NATIONAL HEPATITIS C TESTING POLICY
NATIONAL HEPATITIS C TESTING POLICY v1.2
Reviewed 2016-17
Disclaimer:

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1.0 INTRODUCTION

1.1 Background and context

Australia has a high quality, comprehensive multi-sector pathology service. The regulatory and quality framework for HCV diagnostic testing has evolved with a focus on formal laboratory settings. 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 in order for pathology services to be eligible for the Medicare Benefits Schedule (MBS) rebates. Professional standards for pathology practice are established by the RCPA.

Diagnostic tests used in Australia must pass evaluation by the Therapeutic Goods Administration (TGA), prior to entry onto the Australian Register of Therapeutic Goods (ARTG) and the TGA can place conditions on this entry. The Medical Services Advisory Committee (MSAC) advises which tests should be subsidised through the MBS. It also can recommend any restrictions on eligibility. Tests for blood borne viruses including HIV tests undergo the most stringent of pathology test evaluations.

Some tests could be used outside of the diagnostic laboratory, such as for research or clinical trials (refer chapter 6.0) or those for point-of-care testing (refer chapter 10.0). These tests may therefore be outside the regulatory framework offered by NATA accreditation and/or RCPA standards.

Hepatitis C infection remains a major public health problem in Australia. Since testing began in 1990, it is estimated that over 300,000 people have been exposed to the hepatitis C virus (HCV). There were 10,790 hepatitis C notifications in Australia in 2015.\(^1\) Influenced by multiple factors, infection persists in between 55–85% of those infected. In 2015, an estimated 227,306 Australians were living with chronic hepatitis C. Cirrhosis develops within 20 years in 5–10% of this group (usually associated with other co-morbidities such as co-infection with human immunodeficiency virus (HIV) or hepatitis B virus (HBV), obesity, insulin resistance, alcohol intake > 40g/day) and in a further 10–15% after 40 years.\(^2\) Hepatocellular carcinoma will develop in 3–5% of people per annum who develop cirrhosis.\(^3\)

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 HCV. New treatments, subsidised on the Pharmaceutical Benefits Scheme (PBS) in 2016, will greatly improve HCV sustained viral responses and will increase demand for treatment. Oral pan-genotype medications will reduce the need for some testing both pre and during therapy in future. Therefore, this edition of the Testing Policy document seeks to define the current best practice for testing for exposure to the virus and for defining the current infective status of the person pre, during and post-treatment.

HCV testing can provide people with information regarding exposure to the virus. Appropriate
testing indicates whether they have cleared the virus spontaneously or with antiviral therapy or have an ongoing (chronic) infection.

The benefits of reliable, timely testing are numerous, both for the person and for public health. Detection of HCV infection followed by appropriate education can effectively reduce onward transmission by empowering people living with HCV to modify risk behaviour, modify disease progression through earlier referral for advice and/or 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 infected people in Australia remain undiagnosed.

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 Policy document assumes that all staff involved in the testing process are appropriately trained.

The previous HCV testing policy was released in 2012 and this version was updated in 2016. Differences in this version 1.2 include:

- Updated monitoring treatment (see section 2.4)
- More commentary on testing in Aboriginal and Torres Strait Islander populations and people who inject drugs (see section 3)

1.2 Purpose, scope and objectives

This Policy sets out the framework for providing quality testing and removing real and perceived barriers to testing. It identifies requirements and provides guidance and/or links regarding procedures for the provision of HCV testing.

The Policy is aligned with the Fourth National Hepatitis C Strategy 2014–2017 which identifies the need for a coordinated, accessible and affordable HCV testing system that aims to:

- increase testing of hepatitis C in priority populations
- improve referral and access to high-quality support services at the time of diagnosis for people with or at risk of hepatitis C to initiate a pathway to care
- assess the feasibility, accessibility and cost-effectiveness of the range of existing and emerging testing methods
- implement targeted initiatives for priority populations and local health care services to promote awareness and increase testing

This HCV testing policy will undergo regular review to take account of the continuing rapid change in the knowledge base, particularly related to treatment protocols.

1.3 Principles of HCV testing

The eight basic principles that guide HCV testing in Australia are:

- confidential, voluntary testing with informed consent and post-test discussion as fundamental to Australia’s response to HCV;
• testing is critical to understanding the epidemiology of HCV infection in the community;
• testing must be accessible to all those who are or have been at risk of HCV infection;
• testing will be of the highest possible standard and provided in a timely manner;
• testing is of benefit to the person being tested;
• testing can be critical to interruption of transmission and can support harm minimisation;
• testing to monitor people with HCV before, during and after treatment is an integral part of their care; and
• people should not be 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). De-identified testing should be provided to protect privacy where relevant.

1.4 Policy implementation

Testing policies and practices must comply with all relevant Commonwealth and State and Territory anti-discrimination and public health legislation, and other relevant laws and regulations, including those governing Commonwealth funding of pathology tests.\(^6,7,8\)

Policies relating to HCV testing, specific to individual States, Territories or institutions, should be consistent with the purpose, objectives and principles of this Policy.

1.4.1 Voluntary confidential testing

In Australia, HCV testing is voluntary and confidential. Testing is provided through a range of settings from general practice to specialist HCV, liver and infectious diseases services.

