



Specific Accreditation Guidance

Scope of accreditation - service descriptors for human pathology

November 2023



© Copyright National Association of Testing Authorities, Australia 2018

This publication is protected by copyright under the Commonwealth of Australia Copyright Act 1968.

NATA's accredited facilities or facilities seeking accreditation may use or copy this publication or print or email this publication internally for accreditation purposes.

Individuals may store a copy of this publication for private non-commercial use or copy a reasonable portion of this publication in accordance with the fair dealing provisions in Part III Division 3 of the Copyright Act 1968.

You must include this copyright notice in its complete form if you make a copy of this publication.

Apart from these permitted uses, you must not modify, copy, reproduce, republish, frame, upload to a third party, store in a retrieval system, post, transmit or distribute this content in any way or any form or by any means without express written authority from NATA.



This document lists the descriptors for services currently able to be accredited for Human Pathology.

Human Pathology is generally accredited under ISO 15189 (and the relevant NPAAC Requirements). However in exceptional circumstances there are limited Activities and Services available under ISO/IEC 17025. This document describes both options herein.

ISO 15189 (and relevant NPAAC Requirements)

In addition to referencing ISO 15189, Human Pathology and the applicable services listed below, scopes of accreditation will include the material/item/product tested and the determination.

Scopes of accreditation will also include the technique used and the procedure adopted however, this information will not be made public and is only available to the accredited facility.

The list below will be updated as new services are accredited.

Service	
Anatomical Pathology - Cytopathology	Cervical cytological investigation for abnormalities, precancerous or cancerous changes or conditions
	Gynaecological (non-cervical) cytological investigation for abnormalities, precancerous or cancerous changes or conditions
	Immunocytochemical investigation (on non-paraffin embedded cellular preparations)
	Non-gynaecological cytological investigations of nipple discharge or smears from squamous mucosal sites for the detection of cancerous or precancerous changes
	Non-gynaecological cytological investigations of body fluids, exudates, washings and brushings from non-squamous mucosal sites for the detection of malignancy
	Non-gynaecological cytological investigations on samples obtained via fine needle aspiration biopsy
	Testing for the National Cervical Screening Program
Anatomical pathology - Tissue pathology	Analysis of molecular targets in tissue samples other than by in-situ hybridization

Service	
Anatomical pathology - Tissue pathology	Coronial autopsy services
	Examination of biopsy material
	Examination of biopsy material by electron microscopy
	Examination of skeletal remains
	Gene probes using paraffin fluorescence in-situ hybridisation (FISH)
	Gene probes using paraffin in-situ hybridisation techniques (chromogenic/silver)
	Immediate frozen section diagnosis
	Immunohistochemical (immunofluorescence) investigation
	Immunohistochemical investigation
	Mortuary facilities
	Non-coronial autopsy services
	Skeletal muscle enzyme histochemistry
Chemical pathology	Analysis of calculus
	Analysis of drugs for toxicological (non legal) purposes and ingested or absorbed toxic chemicals
	Biochemical genetic services for the diagnosis of metabolic and enzymological disorders
	Biochemical genetics services - Amino acid quantitation
	Biogenic amines
	Detection and/or quantitation of drugs for therapeutic monitoring
	Detection and/or quantitation of tumour markers

Service	
Chemical pathology	Detection and/or quantitation of tumour markers - Testing for the National Bowel Cancer Screening Program
	Detection of faecal occult blood
	Determination of hormones and hormone binding proteins (other than thyroid function tests)
	Diagnosis and management of diabetes mellitus
	Diagnosis of renal tubular acidosis
	Dynamic tests
	Further investigation of cardiac function
	Further investigation of lipid profiles for diagnosis of types III and IV hyperlipidaemia
	Further investigation of renal and/or hepatic function
	Haem related pigments and precursors (excluding porphyria)
	Investigation and determination of hepatic, cardiac, bone, lipid, renal, skeletal muscle and other profiles and metabolic studies
	Investigation for foetal lung maturity and/or foetal abnormalities
	Investigation for folate deficiency
	Investigation of diarrhoea in children
	Investigation of functional intestinal disorders
	Investigation of Helicobacter pylori colonisation or eradication
	Investigation of malabsorption
	Investigation of malabsorption - Quantitation of solid tissue enzymes
	Investigation of maternal markers to detect foetal abnormality

