



Product Catalogue

RCPAQAP

The Royal College of Pathologists of Australasia
Quality Assurance Programs

RCPA 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 including Molecular Genetics, Biosecurity and Point-of-Care. Our programs are offered in Australia and internationally in over 60 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.

The Anatomical Pathology Programs Safety Data Sheet (SDS) can be accessed [here](#).

ALK Translocation for non-small cell lung carcinoma (NSCLC) [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 block to be stained/processed/interpreted for ALK.

Schedule: February

Measurand/Test: ALK IHC, ALK FISH, ALK Molecular

Storage and Handling: Room temperature

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

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

Brightfield ISH (BRISH) Technical Program [Catalogue Number: 13250102]

Proficiency testing for laboratories performing brightfield in situ hybridisation. Modules can be purchased separately. HER2 for breast and gastric cases will be offered annually. Additional ISH programs will be rotated on an annual basis. In 2022 the additional modules offered are Kappa and Lambda Light Chain in situ hybridisation.

What's new: New modules

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, HER2 BRISH Gastric, Kappa Light Chain ISH, Lambda Light Chain ISH

Storage and Handling: Room temperature

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)

Sample Type: Electron micrographs are available in the myQAP portal. USBs can be purchased separately.

Schedule: September

Measurand/Test: Transmission Electron Microscopy

Additional Comments: EM diagnostic and technical modules continue to be separate enrolments in 2022

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: Lab practice and artefact identification survey. Submission of Electron Micrographs prepared by the laboratory

Schedule: September

Measurand/Test: Transmission Electron Microscopy techniques

Additional Comments: EM diagnostic and technical modules continue to be separate enrolments in 2022

Fluorescence in-situ Hybridisation (FISH) Diagnostic [Catalogue Number: 13310101]

Proficiency testing for laboratories reporting solid tumour fluorescence in-situ hybridisation. A different probe is tested each year (Bcl-6 in 2022).

Frequency (No of surveys/year): 1

Cases/samples per survey: 1

Sample Type: Unstained formalin fixed paraffin sections to be stained and interpreted for Bcl-6 FISH probe. Virtual H&E and Bcl-6 immunohistochemistry will also be available to assist with interpretation separately.

Schedule: April

Measurand/Test: Bcl-6, FISH.

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

HER2 Brightfield ISH (BRISH) Breast Diagnostic [Catalogue Number: 13320102]

Proficiency testing for individual pathologists who are involved in the diagnostic interpretation of results for HER2 BRISH testing in breast cancer

Frequency (No of surveys/year): 2

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, August

Measurand/Test: Single probe or Dual probe HER2 BRISH for breast cancer interpretation

HER2 Brightfield ISH (BRISH) Gastric Diagnostic [Catalogue Number: 13130102]

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

Measurand/Test: HER2 BRISH for gastric cancer interpretation

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, Gata-3 (alternate CK7), CK14 (alternate SMMS-1)

Storage and Handling: 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: Glypican 3 (Alternate CK8/18), CD31 (alternate ERG), Napsin A (alternate CEA)

Storage and Handling: Room temperature

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: CD1a (alternate Langerin), CD68 (alternate CD163), CD23 (alternate CD21)

Storage and Handling: 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.

What's new: New program

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: MLH1 and PMS2 staining on colorectal carcinoma and endometrial carcinoma tissue

Storage and Handling: Room temperature

Immunohistochemistry PD-L1 [Catalogue Number: 13440102]

Proficiency testing for laboratories performing PD-L1 testing. Modules can be purchased separately and include PD-L1 for non small cell lung carcinoma (NSCLC), PD-L1 for triple negative breast cancer (TNBC) and PD-L1 for head and neck squamous cell carcinoma (HNSCC). This is a technical proficiency testing program only.

What's new: New program

Frequency (No of surveys/year): 1

Cases/samples per survey: Varies per module

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

Schedule: May

Measurand/Test: PD-L1 for NSCLC, PD-L1 for TNBC, PD-L1 for HNSCC

Storage and Handling: Room temperature

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

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: OLIG2 and PAS

Storage and Handling: 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 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: July

Measurand/Test: Paediatric Histopathology

Renal Medical Diagnostic [Catalogue Number: 13470102]

Proficiency testing for laboratories and pathologists reporting medical renal 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: June

Measurand/Test: Medical Renal Histopathology

ROS1 Translocation for non-small cell lung carcinoma (NSCLC) [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: August

Measurand/Test: ROS1 IHC, ROS1 FISH, ROS1 Molecular

Storage and Handling: 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 [Catalogue Number: 13480102]

Proficiency testing for laboratories performing and reporting sarcoma gene testing from FFPE tissue. Participants choose the method of testing (IHC/FISH/Molecular modules) for reporting at enrolment. Two genes are assessed annually.

What's new: New program

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: ETV6 and MDM2

Storage and Handling: Room temperature

Additional Comments: This program is under development and currently not covered under the scope of accreditation by NATA.

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

Storage and Handling: Freezing, sectioning and staining of fresh tissue

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, Acid Fast bacilli, Amyloid deposits

Storage and Handling: Room temperature

Thoracic Diagnostic [Catalogue Number: 13490102]

Proficiency testing for laboratories and pathologists reporting thoracic 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: June

Measurand/Test: Thoracic Histopathology

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 Department of Health 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 laboratories and for a fee to approved overseas laboratories with a view to building and enhancing laboratory capacity and capability to detect, analyze, 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.

[Watch our video](#) to find out more about RCPAQAP Biosecurity and the challenges of preparing PT panels for Security Sensitive Biological Agents, all summarised in a short 30-minute presentation.

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

The Biosecurity Safety Data Sheet (SDS) can be access [here](#).

PHLN: SARS-CoV-2 and other coronaviruses [Catalogue Number: 22050502]

COVID-19 Response

What's new: Department of Health funded COVID-19 program. Three rounds of this module were offered in 2020 in response to the COVID-19 pandemic with plans for another in 2021. This module is suitable for all laboratory testing platforms that are utilised in the whole genome sequencing of SARS-CoV-2.

Frequency (No of surveys/year): 1

Cases/samples per survey: TBA

Sample Type: Inactivated virus for Whole Genome Sequencing (wet and dry-lab analysis)

Metagenomic sequence reads for Whole Genome Sequencing (dry lab analysis)

Sample volume: TBA

Schedule: February

Measurand/Test: Diluted SARS-CoV-2 (inactivated)

Storage and Handling: Store samples at -80°C

Additional Comments: Available free of charge to Australian public health laboratories that require the capability to test for SARS-CoV-2. Participation will be by invitation only.

SSBA Bacterial and Toxin Specimen Module [Catalogue Number: 22020102]

Biofire PTP

Frequency (No of surveys/year): 1

Cases/samples per survey: 1

Sample Type: Bacteria (inactivated or attenuated), inactivated toxin for testing with BioFire BioThreat Panel

Sample volume: 1 ml

Schedule: March

Measurand/Test: Inactivated or attenuated bacterial and toxin SSBA

Storage and Handling: Store samples at 4°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 international laboratories for a fee that reflects the cost of the modules' production.

SSBA eLearning Module - Anthrax [Catalogue Number: 24010102]

SSBA eLearning available to all laboratories within Australia, to RCPA Microbiology Registrars free of charge and to Australian Government Department of Health approved 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.

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.

Schedule: Available all year

SSBA eLearning Module - Botulism [Catalogue Number: 24060102]

SSBA eLearning available to all laboratories within Australia, to RCPA Microbiology Registrars free of charge and to Australian Government Department of Health approved 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.

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.

Schedule: Available all year

SSBA eLearning Module - Ebola [Catalogue Number: 24020102]

SSBA eLearning available to all laboratories within Australia, to RCPA Microbiology Registrars free of charge and to Australian Government Department of Health approved 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 - History of Biowarfare/Bioterrorism [Catalogue Number: 24070102]

SSBA eLearning available to all laboratories within Australia, to RCPA Microbiology Registrars free of charge and to Australian Government Department of Health approved 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.

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.

What's new: New for 2021

Schedule: Available all year

SSBA eLearning Module - Plague [Catalogue Number: 24030102]

SSBA eLearning available to all laboratories within Australia, to RCPA Microbiology Registrars free of charge and to Australian Government Department of Health approved 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.

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.

Schedule: Available all year

SSBA eLearning Module - Smallpox [Catalogue Number: 24040102]

SSBA eLearning available to all laboratories within Australia, to RCPA Microbiology Registrars free of charge and to Australian Government Department of Health approved 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.

