

AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE



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Requirements for laboratory testing for human immunodeficiency virus (HIV) and hepatitis C virus (HCV)

Fourth Edition

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- 2006 First edition published
- 2009 Second edition published
- 2013 Third edition published; reprinted and reformatted to be read in conjunction with the *Requirements for Medical Pathology Services*
- 2023 Fourth edition published; reformatted and amended in line with change in laboratory case definition for confirmatory testing for human immunodeficiency virus

Superseded March 2026

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National Pathology Accreditation Advisory Council

The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to consider and make recommendations to the Australian, state and territory governments on matters related to:

- the accreditation of pathology laboratories
- the introduction and maintenance of uniform standards of practice in pathology laboratories throughout Australia

NPAAC formulate standards and initiate and promote education programs about pathology tests.

Publications produced by NPAAC are issued to provide guidance to laboratories about the expected level of safe and good quality laboratory practice. The standards form the basis of awarding accreditation and should be used by accrediting agencies at assessment.

Failure to meet the expected level of practice set out in these standards may pose a risk to public health and patient safety.

Australian Commission on Safety and Quality in Health Care

The Australian Commission on Safety and Quality in Health Care (the Commission) leads and coordinates national improvements in health care safety and quality. The Commission works in partnership with patients, carers, clinicians, the Australian, state and territory health systems, the private sector, managers, healthcare organisations, colleges, and professional organisations to achieve a safe, high-quality, and sustainable health system.

The Commission's statutory functions include formulating model national schemes that provide for the accreditation of organisations that provide health care services and relate to healthcare safety and quality matters.¹

The Commission is responsible for the administration of the National Pathology Accreditation Scheme on behalf of the Australian Government Department of Health and Aged Care (the Department). The Department retains responsibility for the regulation and funding of pathology in Australia.

Scope

The *Requirements for Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV)* is a Tier 4 NPAAC document and must be read in conjunction with the Tier 2 document *Requirements for Medical Pathology Services*. The latter is the overarching document broadly outlining standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, Laboratory staff and referrers (both for pathology requests and inter-Laboratory referrals) are safely and satisfactorily met in a timely manner.

Whilst there must be adherence to all the Requirements in the Tier 2 document, reference to specific Standards in that document are provided for assistance under the headings in this document.

The *Requirements for Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV)* sets the minimum Standards for good pathology practice in Australia for testing for HIV and HCV. This document applies to Australian pathology Laboratories testing for HIV and HCV. Additional requirements may exist for Laboratories that test under the conditions of a licence to the Code of Good Manufacturing Practice (GMP) for Human Blood and Tissues issued by the Therapeutic Goods Administration (TGA). These Requirements do not attempt to incorporate requirements for GMP licensure.

The Requirements, in broad principle, apply to the use of all types of HIV and HCV assays including immunoassays used for diagnosis and confirmatory testing (e.g., western blot and nucleic acid amplification test), qualitative nucleic acid testing, quantitative nucleic acid testing, genotyping and resistance testing.

Superseded May 2026

Abbreviations

| Acronym | Full text |
|----------|---|
| ARTG | Australian Register of Therapeutic Goods |
| AS | Australian Standard |
| bDNA | Branch Chain DNA test |
| GMP | Good Manufacturing Practice |
| HCV | Hepatitis C Virus |
| HIV | Human Immunodeficiency Virus |
| ISO | International Organization for Standardization |
| IVD | In Vitro Diagnostic Medical Device |
| MBS | Medicare Benefits Schedule |
| NAAT | Nucleic Acid Amplification Test |
| NATA | National Association of Testing Authorities, Australia |
| NHMRC | National Health and Medical Research Council |
| NPAAC | National Pathology Accreditation Advisory Council |
| NRL | National Serology Reference Laboratory, Australia |
| PCR | Polymerase Chain Reaction |
| PEP | Post Exposure Prophylaxis |
| QMS | Quality Management System |
| RCPA QAP | Royal College of Pathologists of Australasia Quality Assurance Programs |
| TGA | Therapeutic Goods Administration |