Service	
Chemical pathology	Investigation of maternal markers for pre-eclampsia
	Investigation of porphyria
	Iron studies
	Markers of bone metabolism
	Newborn screening services for the diagnosis of inborn errors of metabolism
	Quantitation of blood gases and other measurements (performed on the same specimen)
	Quantitation of precursor and intermediary metabolites
	Quantitation of vitamin B markers
	Quantitation of vitamins
	Tests for thyroid function
	Trace element analysis
Cytogenetics	Biodosimetry - dicentric analysis
	Detection of defined, unbalanced chromosomal abnormalities by in-situ hybridisation techniques
	Karyotype detection of balanced and/or unbalanced chromosome abnormalities
	Karyotype detection of unbalanced abnormalities
Haematology	Assessment of haemolysis or metabolic enzymes (red cell enzyme assays)
	Bone marrow examination
	Diagnosis of thalassemia
	Examination of blood films by special staining
	Foetal haemoglobin in maternal circulation
	Full blood examination

Service	
Haematology	Haemostasis related analysis (including special coagulation testing and platelet function tests)
	Investigation of haemoglobinopathy, excluding thalassemia
	Investigation of haemolysis
	In-vivo haematological tests
	Limited blood examination
Immunohaematology	Blood group antibody detection
	Blood grouping
	Detection of anti-IgA antibodies in transfusion recipients with low IgA levels
	Detection of markers for transfusion transmitted disease
	Determination of compatibility of blood donor units
	Freeze/thaw of cellular components for transfusion
	Identification and quantitation of blood group antibodies
	Identification of granulocyte antibodies
	Identification of granulocyte antigens
	Identification of platelet antibodies
	Identification of platelet antigens
	Investigation of blood transfusion reactions
	Issue and release of blood and blood product for transfusion
	Storage and distribution of blood and blood components
Immunopathology	Characterisation of leucocyte surface antigens (including immunophenotyping)
	Complete HLA antigen tissue typing

Service	
Immunopathology	Detection of immunoglobulin E specific antibodies (to potential component testing (purified native and/or recombinant allergens))
	Detection of immunoglobulin E specific antibodies (to potential epidermal and animal protein allergens)
	Detection and/or quantitation and/or characterisation of autoantibodies
	Detection of immunoglobulin E specific antibodies (to potential grass pollen allergens)
	Detection of immunoglobulin E specific antibodies (to potential weed pollen allergens)
	Detection of immunoglobulin E specific antibodies (to potential tree pollen allergens)
	Detection of immunoglobulin E specific antibodies (to potential microorganism allergens)
	Detection of immunoglobulin E specific antibodies (to potential epidermal and animal protein allergens)
	Detection of immunoglobulin E specific antibodies (to potential mite allergens)
	Detection of immunoglobulin E specific antibodies (to potential insect allergens)
	Detection of immunoglobulin E specific antibodies (to potential venom allergens)
	Detection of immunoglobulin E specific antibodies (to potential food [fruit and vegetable] allergens)
	Detection of immunoglobulin E specific antibodies (to potential food [seeds, legumes and nuts] allergens)
	Detection of immunoglobulin E specific antibodies (to potential food [spices] allergens)
	Detection of immunoglobulin E specific antibodies (to potential food [fish, shellfish and molluscs] allergens)

Service	
Immunopathology	Detection of immunoglobulin E specific antibodies (to potential food [egg and fowl] allergens)
	Detection of immunoglobulin E specific antibodies (to potential food [meat] allergens)
	Detection of immunoglobulin E specific antibodies (to potential food [milk] allergens)
	Leukocyte antibody testing
	Platelet antibody testing
	Detection of immunoglobulin E specific antibodies (to potential food [additives] allergens)
	Detection of immunoglobulin E specific antibodies (to potential food [miscellaneous] allergens)
	Detection of immunoglobulin E specific antibodies (to potential drug allergens)
	Detection of immunoglobulin E specific antibodies (to potential occupational allergens)
	Detection of immunoglobulin E specific antibodies (to potential miscellaneous allergens)
	Detection of immunoglobulin E specific antibodies (to potential recombinant allergens)
	Investigation and/or assessment of neutrophils (functional tests)
	Investigation of natural killer cell release from target cells
	Killer cell immunoglobulin like receptors (KIR) typing
	Procedures related to the collection, processing, storage and issue of human haemopoietic progenitor cells
	Quantitation of complement proteins
	Quantitative and/or qualitative investigation of proteins

