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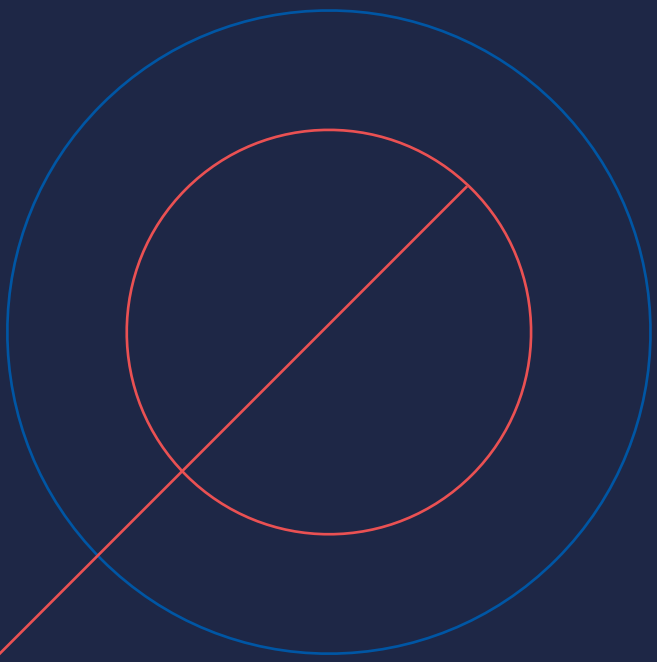
National Hepatitis C Testing Policy 2025



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National Hepatitis C Testing Policy v1.5

Reviewed 2024-2025.

Disclaimer: This Testing Policy has been developed as a concise source of standardised, currently available information to inform those involved in ordering and performing hepatitis C testing. This Policy is not a set of clinical guidelines, and it should not be used as a guide for the clinical management of hepatitis C infection. For clinical management and treatment guidelines, see the Australian recommendations for the management of hepatitis C virus infection: a consensus statement [2022].

This Policy was written by the National Hepatitis C Testing Policy Expert Reference Committee, funded by the Australian Government Department of Health. The review process was coordinated by ASHM Health.

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The web-based version of the National Hepatitis C Testing Policy allows for regular revision, and access to related resources (e.g. related policies, operational guidelines, evidence of best practice) with a download and print function which can be found at: https://testingportal.ashm.org.au/. Any references or web links to products, services or information contained in this publication do not constitute an endorsement of those references or web links.

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National Hepatitis C Testing Policy 2025

The National Hepatitis C Testing Policy is supported by funding from the Australian Government Department of Health.

The National Hepatitis C Testing Policy is being submitted to the Blood Borne Viruses and Sexually Transmissible Infections Committee for endorsement.

Contents

Executive summary

Background and objectives
This Policy provides a framework for best practice approaches to appropriate high-quality hepatitis C testing in the Australian context and recognises that hepatitis C virus (HCV) testing is vital to reducing transmission and facilitating treatment initiation.

HCV infection is a major public health problem globally with an estimated 57 million people living with current infection.[1] In Australia, it was estimated that 68,890 people were living with hepatitis C at the end of 2023.[2] Chronic infection is associated with progressive liver disease, which may lead to liver cirrhosis, liver failure and liver cancer in a large number of people.

In 2016 the World Health Organization (WHO) set the ambitious target of eliminating HCV as a major public health threat by 2030 (defined as 90% reduction in incidence and 65% reduction in HCV-related mortality compared to levels in 2015).[3]

Key areas for action around testing in the Sixth National Hepatitis C Strategy 2025-2030[4] include expanding the rollout and availability of new HCV testing technologies with linkage to care, for clinicians to utilise reflex testing and explore the feasibility of automatic HCV ribonucleic acid (RNA) testing for priority populations.

Approximately 19% of people living with hepatitis C in Australia are unaware of their infection. Many others previously diagnosed are lost to follow-up or otherwise disengaged from hepatitis C care. Diagnosing or re-finding all those with HCV infection is critical to ensure optimal clinical management and the prevention of ongoing transmission. The aim of this National Hepatitis C Testing Policy is to recommend evidence-based testing pathways for the diagnosis of hepatitis C infection.

This policy adheres to five key components outlined by WHO in relation to testing, also known as the 5 Cs:[5]
- Consent
- Confidentiality
- Counselling
- Correct test results
- Connection (linkage to prevention, care and treatment).

WHO notes that hepatitis C testing for diagnosis must always be voluntary, and consent for testing informed by pre-test information. Testing should be linked to prevention, treatment, care and support services to maximise both individual and public health benefits.

Types of HCV testing
People suspected of exposure to HCV should first be tested for the presence of HCV antibodies. A positive result will indicate exposure to HCV. It is then appropriate to reflex test HCV antibody-positive specimens for HCV RNA to determine if the person has a past or current infection.

The presence of HCV RNA indicates current infection, and all such people should be offered information, referral and treatment. Responses should be tailored to the person's circumstances and made with the person's involvement. Such actions can include peer education, referral to harm reduction services, or treatment with direct-acting antiviral (DAA) therapy. With the ready availability of pangenotypic DAA therapies, genotyping is no longer a requirement for treatment initiation.

A major change in this Policy is the inclusion of high-quality point-of-care testing for HCV antibodies and HCV RNA for the diagnosis and management of HCV. These testing techniques, now recognised by the Therapeutics Goods Administration (TGA), facilitate increased testing, including in people who have declined testing in routine laboratory settings. Point-of-care testing provides results rapidly and can facilitate more immediate access to treatment for appropriately informed and supported people.

Indications for HCV testing
The majority of HCV infections in Australia are chronic (having persisted for more than 6 months' duration).

The Sixth National Hepatitis C Strategy 2025-2030 refers to 'people affected by hepatitis C' to collectively frame hepatitis C priority populations and includes those who have lived with, who are living with, and are at risk of hepatitis C.

Informed consent for HCV testing
Informed consent must be obtained for HCV testing and testing should be voluntary, in a private setting.

For people with low English proficiency, an accredited interpreter should be used to obtain informed consent.

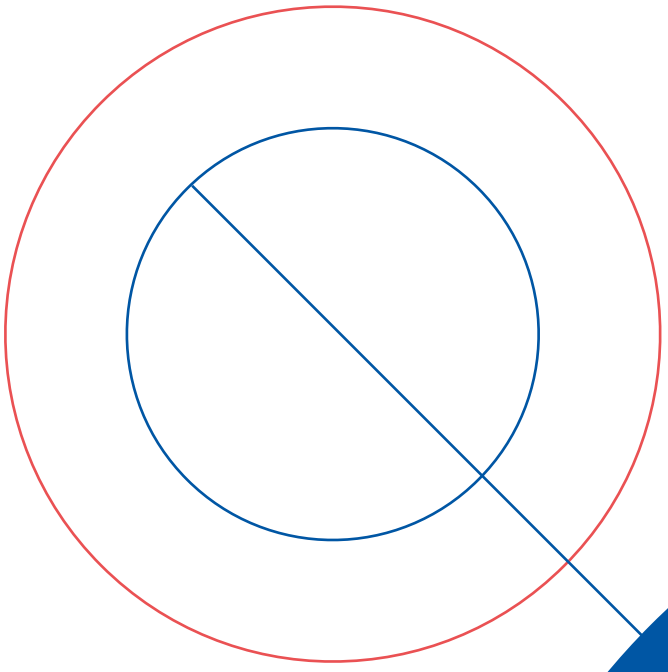
Conveying HCV test results

The healthcare provider conveying the outcome of the HCV test is responsible for ensuring that the person receiving the result understands its implications. Information provided in a single clinical consultation may be insufficient to meet their needs. Consideration should be given to informed-consent and appropriate referral of people to relevant community-based organisations for support after diagnosis.

Funding of HCV testing

Refer to Section 9 of this Policy, Quality Assurance of HCV Testing, for laboratory accreditation requirements.

In an accredited laboratory testing facility, funding for HCV testing is provided directly from the Australian government on a fee-for-service basis through the Medicare funding arrangements (Medicare Benefit Schedule Items 69445, 69475, 69488, 69491, 69499) and through State and Territory funding arrangements. Benefits for these tests are only payable if the request from the referring practitioner identifies in writing that the person is suspected of having acute or chronic hepatitis, either by use of the provisional diagnosis or relevant clinical or laboratory information.



1.0 Introduction

1.1 Background and context

Hepatitis C infection remains a major public health problem in Australia. There were 7,602 hepatitis C notifications in Australia in 2023.[2] In Australia, sharing of unsterile injecting equipment is the predominant mode of transmission, with most new and existing infections occurring among people who inject drugs. Given that no prisons in Australia provide sterile needles or syringes, there is an increased risk of HCV transmission among people who inject drugs while incarcerated.[6] Population groups that are over-represented in custodial settings, including people who inject drugs and Aboriginal and Torres Strait Islander people, bear a disproportionate burden of infection and re-infection.

