

What's New in 2022



Anatomical Pathology Discipline



New Programs:

- In conjunction with the RCPAQAP Molecular Genetics Discipline, Sarcoma Gene Testing will be offered as a new program 2022. Laboratories will receive slides to test and interpret using their routine gene testing method (IHC, FISH or molecular). Genes tested in 2022 are ETV6 and MDM2.
- The RCPAQAP will offer a new PD-L1 technical proficiency testing program in 2022. The program will include separate modules for NSCLC, TNBC and HNSCC consisting of 1 survey per year. Laboratories are encouraged to contact the RCPAQAP for assistance between surveys when validating PD-L1 as a new test or optimising methods after an unsatisfactory result. A mentoring service can be provided by Advisory Committee members.
- A new Brightfield ISH (BRISH) technical proficiency testing program will be offered in 2022. The program will include separate modules for HER2 in breast cancer (not new), HER2 in gastric cancer (not new) and a rotating test. In 2022 the rotating tests will be Kappa and Lambda Light Chains.
- Immunohistochemistry mismatch repair (MMR) proteins will be offered as a separate program in 2022. This program will annually test two MMR antibodies in colorectal cancer and in a non colorectal cancer (rotating). In 2022 the antibodies tested will be MLH1 and PMS2 in colorectal cancer and endometrial cancer.

Program Amendments:

- The rotating diagnostic specialist programs are Thoracic and Medical Renal.
- The RCPAQAP continues to collaborate with the [International Quality Network for Pathology \(IQNPath\)](#) for Biomarker read-out proficiency testing including PD-L1. The portal can be [accessed here](#). The RCPAQAP free access code is 9EhcW4px
- The Technical General program will decrease from 3 surveys per year to 2 surveys per year. Four exercises will continue to be offered in 2022.
- Antibodies and other stains being tested in 2022 are outlined in the [Product Catalogue](#).

Biosecurity Discipline



New Programs:

- **Whole Genome Sequencing Program:** The Whole Genome Sequencing Program will be offered for both viruses and bacterial pathogens. Modules offered under this program will contain a specimen-free dry-lab component, assessing the proficiency of laboratories to analyse sequence data. Depending on the organisms covered in a particular module, a wet-lab component consisting relevant specimens will be included.
- **Environmental Specimen Program:** The SSBA Bacterial and Toxin Specimen Program has been renamed to Environmental Specimen Program. Modules offered under this program focuses on 'White Powder' specimens and includes surveys for the plant-based toxins ricin and abrin. Surveys for other environmental samples are tested for the presence of bacterial SSBA.
- **Tularemia eLearning Module:** This has been added to the suite of eLearning modules for Biosecurity.

Program Amendments:

- Biosecurity programs will be offered under a streamlined schedule:
 - Environmental Specimen Program** - Two surveys per year offered in February and April
 - Whole Genome Sequencing Program** - One survey per year offered in March
 - Simulation Exercise Program** - One exercise per year offered in June
 - Scenario-based exercises with up to eight samples - One exercise per year offered in June. This program will cover scenarios that require laboratories to test for bacteria and viruses classified as Tier 1 or Tier 2 Security Sensitive Biological Agents.
 - Viral Specimen Program** - Two surveys per year offered in July and September - This Program is suitable for laboratories performing molecular testing of viral specimens.
 - Bacterial Specimen Program** - Two surveys per year offered in August and October - This program is suitable for laboratories that require the capability to test for the presence or absence of bacteria classified as Tier 1 or Tier 2 Security Sensitive Biological Agents
 - PHLN Program** - One survey per year offered in November. This program will cover emerging biological threats, and panel composition will be developed based on requests from the Australian Government Department of Health and the Public Health Laboratory Network (PHLN)
 - eLearning & Virtual Program** - A suite of eLearning modules for Biosecurity available all year round.
- All programs will be offered with a new online result entry experience and report design in the new myQAP portal. Survey reports and Final reports will be combined into a single Individual report.

Migration to the New myQAP Portal:

- In 2022, most Biosecurity Programs will transition to the new myQAP portal where data entry will be enabled. Survey reports and Final reports will be combined into a single Individual report.

Chemical Pathology Discipline



New Measurands:

- Special Drugs: Immunosuppressants – Everolimus will be included in 4 of the 24 samples in the Immunosuppressants Program with a view to expand to more samples in 2023.
- Endocrine - Macroprolactin. The option to report macroprolactin post PEG precipitation will be available. While there is no macroprolactin in the Endocrine material, the recovery of prolactin post PEG precipitation is intended to guide on potential method differences
- Liquid Serum Chemistry – Troponin (I and T), Prostate Specific Antigen, C-Reactive Protein, Thyroglobulin.
- Dried Blood Spot (Patient) - Phenylalanine/Tyrosine ratio

Program Amendments:

- General Urine Chemistry and Biogenic Amines – Separate survey reports for General Urine Chemistry, Biogenic Amines Linear and Biogenic Amines patient.
- Special Lipids - Results can be submitted in molar units for Lipoprotein (a)
- Special Drugs – Tricyclic Antidepressant Screen (Qualitative) reintroduced

New Advisory Committee Chair:

Dr Chris Farrell - Chemical Pathology Chair: BSc (Med), MBBS, FAACB, FRACP

Chris is Clinical Director of Chemical Pathology at Nepean Hospital in Sydney. He trained in chemical pathology at Royal North Shore Hospital and Laverty Pathology. After obtaining his Fellowship in 2012, he continued with Laverty Pathology, eventually becoming Director of Clinical Chemistry at Laverty Pathology.

