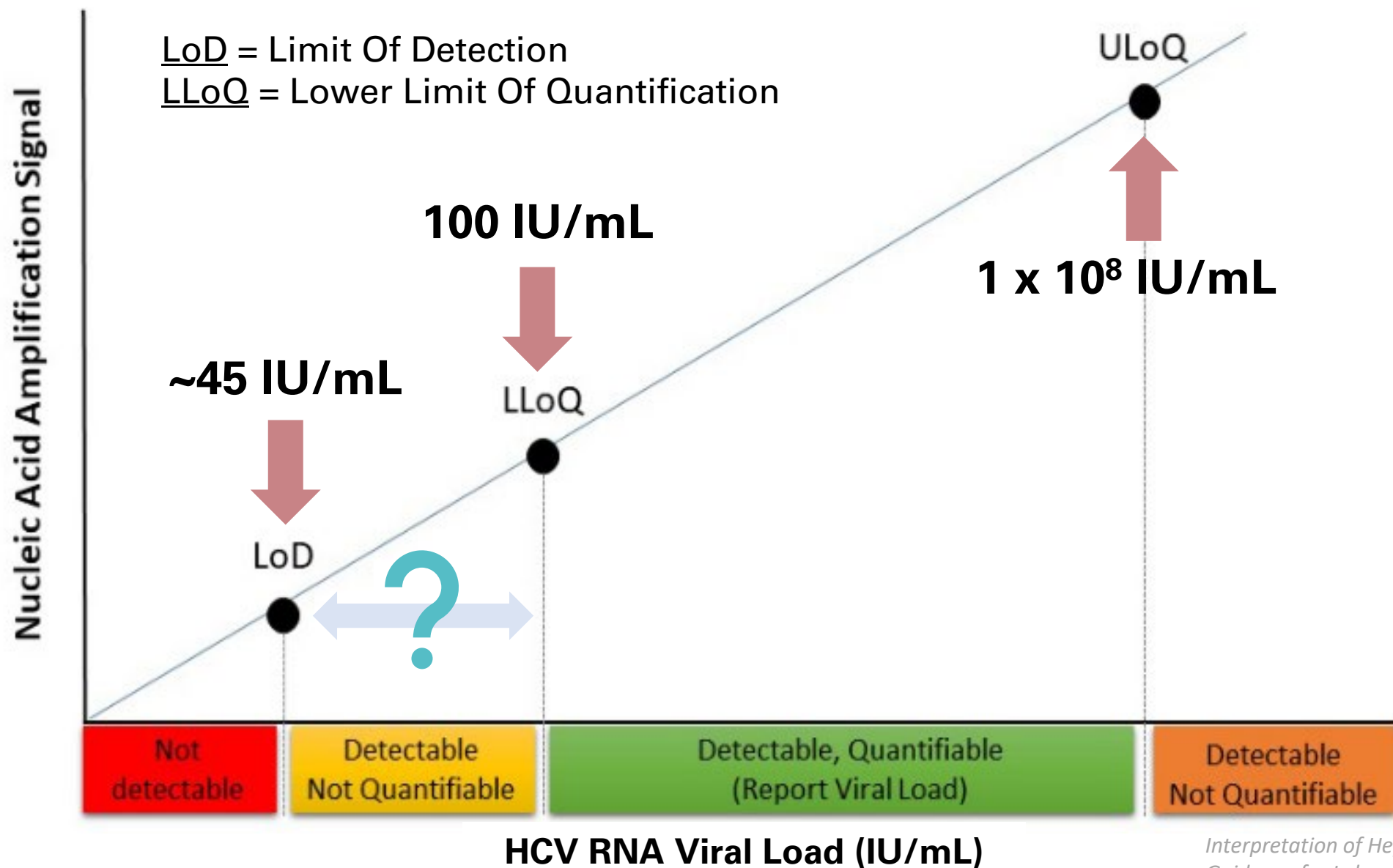
Corey Markus

International Centre for Point-of-Care Testing

Flinders University

August 2026

Xpert HCV RNA VL FS Assay Characteristics