In approximately 30% (15–40%) of people, acute infection is followed by viral clearance, with the remaining 70% (55–85%) progressing to chronic infection.[7] At the end of 2023, it was estimated that 68,890 people in Australia were living with current HCV infection.[2] Cirrhosis develops within 20 years in 5–10% of this group [usually associated with other comorbidities such as co-infection with human immunodeficiency virus (HIV) or hepatitis B virus (HBV), obesity, insulin resistance, metabolic dysfunction-associated steatotic liver disease (MASLD) or metabolic dysfunction-associated fatty liver disease (MAFLD), or alcohol intake over 40 g a day] and in a further 10–15% after 40 years.[8] Hepatocellular carcinoma will develop in 1–5% of people per annum who develop cirrhosis.[9]

Preventive interventions have proven effective in decreasing HCV transmission and therapeutic interventions are effective in improving quality of life and clinical outcomes for people with hepatitis C infection. New treatments subsidised on the Pharmaceutical Benefits Scheme (PBS) since March 2016 have greatly improved HCV sustained viral responses (SVR) and from 2016 to 2022, over 100,000 people achieved a sustained response to their treatment.[10] From 2016 to 2022, primary care physicians and nurse practitioners prescribed over 50% of all treatments for HCV in Australia. Annual treatment numbers have declined since 2016, and a concerted effort is now needed to identify those still in need of treatment.[2]

This edition of the Testing Policy seeks to define the current best practice for testing for exposure (or re-exposure) to HCV and for defining the current infective status of a person before, during and after treatment.

HCV testing can provide people with information regarding exposure to the virus. Appropriate testing indicates whether the person being tested has been exposed to HCV, has cleared the virus or has a current (chronic) infection. A point-of-care HCV RNA test was approved by the TGA and included in the Australian Register of Therapeutic Goods (ARTG) on 1 September 2020.[11] This test can provide confirmatory HCV RNA results within one hour, reducing the time taken for a complete diagnosis and the initiation of the care cascade. Additionally, a point-of-care HCV antibody test was approved by the TGA and included in the ARTG on 17 May 2024.[12]

The benefits of high-quality, reliable and timely testing are numerous, both for the person being tested and for public health. Detection of HCV infection followed by appropriate education can effectively reduce onward transmission, modify disease progression through earlier referral for advice and treatment, and protect the blood, tissue, and organ donation supply. Despite the public health and individual benefits of testing, a significant but undocumented number of people with HCV infection in Australia remain undiagnosed. Many others previously diagnosed are lost to follow-up or otherwise disengaged from HCV care and need to be found again.

It is therefore crucial that those people responsible for implementing this Policy (particularly those obtaining informed consent and providing test results) have the necessary skills and knowledge to fully communicate the significance of each of the available tests to the person being tested. This National Testing Policy assumes that all staff involved in the testing process are appropriately trained and deemed competent.

1.2 Purpose, scope and objectives

The main aim of this Policy is to recommend evidence-based testing pathways for the diagnosis of hepatitis C. This Policy is intended to support health professionals to provide current, innovative and effective testing and care for people at risk of, or living with, hepatitis C.

The Policy has broad scope and applies to laboratory and point-of-care testing for HCV infection. It is adaptable, and through the work of the Expert Reference Committee, allows for timely consideration of emerging technologies and the identification of regulations, legislation or procedures which may need to be modified to reflect evolving evidence, attitudes and expectations regarding HCV testing.

This Policy presents the principles, aims and arrangements for HCV testing in Australia and is aligned with the Sixth National Hepatitis C Strategy 2025-2030[4] which identifies the need to implement approaches that maximise the number of people living with hepatitis C who are diagnosed, including regular testing for HCV among priority populations and in priority settings.

1.3 Principles of HCV testing

The principles that guide HCV testing in Australia are aligned with the WHO five key components in relation to testing, also known as the 5 Cs[5]:

- Consent
- Confidentiality
- Counselling
- Correct test results
- Connection (linkage to prevention, care and treatment).

HCV testing in Australia should ensure:

- confidential, voluntary testing with informed consent and post-test discussion
- testing is accessible to all those who are or have been at risk of HCV infection
- testing is of the highest possible standard and provided in a timely manner, with appropriate access to care
- testing is of benefit to the person being tested
- testing is critical to understanding the epidemiology of HCV infection in the community
- testing is critical to interruption of transmission and supports harm reduction
- testing to monitor people with HCV before, during and after treatment is an integral part of care
- testing is undertaken in a culturally appropriate manner
- people are not denied testing because of fear of having their name associated with an HCV test (e.g. in a small community where confidentiality is harder to maintain, or in prison where access to prevention is limited and risk of re-infection is high among people who inject drugs). While recognising that the law in Australia often obliges notifications of infections to be identifiable, testing should always be conducted in ways that respect and maintain the person's privacy.

1.4 Policy implementation

HCV testing policies and practices must comply with all relevant Commonwealth, State and Territory anti-discrimination and public health legislation, and other relevant laws and regulations, including those governing Commonwealth funding of pathology tests.[13-15]

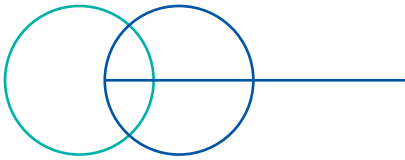
Individual State, Territory and institutional HCV testing policies should be consistent with the purpose, objectives and principles of this Policy, as well as with relevant legislation, and the common law.

Australia has a high quality, comprehensive multi-sector pathology service whose regulatory and quality framework for HCV diagnostic testing has evolved with a focus on formal laboratory settings, with linkage to the Medicare Benefits Schedule (MBS) rebate for tests performed in an accredited laboratory. However, since 2023, the National Hepatitis C Point-of-Care Testing Program has established high quality, point-of-care testing in many high prevalence settings (e.g. alcohol and other drug services, prisons) so the use of high quality point-of care testing is now regarded as a crucial part of the testing processes needed to optimise HCV diagnosis and treatment in Australia.

The National Pathology Accreditation Advisory Council (NPAAC) sets quality standards for pathology laboratories and the National Association of Testing Authorities (NATA) and the Royal College of Pathologists of Australasia (RCPA) accredit medical testing facilities against these standards.

Accreditation is required for pathology services to be eligible for the MBS rebates. Professional standards for pathology practice are established by the RCPA.

Tests for diagnosing HCV are categorised as Class 4 in-vitro diagnostic medical devices (IVDs) due to their



significant public health risk. Consequently, these diagnostic tests must undergo rigorous validation and receive approval from the TGA, before being included in the ARTG. Additionally, to ensure their continued safety and performance, the TGA may impose conditions on their inclusion. The Medical Services Advisory Committee (MSAC) advises which tests should be subsidised through the MBS. It can also recommend any restrictions on eligibility. See Section 9.2, Pre-market regulatory requirements for hepatitis C in-vitro diagnostic devices.

Some tests are performed outside the diagnostic laboratory, e.g. in research or clinical trials or in settings where point-of-care testing is being implemented. These uses may therefore be outside the regulatory framework offered by NATA accreditation and RCPA standards for MBS rebate, however high quality point-of-care testing relies on alignment with best-practice processes described in the regulatory documents

1.4.1 Voluntary confidential testing

Voluntary, confidential testing with informed consent is the standard for HCV testing in Australia. Testing is provided through a range of settings from general practice, remote and community clinics to specialist hepatitis, liver and infectious diseases services.

1.4.2 Mandatory and compulsory testing

- Mandatory testing refers to situations where people may either not participate in certain activities or not access certain services unless they agree to be tested. Circumstances in which mandatory testing is currently required under separate policy or legislation include:
  - as a condition of blood, tissue and organ donation[16]
  - under the migration health requirements applicable to specified visa subclasses
  - as a condition for entering training or service in the armed forces[18]
  - as a condition for purchasing some types of insurance[19]
  - in the context of a legal instruction, including in forensic, coronial or occupational settings.[20]
- Compulsory testing refers to situations where a person has no choice in being tested, (e.g. in the context of a forensic or coronial inquiry, or under legislation in some jurisdictions that allows for forced testing of individuals accused of certain offences, or if a person suspected on reasonable grounds of being positive for HCV infection persistently acts in a way that is perceived to place others at risk of infection). Compulsory testing should only be used when there are no alternatives and where authorised by law. The right of appeal against a decision or order to be tested should always exist.

To all extents reasonable, the processes involved in mandatory or compulsory testing should be in accordance with the principles in this Policy and basic human rights, including rights pertaining to privacy of health information.

1.4.3 Anonymous delinked testing

There may be circumstances where, on public health grounds (e.g. prevalence studies), anonymous delinked testing is legitimately performed in accordance with this Policy. Such testing should occur only where there is compelling scientific justification. This reason must be independently judged by an Ethics Committee constituted in accordance with the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research.[21]

1.4.4 Introduction of new technologies and strategies

Introduction of new technologies[22] or strategies to target new priority populations[23] will continue to evolve (e.g. validating additional point-of-care tests and the use of dried blood spot sampling). In every case, the introduction of new testing processes must be accompanied by appropriate workforce development to ensure that those providing HCV testing are equipped with:

- up-to-date information about hepatitis C, pathophysiology, immunology and epidemiology
- the latest information about HCV treatment and management
- procedures associated with using any new technology
- information related to referral pathways to care and support services (see section 2.0, Types of HCV testing and diagnostic strategies, and section 5.3, Referral for further support).

2.0 Types of HCV testing and diagnostic strategies

2.1 Types and uses of HCV diagnostic tests

All testing technologies for HCV must be approved by the TGA and included in the ARTG[24] before their use in Australia. Inclusion in the ARTG requires pre-market evaluation of the HCV diagnostic test commensurate with the purpose for which the test will be used.

HCV antibody tests

The primary tests used to determine exposure to HCV infection rely on serological detection of HCV antibodies (anti-HCV) and typically use a serum or plasma sample from venous blood. The terms HCV antibody and anti-HCV are equivalent, but in this policy HCV antibody is used throughout. Point-of-care tests are also available to determine the presence or absence of HCV antibody using whole blood from a capillary fingerstick sample. Samples yielding non-reactive results (HCV antibody negative) do not need to be further tested unless clinical considerations demand it, such as suspicion of a very recent infection due to specific risk behaviours.