Chris has a keen interest in the education and training of pathologists and scientists. He was previously the NSW/ACT education representative for the Australasian Association for Clinical Biochemistry and Laboratory Medicine (AACB) and is currently on the AACB Board of Examiners. In his research, he is currently interested in the use of laboratory data to answer clinical questions, streamline laboratory workflows and improve analytical quality.

myQAP Portal Developments:

- Analytics
- Remaining Chemical Pathology programs due to transition to myQAP in 2022.

[Analytical Performance Specifications](#) are now available on the website under the Resource section.

RCPAQAP

The Royal College of Pathologists of Australasia
Quality Assurance Programs

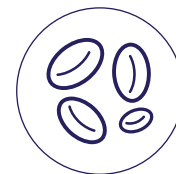
Cytopathology Discipline



Program Amendments:

- The Non-gynaecological Specialty program will consist of thyroid samples in 2022. This program will also include a retrospective thyroid reporting category audit which will open in February and close with the Non-gynaecological Specialty program. Further information regarding this audit will be distributed as it becomes available.
- The Technical program will be a cell block processing exercise.
- Australian laboratories will be assessed on Cervical Screening Result. Further information regarding this change will be distributed to participants as it becomes available.

Haematology Discipline



New Programs:

The following programs will be available to purchase in the first quarter of 2022. Customers will be notified when they are available.

- Doasense – 2 surveys per year / 2 samples per survey. Lyophilised samples. Program suitable for detecting Direct Oral Anticoagulants (DOAC's) in urine samples using (Doasense) urine dipstick.
- Multiplate - 2 surveys / 2 samples per survey. Tube coated with antagonist. Program suitable for detecting platelet function inhibition using the Multiplate instrument.
- Sickle Cell Screening - 4 surveys / 2 sample per survey. Stabilised whole blood - Standalone program sent in the same month as Haemoglobinopathy programs. Program for detecting Haemoglobin S using screening methods. Suitable for solubility and ICT/kit based methods.
- HemoScreen - 4 surveys / 2 samples per survey. Stabilised whole blood - Enrolment for HemoScreen instruments only.

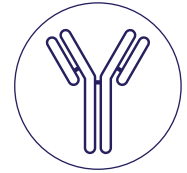
Program Amendments:

- Morphology Program – this program will change from 4 surveys per year / 3 cases per survey to 6 surveys per year / 2 cases per survey.
- Blood Film Program – surveys will be dispatched in the same month as the morphology program.
- Haemostasis Program – Von Clauss and Derived fibrinogen measurands are now separate measurands. Enrolment into an additional instrument for derived fibrinogen is no longer required.
- Thromboelastometry - ROTEM-Delta/ROTEM Sigma Program - CLOTPRO instrument users can now enrol in this program.
- D-Dimer Automated Program – Precision and Accuracy (P&A) analysis is no longer offered for this program.
- Automated Differential Option 2 Program - Alinity hq instrument users can now enrol in this program.
- Automated Differential Option 7 Program - DxH 500/520 instrument users can now enrol in this program.

Migration to the New myQAP Portal:

- In 2022, most Haematology Programs will transition to the new myQAP portal where data entry will be enabled.

Immunology Discipline



Sample Dispatch:

- Material for all enrolments received prior to Friday 11 December 2021 will be dispatched Monday 11 January 2022 (excludes Immunophenotyping, HLA B27 Status, B Cell Subsets).

Program Amendments:

- Reporting of confirmatory testing results will be enabled for the Skin Antibodies program (Desmoglein 1, Desmoglein 3, BP180, BP230).
- Reporting of screening dilutions will be enabled for most indirect immunofluorescence methods.
- Reporting of serum protein electrophoresis fractions will be enabled in the Paraprotein program.
- Reporting of DFS-70 will be enabled in the Extractable Nuclear Antigens (ENA) program.
- Clinical interpretive comments will now be incorporated into the report commentary instead of a reportable field.

Migration to the New myQAP Portal:

- In 2022, most Immunology Programs will transition to the new myQAP portal where data entry will be enabled.
- The following scheduled testing programs will not transition to the new myQAP portal in 2022. Data entry will remain in the Classic myQAP portal.
 1. Food Allergens
 2. Drug Allergens
 3. Neuronal Antibodies

KIMMS Discipline



New Advisory Committee Chair:

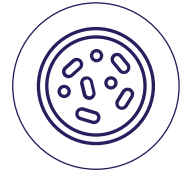
Dr Michael Whiley has been appointed the Chair for the KIMMS program. Michael has been involved in Pre-and Post-analytical services for 25 years as a Chemical Pathologist, AG Director in the ACT and Director of Pathology Queensland. Michael currently holds the position of Chief Pathologist & Director of Medical Services for NSW Health Pathology.