1.4.2 Mandatory and compulsory testing

• **Mandatory testing** refers to situations where people may not either participate in certain activities or access certain services unless they agree to be tested. Circumstances in which mandatory testing are currently required under separate policy or legislation include:

  - as a condition of blood, tissue and organ donation;\(^9\)
  - under the migration Health Requirements applicable to specified visa subclasses;\(^10\)
  - as a condition for entering training or service in the armed forces;\(^11\)
  - as a condition for purchasing some types of insurance;\(^12\) and
  - in the context of a legal instruction, including in forensic or coronial settings.

• **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 hepatitis C positive persistently behaves in a way that places others at risk of infection). Compulsory testing should only be used when there are no alternatives. 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 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 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.¹³

1.4.4 Introduction of new technologies and strategies

Introduction of new technologies¹⁴ or strategies to target new priority populations¹⁵ must be accompanied by appropriate workforce development to ensure that those providing or offering HCV testing are equipped with:

- up-to-date information about HCV infection, pathophysiology, immunology and epidemiology;
- latest information about HCV treatment and management;
- procedures associated with using any new technology; and
- information related to referral pathways to care and support services (see section 10.0 Point of Care tests for HCV in community settings).
2.0 DIAGNOSTIC STRATEGIES

2.1 Types and uses of HCV diagnostic tests – also called in vitro Diagnostic Devices (IVDs)

All tests for HCV must be included on the Australian Register of Therapeutic Goods (ARTG) prior to their use in Australia. Inclusion on the ARTG requires pre-market assessment of the IVD commensurate with the purpose for which the test is used.

Screening tests
Screening tests may be used by laboratories performing diagnostic testing or screening of blood donations to identify samples that are HCV antibody (anti-HCV) negative. Those samples yielding non-reactive results do not need to be further tested unless clinical considerations demand it. Reactive samples must be subjected to supplemental testing to distinguish true reactivity from false.

Supplemental tests
Supplemental tests are used by laboratories to conduct confirmatory or additional testing to define a sample’s status by distinguishing true from false reactivity. Usually this testing is conducted within a diagnostic strategy and a second immunoassay is used; other supplemental testing situations occur (e.g. in a setting of possible seroconversion illness) when the first-used supplemental tests may include nucleic acid tests.

The supplemental testing must confirm the presence of specific antibody, antigen or viral RNA before the result is accepted as a true positive.

Other tests may be used once the HCV status is confirmed. These include tests to quantify viral load and characterise the virus genotype.

2.2 Testing for HCV

This section provides advice on minimum standards for laboratory diagnosis and investigation of HCV. It should be noted that, because of their unique requirements, blood services have developed their own strategies for screening donations. Laboratory investigations are directed towards answering one or more of the following questions:

1. Has the person ever been infected with HCV? This should be determined by testing for HCV antibodies, or antigen and antibodies simultaneously. RNA testing will be negative in past infection with clearance.
2. Does the person have current infection? This is determined by testing for HCV RNA or infrequently HCV antigen, as the latter is currently less sensitive than HCV RNA testing. Further, there is only one test on the ARTG that detects HCV antigen only.
3. What is the current level of viral replication? With current directly acting antiviral (DAA) regimens, the baseline HCV RNA has little impact on the likelihood of achieving a sustained virological response (SVR). However, a pre-treatment baseline quantitative HCV RNA is recommended because it may identify people who are eligible for shorter treatment duration with certain regimens e.g. genotype 1 infection.
4. **What is the infecting virus genotype?** With interferon-based treatment, HCV genotype was a strong predictor of achieving an SVR. Currently with DAA therapy, the genotype determines the drugs to be used. Pan-genotype drug combinations are soon to be released but until then, HCV genotyping must be performed before treatment initiation. It is also required to meet the PBS criteria for the treatment of hepatitis C and must be documented in the patient’s medical history.

**TESTING PATHWAY**

- Screen by HCV IA (a) → NEGATIVE
  - REACTIVE
    - Test by second alternative HCV IA
      - REACTIVE → Additional confirmatory tests may be performed at this stage e.g. HCV RNA, HCV Ag, immunoblot → NEGATIVE
      - NAT for HCV RNA (b) → POSITIVE
        - Active infection → Report to referring doctor who informs patient
          - Doctor refers for further evaluation: genotype; viral load. Notifies relevant bodies
      - NAT for HCV RNA → NEGATIVE
        - Likely past infection with viral clearance OR if liver tests abnormal possible low VL. Repeat HCV RNA in 6 months if infection still a concern → Repeat at 1-2 months if acute infection is suspected
        - Possible very early seroconversion → Repeat at 1-2 months if acute infection is suspected
        - Likely false reactivity in first IA. Repeat HCV RNA in 6 months if infection is still a concern → Report to referring doctor who informs patient
  - Report to referring doctor who informs patient

IA = Immunoassay. Encompasses all approved HCV IAs included on the ARTG for screening
(a) Screening IAs may include Antigen / Antibody combination IAs
(b) HCV Antigen IA may be considered an alternative to NAT
2.3 Diagnostic strategies for HCV

