



# Product Catalogue

**RCPAQAP**

The Royal College of Pathologists of Australasia  
Quality Assurance Programs



**Labcare**



The Royal College of Pathologists of Australasia Quality Assurance Programs are world leaders in the provision of external quality assurance (EQA) for pathology laboratories.

We offer a comprehensive range of EQA for all disciplines of pathology. Our programs are offered in Australia and internationally in over 100 countries. RCPAQAP is committed to providing an efficient and customer-focused service to participants.

Participants are provided with regular and frequent challenges, peer reviewed assessment and educational activities to monitor the quality of their laboratory services ensuring they meet accreditation requirements. Our strength lies in the expertise and support provided by an extensive advisory network consisting of pathologists and scientific staff from Australia and internationally.

## Company accreditation

### ISO/IEC 17043:2010

The RCPAQAP is accredited for compliance to ISO/IEC 17043 *Conformity assessment – General requirements for proficiency testing*.



Accreditation Number: 14863

### ISO 9001:2015

The Company, including all disciplines and support services are certified to ISO 9001:2015 *Quality management systems*



FS 605318

### ISO 14001:2015

The Company, including all disciplines and support services are certified to ISO 14001:2015 *Environmental management systems*



EMS 685459

### ISO 45001:2018

The Company, including all disciplines and support services are certified to ISO 45001:2018 *Occupational Health and Safety management systems*



OHS 700066

# Anatomical Pathology

The RCPAQAP Anatomical Pathology discipline offers programs in the areas of diagnostic and technical proficiency of histopathology laboratories.

Diagnostic survey cases are selected to demonstrate either classical histological features of a disease process, common disease processes observed in routine pathology laboratories or critical disease processes of educational value to participants.

Technical survey cases are selected on similar criteria of classical, common or critical features to be demonstrated by routine methods in the laboratory.

The diagnostic proficiency programs offer enrolments for laboratories, individual pathologists and trainees. Laboratories requiring participation in a technical external proficiency testing program for Australian accreditation may enrol in the technical and immunohistochemistry programs. Each program has an Advisory Committee which is overseen by a convening pathologist.

RCPA trainees wishing to donate material to fulfill portfolio requirements are advised to contact [anatomical.pathology@rcpaqap.com.au](mailto:anatomical.pathology@rcpaqap.com.au)

## **ALK Translocation for non-small cell lung carcinoma (NSCLC): FISH** [Catalogue Number: 13010102]

Proficiency testing for laboratories staining ALK immunohistochemistry. Proficiency testing for laboratories interpreting ALK translocation.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 1

**Sample Type:** Unstained formalin fixed paraffin sections comprising of composite tissue block to be stained/processed/interpreted for ALK.

**Schedule:** May

**Measurand/Test:** ALK FISH

**Storage and Handling:** Upon receipt, store samples at room temperature

## **ALK Translocation for non-small cell lung carcinoma (NSCLC): IHC** [Catalogue Number: 13020102]

Proficiency testing for laboratories staining ALK immunohistochemistry. Proficiency testing for laboratories interpreting ALK translocation.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 1

**Sample Type:** Unstained formalin fixed paraffin sections comprising of composite tissue stained/processed/interpreted for ALK.

**Schedule:** May

**Measurand/Test:** ALK IHC

**Storage and Handling:** Upon receipt, store samples at room temperature

**ALK Translocation for non-small cell lung carcinoma (NSCLC): Molecular** [Catalogue Number: 13030102]

Proficiency testing for laboratories staining ALK immunohistochemistry. Proficiency testing for laboratories interpreting ALK translocation.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 1

**Sample Type:** Unstained formalin fixed paraffin sections comprising of composite tissue block to be stained/processed/interpreted for ALK.

**Schedule:** May

**Measurand/Test:** ALK Molecular

**Storage and Handling:** Upon receipt, store samples at room temperature

**Breast Diagnostic** [Catalogue Number: 13040102]

Proficiency testing for laboratories and pathologists reporting breast pathology. Educational resource for other laboratories/trainees.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 10

**Sample Type:** Stained sections are provided as virtual microscope slide images in the myQAP portal. USBs can be purchased separately.

**Schedule:** March

**Measurand/Test:** Breast Histopathology

**Dermatopathology Diagnostic** [Catalogue Number: 13050102]

Proficiency testing for laboratories and pathologists reporting dermatopathology. Educational resource for other laboratories/trainees.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 10

**Sample Type:** Stained sections are provided as virtual microscope slide images in the myQAP portal. USBs can be purchased separately.

**Schedule:** March

**Measurand/Test:** Skin Histopathology

**Electron Microscopy Diagnostic** [Catalogue Number: 13060102]

Proficiency testing for laboratories and pathologists reporting transmission electron microscopy. Educational resource for other laboratories/trainees.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 3 (educational case may be included)

**Schedule:** September

**Measurand/Test:** Transmission Electron Microscopy

**Electron Microscopy Technical** [Catalogue Number: 13070102]

Proficiency testing for laboratories processing transmission electron microscopy specimens.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 2

**Sample Type:** Submission of Electron Micrographs prepared by the laboratory. Laboratory practice questionnaire.

**Schedule:** September

**Measurand/Test:** Transmission Electron Microscopy techniques

**Fluorescence in-situ Hybridisation (FISH) Diagnostic** [Catalogue Number: 13310102]

Proficiency testing for laboratories reporting solid tumour fluorescence in-situ hybridisation. A different probe is tested each year (CCND1/CCND2 in 2025).

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 1

**Sample Type:** Unstained formalin fixed paraffin sections to be stained and interpreted for 1p/19q FISH probe.

**Schedule:** April

**Measurand/Test:** CCND1/CCND2

**Forensic Diagnostic** [Catalogue Number: 13080102]

Proficiency testing for laboratories and pathologists reporting forensic pathology. Educational resource for other laboratories/trainees.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 10

**Sample Type:** Stained sections are provided as virtual microscope slide images in the myQAP portal. USBs can be purchased separately.

**Schedule:** March

**Measurand/Test:** Forensic Pathology

**Gastrointestinal Diagnostic** [Catalogue Number: 13090102]

Proficiency testing for laboratories and pathologists reporting gastrointestinal pathology. Educational resource for other laboratories/trainees.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 10

**Sample Type:** Stained sections are provided as virtual microscope slide images in the myQAP portal. USBs can be purchased separately.

**Schedule:** July

**Measurand/Test:** Gastrointestinal Histopathology

**General Diagnostic** [Catalogue Number: 13100102]

Proficiency testing for laboratories and pathologists reporting routine Anatomical Pathology. Educational resource for trainees.

**Frequency (No of surveys/year):** 3

**Cases/samples per survey:** 10

**Sample Type:** Stained sections are provided as virtual microscope slide images in the myQAP portal. USBs can be purchased separately.

**Schedule:** February, May, September

**Measurand/Test:** General Histopathology

**Gynaecology Diagnostic** [Catalogue Number: 13110102]

Proficiency testing for laboratories and pathologists reporting gynaecological pathology. Educational resource for other laboratories/trainees.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 10

**Sample Type:** Stained sections are provided as virtual microscope slide images in the myQAP portal. USBs can be purchased separately.

**Schedule:** April

**Measurand/Test:** Gynaecological Pathology

**Head and Neck Diagnostic** [Catalogue Number: 13300102]

Proficiency testing for laboratories and pathologists reporting head and neck pathology. Educational resource for other laboratories/trainees.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 10

**Sample Type:** Stained sections are provided as virtual microscope slide images in the myQAP portal. USBs can be purchased separately.

**Schedule:** July

**Measurand/Test:** Head and Neck Histopathology

**HER2 Brightfield ISH (BRISH) Breast Diagnostic** [Catalogue Number: 13320101]

Proficiency testing for individual pathologists involved in the diagnostic interpretation of results for HER2 BRISH testing in breast cases.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 6

**Sample Type:** Stained sections of H&E, HER2 IHC and HER2 BRISH slides are provided as virtual microscope slide images in the myQAP portal. USBs can be purchased separately.

**Schedule:** March

**Measurand/Test:** Dual probe HER2 BRISH for breast cancer interpretation.

**HER2 Brightfield ISH (BRISH) Breast Technical** [Catalogue Number: 13250102]

Proficiency testing for laboratories performing HER2 brightfield in situ hybridisation in breast cases.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 1

**Sample Type:** Unstained formalin fixed paraffin sections comprising of composite tissue block.

**Schedule:** May

**Measurand/Test:** HER2 BRISH Breast

**Storage and Handling:** Upon receipt, store samples at room temperature

**HER2 Brightfield ISH (BRISH) Gastric Diagnostic** [Catalogue Number: 13130101]

Proficiency testing for individual pathologists who are involved in the diagnostic interpretation of results for HER2 BRISH testing in gastric cases.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 6

**Sample Type:** Stained sections of H&E, HER2 IHC and HER2 BRISH slides are provided as virtual microscope slide images in the myQAP portal. USBs can be purchased separately.

**Schedule:** August



**HER2 Brightfield ISH (BRISH) Gastric Technical** [Catalogue Number: 13260102]

Proficiency testing for laboratories performing HER2 brightfield in situ hybridisation in gastric cases.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 1

**Sample Type:** Unstained formalin fixed paraffin sections comprising of composite tissue block.

**Schedule:** May

**Measurand/Test:** HER2 BRISH Gastric

**Storage and Handling:** Upon receipt, store samples at room temperature

**Immunohistochemistry Breast Markers** [Catalogue Number: 13150102]

Proficiency testing for laboratories processing immunohistochemistry.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 5

**Sample Type:** Unstained formalin fixed paraffin sections comprising of 5 breast cancer cases in a composite tissue block to be stained for ER, PR, HER2 and 2 additional antibodies.

**Schedule:** August

**Measurand/Test:** ER, PR, HER2 IHC, SMMS-1, CK5/6

**Storage and Handling:** Upon receipt, store samples at room temperature

**Additional Comments:** PD-L1 for TNBC interpretation proficiency testing is offered free of charge to RCPAQAP participants through IQNPath. The anatomical pathology team can be contacted for further details.

**Immunohistochemistry Breast Markers Audit** [Catalogue Number: 13160102]

Quality assurance activity for laboratories reporting immunohistochemistry (IHC) and in-situ hybridization (ISH) breast markers through an audit of clinical results. There is no technical component to this survey, but it comprises online submission of the hormone receptor and HER2 status for each case of early invasive primary (not stage 4 disease) breast carcinoma. 50-100 samples are required for assessment. Laboratories providing less than 50 samples will not qualify for assessment.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 100

**Sample Type:** A maximum of 100 cases from the preceding year are submitted.

**Schedule:** February

**Measurand/Test:** Breast marker audit of cases reported by participant



## Immunohistochemistry General [Catalogue Number: 13170102]

Proficiency testing for laboratories processing immunohistochemistry.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 3

**Sample Type:** Unstained formalin fixed paraffin sections comprising of composite tissue block to be stained for 3 general markers

**Schedule:** February

**Measurand/Test:** PRAME (MelanA); Claudin4 (BAP1); PIN4 (P63)

**Storage and Handling:** Upon receipt, store samples at room temperature

## Immunohistochemistry HER2-low scoring in Breast Cancer [Catalogue Number: 13550101]

Proficiency testing for individual pathologists who are scoring HER2 IHC in breast cancer

**What's new:** New for 2025

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 6

**Sample Type:** Stained sections are provided as virtual microscope slide images in the myQAP portal. USBs cannot be purchased for this program.

**Schedule:** July

**Measurand/Test:** HER2 IHC readout

## Immunohistochemistry Lymphoma Markers [Catalogue Number: 13180102]

Proficiency testing for laboratories processing immunohistochemistry. A variety of lymphoma markers are assessed.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 3

**Sample Type:** Unstained formalin fixed paraffin sections comprising of composite tissue block to be stained for 3 lymphoma markers.

**Schedule:** February

**Measurand/Test:** CD3 (Bcl2); C-Myc (CD45); Ki-67 (CD20)

**Storage and Handling:** Upon receipt, store samples at room temperature

## Immunohistochemistry Mismatch Repair (MMR) protein [Catalogue Number: 13430102]

Proficiency testing for laboratories processing immunohistochemistry. Two mismatch repair (MMR) proteins are assessed annually. Colorectal cases are assessed annually and non-colorectal cases are rotated annually.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 4

**Sample Type:** Unstained formalin fixed paraffin sections comprising of composite tissue block to be stained for 2 MMR protein markers.

**Schedule:** May

**Measurand/Test:** MSH2 and MSH6 on colorectal carcinoma and a second tissue type

**Storage and Handling:** Upon receipt, store samples at room temperature

**Immunohistochemistry PD-L1 for HNSCC** [Catalogue Number: 13460102]

Proficiency testing for laboratories performing PD-L1 testing. This is a technical proficiency testing program only.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** Varies per survey

**Sample Type:** Unstained formalin fixed paraffin sections comprising of composite tissue blocks to be stained for PD-L1

**Schedule:** February, August

**Measurand/Test:** PD-L1 for HNSCC

**Storage and Handling:** Upon receipt, store samples at room temperature

**Immunohistochemistry PD-L1 for NSCLC** [Catalogue Number: 13440102]

Proficiency testing for laboratories performing PD-L1 testing. This is a technical proficiency testing program only. For pathologist scoring proficiency testing, please see the new program "Immunohistochemistry PD-L1 scoring in NSCLC (TPS)"

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** Varies per survey

**Sample Type:** Unstained formalin fixed paraffin sections comprising of composite tissue blocks to be stained for PD-L1

**Schedule:** February, August

**Measurand/Test:** PD-L1 for NSCLC

**Storage and Handling:** Upon receipt, store samples at room temperature

**Immunohistochemistry PD-L1 for TNBC** [Catalogue Number: 13450102]

Proficiency testing for laboratories performing PD-L1 testing. This is a technical proficiency testing program only.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** Varies per survey

**Sample Type:** Unstained formalin fixed paraffin sections comprising of composite tissue blocks to be stained for PD-L1

**Schedule:** February, August

**Measurand/Test:** PD-L1 for TNBC

**Storage and Handling:** Upon receipt, store samples at room temperature

**Immunohistochemistry PD-L1 scoring in NSCLC (TPS)** [Catalogue Number: 13560101]

Proficiency testing for individual pathologists who are applying a Tumour Proportion Score (TPS) to PD-L1 IHC in NSCLC

For laboratory technical proficiency testing, please refer to program "Immunohistochemistry PD-L1 for NSCLC"

**What's new:** New for 2025

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 6

**Sample Type:** Stained sections are provided as virtual microscope slide images in the myQAP portal. USBs cannot be purchased for this program.

**Schedule:** August

**Measurand/Test:** PD-L1 in NSCLC TPS readout

**Kappa Light Chain in situ hybridisation** [Catalogue Number: 13410102]

Proficiency testing for laboratories performing kappa light chain in situ hybridisation.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 1

**Sample Type:** Unstained formalin fixed paraffin sections comprising of composite tissue block.

**Schedule:** May

**Measurand/Test:** Kappa ISH

**Mohs Diagnostic** [Catalogue Number: 13190102]

Proficiency testing for dermatopathology Mohs Fellows and trainees.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 10

**Sample Type:** Stained sections are provided as virtual microscope slide images in the myQAP portal.

**Schedule:** March

**Measurand/Test:** Mohs surgery histopathology

**Neuropathology Diagnostic** [Catalogue Number: 13200102]

Proficiency testing for laboratories and pathologists reporting neuropathology. Educational resource for other laboratories and trainees.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 10

**Sample Type:** Stained sections are provided as virtual microscope slide images in the myQAP portal. USBs can be purchased separately.

**Schedule:** April

**Measurand/Test:** Neuropathology

**Neuropathology Immunohistochemistry and Technical** [Catalogue Number: 13140102]

Proficiency testing for laboratories processing neuropathology specimens.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 2

**Sample Type:** This is a combined module where unstained formalin fixed paraffin sections are provided for immunohistochemical and special staining.

**Schedule:** May

**Measurand/Test:** ATRX and Myelin stain

**Storage and Handling:** Upon receipt, store samples at room temperature

**Oral and Maxillofacial Diagnostic** [Catalogue Number: 13210102]

Proficiency testing for laboratories and pathologists reporting oral and maxillofacial histopathology. Educational resource for other laboratories and trainees.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 10

**Sample Type:** Stained sections are provided as virtual microscope slide images in the myQAP portal. USBs can be purchased separately.

**Schedule:** March

**Measurand/Test:** Oral and Maxillofacial Histopathology

**Paediatric Diagnostic** [Catalogue Number: 13220102]

Proficiency testing for laboratories and pathologists reporting paediatric and perinatal pathology. Educational resource for other laboratories and trainees.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 12

**Sample Type:** Stained sections are provided as virtual microscope slide images in the myQAP portal. USBs can be purchased separately.

**Schedule:** July

**Measurand/Test:** Paediatric Histopathology, Perinatal Histopathology

**Renal Medical Diagnostic** [Catalogue Number: 13470102]

Proficiency testing for laboratories and pathologists reporting medical renal pathology. Educational resource for other laboratories/trainees.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 10

**Sample Type:** Stained sections are provided as virtual microscope slide images in the myQAP portal. USBs can be purchased separately.

**Schedule:** July

**Measurand/Test:** Medical Renal Histopathology

**ROS1 Translocation for non-small cell lung carcinoma (NSCLC): FISH** [Catalogue Number: 13360102]

Proficiency testing for laboratories staining ROS1 immunohistochemistry. Proficiency testing for laboratories interpreting ROS1 translocation.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 1

**Sample Type:** Unstained formalin fixed paraffin sections comprising of composite tissue block to be stained/processed/interpreted for ROS1.

**Schedule:** May

**Measurand/Test:** ROS1 FISH

**Storage and Handling:** Upon receipt, store samples at room temperature

**Additional Comments:** In conjunction with the RCPAQAP Molecular Genetics Discipline, this program consists of the following selectable modules: Immunohistochemistry ROS1 staining for technical and interpretation proficiency; ROS1 FISH interpretation proficiency and ROS1 Molecular techniques interpretation proficiency.

**ROS1 Translocation for non-small cell lung carcinoma (NSCLC): IHC** [Catalogue Number: 13370102]

Proficiency testing for laboratories staining ROS1 immunohistochemistry. Proficiency testing for laboratories interpreting ROS1 translocation.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 1

**Sample Type:** Unstained formalin fixed paraffin sections comprising of composite tissue block to be stained/processed/interpreted for ROS1.

**Schedule:** May

**Storage and Handling:** Upon receipt, store samples at room temperature

**Additional Comments:** In conjunction with the RCPAQAP Molecular Genetics Discipline, this program consists of the following selectable modules: Immunohistochemistry ROS1 staining for technical and interpretation proficiency; ROS1 FISH interpretation proficiency and ROS1 Molecular techniques interpretation proficiency.

**ROS1 Translocation for non-small cell lung carcinoma (NSCLC): Molecular** [Catalogue Number: 13380102]

Proficiency testing for laboratories staining ROS1 immunohistochemistry. Proficiency testing for laboratories interpreting ROS1 translocation.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 1

**Sample Type:** Unstained formalin fixed paraffin sections comprising of composite tissue block to be stained/processed/interpreted for ROS1.

**Schedule:** May

**Measurand/Test:** ROS1 Molecular

**Storage and Handling:** Upon receipt, store samples at room temperature

**Additional Comments:** In conjunction with the RCPAQAP Molecular Genetics Discipline, this program consists of the following selectable modules: Immunohistochemistry ROS1 staining for technical and interpretation proficiency; ROS1 FISH interpretation proficiency and ROS1 Molecular techniques interpretation proficiency.

**Sarcoma Gene Testing - FISH** [Catalogue Number: 13480102]

Proficiency testing for laboratories performing and reporting sarcoma gene testing from FFPE tissue. Two genes are assessed annually.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 2

**Sample Type:** Unstained formalin fixed paraffin sections comprising of composite tissue blocks to be processed and reported using the laboratory's preferred method.

**Schedule:** March

**Measurand/Test:** ALK and CIC-DUX4

**Storage and Handling:** Upon receipt, store samples at room temperature

**Sarcoma Gene Testing - IHC** [Catalogue Number: 13500102]

Proficiency testing for laboratories performing and reporting sarcoma gene testing from FFPE tissue. Two genes are assessed annually.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 2

**Sample Type:** Unstained formalin fixed paraffin sections comprising of composite tissue reported using the laboratory's preferred method.

**Schedule:** March

**Measurand/Test:** ALK and CIC-DUX4

**Storage and Handling:** Upon receipt, store samples at room temperature

**Sarcoma Gene Testing - Molecular** [Catalogue Number: 13510102]

Proficiency testing for laboratories performing and reporting sarcoma gene testing from FFPE tissue. Two genes are assessed annually.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 2

**Sample Type:** Unstained formalin fixed paraffin sections comprising of composite tissue blocks to be processed and reported using the laboratory's preferred method.

**Schedule:** March

**Measurand/Test:** ALK and CIC-DUX4

**Storage and Handling:** Upon receipt, store samples at room temperature

**Technical Frozen Section** [Catalogue Number: 13230102]

Proficiency testing for histopathology laboratories performing the frozen section procedure.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 1

**Sample Type:** Participants submit a stained and coverslipped section on a glass slide for assessment of block/section preparation and staining.

**Schedule:** February

**Measurand/Test:** Frozen section

**Technical General** [Catalogue Number: 13240102]

Proficiency testing for laboratories performing general histopathology processes.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 1-2

**Sample Type:** Unstained formalin fixed paraffin sections are provided for most exercises. Unstained tissue sections are submitted by participants for the Processing and Sectioning exercise

**Schedule:** February, August



**Measurand/Test:** H&E, Processing and Sectioning, Iron special stain, Mucicarmine  
Artificial Intelligence laboratory practice questionnaire.

**Storage and Handling:** Upon receipt, store samples at room temperature

**Urology Diagnostic** [Catalogue Number: 13280102]

Proficiency testing for laboratories and pathologists reporting urological pathology. Educational resource for other laboratories and trainees.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 10

**Sample Type:** Stained sections are provided as virtual microscope slide images in the myQAP portal. USBs can be purchased separately.

