AUSTRALIAN INSTITUTE OF
MEDICAL AND CLINICAL SCIENTISTS

Fellowship Discipline Modules

Clinical Microbiology

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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 Microbiology I

Module	BIOLOGY AND IDENTIFICATION OF HUMAN PATHOGENS
Aim	To develop and apply expert knowledge, investigative practice and clinical skills relevant to the identification of infectious diseases in the Clinical Microbiology laboratory.
Module learning outcomes (MLO)	On completion of this module the candidate will be able to: (i) Describe pre-analytical factors which may affect the outcome of laboratory investigations (ii) Describe the investigative techniques employed in the Clinical Microbiology laboratory (iii) Describe the characteristics, epidemiology, transmission, pathogenesis and clinical significance of clinically relevant bacteria (listed below) (iv) Discuss the detection, optimal isolation and culture of clinically relevant bacteria from bodily fluids and tissues (listed below) (v) Explain the mode of action and activity of antibiotics in common use (vi) Critically discuss the pathways and mechanisms of antimicrobial resistance in clinically relevant bacteria (vii) Describe the methods for antimicrobial susceptibility (resistance) testing including the major disc diffusion (EUCAST and CLSI), microdilution and application of gradient strip methods

Theme	Syllabus
Pre-analytical factors **MLO (i)**	• Management of clinical and patient information • Collection, transport and handling of samples • Potential for contamination by regional flora • Transportation and storage of samples
Clinical Microbiology techniques **MLO (ii)**	*Microscopy* • Light microscopy • Phase contrast microscopy • Dark ground microscopy *Staining procedures* • India ink • Gram • Ziehl Neelsen (ZN) • Modified ZN, Kinyoun *Composition and characteristics of media in common use* • General growth media • Enriched media • Selective and differential media • Chromogenic media • Incubation equipment and conditions • Quality control

	Identification procedures • Routine bench tests • Kit and similar tests • Automated and semi-automated systems (identification and susceptibility testing) • MALDI-TOF, principles and applications • Total laboratory automation

Bacteriology
MLO (iii)
	Characteristics of clinically relevant bacteria:
	• Taxonomy
	• General description
	• Clinical significance, epidemiology and transmission
	• Direct examination, isolation and culture
	• Identification and antimicrobial susceptibility
	• Interpretation and reporting
	• Special factors including safety, notification requirements
	
	Clinically relevant bacteria:
	• Gram-positive
	  ○ *Staphylococcus*
	  ○ *Streptococcus*
	  ○ *Enterococci*
	  ○ Other Gram-positive cocci
	  ○ Gram-positive bacilli
	  ○ *Corynebacterium*
	  ○ *Bacillus*
	  ○ Other non-fastidious Gram-positive bacilli
	• Gram-negative
	  ○ *Neisseria*
	  ○ *Moraxella*
	  ○ *Acinetobacter*
	  ○ Other Gram-negative cocco-bacilli
	  ○ *Enterobacteriaceae*
	  ○ *Aeromonas*
	  ○ *Vibrio*
	  ○ *Pseudomonas* and other oxidase positive GNB
	  ○ *Bordetella*
	  ○ *Haemophilus*
	  ○ Miscellaneous Gram-negative bacilli
	  ○ *Campylobacter*
	  ○ Other spiral Gram-negative bacilli
	• *Mycobacterium*
	• *Norcardia*
	• Anaerobic bacteria
	• *Spirochetes, Leptospira, Borrellia*
	• *Mycoplasma, Chlamydiae* and other obligate intracellular bacteria

