AUSTRALIAN INSTITUTE OF
MEDICAL AND CLINICAL SCIENTISTS

Fellowship Discipline Modules

Immunopathology

Australian Institute of Medical and Clinical Scientists (AIMS)
Street address:
7/31 Black Street
Milton QLD 4064
Australia

Postal address:
PO Box 1911
Milton QLD 4064
Australia

ACN 010 985 403
Email: programs@aims.org.au
Website: www.aims.org.au
Phone: (07) 3876 2988

First Published: 2025
Effective from October 2025

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.

Immunopathology I

Module	IMMUNE FUNCTION
Assumed knowledge	Organs, tissue and cells of the immune system and how these develop and operate in providing defence.
Aims	To develop and apply specialist knowledge, investigative practice and clinical skills relevant to: a) the concepts of innate and acquired immunity b) the respective regulatory mechanisms that enable and facilitate an understanding of diagnostic techniques c) the pathophysiology of infectious disease and malignant lesions d) the interpretation and explanation of diagnostic data in the clinical setting.
Module learning outcomes (MLO)	On completion of this module the candidate will be able to: (i) Explain the processes whereby specific immune responses are induced and regulated (ii) Explain the pathophysiology of acute and chronic inflammatory reactions (iii) Relate the principles of immune responses to infections and mechanisms of immune evasion (iv) Explain the immunological basis of immunisation (v) Explain the operational principles and the interpretation and validation of data in relation to enzyme immunoassays, immunoblot analysis, chemiluminescence, standard serological tests, agglutination, molecular detection such as the polymerase chain reaction (PCR), toxin neutralisation assays, indirect fluorescent antibody assays, complement fixation tests (vi) Explain the aetiology and development of solid tumours (vii) Describe technologies required to detect and monitor tumours (viii) Explain the biological basis of the association between infection by some pathogens and malignancy

Theme	Syllabus
Protective and regulatory immune mechanisms **MLO (i)**	*Generation of specific immune responses* • Antigen processing and presentation • Role of antigen receptor molecules • Major Histocompatibility Complex (MHC) in the initiation of immune responses • Antigen presenting cells and mechanisms of antigen processing and presentation by these cells to induce specific T cell and B cell responses to antigen *T cell roles and functions* • T cell responses to antigen • T cell activation and maturation and control • TH1, TH2 and soluble mediators • T cell memory • Cytotoxic T cell responses and NK T cells

	B cell roles and functions • B cell responses to antigen • B cell activation and maturation • Antibodies their nature and role • Antigen-antibody interaction: affinity, avidity and cross-reactivity • B cell memory *Regulation of immune processes* • Regulatory mechanisms of immunity • The genetic basis of immune regulation • The role of cytokines and T cells in orchestrating the immune response and control mechanisms *Complement* • Nature and function of complement molecules • Activation pathways and regulation • Opsonisation and clearance of immunocomplexes, chemotaxis, cytolysis, inflammation and immune regulation *Mucosal Immunity* • Innate mucosal immune mechanisms (structural, mucous, cilia, peristalsis, enzymes, phagocytes, defensins, Toll-receptors) • Mucosal immune induction sites (Peyer's patches, NALT, BALT) • Lymphocyte migration and homing to mucosal effecter sites • IgA: secretion at mucosal surfaces and role in mucosal defence
Inflammatory processes **MLO (ii)**	• Mechanism and control of acute inflammation • Establishment and features of chronic inflammation • The role of cytokines in acute and chronic inflammatory processes

Immune response to pathogens
MLO (iii)
	Viruses
	• Mechanisms of infection
	• Innate and acquired immune responses
	• Mechanisms by which viruses can evade host immune defences
	• Immunopathology of influenza, human immunodeficiency virus (HIV), hepatitis, measles, Epstein-Barr virus (EBV) and Covid 19
	
	Bacteria
	• Mechanisms of infection by Gram-positive and Gram-negative bacteria
	• Innate and acquired immune responses
	• Pathogen-associated molecular patterns (PAMPs) and the role of Toll-like receptors
	• Bacterial superantigens
	• Heat shock proteins and 'danger signals'
	• Organisms:
	  ○ *Corynebacterium diphtheria*
	  ○ *Clostridium tetani*
	  ○ *Helicobacter pylori*
	  ○ *Streptococcus pneumoniae*
	  ○ *Streptococcus pyogenes*
	  ○ *Borrelia burgdorferi*
	  ○ *Mycobacterium tuberculosis*

