

EVALUATION OF HEPATITIS C VIRUS CORE ANTIGEN DIAGNOSTIC PERFORMANCE FOR DETERMINING ACTIVE HEPATITIS C INFECTION

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BACKGROUND AND OBJECTIVES: Chronic HCV infection accounts for 58 million prevalent cases worldwide, representing a substantial global health burden with significant morbidity, mortality, and healthcare costs. Many affected individuals remain undiagnosed, particularly in low- and middle-income countries. Traditional screening uses antibody assays (reflecting exposure) followed by nucleic acid testing (NAT) for confirmation of active infection. However, NAT's high cost and complexity limit accessibility. HCV core antigen (HCVcAg) testing is a cost-effective alternative. This study evaluated HCVcAg assay performance against HCV RNA PCR for confirming active infection.

METHODS: Fifteen archived human serum specimens previously tested by HCV RNA PCR were evaluated using the Abbott ARCHITECT HCV Ag chemiluminescent microparticle immunoassay. Sensitivity, specificity, positive and negative predictive values (PPV/NPV), and accuracy were calculated against HCV RNA. Correlation was assessed through Pearson's coefficient and agreement through Cohen's Kappa.

RESULTS: The HCVcAg assay showed 100% sensitivity, specificity, PPV, NPV, and accuracy. A strong positive correlation was found between log₁₀ HCVcAg and log₁₀ HCV RNA ($r = 0.82$, $p < 0.0001$). Cohen's Kappa showed ideal agreement ($\kappa = 1.00$, $p < 0.001$).

CONCLUSION: HCVcAg demonstrated excellent diagnostic performance and strong correlation with HCV RNA despite the small sample size. It is a reliable, cost-effective NAT alternative for confirming active HCV infection, especially in resource-limited settings. Integrating HCVcAg into South African diagnostic algorithms could enhance early detection and linkage to care, thereby facilitating timely treatment initiation, reducing community transmission, and supporting the World Health Organization's goal of eliminating HCV as a public health threat by 2030.