HANDBOOK

RCPA
The Royal College of Pathologists of Australasia

Extension of Scope of Practice in Molecular Genetics

(NPAAC Supervision Certification Modules)

Microbiology

Contents

Glossary

CPDP	RCPA Continuing Professional Development Program
(F)RCPA	(Fellow of the) Royal College of Pathologists of Australasia
IANZ	International Accreditation New Zealand
MDT	Multi-disciplinary team
NATA	National Association of Testing Authorities
NPAAC	National Pathology Accreditation Advisory Council
PPD	Personal Professional Development
RCPAQAP	RCPA Quality Assurance Programs Pty Ltd
SOP	Standard Operating Procedure
WHS	Workplace Health and Safety

SECTION 1

Introduction

1.1 Introduction

The Royal College of Pathologists of Australasia (the College) currently offers two certification modules in genetic/genomic microbiology for those who have attained FRCPA. A third may be added later.

These modules have been designed to satisfy the recent NPAAC Requirements, particularly as applicable to supervision of testing involving molecular diagnostics and genomics.

The modules do NOT apply to current microbiology practice in molecular diagnostics and Sanger sequencing, which are integral to the existing training, experience and responsibilities of clinical microbiologists. All clinical microbiologists will continue to be able to supervise this testing.

To competently supervise a Whole Genome Sequencing (WGS) service, clinical microbiologists need to have adequate and detailed knowledge of the wet and dry laboratory aspects of the technology and bioinformatics analysis. It is recognised that this knowledge may not be the same as the hands-on experience of the scientist in the WGS laboratory, however, supervising pathologists should be familiar with the limitations and strengths of the methodology, the ethical considerations of data use and reporting, and the clinical relevance for assessing appropriate requesting and reporting.

It is anticipated that in the next few years, WGS will expand beyond specialised and reference laboratories and be integral to the work of pathology laboratories and thus the general Fellowship training program. These modules are designed to provide currently practicing microbiologists with the opportunity to participate in accordance with NPAAC requirements.

1.2 General aims

The genetics/genomic certification modules build on discipline-specific Fellowship training. They are designed to build base knowledge, analytical and interpretive skills, quality assurance and communication capabilities relevant to genetics/genomic testing in Microbiology.

Certification aims to ensure a level of competence required to supervise testing and ensure safe clinical service provision in the relevant field.

The purpose of the modules outlined in this Handbook is to offer Fellows the opportunity to gain certification of expertise for a graduated range of genetic/ genomic testing categories specifically for clinical applications within their pathology discipline.

The certification modules build on discipline specific Fellowship training. Candidates are expected to further develop the skills in management, research, scholarship, and professional qualities they have been developing during their pre- and post-Fellowship years and will continue to develop during their professional life.

Please note: Module 1 is required for those who wish to complete Module 2. The modules may be undertaken simultaneously but Module 2 cannot be taken alone. There will be no opportunity to complete Module 2 without completing Module 1.

Pathogen genomics refers to the use whole genome sequencing (WGS) technologies to obtain read data that can be analysed to enlighten various clinical and public health scenarios. WGS within microbiology pertains to all human pathogens (e.g. bacteria, viruses, fungi and parasites) and can be performed from the isolate or directly from sample.

The goal of targeted sequencing can be considered broadly in 2 groups: those that pertain to a

single pathogen and those projects that examine relationships between multiple numbers of the same pathogen of either specific public health interest or within hospitals. Examples of these two categories include high-resolution identification and characterisation of microbial pathogens; inferring drug resistance from whole genome sequence; relating individual cases to an outbreak of infectious disease and establishing the association between an outbreak and an environmental reservoir.

In contrast, non-targeted sequencing or metagenomics examines for the presence of pathogen(s) or the relative composition of different microbial populations within a specific niche (microbiome). The diagnostic utility of these applications is likely to increase in the future.

To address adequately the wide range of professional competencies required to supervise these activities, it is proposed that post-graduate training and assessment is delivered in two modules (with a third module to be considered in the future directed at non-targeted sequencing). The modules are a practical response to the gradient of technical and complexity within pathogen genomics, as well the differing practical skill sets required.

