AUSTRALIAN INSTITUTE OF
MEDICAL AND CLINICAL SCIENTISTS

Fellowship Discipline Modules

Clinical Pathology

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Introduction

THE DISCIPLINE MODULES HANDBOOK IS TO BE READ IN CONJUNCTION WITH THE AIMS FELLOWSHIP BOOKLET: PROCEDURES AND REGULATIONS.

The AIMS Fellowship is divided into four stages, all of which must be successfully completed.

This booklet contains the four discipline-based modules that comprise Stage 1 (Modules 1 and 2) and Stage 2 (Modules 3 and 4).

Stage 1 (Modules 1 and 2) must be successfully completed before enrolling into Stage 2 (Modules 3 and 4).

Each module documents the aims, learning outcomes, syllabus and provides some learning resources for the topic/s covered. Modules are assessed by written examination conducted in-person or online. Examinations are held twice a year as required in June (applications close at the end of February) and November (applications close at the end of July). Candidates must apply to sit the examinations using the Fellowship Examination Application Form and pay the relevant fee.

Note: A member with less than two (2) years continuous Professional Membership, but with more than five (5) years postgraduate experience (within the previous 10 years), may complete Stage 1 (Modules 1 and 2) prior to enrolling and be granted advanced standing (ie credit) for successfully completed modules when eligible to enrol in the full Fellowship program.

All modules are compulsory.

Clinical Pathology I

Module	HAEMATOLOGY AND HAEMOSTASIS
Assumed knowledge	Normal and abnormal cell physiology, clinical aspects relevant to routine haematological testing and other technical procedures related to cellular haematology.
Aim	To develop and apply expert knowledge, investigative and clinical skills relevant to the routine haematology laboratory.
Module learning outcomes (MLO)	On completion of this module the candidate will be able to: (i) Discuss the importance of preanalytical factors to the quantity of test results and factors that may have an impact on the quality of the sample (ii) Explain the techniques and technology used in the cellular investigations and related procedures performed in the routine haematology laboratory including the principle of each technique, the performance of each technique, limitations of the techniques, problem detection, troubleshooting and the technical and clinical interpretation of results (iii) Describe and appraise the coagulation investigations performed in the Haemostasis laboratory (iv) Interpret, evaluate and explain the laboratory presentation of specific clinical conditions and situations

Theme	Syllabus
Preanalytical phase MLO (i)	The impact of pre-analytical variables on haematology and coagulation test results including sample collection, handling, stability, storage and transport
Principles and applications of techniques in Haematology MLO (ii)	• Principles of automated cell counting • Operation and limitations of the other automation used in the routine laboratory including staining machines, slide makers, ESR analysers • Factors affecting the staining of blood films • Morphological examination of peripheral blood and bone marrow films and body fluids and how this supports the diagnosis of haematological conditions • Performance of manual tests including erythrocyte sedimentation rate (ESR), reticulocytes, Heinz bodies, rapid screening tests for infectious mononucleosis and malaria, and the effectiveness and limitations of these tests • Strategies and standards applied to reporting laboratory results including the units and selection of reference ranges

Principles and applications of techniques in Haemostasis testing MLO (iii)	• PT, INR, APTT, TT, TT correction methods • Fibrinogen, Fibrin/fibrinogen degradation products • Mixing studies • DIC screening • Clotting based factor assays
Clinical conditions and situations MLO (iv)	*Haematological non-malignant conditions* • Anaemias – macrocytic, microcytic, haemolytic, hypoplastic, blood loss • Thalassaemia and haemoglobinopathies • Erythrocytosis – reactive and malignant • Red cell breakdown/degradation • Benign disorders of white blood cells • Thrombocytosis and thrombocytopenia • Haematology of conditions including pregnancy, the neonate, childhood, the elderly, infection *Haematological malignancies* • Chronic and acute leukaemia • Myeloproliferative disorders • Myelodysplastic syndrome • Lymphoproliferative disorders • Immunoproliferative disorders *Coagulation disorders* • Acquired coagulation disorders including those seen in DIC, liver disease, trauma, post-surgery, infection. • Hereditary coagulation factor deficiencies • Acquired and hereditary thrombophilia • Platelet dysfunction

Assessment	Assessment in this module consists of a three-hour written examination. The exam has two parts: • Part A has two essay questions, which should be answered in a separate answer book. Each question is worth 35 marks (70 marks in total). • Part B has 20 limited answer questions, all of which should be answered in the answer book provided. Each question is worth 5 marks (total 100 marks).