Laboratory investigation of infectious disease by sample site **MLO (iv)**	• Blood • CSF and central nervous system • Body fluids and tissue samples • Wounds: skin and soft tissue • Genital tract • Eyes, ears, nose, throat, upper respiratory tract • Lower respiratory tract • Urinary tract • Gastrointestinal tract • Neonatal and paediatric samples • Miscellaneous (catheter tips, testing and sampling equipment, other sources)
Antimicrobial agents and resistance mechanisms **MLO (v), (vii)**	• Penicillin and β-lactam antibiotics • Aminoglycosides • Tetracyclines • Macrolides • Sulphonamides / Trimethoprim • Quinolones • Chloramphenicol • Metronidazole • Nitrofurantoin • Antibiotic inhibitor combinations • Newer antimicrobial therapies • Multi-resistant bacteria and their identification • Mechanisms of antimicrobial resistance in Gram-positive and Gram-negative bacteria
Antimicrobial susceptibility / resistance testing **MLO (vi)**	• Disc diffusion procedures • β-lactamase detection • Fastidious organisms • Microbroth dilution • Automation • Gradient strip methods • Susceptibility methods (Clinical & Laboratory Standards Institute [CLSI], European Committee on Antimicrobial Resistance [EUCAST]) • Measurement of antimicrobial concentrations • Quality control in antimicrobial resistance testing

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:* 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*. 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 Chemistry and Laboratory Medicine Clinical Microbiology Reviews Journal of Clinical Microbiology Journal of Clinical Pathology Journal of Virology Lancet New England Journal of Medicine Virological Methods *Web-based resources* Atlas of Clinical Fungi https://www.atlasclinicalfungi.org/ CDCl 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 DPDx - Laboratory Identification of Parasites of Public Health Concern https://www.cdc.gov/dpdx/index.html EUCAST https://www.eucast.org/ Mycology online https://www.adelaide.edu.au/mycology/national-mycology-reference-centre Pathology tests explained https://www.pathologytestsexplained.org.au 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 Microbiology II

Module	PARASITOLOGY AND MYCOLOGY
Aims	To develop and apply specialist knowledge, investigative practice and clinical skills relevant to the biology and identification of human parasite and fungal pathogens.
Module learning outcomes (MLO)	On completion of this module the candidate will be able to: (i) Describe and evaluate the collection, safe handling and storage of parasites and fungi (ii) Describe the taxonomy and nomenclature of fungi and the concept of one fungus/one name (iii) Describe the characteristics, life cycle, epidemiology, transmission, pathogenesis and significance of the clinically relevant parasites and fungi (listed below) (iv) Describe the investigative techniques employed to identify the clinically relevant parasites and fungi (listed below) (v) Compare and contrast infections caused by blood borne parasites (vi) Discuss the impact and diagnosis of parasitic and fungal infections in the immunosuppressed patient

Theme	Syllabus
Pre-analytical factors **MLO (i)**	• Management of clinical and patient information • Collection, transport and handling of samples • Identification of required sample types • Storage of samples
General aspects relevant to parasites and fungi **MLO (ii), (iii), (iv), (v), (vi)**	*Characteristics of clinically relevant parasites and fungi* • Taxonomy and life cycles • General description • Clinical significance, epidemiology and transmission • Culture and identification of fungal pathogens • Identification of parasitic pathogens • Interpretation and reporting (excluding serological and molecular methods) • Special factors including safety, notification requirements
Parasitology **MLO (ii), (iii), (iv), (v), (vi)**	*Protozoa* • Flagellate • Amoebae (including *Dientamoeba*) • Free living amoebae • *Naegleria* and *Acanthamoeba* • *Balamuthia* • Ciliate protozoa • *Toxoplasma* • *Cryptosporidium*, *Cyclospora, Isospora* • *Blastocystis* • Helminths

