

## Policy

Subject: **Tests that may be performed in Category M and S Laboratories**  
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In Australia The Royal College of Pathologists of Australasia (RCPA) is responsible through the Board of Education and Assessment for approval of scope of practice for Medical Practitioners supervising Category M and Category S laboratories under the NPAAC [Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories \(Fifth Edition\)](http://www.health.gov.au/internet/main/Publishing.nsf/Content/health-npaac-docs-supervision.htm) (<http://www.health.gov.au/internet/main/Publishing.nsf/Content/health-npaac-docs-supervision.htm>). The determination re the scope of practice will be provided to NATA as part of the NATA/RCPA obligations.

This Policy sets out the type of tests that are suitable to be performed by these laboratories:

**Category M (medical)** being a laboratory performing a limited range of pathology services under the supervision of a Medical Practitioner being services only for the patients of the medical practice operated by, or that employs or engages the Medical Practitioner, where the medical practice is co-located with the laboratory.

**Category S (specialised)** being a laboratory which performs a limited range of pathology tests, for a target patient population, under the supervision of a Medical Practitioner with specialist qualifications and competency in the field of those tests and who is not a Pathologist. The tests performed must be restricted to the field of testing directly related to the qualifications and competencies and current Scope of Practice of the Medical Practitioner. If the laboratory proposes to undertake a wider scope of pathology testing the operator must apply for accreditation as a Category GX or GY laboratory.

Pathology is an increasingly specialised field of medicine with many tests that should not be performed without the supervision of a formally trained and accredited Pathologist. Pathologists are trained in conducting complex analyses and interpretations using multiple technologies across the disciplines of anatomical pathology, haematology, genetics, microbiology, forensic pathology, immunopathology and chemical pathology. Care should be taken by medical practitioners operating Category M and S laboratories that they do not practise beyond their credentials and scope of practice. A list of examples of tests that may and a list of those tests that should not be performed without pathologist supervision is given below. The tests listed are indicative but not exhaustive. The RCPA will not approve scope of practice for Medical Practitioners who wish to perform testing outside their training and recency of practice.

### Example of tests that may be performed without pathologist supervision

**1. M Laboratory:**

Validated Point-of-Care assays, simple card, cartridge or reagent strip tests (eg hCG) but not those that require high complexity interpretation eg. HIV

**2. Artificial Reproductive Technology/ In-vitro Fertilisation Category S Laboratory:**

Generally, tests that fall into the scope of practice for interpretation by an Obstetrician/Gynaecologist: ie P8 tests in Category 6 of the Medicare Benefits Schedule (semen analysis, Huhner test, hCG); Luteinising Hormone; Progesterone; Oestradiol; Prolactin; Follicle Stimulating Hormone; Testosterone.

**3. Blood Gas Category M Laboratory:**

Generally, tests that fall into the scope of practice for interpretation by an Intensive Care Specialist or Anaesthetist such as arterial and venous blood gases; lactate; glucose, electrolytes, INR and thromboelastography.

**4. Other Category S Laboratory (eg Endocrine)**

Only tests that fall into the interpretative range of the supervising specialist Medical Practitioner

**Examples of tests that should not be performed without pathologist supervision**

**1. Chemical Pathology**

Vitamin D  
Tumour Markers  
Fe Studies  
B12 / Folate  
Thyroid Hormones

**2. Haematology**

Haematology Morphology  
Complex coagulation (other than INR)  
Flow Cytometry  
Transfusion  
Blood Group & Antibodies

**3. Microbiology**

Viral Serology (including HIV, Hep B & C)  
PCR Testing  
Microbiology Cultures

**4. Immunopathology**

Auto Antibody Testing  
Investigation of Immunodeficiency

**5. Anatomical Pathology**

All Histology and Cytology  
Immunochemistry  
Electron microscopy

**6. Genetics**

All Genetic tests