Learning resources	*Reference books - the current editions of:* Bain BJ, Bates I, Laffan MA. *Dacie and Lewis Practical Haematology*. Elsevier Bain BJ. *Blood Cells: A Practical Guide*. John Wiley & Sons Carr JH. *Clinical Hematology Atlas*. Elsevier DeLoughery TG (ed). *Hemostasis and Thrombosis*. Springer International Publishing Greer JP, Arber DA, Glader B, List AF, Means Jr RT, Praskevas F, Rodgers GM. *Wintrobe's Clinical Hematology*. Lippincott Williams & Wilkins Hoffbrand AV, Higgs DR, Keeling DM, Mehta AB (eds). *Postgraduate Haematology*. Wiley-Blackwell Hoffbrand V, Steensma DP. Hoffbrand's *Essential Haematology.* Wiley-Blackwell Hoffman R, Benz Jr EJ, Silberstien LE, Heslop H, Weitz J, Anastsi J. *Hematology: Basic Principles and Practice*. Elsevier Keohane EM, Otto CN, Walenga JM. *Rodak's Hematology: Clinical Principles and Applications*. Elsevier Key NS, Makris M, Lillicrap D eds. *Practical Hemostasis and Thrombosis*. John Wiley & Sons doi:10.1002/9781118344729 Kitchens CS, Kessler CM, Konkle BA, Streiff MB, Garcia DA. Cons*ultative Hemostasis and Thrombosis*. Elsevier Marder VJ, Aird WC, Bennett JS, Schulman S, White II GC. *Hemostasis and Thrombosis. Basic Principles and Clinical Practice*. Lippincott Williams and Wilkins Pierce A, Pittet JF. 2014. *Practical understanding of hemostasis and approach to the bleeding patient in the OR*. Advances in Anesthesia 32(1):1-21. doi: 10.1016/j.aan.2014.08.009 Saba HI, Roberts HR (eds). *Hemostasis and thrombosis: Practical Guidelines in Clinical Management*. John Wiley & Sons *Journals* American Journal of Hematology Archives of Pathology and Laboratory Medicine Australian Journal of Medical Science Bailliere's Clinical Haematology Blood Blood Reviews British Journal of Haematology CAP Today Clinical and Laboratory Haematology Hematology/Oncology Clinics of North America International Journal of Laboratory Haematology Journal of Clinical Pathology Journal of Thrombosis and Haemostasis Laboratory Hematology Lancet New England Journal of Medicine Seminars in Hematology Seminars in Thrombosis and Hemostasis Thrombosis and Haemostasis Thrombosis Research

	Web-based resources (all accessed XXXX) A laboratory guide to Clinical Haematology https://open.umn.edu/opentextbooks/textbooks/a-laboratory-guide-to-clinical-hematology Inherited Haemoglobin Disorders https://www.intechopen.com/books/inherited-hemoglobin-disorders Merck Manuals https://www.merckmanuals.com/professional/hematology-and-oncology Practical Haemostasis https://practical-haemostasis.com/ University of Prince Edward Island lectures http://people.upei.ca/eaburto/Hematopoietic.htm

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Clinical Pathology II

Module	CLINICAL CHEMISTRY
Assumed knowledge	• Sample collection and transport • Spectrophotometry, Beers law, electrochemistry, principles of antibody antigen interactions • Chemistry underpinning the various chemical assays • Monitoring fluid balance and blood gases
Aims	To develop and apply expert knowledge, investigative and clinical skills relevant to the routine Clinical Chemistry laboratory.
Module learning outcomes (MLO)	On completion of this module the candidate will be able to: (i) Discuss the factors that may impact the quality of test results (ii) Explain the principles of spectrophotometry, densitometry, turbidimetry, nephelometry, fluorometric assays, ion selective electrodes, osmometry and discuss the applications of these techniques to the assay of various analytes (iii) Explain the principles of immunoassay methods, the factors that may invalidate results and to correct these (iv) Discuss the principle of nucleic acid-based technologies and their role diagnosis of disease (v) Explain the role of quality control in chemical analytics (vi) Describe the significant homeostatic role carried out by electrolytes and the water, and their relationship with blood gases (vii) Discuss the laboratory investigation of cardiac, renal, liver and pancreatic diseases (viii) Discuss normal and abnormal blood glucose levels, diabetes (all forms) and laboratory assessment of these conditions (ix) Describe calcium metabolism, methods for measurement of calcium and the impact of disease conditions on calcium levels (x) Describe the metabolism of cholesterol, fatty acids and triglycerides, their role as markers of diseases (xi) Explain the principle and role of electrophoresis in clinical investigations of plasma proteins (xii) Discuss and appraise the impact of a) automation including total laboratory automation and b) point of care testing on clinical chemistry diagnostics