	<u>*Nematodes*</u> • *Trichinella* sp • *Trichuris* sp • *Strongyloides* sp • *Ancylostoma* sp • *Necator* sp • *Trichostrongylus* sp • *Ascaris* sp • Other Nematodes causing infections in humans <u>*Trematodes (Flukes)*</u> • Shistosomes • *Fasciola* sp • *Fasciolopis* sp • Echinostomes • *Paragonimus* sp • *Clonorchis* sp • *Opisthorchis* sp • *Heterophyes* sp • Other Trematodes causing infection in humans <u>*Cestodes (Tape Worms)*</u> • *Taenia* sp • *Diphyllobothrium* sp • *Hymenolepis* sp • *Echinoccus* sp • Other Cestodes causing infection in humans <u>*Arthropods of Medical Importance*</u> • *Pediculus capitis* • *Phthirus pubis* • *Cimex lectularius* • Other arthropods of medical importance
Mycology **MLO (ii), (iii), (iv), (v), (vi)**	<u>*Superficial Mycoses*</u> • *Epidermophyton* sp • *Microsporum* sp • *Trichophyton* sp • Non-dermatophytic causes of superficial mycoses • Black piedra • White piedra • Pityriasis versicolor • Tinea nigra <u>*Yeasts*</u> • *Candida* sp • *Torulopsis* sp • *Cryptococcus* sp • *Rhodotorula* sp • *Geotrichum* sp • Other yeasts • *Pneumocystis*

	Dimorphic fungi causing systemic disease • Histoplasmosis • Blastomycosis • Coccidioidomycosis • Paracoccidioidomycosis *Hyaline hyphomycetes* • *Aspergillus* sp., Penicillium, Fusarium and other opportunistic hyalomycetes • Agents of systemic and subcutaneous Mucormycosis and Entomophthoromycosis • Dematiaceous fungi and agents of Phaeohyphomycosis, Chromoblastomycosis, Sporotrichosis (*Sporothrix schenckii)* • Eumycotic mycetoma • Other pathogenic fungi

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:* Borman AM, Johnson EM. 2023. *Name Changes for Fungi of Medical Importance, 2020 to 2021*. Journal of Clinical Microbiology 61:e00330-22. https://doi.org/10.1128/jcm.00330-22 Carroll KC, Pfaller MA, Karlowsky JA, Landry ML, McAdam AJ, Patel R, Pritt BS (eds). *Manual of Clinical Microbiology, Multi-Volume*. ASM Press Finch RG, Greenwood D, Norrby SR, Whitely RJ. *Antibiotics and Chemotherapy: Anti-infective Agents and Their Use in Therapy*. Elsevier Garcia LS. *Practical Guide to Diagnostic Parasitology*. ASM Press Kidd S, Halliday C, Ellis D. *Descriptions of Medical Fungi*. CABI Leber AL (ed). *Clinical Microbiology Procedures Handbook*. ASM Press Terrero-Salcedo D, Powers-Fletcher MV. 2020. *Updates in Laboratory Diagnostics for Invasive Fungal Infections*. Journal of Clinical Microbiology 58(6):e01487-19. doi: 10.1128/JCM.01487-19 Tille P. *Bailey & Scott's Diagnostic Microbiology*. Elsevier Westblade LF, Burd EM, Lockhart SR, Procop GW. *Larone's Medically Important Fungi: A Guide to Identification*. ASM Press

	Journals Australian Journal of Medical Science Clinical Chemistry and Laboratory Medicine Clinical Microbiology Reviews Journal of Clinical Microbiology Journal of Clinical Pathology Journal of Virology Lancet New England Journal of Medicine Virological Methods *Web-based resources* American Society for Microbiology https:www.asm.org Atlas of Clinical Fungi https://www.atlasclinicalfungi.org/ Australian Society for Microbiology (ASM) https://www.theasm.org.au (password required for some content) CDCl 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 DPDx - Laboratory Identification of Parasites of Public Health Concern https://www.cdc.gov/dpdx/index.html EUCAST https://www.eucast.org/ Mycology online https://www.adelaide.edu.au/mycology/national-mycology-reference-centre Pathology tests explained https://www.pathologytestsexplained.org.au Royal College of Pathologists of Australasia https://www.rcpa.edu.au/library