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.

Schedule: Available all year

SSBA eLearning Module - Toxins [Catalogue Number: 24050102]

SSBA eLearning available to all laboratories within Australia, to RCPA Microbiology Registrars free of charge and to Australian Government Department of Health approved 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.

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.

Schedule: Available all year

SSBA Viral Specimen Module [Catalogue Number: 22040102]

Ebola and Yellow Fever viruses

Frequency (No of surveys/year): 2

Cases/samples per survey: 2

Sample Type: Inactivated virus for nucleic acid testing

Sample volume: 0.5 ml

Schedule: March

Measurand/Test: Ebolavirus; Yellow fever virus

Storage and Handling: Store samples at -80°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 approved private laboratories and international laboratories for a fee that reflects the cost of the modules' production.

Whole Genome Sequencing Module [Catalogue Number: 22010102]

SSBA Bacteria Dry-Lab WGS Exercise

Frequency (No of surveys/year): 1

Cases/samples per survey: 1

Sample Type: Specimen-free for Whole Genome Sequencing (Dry-lab)

Schedule: June

Measurand/Test: SSBA bacterial species

Storage and Handling: Specimen-free

Dangerous Goods (UN3373): Specimen-free

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.

All Chemical Pathology Full Programs are made up of two components:

Data Management - which includes result entry and all associated Survey, End-of-Cycle and KPI reports. A Participant Handbook and Schedules, along with all Result and Method Sheets are supplied in the RCPAQAP myQAP online customer portal.

Full program (material) - a complete set of material containing all the samples to be analysed for the full enrolment year is distributed to participants following enrolment. The material is lyophilised unless indicated otherwise.

Only one method code is permitted per analyte. If a participant wishes to report more than one method code per analyte then a new Participant Number is required and an additional Data Management enrolment may be purchased.

The Chemical Pathology Programs Safety Data Sheet (SDS) can be accessed [here](#).

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: Refrigerate samples (2-8°C) upon receipt

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: Refrigerate samples (2-8°C) upon receipt

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: Refrigerate samples (2-8°C) upon receipt

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, pCO₂, Chloride, Urea, pO₂, Glucose, Creatinine, Sodium, Lactate

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

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: Refrigerate samples (2-8°C) upon receipt. Protect from light.

Body Fluids [Catalogue Number: 15070102]

Frequency (No of surveys/year): 6

Cases/samples per survey: 2

Sample Type: Diluted serum

Sample volume: 3mL

Schedule: Bimonthly

Measurand/Test: Albumin, Amylase, Cholesterol, Creatinine, Glucose, Lactate, Lactate Dehydrogenase, Lipase, Osmolality, pH, Potassium, Protein (total), Sodium, Triglycerides, Urate, Urea, CA19-9, CEA

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

C Reactive Protein [Catalogue Number: 15080102]

Frequency (No of surveys/year): 12

Cases/samples per survey: 2

Sample Type: Serum

Sample volume: 0.5mL

Schedule: Monthly

Measurand/Test: C-Reactive Protein

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

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: 5mL

Schedule: Bimonthly

Measurand/Test: 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), Troponin T (Semi-Qualitative, Roche Cardiac Reader only), Troponin T (Qualitative) | Enzymes: ALT, Alkaline Phosphatase, Amylase, AST, Cholinesterase, Creatine Kinase, CK-MB, GGT, Lactate Dehydrogenase, Lipase,

Iron, TIBC, Transferrin, 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: Refrigerate samples (2-8°C) upon receipt

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

Condensed General Serum Chemistry (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: 5mL

Schedule: Monthly

Measurand/Test: 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), Troponin T (Semi-Qualitative, Roche Cardiac Reader only), Troponin T (Qualitative) | Enzymes: ALT, Alkaline Phosphatase, Amylase, AST, Cholinesterase, Creatine Kinase, CK-MB, GGT, Lactate Dehydrogenase, Lipase, Iron, TIBC, Transferrin, 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: Refrigerate samples (2-8°C) upon receipt

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, pCO₂, Potassium, Haemoglobin, Haematocrit, pO₂, Chloride, Lactate, Creatinine, TCO₂, Urea

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

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: Bimonthly

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

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

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: Refrigerate samples (2-8°C) upon receipt. Protect from 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: Refrigerate samples (2-8°C) upon receipt. Protect from light.

Disaccharidases [Catalogue Number: 15670102]

What's new: New program

Frequency (No of surveys/year): 6

Cases/samples per survey: 2

Sample Type: Lyophilised serum based

Sample volume: 0.5ml

Schedule: Bimonthly

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

Storage and Handling: Refrigerate samples (2-8°C) upon receipt.

Additional Comments: This program is under development and currently not covered under the scope of accreditation by NATA.

Dried Blood Spot [Catalogue Number: 15160202]

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, Phenylalanine/Tyrosine ratio

Storage and Handling: Store samples at -20°C on receipt

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, SHBG, TSH, Free T3, Free T4, Vitamin B12, Macroprolactin

Storage and Handling: Store samples at -20°C on receipt

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: Refrigerate samples (2-8°C) upon receipt

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: Refrigerate samples (2-8°C) upon receipt

Endocrine: Bone Markers [Catalogue Number: 15690102]

What's new: New program

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

Additional Comments: This program is under development and currently not covered under the scope of accreditation by NATA.

Endocrine: Parathyroid Hormone and Renin [Catalogue Number: 15680102]

Frequency (No of surveys/year): 12

Cases/samples per survey: 2

Sample Type: Lyophilised serum

Sample volume: 0.5mL

Schedule: Monthly

Measurand/Test: Parathyroid Hormone, Renin

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

Endocrine: Prostate Specific Antigen [Catalogue Number: 15200102]

Frequency (No of surveys/year): 12

Cases/samples per survey: 2

Sample Type: Lyophilised serum

Sample volume: 3mL

Schedule: Monthly

Measurand/Test: Total PSA, Free PSA

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

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: Refrigerate samples (2-8°C) upon receipt

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 Sulphate, 17 Hydroxyprogesterone, Oestradiol, Oestriol (unconjugated), Progesterone, Testosterone, Total T3, Total T4, Vitamin D3 (25 Hydroxy Vitamin D), Dihydrotestosterone, Active B12 (Holotranscobalamin), 11-Deoxycortisol

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

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: Refrigerate samples (2-8°C) upon receipt

Foetal Fibronectin [Catalogue Number: 15730102]

Frequency (No of surveys/year): 4

Cases/samples per survey: 2

Sample Type: Amniotic Fluid

Sample volume: 0.5mL

Schedule: Quarterly

Measurand/Test: Foetal Fibronectin

Storage and Handling: Store frozen. Bring to room temperature before analysis

Additional Comments: This program is under development and currently not covered under the scope of accreditation by NATA.

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): 24

Cases/samples per survey: 2

Sample Type: Lyophilised serum and matching diluent

Sample volume: 5mL

Schedule: Twice/month

Measurand/Test: 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, 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: Refrigerate samples (2-8°C) upon receipt

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, Creatinine, Free Deoxyepinephrine, Free 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: Refrigerate samples (2-8°C) upon receipt

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: 10mL

Schedule: Monthly

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

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

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: Refrigerate samples (2-8°C) upon receipt

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: Refrigerate samples (2-8°C) upon receipt

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

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

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: Refrigerate samples (2-8°C) upon receipt

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): 1

Cases/samples per survey: 2

Sample Type: Fresh frozen serum

Sample volume: 3mL

Schedule: July

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, eGFR, Free Androgen Index, Osmolar Gap, Globulins, Troponin (I and T), Prostate Specific Antigen, C-Reactive Protein, Thyroglobulin

Storage and Handling: Test as soon as possible or store frozen

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: Refrigerate samples (2-8°C) upon receipt

Patient Report Comments [Catalogue Number: 15320102]

The Patient Report Comments Program is designed for commenting 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: Enrolment is only available for an individual person. Samples are not issued with this program. Please log a New Participant Number Request in the myQAP portal to setup an "Individual" Participant number.

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: Refrigerate samples (2-8°C) upon receipt. Bring to room temperature before analysis. Protect from 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, pCO₂, Potassium, Haemoglobin, Haematocrit, , pO₂, Chloride, Lactate, Creatinine, TCO₂, Urea

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

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: Refrigerate samples (2-8°C) upon receipt

Additional Comments: Suitable for devices such as Abbott i-STAT and Roche cobas h232

Porphyrins: 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: Store frozen. Bring to room temperature before analysis. Protect from light.