- Exposure to HCV is determined by testing for HCV antibodies, or antigen and antibodies simultaneously in serum or plasma.
- A sample non-reactive in the screening immunoassay can be generally regarded as anti-HCV negative. If doubt exists, repeat the test or consider qualitative HCV RNA testing.
- Immunoassays that test for the presence of HCV antibody and antigen simultaneously facilitate earlier detection of people with recently acquired HCV infection. This assay can be used to confirm whether reactivity in an antigen/antibody screening test is attributable to the presence of HCV antigen.\(^\text{16}\)
- A sample reactive in the screening immunoassay must be subject to a minimum of one alternative immunoassay to confirm the result. The alternative immunoassay should include antigens different from the screening test in both specificity, where possible, and method of preparation. Validation using the two tests together should be undertaken to show that samples falsely reactive in the first test are not also falsely reactive in the second. This is necessary because all immunoassays show a degree of false reactivity and it is important to eliminate to the extent possible, false reactivity that is common between two tests that will be used as part of a diagnostic strategy.\(^\text{17}\) A sample reactive in two approved immunoassays can be reported as anti-HCV positive.
- Current HCV infection is determined by qualitative testing for HCV RNA or infrequently HCV antigen testing.
  - The manufacturers of quantitative HCV RNA assays specify that they are not for use as diagnostic tests to confirm the presence of HCV infection. Qualitative RNA testing will be negative in past infection with clearance.
  - Ideally, a second blood sample specifically for HCV RNA testing should be used, in line with NPAAC guidelines for nucleic acid testing (NAT). If not available, then blood or plasma should be set aside at the time of sample collection to allow for any subsequent HCV RNA assay to be done if anti-HCV is confirmed positive. The latter may be achieved by dividing a single specimen to allow the two separate tests to be done as appropriate. This procedure may save additional blood collection/processing for people being tested for HCV notwithstanding significant changes that would be required to laboratory workflow if dividing a single specimen were implemented.
  - HCV antigen assays are not currently used regularly in clinical practice. Instead, NAT is the more usual option chosen due to the lower sensitivity of HCV antigen assays. This situation may be influenced in the future by changes in test platforms.
- HCV genotyping must be performed before treatment initiation, as it determines the regimen and the duration of therapy.

2.4 Monitoring treatment

The introduction of the highly efficacious and well tolerated DAAs for the treatment of HCV has reduced the need for frequent on-treatment monitoring of patients. Eligibility for treatment requires a baseline viral load (quantitative HCV RNA test) and HCV genotyping, as most current treatment regimens are genotype specific. Generally, routine on treatment assessment of HCV RNA levels is not necessary due to the lack of a role for response-guided therapy. In practice, many patients have an assessment at week 4 of therapy during an 8- or 12-week course, as this
can give an indication of patient adherence and/or drug efficacy. Patients on 24-week treatment regimens will also require an assessment at week 12. Qualitative HCV PCR testing at the end of treatment can be performed to determine an end-of-treatment response. A further qualitative HCV PCR test is recommended 12 weeks after the end of DAA therapy to confirm successful viral eradication, also known as a sustained viral response (SVR12), which is defined as an undetectable HCV RNA.

Patients who may require more intense monitoring include those in whom adherence is a concern, patients on ribavirin-containing regimens and people with advanced liver disease (portal hypertension or hepatic decompensation).

For more details on testing frequency and type, see Section 6 of the *Australian Recommendations for the Treatment of Hepatitis C Infection: a Consensus Statement 2016* available at [www.hepcguidelines.org.au](http://www.hepcguidelines.org.au)
3.0 INDICATIONS FOR HCV TESTING

Testing is indicated for people who have risk factors associated with transmission of HCV. A history considering risk factors for acquisition of HCV infection should be taken to help determine whether a HCV test is indicated. In appropriate clinical circumstances, the absence of a declared risk factor should not preclude HCV testing. Clinical suspicion of HCV infection may occur in the context of:

- chronic liver disease or liver cirrhosis;
- hepatocellular carcinoma (liver cancer);
- evaluation of abnormal liver function tests; and
- acute hepatitis.

A number of clinical conditions and symptoms are associated with HCV where clinical suspicion leads to a HCV test.\(^\text{18}\)

Other situations where HCV testing may be indicated include:

- health care workers who perform or may be expected to perform exposure prone procedures (EPPs) must be aware of their HCV (and HIV and hepatitis B) status;\(^\text{19}\)
- contact tracing where exposure to blood of a potentially infected person 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;
- a person who reports a reactive result on a HCV test not approved for supply in Australia; and
- a person who requests a HCV test in the absence of declared risk factors – a small number of people may request a HCV test but choose not to disclose risk factors. A person’s choice not to declare risk factors should be recognised and HCV testing should be offered.

