

Detection and clinical management of low-level hepatitis C RNA following point-of-care HCV RNA testing

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Background: Point-of-care HCV RNA tests enable rapid detection and measurement of HCV RNA levels. Regulatory approved HCV RNA tests are highly sensitive and may detect very low levels of HCV RNA (detectable, not quantifiable), of which the clinical significance is uncertain. We evaluated repeat HCV testing and initiation of treatment among people with detectable, not quantifiable HCV RNA in the Australian HCV Point-of-Care Testing Program.

Methods: The Australian HCV Point-of-Care Testing Program is an observational study evaluating the scale-up of point-of-care HCV testing at 113 sites across all states/territories of Australia. Point-of-care testing is offered to people at HCV risk or attending a service providing care for people at HCV risk. HCV RNA testing is performed using the Xpert HCV VL Fingerstick test (Cepheid, US). HCV RNA detected below the assay limit of quantification (LoQ) is reported as <100 IU/mL. We evaluated the proportion of client tests: a) reported as “detected not quantifiable” HCV RNA (i.e. <100 IU/mL), b) receiving repeat testing, and c) initiating treatment.

Results: From January 2022–October 2025, 33,703 HCV RNA tests were performed, with 417 (1.2%) detected not quantifiable (<100 IU/mL), 4,862 (14.5%) detected and quantifiable, 24,870 (73.8%) not detected and 3,554 (10.5%) unsuccessful tests. Of 417 participants with detected not quantifiable results, 178 (43%) received HCV treatment without retesting, 120 (29%) were retested (point-of-care RNA n=29; venepuncture with laboratory testing n=75; unknown n=16) and 66 (16%) were tested on treatment or early post-treatment. Of 120 participants retested, 53 (44%) were not detected. Among those with repeat not detectable results, 45 (85%) did not initiate treatment, while eight (15%) commenced HCV treatment.

Conclusion: The Xpert HCV RNA test has analytical performance consistent with the manufacturer claims, however repeat testing following low-level HCV RNA (detected not quantifiable) results is recommended to confirm current HCV infection and guide management decisions.

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