Porphyrins: Patient Report Comments [Catalogue Number: 15410102]

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.

Porphyrins: 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: Store frozen. Bring to room temperature before reconstitution. Protect from 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: Store frozen. Bring to room temperature before reconstitution. Protect from light.

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

Porphyryns: Urine Qual PBG only - Full Program [Catalogue Number: 15740102]

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: Store frozen. Bring to room temperature before reconstitution. Protect from light.

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: Refrigerate samples (2-8°C) upon receipt

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: Refrigerate samples (2-8°C) upon receipt

Solutions Glucose Meter [Catalogue Number: 15480202]

Frequency (No of surveys/year): 12

Cases/samples per survey: 2

Sample Type: Stabilised Glucose Solution

Sample volume: 1mL

Schedule: Monthly

Measurand/Test: Glucose

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

Additional Comments: Designed for Roche Accu-Chek type glucose meters. Samples comprise stabilised glucose solutions. Suitable for monitoring glucose meters in hospital and diabetes clinic settings.

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, Methotrexate, Mycophenolate, Amitriptyline, Nortriptyline, Amikacin, Gentamicin, Tobramycin, Vancomycin,

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

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

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

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: 4

Sample Type: Lyophilised whole blood

Sample volume: 2mL

Schedule: Monthly

Measurand/Test: Cyclosporin, Tacrolimus, Sirolimus

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

Additional Comments: Everolimus will be included in 4 of the 24 samples in the Immunosuppressants Program with a view to expand to more samples in 2023.

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: Refrigerate samples (2-8°C) upon receipt

Additional Comments: This program is under development and currently not covered under the scope of accreditation by NATA.

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: Refrigerate samples (2-8°C) upon receipt

StatStrip Glucose [Catalogue Number: 15020102]

What's new: New program

Frequency (No of surveys/year): 6

Cases/samples per survey: 2

Sample Type: Stabilised Glucose Solution

Sample volume: 1mL

Schedule: Bimonthly

Measurand/Test: Glucose

StatStrip ketones [Catalogue Number: 15660102]

What's new: New program

Frequency (No of surveys/year): 6

Cases/samples per survey: 2

Sample Type: Stabilised Glucose Solution

Sample volume: 1mL

Schedule: Bimonthly

Measurand/Test: Ketones

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, Sweat conductivity, Sweat conductivity Interpretation

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

Toxicology Screening: On-Site Urine [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

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

Toxicology Screening: Oral Fluid [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: Refrigerate samples (2-8°C) upon receipt

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: Store samples at -20°C on receipt

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: Store samples at -20°C on receipt

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, Selenium, Thallium, Zinc

Storage and Handling: Store samples at -20°C on receipt

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: Refrigerate samples (2-8°C) upon receipt

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: Refrigerate samples (2-8°C) upon receipt

Urine Pregnancy [Catalogue Number: 15600102]

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: Refrigerate samples (2-8°C) upon receipt

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: Refrigerate samples (2-8°C) upon receipt

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: Store at -20°C on receipt. Protect from 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: Refrigerate samples (2-8°C) upon receipt

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: Refrigerate samples (2-8°C) upon receipt

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. 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.

Performance Measures - 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.

The Cytopathology Programs Safety Data Sheet (SDS) can be accessed [here](#).

Gynaecological Conventional [Catalogue Number: 16010106]

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: 16020106]

Proficiency testing for laboratories, cytologists and pathologists reporting SurePath liquid based 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 ThinPrep [Catalogue Number: 16030106]

Proficiency testing for laboratories, cytologists and pathologists reporting ThinPrep liquid based 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

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]

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

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 module will be showcased each year. In 2022, this specialty will consist of four thyroid cases. A complementary thyroid reporting audit may also be offered.

Performance Measures [Catalogue Number: 16070102]

For Australian laboratories only. Collection of National Cervical Screening Program data as per NPAAC requirements.

Frequency (No of surveys/year): 2

Schedule: February, October

Technical [Catalogue Number: 16080102]

Proficiency testing for laboratories performing general cytopathology processes. In 2022, the Technical Program will consist of a cell block processing exercise. A corresponding laboratory practice questionnaire will also be issued.

Frequency (No of surveys/year): 1

Cases/samples per survey: 1

Schedule: February

Storage and Handling: Refrigerate on arrival

Haematology

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

Data Management - which includes result entry and all associated reports. A Participant Handbook and Schedules, along with all Result and Method Sheets are supplied in the RCPAQAP myQAP online customer portal.

Full program (material) - a complete set of material containing all the samples to be analysed for the full enrolment year is distributed to participants following enrolment.

Data Management Only

Purchasing a Data Management enrolment is useful when the material from the Full Program can be shared with a second instrument or a satellite/branch laboratory on the same site.

The Haematology Programs Safety Data Sheet (SDS) can be accessed [here](#).

Automated Differential [Catalogue Number: 11010102]

Material is provided to assess the white cell differential from 3-part or 5-part differential from automated instruments.
[Option 1: Sysmex Corporation: XT series, XE series, XS series, XN series, Mindray BC 5000/6000 series] Option 2: Abbott Laboratories: Cell-Dyn 3000, 3200/Ruby, 3500, 3700, 4000/Sapphire/Alinity hq| Option 3: Beckman Coulter: Act 5 Diff, ABX Pentra 60C+| Option 4: Bayer Diagnostics: ADVIA 120/2120| Option 7: Beckman Coulter: MaxM, HMX, LH 500/750/755/780, GENS, Unicell Dx, DxH500/520

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: Refrigerate samples (2-8 °C) upon receipt

Additional Comments: If the instrument used is not listed in the above table, contact RCPAQAP Haematology for selection of the correct module.

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, July and November

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: February, August and October

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

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt

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

Factors FII, FV, FVII, FX, FXI FXII

Frequency (No of surveys/year): 3

Cases/samples per survey: 2

Sample Type: Lyophilised plasma

Sample volume: 1mL

Schedule: March, July and December

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

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt

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

Factors VIII and IX

Frequency (No of surveys/year): 6

Cases/samples per survey: 2

Sample Type: Lyophilised plasma

Sample volume: 1mL

Schedule: January, March, May, July, September and December

Measurand/Test: Coagulation Factors VIII and IX

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt

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, June, September and 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: Refrigerate samples (2-8 °C) upon receipt

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: Bimonthly, commencing in February 2022

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: Refrigerate samples (2-8 °C) upon receipt

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: February, May, August, November

Measurand/Test: Prothrombin Time (PT); International Normalised Ratio (INR); Activated Partial Thromboplastin Time (APTT); Fibrinogen (Fib); Thrombin Time (TT)

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt

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: Stabilised liquid

Sample volume: 1mL

Schedule: January, May, August and November

Measurand/Test: D-Dimer - Automated

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt

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: January, May, August and November

Measurand/Test: D-Dimer - Semi quantitative

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt

DOAC Urine Dipstick [Catalogue Number: 11540102]

Program suitable for detecting Direct Oral Anticoagulants in urine samples using (DOASENSE) urine dipstick.

What's new: NEW

Frequency (No of surveys/year): 2

Cases/samples per survey: 2

Sample Type: Lyophilised urine

Schedule: January, July

Measurand/Test: DOAC urine dipstick

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

ESR [Catalogue Number: 11150102]

Option 1: All methods excluding StaRRsed users; 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: June and December

Measurand/Test: Erythrocyte Sedimentation Rate (ESR)

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt

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: Refrigerate samples (2-8 °C) upon receipt

G6PD [Catalogue Number: 11200102]

Frequency (No of surveys/year): 2

Cases/samples per survey: 2

Sample Type: Lyophilised haemolysate

Sample volume: 0.5mL

Schedule: April, September

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

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt

Haemoglobinopathy [Catalogue Number: 11230102]

Frequency (No of surveys/year): 4

Cases/samples per survey: 1

Sample Type: Lyophilised haemolysate

Sample volume: 1mL

Schedule: March, June, August and October

Measurand/Test: Haemoglobin A2 (Hb A2); Haemoglobin F (Hb F); Variant Haemoglobin (Variant)

Storage and Handling: On receipt of the samples refrigerate at 2-8°C and protect from direct light.