Completion of one or more modules would result in extension of scope of practice within Microbiology to the limits defined for each module.

While candidates will gain understanding of the breadth of the field, they must remain aware of the limits of their own knowledge and appreciate when it is in the best interests of patients to refer to, or formally consult with, genetic pathologists or other appropriately credentialed colleagues.

1.3 Registration

Applicants must complete a registration form, obtainable from the RCPA website and submit this with the application fee. The form must clearly state the modules(s) being applied for. Applications for partial exemption from assessments (recognition of prior learning) must be submitted with supporting documentation at the time of registration.

1.4 Training structure and requirements

The modules are outcomes-based, with no fixed time requirements for completion. Candidates must participate in a range of laboratory-based experiences to achieve the listed outcomes. All specified assessment tasks must be completed satisfactorily to achieve certification.

1.5 Supervision

All training must be supervised by an approved Fellow of the RCPA with the required expertise. Supervisors are expected to monitor and provide regular feedback on the candidate's developing competence. Formal meetings with the candidate are expected to occur at least every three months.

The supervisor will complete a Supervisor Report at the end of the training period, along with a completed and signed portfolio summary sheet. If the training period exceeds twelve months, an additional annual Supervisor report will be required.

The supervisor will carry out workplace-based assessments or may delegate this responsibility to another suitably qualified pathologist or senior scientist.

1.6 Assessment

Assessment consists of a range of activities and workplace-based assessments to be documented in a portfolio, and formal examinations as prescribed for each module.

Portfolios may be maintained in paper-based and/or electronic format with back-up. Portfolios do not need to be submitted to the College. The supervisor will verify that all entries and assessment tasks have been completed on the portfolio summary sheet to be submitted with the final Supervisor Report for the module.

1.7 Continuing professional development

Activities carried out and documentation associated with the modules may be included, along with general Microbiology activities, in the relevant categories of the RCPA Continuing Professional Development Program (Professional Performance Framework). Following certification, specialists are expected to undertake ongoing professional development relevant to the modules for which they are certified.

SECTION 2

Learning outcomes and recommended training activities

Module 1: Pathogen identification and characterisation using genome data

This builds on a sound understanding of Sanger and the next-generation sequencing and analysis.

Examples of clinical applications include:

- Identification of an isolate
- Inference of drug resistance from whole genome sequence (pathogen) only
- Inference of virulence determinants
- Inference of multi-locus sequence type

It is anticipated that this module will be progressively incorporated into the microbiology Fellowship curriculum. In time, the need for this module to be offered as a specific post-fellowship training module will disappear. Meanwhile this module is available as a post-fellowship option for microbiologists seeking to take responsibility for the pathology tests in this category.

1.1 Learning outcomes

1.1.1 Theoretical and Technical Knowledge

- Methods covered:
  - Massively parallel sequencing using amplicon-based and/or capture-based assays.
- Knowledge of theory and processes relating to 'Wet Lab':
  - Knowledge of technical performance, limitations and quality issues associated with different library preparation and sequencing techniques
  - Knowledge of technical performance, limitations and quality metrics associated with different sequencing technologies
  - Appropriate specimen types and associated collection methods
  - Genomic DNA/RNA extraction method(s)
  - Nucleic acid quantity and quality indicators
  - The role of positive, negative controls and reference strains/genomes
  - Trouble-shooting failed quality indicators
  - Characteristics of the specific factors pertaining to pathogen (e.g. RNA vs. DNA, gram positive vs. gram negative bacteria) and the design of sequencing experiments
- Knowledge of theory and processes relating to 'Dry Lab':
  - Knowledge of relevant bioinformatics issues including reference selection, capacity and limitations of alignment tools, variant callers used for variable determination (e.g. genes conferring resistance or virulence).
  - Knowledge of sequencing data and meta-data structure, data security/privacy regulations
  - Understanding of available databases used for identification and characterisation of different pathogens, their limitations and processes of maintaining their content currency
  - Understanding of cloud based secondary and tertiary analysis systems

1.1.2 Analytical and interpretive skills

- Ability to evaluate accuracy of WGS platforms and bioinformatics pipelines
- Ability to evaluate accuracy and precision of WGS results as well as their analytical and diagnostic sensitivity, specificity and predictive values
- Synthesis and interpretation of laboratory data in a clinical context.