	<u>*Fungi*</u>
	• Mechanisms of infection
	• Innate and acquired immune responses
	• Mechanisms by which fungi can evade host immune defences
	• Organisms:
	  ○ *Candida albicans*
	  ○ *Aspergillus fumigatus*
	
	<u>*Protozoa*</u>
	• Mechanisms of infection
	• Innate and acquired immune responses
	• Mechanisms by which protozoa can evade host immune defences
	• Organisms:
	  ○ *Toxoplasma gondii*
	  ○ *Plasmodium falciparum*
	  ○ *Giardia lamblia*
	
	<u>Helminths</u>
	• Mechanisms of infection
	• Innate and acquired immune responses
	• Mechanisms by which helminths can evade host immune defences
	• Organisms:
	  ○ *Echinococcus granulosus*
	  ○ *Echinococcus multilocularis*

Vaccines and immunisation MLO (iv)	• Principles of immunisation
	  ○ Active immunisation
	  ○ Passive immunisation
	• Types of vaccines
	  ○ Live attenuated
	  ○ Inactivated (recombinant antigen, viral particle, outer membrane vesicle)
	  ○ Conjugated subunit
	  ○ Unconjugated subunit
	  ○ DNA
	  ○ mRNA
	  ○ Vector based (e.g., adenoviral vector-based vaccines)
	  ○ anti-idiotypic
	• Role of adjuvants and examples
	• Routes of immunisation
	• Adverse reactions
	• Immunisation against infectious disease
	• Immunisation against malignant disease

Laboratory techniques and principles MLO (v)	• Enzyme immunoassays • Immunoblot analysis • Standard serological tests using solid phase support and agglutination • Molecular diagnostic methods • Toxin neutralisation assays • Indirect fluorescent antibody assays • Complement fixation

Tumour immunology **MLO (vi)**	• Genetic basis of cancer • Tumours as allografts • Immune response to tumours • Immunoediting
Tumour markers and laboratory diagnostic procedures and utility **MLO (vii)**	• Breast: CA15.3, CA27.29 • Prostate: PSA • Ovarian: CA-125 • Colorectal: CEA • Pancreatic CA19.9 • Liver: alpha fetoprotein (AFP)
Links between microbial infection and cancer **MLO (viii)**	• *Helicobacter pylori* and gastric cancer • Human papilloma virus and cervical cancer • Epstein Barr Virus and thoracic cancer and malignancies of the immune system

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> Abbas AK, Lichtman AH, Pillai S. *Cellular and Molecular Immunology.* Elsevier Delves PJ, Martin SJ, Burton DR, Roitt IM. *Roitt's Essential Immunology*. Wiley-Blackwell Detrick B, Schmitz JL, Hamilton RG (eds). *Manual of Molecular and Clinical Laboratory Immunology*. ASM Press Elgert KD. *Immunology: Understanding the Immune System*. Wiley-Blackwell Male D, Stokes Peebles R, Male V. *Immunology*. Elsevier Murphy KM, Weaver C, Berg LJ. *Janeway's Immunobiology*. Norton Punt J, Stranford S, Jones P, Owen JA. *Kuby Immunology*. Freeman

	Journals Archives of Pathology and Laboratory Medicine Australian Journal of Medical Science BMC Immunology Cancer Immunology, Immunotherapy Cellular Immunology Current Opinion in Immunology European Journal of Immunology Frontiers in Immunology Immunity Immunology Immunology and Cell Biology Infection and Immunity Journal of Immunity Journal of Immunological Methods Journal of Immunology Molecular Immunology Nature Immunology Nature Reviews Immunology OncoImmunology Pathogens and Immunity Scandinavian Journal of Immunology Science Immunology Seminars in Immunology Seminars in Immunopathology
	Web-based resources British Society for Immunology https://www.immunology.org/ https://www.immunology.org/public-information/bitesized-immunology NIH/NCI Immunotherapy https://www.cancer.gov/research/areas/treatment/immunotherapy Technology Networks Diagnostics. Immunoassays: A Guide https://www.technologynAetworks.com/diagnostics/articles/immunoassays-a-guide-338790