Overview of Point-of-Care HCV RNA Results

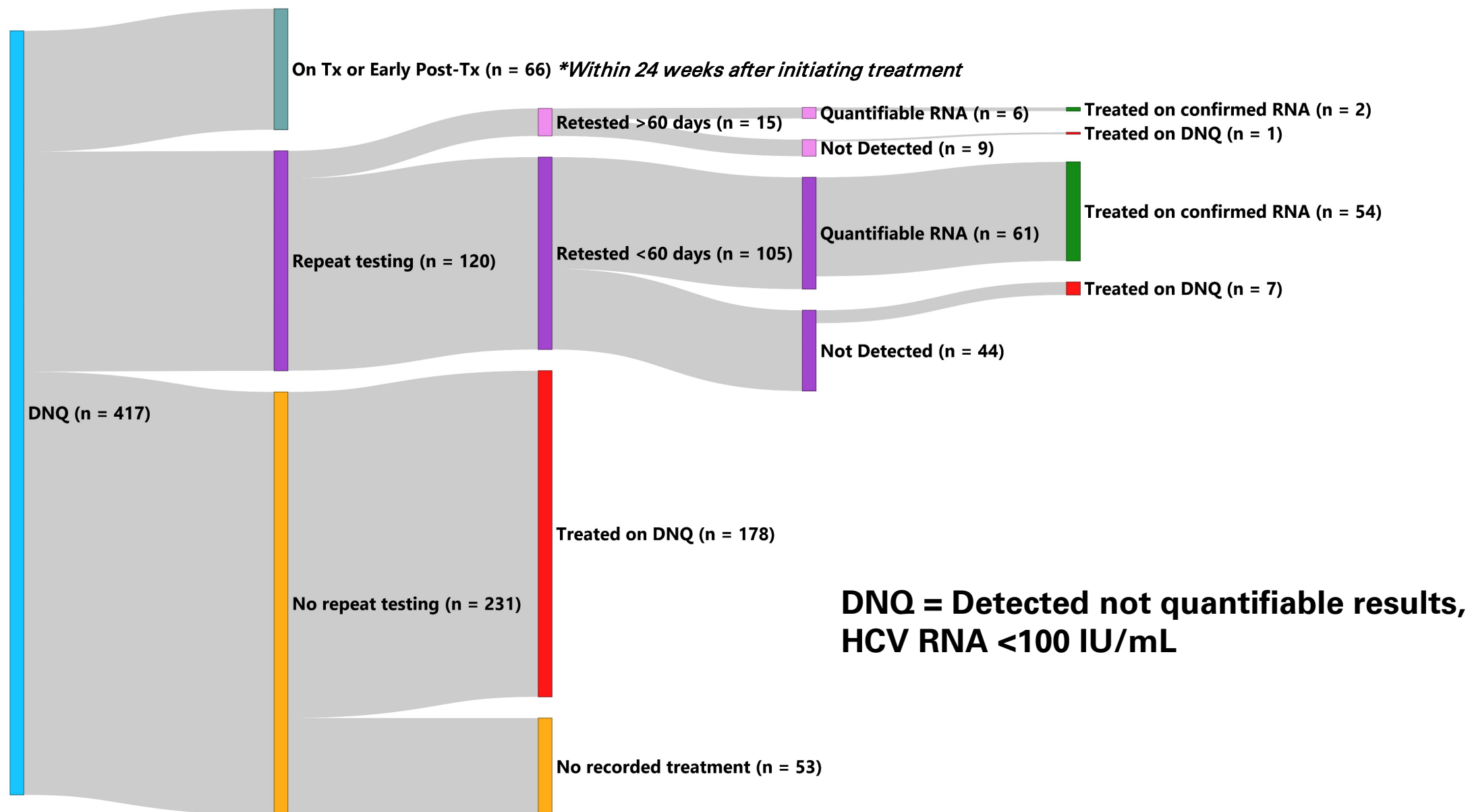
Australian HCV POC Testing Program

- January 2022 to October 2025
- 113 enrolled sites
- 27,606 participants
- 33,703 HCV RNA results