**Schedule:** August

**Measurand/Test:** Urological Histopathology

## Biosecurity

In 2008 the Australian Government established a two-tiered list of Security Sensitive Biological Agents (SSBA) as part of the SSBA Regulatory Scheme for the control of select agents and toxins. Funding was subsequently made available through the Australian Government Department of Health and Aged Care to establish RCPAQAP Biosecurity, with the aim of providing a quality assurance and proficiency testing program (PTP) for Tier 1 and Tier 2 SSBA, other potential agents and communicable disease threats. The program now offers surveys free of charge to Australian public health laboratories and for a fee to Australian private pathology and approved overseas laboratories with a view to building and enhancing laboratory capacity and capability to detect, analyse, identify and report on these agents

### Declaration

This module is funded by the Australian Government's Department of Health. Information such as participation demographics, overall results and kit performance is shared with them only. The information provided is de-identified in such a way that no individual laboratory's results will be disclosed.

Refer to the Australian Government Department of Health and Aged Care website for current [Security Sensitive Biological Agents Lists](#).

### Bacterial Specimen Module [Catalogue Number: 22020102]

**What's new:** For 2024: *Francisella tularensis*/*Yersinia pestis*  
Updates regarding the 2025 enrolment will be sent when it is available

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** Up to 4

**Sample Type:** Live and inactivated bacteria for microscopy, biochemical testing and NAT

**Sample volume:** 1 mL

**Schedule:** August, October

**Measurand/Test:** Bacterial SSBA

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Additional Comments:** Available free of charge to Australian public health laboratories that require the capability to test for SSBA, other potential agents and communicable disease threats and to approved private laboratories and international laboratories for a fee that reflects the cost of the modules' production.

## Biopreparedness Exercise - Viral [Catalogue Number: 22080102]

Available free of charge to Australian public health laboratories that require the capability to test for SSBA, other potential agents and communicable disease threats and to approved private laboratories and international laboratories for a fee that reflects the cost of the modules' production.

Currently, this program can only be offered to Australian laboratories. Overseas laboratories can express interest in the program and the RCPAQAP will try to accommodate these requests if possible.

**What's new:** For 2025: Highly pathogenic influenza

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** Up to 4

**Sample Type:** Inactivated virus for nucleic acid testing

**Sample volume:** 0.5mL

**Schedule:** June

**Measurand/Test:** Highly pathogenic Influenza

**Storage and Handling:** Upon receipt, store samples at 2-8°C

## Emerging Biological Threats - Molecular [Catalogue Number: 22050102]

Available free of charge to Australian public health laboratories that require the capability to test for SSBA, other potential agents and communicable disease threats and to approved private laboratories and international laboratories for a fee that reflects the cost of the modules' production.

Currently, this program can only be offered to Australian laboratories due to regulatory requirements. Overseas Laboratories can express interest in the program and the RCPAQAP will try to accommodate these requests if possible.

**What's new:** For 2024: Avian influenza virus

Updates regarding the 2025 enrolment will be sent when it is available

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** Up to 6

**Sample Type:** Inactivated virus for nucleic acid testing

**Sample volume:** 0.5 mL

**Schedule:** November

**Measurand/Test:** For 2024: Avian influenza virus

**Storage and Handling:** Upon receipt, store samples at 2-8°C

## Environmental Specimen Module [Catalogue Number: 22070102]

For 2025: Anthrax and Botulinum toxin

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** Up to 4

**Sample Type:** Environmental sample containing inactivated toxin or attenuated bacterium

**Sample volume:** 1mL

**Schedule:** February, April

**Measurand/Test:** Anthrax, Botulinum toxin

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Additional Comments:** Available free of charge to Australian public health laboratories that require the capability to test for SSBA, other potential agents and communicable disease threats and to approved private laboratories and international laboratories for a fee that reflects the cost of the modules' production.

### **SSBA eLearning Module - Anthrax** [Catalogue Number: 24010102]

SSBA eLearning is available to all laboratories within Australia and RCPA Microbiology Registrars free of charge, and to Australian Government Department of Health approved private and international laboratories for a fee that reflects the cost of the modules' production.

This module provides general and technical training for laboratory staff. eLearning Modules generally take 60mins to complete and there is a questionnaire at the end. Please note that you will need speakers or preferably earphones to listen to the audio.

**Schedule:** Available all year

### **SSBA eLearning Module - Botulism** [Catalogue Number: 24060102]

SSBA eLearning is available to all laboratories within Australia and RCPA Microbiology Registrars free of charge, and to Australian Government Department of Health approved private and international laboratories for a fee that reflects the cost of the modules' production.

This module provides general and technical training for laboratory staff. eLearning Modules generally take 60mins to complete and there is a questionnaire at the end. Please note that you will need speakers or preferably earphones to listen to the audio.

**Schedule:** Available all year

### **SSBA eLearning Module - Brucellosis** [Catalogue Number: 24140102]

SSBA eLearning is available to all laboratories within Australia and RCPA Microbiology Registrars free of charge, and to Australian Government Department of Health approved private and international laboratories for a fee that reflects the cost of the modules' production.

This module provides general and technical training for laboratory staff. eLearning Modules generally take 60mins to complete and there is a questionnaire at the end. Please note that you will need speakers or preferably earphones to listen to the audio.

**What's new:** New for 2025

**Schedule:** Available all year

### **SSBA eLearning Module - Ebola** [Catalogue Number: 24020102]

SSBA eLearning is available to all laboratories within Australia and RCPA Microbiology Registrars free of charge, and to Australian Government Department of Health approved private and international laboratories for a fee that reflects the cost of the modules' production.

This module provides general and technical training for laboratory staff. eLearning Modules generally take 60mins to complete and there is a questionnaire at the end. Please note that you will need speakers or preferably earphones to listen to the audio.

**Schedule:** Available all year

### **SSBA eLearning Module - Exotic flaviviruses** [Catalogue Number: 24130102]

SSBA eLearning is available to all laboratories within Australia and RCPA Microbiology Registrars free of charge, and to Australian Government Department of Health approved private and international laboratories for a fee that reflects the cost of the modules' production.

This module provides general and technical training for laboratory staff. eLearning Modules generally take 60mins to complete and there is a questionnaire at the end. Please note that you will need speakers or preferably earphones to listen to the audio.

**What's new:** New for 2024

**Schedule:** Available all year

### **SSBA eLearning Module - History of Biowarfare/Bioterrorism** [Catalogue Number: 24070102]

SSBA eLearning is available to all laboratories within Australia and RCPA Microbiology Registrars free of charge, and to Australian Government Department of Health approved private and international laboratories for a fee that reflects the cost of the modules' production.

This module provides general and technical training for laboratory staff. eLearning Modules generally take 60mins to complete and there is a questionnaire at the end. Please note that you will need speakers or preferably earphones to listen to the audio.

**Schedule:** Available all year

### **SSBA eLearning Module - Plague** [Catalogue Number: 24030102]

SSBA eLearning is available to all laboratories within Australia and RCPA Microbiology Registrars free of charge, and to Australian Government Department of Health approved private and international laboratories for a fee that reflects the cost of the modules' production.

This module provides general and technical training for laboratory staff. eLearning Modules generally take 60mins to complete and there is a questionnaire at the end. Please note that you will need speakers or preferably earphones to listen to the audio.

**Schedule:** Available all year

### **SSBA eLearning Module - Smallpox** [Catalogue Number: 24040102]

SSBA eLearning is available to all laboratories within Australia and RCPA Microbiology Registrars free of charge, and to Australian Government Department of Health approved private and international laboratories for a fee that reflects the cost of the modules' production.

This module provides general and technical training for laboratory staff. eLearning Modules generally take 60mins to complete and there is a questionnaire at the end. Please note that you will need speakers or preferably earphones to listen to the audio.

**Schedule:** Available all year

**SSBA eLearning Module - Toxins** [Catalogue Number: 24050102]

SSBA eLearning is available to all laboratories within Australia and RCPA Microbiology Registrars free of charge, and to Australian Government Department of Health approved private and international laboratories for a fee that reflects the cost of the modules' production.

This module provides general and technical training for laboratory staff. eLearning Modules generally take 60mins to complete and there is a questionnaire at the end. Please note that you will need speakers or preferably earphones to listen to the audio.

**Schedule:** Available all year

**SSBA eLearning Module - Tularemia** [Catalogue Number: 24120102]

SSBA eLearning is available to all laboratories within Australia and RCPA Microbiology Registrars free of charge, and to Australian Government Department of Health approved private and international laboratories for a fee that reflects the cost of the modules' production.

This module provides general and technical training for laboratory staff. eLearning Modules generally take 60mins to complete and there is a questionnaire at the end. Please note that you will need speakers or preferably earphones to listen to the audio.

**Schedule:** Available all year

**SSBA eLearning Module - Highly Pathogenic Influenza** [Catalogue Number: 24110102]

SSBA eLearning is available to all laboratories within Australia and RCPA Microbiology Registrars free of charge, and to Australian Government Department of Health approved private and international laboratories for a fee that reflects the cost of the modules' production.

This module provides general and technical training for laboratory staff. eLearning Modules generally take 60mins to complete and there is a questionnaire at the end. Please note that you will need speakers or preferably earphones to listen to the audio.

**Schedule:** Available all year

**Viral Specimen Module** [Catalogue Number: 22040102]

**What's new:** For 2024: Viral haemorrhagic fever viruses  
Updates regarding the 2025 enrolment will be sent when it is available

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** Up to 4

**Sample Type:** Inactivated virus for nucleic acid testing

**Sample volume:** 0.5 mL

**Schedule:** July, September

**Measurand/Test:** Viral SSBA

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** Available free of charge to Australian public health laboratories that require the capability to test

for SSBA, other potential agents and communicable disease threats and to approve international laboratories for a fee that reflects the cost of the modules' production.

## **Whole Genome Sequencing - Viral** [Catalogue Number: 22100102]

**What's new:** Updates regarding the 2025 enrolment will be sent when it is available

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** Up to 10

**Sample Type:** TBC

**Sample volume:** 0.5 mL

**Schedule:** March,

**Measurand/Test:** WGS

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** Available free of charge to Australian public health laboratories and approved private and international laboratories for a fee that reflects the cost of the modules' production.



## Chemical Pathology

The RCPAQAP Chemical Pathology discipline programs are run in association with the Australasian Association of Clinical Biochemists (AACB) whose members provide expertise and assistance via specialised Advisory Committees. The Advisory Committees are involved in setting target values, providing expert opinion for reports, participant queries, and collecting and preparing quality assurance material.

### **Alcohol and Ammonia** [Catalogue Number: 15010102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Aqueous bovine serum albumin

**Sample volume:** 3mL

**Schedule:** Monthly

**Measurand/Test:** Ethanol, Ammonia

**Storage and Handling:** Upon receipt, store samples at 2-8°C

### **B-Natriuretic Peptide (BNP)** [Catalogue Number: 15060102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum

**Sample volume:** 0.5mL

**Schedule:** Monthly

**Measurand/Test:** B-type Natriuretic Peptide (BNP), N-terminal Prohormone B-type Natriuretic Peptide (NT-pro BNP)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

### **Bile Acids** [Catalogue Number: 15030102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum

**Sample volume:** 2mL

**Schedule:** Monthly

**Measurand/Test:** Total Bile Acids

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Blood Gases** [Catalogue Number: 15040102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Aqueous bovine albumin buffered matrix

**Sample volume:** 2.5mL

**Schedule:** Monthly

**Measurand/Test:** pH, Potassium, Ionised Calcium, pCO<sub>2</sub>, Chloride, Urea, pO<sub>2</sub>, Glucose, Creatinine, Sodium, Lactate

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Blood Gases: CO-oximetry** [Catalogue Number: 15050102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised bovine haemoglobin

**Sample volume:** 0.5mL

**Schedule:** Monthly

**Measurand/Test:** Haemoglobin, Oxyhaemoglobin, Carboxyhaemoglobin, Methaemoglobin

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light

**Body Fluids** [Catalogue Number: 15070102]

**Frequency (No of surveys/year):** 3

**Cases/samples per survey:** 2

**Sample Type:** Diluted serum

**Sample volume:** 3mL

**Schedule:** February, July, November

**Measurand/Test:** Albumin, Amylase, Cholesterol, Creatinine, Glucose, Lactate, Lactate Dehydrogenase, Lipase,

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**C Reactive Protein** [Catalogue Number: 15080102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum

**Sample volume:** 0.5mL

**Schedule:** Monthly

**Measurand/Test:** C-Reactive Protein

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Calprotectin** [Catalogue Number: 15780102]

**Frequency (No of surveys/year):** 3

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised faecal sample

**Sample volume:** 0.5 mL

**Schedule:** June, August, October

**Measurand/Test:** Calprotectin, Elastase

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Chemical Pathology Case Study** [Catalogue Number: 15320101]

The Chemical Pathology Case Study Program is designed to comment on patient biochemistry results. A set of patient results is provided to participants. Participants are asked to provide comments they would typically add to the report or give verbally

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 1

**Schedule:** Bimonthly

**Additional Comments:** Samples are not issued with this program. Please log a New Participant Number Request in the myQAP portal to setup an "Individual" Participant number.

**What's new:** New for 2025

**Frequency (No of surveys/year):** 3

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** March, July, October

**Measurand/Test:** Chromogranin A, Copeptin, Cystatin C

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Compact Serum Chemistry (for Overseas Participants only)** [Catalogue Number: 15090102]

Material provided to assess performance across a range of routine chemical pathology assays including therapeutic drugs and endocrine.

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum and matching diluent

**Sample volume:** 3mL

**Schedule:** Bimonthly

**Measurand/Test:** Albumin, Glycated Albumin, Bicarbonate, Bilirubin-Total, Bilirubin-Conjugated, Icterus (Quantitative), Icterus, (Qualitative), Calcium, Chloride, Creatinine, Fructosamine, Glucose, Lactate, Lithium, Magnesium, Osmolality, Phosphate (Inorganic), Potassium, Protein (Total), Sodium, Urate, Urea, Troponin I (Quantitative), Troponin T (Quantitative) | Enzymes: ALT, Alkaline Phosphatase, Amylase, AST, Cholinesterase, Creatine Kinase, CK-MB, GGT, Lactate Dehydrogenase, Lipase, Iron, TIBC, Transferrin, Transferrin saturation, Ferritin | Lipids: Cholesterol, HDL Cholesterol, Triglyceride | Endocrine: Cortisol, Thyroxine, Free T4, TSH, Total T3, Free T3, hCG (Quantitative), hCG (Qualitative) | Drugs: Carbamazepine, Digoxin, Paracetamol, Phenobarbitone, Phenytoin, Salicylate, Theophylline, Valproate, Gentamicin, Vancomycin.

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** This program is only available to participants outside Australia and New Zealand

**Condensed Blood Gases (for overseas participants only)** [Catalogue Number: 15750102]

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Aqueous bovine albumin buffered matrix

**Sample volume:** 2.5mL

**Schedule:** February, March, April, June, August, September

**Measurand/Test:** pH, Potassium, Ionised Calcium, pCO<sub>2</sub>, Chloride, Urea, pO<sub>2</sub>, Glucose, Creatinine, Sodium, Lactate

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Condensed General Serum Chemistry (for overseas participants only)** [Catalogue Number: 15100102]

Material provided to assess performance across a range of routine chemical pathology assays including therapeutic drugs and endocrine

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum and matching diluent

**Sample volume:** 3mL

**Schedule:** Monthly

**Measurand/Test:** Albumin, Glycated Albumin, Bicarbonate, Bilirubin-Total, Bilirubin-Conjugated, Icterus (Quantitative), Icterus, (Qualitative), Calcium, Chloride, Creatinine, Fructosamine, Glucose, Lactate, Lithium, Magnesium, Osmolality, Phosphate (Inorganic), Potassium, Protein (Total), Sodium, Urate, Urea, Troponin I (Quantitative), Troponin T (Quantitative) | Enzymes: ALT, Alkaline Phosphatase, Amylase, AST, Cholinesterase, Creatine Kinase, CK-MB, GGT, Lactate Dehydrogenase, Lipase, Iron, TIBC, Transferrin, Transferrin saturation, Ferritin | Lipids: Cholesterol, HDL Cholesterol, Triglyceride | Endocrine: Cortisol, Thyroxine, Free T<sub>4</sub>, TSH, Total T<sub>3</sub>, Free T<sub>3</sub>, hCG (Quantitative), hCG (Qualitative) | Drugs: Carbamazepine, Digoxin, Paracetamol, Phenobarbitone, Phenytoin, Salicylate, Theophylline, Valproate, Gentamicin, Vancomycin.

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** Troponin T (semi-qualitative) on Roche Instruments. Participants using the Roche Cardiac Reader should enrol in the General Serum Chemistry Program. Participants using Roche Cobas h232 instruments should enrol in the PoCT Troponin Program. This is due to the different cut-offs, standardisation and units for these 2 instruments

**Condensed PoCT: Blood Gases** [Catalogue Number: 15110102]

Designed to assess related methods available on i-STAT type analysers

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Aqueous bovine albumin buffered matrix

**Sample volume:** 2.5mL

**Schedule:** Bimonthly

**Measurand/Test:** pH, Sodium, Glucose, Ionised Calcium, pCO<sub>2</sub>, Potassium, Haemoglobin, Haematocrit, pO<sub>2</sub>, Chloride, Lactate, Creatinine, TCO<sub>2</sub>, Urea

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Condensed PoCT: Troponin** [Catalogue Number: 15120102]

Material provided for assessment of Troponin T and I and Total HCG on PoC devices

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** February, March, April, June, August, September

**Measurand/Test:** Troponin I, Troponin T (semi-quantitative e.g. h232), Total HCG

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**CSF: Chemistry** [Catalogue Number: 15140102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised CSF

**Sample volume:** 2mL

**Schedule:** Monthly

**Measurand/Test:** Total Protein, Immunoglobulin G, Glucose, Lactate, Albumin, Xanthochromia Screen - Haemoglobin (absorbance & qualitative), Xanthochromia Screen - Bilirubin (absorbance, concentration & qualitative)

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light

**CSF: Oligoclonal Bands** [Catalogue Number: 15150102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised CSF and matching serum

**Sample volume:** 0.5mL

**Schedule:** Monthly

**Measurand/Test:** Oligoclonal Banding (CSF), Oligoclonal Banding (serum), Beta-Trace Protein, Beta-Trace Protein (Quantitative), Beta-2 Transferrin, Interpretive Comment

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light

**Disaccharidases** [Catalogue Number: 15670102]

Change to program in 2024. Sample type is now Lyophilised pooled homogenate an  
UN3373 Dangerous Good

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised pooled homogenate

**Sample volume:** 0.5ml

**Schedule:** Bimonthly

**Measurand/Test:** Total Protein, Lactase, Maltase, Suchrase

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN3373

### **Dried Blood Spot** [Catalogue Number: 15160102]

Samples provided to assess inborn errors of metabolism

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 3 samples (6 spots)

**Sample Type:** Whole blood - dried

**Sample volume:** 75uL

**Schedule:** Bimonthly

**Measurand/Test:** 17-Hydroxy-Progesterone (17-OHP), Phenylalanine, Immunoreactive trypsinogen (IRT), TSH, Tyrosine, Androstenedione, Cortisol, 21-deoxycortisol, 11-deoxycortisol, Clinical Evaluation Component, Citrulline, Methionine, C8-acylcarnitine, C3-acylcarnitine, Galactose

**Storage and Handling:** Upon receipt, store samples at -20°C

### **Endocrine** [Catalogue Number: 15190102]

Material provided to assess performance for a range of endocrine assays

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum

**Sample volume:** 3mL

**Schedule:** Monthly

**Measurand/Test:** a Fetoprotein, CA-125, CEA, Ferritin, Folate, FSH, Growth Hormone, Homocysteine, hCG (Total), Insulin, LH, Prolactin, TSH, Free T3, Free T4, Vitamin B12, Macroprolactin, % post PEG precipitation



**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Endocrine: Angiotensin-converting Enzyme** [Catalogue Number: 15170102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum

**Sample volume:** 0.25mL

**Schedule:** Monthly

**Measurand/Test:** Angiotensin Converting Enzyme (ACE)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Endocrine: Anti-Mullerian Hormone** [Catalogue Number: 15180102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum

**Sample volume:** 0.5mL

**Schedule:** Monthly

**Measurand/Test:** Anti-Mullerian Hormone

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Endocrine: Bone Markers** [Catalogue Number: 15690102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum

**Sample volume:** 0.5mL

**Schedule:** Monthly

**Measurand/Test:** P1NP, serum-Beta CTX

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Endocrine: Prostate Specific Antigen** [Catalogue Number: 15200102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum

**Sample volume:** 1mL

**Schedule:** Monthly

**Measurand/Test:** Total PSA, Free PSA

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Endocrine: Red Cell Folate** [Catalogue Number: 15210102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum

**Sample volume:** 1mL

**Schedule:** Monthly

**Measurand/Test:** Red Cell Folate

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Endocrine: Special** [Catalogue Number: 15220102]

Material provided to assess performance for a range of endocrine assays

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum

**Sample volume:** 3mL

**Schedule:** Monthly

**Measurand/Test:** Aldosterone, Androstenedione, Cortisol, DHEA, DHEA Sulphate, 17 Hydroxyprogesterone, Oestradiol, Oestriol (unconjugated), Parathyroid Hormone, Progesterone, Renin, SHBG, Testosterone, Total T3, Total T4, Vitamin D3 (25 Hydroxy Vitamin D), Dihydrotestosterone, Active B12 (Holotranscobalamin), 11-Deoxycortisol, 21-Deoxycortisol

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Faecal Occult Blood** [Catalogue Number: 15230102]

Material provided to assess occult blood levels against assay cutoff

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised human blood

**Sample volume:** 1mL

**Schedule:** Monthly

**Measurand/Test:** Faecal Occult Blood (Quantitative), Faecal Occult Blood (Qualitative)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

### **General Serum Chemistry** [Catalogue Number: 15240102]

Material provided to assess performance across a range of routine chemical pathology assays including therapeutic drugs and endocrine.

**Frequency (No of surveys/year):** 21

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum and matching diluent

**Sample volume:** 3mL

**Schedule:** Twice/month

**Measurand/Test:** Albumin, Glycated Albumin, Bicarbonate, Bilirubin-Total, Bilirubin-Conjugated, Icterus (Quantitative), Icterus, (Qualitative), Calcium, Chloride, Creatinine, Fructosamine, Glucose, Lactate, Lithium, Magnesium, Osmolality, Phosphate (Inorganic), Potassium, Protein (Total), Sodium, Urate, Urea, Troponin I (Quantitative), Troponin T (Quantitative) | Enzymes: ALT, Alkaline Phosphatase, Amylase, AST, Cholinesterase, Creatine Kinase, CK-MB, GGT, Lactate Dehydrogenase, Lipase, Iron, TIBC, Transferrin, Transferrin saturation, Ferritin | Lipids: Cholesterol, HDL Cholesterol, Triglyceride | Endocrine: Cortisol, Thyroxine, Free T4, TSH, Total T3, Free T3, hCG (Quantitative), hCG (Qualitative) | Drugs: Carbamazepine, Digoxin, Paracetamol, Phenobarbitone, Phenytoin, Salicylate, Theophylline, Valproate, Gentamicin, Vancomycin.

