# Evaluation Of A Hepatitis C Virus Core Antigen Assay In Dried-Blood Spots: A Cohort Study

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**Introduction:**
Simple and affordable tests that diagnose active hepatitis C virus (HCV) infection are required to scale up treatment. This study evaluated the performance of HCV core antigen (HCVcAg) detection in plasma samples and capillary-blood samples collected by dried blood spot (DBS).

**Methods:**
Plasma and DBS samples were collected from participants in an observational cohort in Australia. This study evaluated the sensitivity and specificity of the ARCHITECT HCV Ag (Abbott Diagnostics) test for the detection of HCV core antigen (HCVcAg) in plasma and DBS compared with the Abbott RealTime HCV Viral Load assay in plasma.

**Results:**
Of 205 participants enrolled, 200 had paired HCVcAg results on plasma and capillary DBS samples, and HCV RNA on plasma. Participants receiving HCV therapy were excluded (n=14). HCV RNA was detected in 29% of participants ([95% CI 22.6-36.1], 54 of 186). For quantification (≥12 IU/mL) and detection of HCV RNA (≥3,000 IU/mL) in plasma, the sensitivity of the ARCHITECT HCV Ag assay on plasma (>3fmol/L) was 98.1% (95% CI 90–100) and 100% (95% CI 93-100), respectively. For the quantification (≥12 IU/mL) and detection of HCV RNA (≥3,000 IU/mL) in plasma, the sensitivity of the ARCHITECT HCV Ag assay on DBS samples was 90.7% (95% CI 80–97) and 92.5% (95% CI 82-98), respectively. The specificity for HCVcAg in plasma and DBS was 100% (95% CI 97-100), for both RNA thresholds. One participant had a viral load less than 3,000 IU/mL (424 IU/mL), and tested HCVcAg negative on plasma and DBS. Five HCV RNA positive samples were false negatives when assessed for HCVcAg in DBS (424 - 26595 IU/mL).

**Conclusion:**
These data indicate HCVcAg in plasma and DBS may be suitable for HCV surveillance and diagnosis of chronic HCV infection. Further studies are required to evaluate the clinical performance of HCVcAg in individuals with low level viraemia.

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