Detected, not quantifiable*	Detected and quantifiable	Not detected	Unsuccessful tests	Total
417 (1%)	4,862 (15%)	24,870 (74%)	3,554 (10%)	33,703 (100%)

**Detected not quantifiable results, HCV RNA <100 IU/mL*

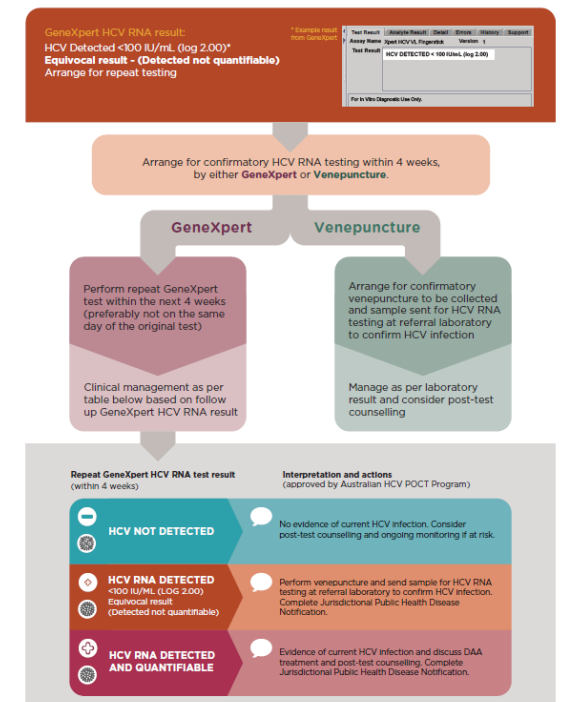
Outcomes of Detected Not Quantifiable (DNQ) Results



Summary

In summary:

- GeneXpert HCV assay can detect low levels of RNA
- Performance is consistent with manufacturer's claims
- On repeat testing, 44% of participants had RNA not detected results
- Repeat testing following DNQ results is recommended to:
 - confirm current HCV infection and
 - guide management decisions.
- Further guidance on management coming

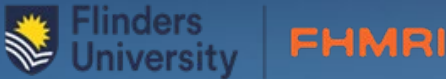


Questions

We acknowledge all people living with hepatitis C and other infectious diseases who have generously participated in research that has informed this presentation.

Disclosures:

