

Tests for hepatitis C (HCV) infection

Test/Type	Application	Comments
Hepatitis C virus antibody (anti-HCV) <ul style="list-style-type: none"> • EIA (enzyme immunoassay) • Supplemental assay (i.e. recombinant immunoblot assay [RIBA™]) 	<ul style="list-style-type: none"> • Indicates past or present infection, but does not differentiate between acute, chronic, or resolved infection • All positive EIA results should be verified with a supplemental assay 	<ul style="list-style-type: none"> • Sensitivity $\geq 97\%$ • EIA alone has low-positive predictive value in low-prevalence populations
HCV RNA (hepatitis C virus ribonucleic acid) <p>Qualitative tests*\cong</p> <ul style="list-style-type: none"> • Reverse transcriptase polymerase chain reaction (RT-PCR) amplification of HCV RNA by in-house or commercial assays (e.g., Amplicor HCV™) 	<ul style="list-style-type: none"> • Detect presence of circulating HCV RNA • Monitor patients on antiviral therapy 	<ul style="list-style-type: none"> • Detect virus as early as 1-2 weeks after exposure • Detection of HCV RNA during course of infection might be intermittent; a single negative RT-PCR is not conclusive • False-positive and false-negative results might occur
Quantitative tests* \cong <ul style="list-style-type: none"> • RT-PCR amplification of HCV RNA by in-house or commercial assays (e.g., Amplicor HCV Monitor™) Branched chain DNA§ (bDNA) assays (e.g., Quantiplex™ HCV RNA Assay)	<ul style="list-style-type: none"> • Determine concentration of HCV RNA • Might be useful for assessing the likelihood of response to antiviral therapy 	<ul style="list-style-type: none"> • Less sensitive than qualitative RT-PCR • Should not be used to exclude the diagnosis of HCV infection or to determine treatment endpoint
Genotype* <ul style="list-style-type: none"> • Several methodologies available (e.g., hybridization, sequencing) 	<ul style="list-style-type: none"> • Group isolates of HCV based on genetic differences, into 6 genotypes and >90 subtypes • With new therapies, length of treatment might vary based on genotype 	<ul style="list-style-type: none"> • Genotype 1 (subtypes 1a and 1b) most common in United States and associated with lower response to antiviral therapy
Serotype* <ul style="list-style-type: none"> • EIA based on immunoreactivity to synthetic peptides (e.g., Murex HCV serotyping 1-6 Assay) 	<ul style="list-style-type: none"> • No clinical utility 	<ul style="list-style-type: none"> • Cannot distinguish between subtypes • Dual infections often involved

*Currently not U.S. Food and Drug Administration approved; lack standardization.

\cong Samples require special handling (e.g., serum must be separated within 2-4 hours of collection and stored frozen [-20 C or -70 C]; frozen samples should be Shipped on dry ice)

§Deoxyribonucleic acid. Source: CDC MMWR