Haemostasis [Catalogue Number: 11240102]

Frequency (No of surveys/year): 8

Cases/samples per survey: 2

Sample Type: Lyophilised plasma

Sample volume: 1mL

Schedule: January, February, April, May, July, August, October, November

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: Refrigerate samples (2-8 °C) upon receipt

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, June, August, 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: Refrigerate samples (2-8°C) upon receipt

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: April, September

Measurand/Test: Malarial Parasite identification of thin and thick blood films; Malarial Parasite Density Count

Malarial Parasite: Rapid Diagnostic [Catalogue Number: 11270102]

Frequency (No of surveys/year): 2

Cases/samples per survey: 2

Sample Type: HRP-II in buffer

Sample volume: 100uL

Schedule: April, September

Measurand/Test: Malarial Parasite Rapid Diagnostic Test

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt

Manual Blood Film Differential [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: Blood Film

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

Measurand/Test: Differential cell count

Storage and Handling: Store slides at room temperature

Morphological Diagnosis [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: February, April, June, August, October, December

Measurand/Test: Morphology

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.

What's new: NEW

Frequency (No of surveys/year): 2

Cases/samples per survey: 2

Sample Type: Tube coated with antagonist

Schedule: January, July

Measurand/Test: TRAP test - Inhibition level, TRAP test - Area under the curve

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

Oncology Immunophenotyping [Catalogue Number: 11210102]

Frequency (No of surveys/year): 4

Cases/samples per survey: 1

Sample Type: Stabilised whole blood

Sample volume: 1mL

Schedule: * March, May, July, September

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° to 10°C until use. For Beckman Coulter systems: the vials should be maintained at 18° to 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 if you are outside these areas. Notification will be sent by email on the day of dispatch.

* Schedules are dependant on patients availability, the above dates are to be used as a guide only.

Paediatric Morphology [Catalogue Number: 11300102]

Frequency (No of surveys/year): 2

Cases/samples per survey: 2

Sample Type: Virtual images. USBs optional.

Schedule: May and November

Measurand/Test: Description 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: The material assayed is fresh whole blood, which quickly deteriorates under normal transport conditions and should be tested within 3-4 days of dispatch.

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 if you are outside these areas. Schedules are dependent on patients availability. Notification will be sent by email on the day of dispatch.

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: Bimonthly, commencing in February 2022

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: Refrigerate samples (2-8 °C) upon receipt

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 Neut/Gran, Lymph, Mono, Eos, Baso

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt. Ensure vials remain upright.

PoCT: INR [Catalogue Number: 11340102]

Frequency (No of surveys/year): 6

Cases/samples per survey: 2

Sample Type: Lyophilised plasma + H₂O + CaCl₂

Sample volume: 0.5mL

Schedule: February, April, June, August, September and November

Measurand/Test: International Normalised Ratio (INR)

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt.

Reticulocyte [Catalogue Number: 11350102]

Option 1 Manual Reticulocyte counting|Option 2: Beckman Coulter (STKS, MAXM, HmX) ; Sysmex Corporation: XT2000i, XE2100, XE5000, XT4000i, XN10); Abbott (Cell Dyn 3200/Ruby, 3500, 3700, 4000/Sapphire; Siemens ADVIA|ption 3: Beckman Coulter (Gen.S, LH500, LH750, LH755 & UniCell DxH 800)

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

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt

Sickling Test [Catalogue Number: 11580102]

Program for detecting Haemoglobin S using screening or confirmatory methods. Suitable for solubility, reduced oxygen and ICT/kit-based methods. Stand-alone program sent in the same month as Haemoglobinopathy program. 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 fresh whole blood

Sample volume: 1.2 mL

Schedule: March, June, August, October

Measurand/Test: Red cell sickling and reaction strength if applicable

Storage and Handling: Refrigerate samples (2-8°C) upon receipt

Additional Comments: Assessment: Qualitative with Positive, Negative, Invalid and not tested for result entry.

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: Refrigerate samples (2-8 °C) upon receipt. Once reconstituted, samples remain stable for 4 hours at 20 ± 5°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: February and August

Measurand/Test: Apixaban (Anti Xa)

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt. Once reconstituted, samples remain stable for 4 hours at 20 ± 5°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: February and August

Measurand/Test: Dabigatran (direct Thrombin Inhibitor)

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt. Once reconstituted, samples remain stable for 4 hours at 20 ± 5°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: February and August

Measurand/Test: Factor VIII Inhibitor

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt. Once reconstituted, samples remain stable for 4 hours at 20 ± 5°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: February and August

Measurand/Test: Factor XIII (Screen and assay)

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt. Once reconstituted, samples remain stable for 4 hours at 20 ± 5°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: February and August

Measurand/Test: Low Molecular Weight Heparin monitoring

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt. Once reconstituted, samples remain stable for 4 hours at 20 ± 5°C.

Special Haemostasis: Lupus Anticoagulant [Catalogue Number: 11440102]

Frequency (No of surveys/year): 3

Cases/samples per survey: 2

Sample Type: Lyophilised plasma

Sample volume: 2mL

Schedule: February, June and August

Measurand/Test: Lupus Anticoagulant

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt. Once reconstituted, samples remain stable for 4 hours at 20 ± 5°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: February and August

Measurand/Test: PFA-100/200

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt.

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: February and August

Measurand/Test: Rivaroxaban (Anti Xa)

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt. Once reconstituted, samples remain stable for 4 hours at 20 ± 5°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: Refrigerate samples (2-8 °C) upon receipt. Once reconstituted, samples remain stable for 4 hours at 20 ± 5°C.

Special Haemostasis: Unfractionated Heparin monitoring [Catalogue Number: 11480102]

Frequency (No of surveys/year): 2

Cases/samples per survey: 2

Sample Type: Lyophilised plasma

Sample volume: 1mL

Schedule: February and August

Measurand/Test: Unfractionated Heparin monitoring

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt. Once reconstituted, samples remain stable for 4 hours at 20 ± 5°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: February and August

Measurand/Test: von Willebrand Factor

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt. Once reconstituted, samples remain stable for 4 hours at 20 ± 5°C.

Thromboelastography [Catalogue Number: 11500102]

Material provided to test the TEG 6s and the TEG-5000 instruments

Frequency (No of surveys/year): 2

Cases/samples per survey: 2

Sample Type: Lyophilised plasma + Diluent + CaCl₂ (TEG-5000 only)

Sample volume: 1.5mL x2

Schedule: April, September

Measurand/Test: Clotting Test

Storage and Handling: Refrigerate samples (2-8°C) upon receipt. Once reconstituted, samples remain stable for 2 hours at 20 ± 5°C. All testing should be performed on freshly reconstituted samples, as the post freezing stability has not been formally assessed.

Thromboelastometry [Catalogue Number: 11520102]

Material provided to test the ROTEM-Delta, ROTEM Sigma and CLOTPRO instrument users

Frequency (No of surveys/year): 2

Cases/samples per survey: 2

Sample Type: Lyophilised plasma + Diluent + CaCl₂ (ClotPro only)

Sample volume: 1.5 mL (Delta + ClotPro) and 3.0 mL (Sigma)

Schedule: April, September

Measurand/Test: Clotting Test

Storage and Handling: Refrigerate samples (2-8 °C) upon receipt. Once reconstituted, samples remain stable for 4 hours at 20 ± 5°C. All testing should be performed on freshly reconstituted samples, as the post freezing stability has not been formally assessed

Immunology

Participating laboratories may select from a group of RCPAQAP Immunology program modules that comprehensively cover the assays performed in Clinical Immunology.

All Immunology programs are made of two components:

Data Management - which includes result entry and all associated reports. A Participant Handbook and Schedules, along with all Result and Method Sheets are supplied in the RCPAQAP myQAP online customer portal.

Purchasing a Data Management enrolment is useful when the material from the Full Program can be shared with a second instrument or a satellite/branch laboratory on the same site.

Full program (material) - a complete set of material containing all the samples to be analysed for the full enrolment year is distributed to participants following enrolment.

The Immunology Programs Safety Data Sheet (SDS) can be accessed [here](#).

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: March, May, August, October

Measurand/Test: Anti-adrenal antibodies

Storage and Handling: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

Additional Comments: This program is under development and not covered under the scope of accreditation by NATA at this stage.

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: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

Antinuclear Antibodies [Catalogue Number: 17010102]

Material is supplied to determine the presence of Antinuclear antibodies including pattern, titre and appropriate commentary.

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: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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 degrees) until processing.

Additional Comments: This program is under development and currently not covered under the scope of accreditation by NATA.