The antibody seroconversion window period for HCV infection is prolonged and can vary from an average of 8 weeks up to 12 weeks.[25,26] In the laboratory, confirmation of HCV antibody reactive (HCV antibody positive) samples is reliant on an alternative supplemental HCV antibody immunoassay. In place of a second confirmatory immunoassay, an HCV RNA test (also known as a nucleic acid amplification test [NAAT]), or an HCV core antigen test, not routinely available in Australia,[27] can be used to ascertain whether the patient is currently infected with hepatitis C.

HCV RNA tests

A major goal of HCV testing is to detect current infection to facilitate linkage to care and treatment. Since HCV antibody assays only test for exposure to the virus, it is critical to ensure that people with a positive antibody test undergo additional testing to confirm current infection. Specifically, HCV RNA testing should be performed on all samples with positive HCV antibody results, where feasible. In the laboratory, this is typically conducted using a serum or plasma sample obtained from whole blood. Additionally, point-of-care tests are available to detect HCV RNA using whole blood from a capillary fingerstick sample.

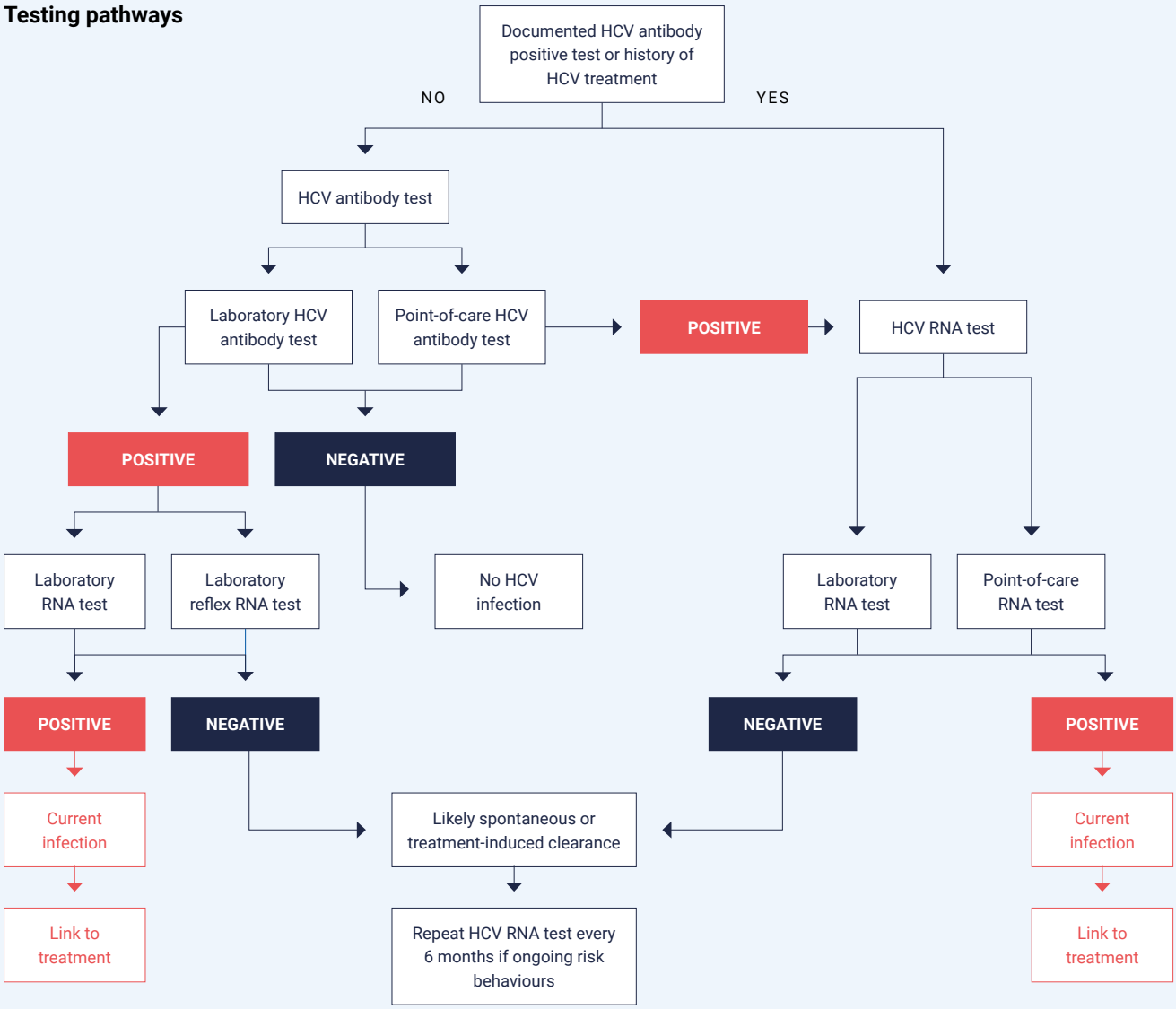
2.2 Testing for HCV

This section provides advice on minimum standards for diagnosis and investigation of HCV infection. Lifeblood services (formerly Australian Red Cross Blood Service) across Australia have developed their own strategies for screening donations because of their unique requirements.[28]

Laboratory investigations are directed towards answering one or more of the following questions:

1. **Has the person ever had HCV infection?**
   This finding should be determined by testing for HCV antibodies. HCV RNA testing should be performed on people that are HCV antibody positive to confirm current HCV infection. HCV antibody-positive samples which are negative for HCV RNA most likely represent past infection with clearance (resolved or cured by therapy). However, past HCV infection with viral clearance does not confer protection against re-infection.[29]
2. **Does the person have current infection?**
   This finding is determined by testing for HCV RNA (or infrequently HCV core antigen, although it is less sensitive than HCV RNA testing). The presence of HCV RNA indicates active viral replication and current infection.
3. **What is the current level of viral replication?**
   Viral load testing for HCV RNA is not required before commencing treatment and the RNA level has no bearing on treatment responses. As such, a qualitative HCV RNA test is sufficient to determine treatment eligibility.
4. **What is the infecting virus genotype?**
   HCV genotyping is no longer required for treatment initiation, given the available therapies are effective against all genotypes (pangenotypic). HCV genotyping was removed from the PBS criteria on 1 April 2020. Nevertheless, if HCV genotyping is performed, it should be documented in the person's medical history.

Testing pathways



2.3 Laboratory-based testing

The NPAAC has published tiered regulatory compliance requirements for good laboratory practice[30] regarding laboratory testing for HIV and HCV infections.[27]

Laboratories and laboratory staff are subject to professional standards established by the RCPA and international standards for medical testing.[31] ISO 15189 is the international standard that specifies the requirements for quality and competence of medical laboratories under which laboratories receive NATA/RCPA accreditation.

For further information on standards for testing, see:

- NPAAC Requirements for Laboratory Testing of Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV)[27]
- ISO 15189 Standard for Medical Laboratories[31]
- NPAAC Requirements for Medical Pathology Services[30]

2.3.1 HCV antibody testing

In the laboratory, exposure to HCV is determined by testing for HCV antibodies in serum or plasma, collected via venous blood.

- A sample non-reactive in the screening immunoassay can be generally regarded as HCV antibody negative. If the antibody result does not match the clinical

history or presentation, consider qualitative HCV RNA testing in people who are immunosuppressed, or in those suspected of acute infection prior to antibody seroconversion. Note that only one qualitative HCV RNA test can receive a Medicare rebate in a 12-month period.

- A sample reactive in the screening immunoassay must be subject to a minimum of one alternative supplemental HCV antibody immunoassay, HCV RNA test or HCV core antigen test. As immunoassays do not have 100% specificity, it is important to eliminate, as much as possible, any common false reactivity between two tests that are to be used as part of a diagnostic strategy. A sample reactive in two approved immunoassays can be reported as HCV antibody positive. In place of testing with a second immunoassay, a qualitative HCV RNA or HCV core antigen test can be used to ascertain whether the person is currently infected with hepatitis C.[27]

2.3.2 HCV RNA testing

In the laboratory, current HCV infection is generally determined by a qualitative or quantitative HCV RNA test using serum or plasma collected from whole blood.

- HCV RNA will be negative in past infection with clearance (resolved infection or cured by therapy) but may also be negative in the very early period post exposure (initial 7-14 days).
- The availability of effective therapies against all HCV genotypes means that HCV genotyping is no longer required before treatment initiation to meet the PBS criteria. Nevertheless, identifying HCV genotype may be clinically useful for certain regimens when treating people with cirrhosis or who have received previous treatment. Furthermore, HCV genotyping can provide helpful information for at-risk populations where there is a high risk of re-infection. A genotype or subtype change may be able to differentiate re-infection from relapse. HCV genotype reimbursement remains on the MBS.

2.3.3 Laboratory-based HCV reflex testing

Laboratory-based reflex HCV RNA testing refers to a testing algorithm where people receiving testing have a single clinical encounter and a single blood sample is collected (this blood sample may be divided into two primary blood collection tubes), or a second tube collected and sent to a central laboratory for testing.

Ideally, a second blood sample, specifically for HCV RNA testing, should be collected at the person's initial visit, instead of obtaining a follow-up sample from a second visit. The availability of two blood samples also offers the advantage of having greater sample volume for other possible blood-borne virus testing. Laboratories may split a single specimen into two aliquots at the sample processing stage before HCV antibody testing, assuming the same sample type is validated for both antibody and RNA testing. This approach avoids the need for the doctor to request a follow-up sample and an associated second consultation.