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** Troponin T (semi-qualitative) on Roche Instruments. Participants using the Roche Cardiac Reader should enrol in the General Serum Chemistry Program. Participants using Roche cobas h232 instruments should enrol in the PoCT Troponin Program. This is due to the different cut-offs, standardisation and units of these 2 instruments.

### **General Urine Chemistry** [Catalogue Number: 15590102]

Material provided to assess performance across a range of chemistry urine assays

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised urine

**Sample volume:** 10mL

**Schedule:** Monthly

**Measurand/Test:** Albumin, ACR, Calcium, Chloride, Cortisol, Cortisone, Creatinine, Metanephrine, Free Normetanephrine, Free 3-Methoxytyramine, Glucose, hCG-Qualitative, hCG-Quantitative, Magnesium, N-Telopeptides, Osmolality, Phosphate, Potassium, Sodium, Total Protein, Urate, Urea

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**General Urine Chemistry: Biogenic Amines** [Catalogue Number: 15580102]

Material provided to assess biogenic amine measurements including metanephrines

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 1

**Sample Type:** Lyophilised urine

**Sample volume:** 5mL

**Schedule:** Monthly

**Measurand/Test:** Noradrenaline, 5HIAA, Adrenaline, Dopamine, HMMA, HVA, 3-Methoxytyramine, Metanephrine, Normetanephrine, Serotonin, Clinical Evaluation Component

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** Urinary Free Metanephrine, Free Normetanephrine and Free 3-Methoxytyramine are included in the General Urine Chemistry material.

**HbA1c: Lyophilised** [Catalogue Number: 15250102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised whole blood

**Sample volume:** 0.2mL

**Schedule:** Monthly

**Measurand/Test:** HbA1c

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** This program is not suitable for Abbott Afinion devices. Participants using the Abbott Afinion should enrol in the HbA1c Whole Blood program.

**HbA1c: Whole Blood** [Catalogue Number: 15650102]

**Frequency (No of surveys/year):** 3

**Cases/samples per survey:** 2

**Sample Type:** Fresh EDTA whole blood

**Sample volume:** 0.3mL

**Schedule:** February, July, November

**Measurand/Test:** HbA1c

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** Suitable for all HbA1c assays and POC devices.

Only available to participants in Australia, New Zealand, Malaysia, Hong Kong and Singapore.

### **i-SENS Glucose Meters** [Catalogue Number: 15820102]

**What's new:** New for 2024

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Stabilised glucose solution

**Sample volume:** 1 mL

**Schedule:** May, June, July, August, September, November

**Measurand/Test:** Glucose

**Storage and Handling:** Upon receipt, store samples at room temperature and protect them from direct light.

**Additional Comments:** This program is suitable for i-SENS POC devices used to test glucose

### **i-SENS Ketone Meters** [Catalogue Number: 15830102]

**What's new:** New for 2024

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Stabilised ketone solution

**Sample volume:** 1 mL

**Schedule:** May, June, July, August, September, November

**Measurand/Test:** Ketones

**Storage and Handling:** Upon receipt, store samples at room temperature and protect them from direct light.

**Additional Comments:** This program is suitable for i-SENS POC devices used to test ketones

### **IGF-1/C Peptide** [Catalogue Number: 15260102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum

**Sample volume:** 1mL

**Schedule:** Monthly

**Measurand/Test:** IGF-1, C Peptide, IGF-BP3

**Storage and Handling:** Upon receipt, store samples at 2-8°C

### **Lactate Meters** [Catalogue Number: 15800102]

**What's new:** New for 2024

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Lactate Solution

**Sample volume:** 1mL

**Schedule:** June, August, October, December

**Measurand/Test:** Lactate- Quantitative

**Storage and Handling:** Upon receipt, store samples at 2-8°C

### **Liquid Serum Chemistry (for Australian and NZ Participants only)** [Catalogue Number: 15270102]

Material provided to assess performance of a range of chemistry and endocrine assays - fully commutable, sourced from haemochromatosis therapeutic venesections

**Frequency (No of surveys/year):** 3

**Cases/samples per survey:** 2

**Sample Type:** Fresh frozen serum

**Sample volume:** 3mL

**Schedule:** March, July, November

**Measurand/Test:** Albumin, Bicarbonate, Bilirubin - Total, Bilirubin - Conjugated, Calcium, Chloride, Creatinine, Fructosamine, Glucose, Lactate, Magnesium, Osmolality, Phosphate(Inorganic), Potassium, Protein (Total), Sodium, Urate, Urea | Enzymes: ALT, Alkaline Phosphatase, Amylase, AST, Cholinesterase, Creatine Kinase, GGT, Lactate Dehydrogenase, Lipase, Iron, TIBC, Transferrin, Transferrin Saturation, Ferritin | Lipids: Cholesterol, HDL Cholesterol, LDL Cholesterol, Triglyceride | Endocrine: Cortisol, DHEA Sulphate, DHT, Folate, FSH, Growth Hormone, LH, Oestradiol, Progesterone, Prolactin, P1NP, SHBG, s-bCTX, Testosterone, Free Testosterone, Vitamin B12, Active B12 (Holotranscobalamin), Vitamin D3, TSH, Free T4, Free T3 | Calculated measurands: Anion Gap, Adjusted Calcium,

**Storage and Handling:** Upon receipt, store samples at -20°C. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Additional Comments:** This program is only available to participants in Australia and New Zealand.

### Neonatal Bilirubin [Catalogue Number: 15290102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum

**Sample volume:** 2mL

**Schedule:** Monthly

**Measurand/Test:** Total Bilirubin, Conjugated Bilirubin

**Storage and Handling:** Upon receipt, store samples at 2-8°C

### On-Site Urine Toxicology Screening [Catalogue Number: 15300102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 1

**Sample Type:** Lyophilised urine

**Sample volume:** 10mL

**Schedule:** Monthly

**Measurand/Test:** Amphetamine Type Substances- Amphetamine, Methamphetamine, Benzodiazepines, Cannabis metabolites, Cocaine metabolites, Opiates, Creatinine

**Storage and Handling:** Upon receipt, store samples at 2-8°C

### Oral Fluid Toxicology Screening [Catalogue Number: 15310102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 1

**Sample Type:** Lyophilised non-human protein base

**Sample volume:** 2mL

**Schedule:** Monthly

**Measurand/Test:** 6-Acetylmorphine, Amphetamine Type Substances - Amphetamine, Methamphetamine, Cannabis



metabolites, Cocaine metabolites, Opiates, Oxycodone

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Plasma Metanephrines** [Catalogue Number: 15330102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 3mL

**Schedule:** Monthly

**Measurand/Test:** Metanephrine, Normetanephrine, 3-Methoxythyramine

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light

**PoCT: Blood Gases** [Catalogue Number: 15350102]

Designed to assess related methods available on i-STAT type analysers

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Aqueous bovine albumin buffered matrix

**Sample volume:** 2.5mL

**Schedule:** Monthly

**Measurand/Test:** pH, Sodium, Glucose, Ionised Calcium, pCO<sub>2</sub>, Potassium, Haemoglobin, Haematocrit, , pO<sub>2</sub>, Chloride, Lactate, Creatinine, TCO<sub>2</sub>, Urea

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**PoCT: Troponin and HCG** [Catalogue Number: 15340102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** Monthly

**Measurand/Test:** Troponin I, Troponin T (semi-quantitative e.g. h232), Total HCG

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** Suitable for devices such as Abbott i-STAT and Roche cobas



**Porphyryns: Faeces** [Catalogue Number: 15380102]

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Faeces

**Schedule:** Bimonthly

**Measurand/Test:** Faecal Dry Weight, Faecal Total Porphyrin, Faecal Porphyrin Components

**Storage and Handling:** Upon receipt, store samples at -20°C and protect from direct light

**Porphyryns: Patient Report Comments** [Catalogue Number: 15760102]

A set of patient porphyrin results is provided to participants. Participants are asked to return comments they would typically add to a report or give verbally. This module is only available to participants who enrol in any of the main Porphyrin programs. There is no extra charge for participation.

**Frequency (No of surveys/year):** 3

**Cases/samples per survey:** 1

**Schedule:** February, May, September

**Additional Comments:** Samples are not issued with this program. The program is complimentary when enrolled in the Porphyrins Program to assist with clinical interpretation.

**Porphyryns: Plasma** [Catalogue Number: 15390102]

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 5mL

**Schedule:** Bimonthly

**Measurand/Test:** Plasma Total Porphyrin, Plasma Porphyrin Components

**Storage and Handling:** Upon receipt, store samples at -20°C and protect from direct light

**Porphyryns: Urine** [Catalogue Number: 15400102]

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised urine

**Sample volume:** 5mL

**Schedule:** Bimonthly

**Measurand/Test:** Urine Total Porphyrin, Urine ALA, Quantitative Porphobilinogen, Urine Porphyrin Components, Qualitative Porphobilinogen

**Storage and Handling:** Upon receipt, store samples at -20°C and protect from direct light

**Additional Comments:** Discounted pricing option available for: Qualitative Porphobilinogen enrolment only

**Porphyryns: Whole Blood** [Catalogue Number: 15370102]

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised whole blood

**Sample volume:** 5mL

**Schedule:** Bimonthly

**Measurand/Test:** Whole Blood Total Porphyrin, Whole Blood Total Porphyrin Clinical Evaluation, Whole Blood Porphyrin Fractions

**Storage and Handling:** Upon receipt, store samples at -20°C and protect from direct light

**Renal Calculi** [Catalogue Number: 15790102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 1

**Sample Type:** Human Renal Calculi

**Schedule:** May, July, September, November

**Measurand/Test:** Qualitative and Quantitative Stone Composition

**Storage and Handling:** Upon receipt, store samples at room temperature

**Salivary Cortisol** [Catalogue Number: 15460102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised non-human protein base

**Sample volume:** 2mL

**Schedule:** Monthly

**Measurand/Test:** Salivary Cortisol, Salivary Cortisone

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Serum Indices** [Catalogue Number: 15470102]

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** Bimonthly

**Measurand/Test:** Haemolysis, Icterus, Lipaemia

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Special Drugs** [Catalogue Number: 15510102]

A range of therapeutic drugs and antibiotics provided

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum

**Sample volume:** 5mL

**Schedule:** Monthly

**Measurand/Test:** Amiodarone, Clozapine, Norclozapine, Methotrexate, Mycophenolate, Amitriptyline, Nortriptyline, Amikacin, Gentamicin, Tobramycin, Vancomycin,

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Special Drugs: Anti-fungals** [Catalogue Number: 15700102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum

**Sample volume:** 5mL

**Schedule:** Monthly

**Measurand/Test:** Itraconazole, Fluconazole, OH-Itraconazole, Posaconazole, Voriconazole, Flucytosine, Isavuconazole

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Special Drugs: Beta-Lactams, Tuberculosis, and Other Drugs** [Catalogue number: 15040102]

Material provided to assess performance of a range of beta-lactams, tuberculosis and Other drugs

**What's new:** New for 2025

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** Monthly

**Measurand/Test:** Amoxycillin, Ciprofloxacin, Ampicillin, Ceftazidime, Flucloxacillin, Cefazolin, Cefepime, Linezolid, Piperacillin, Meropenem, Cefotaxime, Ethambutol, Pyrazinamide, Rifampicin, Isoniazid, Busulfan

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Special Drugs: Everolimus** [Catalogue Number: 15810102]

Material provided to assess the performance of Everolimus assays

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised whole blood

**Sample volume:** 1mL

**Schedule:** Monthly

**Measurand/Test:** Everolimus

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Special Drugs: Immunosuppressants** [Catalogue Number: 15500102]

Material provided to assess performance of a range of immunosuppressant assays

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised whole blood

**Sample volume:** 2mL

**Schedule:** Monthly

**Measurand/Test:** Cyclosporin, Tacrolimus, Sirolimus

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Special Drugs: Thiopurines** [Catalogue Number: 15710102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised whole blood

**Sample volume:** 2mL

**Schedule:** Monthly

**Measurand/Test:** 6-TGN, 6-MMP

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Special Lipids** [Catalogue Number: 15490102]

Material provided to assess a range of common and speciality lipid assays

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum

**Sample volume:** 2mL

**Schedule:** Monthly

**Measurand/Test:** Cholesterol, HDL Cholesterol, LDL Cholesterol, Triglyceride, Apolipoprotein A1, Apolipoprotein B, Lipoprotein(a)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**StatStrip Glucose** [Catalogue Number: 15020102]

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Stabilised Glucose Solution

**Sample volume:** 1mL

**Schedule:** Bimonthly

**Measurand/Test:** Glucose

**Storage and Handling:** Upon receipt, store samples at room temperature and protect from direct light.

**StatStrip Ketones** [Catalogue Number: 15660102]

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Stabilised Glucose Solution

**Sample volume:** 1mL

**Schedule:** Bimonthly

**Measurand/Test:** Ketones

**Storage and Handling:** Upon receipt, store samples at room temperature and protect from direct light.

### **Sweat Testing** [Catalogue Number: 15520102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Aqueous NaCl solution

**Sample volume:** 1mL

**Schedule:** Monthly

**Measurand/Test:** Chloride, Chloride interpretation

**Storage and Handling:** Upon receipt, store samples at 2-8°C

### **Trace Elements: Serum** [Catalogue Number: 15540102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Frozen bovine serum

**Sample volume:** 2mL

**Schedule:** Monthly

**Measurand/Test:** Aluminium, Chromium, Cobalt, Copper, Lithium, Magnesium, Molybdenum, Selenium, Thallium, Vanadium, Zinc

**Storage and Handling:** Upon receipt, store samples at -20°C

### **Trace Elements: Urine** [Catalogue Number: 15550102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Frozen human urine

**Sample volume:** 3mL

**Schedule:** Monthly

**Measurand/Test:** Aluminium, Antimony, Arsenic, Beryllium, Cadmium, Chromium, Cobalt, Copper, Iodine, Iron, Lead, Magnesium, Manganese, Mercury, Nickel, Selenium, Thallium, Vanadium, Zinc

**Storage and Handling:** Upon receipt, store samples at -20°C

**Trace Elements: Whole Blood** [Catalogue Number: 15530102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Frozen human blood

**Sample volume:** 3mL

**Schedule:** Monthly

**Measurand/Test:** Arsenic, Cadmium, Cobalt, Chromium, Lead, Magnesium, Manganese, Mercury, Selenium, Thallium, Zinc

**Storage and Handling:** Upon receipt, store samples at -20°C

**Tumour Markers** [Catalogue Number: 15560102]

Material provided to assess common tumour marker assays

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum

**Sample volume:** 2mL

**Schedule:** Monthly

**Measurand/Test:** ACTH, Alpha-fetoprotein, Beta-2-Microglobulin, Calcitonin, CEA, CA125, CA15-3, CA19-9, Gastrin, HCG, HE4 (Human Epididymis Protein 4), Free PSA, NSE, Total PSA, Prolactin, Thyroglobulin

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Urea Breath Test** [Catalogue Number: 15770102]

EQA program for non-invasive diagnostic testing for Helicobacter pylori infection.

**Frequency (No of surveys/year):** 3

**Cases/samples per survey:** 2

**Sample Type:** Exhaled air



**Schedule:** May, July, October

**Measurand/Test:** C-14 Urea

**Storage and Handling:** Upon receipt, store samples at room temperature

**Additional Comments:** This program is designed to assess Carbon-14 Urea Breath Testing. Not suitable to assess Carbon-13 Urea Breath Testing.

### **Urine Amylase** [Catalogue Number: 15570102]

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised urine

**Sample volume:** 1mL

**Schedule:** Bimonthly

**Measurand/Test:** Urine Amylase

**Storage and Handling:** Upon receipt, store samples at 2-8°C

### **Urine Pregnancy** [Catalogue Number: 15600102]

Not suitable for the Abbott TestPack Plus HCG device

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised urine

**Sample volume:** 10mL

**Schedule:** Bimonthly

**Measurand/Test:** hCG (Qualitative)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

### **Urine Toxicology** [Catalogue Number: 15610102]

Authentic urine samples provided to assess detection of a variety of drugs of abuse

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 1

**Sample Type:** Lyophilised urine

**Sample volume:** 10mL

**Schedule:** Monthly

**Measurand/Test:** Qualitative and Quantitative Drug Testing, Creatinine

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Vitamin C** [Catalogue Number: 15620102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum

**Sample volume:** 2mL

**Schedule:** Monthly

**Measurand/Test:** Vitamin C

**Storage and Handling:** Upon receipt, store samples at -20°C and protect from direct light

**Vitamins: Serum** [Catalogue Number: 15640102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum

**Sample volume:** 2mL

**Schedule:** Monthly

**Measurand/Test:** Vitamin A, Vitamin E, Beta-carotene, Total Carotenoids, Serum Vitamin B6, Methylmalonic acid (MMA)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Vitamins: Whole Blood** [Catalogue Number: 15630102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised whole blood

**Sample volume:** 4mL

**Schedule:** Monthly

**Measurand/Test:** Vitamin B1, Vitamin B2, Vitamin B6

**Storage and Handling:** Upon receipt, store samples at 2-8°C

# Cytopathology

The RCPAQAP Cytopathology discipline offers external quality assurance programs that encompass both gynaecological and non-gynaecological Cytopathology practice. Laboratories may enrol in any or all of the programs.

Gynaecological programs consist of glass slide surveys of conventional or liquid based cervical smears representing a wide range of diagnoses. Diagnoses may include normal findings, pathogens and neoplasia, both squamous and glandular. All high-grade abnormalities are histologically confirmed. Participants have the option of enrolling in any or all of the conventional, ThinPrep and SurePath gynaecological programs.

Non-Gynaecological programs consist of virtual images provided via Sectra hyperlinks and optional USB devices if purchased. Both the General and Fine Needle Aspiration Cytopathology programs consist of specimens from a range of body sites. The Specialty program focuses on a specified sample type on a rotating basis each year. All cases have appropriate clinical and histological follow-up. When appropriate, cases consist of two preparations stained by Papanicolaou and Romanowsky methods. Immunohistochemistry images may also be included.

Technical exercises are selected to assess common or critical features demonstrated by routine methods in the laboratory. Questionnaires on laboratory practice may also be issued.

Cervical Screening Program Indicators - for Australian laboratories only provide an inter-laboratory comparison over a set of measures based on key quantitative data. Retrospective data is collected twice per year covering reporting profiles, such as the proportion of smears reported as unsatisfactory and abnormal, and the results of slide reviews and histological follow-up. An annual report (issued in two parts) summarises individual laboratory data in comparison with the group (national) data and recommended standards.

## **Cervical Screening Program Indicators** [Catalogue Number: 16070102]

Formerly known as the Performance Measures - for Australian laboratories only. Collection of National Cervical Screening Program data as per NPAAC requirements.

**Frequency (No of surveys/year):** 2

**Schedule:** March, October

## **Gynaecological Conventional** [Catalogue Number: 16010105]

Proficiency testing for laboratories, cytologists and pathologists reporting conventional cervical smear cytopathology. Educational resource for other laboratories and trainees.

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 5

**Sample Type:** Glass slides are provided requiring return at the end of each survey

**Schedule:** February, May, July, September

**Gynaecological Liquid based SurePath** [Catalogue Number: 16020105]

Proficiency testing for laboratories, cytologists and pathologists reporting SurePath liquid based cervical cytopathology. Educational resource for other laboratories and trainees.

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 5

**Sample Type:** Glass slides are provided requiring return at the end of each survey

**Schedule:** February, May, July, September

**Gynaecological Liquid based ThinPrep** [Catalogue Number: 16030105]

Proficiency testing for laboratories, cytologists and pathologists reporting ThinPrep liquid based cervical cytopathology. Educational resource for other laboratories and trainees.

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 5

**Sample Type:** Glass slides are provided requiring return at the end of each survey

**Schedule:** February, May, July, September

**Non-gynaecological Fine Needle Aspiration** [Catalogue Number: 16040102]

Proficiency testing for laboratories and pathologists reporting fine needle aspiration biopsy non-gynaecological cytopathology. Educational resource for other laboratories and trainees.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 4

**Sample Type:** Stained preparations are provided as virtual microscope slide images in the myQAP portal. USBs can be purchased separately.

**Schedule:** May, September

**Non-gynaecological General** [Catalogue Number: 16050102]

Proficiency testing for laboratories and pathologists reporting general exfoliative non-gynaecological cytopathology. Educational resource for other laboratories and trainees.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 4

**Sample Type:** Stained preparations are provided as virtual microscope slide images in the myQAP portal. USBs can be purchased separately.

**Schedule:** February, July

**Non-gynaecological Specialty** [Catalogue Number: 16060102]

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 4

**Sample Type:** Stained preparations are provided as virtual microscope slide images in the myQAP portal. USBs can be purchased separately.

**Schedule:** July

**Additional Comments:** One specialty program will be showcased each year. In 2025, this specialty program will consist of four effusion cases.

**Technical** [Catalogue Number: 16080102]

Proficiency testing for laboratories performing general cytopathology processes. In 2025, the Technical Program will consist of a preparatory trouble-shooting exercise. The primary focus will be the Romanowsky stain on non-gynaecological specimens.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 1

**Schedule:** February

# Haematology

Surveys are dispatched each month within the year with a wide range of samples for both routine and specialist Haematology testing.

## **Activated Clotting Time** [Catalogue Number: 11590102]

Activated Clotting Time for iSTAT users only

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** May, October

**Measurand/Test:** Activated Clotting Time

**Storage and Handling:** Upon receipt, store samples at 2-8°C

## **Automated Differential - Option 1** [Catalogue Number: 11010102]

Material is provided to assess the white cell count and 5-part differential from automated instruments.

Option 1: Sysmex XE, XT, XS, XN, XN-L series, Mindray BC 5000/ 6000 series

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 2.0-3.5mL

**Schedule:** March, June, August, November

**Measurand/Test:** WBC Differential; WCC, Neuts, Lymph, Mono, Eos, Baso, Immature Gran

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** If the instrument, series or manufacturer used is not listed in any of the options, please contact us prior to enrolment.

## **Automated Differential - Option 2** [Catalogue Number: 11020102]

Material is provided to assess the white cell count and 5-part differential from automated instruments.