1.1.3 Quality assurance

- No specific guidance pertaining to quality issues, validation and requirements of supervision of massively parallel sequencing pertaining to microbial sequencing has been agreed so far, however, these indicators are discussed in *Requirements for human medical genome testing utilising massively parallel sequencing technologies, National Pathology Accreditation Advisory Council, 2017*.
- Knowledge of potential sources of error
- Knowledge of ethical, clinical and regulatory structures/framework
- Knowledge of technical performance, limitations and quality issues
- Recognition and troubleshooting of challenges
- Competence in monitoring data quality and result verification

1.1.4 Communication and Consultation

- Ability to critically assess the appropriateness of whole genome sequencing to answer specific clinical and public health questions
- Ability to communicate relevant clinical advice regarding pathogen identification using genomic methods
- Work collaboratively with laboratory scientists and pathologists in other disciplines.

1.2. Assessment

1.2.1 Portfolio requirements

Item	Requirements (number/type)	Documentation
Generated Isolate Reports	Generated reports of at least 50 isolates representing at least 5 different pathogens (i.e. not the same species) attained from more than 5 runs).	Log book to include organism, identification, method(s) used, and technical issues requiring review (See Appendix 2)
Process-based Discussions (PbD)	Detailed discussion (at least one (1) page description of method in addition to PbD cover sheet) on two (2) processes. These should include 1 Wet Lab (extraction of DNA, library prep and sequencing) and 1 Dry Lab (sequencing, quality checks & analysis). (**note**: potential problems should be discussed).	PbD Assessment Form (See Appendix 2)
Quality Assurance (QA) Report	One (1) report from the lab with analysis (~500 words). The report should include a brief reflection on what is learned from doing this activity.	QA Report Form (See Appendix 2)

Supervisor Report	One final report, plus additional annual report if module not completed in <12 months.	With sign-off indicating: • the principles of the method(s) are understood; • working knowledge of instrument processes and maintenance requirements; • successful generation of results at a quality level sufficient for reporting; • strong understanding of QC procedures for the method, including internal QA; • working knowledge of method anomalies and associated trouble-shooting requirements. (Supervisor Report, Appendix 2)
Portfolio Summary sheet	To accompany final Supervisor Report	Portfolio Summary Form

1.2.2 Formal examinations

See Appendix 1

1.2.3 Assessment matrix

See Appendix 3

Module 2 – Pathogen genomics for the determination of relationships between isolates / generation of a phylogeny

This builds on a sound understanding of Core Module 1 and can only be undertaken after or in conjunction with Core Module 1.

Similar to Module 1, it is anticipated that this module will be progressively incorporated into the microbiology fellowship curriculum. Meanwhile this module is available as a post-fellowship option for microbiologists seeking to take responsibility for the microbiological tests in this category.

Examples of typical clinical applications include:

- relating individual cases to an outbreak of public health importance
- relating individual cases to an outbreak within a hospital
- investigation of the most likely transmission pathways within the outbreak
- to establish the association between the outbreak and a specific vehicle (e.g. environment or food source).

2.1 Learning outcomes

2.1.1 Theoretical and Technical Knowledge

- Knowledge of limitation and strengths of different typing schemes using WGS data (e.g. in-silico MLST vs. cgMLST vs. wgMLST vs SNP-based similarity assessment)
- Knowledge of the effects of recombination on genome similarity assessment and methods to manage those effects and need to mask regions of recombination.
- Knowledge of the strengths and limitations of different tree building algorithms, software programs and visualisation tools
- Knowledge and experience of microbial genomic analytical software for genome similarity assessment, tree generation and genomic data visualisation

