Kirby Institute

Performance evaluation of the Hologic Aptima HCV Quant Dx assay for detection of HCV RNA from dried blood spots

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I want to begin by acknowledging and thanking the people living with Viral Hepatitis who have generously participated in this research

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BACKGROUND/AIMS & METHODS:

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- 71 million people infected with HCV worldwide
  - WHO goal to eliminate HCV by 2030 but no effective vaccine and only 20% of chronically infected individuals diagnosed
- DAA therapies broadly available in Australia on the PBS schedule
  - >95% cure rate
- Understanding barriers and addressing low rates of HCV testing and diagnosis will be critical
  - Simplified diagnostic models required to link people into care – DBS, POCT

- Study aim: Evaluate the performance of the Aptima® HCV Dx Quant assay for HCV RNA detection with paired venepuncture and DBS (spotted whole blood) samples.
- Methods: Paired EDTA plasma and DBS samples (n=107) prepared from de-identified remnant samples of HCV antibody positive individuals.
  - Samples analysed on the Hologic™ Panther® Platform
- Statistical analysis
  - Sensitivity and Specificity
  - Bland Altman and Deming Regression analysis

RESULTS:

Table 1. Quantitation of HCV RNA positive results in DBS >LLOQ

		Plasma		Total
		Not Detected/ Unquantifiable	Detected ≥10 IU/mL	
DBS	Not Detected/ Unquantifiable	27	2	29
	Detected ≥10 IU/mL	1*	77	78
Total		28	79	107

***Less than <10 detected on PL, 338 for DBS**

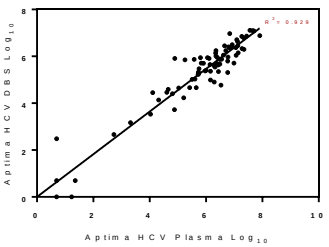
Table 2. Quantitation of HCV RNA in DBS versus Plasma samples at ≥1000 IU

		Plasma		Total
		Not Detected/ Unquantifiable	Detected ≥ 1000 IU/mL	
DBS	Not Detected/ Unquantifiable	31	0	31
	Detected ≥1000 IU/mL	0	76	76
Total		31	76	107

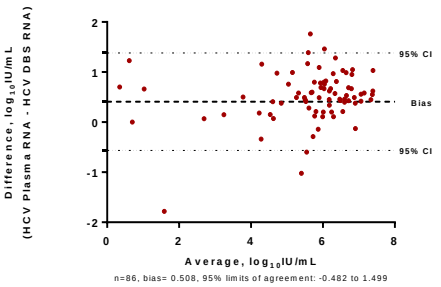
Sensitivity	Specificity
97.5% (95%CI 91-100%)	100% (95%CI 87-100%)

Sensitivity	Specificity
100% (95%CI 95-100%)	100% (95%CI 89-100%)

DBS Haematocrit Correction
X 25.97 (plasma conversion factor)
assumptions 45% haematocrit average per DBS, 70uL DBS volume, 1000ul ATM volume.



(Detectable only) (n= 86), Y = 0.9228*X - 0.07554: R^2 = 0.929



n=86, bias= 0.508, 95% limits of agreement: -0.482 to 1.499

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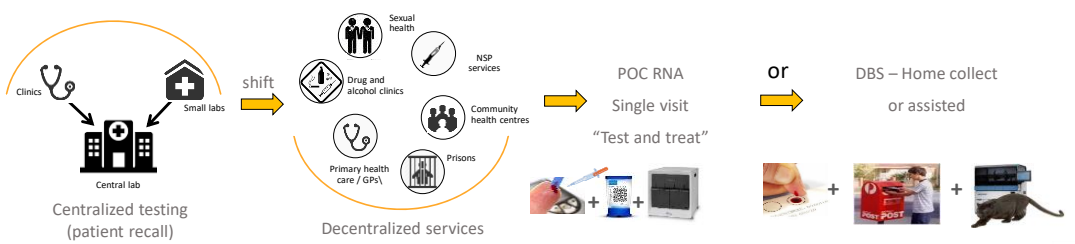
CONCLUSIONS/IMPLICATIONS:

- Aptima HCV Dx Quant detects active infection (DBS) with good sensitivity and specificity especially ≥1000 IU/mL. Correlation, bias and agreement demonstrate DBS as a suitable alternative to plasma for HCV RNA analysis on the Aptima assay
- Applicable for implementing simplified diagnostic strategies in people who inject drugs
  - Home self collection - https://www.hivtest.health.nsw.gov.au
  - Assisted collection through registered decentralized services
  - Further evaluation needed to evaluate real world performance enabling registration of a kit insert claim



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