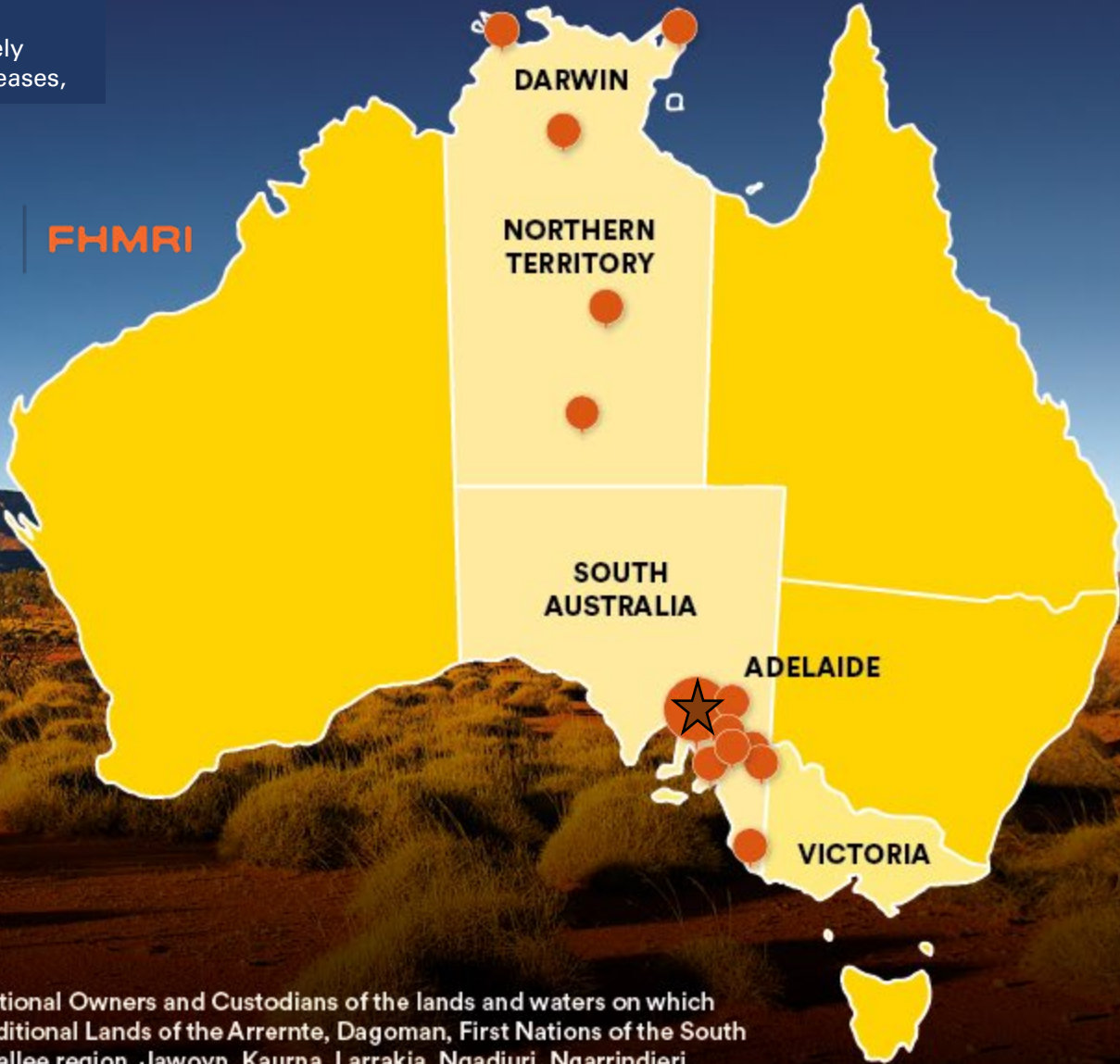
- No known conflicts of interest to declare
- Presenting work on behalf of the National Hepatitis C POC team, led by Professor Jason Grebely
- POCT training evaluation research funding from NHMRC RAPID Consortium for Infectious Diseases,



ADELAIDE
BEDFORD PARK
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VICTORIA SQUARE