- Knowledge of theory and processes relating to Wet Lab:
  - Knowledge of technical performance, limitations and quality issues associated with different library preparation and sequencing techniques
  - Knowledge of technical performance, limitations and quality metrics associated with different sequencing technologies
  - Appropriate specimen types and associated collection methods
  - Genomic DNA/RNA extraction method(s)
  - Nucleic acid quantity and quality indicators
  - The role of positive, negative controls and reference strains
  - Trouble-shooting failed quality indicators
  - Characteristics of the specific factors pertaining to pathogen (e.g. RNA vs. DNA, gram positive vs. gram negative bacteria) and the design of sequencing experiments

- Knowledge of theory and processes relating to Dry Lab:
  - Knowledge of relevant bioinformatics issues including reference selection, capacity and limitations of alignment tools, variant callers used for variable determination (e.g. resistance or virulence genes).
  - Knowledge of sequencing data and meta-data structure, data security/privacy regulations
  - Understanding of available databases used for identification and characterisation of different pathogens, their limitations and processes of maintaining their content currency
  - Understanding of cloud based secondary and tertiary analysis systems

2.1.2 Analytical and interpretive skills

- Ability to evaluate accuracy of WGS platforms and bioinformatics pipelines
- Ability to evaluate accuracy and precision of WGS results as well as their analytical and diagnostic sensitivity, specificity and predictive value
- Synthesis and interpretation of laboratory data in a clinical context

2.1.3 Quality assurance

- No specific guidance pertaining to quality issues, validation and requirements of supervision of massive parallel sequencing pertaining to microbial sequencing exist however, these indicators are discussed in *Requirements for human medical genome testing utilising massively parallel sequencing technologies, National Pathology Accreditation Advisory Council, 2017*.
- Knowledge of potential sources of error
- Knowledge of ethical, clinical and regulatory structures/framework
- Knowledge of technical performance, limitations and quality issues
- Understanding of version control of bioinformatics tools
- Recognition and troubleshooting of challenges
- Competence in monitoring data quality and result verification

2.1.4 Communication and Consultation

- Ability to critically assess the appropriateness of whole genome sequencing to answer specific clinical and public health questions
- Ability to communicate relevant clinical advice regarding pathogen identification using genomic methods
- Work collaboratively with laboratory scientists and pathologists in other disciplines
- Ability to communicate relevant information to hospital staff and committees and to public health authorities as required

2.2. Assessment

2.2.1 Portfolio requirements

Item	Requirements (number/type)	Documentation
Generated Isolate Reports	Generated reports of at least 3 phylogenies (trees) based on a minimum of 10 newly generated sequenced isolates (i.e. not downloaded from publicly available repositories).	Log book to include organism, identification with diagrammatic representation of phylogenies, and description of methods used method(s) used. (See Appendix 2)
Process-based Discussions (PbD)	Detailed discussion (at least one (1) page description of method in addition to PbD cover sheet) on two (2) processes. These should include 1 Wet Lab (extraction of DNA/RNA, library prep and sequencing) and 1 Dry Lab (sequencing, safe data	PbD Assessment Form (See Appendix 2)

	storage, quality checks & analysis e.g., in silico detection of gene targets). (note: potential problems should be discussed)	
Quality Assurance (QA) Report	One (1) report from the lab with analysis (500 words). The report should include a brief reflection on what is learned from doing this activity	QA Report Form (See Appendix 2)
Supervisor Report	One final report, plus additional annual report if module not completed in <12 months.	With sign-off indicating: • the principles of the method(s) are understood (including an adequate understanding of principals set out in core module 1); • working knowledge of the intricacies of phylogenetic analysis and genome similarity assessment; • strong understanding of QC procedures for the method, including internal QA; • working knowledge of method anomalies and associated trouble-shooting requirements. (Supervisor Report, Appendix 2)
Portfolio Summary sheet	To accompany final Supervisor Report	Portfolio Summary Form

2.2.2 Formal examinations

See Appendix 1

2.2.3 Assessment matrix

See Appendix 3

Module 3 - Microbiome

This module is currently on hold in development. It is anticipated that this module will cover metagenomics and specimen-based sequencing.