If the initial test for HCV antibodies in the laboratory is positive, a reflex HCV RNA test using the second aliquot or the duplicate sample is automatically triggered. The results provided to the healthcare provider and person include both the HCV antibody result and, if positive, the HCV RNA result, eliminating the need for additional visits or specimen collections. Laboratory-based reflex testing has been shown to increase the uptake of HCV RNA testing among people who test positive for HCV antibody, potentially improving linkage to care and treatment compared to non-reflex testing.[32]

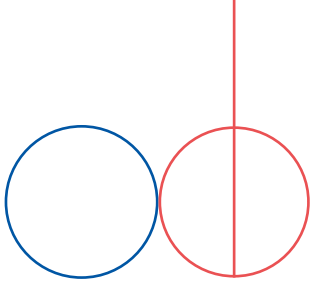
- When ordering an HCV antibody test, a request for HCV RNA testing (reflex testing) should be made if the sample is HCV antibody positive or discordant results are obtained from two serology tests. This request must be documented on the initial pathology form ('HCV RNA if indicated').

2.4 Point-of-care testing

A point-of-care test is conducted at the site where clinical care is provided, with results returned to the person or caregiver on the same day. This approach allows for more timely clinical decisions and linkage to care. Point-of-care tests for HCV infection (antibody and RNA) can simplify testing algorithms, shorten time to diagnosis and increase rates of testing, linkage to care and treatment.[33-35]

All positive point-of-care test results should be notified to the relevant stakeholders.

Point-of-care HCV antibody and RNA tests are now available and have been approved for use in Australia



by the TGA, with some conditions.[11] The test needs to be performed by a laboratory accredited by NATA for HCV testing or by trained health professionals (e.g. in a community health setting) who have an established relationship with a NATA accredited laboratory. As with a central laboratory, in an off-site clinic or community healthcare setting, the TGA requires participation in quality assurance programs and healthcare workers need to be trained and deemed competent in the use of the test.

As with laboratory testing, NPAAC has published regulatory compliance requirements for HCV point-of-care testing.[36]

2.4.1 Point-of-care HCV antibody testing

Point-of-care HCV antibody testing determines exposure to HCV by detecting antibodies in whole blood collected via a capillary fingerstick sample. Where available, the use of finger-stick blood samples offers a significant advantage, avoiding the need for phlebotomy. This method is particularly beneficial in clients where venous access is challenging or there is a client preference to avoid phlebotomy, or phlebotomy services are unavailable.[37,38] Approved point-of-care HCV antibody tests have sensitivity and specificity that are close to those of traditional commercial HCV antibody tests.[39]

- As with laboratory-based testing, a non-reactive point-of-care HCV antibody test can be generally regarded as HCV antibody negative. If doubt with the HCV antibody test result exists, repeat the test. Consider HCV RNA testing in people who are immunosuppressed, or in those suspected of acute infection before antibody seroconversion.
- A sample reactive with the point-of-care HCV antibody test must be tested for HCV RNA to identify current HCV infection (see below for reflex HCV RNA testing options).
- In instances where there is an invalid point-of-care HCV antibody test (i.e. no control visible), repeat testing should be performed.

2.4.2 Point-of-care HCV RNA testing

Point-of-care HCV RNA testing determines current HCV infection by detecting HCV RNA in whole blood, collected via a capillary fingerstick sample. The availability of point-of-care HCV RNA tests for detection of current HCV infection within one hour at the point of care has transformed the clinical management of HCV infection.[37,38] Point-of-care HCV RNA testing coupled with direct-acting antiviral (DAA) HCV treatment enables diagnosis and treatment in a single visit, increases testing acceptability and reduces loss to follow-up, helping address the drop-off in the HCV care cascade. These tests show a similar sensitivity and specificity to traditional commercial HCV RNA tests.[40]

- As with laboratory-based testing, HCV RNA is negative in past infection with clearance (resolved infection or cured by therapy) but may also be negative in the early incubation period.
- In instances where a point-of-care quantitative HCV RNA test result is detectable but below the level of quantification, repeat testing should be performed. If the same result is obtained, a venous plasma or serum sample should be collected and sent for laboratory-based testing to confirm whether HCV RNA is present.
- In instances where there is an invalid point-of-care HCV RNA test, repeat testing should be performed (either point-of-care or laboratory-based testing).
- Point-of-care HCV RNA testing can be used for diagnosis, confirmation of cure and monitoring for HCV re-infection in people who have been successfully treated.

2.4.3 Clinic-based HCV reflex testing

Clinic-based HCV reflex RNA testing refers to a testing algorithm where people have a single clinical encounter. After a positive point-of-care HCV antibody test, a capillary fingerpick specimen is immediately collected for a point-of-care HCV RNA test at the clinic to detect current infection. Alternatively, a venepuncture sample could be taken and referred to a central laboratory for testing.

2.5 HCV self-tests

HCV self-testing involves a person collecting their own specimen (e.g. capillary blood from a finger prick) for HCV testing, applying it to a testing kit or device and interpreting the test result. As at March 2025, there are no devices for self-testing approved by the TGA for supply in Australia.

Some people in the community may access self-administered HCV point-of-care test (self-tests)

from overseas for their personal use. The safety and performance of these devices may not have been independently assessed and verified. The World Health Organization provides recommendations and guidelines for self-testing for HCV.[41]

2.6 Novel sample collection processes and testing technologies

Before their availability in Australia, any new sample collection device or testing technology must be approved by the TGA. As at March 2025, there is no TGA-approved HCV test that is intended for use with self-collected samples, such as dried blood spots. However, there are various provisions for exemption, such as for a clinical trial, that allow for regulated access to unapproved devices.

Dried blood spot sampling for HIV and hepatitis C testing has been successfully used in a government-led pilot study in New South Wales (NSW) since 2016[42,43] under a clinical trial exemption from the TGA. NSW Health has completed a validation of dried blood spot sampling and anticipates a TGA submission during 2024-2025 to allow in-house use of dried blood spots without the need for a clinical trial exemption.

Self-sampling is when a person collects their own biological sample for HCV testing (e.g. blood from a finger prick) and after collection sends it to a laboratory for testing. Unlike HCV point-of-care testing and self-testing, the analysis of a self-collected sample is performed in the laboratory and a confirmed result is obtained.

2.7 Monitoring treatment

The introduction of highly efficacious and well-tolerated therapies for the treatment of HCV infection has reduced the need for frequent on-treatment monitoring. Eligibility for treatment requires evidence of chronic infection, meaning detectable HCV antibody and a positive baseline HCV RNA (qualitative or quantitative HCV RNA test). Generally, routine on-treatment assessment of HCV RNA levels is not necessary, due to the lack of a role for response-guided therapy.

A further qualitative HCV RNA test is required to confirm sustained virological response (SVR), which is defined as an undetectable HCV RNA at 12 weeks after the end of DAA therapy (SVR12). There are now several studies that show that there is a high correlation between obtaining an SVR at 4 weeks post-treatment completion and SVR12.[44,45] Therefore, opportunistic testing of HCV RNA at any time beyond 4 weeks post-treatment completion can be considered, particularly when there is concern about subsequent loss to follow-up.

People who may require more intense monitoring include those for whom adherence is a concern or where there is a high risk of re-infection, those on ribavirin-containing regimens and those with advanced liver disease (cirrhosis, portal hypertension or hepatic decompensation).

For more details on testing frequency and type, see Section 6 of the Australasian recommendations for the management of hepatitis C virus infection: a consensus statement (2022) available at: https://www.hepcguidelines.org.au/wp-content/uploads/2022/11/hepatitis-C-virus-infection-a-consensus-statement-2022.pdf

3.0 Indications for hepatitis C testing

Despite significant effort to encourage testing within the communities at highest risk of having acquired hepatitis C, there continues to be a significant proportion of people living with hepatitis C who are disengaged from care or lost to follow-up, or undiagnosed.

Hepatitis C should be considered, and testing offered in anyone with current or past risk factors for infection as well as anyone presenting with an illness that could be related to hepatitis C. This includes people with abnormal liver function tests, acute hepatitis, chronic liver disease or liver cirrhosis, hepatocellular carcinoma (liver cancer), or the presence of other clinical conditions associated with hepatitis C (e.g. porphyria cutanea tarda, vasculitis, cold agglutinin presentations).[46]

A person's history considering risk factors for acquisition of hepatitis C should be taken and where risk exists, people should be informed of their risks and of the benefits of testing.

In appropriate clinical circumstances, the absence of a declared risk factor should not preclude hepatitis C testing.

Other situations where hepatitis C testing may be indicated include:

- healthcare workers who perform or may be expected to perform exposure-prone procedures (EPPs) must be aware of their hepatitis C (and HIV and hepatitis B) status[47]
- contact tracing where exposure to blood of a person with a potential infection is documented
- testing of a source person in an occupational exposure
- diagnosis of another infection with shared mode of acquisition, such as hepatitis B virus or HIV
- the report of a reactive result on a hepatitis C test not approved for supply in Australia
- a person who requests a hepatitis C test in the absence of declared risk factors – a small number of people may request a hepatitis C test but choose not to disclose risk factors. A person's choice not to declare risk factors should be respected and hepatitis C testing should be offered.