Definitions

| Term | Definition |
|------------------------------------|---|
| Confirmatory Testing | <p>means a procedure performed to verify the truth or validity of something thought to be true or valid.</p> <p>Testing performed to assure that a result achieved is the correct result or is the final test performed to achieve the true diagnosis.</p> |
| Diagnostic test/assay | <p>means a measurement or examination of a diagnostic specimen for the purpose of diagnosis, prevention, or assessing treatment of any disease or the assessment of health or impairment of health of an individual patient.</p> <p>NOTE: Laboratory tests are often called "in vitro diagnostic tests."</p> |
| Management test/assay | <p>means a test to guide the selection of treatment or to monitor treatment/s in subjects known to have the disease.</p> |
| Nucleic Acid Amplification Testing | <p>means Nucleic Acid Amplification Tests such as target amplification, polymerase chain reaction (PCR), signal amplification, Branch Chain DNA (bDNA) assay and DNA sequencing are testing methods for the detection and/or characterisation of DNA and RNA.</p> |
| Post exposure prophylaxis | <p>means a treatment that is designed to protect an individual against a disease agent to which the individual has been recently exposed.</p> |
| Standard Testing | <p>means the standard or most common examination performed in the Laboratory for a particular area of testing. This examination will most often be the most frequently performed examination for a particular testing area and will consequently generate the highest volume in that testing area.</p> |
| Reference measurement procedure | <p>means a thoroughly investigated measurement procedure, described in detail in a written document, shown to yield values having a measurement uncertainty commensurate with its intended use, especially in assessing the trueness of other measurement procedures for the same quantity and in characterising reference materials.</p> |
| Reference procedure | <p>means a procedure with established high quality of results, which can be used for assessment of other procedures i.e., a procedure of testing, measurement, or analysis, thoroughly characterised and proven to be under control, intended for:</p> |

| Term | Definition |
|--|---|
| | <p>(a) quality assessment of other procedures for comparable tasks; or</p> <p>(b) characterisation of reference materials including reference objects; or</p> <p>(c) determination of reference values.</p> <p>The uncertainty of the results of a reference procedure must be adequately estimated and appropriate for the intended use.</p> <p>The term "reference procedure" applies to testing, measurement and analysis, i.e., all procedures for determining characteristics of materials, products and processes. These characteristics can be of quantitative or qualitative kind, and they can be defined independently or by the procedure itself.</p> <p>Reference procedures are used to validate other procedures, to characterise reference materials or reference objects as well as for determining reference values of materials characteristics. Another application field is testing, measurement or analysis as a basis for important decisions, e.g., for authoritative evidence.</p> <p>The definition of a "reference procedure" presumes the existence of several procedures for a specified task or of different realisations of the same methodology. Given this, a reference procedure is qualified by the uncertainty of results, proven to be fit for an agreed purpose. Moreover, it has to be accepted as such by the relevant target groups. In the case of quantitative results, the uncertainty comprises trueness and precision combined in the sense of measurement uncertainty [1]. In the case of qualitative results, the uncertainty is an estimate of the probability of erroneous results. Where possible the assessment of uncertainty includes traceability to the International System of Units (SI) or to other recognised reference systems.</p> |
| Reference testing | means a thoroughly investigated test, described in detail in a written document, shown to yield results having an uncertainty commensurate with its intended use, especially in assessing the trueness of other tests for the same analyte and in characterising specimens containing that analyte. |
| Requirements for Medical Pathology Services (RMPS) | means the overarching document broadly outlining standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, Laboratory staff and referrers (both for pathology requests and inter-Laboratory referrals) are safely and satisfactorily met in a timely manner. |
| Screening test/assay | means a test to systematically detect the presence or absence of a drug or a substance |

| Term | Definition |
|----------------------|---|
| | <p>NOTE: Screening is generally a qualitative procedure and results are described as reactive or nonreactive depending on whether they are greater or less than a designated cut-off value. Nonreactive results can be reported as “antibody negative”</p> <ol style="list-style-type: none"> 1. a test to systematically identify individuals at sufficiently high risk of a specific disorder to benefit from further investigation or direct preventive action, among persons who have not sought medical attention on account of symptoms of that disorder 2. a test given to defined populations (e.g., newborns) to detect increased risk of a specific condition 3. a method used to evaluate large populations of individuals for the presence of a disease or analyte 4. testing of asymptomatic subjects checking for disease when there are no symptoms. |
| Supplemental testing | means any examination other than the standard testing procedure(s) performed in a given testing area to increase the accuracy of diagnosis (or status). |
| Window period | means the period (following infection) when tests in use do not identify the infection is present. |

Superseded March 2020

Introduction

Requirements for Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) is the Tier 4 NPAAC document that sets the minimum standards for good pathology practice in Australia for testing for HIV and HCV. Assays for these viruses are registrable under the *Therapeutic Goods Act (1989)* and are therefore subject to pre- and post-market monitoring to assure their ongoing safety and performance. These Requirements recognise that principles and processes involved in using these assays reflect those for other pathology tests, but the considerable public health significance of the results warrants greater attention and may need the provision of additional information to doctors and their patients and the facilitation of surveillance activities. The implementation of these Requirements is necessary to avoid public health risks.