3.1 Risk factors for exposure to HCV infection

3.1.1 People with a history of injecting drug use\(^\text{20}\)

Over 80% of existing and almost 90% of all new HCV infections are among people with a history of injecting drug use (IDU). People with a history of IDU often experience significant barriers to accessing health services including HCV testing and treatment services. In this context, it is critical that testing is conducted in an appropriate, non-judgmental and non-stigmatising setting to assist people with a history of IDU through the testing and diagnosis process. This will have a profound effect on a person’s understanding of their condition and their likelihood of future engagement with the health system. Peer education and support will optimise testing uptake and reporting and is recommended where these resources are available. Staff in specialist and primary health care services should be cognisant of issues relating to illicit drug use, harm reduction, addressing stigma and discrimination and managing vein care issues.
3.1.1.1 HCV testing frequency in People Who Inject Drugs (PWID)\textsuperscript{21}

An anti-HCV test is recommended for PWID, and if the result is positive, current infection should be confirmed by a qualitative HCV RNA test.

**Recommendations for the frequency of testing in PWID with unsafe (unsterile) injecting practices are:**
- in those people who continue to inject drugs, repeat testing for anti-HCV every 3-6 months is indicated if there is high risk behavior, e.g. needles are shared, or if the individual expresses a concern that they may have been exposed to HCV.

**Recommendations for the frequency of testing in PWID with safe injecting practices are:**
- annual testing (every 12 months) is indicated in PWID who avoid sharing injecting equipment and who are not infected (i.e. anti-HCV negative) on first testing. Testing should also be offered following a high risk injecting episode.

PWID who are anti-HCV antibody positive and HCV RNA negative (through spontaneous or treatment-induced clearance) should receive regular HCV RNA testing, every 12 months or following a high risk injecting episode.

3.1.1.2 Testing for reinfection in PWID

More frequent testing 3-6 monthly in high risk PWID post-treatment is important, but HCV RNA is not funded under the MBS more than annually.

Annual HCV RNA testing for reinfection, with more frequent testing if indicated by clinical symptoms or following a high risk injecting episode, is recommended.\textsuperscript{21}

3.1.2 People who are, or have ever been, incarcerated\textsuperscript{22}

Imprisonment is an independent risk factor for HCV transmission. HCV prevalence for all prisoners in Australia is estimated at 30–40% and is higher for women at 50–60%. A history of previous incarceration is a very strong indication to offer testing for HCV and it should be offered with appropriate discussion of risk and benefits.

For those currently incarcerated, indicators to discuss testing should be based on thorough risk assessment, including any history of drug use or previous incarceration.

HCV treatment while in custody should be considered where treatment services are available.
3.1.3 Recipients of organs, tissues, blood or blood products before February 1990 in Australia, or before the implementation of mandatory screening of blood donors in other countries (or at any time where this is not the case)\(^{24}\)

HCV is efficiently transmitted by transfused blood or blood products. Infections acquired in this way account for 5–10% of all cases in Australia. Individuals in Australia, or other major developed countries, who were transfused or received organ or tissue donations or blood products before HCV screening commenced (February 1990 in Australia) who have not been tested or who do not know test results 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 HCV.\(^{25}\) People who received blood products or organ or tissue donations at any time in overseas countries where screening of the blood/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 HCV at the time a donation is made. An HCV-positive organ may still be used in an HCV-positive recipient.

3.1.4 People with tattoos or skin piercings\(^{26}\)

Skin penetration practices are not independent risk factors for HCV transmission. The indications to test will include a consideration of other factors that may contribute to increased transmission such as population prevalence or 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).

3.1.5 People born in countries with high HCV prevalence\(^{27}\)

The risk of HCV infection may be greater for people born in or who have spent considerable time in countries where there is a high prevalence of HCV infection than it is for people born in Australia.\(^{27}\) 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 HCV. These countries include Africa, the Middle East (in particular Egypt), the Mediterranean, Eastern Europe, and South Asia. In many of these countries, HCV transmission is not predominantly associated with IDU and the disease can be acquired from medical and dental procedures or from occupational exposure to infected materials. Indications to offer testing include a history of HCV in a family member or exposure to medical procedures. In these people, HCV RNA positivity should prompt testing of other family members.

3.1.6 Aboriginal and Torres Strait Islander populations\(^{28}\)

In 2015, 929 (or 9% of the total 10,790 cases) of the newly diagnosed HCV infections in Australia were among the Aboriginal and Torres Strait Islander people. There were a further 6,419 (59%) cases where Indigenous status was not reported.

The notification rate of newly diagnosed hepatitis C infection in the Aboriginal and Torres Strait
Islander population increased by 43% in the last five years whereas the rate in the non-Indigenous population decreased by 10%.

Given that Aboriginal and Torres Strait Islander people constitute just 3% of Australia’s total population, the disproportionate HCV-related burden of disease borne by this group is striking. Risk factors for increased HCV antibody prevalence in this population include higher rates of unsafe injecting drug use practices, and tribal scarring. Aboriginal and Torres Strait Islander people also experience a disproportionately high rate of incarceration, which is an independent risk factor for HCV acquisition.

3.1.7 Sexual partners of people with HCV

The risk of heterosexual transmission of HCV is low. However, there is an increased risk of sexual transmission of HCV for men who have sex with men who are also HIV positive. Testing for infection in this situation should be undertaken regularly. This should take place annually in those who are aware of risk and practicing safe sex and every six months for those who have:

- had more than 10 partners in the past 6 months;
- engaged in unprotected anal sex;
- used recreational drugs; and/or
- engaged in group sexual activities.

Testing should occur in appropriate settings, such as HIV clinics, sexual health clinics or GP surgeries for those with ongoing risk of infection.