3.1 Populations in which hepatitis C testing should be offered:

All people with a risk factor for hepatitis C should be tested. These include:[48]

- People with any history of injecting drug use
- People who have spent time in custodial settings
- People with tattoos or body piercings performed in non-sterile settings
- People who received a blood transfusion or organ transplant before 1990
- People with coagulation disorders who received blood products or plasma-derived clotting factor treatment products before 1993
- Children born to mothers with hepatitis C
- Sexual partners of a person with hepatitis C (people at higher risk of sexual transmission include men who have sex with men and people with HCV–HIV co-infection)
- People with HIV or hepatitis B virus infection
- People with evidence of liver disease (persistently elevated alanine aminotransferase level)
- People who receive haemodialysis
- People who have had a needle-stick injury, sharps or mucosal exposure
- Migrants from high hepatitis C prevalence regions (Egypt, Pakistan, Mediterranean and Eastern Europe, Africa and Asia).

3.2 Risk factors for exposure to hepatitis C

3.2.1 People with a history of injecting drug use

Over 80% of existing and almost 90% of all new HCV infections are among people with a history of injecting drug use.[49] Testing in this population includes diagnosis, any individualised monitoring during treatment and monitoring possible re-activation or re-infection post treatment.

3.2.1.1 Hepatitis C testing frequency in people who inject drugs

Recommendation for the frequency of testing in people who inject drugs who disclose sharing injecting equipment:[50]

- In people who inject drugs who are HCV antibody (anti-HCV) negative, repeat testing for HCV antibody (anti-HCV) every 3-6 months is indicated if there is high risk behaviour, e.g. sharing injecting equipment, or if the person expresses a concern that they may have been exposed to HCV.

Recommendations for the frequency of testing in people who inject drugs who report not sharing injecting equipment:

- Annual testing (every 12 months) is indicated in people who inject drugs who report not sharing injecting equipment and who do not have HCV infection (i.e. HCV antibody negative) on first testing. Testing should also be offered following a high risk injecting episode.

People who inject drugs who are HCV antibody (anti-HCV) positive and HCV RNA negative (through spontaneous or treatment-induced clearance) should receive regular HCV RNA testing every 12 months or from 2 weeks following a high risk injecting episode.[51]

3.2.2 People who are, or have ever been, incarcerated

Imprisonment is an independent risk factor for HCV transmission.[52] It is estimated at least 20% of all people who are incarcerated in Australia are seropositive for hepatitis C and more than 50% of people in prison report a history of injecting drug use.[53] A history of previous incarceration is a very strong indication to offer testing for hepatitis C with appropriate discussion of risk and benefits.

It is recommended that people should be offered hepatitis C testing and results provided within 2 weeks of incarceration, and all those identified with hepatitis C should be offered and supported to undertake antiviral therapy. Re-testing should be offered at least annually for all those incarcerated and offered at any time for people who disclose risk factors or request testing.[53]

3.2.3 Recipients of organs, tissues, blood or blood products

HCV is efficiently transmitted by transfused blood or blood products.[54] Infections acquired in this way have accounted for 5–10% of all cases in Australia. People in Australia, or other major developed countries, who were transfused or received organ or tissue donations or blood products before hepatitis C screening commenced (February 1990 in Australia) who have not been tested or who do not know their status should be offered testing. A number of countries (predominantly in low-resource settings) still do not screen all donated transfusion blood for transmissible infections, including hepatitis C.[55] People who received blood products or organ or tissue donations at any time in overseas countries where screening of the blood and organ donor population has not been routine, or where the screening policy at the time of transfusion or receipt of organ or tissue donation is uncertain, should be offered testing. In Australia, recipients and organ donors are screened for hepatitis C at the time a donation is made. Organs from HCV-positive donors may be offered to both HCV-positive and HCV-negative recipients according to clinical circumstances..

3.2.4 People with tattoos or skin piercings

Skin penetration practices are not independent risk factors for HCV transmission.[56] The indications to test will include a consideration of other factors that may contribute to increased transmission such as population prevalence and poor infection control procedures (e.g. tribal scarring in indigenous populations, tattooing and skin piercings in custodial settings or any other situation where non-registered tattooists perform the task).

3.2.5 People born in countries with high hepatitis C prevalence

The risk of hepatitis C may be elevated for people born in or who have spent considerable time in countries where there is a high prevalence of hepatitis C.[57] It is estimated that 11% of people in Australia who have been exposed to HCV are immigrants from countries where there is a high prevalence of hepatitis C. These regions include Africa, the Middle East (in particular Egypt), the Mediterranean, Eastern Europe and South Asia. In many of these regions, HCV transmission is not predominantly associated with injecting drug use and the virus can be acquired from medical and dental procedures or from occupational exposure to infected materials. Indications to offer testing include a history of hepatitis C in a family member or exposure to medical procedures. In this population, HCV RNA positivity should prompt testing of other family members.

3.2.6 Aboriginal and Torres Strait Islander populations

In 2023, 1,499 (or 19.7% of the total 7,602) people newly diagnosed with hepatitis C in Australia identified as Aboriginal and Torres Strait Islander people.[2] Thirty percent, or 2,310 people, of new hepatitis C cases were notified without an indication of Indigenous status. This is a critical gap which must be addressed through better data capture and reporting processes.

In people aged under 25, the rate of hepatitis C notification in 2023 among Aboriginal and Torres Strait Islander people was more than 10 times higher than in non-Indigenous people (236.1 vs 22.4 per 100,000).[2] Given that Aboriginal and Torres Strait Islander people constitute just 3.8% of Australia's total population,[58] the disproportionate hepatitis C-related burden of disease borne by this group is striking. Risk factors for increased HCV antibody prevalence in this population include higher rates of syringe and other drug equipment sharing[59] and higher rates of incarceration, both of which are driven by ongoing and generational impacts of systemic racism, poverty and poorer access to health and related services.[60]

3.2.7 Sexual partners of people with hepatitis C

The risk of heterosexual transmission of HCV is low.[61] Certain sexual practices increase the risk of HCV transmission and in all instances the use of drugs (injected or orally administered) increases risky behaviours. These behaviours include having:

- had more than 10 partners in the past 6 months
- engaged in condomless anal sex
- engaged in unsterile injecting drug use
- engaged in group sex and drug use.

Testing for hepatitis C should take place annually in those who are aware of risk and practising safe sex and some evidence indicates that more frequent (6 monthly testing) in high risk behaviour groups increases early detection and treatment.[61]

3.2.8 Children born to HCV-positive mothers

See Section 8. Antenatal and Perinatal Testing for more information.

The rate of mother-to-child transmission of HCV is low and is essentially confined to women with detectable HCV RNA. Thus, pregnant women who are HCV antibody (anti-HCV) positive on routine screening need to be tested for HCV RNA. The diagnosis of hepatitis C in neonates is complicated by the passive transfer of maternal antibodies to the baby. Pregnant HCV-positive women should be encouraged to seek specialist advice from a clinician who understands hepatitis C and mother-to-child transmission and can provide support and expertise to the mother, parent, parents and to the people supporting the pregnancy, birthing and early parenting of the child. HCV antibody testing in babies is not recommended before 18 months of age (see Section 8. Antenatal and Perinatal Testing).

3.2.9 Transmission and infection control in healthcare settings

- People on regular haemodialysis should be tested every 6 months for HCV antibody[62]
- In rare situations, clients of healthcare services may need to be offered testing as part of an outbreak investigation or due to failure of infection control practices.

3.3 Occupational exposure

A risk assessment with regard to the type of injury and type of bodily fluid is required to determine management of the person exposed following an occupational exposure to blood or mucosal fluids containing blood. The risk of hepatitis C transmission following a needlestick injury where the source is known to be HCV RNA positive is very low, estimated to be 1.8% (range 0-7%). Saliva where there is no visible blood is not infectious. The exception to this statement is in dental settings where blood is likely to be present even if not visible.[63] Hepatitis C cannot be transmitted by spitting, touching, hugging, kissing or sharing food and drink.

Clinical services should have an evidence-informed occupational exposure policy and procedure implemented so that anyone at any risk of exposure receives training during their onboarding process or as soon as possible thereafter. These policies and procedures should include information about the extremely low risk of a transmission occurrence, followed up with additional education and support should an occupational exposure occur.

In the event of a potential occupational exposure, the person exposed should be referred to an appropriately qualified healthcare practitioner such as a GP, nurse or specialist to undertake a risk assessment. Establishing the hepatitis C status of the source person will help inform the management of the exposed person. Testing of both the source person, if known, and the exposed person should be voluntary and with informed consent.

The window period for hepatitis C seroconversion is 6 to 12 weeks. Qualitative HCV RNA testing between 6 and 12 weeks is recommended. If at 12 weeks both RNA and antibody are negative, then there is no evidence of transmission, and the exposed person can be advised that the risk of transmission is negligible. If the HCV RNA test is not MBS reimbursable, the employer may arrange with the pathology laboratory to pay for the test privately.

If the occupational exposure is determined to be high risk, monitoring of clinical status and liver function tests is warranted. However, high risk occupational exposure is uncommon in the Australian context. One example would be intentionally being injected with a syringe containing someone else's blood. Needlestick wounds that break the skin of the worker or single or multiple injuries resulting in broken skin of the worker would be considered low-medium risk.

