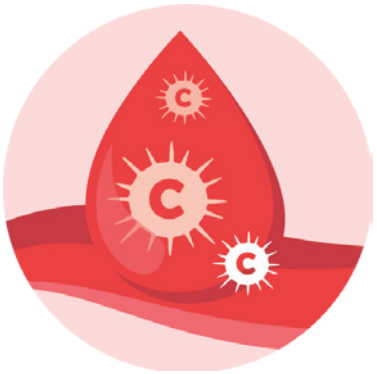
Hepatitis C virus testing and baselining

Has the person ever been exposed to HCV?

Test 1 - The Antibody (Ab) test

A positive HCV Ab result indicates that the person has been exposed to the virus at some point in their life. Note that:

- A positive HCV Ab test result does not distinguish between acute, chronic or cleared infection.
- The presence of HCV antibodies does not provide protection against HCV.



A negative result means that current HCV infection is unlikely. The HCV antibody test has low rates of false negatives or positives. However, this test may need to be repeated if the person has been exposed to risk recently (and possibly tested during the 'window period').

A small number (<5-10%) of immunocompromised hosts, including people living with HIV, may never develop HCV Ab, despite chronic HCV infection. In this case, HCV RNA should be performed to diagnose active HCV infection.

Does the person currently have HCV?

Test 2 - The RNA test

This can be determined by ordering a HCV RNA test. This is a test to detect the presence of virus in the blood, by Polymerase Chain Reaction (PCR).
The HCV RNA test may be qualitative
or quantitative.
A positive result confirms the detection of HCV RNA and current viraemic HCV infection.

Ab
Antobody test EVER come into contact with HCV

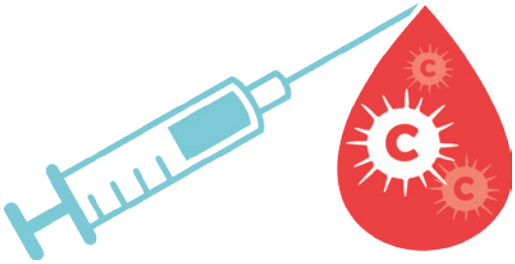
RNA
Infected with the virus NOW

Ab + + RNA + = **Infected** with HCV **NOW**

Ab + + RNA − = **Infected** with HCV in the **PAST**

Ab + + RNA − = **NEVER** infected with HCV

Timing of the tests



Diagnosis of chronic HCV infection

All individuals with a risk factor for HCV infection should be tested.

The appropriate initial test for HCV screening or diagnosis is serology, with anti-HCV Ab, which indicates exposure to HCV, either current or past infection. Current HCV infection should be confirmed by a PCR assay for HCV RNA.

Approximately 25% of acute HCV infections will clear spontaneously within 6 months (and up to 2 years) post exposure; these individuals remain indefinitely HCV Ab positive, but do not have detectable HCV RNA in plasma.

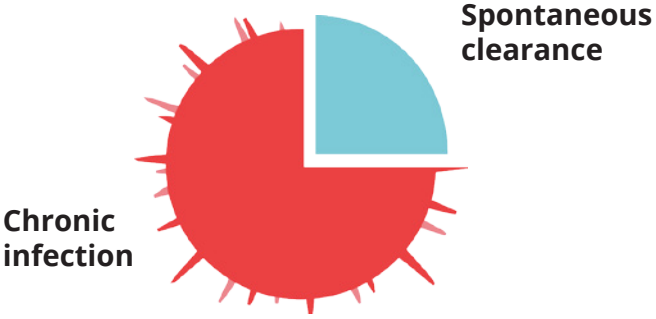
The clinical definition of chronic HCV infection is duration longer than 6 months.

While HCV antibodies are usually detectable within 6-12 weeks of infection, development may take up to 12 months in immunocompromised hosts, including solid-organ transplant recipients, haemodialysis patients and HIV-positive individuals. In a few cases (<5%), HCV antibody formation may not occur; HCV RNA should be performed to diagnose HCV infection.

Diagnosis of acute HCV infection

While HCV RNA is detectable in blood within 2–14 days of exposure, HCV Ab typically develops within 6-12 weeks of exposure. The detection of HCV RNA with a negative HCV antibody followed by HCV Ab seroconversion suggests very recent infection with probable exposure in the prior 6-8 weeks.

If acute HCV infection is suspected, HCV Ab and HCV RNA should be performed.



Screening for HCV

Annual HCV serology testing is recommended for seronegative individuals with ongoing risk factors for HCV transmission (PWID, HIV-positive MSM).

For individuals who are seropositive but have undetectable HCV RNA (indicating past infection), annual HCV RNA testing is recommended in the setting of ongoing risk factors for HCV transmission.

What HCV genotype do they carry?

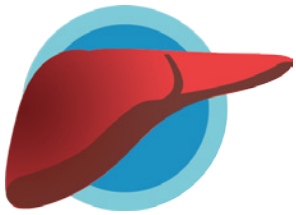
A HCV genotype test is necessary before treatment initiation, as current PBS-listed treatments are genotype-specific. HCV genotyping is a routine laboratory test performed during RNA testing.

As new treatments continue to become available it is likely all 7 genotypes will be easier to treat, with pan-genotypic therapies.

What is the HCV RNA level (HCV “viral load”)?

Quantitative HCV RNA at treatment commencement (baseline) may help predict a person’s response to therapy. A low pre-treatment HCV RNA (“viral load”) may allow for a shorter duration of therapy. A shortened treatment duration of 8 weeks sofosbuvir/ledipasvir may be considered In people with HCV genotype 1, who are treatment naïve, non-cirrhotic and have a baseline HCV RNA level <6 million IU/mL. This test can also be used to monitor response while on therapy.

How is their liver functioning?



Liver Function tests (LFTs) provide a baseline of current liver function and help identify damage to liver cells. The relevant component tests of a routine LFT are bilirubin, ALP, GGT, ALT and AST. Documentation of the presence or absence of cirrhosis influences treatment regimen and duration.