SECTION 3

Appendices

Assessment

Assessment is by

- Formal examinations (see Appendix 1)
- A portfolio of evidence of having participated in a sufficient number and type of work activities (see Appendix 2)
- Satisfactory progress (supervisor reports) (see Appendix 2)

An assessment matrix is provided in Appendix 3.

Portfolio requirements

Portfolio activities are carried out in the workplace provides evidence that fellows have engaged in the appropriate number and type of work-based activities to build base knowledge, analytical and interpretive skills, quality assurance and communication capabilities relevant to genetics/genomic testing in Microbiology. Requirements or each module are summarised in a table at the end of each module in Section 2.

Appendix 2 contains the forms and logbook pages for recording the portfolio activities. Please file the hard copy forms in a **portfolio folder** with separate sections as in the table provided.

A soft copy **portfolio summary** (Excel spreadsheet) should also be compiled so that the fellow can keep track of what has been completed. The spreadsheet can be downloaded from the RCPA website. It is the fellow's responsibility to keep both hard and soft copy records up-to-date.

The portfolio summary spreadsheet should be apprehended to the annual supervisor reports and will be reviewed by the Registrar, Board of Education and Assessment and the Chief Examiner. Signatories and fellows may be contacted to confirm evidence of satisfactory completion.

Appendix 1: Examinations

There will be an oral examination consisting of three stations, each of twenty minutes, with two examiners for each.

Candidates will be allowed 30 minutes pre-reading time, during which they may review data and reports, making notes where applicable, prior to discussion with the examiners.

The examination will focus on ability to:

- Analyse and interpret findings
- Explain principles of the test methods used, identifying any limitations
- Apply quality management principles and troubleshooting methods to explain and prevent possible sources of error
- Communicate clinically relevant conclusions and advice to referring doctors, including discussion of uncertainties
- Discuss broader health implications and/or ethical considerations relevant to the testing performed.

Appendix 2: Forms and log pages for Portfolio

The Royal College of Pathologists of Australasia	**Microbial Genomics** **General Isolate Report**

How to use this form

From the beginning of training, Fellows should log all laboratory-based experiences, including analysis and reporting. Only runs that the Fellow has been directly involved with should be logged.

Modules 1&2: A minimum of 50 isolates representing at least 5 different pathogens should be recorded.

The log book should include:

- Organism
- Identification method used
- Technical issues requiring review

At the end of each Module, the log of reports should be sighted and signed off in the Supervisor Report.

Fellow Name	**Fellow ID**	**Module of Training** (please tick) ☐ Module 1 ☐ Module 2

	Date	***Organism***	***Identification method***	***Test failures requiring review***
1				
2				
3				
4				
5				
6				
7				

8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
Final Outcome (please tick) ☐ Competent ☐ Not Competent				
Signature of Assessor			**Signature of Fellow**	
Name of Laboratory				

Microbial Genomics
PbD Assessment Form
Process based Discussion

Fellow Name	**Fellow ID**	**Module of Training** (please tick) ☐ Module 1 ☐ Module 2
Assessor Name	**Assessor position** ☐ Pathologist ☐ Other (please specify)	

Techniques/methods (tick the box that applies)

Wet lab

.1. DNA extraction for WGS
2. WGS library preparation and QC
3. Pooling and sequencing
.4. Other (insert)_____

Dry lab

.1. QC of read data
2. In-silico detection of gene targets
3. Comparative genomics/phylogenetics
.4. Data storage and management
5. Other (insert)_____

Please comment on whether these aspects of the Fellow's performance	**Yes**	**No**	**N/A**
Understands the principles of the method			
Has a working knowledge of instrument processes and maintenance requirements			
Has observed all phases of an assay successfully and been involved in the production of a valid result that can be reported			
Able to explain the Quality Controls procedures for this method, including internal Quality Assurance.			
Able to discuss anomalies and resolve uncertainties for the method			
Able to explain maintenance and trouble-shooting requirements for the method			