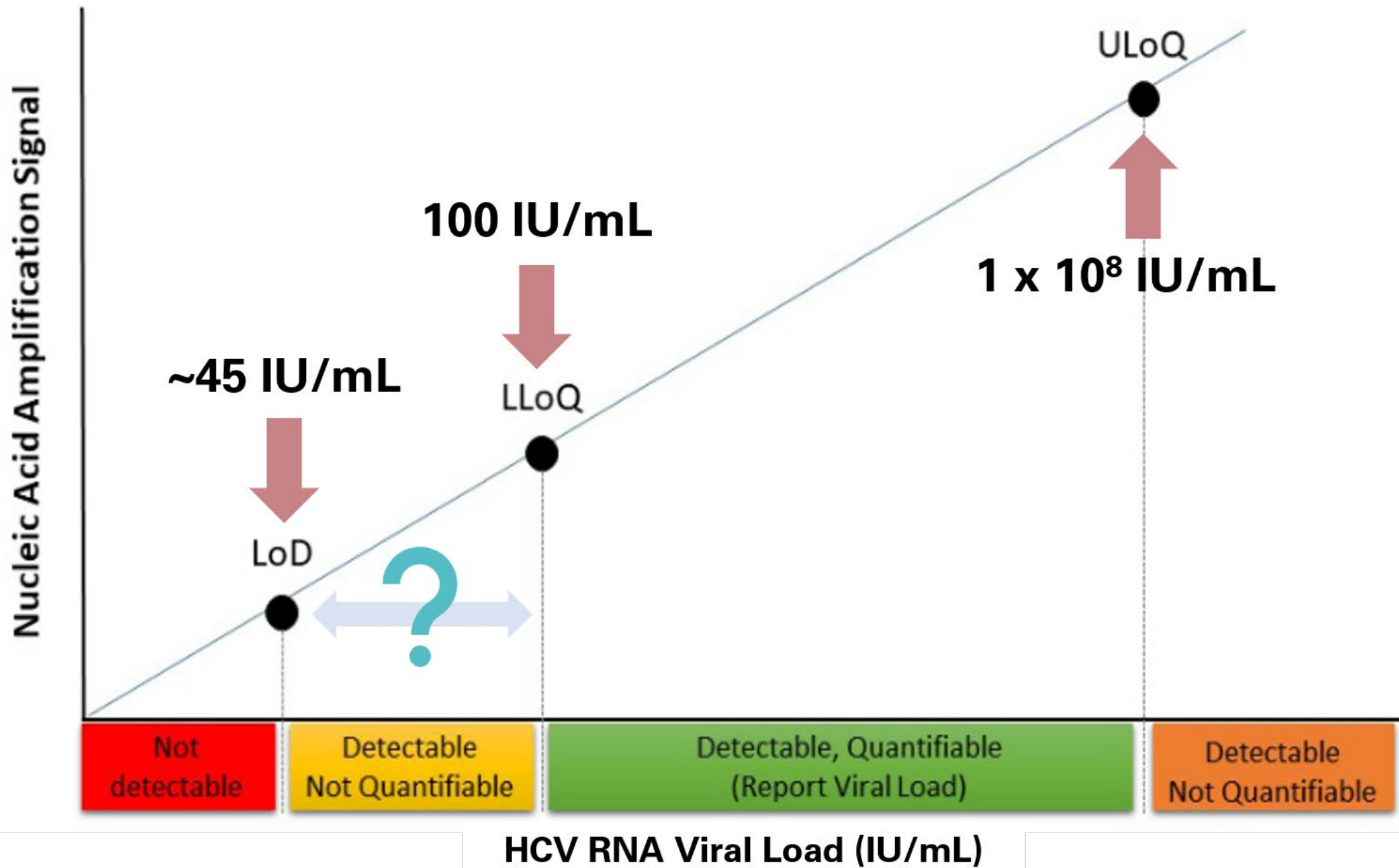
SOUTH AUSTRALIA
BAROSSA
BERRI
MOUNT GAMBIER
MURRAY BRIDGE
RENMARK
VICTOR HARBOR

NORTHERN TERRITORY
ALICE SPRINGS
DARWIN
KATHERINE
NHULUNBUY
TENNANT CREEK

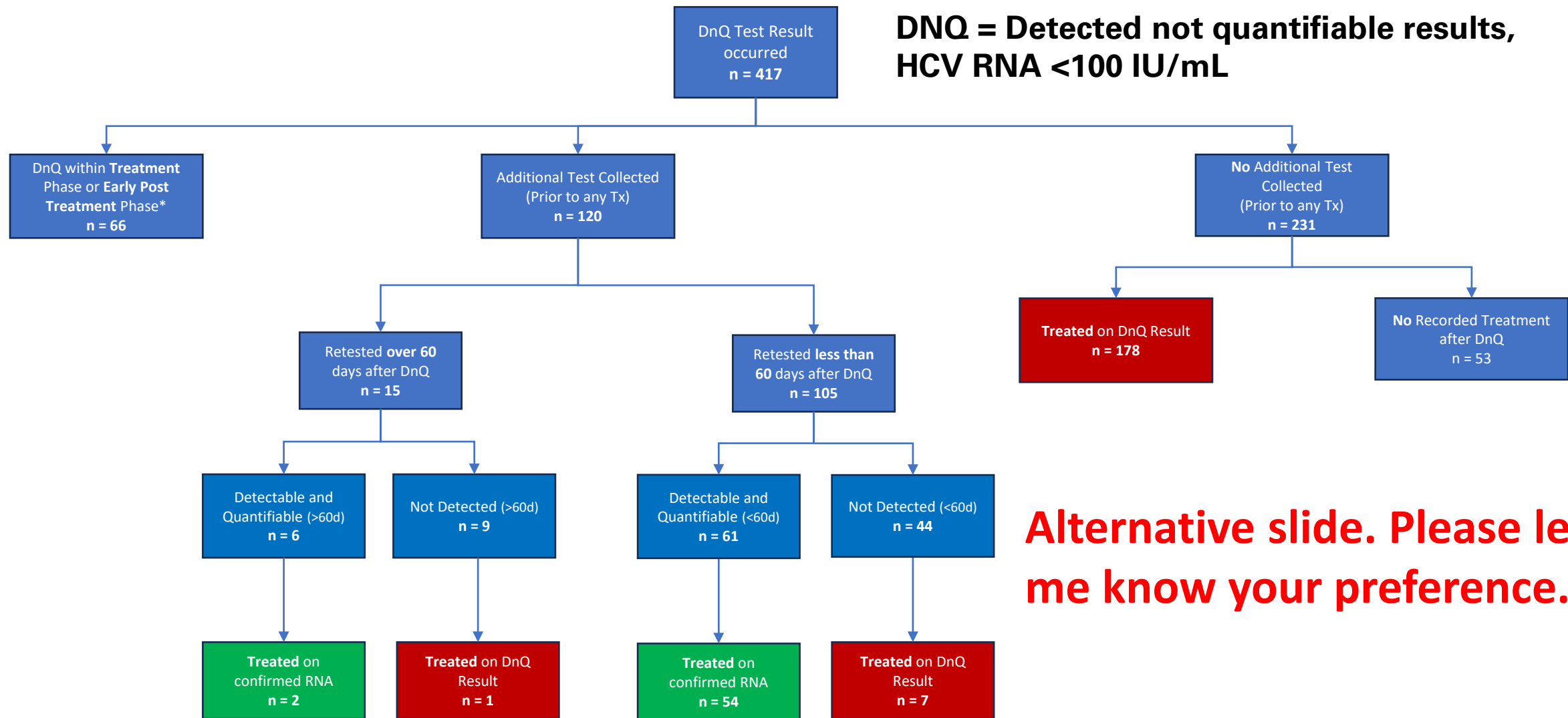


Flinders University acknowledges the Traditional Owners and Custodians of the lands and waters on which its campuses are located, these are the Traditional Lands of the Arrernte, Dagoman, First Nations of the South East, First Peoples of the River Murray & Mallee region, Jawoyn, Kurna, Larrakia, Ngadjuri, Ngarrindjeri, Ramindjeri, Warumungu, Wardaman and Yolngu people. We honour their Elders past, present and emerging.