Version number	*1.0*
Date	*November, 2025*
Review date	*September, 2028*

Immunopathology II

Module	HYPERSENSITIVITY, AUTOIMMUNITY and TRANSPLANTATION IMMUNOLOGY
Aim	To develop and apply specialist knowledge, investigative practice and clinical skills relevant to the immunopathology of hypersensitivity, autoimmunity and allograft rejection.
Module learning outcomes (MLO)	On completion of this module the candidate will be able to: (i) Describe the immunologic basis of the types of hypersensitivity responses (ii) Apply relevant tests for diagnosis and management of hypersensitivity conditions and analyse the results of these tests (iii) Identify limitations of hypersensitivity tests, modify tests where required and implement quality control measures relevant to these tests in the clinical laboratory (iv) Describe mechanisms involved in distinguishing between self and non-self by the immune system (v) Explain autoimmunity and the mechanisms/factors which can result in the breakdown of self-tolerance leading to autoimmune disease (vi) Explain the clinical features and genetic associations of the more common autoimmune disorders (vii) Develop a theoretical basis around the procedures, technology, quality assurance and limitations of laboratory diagnostics for detecting autoimmunity in patients (viii) Explain the immunological basis of allograft recognition and rejection (ix) Develop a theoretical basis for the procedures, technology, quality assurance and limitations of tissue typing procedures for transplantation

Theme	Syllabus

Hypersensitivity: types, mechanisms and causes
MLO (i)
	Classification
	• Type I Hypersensitivity
	  ○ Mast cells and Basophils
	  ❖ Receptors and triggering mechanisms
	  ❖ Effector mechanisms
	  ❖ Disease examples
	• Type II Hypersensitivity
	  ○ Effector mechanisms (immediate vs delayed)
	  ○ Disease examples
	• Type III Hypersensitivity
	  ○ Effector mechanisms Disease examples
	• Type IV Hypersensitivity
	  ○ Effector mechanism
	  ○ Disease examples

	IgE
	• Properties
	• Biological role
	• Generation
	  ○ Role of T cells
	  ○ Role of cytokines
	• IgE receptors
	• Mast cells and basophils
	  ○ Function
	  ○ Mechanisms of action
	  ○ Mediators
	
	Allergens
	• General properties
	• Structure
	  ○ Protein families
	  ○ CCD
	  ○ Profilin
	  ○ nsLTP
	  ○ Storage proteins
	  ○ PR-10P
	• Stability
	• Cross reactions
	• Inhalants, foods, drugs, venoms
	• Immunotherapy
	
	Genetics
	• Hereditary association of asthma and hay fever
	  ○ HLA associations
	• Severe adverse reactions
	  ○ Drug reaction with eosinophilia and systemic symptoms (DRESS)
	  ○ Stevens Johnson syndrome / Toxic epidermal necrolysis
	• Immunogenetics: drug allergy
	  ○ HLA B5701
	  ○ HLA B5801
	  ○ HLA B1502
	  ○ HLA A31O1
	  ○ HLA B13.01
	• Ethnic diversity

Diagnostic tests for hypersensitivity
MLO (ii), (iii)
	• In-Vivo
	  ○ Skin prick tests
	  ○ Intradermal tests
	  ○ Patch tests
	  ○ Challenge tests
	• In-Vitro tests
	  ○ Total IgE
	  ○ Specific IgE tests
	  ○ Component derived testing
	  ○ ISAC microarray system
	  ○ Mast cell tryptase
	  ○ Eosinophilic cationic protein
	  ○ Histamine release assays
	  ○ Lymphocyte transformation tests
	  ○ Basophil activation assays

Autoimmunity: principles and mechanisms **MLO (vi), (v)**	*Self and non self* *Immune tolerance* • Central and peripheral tolerance • T cell tolerance • B cell tolerance • AIRE transcription factor and self-antigen expression in the thymus • Oral tolerance • Maintenance *Apoptosis* • Cellular changes • Signalling, mechanism and pathways *Antigen processing and presentation* • Antigen receptor molecules • Human leukocyte antigen (HLA): genetic origin, functions, variants (polymorphisms • Major Histocompatibility Complex (MHC) *Immune mechanisms* • Causes of autoimmunity • Mechanisms of breakdown of tolerance • Factors contributing to autoimmunity