Service	
Immunopathology	Quantitative and/or qualitative investigation of glycoproteins
	Quantitative investigation and/or assessment of neutrophils
	Quantitative investigations of immunoglobulins and immunoglobulins subclasses
	Single HLA antigen typing
	Tests of cell mediated immunity
	Tests of cellular immunity (cytokine assays)
	Tests of cellular immunity (lymphocyte function tests)
Infertility and pregnancy tests including assisted reproductive technology	Diagnosis of pregnancy
	Diagnosis or follow up of threatened abortion and or diagnosis of ectopic pregnancy
	Investigation of sperm
	Infertility (including in-vitro fertilisation) related endocrinology
	Semen cryopreservation
	Semen examination (including for post vasectomy) and/or examination of cervical mucus
	Semen examination (other than post vasectomy)
	Semen examination and/or examination of cervical mucus
	Sperm preparation
Microbiology - Bacteriology	Detection and identification of crystalline material
	Detection of pathogenic bacteria
	Detection of pathogenic bacteria for epidemiological infection control surveillance

Service	
Microbiology - Bacteriology	Public health investigation and/or monitoring of outbreaks of infection
Microbiology - Environmental investigations and/or infection control	
Microbiology - Molecular biology	Detection, characterisation and/or quantitation of microbial nucleic acids (bacteria)
	Detection, characterisation and/or quantitation of microbial nucleic acids (viruses)
	Detection, characterisation and/or quantitation of microbial nucleic acids (protozoan parasites)
	Detection, characterisation and/or quantitation of microbial nucleic acids (helminth parasites)
	Detection, characterisation and/or quantitation of microbial nucleic acids (ectoparasites)
	Detection, characterisation and/or quantitation of microbial nucleic acids (other parasites)
	Detection, characterisation and/or quantitation of microbial nucleic acids (fungi)
	Detection, characterisation and/or quantitation of microbial nucleic acids (mycobacteria)
	Surveillance programme for the detection of microbial nucleic acids (viruses) in accordance with Commonwealth and/or State Health protocols
	Microbial DNA extraction
	Microbial DNA sequencing
	Microbial genotyping
	Microbial genotyping by whole exome sequencing studies
	Microbial genotyping by whole genome sequencing studies
	Public health investigation and/or monitoring
	Quantitation of microbial nucleic acids

Service	
Microbiology - Mycobacteriology	Detection and identification of mycobacteria
	Public health investigation and/or monitoring
	Tests for antigen lymphocyte stimulation
	Tests for cell mediated immunity
Microbiology - Mycology	Detection of dermatophytes and other fungi causing cutaneous disease
	Detection, isolation and/or identification of yeasts and/or fungal elements
	Public health investigation and/or monitoring
Microbiology - Parasitology	Detection of ova, cysts and parasites
	Public health investigation and/or monitoring
Microbiology - Serology of infection	Microbial antibody and/or antigen detection and/or quantitation
	Microbial typing
	Public health investigation and/or monitoring
Microbiology - Virology	Detection of pathogenic viruses
	Public health investigation and/or monitoring
Molecular genetics	Assay for defined mutation or polymorphism (including Pharmacogenetic testing) - Targeted genes
	Assay for defined mutation or polymorphism (including Pharmacogenetic testing) - Targeted panels for inherited (germline) DNA/RNA changes
	Assay for defined mutation or polymorphism (including Pharmacogenetic testing) - Whole exome sequencing studies for inherited (germline) DNA/RNA changes
	Assay for defined mutation or polymorphism (including Pharmacogenetic testing) - Whole genome sequencing studies for inherited (germline) DNA/RNA changes