Theme	Syllabus
Preanalytical phase MLO (i)	Pre-analytical, analytical and post analytical factors that may impact the quality of test results

Instrumentation and analytical techniques MLO (ii), (iii), (iv)	*Photometry* • Principles of photometric measurements and instruments used • Theoretical basis and applications of the following: ○ reflectance spectrophotometry ○ densitometry ○ turbidimetry ○ nephelometry ○ fluorometric assays ○ atomic absorption *Immunochemistry* • Principles and procedures used in immunochemistry including: ○ Enzyme-Linked Immunosorbent Assay (ELISA) ○ Multiplex Immunoassay ○ Enzyme Multiplied Immunoassay Technique (EMIT) ○ Cloned Enzyme Donor Immunoassay (CEDIA) ○ Luminescent Oxygen Channeling Assay (LOCI) ○ Fluorescence Resonance Energy Transfer (FRET) ○ Chemiluminescence Immunoassay ○ Electrochemiluminescence Immunoassay (ECLIA) • Sources of error in immunoassays including to high-dose hook effect, HAMA, heterophil antibodies, high dose biotin *Nucleic acid-based techniques* • Polymerase Chain Reaction (PCR): principles, methodologies and applications *Automation* • Automated chemistry analysers • Automated immunoassay analysers • Automated PCR units
Quality control (QC) MLO (v)	• Westgard multi-rule system • Warning rule versus a rejection rule • External quality control programs • Matrix effects • Measurement Uncertainty MU)

Electrolytes and blood gases **MLO (vi)**	• Blood collection procedures, requirements and sources of error • Principles and techniques used in determining electrolytes and blood gases • Clinical interpretation of results from blood gas analysis • Chemical buffers • Serum osmolality • Hypernatremia, hyponatremia and the relationship to chloride and potassium • Euvolemia, hypovolemia, hypervolemia • Residual anion concentration • Anion gap in relation to electrolytes and blood gases • Potassium ions in relation to acidosis and alkalosis
Markers of cardiac function and injury **MLO (vii)**	• Pathology of myocardial infarction • The troponin complex • Compare the value CK-MB mass assays to Troponin T or I • Myoglobulin as a marker • Impact of reperfusion and re-infarction on analytical procedures • Congestive Cardiac Failure and Pulmonary Embolism (BNP) • Limitations and pitfalls of the various analytical methods
Liver and pancreas function **MLO (vii)**	• Principles and limitations of methods for assessing liver enzyme levels and clinical interpretation of results • Principles and limitations of methods for assessing bilirubin (including delta bilirubin) levels and clinical interpretation of results • Demonstrate knowledge of the normal function of the pancreas • Principles and limitations of methods for assessing pancreatic enzyme levels and clinical interpretation of results
Metabolic analytes and renal function **MLO (vii)**	• Testing for urea and creatinine, sources of error, creatinine clearance • Estimated glomerular filtration rate (eGFR) in renal disease • Pathology of gout and laboratory testing for uric acid
Carbohydrates and diabetes **MLO (viii)**	• Pathology of diabetes mellitus types 1 and 2, and gestational diabetes mellitus • Testing and monitoring for hypo or hyperglycaemia • Haemoglobin A1c: measurement and clinical impact • Role of self-monitoring for glucose • Glucose tolerance testing in diabetic diagnosis • Testing for ketoacidosis and micro-albuminuria • Clinical effect of potassium on monitoring treatment
Calcium phosphate and magnesium **MLO (ix)**	• Principles of analytical methods for measurement of calcium, phosphate, and magnesium • Clinical interpretation of laboratory test results for calcium, magnesium and phosphates
Lipids and lipoproteins **MLO (x)**	• Pathology of atherosclerosis • Metabolic roles of fatty acids, triglycerides, phospholipids, cholesterol and HDL-in normal and disease conditions • Principles and applications of diagnostic tests for the various lipids