Autoimmune disorders
MLO (vi), (vii)
	Clinical conditions
	• Immunopathology and tissue specificity/target autoantigen/s of the following disorders:
	  ○ Ankylosing spondylitis
	  ○ Antineutrophil cytoplasmic antibody (ANCA) associated vasculitis
	  ○ Antiphospholipid syndrome
	  ○ Autoimmune anaemia
	  ○ Autoimmune hepatitis
	  ○ Coeliac disease
	  ○ Goodpasture's syndrome
	  ○ Graves' disease
	  ○ Hashimoto's thyroiditis
	  ○ Idiopathic thrombocytopenia purpura
	  ○ Inflammatory bowel disease (Crohn's disease and ulcerative colitis)
	  ○ Insulin-dependent diabetes mellitus
	  ○ Multiple sclerosis
	  ○ Myasthenia gravis
	  ○ Pemphigus vulgaris
	  ○ Bullous pemphigoid
	  ○ Pernicious anaemia
	  ○ Rheumatoid arthritis
	  ○ Scleroderma
	  ○ Sjogren's syndrome
	  ○ Systemic lupus erythematosus
	  ○ Limbic encephalitis
	  ○ Neuronal antibodies
	  ○ Myositis
	  ○ anti-HMG-CoA reductase antibodies
	
	Diagnostic tests
	• Procedures including specificity and sensitivity for the disorders listed above
	• Standardization
	• Quality control/assurance

Transplantation Immunology
MLO (ix)
	• Common organs and tissues transplanted
	• Targets for allograft rejection
	  ○ ABO blood group antigens
	  ○ Major histocompatibility antigens (HLA structure and polymorphisms)
	  ○ The nature and role of minor histocompatibility antigens in allograft rejection
	• Immune mechanisms of allograft rejection
	  ○ Hyperacute, acute and chronic rejection
	  ○ The role of T cells, antibodies and cytokines in allograft rejection
	• Graft-versus-host (GVH) disease in recipients who receive allogenic bone marrow transplants
	• Pregnancy as a privileged graft

Tissue typing laboratory procedures **MLO (x)**	• Serological typing of major histocompatibility antigens (MHC) • Molecular MHC typing • T cell activation assays • Testing for preformed HLA antibodies • Typing of minor histocompatibility antigens

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> Abbas AK, *Lichtman* AH, Pillai S. *Basic Immunology: Functions and Disorders of the Immune System*. Elsevier Abbas AK, *Lichtman* AH, Pillai S. *Cellular and Molecular Immunology.* Elsevier Bain BJ, Leach M. *Leukaemia Diagnosis*. Wiley Blackwell Coico R. *Immunology: A Short Course*. Wiley Blackwell Delves PJ, Martin SJ, Burton DR, Roitt IM. *Roitt's Essential Immunology*. Wiley-Blackwell Detrick B, Schmitz JL, Hamilton RG (eds). *Manual of Molecular and Clinical Laboratory Immunology*. ASM Press Loscalzo L, Fauci *AS*, Kasper DL, Hauser SL, Longo DL, Jameson LJ. *Harrison's Principles of Internal Medicine*. McGraw-Hill Male D, Stokes Peebles R, Male V. *Immunology*. Elsevier Murphy KM, Weaver C, Berg LJ. *Janeway's Immunobiology*. Norton Punt J, Stranford S, Jones P, Owen JA. *Kuby Immunology*. Freeman <u>*Journals*</u> Archives of Pathology and Laboratory Medicine Australian Journal of Medical Science BMC Immunology Cancer Immunology, Immunotherapy Cellular Immunology Current Opinion in Immunology European Journal of Immunology Frontiers in Immunology Immunity Immunology Immunology and Cell Biology Infection and Immunity Journal of Immunity Journal of Immunological Methods Journal of Immunology Molecular Immunology Nature Immunology Nature Reviews Immunology OncoImmunology Pathogens and Immunity Scandinavian Journal of Immunology Science Immunology Seminars in Immunology Seminars in Immunopathology

	Web-based resources British Society for Immunology https://www.immunology.org/ https://www.immunology.org/public-information/bitesized-immunology NIH/NCI Immunotherapy https://www.cancer.gov/research/areas/treatment/immunotherapy Technology Networks Diagnostics. Immunoassays: A Guide https://www.technologynAetworks.com/diagnostics/articles/immunoassays-a-guide-338790