Bee Venom IgE [Catalogue Number: 17040102]

Material supplied for the quantitation and qualitative assessment of Specific IgE to Bee Venom

Frequency (No of surveys/year): 8

Cases/samples per survey: 1

Sample Type: Serum

Sample volume: 500uL

Schedule: February, March, April, May, July, August, September, November

Measurand/Test: Specific IgE to Bee Venom (Apis mellifera)

Storage and Handling: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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

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: Immunology program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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: March, May, August, October

Measurand/Test: Specific IgE to Drugs (Latex, Morphine, Chlorhexidine, Penicilloyl V, Penicilloyl G, Cefaclor, Suxamethonium (Succinylcholine), Ampicilloyl, Amoxicilloyl)

Storage and Handling: Immunology program samples are dispatched in January or on Enrolment and should be stored

frozen at a temperature below -15°C, until the relevant survey is open for testing.

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: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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, April, May, 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: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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: March, May, August, October

Measurand/Test: IgG antibodies to *Aspergillus fumigatus*; IgG antibodies to Budgie; IgG antibodies to Pigeon

Storage and Handling: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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: Serum

Sample volume: 500uL

Schedule: Monthly: February to May and July to October

Measurand/Test: High sensitivity CRP (

Storage and Handling: Immunology program samples are dispatched in January or on Enrolment and should be stored refrigerated between 2°C and 8°C, until the relevant survey is open for testing.

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 degrees) 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 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: March, May, August, October

Measurand/Test: Immunoglobulin D (IgD)

Storage and Handling: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

Immunoglobulin G Subclasses [Catalogue Number: 17140102]

Material is provided for quantitation and qualitative assessment of IgG subclasses (IgG1, IgG2, IgG3, IgG4)

Frequency (No of surveys/year): 8

Cases/samples per survey: 1

Sample Type: Serum

Sample volume: 500uL

Schedule: February, March, April, May, July, August, September, November

Measurand/Test: IgG1, IgG2, IgG3, IgG4, Calculated subclass sum and IgG level obtained by total IgG assay

Storage and Handling: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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 degrees) until processing.

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 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, April, May, 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: Immunology program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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: March, May, August, October

Measurand/Test: Liver specific autoantibodies: AMA-M2, M2-3E, LKM-1, LC-1, SLA/LP, Sp100, gp210, PML, Ro-52

Storage and Handling: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

Additional Comments: This program is under development and currently not covered under the scope of accreditation by NATA.

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: March, May, August, October

Measurand/Test: Acetylcholine Receptor Antibodies (AChR); Skeletal (Striated) Muscle Antibodies (Anti-Str)

Storage and Handling: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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: 400uL

Schedule: February, April, May, July, September, November

Measurand/Test: Myositis and scleroderma antibodies: Mi-2, Mi-2a, Mi-2b, Ku, RNA Pol III, Cenp, MDA5, NXP2, SAE1, TIF1g, PL-7, OJ, EJ, Jo-1, PM-Scl, others as appropriate

Storage and Handling: Immunology program samples are dispatched January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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, April, May, July, August, September, November

Measurand/Test: Antibodies to Paraneoplastic Antigens (anti-Hu, anti-Yo, anti-Ri, anti-CV2, anti-Ma2, anti-amphiphysin etc); Anti-NMDA Receptor Antibodies (NMDA-R,); Neuromyelitis Optica Antibodies (NMO/AQP4)

Storage and Handling: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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, April, May, July, August, September, November

Measurand/Test: Serum electrophoresis fractions (albumin, alpha-1, alpha-2, beta, gamma); Paraprotein identification and concentration (urine)

Storage and Handling: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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: Immunology program samples are dispatched in January or on Enrolment and should be stored refrigerated between 2°C and 8°C, until the relevant survey is open for testing.

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: Immunology program samples are dispatched in January or on Enrolment and should be stored refrigerated between 2°C and 8°C, until the relevant survey is open for testing.

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, April, May, 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: Immunology program samples are dispatched in January or on Enrolment and should be stored

refrigerated between 2°C and 8°C, until the relevant survey is open for testing.

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: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

Specific Proteins [Catalogue Number: 17300102]

Material is supplied for quantitation of Specific Proteins

Frequency (No of surveys/year): 12

Cases/samples per survey: 2

Sample Type: Serum

Sample volume: 1mL

Schedule: February, March (x2), April, May, June, July, August (x2), September, October, November

Measurand/Test: Immunoglobulin G (IgG), Immunoglobulin A (IgA), Immunoglobulin M (IgM), Complement component 3 (C3), Complement component 4 (C4), α-1-antitrypsin (A1AT, AAT), C1 esterase inhibitor (C1-inh), Haptoglobin (Hapt), Caeruloplasmin, Prealbumin (Transthyretin)

Storage and Handling: Immunology program samples are dispatched in January or on Enrolment and should be stored refrigerated between 2°C and 8°C, until the relevant survey is open for testing.

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: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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, April, May, July, August, September, November

Measurand/Test: Mast Cell Tryptase (Trypt)

Storage and Handling: Immunology program samples are dispatched in January or on Enrolment and should be stored refrigerated between 2°C and 8°C, until the relevant survey is open for testing.

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)

Storage and Handling: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

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: Immunology program samples are dispatched in January or on Enrolment and should be stored frozen at a temperature below -15°C, until the relevant survey is open for testing.

KIMMS - Key Incident Management and Monitoring System

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.

Sample Type: Data collection only

Additional Comments: This program is not covered under the scope of accreditation by NATA.

KIMMS: Location Fee [Catalogue Number: 21020102]

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.

Sample Type: Data collection only

Additional Comments: This program is not covered under the scope of accreditation by NATA.

Microbiology

The RCPAQAP Microbiology discipline has been developed and evolved under the guidance of the RCPAQAP Microbiology Advisory Committee. Within this discipline, a Molecular Infectious Diseases sub-committee further guides the development of microbiology molecular diagnostics.

The last two decades have seen enormous change in Medical Microbiology. 'New' organisms (*Helicobacter pylori*, HIV, Hepatitis C virus) have been discovered and characterised. 'New' infectious diseases (AIDS, Lyme disease and Legionnaires' disease) have been described. 'Old' infections (tuberculosis, malaria, and pertussis) have re-emerged as major threats and have become increasingly resistant to previously effective antibiotics (MRSA, *Streptococcus pneumoniae*, VRE).

Over this time, advances in technology and molecular medicine (automation, polymerase chain reaction) have added greatly to the Microbiologist's diagnostic armamentarium. At the same time, Microbiology remains very much a 'hands-on' discipline. In many ways, it is an art as much as a science, and one in which an individual pathologist's experience, judgment and interpretive skills are pivotal.

Clinical aspects involve control of outbreaks of infectious disease and dealing with the problems of infections caused by antibiotic-resistant bacteria.

The Microbiology (UN3373) Programs Safety Data Sheet (SDS) can be accessed [here](#).

The Molecular Infectious Diseases Programs Safety Data Sheet (SDS) can be accessed [here](#).

The Parasitology Programs Safety Data Sheet (SDS) can be accessed [here](#).

The Microbiology Gram Stain / Urine Microscopy and Urine Dipstick Programs Safety Data Sheet (SDS) can be accessed [here](#).

Bacterial Serotyping [Catalogue Number: 12010102]

Frequency (No of surveys/year): 4

Cases/samples per survey: 6

Sample Type: Lyophilised sample

Sample volume: 1mL

Schedule: February, April, July, October

Measurand/Test: Serotyping of *Streptococcus pneumoniae*, *Haemophilus* species, *Neisseria meningitidis*

Storage and Handling: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at 2-8°C and protect from direct light.

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

Bacteriology: Difficult/Blood Culture Isolates [Catalogue Number: 12020102]

Frequency (No of surveys/year): 8

Cases/samples per survey: 1

Sample Type: Lyophilised sample

Sample volume: 1mL

Schedule: February, March, April, June, July, September, October, November

Measurand/Test: Difficult/Blood Culture Isolates

Storage and Handling: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at 2-8°C and protect from direct light.

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: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at 2-8°C and protect from direct light.

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: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at 2-8°C and protect from direct light.

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: On receipt of the samples, prompt processing is recommended. Store slides at room temperature and protect from direct light.

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: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at 2-8°C and protect from direct light.

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: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at 2-8°C and protect from direct light.

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: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at 2-8°C and protect from direct light.

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: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at 2-8°C and protect from direct light.

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]

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: Urine cell counts (manual and/or automated methods), Bacterial count, Urine pathogens, Antimicrobial susceptibility testing

Storage and Handling: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at 2-8°C and protect from direct light.

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

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: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at 2-8°C and protect from direct light.

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

Clostridium difficile: Laboratory Detection [Catalogue Number: 12120102]

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: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at 2-8°C and protect from direct light.

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: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at 2-8°C and protect from direct light.