3.1.8 Children born to HCV-positive mothers

See section 8.

3.1.9 Transmission and infection control in healthcare settings

- HCV testing of health care workers should be conducted in accordance with the general principles set out in this document with regard to privacy, confidentiality and access to appropriate health care and support services;
- In keeping with the CDNA guidelines, health care workers must not perform EPPs if they are hepatitis C RNA positive (by nucleic acid test);
- Testing for all BBVs should be undertaken for health care workers following occupational exposure to blood or body substances, for example through needle stick injury;
- People on regular haemodialysis should be tested every six months for anti-HCV, and
- In rare situations, clients of healthcare services may need to be offered testing as part of an outbreak investigation and/or due to failure of infection control practices.
4.0 INFORMED CONSENT FOR TESTING

Informed consent for testing means that the person being tested agrees to be tested on the basis of understanding the testing procedures, the reasons for testing and is able to assess the personal implications. Informed consent is required for HCV testing, except for rare occasions when a legal order is made for compulsory testing or in emergency settings. On these rare occasions where informed consent cannot be attained, pre-test provision of all appropriate information to the person should still take place. The person performing the test should use their clinical judgment in securing informed consent. This should be based on their understanding of the context in which the test is being performed, taking into account:

- the factors which indicate a need for testing such as clinical presentation, risk exposure, prevalence and individual initiation; and
- an assessment of the understanding of the HCV testing process and the consequences of the result to the person being tested.

General principles of professional conduct apply in the case of HCV testing and informed consent. Consent to test should not be sought from sexual partners or family members of the person being tested. In the case of testing a child or person who is incapable of giving consent (perhaps due to mental illness or cognitive disability) then the responsibility for consent rests with the guardian or other person/agency legally authorised to make such decisions on their behalf.

People involved in HCV testing must use whatever additional support is necessary to assist the person considering testing to become adequately informed. This process involves a referral to the support groups listed in section 5.3, including access to telephone interpreters (available nationally for use by private and public health care professionals). Culturally relevant information should be provided when seeking informed consent and providing results.

The person being tested needs to be made aware of confidentiality considerations and protections.
5.0 CONVEYING HCV TEST RESULTS

The process of conveying an HCV test result (previously post-test counselling) to the person being tested, irrespective of the specific result, is affected by the type of test performed, the setting of the consultation, and testing and the extent, if any, of additional testing required in determining the true HCV status of the person. The person who requests 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 addressing the issues that the result raises (see section 5.2). Where an anti-HCV test has been the only test requested, discussion of the need to progress to viral studies will need to be addressed in the process of informing the person of their actual HCV status. In presenting results to people from countries where English is not the primary language, interpreter services should be accessed.

5.1 Conveying a negative result

This may be a negative anti-HCV result or a negative HCV RNA result. The decision on how a negative HCV test result is provided (e.g. in person, by phone, etc.) should be based on the clinical judgement of the person responsible for conveying the result. This assessment should take into account the psychological capacity of the person being tested to deal with the outcome of testing and his/her understanding of the testing process as evident at the time of the sample collection. It is imperative that the meaning of a negative result is fully understood and that the person being tested receives appropriate information about harm reduction in relation to the spread of BBVs.

Further testing following a negative result (anti-HCV or HCV RNA) is indicated in persons who may be in:

- a window period prior to seroconversion (negative anti-HCV or HCV RNA in a high-risk situation); and/or
- the situation of having a known previous infection with persistent anti-HCV positivity but a negative HCV RNA. In this latter 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, two HCV RNA results 6 months apart should be negative before assurance is given that the infection has been cleared.

It is imperative that the clinician makes all attempts to ensure that the result is being provided to the person who was tested.

This includes:

- confirming the person’s identity;
- making repeated contact to ensure the person is aware of the availability of the result; and
- documenting all efforts to contact the person.

5.2 Conveying a confirmed positive result

This may be a positive HCV Ab or a positive HCV RNA result. Both will have a significant impact for a person and their clinician. Laboratories commonly provide information and the
opportunity for consultation to assist the requesting clinician at the time of diagnosis. A positive result **should** always be provided in person by the clinician, except in extenuating circumstances where, for example, it is suspected that the person who has been tested may not return for the result and/or may engage in risk behaviour(s) based on the wrong assumption that they are HCV negative. A positive HCV Ab result will need to be informed by further testing for HCV RNA (or HCV Ag) to clarify whether the person is still infected or has cleared the virus.

The discussion when conveying a positive result **should** include:

- giving the test result in person and in a confidential manner that is sensitive and appropriate to the gender, culture, behaviour, language and literacy level of the person who has been tested;
- providing information on further testing that may be required to clarify the situation;
- assessing the need for and providing information about support mechanisms and making provisions for immediate referral to a support agency as required. Providing information on the next steps in staging HCV disease in those who are HCV RNA positive and discussing potential treatment options. It may be necessary to cover these issues over a period of time, in which case a subsequent consultation **should** be arranged at the time of diagnosis;
- disclosure strategies to partner, family and friends;
- legal obligations to disclose HCV status relevant to where the diagnosis is made; and
- the transmission of HCV and how onward transmission may be prevented.

