AUSTRALIAN INSTITUTE OF
MEDICAL AND CLINICAL SCIENTISTS

Fellowship Discipline Modules

Clinical Chemistry

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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 Chemistry I

Module	ROUTINE AND ACUTE CLINICAL CHEMISTRY
Assumed knowledge	Sample collection and transport Spectrophotometry, Beer's 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 practice 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 pre-analytical 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 how 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 and the role insulin plays in maintenance of normal glucose levels and the development of prediabetic disorders (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 and their relationship to obesity and cardiovascular disease (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
Pre-analytical 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 high-dose hook effect, human anti-mouse antibodies (HAMA), heterophil antibodies, high dose biotin
	
	Nucleic acid-based techniques
	• Amplification, target amplification
	• Hybridization
	• Melting analysis, primer and probe
	• Polymerase chain reaction (PCR), real time PCR, reverse transcription PCR, transcription-mediated amplification (TMA), loop mediated amplification methods (LAMP), strand displacement methods (SDA)
	• Muliplex PCR, nested PCR
	• Applications in Clinical Chemistry
	
	Automation
	• Automated chemistry analysers
	• Automated immunoassay analysers
	
	Total laboratory automation/robotics
	• Open and closed systems, planning, workflow mapping, information technology issues
	• Pre-analytical phase
	• Analytical phase
	• Post-analytical phase

Quality control MLO (v)	• Westgard multi-rule system • Warning rule versus 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)**	• Insulin in normal physiology and development of prediabetic conditions • 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 Clinical Chemistry Journal of the International Federation of Clinical Chemistry and Laboratory Medicine 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 Chemistry II

Module	ENDOCRINOLOGY
Assumed knowledge	Anatomy and function of the endocrine system Source, structure and functions of adrenal, thyroid, parathyroid, pituitary, and pancreatic hormones Effects of excessive or inadequate hormone secretion
Aim	To develop and apply specialist knowledge, investigative practice and clinical skills relevant to clinical endocrinology.
Module learning outcomes (MLO)	On completion of this module the candidate will be able to: (i) Describe pre analytical factors that may affect endocrine system investigations and what can be done to prevent them (ii) List the steroid and peptide hormones and review their source, target organs and biological effects (iii) Explain the hypothalamus, pituitary, adrenal gland axis and feedback mechanisms (iv) Discuss and evaluate laboratory investigations of anterior and posterior pituitary function (v) Discuss and evaluate and laboratory investigations of thyroid and adrenal disease (vi) Discuss and evaluate laboratory investigations of infertility in females and males and hirsutism in females (vii) Discuss the laboratory detection and monitoring of pregnancy and abnormal states (including ectopic pregnancy and gestational trophoblastic neoplasia) (viii) Discuss the laboratory detection and monitoring of foetal abnormalities (ix) Review and evaluate current trends in post-natal screening

Theme	Syllabus
Pre-analytical factors **MLO (i)**	• Pre-analytical factors that may cause spurious results • Effects of stress, episodic secretion and circadian rhythm on diagnostic testing • Effects of drugs on diagnostic test results • Free and bound hormones • Primary, secondary and tertiary states • Effect of heterophilic antibodies on diagnostic test results • Dynamic function tests and use in diagnosis
General aspects **MLO (ii)**	• Tissue source, structure, target site and function of steroid and peptide hormones • Causes and effects of hyper- and hypo- secretion of steroid and peptide hormones • Differentiate between primary and secondary abnormalities
Laboratory investigations **MLO (ii), (iii), (iv), (v)**	*Anterior and posterior pituitary* • Structure and physiology • Principles, clinical purpose, preanalytical factors and results of techniques used in laboratory measurement of ACTH

	Thyroid • Structure and physiology • Production and regulation of thyroid hormone • Pathology of disorders within and external (including immune conditions) to the thyroid gland especially those that impact hormone production • Principles, purpose and results of techniques applied in measuring and monitoring thyroid hormone levels • Factors that may affect investigations of thyroid function • Principles, purpose and results of testing for free hormone • Identify disorders based on clinical history and testing results *Adrenal* • Structure and physiology • Hypothalamic, anterior pituitary, adrenal cortex axis and its function • Pathology of endocrine disorders within adrenal gland • Principles, purpose and results of techniques applied in measuring cortisol and the use of dynamic function testing • Congenital adrenal conditions and implications for diagnosis *Hirsutism in females* • Causes including secondary conditions that may result in hirsutism • Clinical testing, monitoring and treatment options
Male Infertility **MLO (vi)**	• Causes and pathological changes leading to male infertility • Principles, purpose and results of techniques applied in measuring and monitoring male hormones
Female infertility **MLO (vi)**	• Causes, disorders and pathological changes leading to female infertility • Principles, purpose and results of techniques applied in measuring and monitoring female hormones
Pregnancy **MLO (vii), (viii), (ix)**	• Principles, results and sources of error in techniques applied in measuring and monitoring human chorionic gonadotrophin (HCG) in pregnancy • Clinical interpretations of results obtained in measuring and monitoring human chorionic gonadotrophin (HCG) levels • Detection and monitoring of foetal abnormalities • Post-neonatal screening

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:* 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 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 *Journals* Australian Journal of Medical Science Clinical Chemistry Journal of the International Federation of Clinical Chemistry and Laboratory Medicine Medical Journal of Australia The New England Journal of Medicine *Web-based resources* 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 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/ Royal College of Pathologists of Australasia https://www.rcpa.edu.au/library Westgard QC https://westgard.com/westgard-rules.html