Version number	*1.0*
Date	*November, 2025*
Review date	*September, 2028*

Immunopathology III

Module	**IMMUNODEFICIENCY** **NEOPLASIA OF THE LYMPHOID SYSTEM**
Aim	To develop and apply specialist knowledge, investigative practice and clinical skills applicable to human immunodeficiency disorders and neoplasms of the lymphoid system.
Module learning outcomes (MLO)	On completion of this module the candidate will be able to: (i) Explain the immunologic basis of primary and acquired immunodeficiency disorders, the clinical presentation and diagnosis of each disorder (ii) Discuss and evaluate the respective diagnostic tests and quality assurance processes undertaken for primary and acquired immunodeficiency disorders (iii) Describe the biological mechanisms of malignant transformations and the clinical presentation and diagnosis of lymphoproliferative disorders (iv) Discuss and evaluate the respective diagnostic tests and quality assurance processes undertaken for malignant and lymphoproliferative disorders (v) Identify and review the therapeutic agents applied in the treatment of malignant and lymphoproliferative disorders

Theme	Syllabus

Immunodeficiency disorders
MLO (i), (ii)
	Primary Antibody Immunodeficiencies
	• Biological mechanism underpinning the antibody deficiency disorders
	  ○ X-linked hypogammaglobulinaemia
	  ○ Hyper IgM with immunoglobulin deficiency
	  ○ Transient hypogammaglobulinaemia in infancy
	  ○ Common variable immunodeficiency
	  ○ Selective IgA deficiency
	  ○ IgG subclass deficiencies
	• Diagnosis of primary antibody deficiencies
	  ○ Clinical presentations and complications of antibody deficiency
	  ○ Diagnostic methods & quality assurance for detecting antibody deficiency, including antibody classes & subclasses and specific & functional antibodies
	  ○ Characterization of deficiencies by flow cytometry
	• Principles and applications of diagnostic tools for monitoring antibody deficiencies
	  ○ Immunoglobulin replacement therapies
	  ○ Blood transfusion complications

	Primary Cellular Immunodeficiencies
	• Biological mechanisms, clinical presentations and complications of:
	  ○ Severe combined immunodeficiency (SCID)
	  ○ DiGeorge Syndrome
	  ○ Ataxia Telangiectasia
	  ○ Wiskott-Aldrich Syndrome
	  ○ Chronic mucocutaneous candidiasis
	• Principles and applications of diagnostic tools for monitoring clinical management
	  ○ Flow cytometry
	  ○ T cell & B cell function
	  ○ Cell medicated immune function
	  ○ Gene therapy

Primary defects in non-specific immunity MLO (i), (ii)	• Biological defects underpinning neutrophil dysfunction
	  ○ Chronic granulomatous disease
	  ○ Hyper-IgE (Job's) syndrome
	  ○ Chediak-Higashi syndrome
	  ○ Leucocyte adhesion deficiency
	• Deficiencies in complement components and pathways
	• Deficiencies in cytokine functions
	• Principles and applications of diagnostic tools for monitoring clinical management
	  ○ Neutrophil function tests
	  ○ Complement proteins and functional tests
	  ○ Cytokine expression and genetics
	  ○ Cytokine microarrays

Secondary (acquired) causes of immune deficiencies MLO (i), (ii)	• Post viral infections
	• HIV
	• Acquired immune deficiencies through decreased production of immune components
	  ○ Malnutrition
	  ○ Lymphoproliferative diseases – induction & treatment
	  ○ Drug induced suppression
	  ○ Infections
	• Acquired immune deficiencies through increased loss or catabolism of immune components
	  ○ Burns
	  ○ Nephrotic syndrome
	  ○ Protein-losing enteropathy
	• Principles and applications of diagnostic tools for monitoring clinical management
	  ○ Management of HIV infections
	  ○ Immunisation strategies in immunocompromised hosts
	  ○ Infections in immunocompromised hosts