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

Molecular Bordetella pertussis [Catalogue Number: 12220102]

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 using molecular assays

Storage and Handling: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at room temperature and protect from direct light.

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

Molecular Herpes simplex virus type 1 and 2 [Catalogue Number: 12320102]

Frequency (No of surveys/year): 2

Cases/samples per survey: 6

Sample Type: Lyophilised sample

Sample volume: 1mL

Schedule: June, November

Measurand/Test: Simulated clinical material provided to assess the detection of HSV types 1 and 2 using molecular assays

Storage and Handling: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at room temperature and protect from direct light.

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]

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: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at room temperature and protect from direct light.

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

Molecular Varicella zoster virus [Catalogue Number: 12420102]

Frequency (No of surveys/year): 2

Cases/samples per survey: 6

Sample Type: Lyophilised sample

Sample volume: 1mL

Schedule: June, November

Measurand/Test: Simulated clinical material provided to assess the detection of Varicella zoster virus using molecular assays

Storage and Handling: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at room temperature and protect from direct light.

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]

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: Samples are dispatched on dry ice in January/February and should be stored frozen at a temperature of -70°C, until the relevant survey is open for testing.

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 Chlamydia trachomatis and Neisseria gonorrhoeae [Catalogue Number: 12230102]

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: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at room temperature and protect from direct light.

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]

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: Samples are dispatched in February and should be stored frozen at a temperature of -20°C or -70°C, until the relevant survey is open for testing.

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]

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 using molecular assays

Storage and Handling: Samples are dispatched on dry ice in January/February and should be stored frozen at a temperature of -70°C, until the relevant survey is open for testing.

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 Enterovirus [Catalogue Number: 12250102]

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: On receipt of the samples, prompt processing is recommended. If not performing testing

immediately, store the un-reconstituted vials at room temperature and protect from direct light.

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]

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, Multiplex Assays. Clinical material examples include: *Aeromonas hydrophila*, *Campylobacter* sp, *Escherichia coli* O157, *Salmonella* sp, *Shigella* sp, *Vibrio* sp, *Yersinia* sp

Storage and Handling: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at room temperature and protect from direct light.

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]

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, Multiplex Assays. Clinical material examples include: *Blastocystis hominis*, *Cryptosporidium* sp, *Dientamoeba fragilis*, *Entamoeba histolytica*, *Giardia* sp

Storage and Handling: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the vials at 4-8°C and protect from direct light.

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]

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, Multiplex Assays. Clinical material examples include: Adenovirus, Astrovirus, Norovirus, Rotavirus, Sapovirus

Storage and Handling: Samples are dispatched in February/March and should be stored frozen at a temperature of -70°C, until the relevant survey is open for testing.

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

Molecular Hepatitis B Virus DNA [Catalogue Number: 12290102]

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: Samples are dispatched on dry ice in January/February and should be stored frozen at a temperature of -70°C, until the relevant survey is open for testing.

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]

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: Samples are dispatched on dry ice in January/February and should be stored frozen at a temperature of -70°C, until the relevant survey is open for testing.

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]

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 genotype of Hepatitis C

Storage and Handling: Samples are dispatched on dry ice in January/February and should be stored frozen at a temperature of -70°C, until the relevant survey is open for testing.

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]

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 quantitative detection of HIV RNA. HIV-1 RNA Quantitative, HIV Viral load

Storage and Handling: Samples are dispatched on dry ice in January/February and should be stored frozen at a temperature of -70°C, until the relevant survey is open for testing.

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 Human Papillomavirus DNA [Catalogue Number: 12340102]

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 HPV DNA using molecular assays.

Storage and Handling: Samples are dispatched in February and should be stored in the refrigerator, until the relevant survey is open for testing.

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]

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 N1 (avian), Influenza A N1 (pandemic), Influenza B

Storage and Handling: Samples are dispatched in February/March and should be stored frozen at a temperature of -70°C, until the relevant survey is open for testing.

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]

What's new: NEW

Frequency (No of surveys/year): 2

Cases/samples per survey: 2

Sample Type: Whole Blood sample

Sample volume: TBA

Schedule: April, August

Measurand/Test: Simulated clinical material provided to assess the detection of Plasmodium falciparum

Storage and Handling: On receipt of the samples, prompt processing is recommended. Short term storage, in the refrigerator

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]

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 molecular assays

Storage and Handling: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at 2-8°C and protect from direct light.

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]

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: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at room temperature and protect from direct light.

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 [Catalogue Number: 12390102]

Frequency (No of surveys/year): 3

Cases/samples per survey: 4

Sample Type: Liquid sample

Sample volume: 0.8mL

Schedule: April, June, August

Measurand/Test: Simulated clinical material provided to assess the detection of Influenza and RSV using molecular rapid detection methods. Influenza A, Influenza B, RSV

Storage and Handling: Samples are dispatched in February/March and should be stored frozen at a temperature of -20C or -70C, until the relevant survey is open for testing.

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]

Frequency (No of surveys/year): 3

Cases/samples per survey: 6

Sample Type: Liquid sample

Sample volume: 0.5mL

Schedule: April, June, August

Measurand/Test: Simulated clinical material provided to assess the detection and identification of Respiratory Pathogens using molecular assays. Multiplex Assays, Adenovirus, Bordetella spp, Chlamydomphila pneumoniae, Coronavirus (OC43, NL63, SARS-CoV-2), Enterovirus, human Metapneumovirus, Haemophilus influenzae Influenza, Legionella pneumoniae, Mycoplasma pneumoniae, Parainfluenza 1-4, Pneumocystis jirovecii, Rhinovirus, RSV

Storage and Handling: Samples are dispatched in February/March and should be stored frozen at a temperature of -70°C, until the relevant survey is open for testing.

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]

What's new: NEW

Frequency (No of surveys/year): 2

Cases/samples per survey: 6

Sample Type: Liquid sample

Sample volume: 0.8mL

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: Samples are dispatched in March/April and should be stored frozen at a temperature of -70°C, until the relevant survey is open for testing.

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

Molecular Vaccine Preventable Pathogens [Catalogue Number: 12410102]

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: Samples are dispatched in February/March and should be stored frozen at a temperature of -70°C, until the relevant survey is open for testing.

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

Multi-drug resistant gram-negative bacteria (MDR) [Catalogue Number:]

Program suitable for laboratories performing screening and/or laboratory detection of multi-drug resistant gram-negative bacteria by phenotypic and/or molecular methods.

Frequency (No of surveys/year): 2

Cases/samples per survey: 3 samples per survey.

Sample Type: Lyophilised bacteria.

Sample volume: 1mL after reconstitution.

Storage and Handling: On receipt of the samples, prompt processing is recommended.

Dangerous Goods (UN3373): UN3373

Additional Comments: This program is under development and currently not covered under the scope of accreditation by NATA.

Mycology [Catalogue Number: 12140102]

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

Storage and Handling: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the vials at room temperature and protect from direct light

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:]

Program suitable for laboratories performing identification and antimicrobial susceptibilities of non-tuberculous mycobacteria by culture or molecular methods.

Frequency (No of surveys/year): 2

Cases/samples per survey: 3 samples per survey

Sample Type: Lyophilised bacteria

Sample volume: 1mL after reconstitution

Storage and Handling: On receipt of the samples, prompt processing is recommended

Dangerous Goods (UN3373): UN3373

Additional Comments: This program is under development and currently not covered under the scope of accreditation by NATA.

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: Protozoa, helminths and samples containing faecal artefacts. Acid fast staining of oocysts.

Storage and Handling: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the vials at room temperature and protect from direct light.

STAT Microscopy [Catalogue Number: 12170102]

Frequency (No of surveys/year): 4

Cases/samples per survey: 2 urine samples and 2 unstained slides

Sample Type: Lyophilised samples and unstained glass slide

Sample volume: 1mL or 5mL option

Schedule: February, April, July, October

Measurand/Test: Includes urine cell counts and Gram stains of samples

Storage and Handling: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at 2-8°C and protect from direct light.

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

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 antigen

Storage and Handling: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store your un-reconstituted vials at 2-8°C and protect from direct light.

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: 1mL

Schedule: March, June, September, November

Measurand/Test: Leukocyte esterase, Blood, Glucose, Protein, Nitrite, Ascorbic acid, pH, Bilirubin

Storage and Handling: On receipt of the samples, prompt processing is recommended. If not performing testing immediately, store the un-reconstituted vials at 2-8°C and protect from direct light.

