

## HEPATITIS C VIRUS CORE ANTIGEN AND DRIED BLOOD SPOTS AS SIMPLIFIED HEPATITIS C VIRUS DIAGNOSTIC TOOLS

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**Background:** Simplified, affordable diagnostic tools are urgently required to scale up hepatitis C virus (HCV) treatment. This study evaluated the diagnostic performance of HCV core antigen (HCVcAg) detection in plasma and dried blood spot (DBS) samples.

**Methods:** Paired plasma and venous DBS samples were prepared from remnant diagnostic samples. Plasma HCV RNA was quantified by AmpliPrep/COBAS Taqman (Roche). HCVcAg were measured by ARCHITECT HCV Ag (Abbott Diagnostics). The agreement between both assays was assessed by Bland-Altman Bias plot (conversion factor, 1fmol/L = 500IU/mL). The sensitivity and specificity for the HCVcAg assay (>3fmol/L) at a threshold of HCV RNA>1000IU/mL were calculated for both plasma and DBS.

**Results:** Of 120 paired samples tested, 25 had non-quantifiable HCV RNA and 95 quantifiable HCV RNA. The median HCV RNA level in plasma was 5.8 log IU/mL (IQR: 5.2, 6.4). The median HCVcAg level for plasma and DBS was 2.7 log fmol/L (IQR: 2.0, 3.3) and 1.6 log fmol/L (IQR: 1.0, 2.1), respectively. The Bland-Altman bias (95% limits of agreement) for plasma and DBS was 0.37 fmol/L (-0.81, 1.55) with mean difference (95%CI) of 0.37 fmol/L (0.24-0.49) and 1.598 fmol/L (0.32, 2.87) with mean difference (95%CI) of 1.60 fmol/L (1.46-1.74), respectively. Of 4 samples < 1000IU/mL (range 27 to 220IU/mL) in plasma, 0 were reactive for HCVcAg in both plasma and DBS. One HCV RNA negative sample was HCVcAg reactive (7.5fmol/L) in DBS and negative in plasma. For diagnosing HCV RNA>1000IU/mL, the sensitivity of HCVcAg in plasma and DBS was 96.7% (95%CI 89.9-99.1%) and 91.0% (95%CI 83.2-95.5%), respectively. The specificity of HCVcAg in plasma and DBS was 100% (95%CI 85.9-100%) and 96.7% (95%CI 80.9-99.8%), respectively.

**Conclusion:** These data indicates HCVcAg in plasma and DBS may be suitable for HCV surveillance and diagnosis of chronic HCV, particularly in lower and middle-income or high prevalence countries.

**Disclosure of Interest Statement:** The Kirby Institute is funded by the Australian Government Department of Health and Ageing and the National Health and Medical Research Program Grant (#1053206). The views expressed in this publication do not necessarily represent the position of the Australian Government. The content is solely the responsibility of the authors. Jason Grebely and Gail Matthews are supported through NHMRC Career Development Fellowships. Gregory Dore is supported through NHMRC Practitioner Fellowships. Abbott Diagnostics provided for funding for the core antigen testing in this study. Gavin Cloherty is an employee and shareholder of Abbott Laboratories.