Comparative evaluation of point-of-care anti-HCV antibody tests for diagnosis of hepatitis C infection

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Background: Point-of-care HCV antibody assays simplify testing and improve linkage to care, but diagnostic performance may be affected by infection status and treatment history. This study evaluated the diagnostic performance of two fingerstick point-of-care HCV antibody assays (SD Bioline HCV, INSTI HCV Antibody Test) with standard of care (Abbott Alinity i).

Methods: Participants enrolled in an Australian prospective cohort, ETHOS II, between June 2024-August 2025 had paired capillary blood (point-of-care HCV antibody ± RNA) and venepuncture plasma (laboratory HCV antibody + RNA) samples collected. Diagnostic performance of the point-of-care antibody assays was compared with standard of care, overall and stratified by infection status (current – HCV RNA detected, past - antibody reactive, RNA not detected). Paired comparisons between point-of-care antibody assays were performed using McNemar's test. Additionally, testing was performed on stored samples among people with current HCV infection enrolled in three clinical trials (SIMPLIFY, D3FEAT, TARGET3D).

Results: Among 398 ETHOS II participants (women, 29%; injecting drug use in last month, 71%; current opioid agonist treatment, 63%; prior HCV treatment, 48%), HCV antibody and HCV RNA prevalence were 70% and 6%, respectively. Compared with standard of care, sensitivity and specificity of SD Bioline was 94% (95%CI 91-97) and 99% (95%CI 95-100), while sensitivity and specificity of INSTI was 86% (95%CI 81-90) and 100% (95%CI 97-100) (Δ sensitivity SD Bioline vs INSTI, 8% [95%CI 5-12], p<0.001). Compared with standard of care, sensitivity was 100% for both point-of-care antibody assays among participants with current HCV (n=25), but was lower among those with past infection (n=253) - SD Bioline 94% (95%CI 90-96), INSTI 85% (95%CI 80-89). High sensitivity (100%) for both point-of-care antibody assays among people with current infection was confirmed on stored specimens (n=159).

Conclusion: Point-of-care HCV antibody assays demonstrated excellent diagnostic performance among people with current infection, but reduced sensitivity for past infection.

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