### 5.3 Referral for further support

The information and support needs of people who are preparing for diagnostic testing for HCV, or have just received a test result are considerable and diverse. Information provided in a single clinical consultation is often insufficient to meet their needs as understanding develops and different personal factors arise over time. Community-based organisations including hepatitis organisations, Aboriginal Community Controlled Health services, peer-based drug user groups and haemophilia organisations are well placed to assist people who are newly diagnosed to better understand the HCV testing and diagnosis process and provide appropriate support through this critical period. Providing referral to relevant community-based organisations or if available, on-site peer support, to one or more of the following organisations is therefore highly recommended when informed consent for testing is being obtained and as appropriate at other stages of HCV testing and management process.

*Hepatitis Australia*

National Helpline: 1800 437 222 (1800 HEP ABC) [www.hepatitisaustralia.com](http://www.hepatitisaustralia.com)

*The Australian Injecting and Illicit Drug Users’ League (AIVL)*

Telephone: 02 6279 1600 [www.aivl.org.au](http://www.aivl.org.au)

*Haemophilia Foundation Australia (HFA)*

Telephone: 03 9885 7800 [www.haemophilia.org.au](http://www.haemophilia.org.au)
5.4 People with complex needs

5.4.1 People unconvinced by a negative or positive result

Responding to the needs of this group of people can be time-consuming and there may be complex psychological issues that need to be addressed. Assistance in dealing with these people can be obtained from a range of specialist services which can offer help to refer a person in this predicament to an alternative service for a second opinion.\(^{38}\)

5.4.2 People who do not return for positive test results

These people can be unaware of factors that may help them in living with chronic infection and may unknowingly place others at risk. It is important to try and contact these people. This should be done by phone to the person or in written correspondence. The request should be for the person to re-contact the service provider without providing the result per se. Public health units and sexual health clinics can provide advice on person follow-up.

The decision to stop trying to follow-up a person can be a difficult one. Attempts to make contact should be documented in the person’s file. General practice in particular has limited capacity to perform person follow-up and GPs should pass this responsibility on to the local public health unit if they have exhausted their resources. General practitioners should refer to the Royal Australian College of General Practitioners (RACGP) guidelines on follow-up of pathology results.\(^{39}\) All practitioners should be aware of their legal obligations and indemnity cover should they be unable to deliver a positive result.\(^{40}\)

5.4.3 Post-mortem testing

HCV tests are not standardised in the post-mortem setting. A pathologist undertaking HCV testing as part of the process of a coronial examination or other post-mortem examination is responsible for ensuring that the other provisions in this policy are adhered to.
6.0 SURVEILLANCE AND RESEARCH

Laboratories performing HCV testing must notify the relevant State and Territory health authorities of any new positive laboratory diagnosis in accordance with the relevant legislation.36

6.1 Sentinel site surveillance for HCV

HCV testing is routinely carried out at a number of sentinel sites such as sexual health clinics, Aboriginal Community Controlled Health Services, prisons, primary health care sites, drug-user organisations and blood transfusion services. The numbers of people tested and the proportion with diagnosed HCV infection are reported on a regular basis from these sites and provide estimates of HCV prevalence and incidence across various population groups.

6.2 Special annual survey

The Australian Needle and Syringe Program Survey is coordinated by The Kirby Institute (formerly NCHECR) and has been carried out over one week each year since 1995.41 During the designated survey week, needle and syringe programs staff ask all clients who attend to complete a brief, self-administered questionnaire and provide a finger-prick blood sample. The subjects are assured that the specimens are tested under code, so the results cannot be linked back to individuals.

This survey, however, provides limited information on comparisons of HCV infections between jurisdictions and over time.

6.3 Delinked blood surveys

Delinked anonymous surveys are studies in which specimens taken for other purposes (e.g. the neonatal heel-prick specimen survey in 1989–90) are tested for HCV infection without consent after they have been coded so that the results cannot be linked back to the individual who originally provided the specimen. This survey method should be considered for Australian surveillance purposes only where there is no other feasible method for reasonably obtaining appropriate data and should be subject to scientific justification and be endorsed by an institutional ethics committee in accordance with the requirements prescribed by the NHMRC.

6.4 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/or be subject to appropriate ethical review.

6.5 Use of unregistered Invitro Diagnostic Devices (IVDs)

IVDs not currently approved for use in Australia may be required in international collaborative
research. Application **must** be made to the Therapeutic Goods Administration (TGA)\(^{42}\) under the Clinical Trial or Special Access Scheme when IVDs are intended for therapeutic use (e.g. to diagnose infection or determine treatment for an individual). IVDs for research only (e.g. where results are de-identified and not used to determine individual treatment) are exempt under Clause 1.3, Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.\(^{43}\)
7.0 HEALTH CARE WORKERS

Communicable Diseases Network of Australia,\(^4^4\) professional societies, colleges and registration boards may from time to time publish guidelines regarding the testing of health professionals. Any testing done in that context **should** be done in accordance with this Policy. As for all tests where testing of a health care worker is undertaken, confidentiality **must** be maintained.