Proteins **MLO (xi)**	• Principles of analytical methods for measurement of total protein and albumin • Diagnostic value and clinical interpretation of laboratory test results for proteins
Point of care **MLO (xii)**	• Rational for point of care diagnostic testing and range of analytes tested in the clinical setting • Operational factors including instrumentation, implementation, governance, management, quality issues, training and competency determination

Assessment	Assessment in this module consists of a three-hour written examination. The exam has two parts: • Part A has two essay questions, which should be answered in a separate answer book. Each question is worth 35 marks (70 marks in total). • Part B has 20 limited answer questions, all of which should be answered in the answer book provided. Each question is worth 5 marks (total 100 marks).

Learning resources	<u>*Reference books - the current editions of:*</u> Bishop ML, Fody EP, Van Siclen C, Mistler JM Moy M. *Clinical Chemistry: Principles, Techniques, and Correlations*. Jones and Bartlett Learning Gardner DG, Shoback D. *Greenspan's Basic & Clinical Endocrinology*. McGraw Hill Holt RIG, Hanley NA. *Essential Endocrinology and Diabetes*. Wiley Blackwell Lippi G, Da Rin G. The Advantages and Limitations of Total laboratory Automation: A Personal Overview. Clinical Chemistry and Laboratory Medicine 2019; 57(6): 802–811 Marshall WJ, Lapsey M, Day AP, Ayling RM. *Clinical Biochemistry: Metabolic and Clinical Aspects*. Churchill Livingstone Rifai N, Chiu RWK, Young I, Burnham CD, Wittwer CT. *Tietz Textbook of Laboratory Medicine*. Elsevier Rifai N, Chiu RWK, Young I, Wittwer CT. *Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics*. Elsevier <u>*Journals*</u> Australian Journal of Medical Science Journal of the International Federation of Clinical Chemistry and Laboratory Medicine Clinical Chemistry Medical Journal of Australia The New England Journal of Medicine

	Web-based resources Abbott https://www.corelaboratory.abbott/int/en/offerings/brands/architect Association for Diagnostics and Laboratory Medicine https://www.myadlm.org/ Association for Molecular Pathology https://www.amp.org/ Australasian Association for Clinical Biochemistry and Laboratory Medicine www.aacb.asn.au Beckman Coulter https://www.beckmancoulter.com/en/products/chemistry https://www.beckmancoulter.com/en/products/immunoassay Diabetes Australia https://www.diabetesaustralia.com.au/ International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) https://ifcc.org/ NATA https://www.nata.com.au/ National Heart Foundation https://www.heartfoundation.org.au/ National Pathology Accreditation Advisory Council (NPAAC) https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-index.htm Pathology Tests Explained https://pathologytestsexplained.org.au/ Radiometer https://www.radiometer.com.au/ Roche https://diagnostics.roche.com/us/en/products/product-category/cobas-modular-platform.html Royal College of Pathologists of Australasia https://www.rcpa.edu.au/library Siemens https://www.siemens-healthineers.com/en-au/laboratory-diagnostics Westgard QC https://westgard.com/westgard-rules.html

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Clinical Pathology III

Module	**TRANSFUSION SCIENCE** **CLINICAL MICROBIOLOGY**
Assumed knowledge	Immunohaematology techniques and principles. Micro-organisms that are known to commonly cause infection in humans, basic laboratory techniques and clinical correlates.
Aims	To develop and apply expert knowledge, investigative practice and clinical skills relevant to: a) routine pre-transfusion testing and transfusion b) the identification of common infectious diseases
Module learning outcomes (MLO)	On completion of this module the candidate will be able to: (i) Explain the biochemical, molecular and genetic aspects of blood group systems (ii) Explain and evaluate the principles, procedures, any specific requirements, limitations, troubleshooting and effectiveness of techniques routinely performed in the Transfusion Science laboratory (iii) Interpret and explain the basis and laboratory presentation of specific clinical conditions and situations in routine transfusion practice (iv) Describe preanalytical factors which may affect the outcome of laboratory investigations for infectious disease agents (v) Describe investigative techniques employed in the routine Clinical Microbiology laboratory (vi) Describe the characteristics, epidemiology, transmission, pathogenesis and clinical significance of relevant bacteria (as listed) (vii) Discuss the optimal isolation and culture of clinically relevant bacteria from bodily fluids and tissues (as listed) (viii) Explain the mode of action and activity of antibiotics in common use and the antimicrobial resistance pathways (for the agents indicated #) (ix) Critically discuss laboratory techniques for identifying antimicrobial resistance