Option 2: Abbott Cell-Dyn 3000, 3200/Ruby, 3500, 3700, 4000/Sapphire, Alinity hq

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 2.0-3.5mL

**Schedule:** March, June, August, November

**Measurand/Test:** WBC Differential; WCC, Neut/Gran, Lymph, Mono, Eos, Baso

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** If the instrument, series or manufacturer used is not listed in any of the options, please contact us prior to enrolment.

**Automated Differential - Option 4** [Catalogue Number: 11040102]

Material is provided to assess the white cell count and 5-part differential from automated instruments.

Option 4: Siemens ADVIA 120/2120

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 2.0-3.5mL

**Schedule:** March, June, August, November

**Measurand/Test:** WBC Differential; WCC, Neuts, Lymph, Mono, Eos, Baso, LUC

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** If the instrument, series or manufacturer used is not listed in any of the options, please contact us prior to enrolment.

**Automated Differential - Option 5** [Catalogue Number: 11610102]

Material is provided to assess the white cell count and 5-part differential from automated instruments.

Option 5: Beckman Coulter Dxh 500 series

**What's new:** New

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 2.0-3.5mL

**Schedule:** March, June, August, November

**Measurand/Test:** WBC Differential; WCC, Neuts, Lymph, Mono, Eos, Baso

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** If the instrument, series or manufacturer used is not listed in any of the options, please contact us prior to enrolment.

**Automated Differential - Option 7** [Catalogue Number: 11050102]

Material is provided to assess the white cell count and 5-part differential from automated instruments.

Option 7: Beckman Coulter HMX, LH series, Unicel DxH Series and DxH 690t

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 2.0-3.5mL

**Schedule:** March, June, August, November

**Measurand/Test:** WBC Differential; WCC, Neut/Gran, Immature Gran, Lymph, Mono, Eos, Baso

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** If the instrument, series or manufacturer used is not listed in any of the options, please contact us prior to enrolment.

**Blood Film Differential Count** [Catalogue Number: 11280102]

Peripheral Blood Film provided to assess the capabilities to perform a manual white cell differential

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 1

**Sample Type:** Virtual Image or Blood film. USB Optional. Blood film subject to donor availability.

**Schedule:** January, March, May, July, September, November

**Measurand/Test:** Differential cell count

**Storage and Handling:** Upon receipt, store samples at room temperature

**Bone Marrow Morphology** [Catalogue Number: 11060102]

**Frequency (No of surveys/year):** 3

**Cases/samples per survey:** 1

**Sample Type:** Virtual images of peripheral blood films, bone marrow aspirate and trephine sections. USB optional.



**Schedule:** March, June, October

**Measurand/Test:** Description and diagnostic interpretation of peripheral blood films, Bone Marrow aspirate and Trephine sections

**CD34 +** [Catalogue Number: 11070102]

**Frequency (No of surveys/year):** 3

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 0.8mL

**Schedule:** March, August, November

**Measurand/Test:** WCC; %CD34; Total CD34/uL

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Coagulation Factors: II, V, VII, X, XI, and XII** [Catalogue Number: 11080102]

**Frequency (No of surveys/year):** 3

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** March, July, November

**Measurand/Test:** Coagulation Factors II, V, VII, X, XI and XII

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Coagulation Factors: VIII and IX** [Catalogue Number: 11090102]

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** February, April, June, August, October, December

**Measurand/Test:** Coagulation Factors VIII and IX

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Compact Full Blood Count (for Overseas Participants only)** [Catalogue Number: 11110102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 1.5mL

**Schedule:** March, May, September, November

**Measurand/Test:** White Blood Cells (WBC); Red Blood Cells(RBC); Haemoglobin (Hb); Haematocrit (HCT) ; Mean Cell Volume (MCV); Mean Cell Haemoglobin (MCH); Mean Cell Haemoglobin Concentration (MCHC); Red Cell Distribution Width - CV (RDW-CV); Platelet (PLT); Mean Platelet Volume (MPV)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** This program is only available to Overseas Participants.

**Condensed Full Blood Count (for overseas participants only)** [Catalogue Number: 11180102]

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 1.5mL

**Schedule:** February, April, June, August, October, December

**Measurand/Test:** White Blood Cells (WBC); Red Blood Cells(RBC); Haemoglobin (Hb); Haematocrit (HCT) ; Mean Cell Volume (MCV); Mean Cell Haemoglobin (MCH); Mean Cell Haemoglobin Concentration (MCHC); Red Cell Distribution Width - CV (RDW-CV); Platelet (PLT); Mean Platelet Volume (MPV)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** This program is only available to participants outside Australia and New Zealand

**Condensed Haemostasis (for overseas participants only)** [Catalogue Number: 11250102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** March, June, September, December

**Measurand/Test:** Prothrombin Time (PT); International Normalised Ratio (INR); Activated Partial Thromboplastin Time (APTT); Von Claus Fibrinogen (FIB), Derived Fibrinogen (FIB); Thrombin Time (TT)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** This program is only available to participants outside Australia and New Zealand

**D-Dimer: Automated** [Catalogue Number: 11130102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** February, May, August, November

**Measurand/Test:** D-Dimer - Automated

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**D-Dimer: Semi-quantitative** [Catalogue Number: 11140102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 0.5mL

**Schedule:** February, May, August, November

**Measurand/Test:** D-Dimer - Semi quantitative

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**ESR - Option 1** [Catalogue Number: 11150102]

Option 1: All methods excluding StaRRsed users

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 5mL

**Schedule:** April and October

**Measurand/Test:** Erythrocyte Sedimentation Rate (ESR)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**ESR - Option 2 StaRRsed only** [Catalogue Number: 11160102]

Option 2: StaRRsed users only

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 5mL

**Schedule:** April and October

**Measurand/Test:** Erythrocyte Sedimentation Rate (ESR)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**ESR - Option 3** [Catalogue Number: 11600102]

Option 3: Alifax users only

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 4mL

**Schedule:** May, November

**Measurand/Test:** Erythrocyte Sedimentation Rate (ESR)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Full Blood Count** [Catalogue Number: 11190102]

**Frequency (No of surveys/year):** 12

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 1.5mL

**Schedule:** Monthly commencing January

**Measurand/Test:** White Blood Cells (WBC); Red Blood Cells(RBC); Haemoglobin (Hb); Haematocrit (HCT) ; Mean Cell Volume (MCV); Mean Cell Haemoglobin (MCH); Mean Cell Haemoglobin Concentration (MCHC); Red Cell Distribution Width - CV (RDW-CV); Platelet (PLT); Mean Platelet Volume (MPV)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**G6PD** [Catalogue Number: 11200102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised haemolysate

**Sample volume:** 0.5mL

**Schedule:** March, September

**Measurand/Test:** Glucose-6-phosphate dehydrogenase Screen and Assay

**Storage and Handling:** Upon receipt, store samples at 2-8°C

### **Haematology Immunophenotyping** [Catalogue Number: 11210102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 1

**Sample Type:** Stabilised whole blood

**Sample volume:** 1mL

**Measurand/Test:** Haematology Immunophenotyping - (AML, T and B cell ALL and LPD-Diagnostic Interpretation)

**Storage and Handling:** Analysis must be performed within 24 hours. For BD biosciences systems: the sample vials should be maintained at 2°-10°C until use. For Beckman Coulter systems: the vials should be maintained at 18°-30°C until use.

**Additional Comments:** The material assayed is fresh whole blood, which quickly deteriorates under normal transport conditions and should be tested within 3-4 days of dispatch. As such this program is only available to a limited number of destinations outside Australia, New Zealand, Malaysia, Singapore and Hong Kong. Please contact Customer Service at [customer.service@rcpaqap.com.au](mailto:customer.service@rcpaqap.com.au) if you are outside these areas. Notification will be sent by email on the day of dispatch.

\* Schedules are dependant on patients availability

### **Haemoglobinopathy** [Catalogue Number: 11230102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 1

**Sample Type:** Lyophilised haemolysate

**Sample volume:** 1mL

**Schedule:** February, May, August, November

**Measurand/Test:** Haemoglobin A2 (Hb A2); Haemoglobin F (Hb F); Variant Haemoglobin (Variant), Final interpretation

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** February, March, May, June, August, September, November, December

**Measurand/Test:** Prothrombin Time (PT); International Normalised Ratio (INR); Activated Partial Thromboplastin Time (APTT); Von Claus Fibrinogen (FIB), Derived Fibrinogen (FIB); Thrombin Time (TT)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** Von Clauss and Derived fibrinogen measurands are now separate measurands. Enrolment into an additional instrument for derived fibrinogen is no longer required.

**HemoScreen** [Catalogue Number: 11570102]

Enrolment for PixCell HemoScreen instruments only. Additional instruments and additional material enrolments are available.

**What's new:** NEW

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 3.0 mL

**Schedule:** March, July, September, November

**Measurand/Test:** White Blood Cells (WBC); Red Blood Cells (RBC); Haemoglobin (Hb); Haematocrit (HCT); Mean Cell Volume (MCV); Mean Cell Haemoglobin (MCH); Mean Cell Haemoglobin Concentration (MCHC); Red Cell Distribution Width - CV (RDW-CV); Platelet (PLT); Mean Platelet Volume (MPV) WBC Differential (Neut, Lymph, Mono, Eos, Baso)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** Assessment: Quantitative with APS

**Malarial Parasite** [Catalogue Number: 11260102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Virtual images

**Schedule:** May, October

**Malarial Parasite: Rapid Diagnostic** [Catalogue Number: 11270102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** HRP-II in buffer with whole blood

**Sample volume:** 100uL

**Schedule:** May, October

**Measurand/Test:** Malarial Parasite Rapid Diagnostic Test

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Morphology** [Catalogue Number: 11290102]

Stained Peripheral Blood Smears or Virtual images provided to assess the capabilities to describe and diagnose blood film morphology.

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Blood Film and/or virtual images. USBs optional.

**Schedule:** January, March, May, July, September, November

**Measurand/Test:** White cell, red cell, platelet descriptions and diagnostic interpretation of blood films

**Additional Comments:** Enrol in Blood Film Differential Count for cell counting

**Multiplate** [Catalogue Number: 11550102]

Program suitable for detecting platelet function inhibition using the Multiplate instrument. Participants will need to add normal hirudinised blood to the tubes provided.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Tube coated with antagonist

**Schedule:** May, November

**Measurand/Test:** TRAP test - Inhibition level, TRAP test - Area under the curve

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Paediatric Morphology** [Catalogue Number: 11300102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Virtual images. USBs optional.

**Schedule:** April, September

**Measurand/Test:** White cell, red cell, platelet descriptions and diagnostic interpretation of paediatric blood films

**Paroxysmal Nocturnal Haemoglobinuria** [Catalogue Number: 11220102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 1mL

**Measurand/Test:** Paroxysmal Nocturnal Haemoglobinuria - PNH Testing

**Storage and Handling:** Analysis must be performed within 24 hours. For BD biosciences systems: the sample vials should be maintained at 2°-10°C until use. For Beckman Coulter systems: the vials should be maintained at 18°-30°C until use.

**Additional Comments:** The material assayed is fresh whole blood, which quickly deteriorates under normal transport conditions and should be tested within 3-4 days of dispatch. As such this program is only available to a limited number of destinations outside Australia, New Zealand, Malaysia, Singapore and Hong Kong. Please contact Customer Service at [customer.service@rcpaqap.com.au](mailto:customer.service@rcpaqap.com.au) if you are outside these areas. Schedules are dependent on patients availability. Notification will be sent by email on the day of dispatch.

\* Schedules are dependant on patients availability

**PoCT: Condensed Full Blood Count (For Australian and NZ Participants only)** [Catalogue Number: 11310102]

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 1.5mL

**Schedule:** February, April, June, August, October, December

**Measurand/Test:** White Blood Cells (WBC); Red Blood Cells(RBC); Haemoglobin (Hb); Haematocrit (HCT) ; Mean Cell Volume (MCV); Mean Cell Haemoglobin (MCH); Mean Cell Haemoglobin Concentration (MCHC); Red Cell Distribution Width - CV (RDW-CV); Platelet (PLT); Mean Platelet Volume (MPV)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** This program is only available to participants in Australia and New Zealand



**PoCT: HemoCue WBC Automated Differential** [Catalogue Number: 11330102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 2mL

**Schedule:** March, June, September and December

**Measurand/Test:** WBC Differential; WCC, Neuts, Lymph, Mono, Eos, Baso

**Storage and Handling:** Upon receipt, store samples at 2-8°C. Ensure vials remain upright.

**Point of Care - INR** [Catalogue Number: 11340102]

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma + H<sub>2</sub>O + CaCl<sub>2</sub>

**Sample volume:** 0.5mL

**Schedule:** January, March, May, July, September, November

**Measurand/Test:** International Normalised Ratio (INR)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Reticulocyte - Option 1 Manual** [Catalogue Number: 11350102]

Option 1: Manual Reticulocyte counting

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 1-2mL

**Schedule:** February, April, June, August, October and December

**Measurand/Test:** Reticulocyte count % and Absolute

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Reticulocyte - Option 2 Automated** [Catalogue Number: 11360102]

Option 2: Sysmex XE, XT, XS, XN, XN-L series, Mindray BC 6000 series, Abbott 3200/Ruby, 4000/Sapphire, Alinity hq,

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 1-2mL

**Schedule:** February, April, June, August, October and December

**Measurand/Test:** RCC, Reticulocyte count % and Absolute

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** If the instrument, series or manufacturer used is not listed in any of the options, please contact us prior to enrolment.

### **Reticulocyte - Option 3 Beckman Coulter** [Catalogue Number: 11370102]

Option 3: Beckman Coulter LH series UniceL DxH series and DxH 690t

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood

**Sample volume:** 1-2mL

**Schedule:** February, April, June, August, October and December

**Measurand/Test:** RCC, Reticulocyte count % and Absolute

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** If the instrument, series or manufacturer used is not listed in any of the options, please contact us prior to enrolment.

### **Sickling Test** [Catalogue Number: 11580102]

Detection of Haemoglobin S using screening or confirmatory methods. Suitable for solubility, reduced oxygen and ICT/kit-based methods.

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Stabilised fresh whole blood

**Sample volume:** 1.2 mL

**Measurand/Test:** Red cell sickling and reaction strength if applicable

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** Assessment: Qualitative with Positive, Negative, Invalid and

\* Schedules are dependant on patients availability

**Special Haemostasis: Activated Protein C resistance** [Catalogue Number: 11380102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** February and August

**Measurand/Test:** Activated Protein C resistance

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Special Haemostasis: Apixaban (Anti Xa)** [Catalogue Number: 11390102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** March, September

**Measurand/Test:** Apixaban (Anti Xa)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Special Haemostasis: Dabigatran** [Catalogue Number: 11400102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** March, September

**Measurand/Test:** Dabigatran (direct Thrombin Inhibitor)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Special Haemostasis: FVIII Inhibitor** [Catalogue Number: 11410102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** April, October

**Measurand/Test:** Factor VIII Inhibitor

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Special Haemostasis: FXIII** [Catalogue Number: 11420102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** April, October

**Measurand/Test:** Factor XIII (Screen and assay)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Special Haemostasis: Low Molecular Weight Heparin monitoring** [Catalogue Number: 11430102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** March, September

**Measurand/Test:** Low Molecular Weight Heparin monitoring

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Special Haemostasis: Lupus Anticoagulant** [Catalogue Number: 11440102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 1

**Sample Type:** Lyophilised plasma

**Sample volume:** 2 x 1 mL

**Schedule:** February, May, August, November

**Measurand/Test:** Lupus Anticoagulant

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Special Haemostasis: PFA-100/200** [Catalogue Number: 11450102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Tube with dried agonist

**Schedule:** May, November

**Measurand/Test:** PFA-100/200

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Special Haemostasis: Rivaroxaban (Anti Xa)** [Catalogue Number: 11470102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** March, September

**Measurand/Test:** Rivaroxaban (Anti Xa)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Special Haemostasis: Thrombophilia** [Catalogue Number: 11460102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** February and August

**Measurand/Test:** Protein C, Protein S and Antithrombin

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Special Haemostasis: Unfractionated Heparin monitoring** [Catalogue Number: 11400102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** March, September

**Measurand/Test:** Unfractionated Heparin monitoring

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Additional Comments:** Participants enrolling in the Heparin Monitoring must enrol in both options if monitoring unfractionated and low molecular weight heparin.

**Special Haemostasis: von Willebrand Factor** [Catalogue Number: 11490102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma

**Sample volume:** 1mL

**Schedule:** April, October

**Measurand/Test:** von Willebrand Factor Antigen, Activity, Ristocetin Co-Factor, Collagen binding, FVIII Coagulant, Ratios, Multimers, Diagnosis

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Thromboelastography: TEG-5000** [Catalogue Number: 11500102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma + Diluent + CaCl<sub>2</sub> (TEG-5000 only)

**Sample volume:** 1.5 mL

**Schedule:** April, October

**Measurand/Test:** Clotting Test

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Thromboelastography: TEG-6s** [Catalogue Number: 11510102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma + Diluent

**Sample volume:** 1.5 mL

**Schedule:** April, October

**Measurand/Test:** Clotting Test

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Thromboelastometry: ClotPro** [Catalogue Number: 11560102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma + Diluent + CaCl<sub>2</sub> (ClotPro only)

**Sample volume:** 1.5 mL

**Schedule:** April, October

**Measurand/Test:** Clotting Test

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Thromboelastometry: ROTEM-Delta** [Catalogue Number: 11520102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma + Diluent

**Sample volume:** 1.5 mL

**Schedule:** April, October

**Measurand/Test:** Clotting Test

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Thromboelastometry: ROTEM-Sigma** [Catalogue Number: 11530102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised plasma + Diluent

**Sample volume:** 3.0 mL

**Schedule:** April, October

**Measurand/Test:** Clotting Test

**Storage and Handling:** Upon receipt, store samples at 2-8°C



# Immunology

Participating laboratories may select from a group of RCPAQAP Immunology program modules that comprehensively cover the assays performed in Clinical Immunology.

## **Adrenal Antibodies** [Catalogue Number: 17360102]

Material is supplied to determine the presence of Anti-adrenal antibodies.

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** February, May, July, October

**Measurand/Test:** Anti-adrenal antibodies

**Storage and Handling:** Upon receipt, store samples at -20°C

## **Anti-Saccharomyces Cerevisiae Antibodies** [Catalogue Number: 17030102]

Material is supplied for the quantitation and qualitative assessment of Anti-Saccharomyces cerevisiae antibodies (IgG, IgA)

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** February, April, May, July, September, November

**Measurand/Test:** Anti-Saccharomyces cerevisiae IgA and IgG Antibodies (ASCA)

**Storage and Handling:** Upon receipt, store samples at -20°C

## **Antinuclear Antibodies** [Catalogue Number: 17010102]

Material is supplied to determine the presence of Antinuclear antibodies including pattern, titre and appropriate commentary. 19 samples and 1 virtual sample are provided per year.

**Frequency (No of surveys/year):** 10

**Cases/samples per survey:** 2

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** February to November

**Measurand/Test:** Antinuclear antibodies pattern; Antinuclear antibodies titre (ANA)

**Storage and Handling:** Upon receipt, store samples at -20°C

**Antiphospholipid Antibodies** [Catalogue Number: 17020102]

Material is supplied for quantitation and qualitative assessment of Anticardiolipin and Anti-Beta 2-Glycoprotein 1 antibodies (IgG, IgA and IgM)

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** Monthly: February to May and July to October

**Measurand/Test:** Cardiolipin IgG, IgA and IgM antibodies (aCL Abs), B2 Glycoprotein 1 IgG, IgA and IgM antibodies (b2GP1 Abs)

**Storage and Handling:** Upon receipt, store samples at -20°C

**B Cell Subsets** [Catalogue Number: 17390102]

Material is supplied to quantitate B Cell Lymphocyte Subsets, specifically those related to Memory B Cell testing. The material assayed is fresh whole blood, which quickly deteriorates under normal transport conditions and should be tested within 48 hours of dispatch. As such this program is only available to a limited number of destinations outside Australia, New Zealand and Malaysia. Please contact Customer Service Team if you are outside these areas.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** EDTA whole blood

**Sample volume:** 1.3 mL

**Schedule:** May, September

**Measurand/Test:** B Cells of the following subtypes (percentage of PBLs and B Cells): memory B cells, naive B Cells, marginal zone B Cells, transitional B Cells, switched memory B cells, CD21low cells.

**Storage and Handling:** Samples must be tested within 24 hours of receipt. Store at room temperature (18-24°C ) until processing.

**Bee Venom IgE** [Catalogue Number: 17040102]

Material supplied for the quantitation and qualitative assessment of Specific IgE to B

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** February, March, May, June, July, August, September, November

**Measurand/Test:** Specific IgE to Bee Venom (*Apis mellifera*)

**Storage and Handling:** Upon receipt, store samples at -20°C

### **Coeliac Disease Antibodies** [Catalogue Number: 17060102]

Material is supplied for quantitation and qualitative assessment of Coeliac disease antibodies.

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** Monthly: February to May and July to October

**Measurand/Test:** Deamidated Gliadin IgG and IgA (DGP); Tissue transglutaminase IgG and IgA (tTG); Endomysial antibodies (EMA)

**Storage and Handling:** Upon receipt, store samples at -20°C

### **Cyclic Citrullinated Peptide** [Catalogue Number: 17070102]

Material is supplied for quantitation and qualitative assessment of Cyclic citrullinated peptide antibody

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** Monthly: February to May and July to October

**Measurand/Test:** Cyclic citrullinated peptide antibody (CCP)

**Storage and Handling:** Upon receipt, store samples at -20°C

### **Drug Allergens** [Catalogue Number: 17080102]

Material is supplied for quantitation and qualitative assessment of Specific IgE to a range of Drug Allergens

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** February, May, July, October

**Measurand/Test:** Specific IgE to Drugs (Latex, Morphine, Chlorhexidine, Penicilloyl V, Penicilloyl G, Cefaclor, Suxamethonium (Succinylcholine), Ampicilloyl, Amoxicilloyl)

**Storage and Handling:** Upon receipt, store samples at -20°C

**dsDNA and Associated Antibodies** [Catalogue Number: 17370102]

Material is supplied to determine the presence of dsDNA and associated antibodies (nucleosome and histone).