Health care workers **must not** request or perform tests on themselves.
8.0 ANTENATAL AND PERINATAL TESTING

8.1 Routine testing

Women contemplating pregnancy or seeking antenatal care should be made aware of the benefits of diagnosis of HCV infection and management and prevention strategies available for both the mother and the infant. Antenatal testing must only be performed with informed consent of the woman. HCV testing must be offered in the context of appropriate risk assessment and discussion. Testing should be encouraged for those with clinical suspicion of infection (see section 3.0) and/or at risk of past infections (see section 3.1). There is a greater risk of a false positive anti-HCV result during pregnancy and HCV RNA testing should be used to confirm the HCV status of a person shown to be anti-HCV positive.

8.2 Testing of infants born to HCV-infected mothers

The risk of perinatal HCV transmission is 4% to 6%, and is two to threefold higher for mothers with HIV/HCV co-infection. 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 HCV-infected mothers is established by testing for HCV RNA. It is recommended that HCV RNA be tested at 8 weeks and again 4 to 6 weeks later to confirm ongoing infection and to exclude transient viraemia which can occur in infants. If the test returns positive on both occasions, the child should be referred to a Paediatric Gastroenterology or Infectious Diseases Unit for 6 monthly monitoring of liver function (this may require travel to a major centre where this service is available).

All children born to anti-HCV positive mothers should have antibody testing at 18 months of age because in rare instances transmission occurs from mothers with low and/or fluctuating HCV RNA levels and who test negative at the time of delivery. Where the mother’s RNA status is unknown at time of delivery it should be assumed to have been positive unless previous viral clearance has been demonstrated.
9.0 QUALITY ASSURANCE OF HCV TESTING

For more information and background on HCV IVD regulation and quality assurance, refer to the TGA.

9.1 Laboratories

Laboratories that perform HCV testing:
- must be NATA accredited for medical testing;\(^{47}\)
- must participate in an external quality assessment scheme (EQAS);\(^{48}\)
- must comply with the National Pathology Accreditation Advisory Council (NPAAC) standards;\(^{49}\) and
- should contribute testing statistics to National Serology Reference Laboratory (NRL) to ensure the completeness of test denominator data.\(^{17}\)

9.2 Pre-market quality assurance of HCV IVDs

The TGA has regulatory responsibility for IVDs through the Therapeutic Goods Act 1989 (the Act) and its associated regulations.\(^{50}\)

9.3 Post-marketing quality assurance of HCV IVDs

IVD manufacturers, sponsors and the TGA have responsibility for post-market monitoring of the IVDs. Corrective action must be initiated by the manufacturer and sponsor of an IVD in consultation with the TGA. This must occur as soon as practicable after becoming aware of information relating to any adverse events, malfunction or deterioration in the performance, or inadequacy in the design production and labelling of an IVD. Users are encouraged to report any issues with an IVD to the sponsor and the TGA. Reports to the TGA can be submitted through the TGA’s Incident Reporting Investigation Scheme (IRIS).

10.0 POINT OF CARE TESTS FOR HCV IN COMMUNITY SETTINGS

No Point of Care (PoC) tests for HCV are currently approved for use in Australia, however, a number of anti-HCV tests which show a similar sensitivity and specificity to commercial laboratory anti-HCV enzyme immunoassays have Food and Drug Administration (FDA) approval and CE marking. Such rapid assays may yet find a niche in HCV testing in Australia; they offer an opportunity for testing of people who may otherwise not seek help from traditional medical settings and can provide a result without the individual returning to the site at a later date.

These tests are likely to be inappropriate for testing of low prevalence populations.

When a PoC test is approved for use in Australia, this section of the policy will be updated.

Some people in the community may access self-administered PoC test from overseas for their personal use. Due to the lack of TGA approval and the variability in test sensitivity and specificity, if a person indicates they have received a positive or negative PoC test result, this then should be confirmed by standard HCV testing in a NATA accredited diagnostic laboratory.
11.0 FUNDING OF HCV TESTING

11.1 Funding of HCV testing

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

11.2 Funding arrangements for HCV diagnostic and monitoring tests

More detailed information on Medicare benefits for hepatitis C tests is available here: http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/downloads (See the most recent schedule Category 6–Pathology items and descriptions).51

A Medicare benefit for pathology testing for hepatitis C will be payable where the service was determined to be necessary by the patient’s medical practitioner, was provided by an accredited pathology laboratory, and the patient 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 patient’s individual circumstances.

11.3 Schedule Interpretation

The Department of Human Services is responsible for the day-to-day administration and payment of benefits under the Medicare arrangements. Any inquiries concerning matters of interpretation of Schedule items should be directed to the Department of Human Services in the first instance. For enquiries relating exclusively to the Schedule, phone 132 150.

Alternatively, send an email to askMBS@humanservices.gov.au.
12.0 GLOSSARY

12.1 Abbreviations and acronyms

ARTG  Australian Register of Therapeutic Goods
ASHM  Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine
CDNA  Communicable Diseases Network of Australia
EPP   Exposure Prone Procedure
EQAS  External Quality Assessment Scheme
HCV   Hepatitis C virus
HIV   Human immunodeficiency virus
IDU   Injecting Drug Use
IVD   In-Vitro Diagnostic Device
MBS   Medicare Benefits Schedule
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
NSP   Needle and Syringe Program
PoC   Point of Care testing
PWID  People who inject drugs
RNA   Ribonucleic Acid
STI   Sexually Transmissible Infection
TGA   Therapeutic Goods Administration

12.2 Glossary

CE marking
indicates a product’s compliance with the applicable EU 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 health care 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 health care worker to patient during medical or dental procedures.

