Australian Commission on Safety and Quality in Health Care

NPAAC National Pathology Accreditation Advisory Council

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

Fifth Edition

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Acknowledgement

We acknowledge the Traditional Owners and Custodians of Country throughout Australia. We recognise their continuing connection to land, waters and community and acknowledge their ongoing contribution to the health system and community. We pay our respects to Elders past and present.

Contents

Background

This section provides and overview of the relevant authorities that provide oversight of the pathology sector.

About the Australian Commission on Safety and Quality in Health Care

The Australian Commission on Safety and Quality in Health Care (the Commission) partners with the Australian Government, state and territory governments and the private sector to achieve a safe, high-quality, sustainable health system. It also works closely with patients, carers, clinicians, medical scientists, managers, healthcare organisations and policymakers.

Key functions of the Commission include:

- developing national safety and quality standards
- developing clinical care standards to improve the implementation of evidence-based health care
- coordinating work in specific areas to improve outcomes for patients
- providing information, publications and resources about safety and quality.

The Commission works in four priority areas:

- High-quality care in an evolving environment
- Strong outcome-focused clinical governance
- Empowered patients, carers and communities
- An improvement driven workforce culture.

About the National Pathology Accreditation Scheme

The National Pathology Accreditation Scheme (NPAS) is an accreditation scheme that requires pathology practices to meet relevant standards for their pathology services to be eligible to provide Medicare benefit services. The *Health Insurance (Accredited Pathology Laboratory-Approval) Principles 2017* (the Approval Principles) underpin NPAS. The Approval Principles set the categories of accredited pathology laboratories, specify the standards to be met and the kind of pathology services provided.

The Approval Principles ensure that pathology practices providing Medicare eligible pathology services meet and maintain compliance with the standards. The Approval Principles objectives include:

- supporting the diagnosis and treatment of illness by linking Medicare benefits to pathology services that provide reliable results
- reducing the risk of misdiagnosis from pathology services that provide unreliable results
- maintaining public confidence in pathology services.

The Commission administers the NPAS behalf of the Australian Government Department of Health, Disability and Ageing (the Department). The Department manages the policy and regulatory framework for pathology practice accreditation that are approved to provide Medicare eligible pathology services.

About the 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 practices and the introduction and maintenance of uniform standards of practice in pathology practices throughout Australia. NPAAC is responsible for formulating standards which pathology practices are assessed against.

The Approval Principles give effect to NPAAC endorsed standards by listing the standards and accreditation materials pathology practices seeking approval to provide Medicare eligible pathology services must meet. The pathology practice's conformity with the standards is assessed by the accrediting agencies defined in the Approved Principles.

Introduction

The purpose of this document is to assist medical and scientific laboratory professionals to find relevant information and to ensure pathology practice related to HIV and HCV is safe and of high quality.

Requirements for Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) (Requirements) 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.

Aboriginal and Torres Strait Islander peoples experience disproportionately higher rates of HIV, HCV and other blood-borne viruses, such as HTLV-1, and may face unique cultural, geographic and social circumstances influencing testing, follow-up and access to care. Laboratories must ensure that procedures support culturally safe, respectful and high-quality services for Aboriginal and Torres Strait Islander patients.

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 (ISO) including:

- 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
- 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 **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.

Terminology

Confirmatory Testing

means a procedure performed to verify the truth or validity of something thought to be true or valid.

Testing performed to assure that a result achieved is the correct result or is the final test performed to achieve the true diagnosis.

Diagnostic test/assay

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.

NOTE: Laboratory tests are often called "in vitro diagnostic tests."

Management test/assay

means a test to guide the selection of treatment or to monitor treatment/s in subjects known to have the disease.

Nucleic Acid Amplification Testing

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.

Post exposure prophylaxis

means a treatment that is designed to protect an individual against a disease agent to which the individual has been recently exposed.

Standard Testing

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.

Reference measurement procedure

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.

Reference procedure

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: quality assessment of other procedures for comparable tasks; or

characterisation of reference materials including reference objects; or determination of reference values.

The uncertainty of the results of a reference procedure must be adequately estimated and appropriate for the intended use.

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.

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.

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.

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.

Screening test

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”.

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

a test given to defined populations (e.g., newborns) to detect increased risk of a specific condition

a method used to evaluate large populations of individuals for the presence of a disease or analyte 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.