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** Monthly: February to May and July to October

**Measurand/Test:** dsDNA, nucleosome, histone.

**Storage and Handling:** Upon receipt, store samples at -20°C

**Extractable Nuclear Antigen (ENA) Antibodies** [Catalogue Number: 17380102]

Material is supplied to determine the presence of Extractable Nuclear Antigen (ENA) antibodies

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** Monthly: February to May and July to October

**Measurand/Test:** Extractable Nuclear Antigen (ENA) antibodies: SS-A (Ro60), SS-B, PCNA, Centromere, Jo-1, Pm-Scl, Sm, Ribosomal P, Ro52, RNP, Scl-70, DFS-70.

**Storage and Handling:** Upon receipt, store samples at -20°C

**Food Allergens** [Catalogue Number: 17090102]

Material is supplied for quantitation and qualitative assessment of Specific IgE to a range of Food Allergens

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** February, March, May, June, July, August, September, November

**Measurand/Test:** Specific IgE to Food Allergens (Prawn, peanut, cashew, cow's milk, egg, sesame seed, soy, wheat grain, Omega-5 gliadin, Ovomucoid, Ara-h2)

**Storage and Handling:** Upon receipt, store samples at -20°C

**Fungal and Avian Antibodies** [Catalogue Number: 17380202]

Material is supplied for the quantitation and qualitative assessment of Fungal and Avian antibodies.

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** February, May, July, October

**Measurand/Test:** IgG antibodies to Aspergillus fumigatus; IgG antibodies to Budgie; IgG antibodies to Pigeon

**Storage and Handling:** Upon receipt, store samples at -20°C

**High Sensitivity C Reactive Protein (hsCRP)** [Catalogue Number: 17120102]

Material is supplied for quantitation of high sensitivity CRP (<20mg/L)

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** Liquid sample

**Sample volume:** 500uL

**Schedule:** Monthly: February to May and July to October

**Measurand/Test:** High sensitivity CRP (

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**HLA B27 Status** [Catalogue Number: 17130102]

Material is supplied to determine the presence of Human Leukocyte Antigen B27. The material assayed is fresh whole blood, which quickly deteriorates under normal transport conditions and should be tested within 48 hours of dispatch. As such this program is only available to a limited number of destinations outside Australia, New Zealand and Malaysia. Please contact Customer Service Team if you are outside these areas.

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** EDTA whole blood

**Sample volume:** 1mL

**Schedule:** February, March, May, June, July, August, September, November

**Measurand/Test:** Human Leukocyte Antigen B27 (HLA B27)

**Storage and Handling:** Samples must be tested within 24 hours of receipt. Store at room temperature (18-24°C) until processing.

**Additional Comments:** The material assayed is fresh whole blood, which quickly deteriorates under normal transport conditions and should be tested within 48 hours of dispatch. As such this program is only available to a limited number of destinations outside Australia, New Zealand and Malaysia. Please contact Customer Service at [customer.service@rcpaqap.com.au](mailto:customer.service@rcpaqap.com.au) if you are outside these areas.

**Immunoglobulin D** [Catalogue Number: 17150102]

Material is supplied for quantitation of serum Immunoglobulin D (IgD)

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** February, May, July, October

**Measurand/Test:** Immunoglobulin D (IgD)

**Storage and Handling:** Upon receipt, store samples at -20°C

**Immunoglobulin E** [Catalogue Number: 17160102]

Material is supplied for quantitation of serum Immunoglobulin E (IgE)

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** February, March, May, July, August, October

**Measurand/Test:** Immunoglobulin E (IgE)

**Storage and Handling:** Upon receipt, store samples at -20°C

## Immunoglobulin G Subclasses [Catalogue Number: 17140102]

Material is provided for quantitation and qualitative assessment of IgG subclasses

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** February, March, May, June, July, August, September, November

**Measurand/Test:** IgG1, IgG2, IgG3, IgG4, Calculated subclass sum and IgG level obtained by total IgG assay

**Storage and Handling:** Upon receipt, store samples at -20°C

## Immunology Case Study [Catalogue Number: 17050302]

This program offers Immunology clinical case studies. This is a paperwork only program and no samples are provided. Five clinical cases are provided per year and the program is available to all staff from an enrolled Participant site.

**Frequency (No of surveys/year):** 5

**Cases/samples per survey:** 1

**Sample Type:** No sample

**Schedule:** February, April, June, August, October

## Immunophenotyping [Catalogue Number: 17170102]

Material is supplied to quantitate T and B Cell Lymphocyte Subsets (Percentages and Absolute Numbers). The material assayed is fresh whole blood, which quickly deteriorates under normal transport conditions and should be tested within 3-4 days of dispatch. As such this program is only available to a limited number of destinations outside Australia, New Zealand, Malaysia, Singapore and Hong Kong. Please contact the Customer Service Team if you are outside these areas.

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 2

**Sample Type:** EDTA whole blood with commercial cell stabiliser

**Sample volume:** 1.2mL

**Schedule:** February, March, May, June, July, August, September, November

**Measurand/Test:** Lymphocytes of the following phenotypes (percentages): CD3+, CD3+CD4+, CD3+CD8+, CD19+, CD3-CD16+, CD3-CD56+, CD3-CD16+CD56+, Alpha-Beta|Double negative or double positive lymphocyte percentages|Lymphocytes of the following phenotypes (absolute numbers); CD3+, CD3+CD4+, CD3+CD8+, CD19+

**Storage and Handling:** Samples must be tested within 24 hours of receipt. Store at room temperature (18-24°C) until processing.

**Additional Comments:** The material assayed is fresh whole blood, which quickly degrades under certain conditions and should be tested within 3-4 days of dispatch. As such this program is only available for destinations outside Australia, New Zealand, Malaysia, Singapore and Hong Kong. Please contact Customer Service at [customer.service@rcpaqap.com.au](mailto:customer.service@rcpaqap.com.au) if you are outside these areas.

### **Inhalant Allergens** [Catalogue Number: 17180102]

Material is supplied for quantitation and qualitative assessment of Specific IgE to a range of Inhalant Allergens

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 1mL

**Schedule:** February, March, May, June, July, August, September, November

**Measurand/Test:** Specific IgE to Cat epithelium/dander, Rye grass pollen, Bermuda grass, House dust mite (*Dermatophagoides pteronyssinus*), *Aspergillus fumigatus*, *Alternaria alternata/tenuis*, Grass Pollen mix, Animal Epithelium mix, Mould mix, Birch

**Storage and Handling:** Upon receipt, store samples at -20°C

### **Liver Antibodies** [Catalogue Number: 17190102]

Material is supplied to determine the presence of Liver Specific Antibodies.

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** February, May, July, October

**Measurand/Test:** Liver specific autoantibodies: AMA-M2, M2-3E, LKM-1, LC-1, SLA/LP, Sp100, gp210, PML, Ro-52

**Storage and Handling:** Upon receipt, store samples at -20°C

### **Myasthenia Gravis Antibodies** [Catalogue Number: 17210102]

Material is supplied for assessment of the presence of Acetylcholine Receptor antibodies and Skeletal Muscle antibodies

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 1

**Sample Type:** Serum/Plasma

**Sample volume:** 400uL



**Schedule:** February, May, July, October

**Measurand/Test:** Acetylcholine Receptor Antibodies (AChR); Skeletal (Striated) Muscle Antibodies (Anti-Str)

**Storage and Handling:** Upon receipt, store samples at -20°C

**Myositis Specific and Scleroderma Antibodies** [Catalogue Number: 17220102]

Material is supplied to determine the presence of Myositis specific or Scleroderma antibodies

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** February, April, May, July, September, November

**Measurand/Test:** Myositis and scleroderma antibodies: Mi-2, Mi-2a, MI-2b, Ku, RNA Pol III, Cenp A, Cenp B, MDA5, NXP2, SAE, TIF1g, PL-7, PL-12, OJ, EJ, Jo-1, PM-Scl75, PM-Scl100, SRP, Ro52, Scl-70, Fibrillarin, NOR-90, Th/To, PDGFR, cN-1A, HMGCR, others as appropriate

**Storage and Handling:** Upon receipt, store samples at -20°C

**Neuronal Antibodies** [Catalogue Number: 17230102]

Material is supplied to determine the presence of Neuronal antibodies

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** February, March, May, June, July, August, September, November

**Measurand/Test:** Antibodies to Paraneoplastic Antigens (Hu, Yo, Ri, CV2, PNMA2 (Ma2/Ta), Amphiphysin, Recoverin, SOX1, Titin, Zic4, GAD65, Tr (DNER)); Anti-NMDA Receptor Antibodies (NMDA-R,); Neuromyelitis Optica Antibodies (NMO/AQP4)

**Storage and Handling:** Upon receipt, store samples at -20°C

**Paraproteins** [Catalogue Number: 17240102]

Material is supplied to measure and report electrophoresis fractions and determine the presence (identification and quantitation) of paraproteins

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 2

**Sample Type:** Serum and Urine

**Sample volume:** 500uL and 20mL

**Schedule:** February, March, May, June, July, August, September, November

**Measurand/Test:** Serum electrophoresis fractions (albumin, alpha-1, alpha-2, beta, beta-1, beta-2, gamma, residual gamma); Paraprotein identification and concentration (urine)

**Storage and Handling:** Upon receipt, store samples at -20°C

**Procalcitonin** [Catalogue Number: 17250102]

Material is supplied for quantitation (or semi-quantitation) of Procalcitonin

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** Lyophilised serum

**Sample volume:** 500uL

**Schedule:** Monthly: February to May and July to October

**Measurand/Test:** Procalcitonin (PCT)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Rheumatoid Factor** [Catalogue Number: 17270102]

Material is supplied for quantitation and qualitative assessment of Rheumatoid Factor.

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** February, March, May, July, August, October

**Measurand/Test:** Rheumatoid Factor (RF)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Serum Free Light Chains** [Catalogue Number: 17280102]

Material is supplied for quantitation and qualitative assessment of Serum Free Light Chains and Serum Free Light Chain Ratio

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** Lyophilised serum

**Sample volume:** 500uL

**Schedule:** February, March, May, June, July, August, September, November

**Measurand/Test:** Serum free kappa light chains (FKLC); Serum free lambda light chains (FLLC); Serum free light chain ratio (K:L Ratio)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

### **Skin Antibodies** [Catalogue Number: 17290102]

Material is supplied to determine the presence of Skin antibodies

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 650uL

**Schedule:** February, April, May, July, September, November

**Measurand/Test:** Skin Intercellular Substance antibodies (ICS), Skin Basement Membrane antibodies (BMZ), Desmoglein 1, Desmoglein 3, BP180, BP230.

**Storage and Handling:** Upon receipt, store samples at -20°C

### **Specific Proteins** [Catalogue Number: 17300102]

Material is supplied for quantitation of Specific Proteins

**Frequency (No of surveys/year):** 10

**Cases/samples per survey:** 2

**Sample Type:** Serum

**Sample volume:** 1mL

**Schedule:** February, March, April, May, June, July, August, September, October, November

**Measurand/Test:** Immunoglobulin G (IgG), Immunoglobulin A (IgA), Immunoglobulin M (IgM), Complement component 3 (C3), Complement component 4 (C4),  $\alpha$ -1-antitrypsin (A1AT, AAT), C1 esterase inhibitor (C1-inh), Haptoglobin (Hapt), Caeruloplasmin, Prealbumin (Transthyretin)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

### **Thyroid antibodies** [Catalogue Number: 17310102]

Material is supplied for quantitation and qualitative assessment of Thyroid antibodies

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** Monthly: February to May and July to October

**Measurand/Test:** Thyroglobulin antibodies (TgAb), Thyroid microsome antibodies (TPO), Thyroid receptor antibodies (TRAb), Thyroid Stimulating Immunoglobulin

**Storage and Handling:** Upon receipt, store samples at -20°C

**Tissue Autoantibodies** [Catalogue Number: 17320102]

Material is supplied to determine the presence of Tissue Autoantibodies

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** Monthly: February to May and July to October

**Measurand/Test:** Gastric Parietal Cell antibodies (APC), Smooth Muscle antibodies (SMA), F-Actin antibodies (F-actin), Mitochondrial antibodies (AMA), Liver/Kidney Microsome antibodies (LKM), Intrinsic Factor antibodies (Blocking antibody) (IF)

**Storage and Handling:** Upon receipt, store samples at -20°C

**Tryptase** [Catalogue Number: 17330102]

Material is supplied for quantitation of mast cell Tryptase

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** Lyophilised serum

**Sample volume:** 500uL

**Schedule:** February, March, May, June, July, August, September, November

**Measurand/Test:** Mast Cell Tryptase (Trypt)

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Type I Diabetes Antibodies** [Catalogue Number: 17340102]

Material is supplied for quantitation and qualitative assessment of Type 1 Diabetes antibodies

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** Monthly: February to May and July to October

**Measurand/Test:** Islet cell antibodies (ICA); Glutamic Acid Decarboxylase antibodies (GAD); Insulinoma-associated-2 autoantibodies (IA2 antibodies), Znt8

**Storage and Handling:** Upon receipt, store samples at -20°C

**Vasculitis Antibodies** [Catalogue Number: 17350102]

Material is supplied to determine the presence of Anti-Neutrophil Cytoplasmic antibodies (ANCA), Myeloperoxidase (MPO) antibodies, Proteinase 3 (PR3) antibodies and Anti-Glomerular Basement Membrane (GBM) antibodies

**Frequency (No of surveys/year):** 8

**Cases/samples per survey:** 1

**Sample Type:** Serum

**Sample volume:** 500uL

**Schedule:** Monthly: February to May and July to October

**Measurand/Test:** Anti-neutrophil Cytoplasmic Antibodies (ANCA), Myeloperoxidase Antibodies (MPO-ANCA), Proteinase 3 Antibodies (PR3-ANCA), Anti-glomerular basement membrane (GBM)

**Storage and Handling:** Upon receipt, store samples at -20°C

## KIMMS

The Key Incident Monitoring & Management Systems (KIMMS) project was initiated by the Royal College of Pathologists of Australasia (RCPA). KIMMS aims to monitor the pre- and post-analytical phase of the laboratory quality system and is designed to provide pathology practices with the tools for continuous measurement and monitoring of key incident quality indicators.

**KIMMS: Base Rate** [Catalogue Number: 21010102]

KIMMS (Key Incident Monitoring and Management System) monitors the pre- & post-analytical phase of the laboratory quality system and is designed to provide pathology practices with the tools for continuous measurement and monitoring of key incident quality indicators (QI). No samples are provided. Participants are asked to collect specific data from their LIS system and enter it online.

**Frequency (No of surveys/year):** 4

**Sample Type:** Data collection only

**Schedule:** January, April, July, October

**Additional Comments:** This program is not covered under the scope of accreditation by NATA.

## Microbiology

In addition to the comprehensive suite of EQA programs covering microbiology and molecular infectious disease testing, RCPAQAP offers tailored solutions that ensure laboratories maintain the highest standards in diagnostics and patient care.

Our programs are designed to meet global and national regulatory requirements, equipping laboratories with the tools to improve accuracy and performance in critical areas of disease detection.

One key advantage at the RCPAQAP is our ability to rapidly adapt to new threats, which supports laboratories worldwide in maintaining testing accuracy routinely and during recent pandemics.

### **Bacterial Serotyping** [Catalogue Number: 12010102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** February, July

**Measurand/Test:** Serotyping of *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Neisseria meningitidis*

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Bacteriology: Blood Culture Isolates** [Catalogue Number: 12020102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 1

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** February, April, July, October

**Measurand/Test:** Blood Culture Isolates, Antimicrobial susceptibility testing (anaerobe)

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Bacteriology: Faecal Pathogens** [Catalogue Number: 12030102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** February, April, July, October

**Measurand/Test:** Faecal Pathogens

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Bacteriology: Genital Swabs** [Catalogue Number: 12040102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 1

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** February, April, July, October

**Measurand/Test:** Genital Pathogens

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Bacteriology: Mycobacteriology Acid Fast Smears** [Catalogue Number: 12050102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Fixed unstained smear on glass slide



**Sample volume:** n/a

**Schedule:** March, June, September, November

**Measurand/Test:** Acid Fast bacilli

**Storage and Handling:** Upon receipt, store samples at room temperature and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Bacteriology: Mycobacteriology Culture** [Catalogue Number: 12060102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** March, June, September, November

**Measurand/Test:** Mycobacteriology Culture

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Bacteriology: Nose/Throat Pathogens** [Catalogue Number: 12070102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 1

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** March, June, September, November

**Measurand/Test:** Nose/Throat Pathogens

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Bacteriology: Respiratory Pathogens** [Catalogue Number: 12080102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** February, April, July, October

**Measurand/Test:** Respiratory Pathogens, Antimicrobial susceptibility testing

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Bacteriology: Skin/Eye/Ear Pathogens** [Catalogue Number: 12090102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 1

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** March, June, September, November

**Measurand/Test:** Skin/Eye/Ear Pathogens, Antimicrobial susceptibility testing

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Bacteriology: Urine** [Catalogue Number: 12100102 (1mL) / 12490102 (5mL)]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL or 5mL option

**Schedule:** March, June, September, November

**Measurand/Test:** Simulated clinical material provided to assess urine cell counts (manual and/or automated methods), and the detection and identification of urinary pathogens, bacteria count, and antimicrobial susceptibility testing

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological

### **Bacteriology: Wound Anaerobes** [Catalogue Number: 12110102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 1

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** February, April, July, October

**Measurand/Test:** Aerobic organisms, Anaerobic organisms, Antimicrobial susceptibility testing (aerobes)

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Clostridioides difficile: Laboratory Detection** [Catalogue Number: 12120102]

This unique program serves a global customer base. It combines culture, molecular, and toxin detection, with lyophilised samples ensuring stability, offering comprehensive testing for Clostridioides difficile detection.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 4

**Sample Type:** Lyophilised sample

**Sample volume:** 2mL

**Schedule:** July, November

**Measurand/Test:** Detection of Clostridium difficile culture, antigen and toxin

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Detection of Antimicrobial Resistance** [Catalogue Number: 12540102]

This program is designed to identify critical antimicrobial-resistant organisms aligned with Australia's CARAlert priority organisms. It evaluates laboratories on pathogen identification, resistance mechanisms, susceptibility testing, and overall interpretation (molecular or phenotypic). An effective measure for ensuring complete or referral-based antimicrobial resistance identification.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 5

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** April, September

**Measurand/Test:** Simulated clinical material provided to access the detection and identification of Vancomycin-resistant Enterococci (VRE), multi-drug resistant Enterococci, multi-drug resistant Neisseria gonorrhoeae, Multi-drug resistant Shigella and Salmonella, Carbapenem-resistant Enterobacterales (CRE), Carbapenem-resistant Acinetobacter baumannii (CRAB), Carbapenem-resistant Pseudomonas aeruginosa (CRPA) and Candida auris and other resistant bacteria. Molecular testing and antimicrobial susceptibility testing.

**Storage and Handling:** Upon receipt, store samples at 2-8°C. Protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Additional Comments:** Antimicrobial resistance (AMR) is a pressing global issue associated with nearly a million deaths annually, projected to exceed ten million by 2050. This program will access the laboratories' ability to detect and identify significant resistant organisms such as Vancomycin-resistant Enterococci (VRE), Methicillin-resistant Staphylococcus aureus (MRSA), Carbapenem-resistant Enterobacterales (CRE), Carbapenem-resistant Acinetobacter baumannii (CRAB) and others in a clinical setting.

### **Detection of Mycobacterium chimaera in Heater-Cooler Units (HCUs)** [Catalogue Number: 12530102]

Responding to the global rise in M. chimaera infections linked to cardiopulmonary bypass surgery, this program simulates real-world conditions using in-house lyophilised samples. With protocols aligned to Public Health England and Australian PHLN guidelines, it supports laboratories in identifying contamination risks and enhancing maintenance, cleaning, and disinfection practices for HCUs.

**What's new:** New for 2025

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 4

**Sample Type:** Lyophilised sample

**Sample volume:** 1 mL

**Schedule:** April

**Measurand/Test:** Simulated clinical material provided to assess the detection and identification of M. chimaera detection in Heater cooler units

**Storage and Handling:** Upon receipt, store samples at -20°C. Protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Endoscope and Bronchoscope Surveillance Culture** [Catalogue Number: 12130102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** March, September

**Measurand/Test:** Microbiological Surveillance Culture for endoscopes and bronchoscopes

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Helicobacter pylori Faecal Antigen** [Catalogue Number: 12580102]

Helicobacter pylori is associated with chronic gastritis, peptic ulcers, and gastric cancer, which affect both adult and paediatric populations. Noninvasive diagnostic tests, such as faecal antigen testing, have remarkably high sensitivity and specificity in diagnosing H. pylori infections.

**What's new:** New for 2025

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 3

**Sample Type:** Liquid sample

**Sample volume:** 1mL

**Schedule:** June, October

**Measurand/Test:** Simulated clinical material provided to assess the detection of H. pylori faecal antigen

**Storage and Handling:** Upon receipt, store samples at 2-8°C. Protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Molecular Alphavirus and Flavivirus** [Catalogue Number: 12210102]

Designed in response to the rise of Alphavirus and Flavivirus cases in the Asia-Pacific region, this program covers a wide range of viruses, including Zika and newly circulating strains like JEV genotype IV. It supports laboratories in ensuring assay accuracy for species differentiation and includes Dengue typing to assess disease severity.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Liquid sample

**Sample volume:** 0.25mL

**Schedule:** February, August

**Measurand/Test:** Simulated clinical material provided to assess the detection and identification of Alphaviruses and Flaviviruses using molecular assays. Alphavirus Group, Barmah Forest virus, Chikungunya virus, Ross River virus, Sindbis virus, Flavivirus Group, Dengue virus, Japanese Encephalitis virus, Kunjin virus, Murray Valley Encephalitis virus, Yellow Fever virus, West Nile virus, Zika virus

**Storage and Handling:** Upon receipt, store samples at -70°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Dangerous Goods (UN1845):** This survey material was packed in compliance with IATA PI.954 for Dry Ice, UN 1845

**Molecular Bordetella pertussis** [Catalogue Number: 12220102]

A dedicated program for detecting Bordetella pertussis enhances laboratory testing for this pathogen using single and multiplex testing methods. Differential organisms provide opportunities for challenging specificity, an important aspect affecting patient treatment and outcomes.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** February, October

**Measurand/Test:** Simulated clinical material provided to assess the detection of Bordetella pertussis including Bordetella parapertussis using molecular assays

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Molecular Chlamydia trachomatis and Neisseria gonorrhoeae** [Catalogue Number: 12230102]

A dual program for the molecular detection of C. trachomatis and N. gonorrhoeae is an essential adjunct to this stalwart testing by many laboratories. This program accommodates protocols for supplemental testing and final interpretation and allows participants to report according to clinical guidelines for N. gonorrhoeae testing.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Lyophilised sample

**Sample volume:** 5mL

**Schedule:** March, July

**Measurand/Test:** Simulated clinical material provided to assess the detection of Chlamydia trachomatis and Neisseria gonorrhoeae using molecular assays

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Molecular Coronavirus SARS-CoV-2** [Catalogue Number: 12430102]

Designed to support laboratories in detecting and identifying SARS-CoV-2, this program remains essential for assessing assays against current and evolving strains. It provides simulated respiratory samples to best replicate clinical samples to assess the entire testing process and ensure accurate and reliable patient results. Developed in collaboration with WHO reference laboratories, the program has proven instrumental in identifying key mutations, such as Omicron, and is positioned to meet ongoing and future laboratory needs as the virus evolves, enabling the review and critical analysis of assay target genes.