The purpose of this document is to assist medical and scientific Laboratory professionals in finding relevant information and to reduce the need for constant cross referencing of other documents.

These Requirements are intended to serve as minimum standards in the accreditation process and have been developed with reference to current and proposed Australian regulations and other standards from the International Organization for Standardization including:

AS ISO 15189 *Medical laboratories – Requirements for quality and competence*

These Requirements should be read within the national pathology accreditation framework including the current versions of the following NPAAC documents:

Tier 2 document:

- *Requirements for Medical Pathology Services*

All Tier 3 documents:

Tier 4 document:

- *Requirements for the Medical Testing for Human Genetic Variation*

In addition to these Standards, Laboratories must comply with all relevant state and territory legislation (including any reporting requirements).

These Requirements are written as specific principles and are designed to serve without alteration until the next revision date. The following principles cover the entire document:

- Laboratories must be able to demonstrate continued compliance with NPAAC Standards in their assessment history.
- Failure to meet these minimum Standards poses a potential risk to public health and patient safety.

In each section of this document, points deemed important for practice are identified as either 'Standards' or 'Commentaries'.

- A Standard is the minimum requirement for a procedure, method, staffing resource or facility that is required before a Laboratory can attain accreditation – Standards are printed in bold type and prefaced with an ‘S’ (e.g., **S2.2**). The use of the word ‘**must**’ in each Standard within this document indicates a mandatory requirement for pathology practice.
- A Commentary is provided to give clarification to the Standards as well as to provide examples and guidance on interpretation. Commentaries are prefaced with a ‘C’ (e.g., C1.2) and are placed where they add the most value. Commentaries may be normative or informative depending on both the content and the context of whether they are associated with a Standard or not. Note that when comments are expanding on a Standard or referring to other legislation, they assume the same status and importance as the Standards to which they are attached. Where a Commentary contains the word ‘**must**’ then that Commentary is considered to be **normative**.

Please note that Appendix A is **normative** and should be considered to be an integral part of this document.

NPAAC documents can be accessed at the Australian Commission on Safety and Quality in Health Care website.

Comments on this document from users can be directed to:

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1. Laboratory ethics

(Refer to Standard 1 in *Requirements for medical pathology services*)

Superseded March 2026

2. Quality management system

(Refer to Standard 3 in *Requirements for medical pathology services*)

Superseded March 2026

3. Staffing, supervision and consultation

(Refer to Standard 3 and Standard 4 in *Requirements for Medical Pathology Services*)

S3.1 The staff **must** understand the regulatory framework for HIV and HCV test kits and mechanisms for reporting problems with those kits.

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4. Facilities

(Refer to Standard 5 in *Requirements for Medical Pathology Services*)

S4.1 Storage and handling of HIV/HCV specimens **must** minimise the risk of cross-contamination of specimens.

S4.2 The level of security in the Laboratory **must** ensure the confidentiality of HIV/HCV results.

Superseded March 2026

5. Pre-analytical phase

(Refer to Standard 1 and Standard 6A in *Requirements for Medical Pathology Services*)

Tests for HIV and HCV are conducted with the aim of making a diagnosis for the purpose of treatment, patient management or are supported as routine public health measures by a jurisdictional department of health (e.g., sexual health screening). These tests require verbal consent of the individual being tested (or their legal guardian). Obtaining appropriate consent is the responsibility of the health care practitioner requesting the test and does not require specific pre-test discussion with pathology personnel.

S5.1 Where tests are undertaken at the request of a third party (e.g. life insurance or visa applications) rather than for screening of a person at risk, the Laboratory **must** ensure that the individual being tested or a third-party requester has nominated a medical practitioner who will take responsibility for receiving the result in the case of a reactive result.

C5.1(i) Jurisdictions may have individual legal requirements for emergency situations regarding the management of collection of pathology specimens from a patient unable to provide consent. When the request form indicates the reason for referral is a result of a biohazard injury, Laboratories must have a policy in place for automated or cascading (sequential testing based on preceding results) reflex testing associated with biohazard injury that includes the following:

- permission from the source individual and exposed individual (this involves a combined policy with the infection control committee of a recognised hospital/health center [or equivalent] or direct liaison with the referring medical practitioner)
- identification of the appropriate individual/medical practitioner to advise of results.

C5.1(ii) In emergency situations patient consent may not be possible to obtain (e.g. if a person were unconscious). In such circumstances, a medical practitioner acting as an “agent of necessity” should arrange for any test which is clinically relevant.

S5.2 The primary specimen collection manual used by the Laboratory and/or specimen reception **must** include instructions for the use and production of patient identifiers used in the processing of specimens in a coded manner. This document **must** be part of the document control system.