Migration to the New myQAP Portal:

In 2022, the KIMMS program will migrate to the new myQAP portal. The KIMMS Advisory Committee will revise incidents and their definitions, and a new calculation for risk will be introduced. The program will continue to operate 4 surveys per year, covering the 4 quarters Oct-Dec, Jan-Mar, Apr-Jun, Jul-Sep.

The RCPAQAP will provide adequate notice to our customers of any program changes in order that modification to current data extracts can be made by participants.

Microbiology Discipline



New Programs:

- **Molecular Malaria** – 2 samples per survey / 2 surveys per year. Liquid whole blood sample. This program is suitable for laboratories performing molecular testing for the detection of *Plasmodium falciparum*.
- **Molecular Sexually Transmitted Pathogens** – 6 samples per survey / 2 surveys per year. Liquid sample. This program is suitable for laboratories performing molecular testing for the detection of Sexually Transmitted Pathogens using multiplex assays including *Chlamydia trachomatis*, *Herpes Simplex Virus*, *Mycoplasma genitalium*, *Neisseria gonorrhoeae*, *Treponema pallidum*, *Trichomonas vaginalis*.

Program Amendments:

- **Molecular Coronavirus SARS-CoV-2:** The format of the program has changed from 4 samples per survey / 2 surveys per year to 2 samples per survey / 4 surveys per year.
- **Molecular Cytomegalovirus:** The format of the samples has changed from lyophilised simulated plasma samples to liquid plasma samples (volume 1.2mL). The dispatch of the samples has changed from ambient, and surveys dispatched throughout the year to frozen samples and, dispatched in one shipment on dry ice at the beginning of the year. Samples to be stored frozen at a temperature of -20°C or -70°C, until the relevant survey is open for testing
- **Molecular Hepatitis B and Hepatitis C:** Additional samples for separate qualitative and quantitative testing for these programs will no longer be available.

Molecular Genetics Discipline



New Programs:

- **Sarcoma Gene Testing:**
 - Joint program with the RCPAQAP Anatomical Pathology discipline
 - Laboratories will be required to enrol using their Anatomical Pathology participant number
 - Appropriate for laboratories performing IHC, FISH and/or molecular techniques for gene rearrangement or copy number analysis
 - 2022 measurands: ETV6 and MDM2.

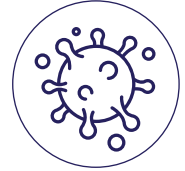
Program Amendments:

- Increased survey frequency for all modules (except sample exchanges) with no change (or similar) to total number of EQA samples per year. Refer to Product Catalogue for survey schedule.
- Enrolment module options are now available for all programs:
 - Additional material
 - o additional cost for material only
 - o data management or analysis will not be provided
 - Data management
 - o additional cost for second instrument/method performed within the same laboratory
 - o submitted data will be assessed separately for the second instrument/method
 - o no additional material will be provided
- Measurands added to existing modules:
 - Mutation Detection in Lung Cancer: KRAS genotyping
 - Mutation Detection in Colorectal Cancer: BRAF genotyping
 - BCR-ABL Qualitative Testing: Clinical interpretation
 - Hereditary Haemochromatosis: Clinical interpretation
- Modules to migrate to the new myQAP portal for data entry:
 - Acute Myeloid Leukaemia NGS Panel Testing
 - FLT-3 ITD and TKD
 - Quality Assessment of DNA Extracts
 - Quality Assessment of FFPE DNA Extracts
 - Sanger DNA Sequencing
 - Thalassaemia
 - TP53 Deletions at 17p13.1 in CLL (FISH)

Upcoming Educational Webinars:

- Limit of detection
- EQA focus What does it mean to get a discordant EQA result?
- Improving performance in Molecular Genetics EQA

Serology Discipline



New Programs:

- Coronavirus SARS CoV-2 Antigen – New program offered for the detection of SARS-CoV-2 antigen. The specimen type for this program is 'simulated respiratory sample'.

Program Amendments:

- Data Management – Enrolment in programs which offer a Data Management/Additional Instruments option allows material from a Full Program to be directly shared with a second instrument/method performed within the same laboratory. The submitted data will be assessed separately for this second instrument/methodology.

Transfusion Discipline



New Programs:

- ABO Titration. This program is suitable for laboratories performing ABO titrations to support ABO incompatible solid organ or stem cell transplants. Planned for release mid-2022.

Blood grouping and Antibody Screen Program:

- This program transitioned to the new myQAP portal in February 2021.
- Options for Laboratories and their individual staff to enrol remain the same for 2022

Program Amendments:

- Snake Venom Detection, Transfusion Competency, and the entire General Transfusion Program including Antibody Titre, Phenotyping and Compatibility modules transitioned to the new myQAP portal for result entry and new report design.
- New reporting format for General Transfusion and Transfusion Competency programs is designed to enhance method comparisons across different testing platforms and reagents.
- The reporting measurand for Snake Venom Detection Program will include the recording of positive wells and their reaction strength.