Vancomycin-Resistant Enterococci (VRE) [Catalogue Number: 12200102]

Frequency (No of surveys/year): 2

Cases/samples per survey: 4

Sample Type: Lyophilised sample

Sample volume: 1mL

Schedule: April, October

Measurand/Test: VRE screening, phenotypic testing, antibiotic susceptibility testing and/or molecular testing.

Storage and Handling: On receipt of your samples, prompt processing is recommended. If not performing testing immediately, store your un-reconstituted vials at 4-8°C and protect from direct light.

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

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](#)

Genomics Quality Assessment (GenQA)

Australasian Society of Diagnostic Genomics (ASDG)

The Molecular Genetics Programs Safety Data Sheet (SDS) can be accessed [here](#).

Acute Myeloid Leukemia 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: May, September

Measurand/Test: Next generation sequencing for AML-associated gene variants.

Storage and Handling: Store DNA samples below 4°C or according to your standard operating procedure, upon receipt.

Additional Comments: Available to order in myQAP under the Haematology Discipline.

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): 3

Cases/samples per survey: 1

Sample Type: RNA

Sample volume: 2µg of lyophilised, purified RNA provided in each case

Schedule: March, June, October

Measurand/Test: Molecular genetic testing for BCR-ABL1 fusion transcripts (p190, p210, e1a2, e1a3, e13a2, e13a3, e14a2, e14a3).

Storage and Handling: Store RNA samples at -80°C or according to your standard operating procedure, upon receipt.

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): 3

Cases/samples per survey: 1

Sample Type: DNA

Sample volume: 1.5µg of purified DNA in TE pH 8.0 provided in each case

Schedule: March, July, September

Measurand/Test: Chimerism analysis.

Storage and Handling: Store DNA samples below 4°C or according to your standard operating procedure, upon receipt.

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): 3

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, November

Measurand/Test: Molecular genetic testing for HLA-DQA1 and HLA-DQB1 alleles.

Storage and Handling: Store DNA samples below 4°C or according to your standard operating procedure, upon receipt.

FLT-3 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: May, September

Measurand/Test: Molecular genetic testing for FLT3 ITD and TKD gene variants.

Storage and Handling: Store DNA samples below 4°C or according to your standard operating procedure, upon receipt.

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 hemochromatosis gene variants (C282Y, H63D).

Frequency (No of surveys/year): 4

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, May, August, November

Measurand/Test: Molecular genetic testing for HFE gene variants, C282Y and H63D.

Storage and Handling: Store DNA samples below 4°C or according to your standard operating procedure, upon receipt.

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*5701 allele.

Frequency (No of surveys/year): 4

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, May, August, November

Measurand/Test: Molecular genetic testing for HLA-B*57:01.

Storage and Handling: Store DNA samples below 4°C or according to your standard operating procedure, upon receipt.

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): 3

Cases/samples per survey: 1

Sample Type: DNA

Sample volume: 1µg of purified DNA in TE pH 8.0 provided in each case

Schedule: February, May, September

Measurand/Test: Molecular genetic testing for IDH1 and IDH2 gene variants.

Storage and Handling: Store DNA samples below 4°C or according to your standard operating procedure, upon receipt.

Additional Comments: Available to order in myQAP under the Haematology Discipline

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): 3

Cases/samples per survey: 1

Sample Type: DNA

Sample volume: 2.5µg of purified DNA in TE pH 8.0 provided in each case

Schedule: March, July, October

Measurand/Test: Molecular genetic testing for IgH and TCR gene rearrangement.

Storage and Handling: Store DNA samples below 4°C or according to your standard operating procedure, upon receipt.

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: 3

Sample Type: DNA

Sample volume: 1µg of purified DNA provided in each case

Schedule: June

Measurand/Test: Molecular genetic testing for CAG trinucleotide repeat expansion in the AR gene.

Storage and Handling: Store DNA samples below 4°C or according to your standard operating procedure, upon receipt.

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.

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): 3

Cases/samples per survey: 1 family trios

Sample Type: DNA

Sample volume: 1µg of purified DNA in TE pH 8.0 provided in each case

Schedule: March, August, November

Measurand/Test: Maternal cell contamination studies.

Storage and Handling: Store DNA samples below 4°C or according to your standard operating procedure, upon receipt.

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 (patient derived)

Sample volume: Virtual H&E and five unstained 6µM sections (mounted) provided in each case.

Schedule: May, September

Measurand/Test: FFPE DNA extraction; Molecular genetic testing for IDH1 and IDH2 gene variants, and MGMT gene methylation.

Storage and Handling: Store FFPE samples below 4°C or according to your standard operating procedure, upon receipt.

Additional Comments: This program is under development and currently not covered under the scope of accreditation by NATA.

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.

What's new: BRAF genotyping is now included in this module.

Frequency (No of surveys/year): 2

Cases/samples per survey: 2

Sample Type: FFPE tissue (patient derived)

Sample volume: Virtual H&E and five unstained 6µM sections (mounted) provided in each case.

Schedule: March, September

Measurand/Test: FFPE DNA extraction; Molecular genetic testing for KRAS, NRAS and/or BRAF gene variants.

Storage and Handling: Store FFPE samples below 4°C or according to your standard operating procedure, upon receipt.

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.

What's new: KRAS genotyping is now included in this module.

Frequency (No of surveys/year): 2

Cases/samples per survey: 2

Sample Type: FFPE tissue (patient derived)

Sample volume: Virtual H&E and five unstained 6µM sections (mounted) provided in each case.

Schedule: May, September

Measurand/Test: FFPE DNA extraction; Molecular genetic testing for EGFR and/or KRAS gene variants.

Storage and Handling: Store FFPE samples below 4°C or according to your standard operating procedure, upon receipt.

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 (patient derived)

Sample volume: Virtual H&E and five unstained 6µM sections (mounted) provided in each case.

Schedule: March, September

Measurand/Test: FFPE DNA extraction; Molecular genetic testing for BRAF and NRAS gene variants.

Storage and Handling: Store FFPE samples below 4°C or according to your standard operating procedure, upon receipt.

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): 4

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, May, August, November

Measurand/Test: Molecular genetic testing for JAK2, CALR and MPL gene variants.

Storage and Handling: Store DNA samples below 4°C or according to your standard operating procedure, upon receipt.

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): 3

Cases/samples per survey: 1

Sample Type: DNA

Sample volume: 1µg of purified DNA in TE pH 8.0 provided in each case

Schedule: January, May, September

Measurand/Test: Molecular genetic testing for NPM1 gene variants.

Storage and Handling: Store DNA samples below 4°C or according to your standard operating procedure, upon receipt.

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): 3

Cases/samples per survey: 1

Sample Type: RNA

Sample volume: 2µg of lyophilised, purified RNA provided in each case

Schedule: March, June, October

Measurand/Test: Molecular genetic testing for PML-RARa fusion transcripts.

Storage and Handling: Store RNA samples at -80°C or according to your standard operating procedure, upon receipt.

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: June

Measurand/Test: Molecular genetic testing for PTEN gene variants.

Storage and Handling: Store DNA samples below 4°C or according to your standard operating procedure, upon receipt.

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 up to five DNA samples of their choice to the RCPAQAP for quality assessment.

Frequency (No of surveys/year): 2

Cases/samples per survey: 2

Sample Type: DNA

Sample volume: n/a

Schedule: May, August

Measurand/Test: Genomic DNA extraction from any tissue type except FFPE.

Storage and Handling: Return DNA extracts at ambient temperature to RCPAQAP Molecular Genetics.

Additional Comments: This program is under development and not currently covered under the scope of accreditation by NATA.

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 along with up to four DNA samples of their choice to the RCPAQAP for quality assessment.

Frequency (No of surveys/year): 2

Cases/samples per survey: 2

Sample Type: FFPE DNA

Sample volume: One 15µM to 20µM FFPE section (vial) provided for DNA extraction.

Schedule: March, August

Measurand/Test: FFPE DNA extraction.

Storage and Handling: Return FFPE DNA extracts at ambient temperature to RCPAQAP Molecular Genetics.

Additional Comments: This program is under development and currently not covered under the scope of accreditation by NATA.

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.

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: Store PCR products and primers below 4°C or according to your standard operating procedure, upon receipt.

Thalassaemia (alpha, beta) [Catalogue Number: 23230102]

This module qualitatively assesses laboratory performance in the detection of α-thalassemia (HBA1/HBA2) and/or β-thalassemia (HBB) gene variants.

Frequency (No of surveys/year): 3

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: March, July, October

Measurand/Test: Molecular genetic testing for HBA1/HBA2 and/or HBB gene variants.