Abbreviations

Acronym	Full text
cfDNA	Cell-free DNA
FISH	Fluorescence *in situ* hybridisation
ISCN	International System of Cytogenetic Nomenclature
ISH	*In situ* Hybridisation
ISO	International Organization for Standardization
NHMRC	National Health and Medical Research Council
NIPS	Non-invasive prenatal screening
NPAAC	National Pathology Accreditation Advisory Council
PCR	Polymerase Chain Reaction
PPE	Personal Protective Equipment

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Standards

1. Workforce

Standard No.	Standard and commentary
S 1.01	The staff **must** understand the regulatory framework for HIV and HCV test kits and mechanisms for reporting problems with those kits.

2. Facilities

Standard No.	Standard and commentary
S 2.01	Storage and handling of HIV/HCV specimens **must** minimise the risk of cross-contamination of specimens.
S 2.02	The level of security in the Laboratory **must** ensure the confidentiality of HIV/HCV results.

3. Specimen Collection

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.

Standard No.	Standard and commentary
S 3.01	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.
	C 3.01 a 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: i. permission from the source individual and exposed individual (this involves a combined policy with the infection control committee of a recognised hospital/health centre [or equivalent] or direct liaison with the referring medical practitioner) ii. identification of the appropriate individual/medical practitioner to advise of results
	C 3.01 b 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.

Standard No.	Standard and commentary
S 3.02	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.
	C 3.02 a 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 the 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.
	C 3.02 b To ensure that patients and their specimens are correctly identified, three unique identifiers should be provided where possible.
	C 3.02 c 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.
	C 3.02 d 'Code books' that contain the patient's true identity and their 'coded' identity are not the responsibility of medical Laboratories.
	C 3.02 e 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.

4. Specimen testing

Standard No.	Standard and commentary	
S 4.01	Only methods included or registered on the ARTG **must** be used.	
	C 4.01 a	An updated list of test kits registered/included on the ARTG is available from the TGA website.
S 4.02	Confirmation of reactive results **must** be carried out as specified in the National HIV and HCV Testing Policies.	
	C 4.02 a	Procedures must be in place to confirm initially reactive and repeat reactive screening results.
	C 4.02 b	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
	C 4.02 c	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

Standard No.	Standard and commentary
C 4.02 d	Acute HIV/HCV infection and window periods: i. Anti-HIV tests are presently available as third and fourth generation tests. Fourth generation tests include the facility to identify both antigen and antibody ii. 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. iii. 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. iv. 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%).

5. Results

Standard No.	Standard and commentary
S 5.01	There must be no written reports of reactive or equivocal screening results for HIV or HCV issued until supplemental test results are available.
	C 5.01 a 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.
	C 5.01 b The event of a specimen being confirmed positive should trigger provision to the requesting doctor information about the result and further information.
S 5.02	Final validation of a reactive or equivocal result must be by the specialist pathologist or senior scientist.
	C 5.02 a Laboratory directors should have available the means to control access to HIV results through written policies.

6. Requirements for laboratories providing reference testing

Standard No.	Standard and commentary	
S 6.01	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.	
	C 6.01 a	The pathologists, pathologist trainees and experienced scientific staff must provide expert advice on test interpretation.
	C 6.01 b	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.
	C 6.01 c	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 *4. Specimen testing* equally applies 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 NAAT to confirm the result. This assay must be intended for diagnosis of infection and/or confirmation of initial reactive results.
- Detectable HIV RNA using a qualitative or quantitative NAAT compliant with C 4.02 b is confirmatory evidence of HIV infection.
- 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 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.
- 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. To aid the diagnosis of HCV infection, detection of HCV RNA confirms that the virus is actively replicating, and therefore indicative of active infection.

- Detectable HCV RNA using a qualitative or quantitative NAAT compliant with C4.02 b is confirmatory evidence of HCV infection
- For the purposes of HCV testing, a single tube may be used for serology and molecular testing without the requirement of dedicated samples or the use of aliquots taken prior to the screening immunoassay.
- For samples that are reactive in the HCV screening immunoassay, but where HCV RNA is not detected (such as with resolved infection or cure following antiviral therapy), a second immunoassay may be performed to confirm non-active HCV infection.

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.

Glossary

Term	Definition
CE marking	Conformité Européenne (CE): 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 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.
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 include testing 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.
Serology	Testing for the presence, evidence of, or quantity of antibodies specific for infectious or other agents, biochemistry, or substances in blood (serum, 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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