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Liquid sample

**Sample volume:** 1mL

**Schedule:** February, June, August, October

**Measurand/Test:** Simulated clinical material provided to assess the detection of Coronavirus SARS-CoV-2 using molecular assays with various gene target detection

**Storage and Handling:** Upon receipt, store samples at -70°C or -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN3373

### **Molecular CSF Pathogens** [Catalogue Number: 12500102]

Introduced in 2023, the Molecular CSF Pathogens Program offers a multiplex approach with simulated CSF samples for detecting critical pathogens. With regular updates to include new targets as assays advance, this program ensures laboratories remain equipped for accurate and comprehensive CSF pathogen detection.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Liquid Sample

**Sample volume:** 0.5mL

**Schedule:** June, August

**Measurand/Test:** Simulated clinical material provided to assess the detection and identification of pathogens in CSF

using molecular assays. Cryptococcus spp., Cytomegalovirus, Enterovirus, Haemophilus influenzae, Herpesvirus 6, Listeria monocytogenes, Neisseria meningitidis, Parechovirus, Streptococcus pneumoniae, Varicella zoster virus

**Storage and Handling:** Upon receipt, store samples at -70°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN3373

### **Molecular Cytomegalovirus** [Catalogue Number: 12240102]

Refined in 2022 to use liquid plasma for a closer representation of real samples, the Molecular Cytomegalovirus Program addresses the critical challenge of standardising CMV viral load reporting. By identifying variations in testing methods and assay standards, this program educates participants and drives progress toward achieving consistency in diagnostic practices, ensuring reliability and accuracy in CMV DNA testing.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Plasma

**Sample volume:** 1.2mL

**Schedule:** April, September

**Measurand/Test:** Clinical material provided to assess the qualitative and quantitative detection of CMV DNA. CMV Qualitative DNA, CMV Quantitative DNA, CMV Viral load

**Storage and Handling:** Upon receipt, store samples at -70°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Dangerous Goods (UN1845):** This survey material was packed in compliance with IATA PI.954 for Dry Ice, UN 1845

### **Molecular Dermatophytes** [Catalogue Number: 12590102]

This program evaluates molecular identification of a comprehensive range of dermatophytes, including Microsporum spp., Trichophyton spp., Nannizzia spp. and Epidermophyton spp., transitioning from morphology-based to molecular testing. Mixed and individual isolates included in this program provide laboratories with real-life challenges reflecting testing using multiplexed assays

**What's new:** New for 2025

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Liquid sample

**Sample volume:** 1mL

**Schedule:** June, November

**Measurand/Test:** Simulated clinical material provided to assess the detection and identification of dermatophytes



causing onychomycosis using molecular methods.

**Storage and Handling:** Upon receipt, store samples at 2-8°C. Protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Molecular Enterovirus** [Catalogue Number: 12250102]

The program features both Enterovirus and Coxsackieviruses for detection and also includes differential pathogens, including Rhinovirus and Parechovirus to determine assay specificity. An important laboratory test, particularly in children, this program is formulated to ensure accurate and reliable testing.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** March, July

**Measurand/Test:** Simulated clinical material provided to assess the detection of Enteroviruses including Parechovirus using molecular assays

**Storage and Handling:** Upon receipt, store samples at 2-8 °C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Molecular Gastrointestinal Pathogens: Bacteria** [Catalogue Number: 12260102]

This multiplex program features simulated faecal samples designed to feature key enteric bacterial pathogens, including circulating and mixed strains for a realistic testing experience. With tailored panels aligning to bacterial, viral, and parasite assays, this program identifies gaps in assay performance and sparks valuable investigations by manufacturers to refine targets and assays.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** February, July

**Measurand/Test:** Simulated clinical material provided to assess the detection of Gastrointestinal Bacteria Pathogens using molecular assays. Clinical material examples include: Aeromonas hydrophila, Campylobacter spp., Plesiomonas spp, Salmonella spp, Shigella spp, Vibrio spp, Yersinia spp

**Storage and Handling:** Upon receipt, store samples at 2-8 °C and protect from direct light. Testing within 24-48 hours is

recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Molecular Gastrointestinal Pathogens: Parasites** [Catalogue Number: 12270102]

This multiplex program features simulated faecal samples designed to feature key enteric parasitic pathogens, including circulating and mixed strains for a realistic testing experience. With tailored panels aligning to bacterial, viral, and parasite assays, this program identifies gaps in assay performance and sparks valuable investigations by manufacturers to refine targets and assays.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Liquid sample

**Sample volume:** 1mL

**Schedule:** March, November

**Measurand/Test:** Simulated clinical material provided to assess the detection of Gastrointestinal Parasite Pathogens using molecular assays. Clinical material examples include: Blastocystis hominis, Cryptosporidium spp, Dientamoeba fragilis, Entamoeba histolytica, Giardia spp

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Molecular Gastrointestinal Pathogens: Viral** [Catalogue Number: 12280102]

This multiplex program features simulated faecal samples designed to feature key enteric viral pathogens, including circulating and mixed strains for a realistic testing experience. With tailored panels aligning to bacterial, viral, and parasite assays, this program identifies gaps in assay performance and sparks valuable investigations by manufacturers to refine targets and assays.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Liquid sample

**Sample volume:** 0.5mL

**Schedule:** April, July

**Measurand/Test:** Simulated clinical material provided to assess the detection of Gastrointestinal Viral Pathogens using molecular assays. Clinical material examples include: Adenovirus, Astrovirus, Norovirus, Rotavirus, Sapovirus

**Storage and Handling:** Upon receipt, store samples at -70°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological

**Molecular Hepatitis B Virus DNA** [Catalogue Number: 12290102]

Designed to include a range of DNA levels and diverse genotypes, this program has driven the standardisation of viral load reporting, directly enhancing treatment outcomes. It ensures consistency and reliability in diagnostics while staying at the forefront of advancements in hepatitis testing.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Plasma

**Sample volume:** 1.2mL

**Schedule:** February, August

**Measurand/Test:** Clinical material provided to assess the qualitative and quantitative detection of Hepatitis B DNA. HBV Qualitative DNA, HBV Quantitative DNA, HBV Viral load

**Storage and Handling:** Upon receipt, store samples at -70°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Dangerous Goods (UN1845):** This survey material was packed in compliance with IATA PI.954 for Dry Ice, UN 1845

**Molecular Hepatitis C Virus RNA** [Catalogue Number: 12300102]

Designed to include a range of RNA levels and diverse genotypes, this program has driven the standardisation of viral load reporting, directly enhancing treatment outcomes. It ensures consistency and reliability in diagnostics while staying at the forefront of advancements in hepatitis testing.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Plasma

**Sample volume:** 1.2mL

**Schedule:** February, July

**Measurand/Test:** Clinical material provided to assess the qualitative and quantitative detection of Hepatitis C RNA. HCV Qualitative RNA, HCV Quantitative RNA, HCV Viral load

**Storage and Handling:** Upon receipt, store samples at -70°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Dangerous Goods (UN1845):** This survey material was packed in compliance with IATA PI.954 for Dry Ice, UN 1845

**Molecular Hepatitis C Virus RNA Genotyping** [Catalogue Number: 12310102]

Featuring a wide array of HCV genotypes, this program evolves to keep pace with a and progresses toward standardised reporting. Ensuring accurate genotype identification and interpretation, this program enables laboratories to support effective patient care.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Plasma

**Sample volume:** 1.2mL

**Schedule:** April, September

**Measurand/Test:** Clinical material provided to assess the genotyping of Hepatitis C virus

**Storage and Handling:** Upon receipt, store samples at -70°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Dangerous Goods (UN1845):** This survey material was packed in compliance with IATA PI.954 for Dry Ice, UN 1845

### **Molecular HIV-1 RNA** [Catalogue Number: 12330102]

Designed to include a range of RNA levels, this program has driven the standardisation of HIV viral load reporting, directly enhancing treatment outcomes and ensuring consistency and reliability in diagnostics.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Plasma

**Sample volume:** 1.2mL

**Schedule:** April, September

**Measurand/Test:** Clinical material provided to assess the qualitative and quantitative detection of HIV RNA. HIV Qualitative RNA, HIV-1 RNA Quantitative, HIV Viral load

**Storage and Handling:** Upon receipt, store samples at -70°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Dangerous Goods (UN1845):** This survey material was packed in compliance with IATA PI.954 for Dry Ice, UN 1845

### **Molecular HSV/VZV** [Catalogue Number: 12560102]

This program was developed by combining two programs to replicate the syndromic assessment of vesicle fluid for HSV and VZV. It enables pathogen detection, identification and differentiation of these human herpes viruses ensuring reliable patient results and clinical outcomes.

**What's new:** New for 2024

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Liquid sample

**Sample volume:** 0.5 mL

**Schedule:** April, October

**Measurand/Test:** Simulated clinical material provided to assess the detection and identification of HSV-1, HSV-2 and Varicella zoster virus using molecular assays.

**Storage and Handling:** Upon receipt, store samples at -70°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Molecular Human Papillomavirus DNA** [Catalogue Number: 12340102]

Utilising clinical samples that mimic real patient scenarios, this program challenges internal cell controls and accounts for contaminating factors including blood. Developed in close collaboration with WHO collaborating laboratories, it provides comprehensive coverage of different HPV risk groups and genotypes, ensuring accurate and reliable diagnostics.

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 3

**Sample Type:** PreservCyt(R) solution

**Sample volume:** 2mL (4mL hc2/Cervista)

**Schedule:** February, May, July, September

**Measurand/Test:** Clinical material provided to assess the detection and typing of high risk HPV DNA using molecular assays.

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Molecular Influenza** [Catalogue Number: 12350102]

Stay prepared for influenza outbreaks with the comprehensive Molecular Influenza Program. Expanding on targeted H5 and H1N1pdm programs, this combined offering now covers all influenza strains for detection and typing. Developed in close collaboration with WHO reference laboratories, it ensures the inclusion of currently circulating strains, providing laboratories with the tools to deliver precise and timely influenza diagnostics.

**Frequency (No of surveys/year):** 3

**Cases/samples per survey:** 6

**Sample Type:** Liquid sample

**Sample volume:** 1mL

**Schedule:** March, May, August

**Measurand/Test:** Simulated clinical material provided to assess the detection and typing of Influenza using molecular assays. Influenza A Matrix, Influenza A H1, Influenza A H1 (pandemic), Influenza A H3, Influenza A H5, Influenza A H7, Influenza A H9, Influenza A N1 (avian), Influenza A N1 (pandemic), Influenza B

**Storage and Handling:** Upon receipt, store samples at -70°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Molecular Malaria** [Catalogue Number: 12470102]

The Molecular Malaria program for the detection of malarial DNA features a simulated whole blood sample designed to closely mimic a clinical sample. It allows for the rapid detection of malarial species by molecular techniques and typing to species level. This program has already uncovered critical risks, such as carry-over contamination in molecular techniques, empowering laboratories to refine their practices and enhance diagnostic accuracy.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Whole Blood sample

**Sample volume:** 600µL

**Schedule:** April, August

**Measurand/Test:** Simulated clinical material provided to assess the molecular detection of Plasmodium spp.

**Storage and Handling:** Upon receipt, store samples at 2-8°C. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Molecular mec A/nuc gene** [Catalogue Number: 12370102]

This program offers an essential tool to ensure the accurate detection and identification of MRSA pathogens in the laboratory. It accommodates a wide range of testing assays, focusing on the mec A and nuc gene targets. It also allows for comparisons with other assay groups and within the same groups, which is paramount to ensuring these important pathogens are correctly reported.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** February, October

**Measurand/Test:** Simulated clinical material provided to assess the detection of MRSA (mecA/nuc genes) using

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Molecular Mycobacterium tuberculosis and M. avium complex** [Catalogue Number: 12360102]

This program is essential for the molecular detection of Mycobacterium tuberculosis and features M. avium complex, an important differential organism.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** April, September

**Measurand/Test:** Simulated clinical material provided to assess the detection of Mycobacterium tuberculosis & Mycobacterium avium complex and rifampicin resistance in M. tuberculosis complex using molecular assays

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Molecular Neisseria meningitidis** [Catalogue Number: 12380102]

This program focuses on the molecular detection of Neisseria meningitidis and includes various types to challenge laboratories with this important pathogen to ensure reliable and accurate patient results.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** February, June

**Measurand/Test:** Simulated clinical material provided to assess the detection of Neisseria meningitidis using molecular assays

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

## Molecular Rapid Diagnostics Influenza/RSV/SARS-CoV-2 [Catalogue Nu



The Molecular Rapid Diagnostics program is designed to detect and identify Influenza A and B, RSV, and SARS-CoV-2 using rapid molecular assays. It features a reduced panel of current circulating strains and a shorter survey time to simulate real-world clinical testing using these assays.

**Frequency (No of surveys/year):** 3

**Cases/samples per survey:** 4

**Sample Type:** Liquid sample

**Sample volume:** 1mL

**Schedule:** April, May, August

**Measurand/Test:** Simulated clinical material provided to assess the detection of Influenza, RSV and SARS-CoV-2 using molecular rapid detection methods. Influenza A, Influenza B, RSV and SARS-CoV-2

**Storage and Handling:** Upon receipt, store samples at -70°C or -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

## Molecular Respiratory Pathogens [Catalogue Number: 12400102]

This program is designed to be a true syndromic testing experience, featuring over 40 pathogens, including various virus types and bacterial strains. It allows for multiple testing platforms and assays and enables participants to identify and differentiate pathogens that would be experienced clinically. Continuous development enables this program to remain clinically relevant and expand to participant needs to continuously keep patient care at the forefront of mind.

**Frequency (No of surveys/year):** 3

**Cases/samples per survey:** 6

**Sample Type:** Liquid sample

**Sample volume:** 0.5mL

**Schedule:** March, June, September

**Measurand/Test:** Simulated clinical material provided to assess the detection and identification of Respiratory Pathogens using molecular assays. Multiplex Assays, surveys can include Adenovirus, Bocavirus, Bordetella pertussis, Bordetella parapertussis, Chlamydomphila pneumoniae, Coronavirus (229E, HKU1, OC43, NL63, SARS-CoV-2), Enterovirus, human Metapneumovirus, Haemophilus influenzae, Influenza, Legionella pneumoniae, Mycoplasma pneumoniae, Parechovirus, Parainfluenza 1-4, Pneumocystis jirovecii, Rhinovirus, RSV, Streptococcus pneumoniae

**Storage and Handling:** Upon receipt, store samples at -70°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

## Molecular Sexually Transmitted Pathogens [Catalogue Number: 12480102]

This program, developed in 2022, features simulated swabs and urine samples and expands routine testing beyond Ct/Ng to a broader range of STIs. It can detect drug-resistant organisms, enabling laboratories to stay ahead in



identifying and addressing emerging challenges in STI diagnostics.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Liquid sample

**Sample volume:** 2mL

**Schedule:** May, October

**Measurand/Test:** Simulated clinical material provided to assess the detection and identification of Sexually Transmitted Pathogens using molecular assays. Multiplex Assays, Chlamydia trachomatis, Herpes Simplex Virus, Mycoplasma genitalium, Neisseria gonorrhoeae, Treponema pallidum, Trichomonas vaginalis.

**Storage and Handling:** Upon receipt, store samples at -70°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Molecular Strongyloides** [Catalogue Number: 12520102]

This program provides simulated samples, developed in collaboration with world-leading experts, to ensure accurate DNA detection of the presence of Strongyloides spp. in faecal specimens. One of only two global offerings, it supports laboratories in maintaining proficiency in identifying this challenging pathogen.

**What's new:** New for 2025

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 3

**Sample Type:** Lyophilised Sample

**Sample volume:** 200µL

**Schedule:** April, October

**Measurand/Test:** Simulated clinical material provided to assess the detection of Strongyloides using molecular assays

**Storage and Handling:** Upon receipt, store samples at -20°C. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN3373

### **Molecular Vaccine Preventable Pathogens** [Catalogue Number: 12410102]

This program features vaccine-preventable pathogens such as measles, mumps, and rubella. It also includes other pathogens for differential identification, including VZV and influenza. A dedicated program for these pathogens allows improved coverage, enhancing laboratory testing confidence.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 6

**Sample Type:** Liquid sample

**Sample volume:** 0.5mL

**Schedule:** May, August

**Measurand/Test:** Simulated clinical material provided to assess the detection and identification of Vaccine Preventable Pathogens using molecular assays. Multiplex Assays, Bordetella sp, Influenza A/B, Measles, Mumps, Rubella, Varicella zoster virus

**Storage and Handling:** Upon receipt, store samples at -70°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Mycology** [Catalogue Number: 12140102]

This program offers detailed grading for identification and antifungal susceptibility testing, with expert commentary highlighting laboratory performance and potential issues. Annual updates to mycological nomenclature by the Australian Mycology Reference Laboratory ensure participants stay current. It also provides critical advice and education to address errors in methodology and interpretation.

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 3

**Sample Type:** Liquid

**Sample volume:** 1mL

**Schedule:** March, June, September, November

**Measurand/Test:** Dermatophytes, systemic mycotic pathogens, clinically significant yeast and contaminants of interest. Susceptibility testing of yeasts and aspergillus species.

**Storage and Handling:** Upon receipt, store samples at room temperature and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Non-tuberculous mycobacteria (NTM)** [Catalogue Number: 12460102]

Nontuberculous Mycobacteria (NTM) are categorised into slow-growing and rapid-growing, and both cause acute and chronic disease in immunocompromised and immunocompetent individuals. Accurate and timely diagnosis of these pathogens is necessary to limit the progression of pulmonary disease, lymphadenitis, cutaneous disease, and life-threatening disseminated disease in patients.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 3 samples per survey

**Sample Type:** Lyophilised bacteria

**Sample volume:** 1mL

**Schedule:** March, September

**Measurand/Test:** Simulated clinical material provided to assess the detection of Non-tuberculous Mycobacteria

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Parasitology** [Catalogue Number: 12160102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Fixed faecal suspensions or unstained glass slide

**Sample volume:** 1mL

**Schedule:** February, April, July, October

**Measurand/Test:** Faecal samples containing protozoa, helminths and faecal artefacts for parasitic staining and microscopy.

**Storage and Handling:** Upon receipt, store samples at room temperature and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

### **STAT Microscopy: Gram Stain** [Catalogue Number: 12440102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Unstained glass slides

**Schedule:** February, April, July, October

**Measurand/Test:** Gram stain

**Storage and Handling:** Upon receipt, store samples at room temperature. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

### **STAT Microscopy: Urine Microscopy** [Catalogue Number: 12170102 (1mL) / 12170502 (5mL)]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised samples

**Sample volume:** 1mL or 5mL options

**Schedule:** February, April, July, October

**Measurand/Test:** Simulated clinical material provided to assess the detection of urine cell counts (manual and/or automated methods)

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Streptococcus pneumoniae: urinary antigen detection** [Catalogue Number: 12180102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 4

**Sample Type:** Lyophilised sample

**Sample volume:** 1mL

**Schedule:** April, October

**Measurand/Test:** Detection of pneumococcal urinary antigen

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Urine Dipstick Chemistry** [Catalogue Number: 12190102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised sample

**Sample volume:** 10mL

**Schedule:** March, June, September, November

**Measurand/Test:** Leukocyte esterase, Blood, Glucose, Protein, Nitrite, Ascorbic acid, pH

**Storage and Handling:** Upon receipt, store samples at 2-8°C and protect from direct light. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

# Molecular Genetics

Genetics is an integral part of pathology with implications in disease pathogenesis and progression, identification of diagnostic and prognostic biomarkers, as well as targeted treatments. The RCPAQAP Molecular Genetics discipline offers diagnostic and technical proficiency testing programs for inherited diseases, oncology, molecular haematology and rare genetic disorders (as sample exchanges).

In addition, the RCPAQAP Molecular Genetics discipline partners with major external quality assurance providers to provide customers with as many options for molecular genetics testing as is currently available, this includes the:

European Molecular Genetics Quality Network (EMQN) - [View catalogue](#)

Cystic Fibrosis European Network (CF Network) - [View catalogue](#)

UK National External Quality Assessment Scheme for Leucocyte Immunophenotyping (UK NEQAS LI) - [View catalogue](#)

Quality Control for Molecular Diagnostics (QCMD) - [View Catalogue](#)

Australasian Society of Diagnostic Genomics (ASDG)

## **BCR-ABL Qualitative** [Catalogue Number: 23140102]

This module qualitatively assesses laboratory performance in the detection and identification of BCR-ABL fusion transcripts in chronic myeloid leukaemia (CML) and acute lymphoblastic leukaemia (ALL).

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** RNA

**Sample volume:** Up to 2µg of lyophilised, purified RNA provided in each case

**Schedule:** April, September

**Measurand/Test:** Molecular genetic testing for BCR-ABL1 fusion transcripts (p190, p210, e1a2, e1a3, e13a2, e13a3, e14a2, e14a3).