Theme	**Syllabus**
Blood group systems **MLO (i)**	• ABO, Rh, Kell, Duffy, Kidd, P, Le, H, MNSs • The genetic basis for the major antigens of the known red cell blood group systems, including their gene frequencies • Molecular structure forming the basis of DNA-based methods and for determining the commonly used phenotypes of the ABO, Rh, Kell, Fy, Jk, MNSs systems

Laboratory techniques routinely used in the transfusion laboratory **MLO (ii)**	• Pre-transfusion blood collection requirements • ABO blood grouping techniques, monoclonal reagents, lectins, ABO variants and causes of ABO discrepancies • Rh blood grouping techniques, monoclonal reagents, and characterisation of RhD variants • Pre-transfusion testing: antibody screening, antibody investigations and identification, crossmatching (serological and electronic) and selection of blood products • Specialised techniques: DAT, elutions, red cell adsorptions, DTT, neutralisations, enzyme methods, HPC absorptions • Transfusion reaction investigations • Strategies and standards applied to reporting of laboratory results and other findings
Clinical practice in transfusion science **MLO (iii)**	• Haemolytic transfusion reactions • Febrile, non-haemolytic transfusion reactions
Pre-analytical factors to be considered with infectious disease samples **MLO (iv)**	• Management of clinical and patient information • Collection, transport and handling of samples • Potential for contamination by regional flora • Transportation and storage of samples
Laboratory techniques to identify infectious agents **MLO (v)**	• Gram staining • Growth media in common use including incubation equipment and conditions and quality control • Routine bench tests • Kit and similar tests • Molecular equipment and common applications ○ cartridge-based PCR units ○ commercially available kit-based tests • Role and applications of emergent identification platforms ○ MALDI-TOF mass spectrometry
Bacteriology **MLO (vi)**	*<u>Characteristics of the common clinically relevant bacteria (as listed)</u>* • Clinical significance, epidemiology and transmission • Direct examination, isolation and culture • Identification and antimicrobial susceptibility • Interpretation and reporting • Special factors including safety, notification requirements *<u>Common clinically relevant bacteria</u>* • Gram-positive ○ *Staphylococcus aureus, S. saprophyticus, S. epidermidis* ○ *Streptococcus (B-hemolytic groups A and B, and S. pneumoniae)* ○ *Enterococcus faecalis and E. faecium* ○ *Corynebacterium species (general features)* ○ *Bacillus cereus*

	• Gram-negative ○ *Neisseria gonorrhoeae and N. meningitidis* ○ *Moraxella catarrhalis* ○ *Acinetobacter baumanii* and *Stenotrophomonas maltophilia* ○ *Enterobacteriaceae* ○ *Aeromonas hydrophila* ○ *Vibrio cholerae, V. parahaemolyticus, V. vulnificus* ○ *Pseudomonas aeruginosa* ○ *Bordetella pertussis* ○ *Haemophilus influenzae, H. parainfluenzae* ○ *Campylobacter jejuni* • Anaerobic bacteria ○ *Clostridium perfringens* ○ *Bacteroides fragilis group* ○ *Peptostreptococcus anaerobius*
Laboratory investigation of common infectious disease by sample site MLOs (vii)	• Blood • CSF • Body fluids and tissue samples • Wounds: skin and soft tissue infection • Genital tract • Eyes, ears, nose, throat, upper respiratory tract • Lower respiratory tract • Urinary tract • Gastrointestinal tract •
Antimicrobial agents and resistance mechanisms (<u>where indicated #</u>) MLO (viii)	• β-lactam antibiotics (common penicillins, cephalosporins, carbapenems) **<u>#</u>** • B-lactam inhibitors (clavulanate, sulbactam, tazobactam) • Aminoglycosides (gentamicin, tobramycin and amikacin) • Tetracyclines (tetracycline, minocycline) • Macrolides (erythromycin, azithromycin, clarithromycin) • Sulphonamides/Trimethoprim • Quinolones (nalidixic acid, norfloxacin, ciprofloxacin) • Multi-resistant bacteria (MRSA, VRE, CRE) and their identification
Antimicrobial susceptibility / resistance testing MLO (ix)	• Disc diffusion procedures (Clinical & Laboratory Standards Institute [CLSI], European Committee on Antimicrobial Resistance [EUCAST]) • β-lactamase detection • Microbroth dilution • Automation • Gradient strip methods • Quality control