C5.2(i) The request form must contain unique identifiers for the individual being tested, whether this is a combination of the individual’s name, date of birth, a unique code or other unique identifier. It will allow identification of the individual being tested to the medical practitioner originating the request. The Laboratory must ensure that it has sufficient information to link the specimen and request form accurately.

C5.2(ii) To ensure that patients and their specimens are correctly identified, three unique identifiers should be provided where possible.

C5.2(iii) It is the right of any patient to request deidentified testing for HIV status. In the pre-analytical phase, discussion about the need for testing should constitute implicit consent. Importantly, at the time of specimen collection, pathologists

recognise the right of the patient to refuse the collection of the specimen unless the patient is subject to a legal directive requiring the specimen to be collected.

C5.2(iv) 'Code books' that contain the patient's true identity and their 'coded' identity are not the responsibility of medical Laboratories.

C5.2(v) NPAAC acknowledges that the issue of HIV and HCV pre-test discussion with patients is outlined in the relevant policy document and notes that discussion requirements are unable to be addressed by the staff of medical Laboratories.

Superseded March 2026

6. Analytical phase

(Refer to Standard 6B in *Requirements for Medical Pathology Services*)

S6.1 Only methods included or registered on the ARTG **must** be used.

C6.1 An updated list of test kits registered/included on the ARTG is available from the TGA website¹.

S6.2 Confirmation of reactive results **must** be carried out as specified in the National HIV and HCV Testing Policies.

C6.2(i) Procedures must be in place to confirm initially reactive and repeat reactive screening results.

C6.2(ii) Test kits for HIV and HCV are evaluated prior to registration by the TGA and their ongoing performance is assessed during their use. The TGA's review of these kits includes the assignment of a testing status based on a combination of the assay's stated intended purpose and the outcomes of performance testing. This status is either as a standard test or as a reference test for diagnostic purposes.

C6.2(iii) Algorithms for the use of supplemental or follow-up testing methods should be based in knowledge of their antigenic composition along with that of the screening assay. Standard text should be developed to accompany a HCV antibody positive PCR negative result and HCV antibody positive PCR positive result.

C6.2(iv) Acute HIV/HCV infection and window periods:

- Anti-HIV tests are presently available as third and fourth generation tests. Fourth generation tests include the facility to identify both antigen and antibody
- The window period or time between infection and when a test's target analyte(s) can first be detected, varies from test to test. The window period for third and fourth generation anti-HIV tests is three to five weeks after infection. For qualitative NAAT the window period is approximately two weeks.
- For anti-HCV tests the window period is nine to 11 weeks. For combination tests the window period is approximately six weeks and for qualitative NAAT the average is three weeks.
- If there is an indication of a high risk of seroconversion and the first test result is negative or equivocal, a reporting comment should be included suggesting testing should be performed again on a specimen drawn one to two weeks following the first specimen for HIV and after three to 12 weeks for HCV depending on when the exposure occurred relative to the first test. If there is no change, testing should be performed again at 12 weeks after the exposure for HIV and in approximately 24 weeks for HCV where the chance of conversion is 3 SD outside the mean seroconversion time (or the chance of seroconversion is less than 1%).

¹ <http://tga.gov.au/docs/html/artg.htm>

7. Post-analytical phase

(Refer to Standard 6C in *Requirements for Medical Pathology Services*)

- S7.1 There must be no written reports of reactive or equivocal screening results for HIV or HCV issued until supplemental test results are available.
- C7.1(i) When HIV antibody test results are reactive or equivocal in an individual for the first time, the Laboratory should undertake confirmatory testing to confirm or resolve the result. The responsible referring medical practitioner must be contacted by telephone, at an appropriate time, to discuss the results. (Note: in some jurisdictions, medical boards have stipulated communication must be between medical practitioners). There should also be an arrangement between referring and referral Laboratories to ensure the referring medical practitioner can be contacted to discuss HIV results that are reactive or equivocal.
- C7.1(ii) The event of a specimen being confirmed positive should trigger provision to the requesting doctor information about the result and further information.
- S7.2 Final validation of a reactive or equivocal result must be by the specialist pathologist or senior scientist.
- C7.2 Laboratory Directors should have available the means to control access to HIV results through written policies.

Superseded March 2019

8. Health and safety

(Refer to Standard 3 and Standard 4 in *Requirements for Medical Pathology Services*)

Superseded March 2026

9. Audit and assessment

(Refer to Standard 7 in *Requirements for Medical Pathology Services*)

Superseded March 2026

10. Requirements for Laboratories providing reference testing

(Refer to Standard 4 and Standard 7 in *Requirements for Medical Pathology Services*)

S10.1 The supervising pathologists and scientific staff must have extensive experience in the diagnostic testing for HIV and HCV, and must maintain their knowledge and expertise in the relevant areas of specialised testing.