**Storage and Handling:** Upon receipt, store samples at -70°C or according to your standard operating procedure

**Additional Comments:** Available to order in myQAP under the Haematology Discipline

## **Chimerism Analysis** [Catalogue Number: 23150102]

This module quantitatively assesses laboratory performance in the evaluation and reporting of donor versus recipient cells in post-transplant peripheral blood or bone marrow specimens.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** DNA

**Sample volume:** Up to 1.5µg of purified DNA in TE pH 8.0 provided in each case

**Schedule:** February, July

**Measurand/Test:** Chimerism analysis of donor and recipient DNA.

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

**Additional Comments:** Available to order in myQAP under the Haematology Discipline

### **Coeliac Disease HLA Genotyping** [Catalogue Number: 23010102]

This module qualitatively assesses laboratory performance in the detection, reporting and interpretation of the HLA-DQ haplotypes and associated HLA-DQA1 and HLA-DQB1 alleles.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** DNA

**Sample volume:** 1µg of purified DNA in TE pH 8.0 provided in each case

**Schedule:** January, June

**Measurand/Test:** Molecular genetic testing for HLA-DQA1 and HLA-DQB1 alleles.

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

### **FLT3 ITD and TKD** [Catalogue Number: 23160102]

This module qualitatively and quantitatively assesses laboratory performance in the detection of internal tandem duplication (ITD) and tyrosine kinase domain (TKD) variants of the fms related receptor tyrosine kinase 3 (FLT3) gene.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** DNA

**Sample volume:** 1µg of purified DNA in TE pH 8.0 provided in each case

**Schedule:** March, August

**Measurand/Test:** Molecular genetic testing for FLT3 ITD and TKD gene variants.

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

**Additional Comments:** Available to order in myQAP under the Haematology Discipline

### **Hereditary Haemochromatosis (HFE)** [Catalogue Number: 23170102]

This module qualitatively assesses laboratory performance in the detection of hereditary variants (C282Y, H63D).

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** DNA

**Sample volume:** 1µg of purified DNA in TE pH 8.0 provided in each case

**Schedule:** February, July

**Measurand/Test:** Molecular genetic testing for HFE gene variants, C282Y and H63D.

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

**Additional Comments:** Available to order in myQAP under the Haematology Discipline

### **Human Leukocyte Antigen B\*57** [Catalogue Number: 23020102]

This module qualitatively assesses laboratory performance in the detection, reporting and interpretation of the HLA-B\*57:01 allele.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** DNA

**Sample volume:** 1µg of purified DNA in TE pH 8.0 provided in each case

**Schedule:** January, June

**Measurand/Test:** Molecular genetic testing for HLA-B\*57:01.

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

### **IDH Mutation Analysis in AML (IDH1, IDH2)** [Catalogue Number: 23180102]

This module qualitatively assesses laboratory performance in the detection of isocitrate dehydrogenase (IDH) 1 and 2 gene variants in acute myeloid leukaemia (AML).

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** DNA

**Sample volume:** 1µg of purified DNA in TE pH 8.0 provided in each case

**Schedule:** January, June

**Measurand/Test:** Molecular genetic testing for IDH1 and IDH2 gene variants.

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

**Additional Comments:** Available to order in myQAP under the Haematology Discip

**Immunogenotyping (IgH,TCR)** [Catalogue Number: 23190102]

This module qualitatively assesses laboratory performance in the detection of immunoglobulin heavy chain (IgH) and T-cell receptor (TCR) gene rearrangements.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** DNA

**Sample volume:** Up to 2µg of purified DNA in TE pH 8.0 provided in each case

**Schedule:** May, October

**Measurand/Test:** Molecular genetic testing for IgH and TCR gene rearrangement.

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

**Additional Comments:** Available to order in myQAP under the Haematology Discipline

**Kennedy's Disease** [Catalogue Number: 23070102]

This module qualitatively assesses laboratory performance in the detection of androgen receptor (AR) gene variants.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 2

**Sample Type:** DNA

**Sample volume:** 1µg of purified DNA in TE pH 8.0 provided in each case

**Schedule:** April

**Measurand/Test:** Molecular genetic testing for CAG trinucleotide repeat expansion in the AR gene.

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

**Additional Comments:** This program is not covered under the scope of accreditation by NATA. This is a sample exchange program where participating laboratories provide samples to RCPAQAP. All samples will be de-identified, re-labelled and distributed.

**Lymphoid NGS Panel Testing** [Catalogue Number: 23260102]

This module qualitatively assesses laboratory performance in the detection and reporting of various genes associated with lymphoid haematological malignancy using next generation sequencing (NGS).

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 1

**Sample Type:** DNA



**Sample volume:** 1µg of purified DNA in TE pH 8.0 provided in each case

**Schedule:** June

**Measurand/Test:** Next generation sequencing; Molecular genetic testing for ALK, ARID1A, ATM, BCL2, BCL6, BIRC3, B2M, BRAF, BTK, CARD11, CD274, CD79B, CDKN2A, CREBBP, CXCR4, DNMT3A, EP300, ETV6, EZH2, FOXO1, HAVCR2, ID3, IDH1, IDH2, IKZF1, JAK1, JAK2, JAK3, KLF2, KMT2A, KRAS, MEF2B, MYC, MYD88, NFKBIE, NOTCH1, NRAS, PDCD1LG2, PIM1, PTPRD, RHOA, RUNX1, SF3B1, SOCS1, STAT3, STAT5B, STAT6, TCF3, TET2, TNFAIP3, TP53, XPO1 gene variants

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

### **Maternal Cell Contamination** [Catalogue Number: 23090102]

This module qualitatively and quantitatively assesses laboratory performance in the detection, determination and interpretation of maternal cell contamination levels in mock prenatal samples.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2 family trios

**Sample Type:** DNA

**Sample volume:** 1µg of purified DNA in TE pH 8.0 provided in each case

**Schedule:** February, July

**Measurand/Test:** Maternal cell contamination studies.

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

### **Molecular Testing in Glioma (IDH1/2, MGMT)** [Catalogue Number: 23030102]

This module qualitatively assesses laboratory performance in the detection, reporting and interpretation of isocitrate dehydrogenase (IDH) 1 and 2 gene variants, and methylguanine-DNA Methyltransferase (MGMT) promoter methylation in glioma.

**What's new:** This program is previously called IDH Mutation Analysis in Glioma. MGMT promoter methylation is now included in this module.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** FFPE tissue sections (patient derived)

**Sample volume:** Virtual H&E and five unstained 6µM sections (mounted) provided in each case

**Schedule:** May, October

**Measurand/Test:** FFPE DNA extraction; Molecular genetic testing for IDH1 and IDH2 gene variants, MGMT gene methylation and variant allele frequency

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

## **Mutation Detection in Colorectal Cancer** [Catalogue Number: 23040102]

This module qualitatively assesses laboratory performance in the detection, reporting and interpretation of KRAS proto-oncogene, GTPase (KRAS), NRAS proto-oncogene, GTPase (NRAS) and/or B-Raf proto-oncogene, serine/threonine kinase (BRAF) gene variants in colorectal cancer.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** FFPE tissue sections (patient derived)

**Sample volume:** Virtual H&E and five unstained 6µM sections (mounted) provided in each case.

**Schedule:** April, September

**Measurand/Test:** FFPE DNA extraction; Molecular genetic testing for KRAS, NRAS and/or BRAF gene variants and variant allele frequency

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

## **Mutation Detection in Lung Cancer (NSCLC)** [Catalogue Number: 23050102]

This module qualitatively assesses laboratory performance in the detection, reporting and interpretation of epidermal growth factor receptor (EGFR) and/or KRAS proto-oncogene, GTPase (KRAS) gene variants in lung cancer.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** FFPE tissue sections (patient derived)

**Sample volume:** Virtual H&E and five unstained 6µM sections (mounted) provided in each case.

**Schedule:** May, October

**Measurand/Test:** FFPE DNA extraction; Molecular genetic testing for EGFR and/or KRAS gene variants and variant allele frequency

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

## **Mutation Detection in Melanoma** [Catalogue Number: 23060102]

This module qualitatively assesses laboratory performance in the detection, reporting and interpretation of B-Raf proto-oncogene, serine/threonine kinase (BRAF) and/or NRAS proto-oncogene, GTPase (NRAS) gene variants in melanoma.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** FFPE tissue sections (patient derived)

**Sample volume:** Virtual H&E and five unstained 6µM sections (mounted) provided in each case.

**Schedule:** April, September

**Measurand/Test:** FFPE DNA extraction; Molecular genetic testing for BRAF and NF frequency

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

**Myeloid NGS Panel Testing** [Catalogue Number: 23130102]

This module qualitatively assesses laboratory performance in the detection and reporting of various genes associated with acute myeloid leukaemia (AML) using next generation sequencing (NGS).

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 1

**Sample Type:** DNA

**Sample volume:** 1µg of purified DNA in TE pH 8.0 provided in each case

**Schedule:** April, September

**Measurand/Test:** Next generation sequencing; Molecular genetic testing for ASXL1, BCOR, BRAF, CALR, CBL, CEBPA, CSF3R, DDX41, DNMT3A, ETV6, EZH2, FLT3, GATA2, IDH1, IDH2, JAK2, KIT, KRAS, MPL, NPM1, NRAS, PTPN11, RUNX1, SETBP1, SF3B1, SRSF2, STAG2, TET2, TP53, U2AF1, WT1, ZRSR2 gene variants

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

**Additional Comments:** Available to order in myQAP under the Haematology Discipline.

**Myeloproliferative Neoplasms (JAK2, CALR, MPL)** [Catalogue Number: 23200102]

This module qualitatively assesses laboratory performance in the detection of janus kinase 2 (JAK2), calreticulin (CALR) and MPL proto-oncogene, thrombopoietin receptor (MPL) gene variants associated with myeloproliferative neoplasms.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** DNA

**Sample volume:** Up to 1.5µg of purified DNA in TE pH 8.0 provided in each case

**Schedule:** February, July

**Measurand/Test:** Molecular genetic testing for JAK2, CALR and MPL gene variants and JAK2 variant allele frequency

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

**Additional Comments:** Available to order in myQAP under the Haematology Discipline

**NPM1** [Catalogue Number: 23210102]

This module qualitatively assesses laboratory performance in the detection of nucleophosmin 1 (NPM1) gene variants.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** DNA

**Sample volume:** 1µg of purified DNA in TE pH 8.0 provided in each case

**Schedule:** March, August

**Measurand/Test:** Molecular genetic testing for NPM1 gene variants.

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

**Additional Comments:** Available to order in myQAP under the Haematology Discipline

**PML-RARA** [Catalogue Number: 23220102]

This module qualitatively assesses laboratory performance in the detection of PML nuclear body scaffold/retinoic acid receptor alpha (PML-RARA) fusion gene.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** RNA

**Sample volume:** Up to 2µg of lyophilised, purified RNA provided in each case

**Schedule:** April, September

**Measurand/Test:** Molecular genetic testing for PML-RARA fusion transcripts (bcr1, bcr2, bcr3).

**Storage and Handling:** Upon receipt, store samples at -70°C or according to your standard operating procedure

**Additional Comments:** Available to order in myQAP under the Haematology Discipline

**PTEN** [Catalogue Number: 23080102]

This module qualitatively assesses laboratory performance for the detection of phosphatase and tensin homolog (PTEN) gene variants.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 3

**Sample Type:** DNA

**Sample volume:** 1µg of purified DNA provided in each case

**Schedule:** March

**Measurand/Test:** Molecular genetic testing for PTEN gene variants.

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

**Additional Comments:** This program is not covered under the scope of accreditation by NATA. This is a sample exchange program where participating laboratories provide samples to RCPAQAP. All samples will be de-identified, re-labelled and distributed.

## Quality Assessment of DNA Extracts [Catalogue Number: 23100102]

This module assesses and validates the quality of genomic DNA extracts from various tissue types (except FFPE tissue). Participants will be required to extract and return DNA samples of their choice to the RCPAQAP for quality assessment.

Purity ratio of DNA extracts submitted will be assessed.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** DNA

**Sample volume:** n/a

**Schedule:** May, October

**Measurand/Test:** Genomic DNA extraction from any tissue type except FFPE.

## Quality Assessment of FFPE DNA Extracts [Catalogue Number: 23110102]

This module assesses and validates the quality of DNA extracts from FFPE tissue. Participants will be required to extract DNA from the tissue provided and return the DNA samples of their choice to the RCPAQAP for quality assessment.

Purity ratio of FFPE DNA extracts submitted will be assessed.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** FFPE tissue curl (cell line or patient derived)

**Sample volume:** One 15µM to 20µM FFPE section (vial) provided for DNA extraction.

**Schedule:** March, August

**Measurand/Test:** Genomic DNA extraction from FFPE.

## RCPAQAP DPYD Genotyping [Catalogue Number: 23290102]

This module qualitatively assesses laboratory performance in the detection, reporting and interpretation of clinically relevant dihydropyrimidine dehydrogenase (DPYD) variants for fluoropyrimidine toxicity.

**What's new:** New for 2025

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 2

**Sample Type:** Purified DNA

**Schedule:** August

**Measurand/Test:** Molecular testing of clinically relevant DPYD variants

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your s

### **RCPAQAP Non-Small Cell Lung Carcinoma Panel Testing** [Catalogue Number: 23280102]

This module qualitatively assesses laboratory performance in the detection, reporting and interpretation of nucleic acid-based multi-gene panel test of non-small cell lung carcinoma for variants in EGFR, BRAF, KRAS, MET and fusion status of ALK, ROS1, RET and NTRK1/2/3.

**What's new:** New for 2025

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 2

**Sample Type:** Virtual H&E and five unstained 6µM sections (mounted) provided in each case

**Schedule:** May

**Measurand/Test:** Molecular genetic testing for EGFR, BRAF, KRAS and MET exon 14, and fusion status of ALK, ROS1, RET, NTRK1, NTRK2 and NTRK3 genes

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

### **Reproductive Carrier Screening** [Catalogue Number: 23270102]

**What's new:** New for 2025

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** DNA

**Sample volume:** 1µg of purified DNA in TE pH8.0 provided in each case

**Schedule:** March, August

**Measurand/Test:** Genotyping and clinical interpretation of the CFTR, FMR1 and SMN1 genes

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

### **Sanger DNA Sequencing** [Catalogue Number: 23120102]

This is a technical module to assess laboratory performance in Sanger sequencing. There are two components in this module; (i) Technical component - participants are required to submit raw sequencing data files for analysis, (ii) Diagnostic component - participants are required to report gene variants detected.

Variant nomenclature and zygosity status of variant detected will be assessed under the Diagnostic component.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 1

**Sample Type:** PCR products and sequencing primers

**Sample volume:** 20µL of PCR products provided in each case  
Lyophilised forward and reverse primers at 10µM

**Schedule:** March, August

**Measurand/Test:** PCR product clean-up; Post-sequencing clean-up; Sanger sequencing

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

**Thalassaemia (alpha, beta)** [Catalogue Number: 23230102]

This module qualitatively assesses laboratory performance in the detection and interpretation of a-thalassemia (HBA1/HBA2) and/or b-thalassemia (HBB) gene variants.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** DNA

**Sample volume:** Up to 1.5µg of purified DNA in TE pH 8.0 provided in each case

**Schedule:** May, October

**Measurand/Test:** Molecular genetic testing for HBA1/HBA2 and/or HBB gene variants.

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

**Additional Comments:** Available to order in myQAP under the Haematology Discipline

**Thrombosis (F5, F2)** [Catalogue Number: 23240102]

This module qualitatively assesses laboratory performance in the detection of coagulation factor V (F5) and coagulation factor II, thrombin (F2) gene variants.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** DNA

**Sample volume:** 1µg of purified DNA in TE pH 8.0 provided in each case

**Schedule:** February, July

**Measurand/Test:** Molecular genetic testing for F5 and F2 gene variants.

**Storage and Handling:** Upon receipt, store samples at 2-8°C or according to your standard operating procedure

**Additional Comments:** Available to order in myQAP under the Haematology Discipline

**TP53 Deletions at 17p13.1 in CLL (FISH)** [Catalogue Number: 23250102]

In collaboration with Australasian Society of Diagnostic Genomics (ASDG), this module qualitatively assesses laboratory performance in the detection of TP53 deletions at 17p13.1 in chronic lymphocytic leukaemia (CLL) using fluorescence in-situ hybridisation (FISH).

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 2

**Sample Type:** Interphase nuclei (bone marrow)

**Sample volume:** Two slides provided in each case

**Schedule:** July

**Measurand/Test:** Fluorescence in situ hybridisation testing for TP53 deletion in 17p13.1

**Storage and Handling:** Upon receipt, store samples at room temperature or according to your standard operating procedure

**Additional Comments:** Available to order in myQAP under the Haematology Discipline



# Serology

The RCPAQAP has a comprehensive range of EQA programs covering a variety of diagnostic tests used in infectious serological screening, surveillance and immunity evaluation.

Key features of the program include;

One sample dispatch per year with the exception of HIV Point-of-Care

Comprehensive assessment of over 50 analytes;

Detection of antibodies, antigens;

Result entry via the website;

Trend analysis with a minimum of 2 surveys/year (for most analytes);

Participants are able to request archived survey material, including relevant reports for validation studies. This may incur a postage and handling fee.

## **Alphavirus** [Catalogue Number: 20410102]

Clinical material provided to assess the detection of various Alphaviruses using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.35mL

**Schedule:** March, September

**Measurand/Test:** Barmah Forest Virus IgG; IgM; Total Antibody. Chikungunya Virus IgG; IgM; Total Antibody. Ross River Virus IgG; IgM; Total Antibody. Sindbis Virus IgG; IgM; Total Antibody

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

## **Bartonella** [Catalogue Number: 20490102]

**What's new:** NEW

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.2mL

**Schedule:** April

**Measurand/Test:** Bartonella IgG, Bartonella IgM, Bartonella Total Antibody

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Bordetella pertussis** [Catalogue Number: 20350102]

Clinical material provided to assess the detection of Bordetella pertussis using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.25mL

**Schedule:** February, August

**Measurand/Test:** Bordetella pertussis IgA; IgG; Bordetella pertussis Toxin & FHA IgA; Toxin & FHA IgG. Bordetella pertussis Toxin IgA; Toxin IgG; Toxin IgM.

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Brucella** [Catalogue Number: 20030102]

Clinical material provided to assess the detection of various Brucella species using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.3mL

**Schedule:** January, July

**Measurand/Test:** Brucella abortus Agglutination; Brucella melitensis Agglutination; Brucella abortus/melitensis/bovis/suis grp Agglutination; Brucella Anti-human Globulin; Brucella IgG-IgM Differential; CFT; IgG; IgM; Immunocapture-agglutination (ICA)

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with Substance Category B, UN 3373

**Chlamydia genus** [Catalogue Number: 20040102]

Clinical material provided to assess the detection of various Chlamydia species using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.3mL

**Schedule:** January, July

**Measurand/Test:** Chlamydia genus IgA; IgG; IgM; Total Antibody. Chlamydia pneumoniae IgA; IgG; IgM; Total Antibody. Chlamydia psittaci IgA; IgG; IgM; Total Antibody. Chlamydia trachomatis Antibody IgA; IgG; IgM

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Coronavirus SARS CoV-2 Antibodies** [Catalogue Number: 20460102]

Clinical material provided to assess the detection of Coronavirus (SARS CoV-2) antibodies using serological markers

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.5mL

**Schedule:** February, May, September, October

**Measurand/Test:** SARS CoV-2 Antibodies: IgA; IgG; IgM; Total Antibody; Point of Care; Spike Associated; Nucleocapsid only; Neutralising Antibody

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Coronavirus SARS-CoV-2 Antigen** [Catalogue Number: 20480102]

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Simulated respiratory sample

**Sample volume:** 0.5 ml

**Schedule:** March, May, August, October

**Measurand/Test:** Measurand/Test Simulated clinical material provided to assess the detection of Coronavirus SARS-CoV- 2 antigen

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Cryptococcal Antigen** [Catalogue Number: 20220102]

Clinical or culture material provided to assess the detection of Cryptococcal Antigen

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum or culture supernatant

**Sample volume:** 0.5mL

**Schedule:** April, September

**Measurand/Test:** Cryptococcus Antigen Detection

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Cytomegalovirus** [Catalogue Number: 20180102]

Clinical material provided to assess the detection of Cytomegalovirus using serological markers

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.6mL

**Schedule:** February, May, September, October

**Measurand/Test:** CMV Avidity; IgG; IgM; Total Antibody

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Dengue virus** [Catalogue Number: 20420102]

Clinical material provided to assess the detection of Dengue virus only using serological markers.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.4mL

**Schedule:** April, October

**Measurand/Test:** Dengue IgG: Sero-prevalence; Capture; IgM; NS1 Antigen; ICT NS1/IgG/IgM; Total Antibody

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Additional Comments:** Enrol in this program if you test for Dengue virus ONLY. Enrol in the Flavivirus program to assess the detection of flaviviruses including dengue virus.

### **Entamoeba** [Catalogue Number: 20230102]

Clinical material provided to assess the detection of Entamoeba using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.5mL

**Schedule:** April, September

**Measurand/Test:** Entamoeba IgG; Total Antibody

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Epstein Barr virus** [Catalogue Number: 20190102]

Clinical material provided to assess the detection of Epstein Barr Virus using serological markers

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.6mL

**Schedule:** February, May, September, October

**Measurand/Test:** EBV Avidity; EBV EA and EBNA IgA; EBV EA IgA; EBV EA IgG; EBV EBNA IgG; EBV EBNA IgM; EBV VCA IgA; EBV VCA IgG; EBV VCA IgM; Heterophile Antibody

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Flavivirus** [Catalogue Number: 20430102]

Clinical material provided to assess the detection of various Flaviviruses using serological markers/includes Dengue Fever

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.4mL

**Schedule:** March, September

**Measurand/Test:** Dengue IgG: Sero-prevalence; Capture; IgM; NS1 Antigen; ICT NS1/IgG/IgM; Total Antibody. Flavivirus IgG; IgM; Total Antibody. Japanese Encephalitis Virus IgG; IgM. Kokobera; IgM; Total Antibody. Kunjin (West Nile) Virus IgG; IgM; Total Antibody. Murray Valley Encephalitis Virus IgG; IgM; Total Antibody. Yellow Fever IgG; IgM. Zika Virus IgG; IgM; Total Antibody

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Additional Comments:** Enrol in this program to assess the detection of flaviviruses including dengue virus. If you test for Dengue virus only, enrol in the Dengue virus program.