Assessment	Assessment in this module consists of a three-hour written examination. The exam has two parts: • Part A has two essay questions, which should be answered in a separate answer book. Each question is worth 35 marks (70 marks in total). • Part B has 20 limited answer questions, all of which should be answered in the answer book provided. Each question is worth 5 marks (total 100 marks).

Learning resources	*Reference book - the current edition of:* Harmening DM. *Modern Blood Banking & Transfusion Practices*. FA Davis Simon TL, Gehrie EA, McCullough J, Roback JD, Snyder EL. *Rossi's Principles of Transfusion Medicine*. Wiley Bush K, Jacoby GA. 2010. *Updated Functional Classification of β-Lactamases*. Antimicrobial Agents and Chemotherapy 54:969-76. doi: 10.1128/AAC.01009-09 Bush K. 2018. *Past and Present Perspectives on β-Lactamases*. Antimicrobial Agents and Chemotherapy 62(10):e01076-18. doi: 10.1128/AAC.01076-18 Carroll KC, Pfaller MA, Karlowsky JA, Landry ML, McAdam AJ, Patel R, Pritt BS (eds). *Manual of Clinical Microbiology, Multi-Volume*. ASM Press De Oliveira DMP, Forde BM, Kidd TJ, Harris PNA, Schembri MA, Beatson SA, Paterson DL, Walker MJ. 2020. *Antimicrobial Resistance in ESKAPE Pathogens*. Clinical Microbiology Reviews: 33:10.1128/cmr.00181-19 Finch RG, Greenwood D, Norrby SR, Whitely RJ. *Antibiotics and Chemotherapy: Anti-infective Agents and Their Use in Therapy*. Saunders Elsevier Jacoby GA. 2009. *AmpC β-lactamases*. Clinical Microbiology Reviews 22:161-82. doi: 10.1128/CMR.00036-08 Leber AL (ed). *Clinical Microbiology Procedures Handbook*. ASM Press Tille P. *Bailey & Scott's Diagnostic Microbiology*. Elsevier Walsh C, Wencewicz T. *Antibiotics: Challenges, Mechanisms, Opportunities*. ASM Press *Journals* Australian Journal of Medical Science Clinical Microbiology Reviews Journal of Clinical Microbiology Journal of Clinical Pathology Lancet New England Journal of Medicine Transfusion Transfusion Medicine Transfusion Medicine Reviews Vox Sanguinis *Web-based resources* ANZSBT – Australian & New Zealand Society of Blood Transfusion http://www.anzsbt.org.au ARCBS – Australian Red Cross Blood Service http:/www.redcross.org.au CDCI https://www.cdc.gov/ CLSI https://clsi.org/standards/products/free-resources/access-our-free-resources/ Communicable diseases Intelligence https://www1.health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-cdi-cdicur.htm EUCAST https://www.eucast.org/ Royal College of Pathologists of Australasia https://www.rcpa.edu.au/library Therapeutic Guidelines: Antibiotic. Melbourne: Therapeutic Guidelines Limited https://www.tg.org.au

