What's New 2025

RCPAQAP

The Royal College of Pathologists of Australasia
Quality Assurance Programs

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myQAP Enhancements

Dashboard Development

In 2025 we will continue enhancing your dashboard functionality, offering customers more performance information and greater oversight of your EQA participation. This update will provide detailed performance insights, allowing you to easily track your results, identify trends of your performance across all programs. With these additional tools you will be able to make informed decisions and manage your EQA activities more effectively.

Factoring

This new development will make result submission more efficient. Soon, you will be able to enter post-analytical correction factors directly into the result entry portal for select programs. This improvement will automate the de-factoring process, allowing you to save time by retaining factors like slope and intercept between rounds, with the option to update them before the survey closes. If you do not use factors or prefer manual de-factoring, you will not need to make any changes. More information will be shared soon.

Flagging Quantitative Survey Results for Review

Results outside the analytical performance specifications (APS) are currently highlighted in red and listed as low or high in the "Overall Performance" section of RCPAQAP reports.

To help participants prioritise reviews:

- A result outside the APS of the 'all method' median or specific target but within the peer group's APS, will now be highlighted in amber instead of red.
- New messages will highlight results within the target APS but outside the peer group APS.
- Supervisor reports will adopt this logic, with amber indicating results that need attention but are within peer group limits.

Combined Instrument Groups

When manufacturers determine that individual analyser models are equivalent, some reports now present combined performance data alongside statistics for each specific analyser. This will benefit smaller peer groups.

Anatomical Pathology Discipline

New Programs:

- Immunohistochemistry HER2-low scoring in breast cancer - Proficiency testing for individual pathologists who are scoring HER2 IHC in breast cancer
- Immunohistochemistry PD-L1 scoring in NSCLC (TPS) - Proficiency testing for individual pathologists who are applying a Tumour Proportion Score (TPS) to PD-L1 IHC in NSCLC

Program Amendments:

- The HER2 Brightfield ISH (BRISH) Diagnostic program for breast cancer will decrease from 2 surveys to 1 survey
- The rotating diagnostic specialist programs are 'Head and Neck' and 'Renal (Medical)'
- The Mohs Diagnostic Program will change to a coded response plus free text option format in 2025
- Similar to 2024, the Immunohistochemistry Breast Markers Audit will be open for 2 months rather than 6 months. This shorter open period allows laboratories to take timely action on non-conformances
- FISH Diagnostic: the probe for 2025 will be CCND1/CCND2
- Brightfield ISH (BRISH) Technical Program: the additional module offered is Kappa Light Chain in situ hybridisation
- Technical General: this will include an iron special stain, Mucicarmine special stain and artificial intelligence laboratory practice questionnaire
- Sarcoma Gene Testing: the tests will be ALK and CIC-DUX4
- Neuropathology Immunohistochemistry and Technical: the tests will be ATRX and Myelin stain Immunohistochemistry Lymphoma Markers: tests include CD3 (alternate Bcl2); C-Myc (alternate CD45); Ki-67 (alternate CD20)
- Immunohistochemistry Mismatch Repair (MMR) Protein: tests include MSH2 and MSH6 on colorectal carcinoma and a second tissue type
- Immunohistochemistry General: tests include PRAME (alternate MelanA); Claudin4 (alternate BAP1); PIN4 (alternate P63)
- Immunohistochemistry Breast Markers: tests include ER, PR, HER2 IHC, SMMS-1, CK5/6

Biosecurity Discipline

New Programs:

- SSBA eLearning module for Brucellosis will be added to the suite of eLearning modules for Biosecurity in 2025
- **Whole Genome Sequencing:** Bacterial (Mycobacterial) program for selected laboratories (by invitation only), consisting of wet-lab and subsequent bioinformatics analysis of sequence data derived from the WGS wet-lab workflow will be offered in June 2025

Program Amendments:

- Emerging Biological Threats Program for avian influenza virus, consisting of inactivated viruses for nucleic acid testing (NAT) will be offered in November 2024
- Emerging Biological Threats Program for the Monkeypox virus will be offered in 2025. This program can only be offered to Australian laboratories. Overseas laboratories can express interest in the program and the RCPAQAP will try to accommodate these requests if possible
- Simulation Exercise Program (Biopreparedness Exercise – Viral), consisting of highly pathogenic influenza will be offered in June 2025. The program provides scenario-driven exercises to assess laboratories' testing capabilities and ensure timely result reporting, which assists with public health responses.
- Organisms that will be included in Whole Genome Sequencing - Viral, Viral Specimen and Bacteria Specimen Programs are yet to be determined. Updates regarding the 2025 enrolment will be sent once available

Upcoming Webinar:

A follow-up webinar to the Whole Genome Sequencing – Viral program will be offered in May 2025

Chemical Pathology Discipline

New Programs:

- **Chromogranin A and Copeptin:** full program consisting of 3 surveys/2 samples per year. This program covers Chromagranin A, Copeptin and Cystatin C
- **Special Drugs:** Beta-Lactams, Tuberculosis, and Other Drugs Full Program consisting of 12 surveys/2 samples per year. This is a lyophilised sample. This program covers a range of beta-lactams, tuberculosis and other drugs, including busulfan
- **Reference Interval Program:** this will be complimentary with the Liquid Serum Chemistry program enrolment

Program Amendments:

- **Body Fluids:** the number of surveys has been reduced from 6 to 3
- **General Serum / Condensed / Compact Chemistry:** the volume has been reduced from 5ml to 3ml*, Transferrin Saturation measurand will be available in 2025, Glycated Albumin measurand is available in 2025. Some method categories with fewer than 6 participants will be combined for statistical analysis
- **General Serum Chemistry:** the number of surveys has been reduced from 24 to 21*, thereby reducing the number of samples from 48 to 42
- **Endocrine PSA:** the volume has been reduced from 3mL to 1mL due to price increases from our supplier
- **Biogenic Amines Patient and Linear:** the volume change has been reduced from 10mL to 5mL
- **Dried Blood Spot**: Galactose measurand is available in 2025, TSH, IRT and 17OHP immunoassay measurands will be assessed in 2025
- **Liquid Serum Chemistry:** the number of surveys has been increased from 2 to 3
- **Patient Report Comments:** this program will be renamed Chemical Pathology Case Study and will transition to self-assessment. Keyword grading will no longer be assessed, and target responses will be provided for self-assessment. The number of surveys has been reduced from 6 to 5
- **General Urine Chemistry:** Cortisone measurand is available in 2025
- **Lot number recording:** the option to record Lot numbers will be available for HbA1c whole blood and lyophilised, Oral Fluid Toxicology, On-Site Urine toxicology, PoCT and Dried Blood Spot programs.

* *Despite these changes, we estimate the volumes to be sufficient for approximately 600 tests, which is adequate for testing on additional instruments. Due to significant cost increases from our supplier, we have adjusted the sample volumes to avoid significant increases in the price of these programs.*

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Assessment Category Amendments:

- **CRP:** changing from all result median to measurement system
- **General Chemistry:** Amylase, Total Bilirubin, Conjugated Bilirubin and LDH changing from specific target to measurement system.
- **Neonatal bilirubin:** Conjugated bilirubin changing from all result median to measurement system.

Programs launched in 2024:

- i-Sens Glucose and i-Sens Ketone meters
- Special Drugs: Everolimus consisting of 12 surveys / 2 samples per survey. The sample is lyophilised whole blood. With guidance from the Special Drug Advisory Committee, this material has been developed to allow the full range of concentration for Everolimus to be assessed without interference from Sirolimus.
- Lactate Meters: consisting of 4 surveys / 2 samples per survey. The sample is liquid lactate solution. This program is suitable for any point-of-care device used to test lactate.

Programs in Development:

- mTBI Markers for traumatic brain injury
- Pre-eclampsia markers – sFlT-1/PlGF
- phIGF-BP1 marker

Discontinued Program:

- **Foetal Fibronectin:** this program has been discontinued due to reagent unavailability. A replacement program is being investigated.

Cytopathology Discipline

Program Amendments:

- Non-gynaecological FNA and General programs will change to a free-text only format in 2025 to align with the Specialty program
- Non-gynaecological Specialty program will consist of effusion samples in 2025
- Technical program will be a preparatory trouble-shooting exercise with a focus on the Romanowsky stain of non-gynaecological samples
- The program previously known as ‘Performance Measures’ will change to ‘Cervical Screening Program Indicators’ in 2025
- Gynaecological programs assessment mapping document is subject to change in 2025.

Haematology Discipline

Program Amendments:

- **Haemostasis program:** measurand configuration at result entry is now available.
- **Lupus:** survey samples will be sent in bulk for the year in a box. Sample volume will be 1mL in each vial. 2 vials will be provided for each survey sample. A total of 8 vials will be included in the kit
- **D-Dimer:** survey material composition is changing from liquid to lyophilised plasma. Reconstitution with 1.0mL water will be required
- **Morphology and Blood Film Differential programs:** data management will be available for these programs to allow individual submissions. The laboratory should enrol in the full program, and any individual submissions can be enrolled as data management. Data management enrolment is suitable for both pathologists and scientists. Pathologists and registrars in clinical-only practice should enrol as individual registrars and individual pathologists
- Participant comments will appear on survey reports for the following programs: Morphology, Blood film differential, Paediatric morphology, Malaria morphology, Bone marrow, Haemoglobinopathy.