Questions



Outcomes of Detected Not Quantifiable (DNQ) Results



* Within 24 weeks after initiating treatment

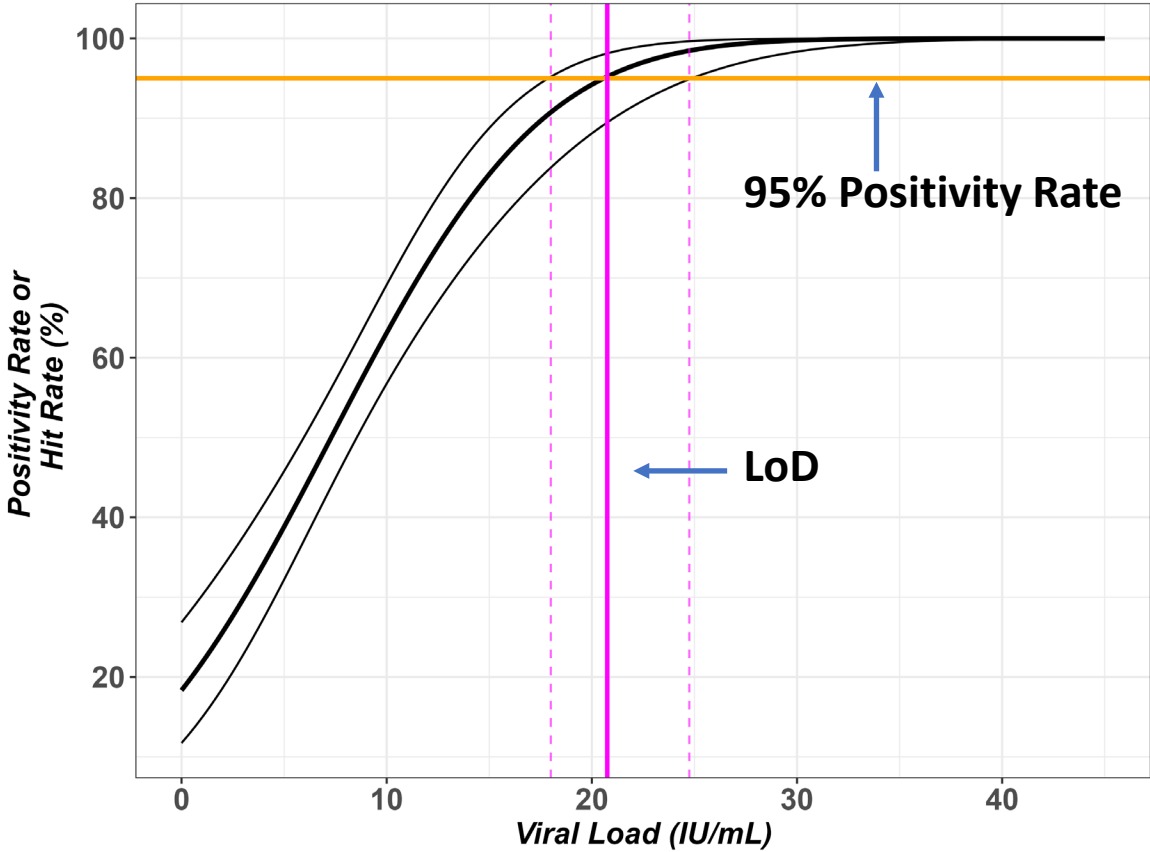
Xpert HCV VL FS Assay LoD

Positivity Rate or Hit Rate:

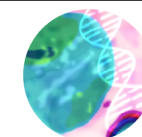
- Number of replicates that are detected at specific nominal concentration.

Table 2. Limit of Detection for the Xpert HCV VL FS Assay using PROBIT Regression

Genotype	Nominal Concentration (IU/mL)	Number of Valid Replicates	Number of Positives	Positivity Rate (%)	LOD with 95% Probability Estimated by PROBIT (95% Confidence Interval)
1a	45	72	72	100%	22 IU/mL ^a (95% CI: 17 – 27 IU/mL)
	30	72	70	97%	
	15	72	59	82%	
	10	72	59	82%	
	5	72	30	42%	
	2.5	72	9	13%	



Xpert HCV VL FS Assay LoD



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National Australian Hepatitis C Point-of-Care Testing Program

