Internal Quality Assurance Framework

Genetic Pathology

The Royal College of Pathologists of Australasia received funding from the Department of Health, under the Quality Use of Pathology Program (QUPP) to develop a comprehensive framework for internal quality assurance, focused on the morphological disciplines of Histopathology, Cytopathology, Haematology and Forensic Pathology. The overall governance of this project was provided by the College, and was supported by a Steering Committee that included representatives of the morphological disciplines. The Board of Education and Assessment and the Board of Directors further decided to develop separate discipline specific Frameworks.

The Genetic Pathology IQA Framework contains activities that will aim to help monitor performance, drive improvement and provide a collaborative on-going professional practice process. The IQA Framework activities focus on peer-review and clinical audit and require documented evidence of a pathologist's involvement in these internal quality activities. The Framework is practice based and the Genetic Pathology Advisory Committee provided guidance with the development of the Genetic Pathology Framework activities.

Implementation of the Genetic Pathology IQA Framework will be undertaken in 2017 in consultation with the Fellowship.

For any queries about the Framework or the project, contact the DCEO, Dr Bronwen Ross at bronwenr@rcpa.edu.au

Framework Features

The Internal Quality Assurance framework divides laboratory activities into 3 specific cycles:

1. *Pre-analytic* phase of the test cycle includes specimen delivery and accessioning, specimen handling and laboratory technical processing.

2. *Analytic* phase of the test cycle, in the current context, relates to the pathologist diagnostic component.

3. *Post-analytic* phase of the test cycle begins with report authorisation through to report delivery, and may include adjunct activities such as billing.

The Framework records these activities under 2 sections:

Section 1: Diagnostic Measures (the analytic phase) relates to peer review activities, participation in 10 hours per annum required.

Section 2: Technical Laboratory Measures (pre-analytic) and Service Performance (post analytic/overview) relate to clinical audit activities, participation in 10 hours per annum recommended.

Please refer to the tables on the following pages for information on examples of suitable activities and further document requirements.

FRAMEWORK Internal Quality Assurance Activities GENETIC PATHOLOGY		
Section 1: DIAGNOSTIC MEASURES - (engaging in peer review activities) **Requirement: Minimum 10 hours per annum Diagnostic Measures**		
Activity	**Quality activity monitor related**	**Suggested document requirements**
Case Reviews Using clinical audit techniques	• Internal random case review - *examples could include*: - Defined % of cases	Document the review type - Who performed the review - What was reviewed - What cases were reviewed - Time taken Document discordance as - None (agreement) - Minor non clinical - Minor clinical (no impact on patient care) - Major clinical (potential impact on patient care)
	• Internal target case review - *examples could include*: - Specific case types, selected by clinical presentation - Specific case types, selected by testing method - Or other specific case types	
	• Internal correlations - *examples could include*: - Screening and diagnostic testing - Cytogenetic and molecular and biochemical genetic testing - Or other types of correlations performed - e.g. NIPT follow-up by amniocentesis/ Chronic villus sampling (CVS), array follow-up by karyotype/ FISH	
	• Inter institutional correlations - *examples could include*: - Second opinions (incoming and outgoing) - Or in the context of sample/data swapping as part of a validation process	
	• Intradepartmental correlations - *examples could include*: - Formal and informal second opinions	
	• Multi Disciplinary Team (MDT) case presentations - Any discordant opinions	Document discordance as - None (agreement) - Minor non clinical - Minor clinical - Major clinical
	• Audit of corrected/ amended reports	
	• Audit of compliance with current published reporting requirements – *examples could include:* - NATA/NPAAC requirements	
Formal Peer Review	• Validated 360 degree peer review completed	Date, time and duration and brief description of activity.

Each laboratory must have documented processes for handling diagnostic discordances when detected.

FRAMEWORK
Internal Quality Assurance Activities
GENETIC PATHOLOGY

Section 2: TECHNICAL MEASURES - laboratory based non-conformances (audit activities)

Recommended: Minimum 10 hours per annum combined Technical Measures/Service Performance

Activity	Examples of quality monitors related to lab based non-conformances	Suggested document Requirements
Non-conformance reporting A laboratory non-conformance is an incident that has the potential to cause an error or harm. Documentation of these is a requirement. Laboratories should have existing policies, procedures and processes in place if such an incident occurs. The examples stated in this table should be reported.	• Specimen receipt issues* - *examples could include:* - Incorrect identifiers - Labelling errors - Lost specimens • Specimen handling issues - *examples could include:* - Test selection • Laboratory technique issues - *examples could include:* - Nucleic acid extraction failure - Prenatal culture failure - Lymphocyte culture failure - Assay QC failure	Incidence +/- % of non-conformances
Section 2: SERVICE PERFORMANCE - suggested examples below of types of service activities that may Be monitored and specific data collected		
Audit of Service Performance The goal is to monitor and improve internal laboratory performance using auditable measures and collect acceptable data to develop benchmarks for the future.	• Service and Performance - *examples could include:* - Turn Around Times** - Whole workload or - Selected case type • Report format review - *examples could include:* - Typographical & - Transcript errors • Billing Errors	Documentation of TAT - Overall - Different phases of reporting process - By different case type - % of errors post audit

* Laboratories must have policies for handling detected non-conformances

** Consider criteria from NPAAC/NATA guidelines

Establishing a Genetic Pathology IQA Framework that will be used to routinely review processes in the discipline should facilitate improved laboratory practices. It provides a mechanism for peer review, introduces a mechanism for laboratories to benchmark their processes to measure improvements, reduces the risk of aberrant/uninformative/false reports being issued in a clinical environment, thereby improving the quality of patient management and/or outcomes.

Activities performed from the Genetic Pathology IQA Framework will be linked to the RCPA CPD Program and will likely be an important part of any Revalidation Framework the College may need to adopt in the future.

The completion of these activities could form part of the RCPA audit substantiation for the RCPA CPD Program in the future.