Recommended baseline HCV testing for source person if known

Status	Recommended baseline testing
HCV antibody positive	**HCV PCR at baseline**
HCV unknown or potentially in the window period	**HCV antibody with reflex HCV PCR at baseline**

Recommended testing for exposed person if the assessment determines there is a transmission risk

Status of source person	Baseline	6 -12 weeks	12 weeks
HCV positive or unknown	**HCV antibody with reflex HCV PCR***	**HCV PCR**	**HCV antibody**
HCV negative	**HCV antibody with reflex HCV PCR***	**No further testing required**	

* Only HCV PCR if exposed person is known to be antibody positive

4.0 Informed consent for testing

Except in specific circumstances, described in more detail (see below), all healthcare including pathology testing requires valid informed consent expressed verbally, in writing or implied. Ensuring informed consent is properly obtained is a legal, ethical and professional requirement on the part of all treating health professionals and supports person-centred care. Good clinical practice involves ensuring that informed consent is validly obtained and appropriately timed.[64] The involvement of the community of people affected by hepatitis C, particularly people who inject drugs, is essential in increasing understanding of informed consent in the context of clinical and other health-related services.

4.1 What is informed consent?

Informed consent for testing means that the person being tested:

- has the legal capacity to consent (defined further below)
- gives their consent voluntarily
- gives their consent to the specific test being discussed or offered
- has enough information (e.g. about the condition being tested for, testing procedures, relevant benefits and risks, what notification means for them), and opportunities to ask questions and discuss any concerns
- is empowered to agree or refuse and has enough autonomy and information to be able to make an informed decision, in relation to their own choices in the setting in which the service is being provided.

In the context of hepatitis C testing, a person has legal capacity to consent when they are able to:[64]

- understand the facts involved
- understand their choices
- understand how the implications of testing affect them
- retain the information and recall the details
- weigh up the consequences of their choices, including the choice to decline testing
- communicate their decision and understanding of its implications
- believe they will not be punished for making the choice they want to make including refusing to undertake testing.

It is important that all people being offered but not required to do testing understand they have the right to refuse.

There are some rare exceptions to the requirement for informed consent, or to having the right to refuse testing, such as emergency situations and cases where there is a valid legal order authorising testing. See Section 1.4.2 Mandatory and compulsory testing. On the rare occasions when compulsory testing is authorised by a valid legal order, the need to obtain informed consent is overridden by law. However, the person performing the test should use their clinical judgement in attempting to obtain informed consent.

4.2 Gaining informed consent

Hepatitis C and the risk factors often leading to exposure can be highly stigmatising for people affected. Aspects of the testing process such as vein damage and venous access, as well as previous experience of stigma and discrimination associated with health services can also create significant barriers to hepatitis C testing and care. It is crucial that testing is offered using a preferred modality if available and conducted in an appropriate non-judgemental and non-stigmatising manner and setting. This approach can:

- assist people with experience of stigma (relating to injecting drug use) through the testing and diagnosis process.
- improve relationships between the person being tested and the person conducting the test.
- support a person to better understand the hepatitis C virus, prevention, testing and treatment options, and outcomes for participating or not in the testing and treatment process.
- increase likelihood of future engagement with the health system.

When making decisions about whether informed consent has been obtained, everyone responsible for testing should consider the context in which the test is being performed, and how that context might influence people's understandings of their rights. Without limiting relevant factors that might be contemplated, testers should consider:

- The factors which prompted a discussion about testing such as clinical presentation, risk exposure, community prevalence, person's request for testing.

- The environment within which the test is being discussed and performed, including whether it is being discussed and performed in a closed setting (such as a prison) or hospital.
- The implications of the result to the person being tested.

Clinical decision-making should be based on the context in which the test is being performed, and should consider:

- The factors which indicate a need for testing such as clinical presentation, risk exposure, community prevalence and the person's request for testing.
- An assessment of the understanding of the hepatitis C testing process and the implications of the result to the person being tested including how to manage transmission risk and health factors associated with a positive result.
- That all persons tested should be advised and understand how the test result will be conveyed to them and be made aware of other relevant issues including that hepatitis C is a notifiable disease, which will be reported to jurisdictional public health units. They should be made aware of the key implications of this notification.

General principles of professional conduct apply in the case of hepatitis C testing and informed consent. See: Fact sheet for clinicians: Informed consent in health care. Consent should not be sought from sexual partners or family members of the person being tested. However, in the case of testing a child or person who does not have the capacity to consent then the responsibility for providing consent rests with the guardian or other person or agency legally authorised to make such decisions on their behalf.

If providing incentives to a person to be tested for hepatitis C, informed consent is still required. Ensure the person undergoing the tests has all the same information necessary to make their choice including the option to continue or refuse testing.

4.3 Supporting people contemplating testing

Access to peer education, peer testing and peer support for people with a history of injecting drug use is recommended as it can optimise disclosure of hepatitis C risk factors, enhance safety using education to prevent further blood-borne virus transmissions and increase the uptake of testing. All people who provide testing, including peers and clinical staff, should know how to sensitively discuss issues relating to illicit drug use and harm reduction, know the harm reduction, testing and treatment options available, and be aware of how to provide stigma-sensitive and non-discriminatory care, including when referring people at risk of hepatitis C and their significant others, undertaking testing and managing vein care issues.[65]

Additional supports are available and should be offered where required to assist the person considering testing to become adequately informed and to maintain equity of health outcomes. This information includes referral to the support services listed in Section 5.3, and access to publicly funded and accredited telephone interpreters (available nationally for use by private and public healthcare professionals).[66] The Translating and Interpreting Service (TIS National) is available to doctors 24 hours a day. TEL: 1300 131 450. Culturally relevant information should be provided when seeking informed consent and providing results.[67]

4.4 Legal duties and responsibilities

In addition to the various principles and responsibilities set out above, it is important to note that where data generated through testing are also used for research, the principles and requirements set out in the NHMRC National Statement on Ethical Conduct in Human Research[21] must also be followed. Importantly, researchers and clinicians are not exempt from the overarching legal obligations outlined in this section regarding informed consent when a Human Rights Ethics Committee (HREC) has provided permission to conduct research. In addition, it is important to involve people affected by hepatitis C, and people at risk of hepatitis C, including through representative peer-led organisations, to manage ethical considerations involved in testing.

A person who tests HCV-positive should be made aware of certain rights and must be informed of their responsibilities regarding transmission reduction where required by state or territory public health law and regulations including disclosure responsibilities.[68]

5.0 Conveying hepatitis C test results

Conveying hepatitis C test results (previously post-test counselling) is an important part of hepatitis C care. This exchange with people receiving hepatitis C test results is shaped by the type of test performed, the setting of the consultation, the reason for testing and the extent, if any, of additional testing required in determining the current HCV status of the person. The person who requests or performs the test is responsible for ensuring that the delivery of the test result is carried out in a setting conducive to discussing the implications of the result and talking through any concerns that the result raises (see Section 5.2 Conveying a confirmed positive result). Where an HCV antibody test has been the only test requested, it is important to convey to the person being tested that further viral studies are required to determine their current hepatitis C status if the antibody test is positive. However, reflex testing (as discussed in Sections 2.3.3 and 2.4.3), is the preferred mode of testing. In presenting results to people for whom English is not their primary language, interpreter services should be accessed. Care should be taken to provide adequate privacy of consultation in a prison setting.

5.1 Conveying a negative result

The outcome may be a negative HCV antibody result or a negative HCV RNA result. A negative result should ideally be provided in person to allow for adequate reassurance of the person, identification of ongoing risk factors for infection and provision of information about appropriate prevention strategies.

Further testing following a negative result (HCV antibody or HCV RNA) is indicated in people who may be in:

- a window period before seroconversion (negative HCV antibody or HCV RNA in a high risk situation)
- the situation of having a known previous infection with persistent HCV antibody positivity but a negative HCV RNA. In this situation, a single HCV RNA negative result is highly likely to reflect viral clearance. If liver tests remain abnormal or if re-exposure is possible, 2 HCV RNA results 6 months apart should be negative before assurance is given that the infection has been cleared
- a high-risk group for re-infection (such as people in prison).

5.2 Conveying a confirmed positive result

This outcome may be a positive HCV antibody or a positive HCV RNA result. A positive result should ideally be provided in person by the clinician or person responsible for communicating test results (in some instances this may be a peer worker or other non-clinician). Please note: a positive HCV antibody result does not confirm current HCV infection and will need to be confirmed by further testing for HCV RNA to clarify whether the person currently has HCV infection or has cleared the virus. See section 2.2.

The discussion when conveying a positive result (HCV antibody or HCV RNA) should include:[69,70]

- giving the test result in a confidential and mutually agreed upon manner that is sensitive and appropriate to the gender, culture, emotional state, language, literacy level and environment (i.e. in the community or prison) of the person who has been tested
- education regarding modes of transmission of hepatitis C and prevention strategies to prevent possible onward transmission.

If the person tests HCV antibody positive, the discussion should also include:

- information on further testing required to confirm current infection (HCV RNA) or clearance and explanation that the result may not indicate chronic HCV infection
- information on curative treatments available for those who do test HCV RNA positive
- information about where to access support and information, including peer support and peer education (see Section 5.3 for peer-based organisations)
- information about the treatments available including clarification about eligibility and confirming accessibility for people who may previously have had treatment or those with ongoing risk factors, and education about the efficacy and suitability of currently available treatments assessed against the person's knowledge about HCV treatment

If the person tests HCV RNA positive, the discussion should also include:

- treatments available for those who have tested HCV RNA positive
- their rights and responsibilities
- the mode of transmission of HCV and how onward transmission may be prevented

- considerations regarding disclosure to partner, family and friends, as well as injecting partners and networks for people who may be sharing injecting equipment (particularly those within prison).[71,72] These considerations should include working with the person to understand prevention strategies and to make decisions they are comfortable making, and, if appropriate, referral to peer organisations (see Section 5.3) who might be able to talk through whatever strategies they might need in relation to whatever they decide regarding disclosure
- where a person tests HCV RNA positive and is offered treatment, offer testing (and treatment) to people within their injecting networks if they are comfortable having this discussion with them.