Genotype	Nominal Concentration (IU/mL)	Number of Valid Replicates	Number of Positives	Positivity Rate (%)	LOD with 95% Probability Estimated by PROBIT (95% Confidence Interval)
2b	45	24	24	100%	13 IU/mL (95% CI: 10 – 16 IU/mL)
	30	24	24	100%	
	15	24	24	100%	
	10	24	18	75%	
	5	24	12	50%	
	2.5	24	9	38%	
3a	45	24	24	100%	28 IU/mL (95% CI: 21 – 34 IU/mL)
	30	24	22	92%	
	15	24	17	71%	
	10	24	14	58%	
	5	24	12	50%	
	2.5	24	4	17%	
4	45	24	24	100%	15 IU/mL (95% CI: 13 – 20 IU/mL)
	30	24	24	100%	
	15	24	20	83%	
	10	24	21	88%	
	5	24	16	67%	
	2.5	24	8	33%	
5	45	24	24	100%	28 IU/mL (95% CI: 21 – 36 IU/mL)
	30	23	21	91%	
	15	24	17	71%	
	10	24	15	63%	
	5	24	11	46%	
	2.5	24	9	38%	
6e	60	24	24	100%	35 IU/mL (95% CI: 28 – 42 IU/mL)
	45	24	23	96%	
	30	24	22	92%	
	15	24	14	58%	
	10	24	11	46%	
	5	24	10	42%	
	2.5	24	3	13%	

Table 2. Limit of Detection for the Xpert HCV VL FS Assay using PROBIT Regression

Genotype	Nominal Concentration (IU/mL)	Number of Valid Replicates	Number of Positives	Positivity Rate (%)	LOD with 95% Probability Estimated by PROBIT (95% Confidence Interval)
1a	45	72	72	100%	22 IU/mL ^a (95% CI: 17 – 27 IU/mL)
	30	72	70	97%	
	15	72	59	82%	
	10	72	59	82%	
	5	72	30	42%	
	2.5	72	9	13%	
1b	45	24	24	100%	23 IU/mL (95% CI: 18 – 32 IU/mL)
	30	24	23	96%	
	15	24	19	79%	
	10	24	18	75%	
	5	24	13	54%	
	2.5	24	11	46%	

a. The highest estimated LOD for genotype 1a based on testing and analysis of each of three reagent lots.

Table 5. Precision/Reproducibility of the Xpert HCV VL FS Assay

HCV RNA Concentration (log10 IU/mL)			Contribution to Total Variance SD (CV%)										Total Precision	
Expected	Actual	N	Site/Inst		Lot		Day		Operator/Run		Within-run		SD	CV ^b
			SD	(%) ^a	SD	(%) ^a	SD	(%) ^a	SD	(%) ^a	SD	(%) ^a		
8.00	7.73	216	0.09	30.2	0.06	16.5	<0.01	<0.1	0.04	7.2	0.11	46.1	0.15	36.8
7.00	6.77	216	0.08	36.8	0.05	15.5	0.04	8.7	0.03	5.1	0.08	33.9	0.14	32.8
5.70	5.68	216	<0.01	<0.1	0.06	27.0	0.02	5.3	0.01	0.7	0.09	66.9	0.11	25.1
4.00	3.88	216	0.09	35.9	0.04	5.9	<0.01	<0.1	0.01	0.8	0.11	57.3	0.15	35.1
3.00	3.00	213 ^c	0.04	11.8	<0.01	<0.1	0.02	3.5	0.01	1.0	0.10	83.7	0.11	26.4
2.00	1.97	216	0.03	2.2	<0.01	<0.1	0.03	2.5	<0.01	<0.1	0.20	95.3	0.20	49.2

- a. (%) is contribution of variance component to overall variance
- b. "CV" is lognormal CV, as obtained using the formula: $\text{Lognormal CV}(\%) = \sqrt{10^{[\text{SD}^2 * \ln(10)]} - 1} * 100$
CV(%) = percent coefficient of variation; SD = standard deviation; sqrt = square root