Neoplasms
MLO (iii), (iv)
	Leukaemia
	• Malignant transformation underpinning each type of leukaemia
	  ○ Acute leukaemia
	  ○ Chronic lymphocytic leukaemias
	  ○ T cell leukaemia/lymphomas
	  ○ Hairy cell leukaemia
	• Principles and applications of tests for diagnosis and monitoring of treatment
	  ○ Flow cytometry
	  ○ Chromosomal aberrations
	
	Lymphoma
	• Malignant transformation underpinning each type of lymphoma
	  ○ Hodgkin's Disease
	  ○ Non-Hodgkin's lymphoma
	  ○ Other lymphomas
	• Principles and applications of tests for diagnosis and monitoring of treatment
	  ○ Flow cytometry
	  ○ Chromosomal aberrations
	
	Plasma cell dyscrasia
	• Malignant transformation underpinning plasma cell malignancies
	  ○ Multiple myeloma
	  ○ Monoclonal gammopathy of unknown significance (MGUS) / benign paraproteinaemia
	  ○ Monoclonal gammopathy of renal significance
	  ○ Waldenstrom's macroglobulinaemia
	  ○ Heavy chain disease
	  ○ Plasmacytoma
	  ○ POEMS
	  ○ Amyloidosis
	• Principles and applications of tests for diagnosis and monitoring of treatment
	  ○ Identification of monoclonal antibodies/proteins by malignant plasma cells
	  ❖ Protein electrophoresis (agarose and capillary)
	  ❖ Immunofixation and immunosubtraction
	  ❖ Isoelectric focusing.
	  ❖ Immunoglobulin levels
	  ❖ Serum free light chains
	  ❖ Mass spectrometry
	  ○ β2 microglobulin
	  ○ Cryoglobulin
	  ○ Flow cytometry

Therapeutic agents **MLO (v)**	• Targets of available therapeutic monoclonal antibodies • Potential interference of therapeutic agents with diagnostic tests

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> Abbas AK, *Lichtman* AH, Pillai S. *Basic Immunology: Functions and Disorders of the Immune System*. Elsevier Abbas AK, *Lichtman* AH, Pillai S. *Cellular and Molecular Immunology.* Elsevier Bain BJ, Leach M. *Leukaemia Diagnosis*. Wiley Blackwell Coico R. *Immunology: A Short Course*. Wiley Blackwell Delves PJ, Martin SJ, Burton DR, Roitt IM. *Roitt's Essential Immunology*. Wiley-Blackwell Detrick B, Schmitz JL, Hamilton RG (eds). *Manual of Molecular and Clinical Laboratory Immunology*. ASM Press Loscalzo L, Fauci *AS*, Kasper DL, Hauser SL, Longo DL, Jameson LJ. *Harrison's Principles of Internal Medicine*. McGraw-Hill Male D, Stokes Peebles R, Male V. *Immunology*. Elsevier Murphy KM, Weaver C, Berg LJ. *Janeway's Immunobiology*. Norton Punt J, Stranford S, Jones P, Owen JA. *Kuby Immunology*. Freeman <u>*Journals*</u> Archives of Pathology and Laboratory Medicine Australian Journal of Medical Science BMC Immunology Cancer Immunology, Immunotherapy Cellular Immunology Current Opinion in Immunology European Journal of Immunology Frontiers in Immunology Immunity Immunology Immunology and Cell Biology Infection and Immunity Journal of Immunity Journal of Immunological Methods Journal of Immunology Molecular Immunology Nature Immunology Nature Reviews Immunology OncoImmunology Pathogens and Immunity Scandinavian Journal of Immunology Science Immunology Seminars in Immunology Seminars in Immunopathology

	Web-based resources British Society for Immunology https://www.immunology.org/ https://www.immunology.org/public-information/bitesized-immunology NIH/NCI Immunotherapy https://www.cancer.gov/research/areas/treatment/immunotherapy Technology Networks Diagnostics. Immunoassays: A Guide https://www.technologynAetworks.com/diagnostics/articles/immunoassays-a-guide-338790

Version number	*1.0*
Date	*November, 2025*
Review date	*September, 2028*

Immunopathology 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 Immunopathology laboratory manager.
Module learning outcomes (MLO)	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 Immunopathology / Serology 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 Immunopathology 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 Immunopathology / Serology 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 Immunopathology / Serology 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 Immunopathology / Serology 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/

Version number	*1.0*
Date	*November, 2025*
Review date	*September, 2028*