Storage and Handling: Store DNA samples below 4°C or according to your standard operating procedure, upon receipt.

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.

What's new: MTHFR testing is no longer included.

Frequency (No of surveys/year): 4

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, May, August, November

Measurand/Test: Molecular genetic testing for F5 and F2 gene variants.

Storage and Handling: Store DNA samples below 4°C or according to your standard operating procedure, upon receipt.

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: 3

Sample Type: Interphase nuclei (bone marrow)

Sample volume: Two slides provided in each case

Schedule: July

Measurand/Test: Molecular/cytogenetic testing for TP53 deletion in 17p13.1.

Storage and Handling: Store samples at room temperature or according to your standard operating procedure, upon receipt.

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.

The Serology (UN3373) Programs Safety Data Sheet (SDS) can be accessed [here](#).

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: 0.4mL

Schedule: March, August

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: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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: May, September

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: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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: 0.5mL

Schedule: January, June

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: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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

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: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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

What's new: New program

Frequency (No of surveys/year): 4

Cases/samples per survey: 2

Sample Type: Serum/plasma

Sample volume: 0.5mL

Schedule: February, April, July, September

Measurand/Test: SARS CoV-2 Antibodies: IgA; IgG; IgM; Total Antibody; Point of Care

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

Coronavirus SARS-CoV-2 Antigen [Catalogue Number: 20480102]

What's new: NEW program

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, September

Measurand/Test: Measurand/Test Simulated clinical material provided to assess the detection of Coronavirus SARS-CoV-2 antigen

Storage and Handling: Stored frozen at a temperature of -20C or -70C, until the relevant survey is open for testing

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

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: March, August

Measurand/Test: Cryptococcus Antigen Detection

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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, April, July, September

Measurand/Test: CMV Avidity; IgG;IgM; Total Antibody

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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, August

Measurand/Test: Dengue IgG: Sero-prevalence; Capture; IgM; NS1 Antigen; ICT NS1/IgG/IgM; Total Antibody

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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: March, August

Measurand/Test: Entamoeba IgG; Total Antibody

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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, April, July, September

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: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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, August

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: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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, August

Measurand/Test: Helicobacter pylori; IgG; Total Antibody

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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, July, August, October

Measurand/Test: Anti-HAV IgG; IgM; Total Antibody

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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, July, August, October

Measurand/Test: HBsAg; HBsAg-Confirmatory; Anti-HBs; Anti-HBc; Anti-HBc IgM; HBeAg; Anti-HBe

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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, July, August, October

Measurand/Test: HCV Ag; HCV Ag-Ab; Anti-HCV Ab; Anti-HCV-Confirmatory

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and

should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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: May, 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: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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, July, September, October

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: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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, July, September, October

Measurand/Test: HTLV Antibody; HTLV Confirmatory

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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: March, August

Measurand/Test: Hydatid IgG; Total Antibody; Western Blot

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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, July, September, October

Measurand/Test: Infectious Mononucleosis

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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: March, June

Measurand/Test: Influenza A IgA; IgG; IgM; Total Antibody. Influenza B IgA; IgG; IgM; Total Antibody.

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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: May, September

Measurand/Test: Legionella IgG; IgM; Total Antibody (EIA & IFA). L. pneumophila and L. longbeachae

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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: May, September

Measurand/Test: Legionella Urinary Antigen Detection

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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: May, October

Measurand/Test: Leptospirosis Agglutination; IgG; IgM

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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: May, October

Measurand/Test: Lyme Disease IgG Confirmatory; IgM Confirmatory; IgG; IgM; Total Antibody

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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, June

Measurand/Test: Measles IgG; IgM; Total Antibody

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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]

Clinical material provided to assess the detection of Mumps using serological markers

Frequency (No of surveys/year): 2

Cases/samples per survey: 2

Sample Type: Serum/plasma

Sample volume: 0.25mL

Schedule: February, June

Measurand/Test: Mumps IgG; IgM

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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, June

Measurand/Test: Mycoplasma IgA; IgG; IgM; Total Antibody

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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: May, October

Measurand/Test: Parvovirus IgG; IgM

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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, September

Measurand/Test: HIV Antigen PoCT; HIV Antibody PoCT

Storage and Handling: HIV POCT are whole blood samples and are dispatched on the survey open date. These samples should be tested on receipt as soon as practicable, if this is not possible, they can be stored at 2-8°C until testing can be performed.

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): 4

Cases/samples per survey: 2

Sample Type: Inactivated viral culture lysate

Sample volume: 0.5mL

Schedule: February, May, August, September

Measurand/Test: Influenza A Antigen PoCT; Influenza B Antigen PoCT

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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): 4

Cases/samples per survey: 2

Sample Type: Inactivated viral culture lysate

Sample volume: 0.5mL

Schedule: March, May, August, September

Measurand/Test: RSV Antigen PoCT

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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: May, September

Measurand/Test: Q fever Phase 1 IgA; IgG; IgM; Total Antibody. Q fever Phase 2 IgA; IgG; IgM; Total Antibody

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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

QuantiFERON-TB [Catalogue Number: 20090102]

Material provided to assess the detection of QuantiFERON - TB

Frequency (No of surveys/year): 2

Cases/samples per survey: 2

Sample Type: Lyophilised serum/plasma

Schedule: March, August

Measurand/Test: QuantiFERON - TB

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored refrigerated at a temperature between 2-8°C, until the relevant survey is open for testing.

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: May, September

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: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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, June, August

Measurand/Test: Rubella Avidity; IgG; IgM

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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: May, October

Measurand/Test: Schistosomiasis Confirmatory; IgG; IgM; Total Antibody

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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

Specimen Free [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 'scored' assessed and is designed as an educational tool for staff. All individual responses are returned to the primary contact for review and distribution.

Frequency (No of surveys/year): 5

Cases/samples per survey: 1

Schedule: February, April, June, 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, August

Measurand/Test: Streptococcus ASOT; Streptozyme; Anti-DNase B

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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

What's new: New program

Frequency (No of surveys/year): 2

Cases/samples per survey: 2

Sample Type: Serum/plasma

Sample volume: 0.2mL

Schedule: March, August

Measurand/Test: Strongyloides IgG; Total Antibody

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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

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, June, August

Measurand/Test: Syphilis Agglutination (TPHA/TPPA); Confirmatory assay; FTA-ab; IgG; IgM; RPR; Total Antibody; VDRL; Point of Care

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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, April, July, September

Measurand/Test: Toxoplasmosis Avidity; IgA; IgG; IgM; Total Antibody

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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: May, September

Measurand/Test: Varicella zoster IgG; IgM; Total Antibody

Storage and Handling: Serological program samples are dispatched in December and January or on Enrolment and should be stored frozen at a temperature between -20°C and -80°C, until the relevant survey is open for testing.

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.

The Synovial Fluid Crystals Program Safety Data Sheet (SDS) can be accessed [here](#).

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: Samples must be stored at room temperature but should be examined as soon as possible

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 to maintain 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.

The Transfusion Programs Safety Data Sheet (SDS) can be accessed [here](#).

The Snake Venom Detection Program Safety Data Sheet (SDS) can be accessed [here](#).

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, April, 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.

Foeto-Maternal Haemorrhage Estimation [Catalogue Number: 19020102]

The aim of this program is to assess percentage and volume of foetal 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, April, August, October

Measurand/Test: Foetal Maternal 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 Transfusion - 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

Measurand/Test: Anti-D 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.

General Transfusion - 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): 4

Cases/samples per survey: 1

Sample Type: EDTA whole blood and red cells

Sample volume: 4mL and 2mL

Schedule: March, May, July, September

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.

General Transfusion - 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.

General Transfusion - 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: Red cells

Sample volume: 4mL

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

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, April, 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, April, 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, April, June, August, October, November

Measurand/Test: Blood grouping, Weak D testing, DAT, Antibody identification, Antibody screen, Phenotyping (Rh/ K antigens only), 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 - 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: 2

Sample Type: 2 red cell donor units

Sample volume: 4mL + 2mL

Schedule: February, April, 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, April, 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 [Catalogue Number: 19160102]

The aim of this program is to assess blood grouping, antibody screen, antibody identification, crossmatching, DAT, Rh

and K antigens and weak D testing. Participants can select which tests they would like to enrol.

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, April, 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, April, 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.

Transfusion Competency - Weak D testing Module (Overseas participants only) [Catalogue Number: 19150102]

The aim of this program is to assess weak D testing

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, April, June, August, October, November

Measurand/Test: Weak D 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.