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Clinical Microbiology III

Module	VIROLOGY, SEROLOGY AND MOLECULAR TESTING
Assumed knowledge	Microorganisms known to cause infection in humans, basic laboratory techniques and clinical symptoms.
Aims	To develop and apply expert knowledge, investigative practice and clinical skills relevant to serological and molecular pathology procedures in the diagnosis and monitoring of human pathogens including bacteria, viruses, parasites and fungi.
Module learning outcomes	On completion of this module the candidate will be able to: (i) Describe the preanalytical factors and optimal collection, transport and storage of samples for serological and molecular investigations (ii) Discuss the pathogenesis, clinical significance, epidemiology and transmission of agents of viral disease (listed below) (iii) Describe the diseases caused by, and clinical significance of, viral conditions which can occur in bodily fluids and tissues (iv) Explain the immune response to infectious agents and its application to laboratory diagnosis (v) Describe the principles of serological techniques in the diagnosis and investigation of infectious disease (vi) Describe the principles of molecular methods used in the diagnosis and investigation of infectious disease (vii) Discuss the laboratory identification including deficiencies, limitations and interpretation of results of infectious agents principally by serological methods (viii) Discuss the laboratory identification including deficiencies, limitations and interpretation of results of infectious agents principally by molecular methods

Theme	Syllabus
Pre-analytical factors **MLO (i)**	• Management of clinical and patient information • Collection, transport and handling of samples • Storage of samples
General aspects **MLO (ii)**	*Aspects of clinically relevant viruses* • Morphology • Classification • DNA and RNA viruses • Viral replication • Virulence factors • Pathogenesis, clinical significance, epidemiology and transmission • Interpretation and reporting • Special factors including safety, notification requirements
Virology **MLO (ii)**	*DNA viruses* • Parvoviridae • Papovaviridae • Adenoviridae • Herpesviridae • Poxviridae • Hepadnaviridae

	RNA viruses • Picornaviridae • Togaviridae • Flaviviridae • Coronaviridae • Paramyxoviridae • Rhabdoviridae • Orthomyxoviridae • Retroviridae • Other RNA viruses
Viral diseases and syndromes **MLO (iii)**	• Respiratory tract • Gastrointestinal tract • Blood-borne • Central nervous system • Skin rashes • Eye • Genital tract • Congenital and perinatal infections • Viral hepatitis • Cardiac disease • Viral infection in the immunocompromised patient (including HIV/AIDS)
Immune response to infectious agents **MLO (iv)**	Bacterial, fungal, parasitic and viral pathogens

Serological techniques and applications
MLO (v)
	Enzyme Immunoassays
	• Assay types
	  ○ Instrument based assays
	  ○ Microtitre plate assays
	  ○ Reverse capture
	  ○ Competitive
	• Detection systems
	  ○ Enzyme colourimetric
	  ○ Fluorescent
	  ○ Chemiluminescent
	
	Rapid and Point of Care Tests including
	• Agglutination
	• Cartridge assays (lateral flow devices)
	• Direct antigen detection
	
	Biological functional serology techniques including
	• Complement fixation
	• Haemagglutination
	• Plaque neutralisation
	• Diffusion

	Confirmatory Techniques • Western blot • Neutralisation *Other serology techniques* • Immunofluorescent • Northern blots • Southern blots • Line/dot blots • Serotyping • Quality assurance of serology assays

Molecular pathology techniques and application
MLO (vi)
	• Sample selection and storage
	• Polymerase Chain Reaction (PCR)
	  ○ Principles and applications
	  ○ qPCR
	  ○ Droplet digital PCR
	  ○ Multiplex assays
	• Other molecular techniques
	  ○ Branched DNA
	  ○ Transcription Mediated Amplification
	  ○ Non-Amplification Nucleic Acid Tests
	  ○ Nucleic acid extraction techniques
	  ○ Automation of molecular assays
	  ○ CRISPR
	• Sequencing
	  ○ Sanger sequencing
	  ○ Next Generation Sequencing
	  ○ Hybridization
	  ○ Other methods
	• Point of care
	  ○ Equipment including cartridge-based PCR units
	  ○ Applications
	  ○ Management
	• Quality assurance