**Helicobacter pylori** [Catalogue Number: 20050102]

Clinical material provided to assess the detection of Helicobacter pylori using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.35mL

**Schedule:** March, September

**Measurand/Test:** Helicobacter pylori; IgG; Total Antibody

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Hepatitis A** [Catalogue Number: 20120102]

Clinical material provided to assess the detection of Hepatitis A using serological markers

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.5mL

**Schedule:** February, April, May, August, September, November

**Measurand/Test:** Anti-HAV IgG; IgM; Total Antibody

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Hepatitis B** [Catalogue Number: 20130102]

Clinical material provided to assess the detection of Hepatitis B using serological markers

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 1.5mL

**Schedule:** February, April, May, August, September, November

**Measurand/Test:** HBsAg; HBsAg-Confirmatory; Anti-HBs; Anti-HBc; Anti-HBc IgM; HBeAg; Anti-HBe

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Hepatitis C** [Catalogue Number: 20140102]

Clinical material provided to assess the detection of Hepatitis C using serological markers

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.5mL

**Schedule:** February, April, May, August, September, November

**Measurand/Test:** HCV Ag; HCV Ag-Ab; Anti-HCV Ab; Anti-HCV-Confirmatory

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Hepatitis D** [Catalogue Number: 20150102]

Clinical material provided to assess the detection of Hepatitis D using serological markers

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.5mL

**Schedule:** May

**Measurand/Test:** HDAg; Anti-HD IgM; Anti-HDV Total Antibody

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Hepatitis E** [Catalogue Number: 20160102]

Clinical material provided to assess the detection of Hepatitis E using serological markers

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.3mL

**Schedule:** July

**Measurand/Test:** Anti-HEV IgG; Anti-HEV IgM;

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Herpes simplex** [Catalogue Number: 20440102]

Clinical material provided to assess the detection of Herpes Simplex Virus using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2



**Sample Type:** Serum/plasma

**Sample volume:** 0.5mL

**Schedule:** April, October

**Measurand/Test:** Herpes Simplex 1 & 2 IgG; Herpes Simplex - 1 IgG. Herpes Simplex - 2 IgG; Herpes Simplex 1 & 2 IgM. Herpes Simplex - 1 IgM; Herpes Simplex - 2 IgM. Herpes Simplex CFT; Herpes Simplex -Confirmatory Test

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Human Immunodeficiency Virus** [Catalogue Number: 20320102]

Clinical material provided to assess the detection of HIV using serological markers

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma/inactivated viral culture lysate

**Sample volume:** 1.0mL

**Schedule:** January, April, May, June, September, November

**Measurand/Test:** HIV Ag/Ab Combination; HIV Antibody ONLY; HIV Antigen ONLY; HIV Antigen ONLY Confirmatory; HIV 1/2 Antibody Confirmatory; HIV 1 Only Antibody Confirmatory; HIV 2 Only Antibody Confirmatory

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Human T-Lymphotropic Virus** [Catalogue Number: 20330102]

Clinical material provided to assess the detection of HTLV using serological markers

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.6mL

**Schedule:** January, April, May, August, September, November

**Measurand/Test:** HTLV Antibody; HTLV Confirmatory

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Hydatid** [Catalogue Number: 20240102]

Clinical material provided to assess the detection of Hydatid using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.25mL

**Schedule:** April, September

**Measurand/Test:** Hydatid IgG; Total Antibody; Western Blot

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Infectious Mononucleosis** [Catalogue Number: 20170102]

Clinical material provided to assess the detection of Infectious Mononucleosis

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.2mL

**Schedule:** January, April, May, August, September, November

**Measurand/Test:** Infectious Mononucleosis

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Influenza A and B Antibody** [Catalogue Number: 20360102]

Clinical material provided to assess the detection of Influenza A & Influenza B using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.5mL

**Schedule:** February, July

**Measurand/Test:** Influenza A IgA; IgG; IgM; Total Antibody. Influenza B IgA; IgG; IgM; Total Antibody.

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Legionella Antibody** [Catalogue Number: 20060102]

Clinical material provided to assess the detection of various Legionella species using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum

**Sample volume:** 0.3mL

**Schedule:** April, October

**Measurand/Test:** Legionella IgG; IgM; Total Antibody (EIA & IFA). L. pneumophila and L. longbeachae

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Legionella Antigen** [Catalogue Number: 20070102]

Clinical material provided to assess the detection of Legionella urinary antigen

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Urine

**Sample volume:** 1mL

**Schedule:** April, October

**Measurand/Test:** Legionella urinary L. pneumophila Antigen, L. longbeachae Antigen

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Leptospirosis** [Catalogue Number: 20250102]

Clinical material provided to assess the detection of Leptospirosis using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum

**Sample volume:** 0.5mL

**Schedule:** April, October

**Measurand/Test:** Leptospirosis Agglutination; IgG; IgM

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Lyme Disease** [Catalogue Number: 20260102]

Clinical material provided to assess the detection of Lyme Disease using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.5mL

**Schedule:** April, October

**Measurand/Test:** Lyme Disease IgG Confirmatory; IgM Confirmatory; IgG; IgM; Total Antibody

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Measles** [Catalogue Number: 20370102]

Clinical material provided to assess the detection of Measles using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.25mL

**Schedule:** February, July

**Measurand/Test:** Measles IgG; IgM; Total Antibody

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Mumps** [Catalogue Number: 20380102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.25mL

**Schedule:** February, July

**Measurand/Test:** Mumps IgG; IgM

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Mycoplasma** [Catalogue Number: 20080102]

Clinical material provided to assess the detection of Mycoplasma pneumoniae using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.5mL

**Schedule:** January, July

**Measurand/Test:** Mycoplasma IgA; IgG; IgM; Total Antibody

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Parvovirus** [Catalogue Number: 20450102]

Clinical material provided to assess the detection of Parvovirus using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.25mL

**Schedule:** April, October

**Measurand/Test:** Parvovirus IgG; IgM

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**PoCT: Human Immunodeficiency Virus** [Catalogue Number: 20290102]

Clinical material provided to assess the detection of HIV using Point of Care Assays

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Stabilised whole blood/inactivated viral culture lysate

**Sample volume:** 0.4mL

**Schedule:** March, May, August, October

**Measurand/Test:** HIV Antigen PoCT; HIV Antibody PoCT

**Storage and Handling:** HIV POCT are whole blood samples that are dispatched on the survey open date. Samples should be tested immediately on receipt. If not possible, samples should be stored at 2-8°C and testing performed as soon as practicable.

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**PoCT: Influenza A and B Antigen** [Catalogue Number: 20300102]

Simulated clinical material provided to assess the detection of Influenza antigen using Point of Care Assays

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Inactivated viral culture lysate

**Sample volume:** 0.5mL

**Schedule:** March, August

**Measurand/Test:** Influenza A Antigen PoCT; Influenza B Antigen PoCT

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**PoCT: RSV Antigen** [Catalogue Number: 20310102]

Simulated clinical material provided to assess the detection of RSV antigen using Point of Care Assays

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Inactivated viral culture lysate

**Sample volume:** 0.5mL

**Schedule:** March, August

**Measurand/Test:** RSV Antigen PoCT

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Q Fever** [Catalogue Number: 20390102]

Clinical material provided to assess the detection of Q Fever using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.4mL

**Schedule:** February, August

**Measurand/Test:** Q fever Phase 1 IgA; IgG; IgM; Total Antibody. Q fever Phase 2 IgA; IgG; IgM; Total Antibody

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**QuantiFERON (TB and CMV)** [Catalogue Number: 20090102]

Material provided to assess the detection of QuantiFERON - TB and CMV

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Lyophilised serum/plasma

**Schedule:** March, September

**Measurand/Test:** QuantiFERON, interferon gamma, TB, CMV

**Storage and Handling:** Upon receipt, store samples at 2-8°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Rickettsia** [Catalogue Number: 20100102]

Clinical material provided to assess the detection of various Rickettsial species using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.4mL

**Schedule:** April, October

**Measurand/Test:** Scrub Typhus Group IgG; IgM; Total Antibody. Spotted Fever Group IgG; IgM; Total Antibody. Typhus Group IgG; IgM ;Total Antibody.

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Rubella** [Catalogue Number: 20010102]

Clinical material provided to assess the detection of Rubella using serological markers

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.7mL

**Schedule:** January, April, July, October

**Measurand/Test:** Rubella Avidity; IgG; IgM

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Schistosomiasis** [Catalogue Number: 20270102]

Clinical material provided to assess the detection of Schistosomiasis using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.25mL

**Schedule:** April, October

**Measurand/Test:** Schistosomiasis Confirmatory; IgG; IgM; Total Antibody

**Storage and Handling:** Upon receipt, store samples at -20°C



**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Serology Case Study** [Catalogue Number: 20340102]

This program offers Serology clinical case studies. Five case studies or scenarios will be issued to enrolled participants and is available to all staff from an enrolled Participant site. This module is not assessed and is designed as an educational tool for staff.

**Frequency (No of surveys/year):** 5

**Cases/samples per survey:** 1

**Schedule:** February, April, May, August, October

**Measurand/Test:** Clinical case study

### **Streptococcus** [Catalogue Number: 20110102]

Clinical material provided to assess the detection of Group A Streptococcal using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.5mL

**Schedule:** March, September

**Measurand/Test:** Streptococcus ASOT; Streptozyme; Anti-DNase B

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

### **Strongyloides** [Catalogue Number: 20280102]

Clinical material provided to assess the detection of Strongyloides using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.2mL

**Schedule:** March, September

**Measurand/Test:** Strongyloides IgG

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological

**Syphilis** [Catalogue Number: 20020102]

Clinical material provided to assess the detection of Syphilis using serological markers

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.5mL

**Schedule:** January, April, July, October

**Measurand/Test:** Syphilis Agglutination (TPHA/TPPA); Confirmatory assay; FTA-ab; IgG; IgM; RPR; Total Antibody; VDRL; Point of Care

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Toxoplasma** [Catalogue Number: 20200102]

Clinical material provided to assess the detection of Toxoplasma using serological markers

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.6mL

**Schedule:** February, May, September, October

**Measurand/Test:** Toxoplasmosis Avidity; IgA; IgG; IgM; Total Antibody

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

**Varicella zoster** [Catalogue Number: 20400102]

Clinical material provided to assess the detection of Varicella zoster virus using serological markers

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** Serum/plasma

**Sample volume:** 0.35mL

**Schedule:** February, August

**Measurand/Test:** Varicella zoster IgG; IgM; Total Antibody

**Storage and Handling:** Upon receipt, store samples at -20°C

**Dangerous Goods (UN3373):** This survey material was packed in compliance with IATA PI.650 for Biological Substance Category B, UN 3373

## Synovial Fluid

The RCPAQAP Synovial Fluid discipline assesses the ability of laboratories to detect the key disease-related crystals (monosodium urate monohydrate, calcium pyrophosphate dihydrate) and to differentiate those from other crystalline structures such as corticosteroid, cholesterol and cartilage that may be found in synovial fluid.

### **Synovial Fluid Crystals** [Catalogue Number: 18010102]

The aim of this program is to assess the detection of key disease related crystals found in synovial fluid.

The Educational Component includes videos of microscopic examination of synovial fluid and is complementary with the program.

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 3

**Sample Type:** Synovial fluid

**Sample volume:** 25uL

**Schedule:** April, November

**Measurand/Test:** Monosodium urate monohydrate (Urate), calcium pyrophosphate dihydrate (CPPD) or other crystals

**Storage and Handling:** Upon receipt, store samples at room temperature. Testing within 24-48 hours is recommended to reduce the risk of sample deterioration.

**Additional Comments:** The Education Component is not covered under the scope of accreditation by NATA.

# Transfusion

The RCPAQAP Transfusion discipline covers all routine tests performed in a pre-transfusion testing laboratory including clinical decision making on given scenarios. The Individual Assessment program is designed to assist laboratory supervisors in maintaining and assess individual staff competencies while also enabling individual staff to meet EQA participation requirements as stipulated by the guidelines. The Foetal Maternal Haemorrhage Estimation program is for assessing laboratories on methods used in estimating foetal red cells in maternal samples.

## ABO Titration [Catalogue Number: 19170102]

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 3

**Sample Type:** Plasma and red cells

**Sample volume:** 4mL Plasma, 2 mL red cells

**Schedule:** January, October

**Measurand/Test:** anti-A titre, anti-B titre

**Storage and Handling:** Store samples at 2-8°C. RCPAQAP Transfusion samples must be tested within five (5) days of receipt because they are liable to haemolysis on prolonged storage. Some degree of haemolysis can be expected in the survey material, however based on historical records, there has been no negative effect in performance for participants reporting results on mild to moderately haemolysed survey samples. A haemolysis index diagram is provided.

**Additional Comments:** Designed for laboratories that performed BMT, Kidney and other solid organ donation with an ABO mismatched.

Report displayed will be according to clinical stream (i.e. BMT or Kidney)

Red cells closely represent actual patient samples

## Antibody Titre [Catalogue Number: 19030102]

The aim of this program is to assess the level of anti-D titre in the sample

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 1

**Sample Type:** Plasma

**Sample volume:** 2mL

**Schedule:** March, May, July, September

**Storage and Handling:** Store samples at 2-8°C. RCPAQAP Transfusion samples must be tested within five (5) days of receipt because they are liable to haemolysis on prolonged storage. Some degree of haemolysis can be expected in the survey material, however based on historical records, there has been no negative effect in performance for participants reporting results on mild to moderately haemolysed survey samples. A haemolysis index diagram is provided.

**Basic Compatibility** [Catalogue Number: 19040102]

This program is based on various clinical scenarios. Based on the clinical scenario, participants are required to perform blood group, antibody screen, DAT and crossmatch

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** Variable

**Sample Type:** EDTA whole blood and red cells

**Sample volume:** 4mL and 2mL

**Schedule:** January, March, May, July, September, November

**Measurand/Test:** Blood grouping, Antibody screen, Crossmatch/ compatibility testing, DAT

**Storage and Handling:** Store samples at 2-8°C. RCPAQAP Transfusion samples must be tested within five (5) days of receipt because they are liable to haemolysis on prolonged storage. Some degree of haemolysis can be expected in the survey material, however based on historical records, there has been no negative effect in performance for participants reporting results on mild to moderately haemolysed survey samples. A haemolysis index diagram is provided.

**Blood Grouping and Antibody Screen/Identification** [Catalogue Number: 19010102]

The aim of this program is to assess blood grouping only or antibody screen and identification.

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 2

**Sample Type:** EDTA whole blood

**Sample volume:** 6mL

**Schedule:** February, March, June, August, October, November

**Measurand/Test:** Blood grouping, Antibody Screen/Identification - Optional

**Storage and Handling:** Store samples at 2-8°C. RCPAQAP Transfusion samples must be tested within five (5) days of receipt because they are liable to haemolysis on prolonged storage. Some degree of haemolysis can be expected in the survey material, however based on historical records, there has been no negative effect in performance for participants reporting results on mild to moderately haemolysed survey samples. A haemolysis index diagram is provided.

**Fetomaternal Haemorrhage** [Catalogue Number: 19020102]

The aim of this program is to assess percentage and volume of fetal cells and the number of anti-D vials.

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 2

**Sample Type:** EDTA whole blood

**Sample volume:** 2mL

**Schedule:** February, March, August, October

**Measurand/Test:** Fetomaternal Haemorrhage Estimation

**Storage and Handling:** Store samples at 2-8°C. RCPAQAP Transfusion samples must be tested within 72 hours of receipt because they are liable to haemolysis on prolonged storage. Some degree of haemolysis can be expected in the survey material, however based on historical records, there has been no negative effect in performance for participants reporting results on mild to moderately haemolysed survey samples. A haemolysis index diagram is provided.

**General Compatibility** [Catalogue Number: 19050102]

This program is based on various clinical scenarios.

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** Variable

**Sample Type:** EDTA whole blood and red cells

**Sample volume:** 4mL and 2mL

**Schedule:** January, March, May, July, September, November

**Measurand/Test:** Blood grouping, Antibody screen, Antibody identification, Crossmatch/ compatibility testing, Phenotyping, DAT, Elution studies.

**Storage and Handling:** Store samples at 2-8°C. RCPAQAP Transfusion samples must be tested within five (5) days of receipt because they are liable to haemolysis on prolonged storage. Some degree of haemolysis can be expected in the survey material, however based on historical records, there has been no negative effect in performance for participants reporting results on mild to moderately haemolysed survey samples. A haemolysis index diagram is provided.

**Haemolytic Disease of the Newborn** [Catalogue Number: 19180102]

**What's new:** New for 2025

**Frequency (No of surveys/year):** 2

**Cases/samples per survey:** 2

**Sample Type:** EDTA whole blood and EDTA plasma

**Sample volume:** 2mL

**Schedule:** June, November

**Measurand/Test:** Blood grouping, antibody screen, antibody identification, DAT, elution studies

**Storage and Handling:** Store samples at 2-8°C. RCPAQAP Transfusion samples must be tested within five (5) days of receipt because they are liable to haemolysis on prolonged storage. Some degree of haemolysis can be expected in the

survey material, however based on historical records, there has been no negative effect in performance for participants reporting results on mild to moderately haemolysed survey samples. A haemolysis index diagram is provided.

### **Phenotyping** [Catalogue Number: 19060102]

The aim of this program is to assess on results for antisera held in laboratories.

**Frequency (No of surveys/year):** 4

**Cases/samples per survey:** 1

**Sample Type:** EDTA whole blood

**Sample volume:** 4mL

**Schedule:** March, May, July, September

**Measurand/Test:** Extended Red Cell Antigen Phenotyping

**Storage and Handling:** Store samples at 2-8°C. RCPAQAP Transfusion samples must be tested within five (5) days of receipt because they are liable to haemolysis on prolonged storage. Some degree of haemolysis can be expected in the survey material, however based on historical records, there has been no negative effect in performance for participants reporting results on mild to moderately haemolysed survey samples. A haemolysis index diagram is provided.

### **Snake Venom Detection** [Catalogue Number: 19080102]

A dry swab is supplied for the detection of Australian snake venom.

**Frequency (No of surveys/year):** 1

**Cases/samples per survey:** 1

**Sample Type:** Swab

**Sample volume:** n/a

**Schedule:** September

**Measurand/Test:** Snake venom detection

**Storage and Handling:** Samples should be stored at 2-8°C. RCPAQAP Transfusion samples must be tested within five (5) days of receipt.

### **Transfusion Competency - Antibody Identification Module (Overseas participants only)** [Catalogue

Number: 19090102]

The aim of this program is to assess antibody identification

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 1

**Sample Type:** EDTA whole blood

**Sample volume:** 4mL



**Schedule:** February, March, June, August, October, November

**Measurand/Test:** Antibody identification

**Storage and Handling:** Store samples at 2-8°C. RCPAQAP Transfusion samples must be tested within five (5) days of receipt because they are liable to haemolysis on prolonged storage. Some degree of haemolysis can be expected in the survey material, however based on historical records, there has been no negative effect in performance for participants reporting results on mild to moderately haemolysed survey samples. A haemolysis index diagram is provided.

**Transfusion Competency - Antibody Screen Module (Overseas participants only)** [Catalogue Number: 19100102]

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 1

**Sample Type:** EDTA whole blood

**Sample volume:** 4mL

**Schedule:** February, March, June, August, October, November

**Measurand/Test:** Antibody screen

**Storage and Handling:** Store samples at 2-8°C. RCPAQAP Transfusion samples must be tested within five (5) days of receipt because they are liable to haemolysis on prolonged storage. Some degree of haemolysis can be expected in the survey material, however based on historical records, there has been no negative effect in performance for participants reporting results on mild to moderately haemolysed survey samples. A haemolysis index diagram is provided.

**Transfusion Competency - Blood Grouping Module (Overseas participants only)** [Catalogue Number: 19110102]

The aim of this program is to assess blood grouping

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 3

**Sample Type:** EDTA whole blood and red cells

**Sample volume:** 4mL and 2mL

**Schedule:** February, March, June, August, October, November

**Measurand/Test:** Blood grouping

**Storage and Handling:** Store samples at 2-8°C. RCPAQAP Transfusion samples must be tested within five (5) days of receipt because they are liable to haemolysis on prolonged storage. Some degree of haemolysis can be expected in the survey material, however based on historical records, there has been no negative effect in performance for participants reporting results on mild to moderately haemolysed survey samples. A haemolysis index diagram is provided.

**Transfusion Competency - Crossmatching / Compatibility Testing Module (Overseas participants only)** [Catalogue Number: 19120102]

The aim of this program is to assess crossmatching

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 3

**Sample Type:** 1 EDTA Whole Blood, 2 red cells donor units

**Sample volume:** 4mL + 2mL

**Schedule:** February, March, June, August, October, November

**Measurand/Test:** Crossmatching / Compatibility Testing

**Storage and Handling:** Store samples at 2-8°C. RCPAQAP Transfusion samples must be tested within five (5) days of receipt because they are liable to haemolysis on prolonged storage. Some degree of haemolysis can be expected in the survey material, however based on historical records, there has been no negative effect in performance for participants reporting results on mild to moderately haemolysed survey samples. A haemolysis index diagram is provided.

### **Transfusion Competency - DAT Module (Overseas participants only)** [Catalogue Number: 19130102]

The aim of this program is to assess DAT

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 1

**Sample Type:** EDTA red cells

**Sample volume:** 2mL

**Schedule:** February, March, June, August, October, November

**Measurand/Test:** DAT

**Storage and Handling:** Store samples at 2-8°C. RCPAQAP Transfusion samples must be tested within five (5) days of receipt because they are liable to haemolysis on prolonged storage. Some degree of haemolysis can be expected in the survey material, however based on historical records, there has been no negative effect in performance for participants reporting results on mild to moderately haemolysed survey samples. A haemolysis index diagram is provided.

### **Transfusion Competency - Full Program (Overseas participants only)** [Catalogue Number: 19160102]

Participants select which tests they would like to perform from the Transfusion Competency Modules

**Frequency (No of surveys/year):** 6

**Sample Type:** EDTA whole blood and red cells

**Sample volume:** 4mL and 2mL

**Schedule:** February, March, June, August, October, November

**Storage and Handling:** Store samples at 2-8°C. RCPAQAP Transfusion samples must be tested within five (5) days of receipt because they are liable to haemolysis on prolonged storage. Some degree of haemolysis can be expected in the survey material, however based on historical records, there has been no negative effect in performance for participants reporting results on mild to moderately haemolysed survey samples. A haemolysis index diagram is provided.

## **Transfusion Competency - Phenotyping (Rh / K antigens only) Module (Overseas participants only)** [Catalogue Number: 19140102]

The aim of this program is to assess Rh/K antigens

**Frequency (No of surveys/year):** 6

**Cases/samples per survey:** 3

**Sample Type:** EDTA whole blood and red cells

**Sample volume:** 4mL and 2mL

**Schedule:** February, March, June, August, October, November

**Measurand/Test:** Phenotyping (Rh/ K antigens only)

**Storage and Handling:** Store samples at 2-8°C. RCPAQAP Transfusion samples must be tested within five (5) days of receipt because they are liable to haemolysis on prolonged storage. Some degree of haemolysis can be expected in the survey material, however based on historical records, there has been no negative effect in performance for participants reporting results on mild to moderately haemolysed survey samples. A haemolysis index diagram is provided.