Perceptions regarding testing and treatment are unique to each person and should be discussed. Relevant information may need to be conveyed more than once and possibly by different people including peers. People diagnosed with hepatitis C may have misconceptions about treatment eligibility, cost and side-effects based on the experiences of those treated with the previous interferon-based regimens.[73] Care should be taken to communicate to people that DAA therapies are available with substantially fewer restrictions than previous hepatitis C therapies. For example, people who inject drugs or are incarcerated are eligible for treatment. There are few out-of-pocket expenses (and no out-of-pocket expenses for those in prison), with access to DAA treatments made available on the PBS and testing costs covered by the MBS, although GP or clinician fees may vary as not all providers bulk bill. DAA treatments are safe and well tolerated for **most people**, and this fact should be emphasised with anyone considering treatment as some misconceptions remain about treatment side-effects and treatment efficacy.[74]

5.3 Referral for further support

The potential psychological impact of a diagnosis of hepatitis C has changed considerably since the availability of the DAA therapies, which have led to very high cure rates with shortened treatment duration and high tolerability of treatment. However, not all people are aware of this change while others may face other barriers such as poor vein access or have experienced stigma and discrimination at health services. It is important to proactively manage these potential sources of anxiety, and any other issues that may arise from a positive diagnosis. Where more support is required, a referral can be made to the relevant community-based organisation or, if available, a peer-support service.

Hepatitis Australia
HepLink Australia: 1800 437 222 (1800 HEP ABC)
www.heplink.au
Note: *This number will route the caller to the relevant state or territory hepatitis organisation and can be dialled toll free from within prisons*

The Australian Injecting and Illicit Drug Users' League (AIVL)
Telephone: 02 5110 3018
Email: info@aivl.org.au
www.aivl.org.au
Note: *AIVL is the national organisation representing people who use drugs. AIVL operates Monday to Friday, 9am to 5pm. AIVL member organisations can be found in every state or territory across Australia. AIVL can refer people to organisations or services in their local area, where available.*

5.4 People who do not return for positive test results

People who are unaware of their positive result can unknowingly place others at risk and may be unaware of current options for treatment, so it is important to contact people who do not return for results. However, not all people awaiting hepatitis C test results have access to a phone or a fixed address. As such, the manner for conveying test results should be mutually agreed (see 5.2 above) at time of testing.

Attempts to make contact should be documented in the person's file. Referring clinicians should liaise with their local Public Health Unit for people lost to follow-up. General practitioners should refer to the Royal Australian College of General Practitioners (RACGP) guidelines on follow-up of pathology results.[75]

People in prison may be released or transferred before receiving test results. Adhere to the Justice Health guidelines of the relevant state or territory regarding follow-up for people in prison who are released (or are transferred to another prison within the state or territory) before obtaining their results.

6.0 Surveillance and research

Laboratories performing hepatitis C testing must notify the relevant state and territory health authorities of any new positive laboratory diagnosis in accordance with the relevant legislation.[76]

6.1 Sentinel site surveillance for hepatitis C

Hepatitis C testing is routinely carried out at clinical sites such as sexual health clinics, Aboriginal Community Controlled Health Services, prisons, primary healthcare clinics, community clinics serving people who inject drugs, and blood transfusion services. The number of people tested and the proportion with hepatitis C or the rate of new hepatitis C infections are reported on a regular basis from some of these sites and are included in surveillance reports to monitor hepatitis C prevalence and incidence across various population groups. Emergency Department hepatitis C testing has recently been piloted as an additional surveillance setting.[77,78]

6.2 Australian Needle and Syringe Program Survey

The Australian Needle and Syringe Program Survey is coordinated by The Kirby Institute and has been conducted over one week each year since 1995.[79] During the designated survey week, the staff of needle and syringe programs in a national network of sites ask all clients who attend to complete a brief, self-administered questionnaire and provide a finger-prick dried blood spot sample. The specimens are tested anonymously under code, and the results cannot be linked back to individual people.

HCV antibody prevalence has been monitored since 1995, with the addition of HCV RNA testing of dried blood spot samples since 2015 to monitor viraemic prevalence in relation to hepatitis C elimination strategies.[80] The survey also provides estimates of previous hepatitis C testing, including antibody and RNA testing, and the impact of the DAA therapy era on hepatitis C incidence.[81]

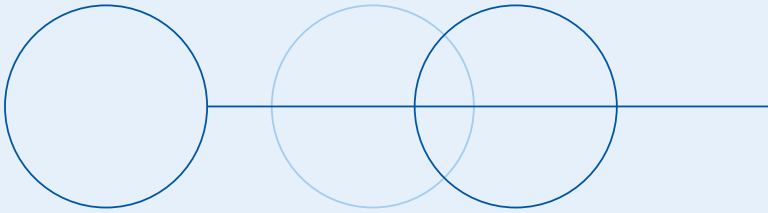
6.3 Use of stored blood for research on diagnostic technologies

Retrospective analysis of stored samples, particularly for the testing of new diagnostic technology or testing epidemiological hypotheses must only be conducted on delinked or de-identified samples and be subject to appropriate ethical review and in accordance with relevant laws.[30]

6.4 Use of unapproved in-vitro diagnostic devices

Hepatitis C in-vitro diagnostic devices must be approved by the TGA and included in the ARTG before they can be used in Australia. Note that these in-vitro diagnostic devices may be approved for specific intended uses, such as for blood samples, but not for other sample types like dried blood spots, or they may be approved solely for diagnosis and not for monitoring. Unapproved in-vitro diagnostic devices (those not included in the ARTG) or off-label use in-vitro diagnostic devices (those not approved for a particular intended use) may be required in special circumstances and for international collaborative research. To access an unapproved in-vitro diagnostic device, an application must be made to the TGA under the Clinical Trial or Special Access Scheme.[82] In-vitro diagnostic devices for research only (e.g. where results are de-identified and not used to determine individual treatment) are exempt from inclusion in the ARTG under Item 1.3, Schedule 4 of the Therapeutic Goods (Medical Devices) Regulations 2002.[83]

As at March 2025, hepatitis C testing in-vitro diagnostic devices for use with dried blood spots are not approved by the TGA. However, there are various provisions for exemptions, such as for a clinical trial, that allow for regulated access to unapproved devices. These studies are currently in the development and validation phase. If a dried blood spot test returns a positive result for hepatitis C, it should be confirmed with standard hepatitis C testing.



7.0 Healthcare workers

The risk of transmission of hepatitis C from an HCV RNA positive health worker to other health workers or people, or from an HCV RNA positive person to health workers, is very low. Transmission risk between people with hepatitis C and healthcare workers may arise during exposure-prone procedures. The Centers for Disease Control and Prevention in the USA has estimated that the risk of hepatitis C after a needlestick or sharps injury from an HCV RNA positive person is less than 2%.[62] Other exposures involving mucous membrane or splash injuries are probably lower risk than percutaneous injuries. Individual health service providers have developed their own diagnostic algorithms for testing healthcare workers who have undergone a blood or body fluid exposure. In general, they recommend confirming HCV viraemia in the exposure source, and following up the recipient for up to 3 months after exposure for the detection of HCV antibodies.

The Communicable Diseases Network Australia published guidelines regarding the testing of health professionals and the settings in which healthcare workers might need to limit performing exposure-prone procedures.[84] Any testing, counselling and follow-up performed in that context should be done in accordance with these guidelines.

As for all tests where testing of a healthcare worker is undertaken, confidentiality must be maintained and support provided.

Healthcare workers who are exposed to hepatitis C, or experience a potential exposure incident, should be supported by their practice or institution to access testing, counselling, and specialist referral. Healthcare workers who are known to be living with blood-borne viruses should be in the care of their own medical practitioner and should not initiate diagnostic or monitoring tests on themselves.

8.0 Antenatal and perinatal hepatitis C testing

8.1 Routine testing

Women contemplating pregnancy or seeking antenatal care should be made aware of the benefits of routine screening for hepatitis C and offered HCV (anti-HCV) antibody testing. People who are HCV antibody positive also need to be tested for HCV RNA because the small risk of perinatal transmission is conditional on the presence of maternal HCV RNA. Pre-natal hepatitis C testing provides the opportunity for counselling and treatment for those considering future pregnancies.[85]

8.2 Testing of infants born to mothers with hepatitis C

The risk of perinatal hepatitis C transmission is 4% to 6% and is 2- 3 fold higher for mothers with HIV/HCV co-infection.[86] Maternal antibodies may persist in an infant born to an HCV - positive mother for up to 18 months. Diagnosis of HCV infection in infants born to mothers with hepatitis C is therefore established by testing the child for HCV RNA. It is recommended that HCV-RNA testing of the infant occur from 8 weeks of age. This will enable early identification and early referral to a paediatric hepatology or infectious diseases clinic for appropriate follow up.[75,87]

All children born to HCV antibody-positive mothers should have HCV antibody testing at 18 months of age because in rare instances vertical transmission occurs from mothers with low and fluctuating HCV RNA levels who test negative at the time of delivery.