Program in Development:

- Viable CD34

Sample Dispatch :

Samples for the following Special Haemostasis programs will be sent in bulk in 2025: Activated Protein C resistance, Apixaban (Anti Xa), Dabigatran, FVIII Inhibitor, FXIII, Low Molecular Weight Heparin monitoring, Lupus Anticoagulant, Thrombophilia, Rivaroxaban (Anti Xa), Unfractionated Heparin monitoring, von Willebrand Factor. The bulk dispatch of these samples is scheduled for the first week of February.

Immunology Discipline

Program Amendments:

- **Myositis and Scleroderma Specific Antibodies:** RNAP-III / RP11 / RP155 will be separated into anti-RNA pol III antibodies, anti-RP11 antibodies, and anti-RP155 antibodies measurands.

New Packaging:

We are excited to announce a significant improvement in our packaging. We will be transitioning from soft plastic to a more sustainable cardboard kit for most programs. The new packaging has been validated for long-term storage at temperatures below -30 degrees Celsius.

Case Study Changes:

The Immunology Case Study program is migrating to the myQAP portal. This ensures a more efficient and secure process for managing your Immunology Case Study participation. Instead of emailing reports, all Case Studies and individual reports will now be securely uploaded to the portal. Case questions will be linked in the myQAP portal survey instructions, and responses submitted through the result entry tab.

Individual responses will be submitted via additional data management enrolments at no extra cost to your full program enrolment. Laboratories will need to assign participant numbers (e.g., IM/123.1, IM/123.2) to each respondent. Ensure you enrol in the required number of data management module options for the number of respondents from your laboratory.

Sample Dispatch:

For enrolments received prior to Monday 23 December 2024, dispatch will commence on a weekly schedule starting Monday 6 January 2025 (excludes Immunophenotyping, HLA B27 Status, B Cell Subsets).

Microbiology Discipline

New Programs:

- **Molecular Dermatophytes:** consisting of 6 samples/2 surveys. This is a liquid sample. This new program is suitable for laboratories performing molecular testing for the detection and identification of dermatophytes such as *Microsporum*, *Trichophyton* and *Epidermophyton*
- ***Helicobacter pylori* faecal antigen:** consisting of 3 samples/2 surveys. This is a liquid sample. This new program is suitable for laboratories performing testing for *H. pylori* antigens in human stool samples. This program is not suitable for molecular assays.

Program Amendments:

- **Blood Culture program:** anaerobic susceptibility testing will be included in one survey in 2025
- **Molecular CSF:** additional targets, *Listeria monocytogenes*, *Streptococcus agalactiae*, and HHV-6, have been included for 2025.

Programs launched in 2024:

- **Detection of Antimicrobial Resistance:** consisting of 5 samples/2 surveys. This is a lyophilised sample. This comprehensive program replaces two previous programs - Vancomycin Resistant Enterococci (VRE) and multidrug-resistant Gram-negative (MDR) - which are no longer offered. This program is suitable for laboratories that perform routine bacteriology and/or surveillance screening for resistant bacteria and fungi that may cause hospital outbreaks. The program will include but is not limited to organisms such as Carbapenem-resistant *Acinetobacter baumannii* (CRAB), Carbapenem-resistant Enterobacterales (CRE) *Pseudomonas aeruginosa*, *Salmonella* species, *Shigella* species, VRE and *Candida auris*.
- **Detection of *Mycobacterium chimaera* in Heater-Cooler Units:** consisting of 4 samples/1 survey. This is a lyophilised sample. This program is suitable for laboratories performing microbiological and molecular testing for the detection of *Mycobacterium chimaera* in simulated water samples.

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Programs launched in 2024:

- **Molecular Strongyloides:** consisting of 3 samples/2 surveys. This is a lyophilised sample. This program is suitable for laboratories performing molecular testing for the detection of Strongyloides in simulated faecal samples.
- **Molecular HSV/VZV:** consisting of 6 samples/2 surveys. This is a liquid sample. This combined program is suitable for laboratories performing molecular testing for the detection of HSV and VZV in simulated vesicle fluid, using single and multiplex assays.

Programs in Development:

- Whole Genome Sequencing – General Bacterial
- Molecular Transplantation Pathogens
- Molecular HPV DNA – Swabs

Molecular Genetics Discipline

Program Amendments:

- **Acute Myeloid Leukaemia NGS Panel testing:** the module name has changed to Myeloid NGS Panel testing. The module has been updated to cover other myeloid malignancies including acute myeloid leukaemia, myeloproliferative neoplasms and myelodysplastic syndrome
- **Kennedy's Disease:** this program is no longer offered as a sample exchange. Participating laboratories will be provided with purified genomic DNA for molecular testing of CAG repeats in the androgen receptor *(AR)* gene. Laboratories will be assessed for the identification of CAG repeats and clinical interpretation.