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Clinical Pathology IV

Module	**ADVANCED PRACTICE** **LEADERSHIP, MANAGEMENT AND SUPERVISION**
Aims	To explore innovative technologies and to describe the knowledge and attributes required for leadership as a clinical scientist and clinical pathology laboratory manager.
Module learning outcomes	On completion of this module the candidate will be able to: (i) Critically evaluate relevant research to predict and prepare for emerging laboratory practices and directional shifts (ii) Discuss the components and requirements of a quality management system with reference to the role of internal and external Quality Control (QC) and Quality Assurance (QA) (iii) Discuss the models in use and provision of pathology services in Australia (iv) Describe the principles of pathology laboratory accreditation and the procedures necessary to gain and maintain accreditation (v) Formulate and evaluate operational requirements in the Clinical Pathology laboratory including occupational health and safety, standard operating procedures, laboratory information systems and all records and databases (vi) Specify the attributes necessary for a leadership and supervisory role as a clinical scientist and laboratory manager

Theme	Syllabus
Evidence-based practice in Clinical Pathology MLO (i)	• Applying research principles to ensure diagnostics are fit for purpose and to address and resolve issues in practice • The Evidence-Based Practice (EBP) process • Establishment and validation of new methods • Applications and limitations of statistical analyses used in the clinical laboratory • Anticipating, evaluating and responding to strategic direction shifts
Quality management MLO (ii)	• Quality management components of ISO15189 in pathology laboratories • Quality control, quality assurance and quality management • Standardisation • Quality audit processes
Pathology in Australia MLO (iii)	• The organisation and delivery pf pathology services • The public pathology model • The private pathology model • Definitions and operational roles of personnel in the laboratory workforce • The oversight hierarchy for Laboratory Medicine • The function and responsibilities of NPAAC • The function and responsibilities of NATA • State and Federal responsibilities • Medicare funding of pathology

Practice and accreditation standards MLO (iv)	• Australian Standards for operation of pathology laboratories • ISO15189 structure, components, requirements • The accreditation process • NATA accreditation requirements and processes • Application of ISO15189 by NATA • Non-conformance • The role and impact of TGA and IVD issues for the Clinical Pathology laboratory
Laboratory operations MLO (v)	*Functional requirements* • Ethical practice in collection, usage, storage and reporting confidential information • Occupational Health and Safety (OHS) obligations of employers and employees • Legislation and codes of practice • Hierarchy of responsible persons • Promotion of safe working practices • Specific operational requirements in the Clinical Pathology laboratory • MSDS and Standard Operational Procedures (SOP) • Processes and requirements for workplace inspections *Risk assessment and risk management* • Implementing safety controls to minimize risk • Waste management and waste reduction, solvent and reagent recycling • Identification and management of chemical, biological, genetic and equipment hazards, environmental issues • Green laboratories – ISO standards • Federal and state waste protocols
Leadership and supervision in the Clinical Pathology laboratory MLO (vi)	*Principles of Leadership* • Team dynamics, development and motivation in the laboratory setting • Education and training for co-workers, support personnel, students • Engagement with Continuing Professional Development (CPD) for self and workforce • Involvement with professional societies, activities, conferences and symposia *Managing people* • Communication strategies, facilitating group dynamics, conflict resolution, workplace harassment and bullying • Identifying and resolving errors • Performance Management Techniques • 'Managing change' processes • Human resource management: Recruiting, Hiring, Evaluating • Equal Employment Opportunity (EEO) Legislation and obligations *Managing resources* • Financial probity • Time Management Skills • Lean management principles in pathology

Assessment	Assessment in this module consists of a three-hour written examination. The exam has two parts: • Part A has two essay questions, which should be answered in a separate answer book. Each question is worth 35 marks (70 marks in total). • Part B has 20 short answer questions, all of which should be answered in the answer book provided. Each question is worth 5 marks (total 100 marks).

Learning resources	*Reference books – the current edition of:* McPherson RA, Pincus MR. *Henry's Clinical Diagnosis and Management by Laboratory Methods*. Elsevier Health Sciences *Journals* American Journal of Clinical Pathology Australian Journal of Medical Science New Zealand Journal of Medical Laboratory Science British Medical Journal Clinical Laboratory Medicine *Web-based resources* Public Pathology Australia https://publicpathology.org.au/ Australian Pathology https://www.australianpathology.com/ National Pathology Accreditation Advisory Council (NPAAC) https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-index.htm NATA http://www.nata.com.au/ TGA and IVD http://www.tga.gov.au/industry/ivd-regulatory-requirements.htm Pathology Funding Agreement (2012) MBS Schedule Category 6 – Pathology WorkSafe Australia https://www.safeworkaustralia.gov.au/

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