Service	
Molecular genetics	Bioinformatic analysis
	Molecular genetics - Detection and characterisation of cell free RNA (cfRNA) / cell free DNA (cfDNA) in cancer screening and/or cancer genetic testing
	DNA extraction
	DNA fragment size analysis
	DNA sequencing
	Estimation of risk of inheritance of an unknown mutation (Bayesian and linkage calculations)
	Genetic testing for chimerism and mosaic gene variants (cancer and somatic mosaicism) - Targeted genes
	Genetic testing for chimerism and mosaic gene variants (cancer and somatic mosaicism) - Targeted panels for non-inherited (somatic) DNA/RNA changes
	Genetic testing for chimerism and mosaic gene variants (cancer and somatic mosaicism) - Whole exome sequencing for non-inherited (somatic) DNA/RNA changes
	Genetic testing for chimerism and mosaic gene variants (cancer and somatic mosaicism) - Whole genome sequencing for non-inherited (somatic) DNA/RNA changes
	Heterozygous loci determinations
	Investigation of constitutional genetic variants - Diagnostic testing - Targeted genes
	Investigation of constitutional genetic variants - Diagnostic testing - Targeted panels for inherited (germline) DNA/RNA changes
	Investigation of constitutional genetic variants - Diagnostic testing - Whole exome sequencing studies for inherited (germline) DNA/RNA changes

Service	
Molecular genetics	Investigation of constitutional genetic variants - Diagnostic testing - Whole genome sequencing studies for inherited (germline) DNA/RNA changes
	Investigation of constitutional genetic variants - Carrier testing - Targeted genes
	Investigation of constitutional genetic variants - Carrier testing - Targeted panels for inherited (germline) DNA/RNA changes
	Investigation of constitutional genetic variants - Carrier testing - Whole exome sequencing studies for inherited (germline) DNA/RNA changes
	Investigation of constitutional genetic variants - Carrier testing - Whole genome sequencing studies for inherited (germline) DNA/RNA changes
	Mitochondrial investigation for heteroplasmy of constitutional genetic variants - Carrier testing
	Mitochondrial investigation for heteroplasmy of constitutional genetic variants - Diagnostic testing
	Non-invasive prenatal (genetic) screening
	Predictive genetic testing - Targeted genes
	Predictive genetic testing - Targeted panels for inherited (germline) DNA/RNA changes
	Predictive genetic testing - Whole exome sequencing studies for inherited (germline) DNA/RNA changes
	Predictive genetic testing - Whole genome sequencing studies for inherited (germline) DNA/RNA changes
	Predictive mitochondrial genetic testing
	Pre-implantation genetic testing
	Prenatal genetic testing (excluding non-invasive prenatal (genetic) screening)
	RNA extraction

Service	
Molecular genetics	RNA sequencing
	Screening for an unknown mutation - Targeted panels for non-inherited (somatic) DNA/RNA changes
	Screening for an unknown mutation - Microarray analysis for inherited (germline) DNA/RNA changes
	Screening for an unknown mutation - Targeted genes
	Screening for an unknown mutation - Targeted panels for inherited (germline) DNA/RNA changes
	Screening for an unknown mutation - Whole exome sequencing studies for inherited (germline) DNA/RNA changes
	Screening for an unknown mutation - Whole exome sequencing for non-inherited (somatic) DNA/RNA changes
	Screening for an unknown mutation - Whole genome sequencing studies for inherited (germline) DNA/RNA changes
	Screening for an unknown mutation - Whole genome sequencing for non-inherited (somatic) DNA/RNA changes
Non-clinical biomarkers	

ISO/IEC 17025

In addition to referencing ISO/IEC 17025, Human Pathology and the applicable services listed below, scopes of accreditation will include the material/item/product tested and the determination.

The list below will be updated as new services are accredited.

Service	
Chemical Pathology ¹	Routine non-diagnostic analysis in support of clinical trials

Service	
Haematology ¹	Routine non-diagnostic analysis in support of clinical trials
Microbiology ¹	Routine non-diagnostic analysis in support of clinical trials
Microbiology - Bacteriology ²	Detection of pathogenic bacteria
Microbiology - Molecular biology ²	Detection, characterisation and/or quantitation of microbial nucleic acids (bacteria)
	Detection, characterisation and/or quantitation of microbial nucleic acids (viruses)
Microbiology - Serology of infection ²	Microbial antibody and/or antigen detection and/or quantitation
Microbiology - Virology ²	Detection of pathogenic viruses

Human pathology accreditation under ISO/IEC 17025 is only available in exceptional circumstances.

1. Only available for facilities performing routine pathology testing in the context of clinical trials support. No diagnostic results are made available.
2. Only available for non-medical testing facilities (i.e. facilities predominantly testing animal products) as considered by NATA on a case-by-case basis and as aligned with the TGA IVD Regulations

Amendment Table

The table below provides a summary of changes made to the document with this issue.

Amendment
Updated to clarify scope information for ISO/IEC 17025