Please comment on other relevant aspects, especially on aspects for improvement (use the reverse side if insufficient room)

Final Outcome (please tick)

☐ Competent ☐ Not Competent

Signature of Assessor	**Signature of Fellow**

Name of Laboratory

The Royal College of Pathologists of Australasia	**Microbial Genomics** **Quality Assurance Report**	
Fellow Name	**Fellow ID**	**Module of Training** (please tick) ☐ Module 1 ☐ Module 2
Nature of activity		
Your role in the activity		
The report should include (where relevant): o Description of procedures o Results/findings o Technical problems identified o Quality improvement opportunities o Actions taken o Resource considerations o References to published methods and standards		
Fellow signature		**Date**
Supervisor name (please print) and signature		**Date**
Name of Laboratory		

Microbial Genomics Supervisor Report

Please review the Fellow's portfolio and logbook before completing this report

Fellow Name (please print)	**Fellow ID**	**Module of Training** (please tick) ☐ Module 1 ☐ Module 2
Name of Organisation		
Training period: _____/_____/_____ to ___/_____/_____		
Name of supervisor (please print)	Supervisor RCPA ID no.	

Please inspect the forms in the Fellow's portfolio and use the Table below to record evidence of completion

Portfolio items for which there is a minimum requirement

	Previous total (if applicable)	Number in current year/ module	Cumulative Total	Minimum for completion of module
Generated Isolate Reports				Module 1: 50 Module 2: 3
Process-based discussion (PbD)				2 challenging processes (1 Wet lab; 1 Dry lab)
QA Report				1 report with analysis
Supervisor's report				1 report/ 12 months
Portfolio Summary				

Does the print-out of the portfolio summary spreadsheet accurately record the contents of the portfolio?

☐ Yes ☐ No

Please score the Fellow's performance using this scale

1 = Performance currently falls far short of expected standards for level of training.
There is a serious problem that may have implications for accreditation of the current training period. The problem must be stated clearly on the final page.

2 = Performance currently falls short of expected standards for level of training.
There is an area of lower than expected performance. The problem must be stated clearly on the final page.

3 = Performance is consistent with the expected level of training.
About 80% of fellows will merit this grade.

4 = Performance is better than expected for level of training.
About 10% of fellows will merit this grade.

5 = Performance is exceptional.
Very few fellows will merit this grade.

N/A = Not Applicable to this training period

	Score
The principles of all methods are understood	
Working knowledge of method anomalies and associated trouble-shooting requirements	
Successful generation of results from each method, at a quality level sufficient for reporting	
Strong understanding of QC procedures for the methods, including internal and external QA	
Ability to communicate relevant clinical advice regarding pathogen identification using genomic methods	
Work collaboratively with laboratory scientists and pathologists in other disciplines	
Ability to communicate relevant information to hospital staff and committees and to public health authorities as required	

Overall evaluation

Have the outcomes of this module been satisfactorily achieved?
☐ Yes ☐ No

Is specific further professional development required? If yes, please outline process
☐ Yes ☐ No

Signatures

Fellow (please PRINT name and sign)	Date
Supervisor name (please PRINT name and sign)	Date
Other senior staff member/second supervisor (if applicable) (please PRINT name and sign)	Date
Head of Department (please PRINT name and sign)	Date

Comments by Fellow:

Please return this Supervisor's Report to:

The Royal College of Pathologists of Australasia
207 Albion Street
Surry Hills NSW 2010 AUSTRALIA

Faxed reports will not be accepted

THE ROYAL COLLEGE OF PATHOLOGISTS OF AUSTRALASIA USE ONLY

Signature

Registrar/Deputy Registrar, Board of Education and Assessment (please PRINT name and sign)	Date

Appendix 3 – Assessment matrix

	Portfolio of workbased activities			Supervisor report	Oral exam
	General Isolate Report	PbD	QA Report		
Theoretical & technical knowledge	Y	Y		Y	Y
Analytical and interpretive skills		Y	Y	Y	Y
Quality assurance		Y	Y	Y	Y
Communication & consultation		Y	Y	Y	Y