Identification of infectious agents principally by serological methods **MLO (vii)**	*Infectious agents* • Group A streptococcal infections • Blood-borne infections: HIV, HCV, HTLV • Spirochete infections: syphilis, leptospirosis, Lyme disease • Congenital and paediatrics infections: rubella, CMV, toxoplasmosis • Rash causing agents: CMV, VZV, EBV • Arboviruses: RRV, MVE, JEV, WNV • Rickettsiae, mycoplasma, chlamydia and other obligate intracellular parasites • Parasitic agents: strongyloides, hydatid

	Implementation and efficacy of pathology diagnostics • Diagnosis of infectious diseases • Monitoring of disease progression • Access to testing • Blood and tissues screening • Epidemiology • Point of care testing
Identification of infectious agents principally by molecular methods MLO (viii)	*Infectious agents* • Blood-borne viruses • Sexually transmitted infections including Ct, Ng, Tv, Uu • Respiratory infections: Influenza A, Influenza B, COVID, RSV, adenovirus) • Faecal agents (bacterial, viral, parasites) • CNS • Fungal agents *Implementation and efficacy of pathology diagnostics* • Diagnosis of infectious diseases • Monitoring of disease progression • Access to testing • Blood and tissues screening • Epidemiology • Point of care testing

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:* Burrell CJ, Howard CR, Murphy FA. *Fenner and White's Medical Virology*. Elsevier Carroll KC, Pfaller MA, Karlowsky JA, Landry ML, McAdam AJ, Patel R, Pritt BS (eds). *Manual of Clinical Microbiology, Multi-Volume*. ASM Press Detrick B, Schmitz JL, Hamilton RG. *Manual of Molecular and Clinical Laboratory Immunology*. Wiley Finch RG, Greenwood D, Norrby SR, Whitely RJ. *Antibiotics and Chemotherapy: Anti-infective Agents and Their Use in Therapy*. Elsevier Flint J, Racaniello VR, Rall GF, Hatziioannou T, Skalka AM. P*rinciples of Virology, Multi-Volume*. Wiley Garcia LS. *Practical Guide to Diagnostic Parasitology*. ASM Press Khare R. *Guide to Clinical and Diagnostic Virology*. ASM Press Kidd S, Halliday C, Ellis D. *Descriptions of Medical Fungi*. CABI Leber AL (ed). *Clinical Microbiology Procedures Handbook*. ASM Press

	Loeffelholz MJ, Hodinka RL, Young SA, Pinsky BA (eds). *Clinical Virology Manual*. Wiley Strich JR, Chertow DS. 2019. *CRISPR-Cas Biology and Its Application to Infectious Diseases*. Journal of Clinical Microbiology 57:10.1128/jcm.01307-18 https://doi.org/10.1128/jcm.01307-18 Tille P. *Bailey & Scott's Diagnostic Microbiology*. Elsevier Westblade LF, Burd EM, Lockhart SR, Procop GW. *Larone's Medically Important Fungi: A Guide to Identification*. ASM Press *Journals* Australian Journal of Medical Science Clinical Chemistry and Laboratory Medicine Clinical Microbiology Reviews Journal of Clinical Microbiology Journal of Clinical Pathology Journal of Virology Lancet New England Journal of Medicine Virological Methods *Web-based resources* American Society for Microbiology https:www.asm.org Australian Institute of Medical and Clinical Scientists https://www.aims.org.au/ Australian Society for Microbiology (ASM) https://www.theasm.org.au (password required for some content) CDCl 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/ Pathology tests explained https://www.pathologytestsexplained.org.au Royal College of Pathologists of Australasia https://www.rcpa.edu.au/library

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Clinical Microbiology 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 Microbiology 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 Microbiology 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 Microbiology 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 Microbiology 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 Microbiology 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 Microbiology 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 *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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