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Clinical Chemistry III

Module	**SPECIAL TESTS** **TOXICOLOGY**
Aim	To develop and apply specialist knowledge, investigative practice and clinical skills relevant to specialist clinical chemistry and toxicological testing.
Module learning outcomes (MLO)	On completion of this module the candidate will be able to: (i) Discuss the importance of pre-analytical factors on the quantity and quality of test results (ii) Explain the principles and applications of gas chromatography/mass spectrometry (GCMS) for assay of various analytes (iii) Explain key concepts in therapeutic drug monitoring (TDM) and describe methods used to monitor these drugs (iv) Discuss the laboratory investigation of toxic agents and the methods available for their detection and assay (v) Discuss the laboratory investigation of drugs of abuse and the methods available for their detection and assay (vi) Describe the structure and composition of bone, conditions of low bone density and the laboratory investigation of disorders of bone metabolism (vii) Discuss the pathophysiology and laboratory investigation of porphyria (viii) Describe tumour markers and explain the significance and limitations of their detection (ix) Discuss the clinical significance of prostate specific antigen (PSA) and the value of screening (x) Explain the diagnostic significance of total PSA, free PSA and PSA velocity (xi) Discuss the serological investigation of viral disease and other infectious agents

Theme	**Syllabus**
Pre-analytical factors **MLO (i)**	Pre-analytical factors that may affect specialist clinical chemistry, drug monitoring and toxicological testing
Instrumentation **MLO (ii)**	Principles and clinical applications of gas chromatography/mass spectrometry (GCMS)

Therapeutic drug monitoring
MLO (ii), (iii)
	• Concepts of pharmacokinetics, therapeutic drug monitoring (TDM) and therapeutic range
	• Principles and applications of techniques used for TDM
	• Anticonvulsant, bronchodilatation, cardioactive, psychotropic and immunosuppressant agents
	• Principles for interpretation of plasma drug concentration
	• Factors affecting drug absorption, metabolism, and excretion
	• Peak and trough measurements and their use in TDM
	• Aspects influencing drug measurement including
	  ○ half-life
	  ○ steady state
	  ○ active metabolites
	  ○ albumin and other proteins
	• Issues with measurement of digoxin

Toxicology **MLO (iv), (v)**	• Sample collection sites and considerations • Toxic agents • Drugs of abuse • Paracetamol, clinical importance of testing • Rumack-Matthew nomogram • Principles and applications of analytical techniques • Sources of error in toxicology assays
Bone metabolism: biochemical markers **MLO (vi)**	• Bone structure, composition, biochemistry and response to parathyroid hormone, oestrogen, insulin, triiodothyronine (T3), testosterone, cortisol, calcitonin, vitamin D • Bone markers in resorption and disease • Low bone mass • Bone degradation • C-and N-telopeptides
Porphyria **MLO (vii)**	• Pre-analytical factors that may affect testing • Metabolic pathway and relationship to iron metabolism • Causes, pathophysiology and clinical outcomes • δ-aminolevulinate (δ-ALA) and porphobilinogen • Pseudoporphyria • Role and limitations of screening tests

Neoplasia and tumour markers
MLO (viii), (ix), (x)
	• Carcinogenesis, phases of tumour development, morphological features of malignant cells, clinical effects of tumours
	• Tumour markers: types, functions, associated cancers, impact in clinical diagnostics
	• Prostatic specific antigen (PSA)
	  ○ Source, physiological aspects and relationship to prostatic malignancy
	  ○ Significance as a tumour marker
	  ○ Value of PSA screening and changes with age
	  ○ PSA testing, total PSA, free PSA, PSA velocity
	• Carcinoembryonic antigen (CEA) and colon-rectal tumours

Viral disease
MLO (xi)
	• Hepatitis
	  ○ Viral types and clinical significance
	  ○ Laboratory testing
	  ○ Markers and the carrier state
	• Epstein-Barr Virus (EBV)
	  ○ Laboratory testing including for immunological responses
	• Human Immunodeficiency Virus (HIV)
	  ○ Genomic features
	  ○ Laboratory testing for relevant CD ratio

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 editions of:* 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 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 *Journals* Australian Journal of Medical Science Clinical Chemistry Journal of the International Federation of Clinical Chemistry and Laboratory Medicine Medical Journal of Australia The New England Journal of Medicine *Web-based resources* Asia-Pacific Federation for Clinical Biochemistry and Laboratory Medicine https://apfcb.org/ 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 Diabetes Australia https://www.diabetesaustralia.com.au/ International Federation of Clinical Chemistry and Laboratory Medicine 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/ Royal College of Pathologists of Australasia https://www.rcpa.edu.au/library Westgard QC https://westgard.com/westgard-rules.html

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Clinical Chemistry 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 Chemistry 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 Chemistry 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 Chemistry 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 Chemistry 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 Chemistry 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 Chemistry 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:* Cohen S, ed. *Artificial Intelligence and Deep Learning in Pathology*. Elsevier Garcia LS, Allen TC, Baselski VS, Church DL, Karcher DS, Lewis MR, Linscott AJ, Poulter MD, Procop GW, Weissfeld AS, Wolk DM. *Clinical Laboratory Management*. Wiley 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 British Medical Journal Clinical Laboratory Medicine New Zealand Journal of Medical Laboratory Science New Zealand Journal of Medical Laboratory Science *Web-based resources* Public Pathology Australia https://publicpathology.org.au/ Digital Pathology Association https://digitalpathologyassociation.org Australian Pathology https://www.australianpathology.com/ MBS Schedule Category 6 – Pathology NATA https://www.nata.com.au/ National Pathology Accreditation Advisory Council (NPAAC) https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-index.htm Pathology Funding Agreement (2012) TGA and IVD http://www.tga.gov.au/industry/ivd-regulatory-requirements.htm WorkSafe Australia https://www.safeworkaustralia.gov.au/

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