Frequency of surveys reduced to 2:

- Human Leukocyte Antigen B*57
- Coeliac Disease HLA Genotyping
- Maternal Cell Contamination (changed from 1 family trio to 2 family trios per survey)
- IDH Mutation Analysis in AML (changed from 1 to 2 samples per survey)
- Myeloproliferative Neoplasms
- Hereditary Haemochromatosis
- Thrombosis
- NPM1 (changed from 1 to 2 samples per survey)
- BCR-ABL Qualitative Testing (changed from 1 to 2 samples per survey)
- PML-RARA (changed from 1 to 2 samples per survey)
- Chimerism Analysis (changed from 1 to 2 samples per survey)
- Immunogenotyping (changed from 1 to 2 samples per survey)

Program launched in 2024:

Lymphoid NGS Panel Testing: consisting of 1 survey / 1 sample. This is a DNA sample. This module qualitatively assesses laboratory performance in the detection and reporting of various genes associated with lymphoid haematological malignancy using next generation sequencing.

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Programs in Development:

- 3 Gene Carrier Screening (CFTR, FMR1, SMN1)
- RCPAQAP Non-Small Cell Lung Carcinoma Panel Testing
- RCPAQAP DPYD genotyping
- RCPAQAP HLA-B*15:02 and HLA-A*31:01
- RCPAQAP HLA-B*58:01

Sample Exchange:

The RCPAQAP Molecular Genetics discipline currently runs a sample exchange program for tests on rare genetic disorders performed by a small number of laboratories. Current sample exchanges can be viewed in the Product Catalogue.

RCPAQAP will facilitate the exchange of test samples between participating laboratories, result submission and assessments, and a survey report summarising the results and performance will be provided. A minimum of 2 laboratories is required to initiate an exchange. Participating laboratories are expected to provide samples to the RCPAQAP, which will be re-labelled and distributed to participating laboratories.

Laboratory interest is welcomed for the following tests:

- 1p/19q co-deletion
- BRCA1 promoter methylation
- MLH1 methylation

Laboratories are encouraged to submit their interest by completing the new program request form.

Serology Discipline

Program Amendments:

- **Point of Care Testing RSV:** the number of surveys has been reduced from 4 to 2
- **Point of Care Testing Influenza A and B:** the number of surveys has been reduced from 4 to 2.

Specimen Free Case Study:

The Specimen Free Case Study program is migrating to the myQAP portal and will be renamed Serology Case Study. This ensures a more efficient and secure process for managing your Serology Case Study participation. Instead of emailing reports, all Case Studies and individual reports will now be securely uploaded to the portal. Case questions will be linked in the myQAP portal survey instructions, and responses submitted through the result entry tab.

Individual responses will be submitted via additional data management enrolments at no extra cost to your full program enrolment. Laboratories will need to assign participant numbers (e.g., SE/123.1, SE/123.2) to each respondent. Ensure you enrol in the required number of data management module options for the number of respondents from your laboratory.

Sample Dispatch:

For enrolments received prior to Monday 28 October 2024, dispatch will commence on a weekly to biweekly schedule starting Monday 11 November 2024 (excludes HIV PoCT).

Transfusion Discipline

New Program:

- **Haemolytic Disease of the Newborn:** consisting of 2 surveys/ 2 samples. This is an EDTA whole blood sample. This program will evaluate the participant's proficiency in processing newborn samples and conducting investigations into haemolytic disease of the newborn.

Program Amendments:

- **Antibody Titre:** the number of surveys has been reduced from 5 to 4. The myQAP portal now includes reporting titre levels below neat and at neat.
- **Fetomaternal Haemorrhage Estimation:** the Fetomaternal Haemorrhage Program has discontinued reporting fetal cell percentages from the Kleihauer test to align with recent updates to the ANZSBT guidelines.

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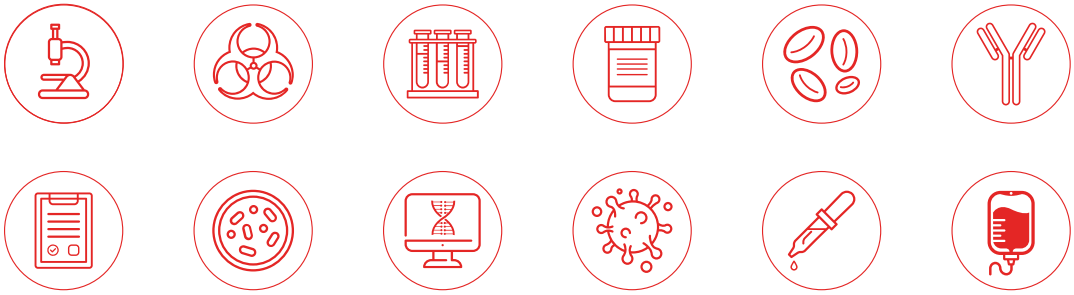

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