- C10.1(i) The pathologists, pathologist trainees and experienced scientific staff must provide expert advice on test interpretation
- C10.1(ii) Laboratories conducting reference testing may include HIV-1 p24 antigen and/or HIV NAAT as part of confirmatory testing for HIV. NAAT is a useful supplemental test for confirmation of HCV and HIV prior to seroconversion of supplemental serology tests but should be performed on a dedicated primary sample that has not been accessed for other laboratory testing.
- C10.1(iii) Reference tests are used by Laboratories to conduct supplemental and/or confirmatory testing for HIV and HCV. Reference testing is performed in facilities that provide higher level testing for HCV and HIV that is sufficient to provide final determinations on the status of individual patients as being positive, negative, or indeterminate. This is achieved by using test kits designated as reference tests. Laboratories may provide both reference and non-reference level testing services and would be expected to be accredited by the independent accrediting body/bodies (e.g. NATA/RCPA). Where these Laboratories provide such tests for other Laboratories they are known as Reference Laboratories.

Appendix A — (Normative)

Standards that apply to the Analytical phase testing (Section 6) equally apply to supplemental and confirmatory testing.

In line with test-kit manufacturer's directions, the Australian HIV and HCV Testing Policies and the recommendations of many regulatory agencies, a single reactive test for HIV or HCV should not be reported unless the result is confirmed. Suggested approaches for confirmatory testing are given in the Australian HIV and HCV Testing Policies. The principles of testing in the policies, in précis, include:

- Exposure to HIV or HCV is determined by testing for antibodies in serum or plasma
- A specimen not reactive in the screening immunoassay can be generally regarded as negative and requires no further testing in the absence of specific risk behaviour
- A specimen reactive in the screening immunoassay **must** be subject to a minimum of one alternative supplemental immunoassay or one qualitative NAAT to confirm the result
- When using a quantitative or combination NAAT the manufacturer's instructions must clearly state intended use for confirmation testing. Alternatively, a detectable HIV RNA qualitative or quantitative NAAT result using test compliant with C6.2(ii) is confirmatory evidence of HIV infection.
- Compliance to NPAAC standards requiring dedicated samples for molecular testing or use of aliquots taken prior to immunoassay screening is also required.
- Where a HIV RNA NAAT has been utilised as a confirmatory assay and a Not Detected result has been obtained, repeat testing after a four to six week time interval is recommended, using either a HIV Western blot, repeat HIV RNA NAAT or HIV proviral DNA NAAT
- Nucleic acid detection assays (RNA/DNA) may be used to confirm the presence of HIV-1 or HIV-2 infection in an individual with specimens reactive or indeterminate for HIV-1 or HIV-2 antibodies or antigens. Nucleic acid tests may also be used as a testing strategy to aid in the diagnosis of infection in pre-seroconversion with HIV-1 and/or HIV-2 and in in paediatric subjects and pregnant women.
- A specimen reactive in two immunoassays with different antigen specificity can be reported as anti-HCV positive
- Confirmation of an initially reactive immunoassay may also be performed by HCV NAAT or HCV antigen detection.
- A specimen positive on HIV immunoassay that fulfils the criteria for a positive western blot may be considered and reported as anti-HIV positive
- HIV-1/HIV-2 Nucleic acid tests (RNA/DNA) can be used as a supplemental test to confirm HIV-1 infection in individuals who have reactive or inconclusive results with HIV immunoassays.
- A specimen positive on immunoassay that subsequently has HIV RNA detected on a qualitative or approved combination NAAT may be considered and reported as anti-HIV positive, and the HIV-1 infection status should be reported as positive.

In general, assays for supplemental testing algorithms should be selected so that:

- Testing with a second immunoassay **must** be conducted with a test that uses antigen combinations that differ from those used in the first assay

- If second line antibody testing is equivocal or discordant, a qualitative test for presence of specific antigen or nucleic acid may be included
- Many assays now include HIV antibody and HIV antigen testing in procedure. In these tests the antibody and qualitative test presence for a specific antigen are performed simultaneously.

Western and other immuno-blots **must** be:

- Carried out according to Standards cited in Section 6
- Interpreted against validated interpretation criteria
- Conducted with sufficient frequency to maintain proficiency.

All the above assays **must** be conducted frequently, and such proficiency evaluated by Australian assessment bodies i.e., NATA and TGA.

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¹ National Health Reform Act 2011 (Cth)

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