9.0 Quality assurance of hepatitis C testing

For more information and background on hepatitis C in-vitro diagnostic device regulation, refer to the TGA. Refer to referenced NPAAC guidelines for more information on quality assurance.[27]

9.1 Testing sites

9.1.1 Laboratories

Laboratories that perform hepatitis C testing:

- must be NATA accredited for medical testing[88]
- must have a comprehensive quality management system, including standard operating procedures, documented training and competency assessment, internal quality control, incident reporting and result escalation pathways
- must participate in an external quality assessment scheme (EQAS)[89]
- must comply with the National Pathology Accreditation Advisory Council (NPAAC) standards.[27]

9.1.2 Point-of-care testing sites

- must participate in an external quality assessment scheme (EQAS)[90]
- should assess the competence of operators before testing and periodically consider accreditation under the National General Practice Accreditation Scheme, if appropriate[90]
- should perform regular quality control, monitor quantitative results graphically, have a validated method for establishing quality control acceptance limits and a documented procedure for managing result outside the acceptance criteria
- should comply with the Royal Australian College of General Practitioners Standards for point-of-care testing.[91]

9.2 Pre-market regulatory requirements for hepatitis C in-vitro diagnostic devices

The TGA regulates in-vitro diagnostic devices under the Therapeutic Goods Act 1989 (the Act) and its associated regulations.[92] All commercially supplied hepatitis C in-vitro diagnostic devices must be included in the ARTG. Before being included in the ARTG, these in-vitro diagnostic devices are evaluated to ensure they are safe and perform as intended. Commercial kits labelled as Research Use Only (RUO), or approved in-vitro diagnostic devices used off label (not as described in the instructions for use), must be fully validated by the user before they can be approved by the TGA. Evidence of this validation must be submitted to the TGA for the test to be included as an in-house in-vitro diagnostic device in the ARTG.

Laboratory users of commercially available hepatitis C assays can determine which are currently registered for use in Australia by searching the publicly accessible ARTG at https://www.tga.gov.au/resources/artg.

To obtain a complete list of all available assays enter 'hepatitis C' into the 'Search for' field. Avoid using the abbreviation HCV, as only partial lists will be displayed. To find a particular assay, you may search by either the sponsor or assay name. Users of commercially available assays should seek advice from the sponsors of these kits to determine the purpose for which the assay is included in the ARTG.

Alternatively, https://compliance.health.gov.au/artg/ may be used for advanced search functionality.

To obtain a complete list of hepatitis C assays, follow the ARTG search flowchart on the next page.

9.3 Post-market monitoring of hepatitis C in-vitro diagnostic devices

In-vitro diagnostic device manufacturers and sponsors in Australia have ongoing mandatory post-market monitoring responsibilities. Due to the high public health risk associated with hepatitis C in-vitro diagnostic devices, the TGA may impose specific post-market surveillance requirements as a condition of their inclusion in the ARTG. For instance, sponsors of point-of-care hepatitis C in-vitro diagnostic devices included in the ARTG must ensure that organisations using their in-vitro diagnostic devices participate in a hepatitis C point-of-care quality assurance program. These requirements can be found by searching for the specific hepatitis C in-vitro diagnostic device in the ARTG.

To comply with TGA legislation, sponsors must adhere to all imposed post-market surveillance requirements and report any known adverse events to the TGA. Manufacturers are responsible for investigating, implementing appropriate risk management procedures, and taking corrective and preventive actions related to their in-vitro diagnostic devices. If

there are issues or deficiencies in safety, quality, or performance of in-vitro diagnostic devices already on the market, sponsors must initiate corrective actions in consultation with the TGA Recalls Section. This action must be undertaken as soon as practicable after becoming aware of any adverse events, malfunctions or deterioration in the performance, or inadequacies in the design, production or labelling of an in-vitro diagnostic device.

Users are encouraged to report any issues with an in-vitro diagnostic device to the sponsor and the TGA. Reports to the TGA can be submitted through the TGA's Incident Reporting Investigation Scheme (IRIS) at: https://www.tga.gov.au/resources/resource/guidance/medical-device-incident-reporting-investigation-scheme-iris.

ARTG search flowchart

01 Type **ARTG** in search engine or go to https://www.tga.gov.au/resources/artg and click in **Access our ARTG search page** for advanced search functionality (https://compliance.health.gov.au/artg/)

02 On left hand side of ARTG Search Visualisation Tool dashboard, select **Medical Devices** in Advanced Search

03 Type **Hepatitis C** in **Search ARTG Medical Devices** search bar on right hand side above table of entries and click on the search icon.

04 Search results show # of ARTG Entries.
Above the table of entries, in "Hover here to see more options..",
select **More options** and **Export data** then click on required format.and **Export** button.

10.0 Funding of hepatitis C testing

10.1 Funding of hepatitis C testing

Funding for hepatitis C testing is provided both directly from the Commonwealth on a fee-for-service basis through Medicare funding arrangements and through specific state and territory funding arrangements, which may include provision of free and de-identified hepatitis C testing when used to inform treatment or when clinically indicated.

10.2 Funding arrangements for hepatitis C diagnostic and monitoring tests

More detailed information on Medicare benefits for hepatitis C tests can be found on MBS Online (schedule Category 6– Pathology items and descriptions).[15]

A Medicare benefit for pathology testing for hepatitis C will be payable where the service was determined to be necessary by the person's medical practitioner, was provided by an accredited pathology laboratory, and where the person meets the requirements for the relevant MBS Item. Benefits would be payable for the attendance and tests which are considered reasonably necessary according to a person's individual circumstances.

Medicare Benefit Schedule interpretation

Any inquiries concerning matters of interpretation of MBS Items, including eligibility, should be directed to the Department of Health and Aged Care in the first instance via email to: askMBS@health.gov.au

Services Australia is responsible for the day-to-day administration and payment of benefits under the Medicare arrangements. For enquiries relating to Medicare payments, phone 132 150.

11.0 Abbreviations and Acronyms

ACCESS	Australian Collaboration for Coordinated Enhanced Sentinel Surveillance of sexually transmitted infections and bloodborne viruses
AHPC	Australian Health Protection Committee
ARTG	Australian Register of Therapeutic Goods
ASHM	Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine
BBVSS	Blood Borne Viruses and Sexually Transmissible Infections Standing Committee of the AHPC
CDNA	Communicable Diseases Network of Australia
CE	Conformité Européene
DAA	Direct acting antiviral
DBS	Dried blood spot
EPP	Exposure-Prone Procedure
EQAS	External Quality Assessment Scheme
FDA	Food and Drug Administration (US)
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HREC	Human Rights Ethics Committee
IRIS	Immune reconstitution inflammatory syndrome
IVD	In-vitro diagnostic device
MBS	Medicare Benefits Schedule
MAFLD	Metabolic dysfunction-associated fatty liver disease
MASLD	Metabolic dysfunction-associated steatotic liver disease
MBS	Medicare Benefits Schedule
MSAC	Medical Services Advisory Committee
NATA	National Association of Testing Authorities
NHMRC	National Health and Medical Research Council
NPAAC	National Pathology Accreditation Advisory Council
NRL	National Serology Reference Laboratory, Australia
PBS	Pharmaceutical Benefits Scheme
RACGP	Royal Australian College of General Practitioners
RCPA	Royal College of Pathologists of Australasia
RNA	Ribonucleic acid
STI	Sexually transmissible infection
SVR	Sustained virological response
TGA	Therapeutic Goods Administration

12.0 Glossary

CE marking
Conformité Européenne: subject to one or more European product safety Directives. It indicates a product's compliance with the applicable European Union regulations and enables the commercialisation of a product in 32 European countries

Compulsory testing
Where a person has no choice in being tested, e.g. as directed under a Public Health Order

Exposure-Prone Procedure
Defined by the Infection Control Guidelines as a subset of 'invasive procedures' characterised by the potential for direct contact between the skin (usually finger or thumb) of the healthcare worker and sharp surgical instruments, needles or sharp tissues (spicules of bone or teeth) in body cavities or in poorly visualised or confined body sites (including the mouth). In the broader sense, an exposure-prone procedure is considered to be any situation where there is a potentially high risk of transmission of blood-borne disease from healthcare worker to person during medical or dental procedures

HCV antibody
Antibody to hepatitis C virus, which can be detected in the blood usually within 2 or 3 months of hepatitis C infection or exposure. The terms HCV antibody and anti-HCV antibody are equivalent, but in these guidelines, HCV antibody is used throughout

Mandatory testing
Refers to situations where people may neither participate in certain activities nor access certain services unless they agree to be tested. Examples of circumstances in which mandatory testing is appropriate include before blood, tissue and organ donation, and for immigration purposes

Occupational exposure
An exposure that may place an employee at risk of HIV or hepatitis C virus infection through percutaneous injury (e.g. a needlestick or cut with a sharp object, contact of mucous membranes, or contact of skin with blood, tissues or other potentially infectious body fluids to which Universal Precautions apply)

Point-of-care testing
Defined by TGA in the dictionary of Regulations as: for an in-vitro diagnostic medical device, means testing performed outside the laboratory environment, near to or at the side of the patient, that is not done under the supervision of a trained laboratory professional.

Defined by NPAAC as: pathology testing performed in close proximity to a patient by a healthcare worker, usually outside the precincts of a traditional laboratory. Testing is undertaken at the time of, and for use during, a consultation or episode of care.[36]

Serology
Is testing for the presence, evidence of, or quantity of antibodies specific for infectious or other agents, biochemistry, or substances in blood (serum or plasma or whole blood)

Specificity
The probability that a person without the disease will have a negative test result

Sustained virological response (SVR12)
Undetectable viral load 12 weeks after completion of antiviral therapy for hepatitis C

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