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 HCV 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).

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 HCV
13.0 REFERENCES

1.0 Introduction

2.0 Diagnostic strategies


3.0 Indications for HCV testing


4.0 Informed consent for testing

5.0 Conveying HCV test results

6.0 Surveillance and research

7.0 Health care workers

8.0 Antenatal and perinatal testing

9.0 Quality assurance of HCV testing
11.0 Funding of HCV testing
### ATTACHMENT A: MEMBERSHIP OF THE EXPERT REFERENCE COMMITTEE 2015-2017

<table>
<thead>
<tr>
<th>FIRST NAME</th>
<th>LAST NAME</th>
<th>POSITION in FULL</th>
<th>ORGANISATION</th>
<th>AFFILIATION ON ERC</th>
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<tbody>
<tr>
<td>Bob</td>
<td>Batey</td>
<td>Clinical Professor of Medicine University of Sydney; Professorial Fellow, Flinders University at Department of Medicine, Alice Springs Hospital, NT</td>
<td>University of Sydney; Alice Springs Hospital</td>
<td>Chair</td>
</tr>
<tr>
<td>Edmund</td>
<td>Tse</td>
<td>Gastroenterologist</td>
<td>Royal Adelaide Hospital; ALA/GESA</td>
<td>ALA/GESA representative</td>
</tr>
<tr>
<td>Bill</td>
<td>Rawlinson</td>
<td>Senior Medical Virologist (POW/SEALS) &amp; Chairman (RCPA Serology)</td>
<td>Prince of Wales Hospital/SEALS; Royal College of Pathologists of Australasia (RCPA)</td>
<td>PHLN representation</td>
</tr>
<tr>
<td>Susan</td>
<td>Best</td>
<td>Director</td>
<td>National Serology Reference Laboratory (NRL National Serology Reference Laboratory, Australia)</td>
<td>NRL representative</td>
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<tr>
<td>Scott</td>
<td>Bowden</td>
<td>A/Prof</td>
<td>Victorian Infectious Diseases Reference Laboratory (VIDRL)</td>
<td>VIDRL representative</td>
</tr>
<tr>
<td>Judith</td>
<td>Bevan</td>
<td>Senior Policy and Planning Officer</td>
<td>Sexual Health and Blood-borne Virus Program, Department of Health WA</td>
<td>BBVSBlood Borne Virus and Sexually Transmissible Infection Subcommittee representative</td>
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<tr>
<td>Lisa</td>
<td>Bastian</td>
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<tr>
<td>Joseph</td>
<td>Doyle</td>
<td>Consultant Physician and Senior Lecturer</td>
<td>The Alfred &amp; Monash University Department of Infectious Diseases; Australasian Society of Infectious Diseases</td>
<td>ASID representative</td>
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<tr>
<td>Carla</td>
<td>Treloar</td>
<td>Deputy Director</td>
<td>Centre for Social Research in Health (CSRH)</td>
<td>CSRH representative</td>
</tr>
<tr>
<td>Michelle</td>
<td>McNiven</td>
<td>Director, IVD Reforms, Business Improvement Section</td>
<td>Therapeutic Goods Administration</td>
<td>TGATherapeutic Goods Administration representative</td>
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<tr>
<td>Kevin</td>
<td>Marriott</td>
<td>Director – Policy and Programs</td>
<td>Hepatitis Australia</td>
<td>Community representative</td>
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<tr>
<td>Robert</td>
<td>Project Officer</td>
<td>Aboriginal and Torres Strait Islander Health Program</td>
<td>Aboriginal and Torres Strait Islander Health Program, The Kirby Institute, representative</td>
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<tr>
<td>Marlene</td>
<td>Program Head</td>
<td>The Kirby Institute</td>
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<td>Jude</td>
<td>Senior Project Officer</td>
<td>Australian Injecting and Illicit Drug Users League (AIVL)</td>
<td>AIVL representative</td>
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<td>Byrne</td>
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<td>Teresa</td>
<td>Director, Blood Borne Viruses &amp; Sexually Transmissible Infections Section</td>
<td>BBV and STI Section – Australian Government Department of Health</td>
<td>Australian Government Department of Health representative</td>
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<td>Gorondi</td>
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<tr>
<td>Jennie</td>
<td>Assistant Director, Blood Borne Viruses &amp; Sexually Transmissible Infections Section</td>
<td>BBV and STI Section – Australian Government Department of Health</td>
<td>Australian Government Department of Health representative</td>
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<tr>
<td>Michael</td>
<td>Policy Officer</td>
<td>BBV and STI Section – Health Protection Policy Branch, Office of Health Protection</td>
<td>Australian Government Department of Health representative</td>
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<td>Lidman</td>
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<tr>
<td>Sonja</td>
<td>Senior Project Officer</td>
<td>ASHM</td>
<td>ASHM secretariat</td>
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<td>Hill</td>
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