



SYLLABUS

IMMUNOLOGY

MEDICAL TECHNICIANS

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1. INTRODUCTION

Immunology is the branch of science that studies:

- All the aspects of the immune system
- The disorders that are caused by dysfunction of the immune system
- The laboratory tests that are used to diagnose disorders of the immune system.

The objective of this syllabus is to provide the student with a guideline on the essential aspects that must be covered in order to adequately prepare for the HPCSA's Professional Board of Medical Technicians examination.

The examination is in the form of two hour papers which will be based on the contents of this syllabus. Paper 1 will assess theoretical knowledge and Paper 2 will assess practical knowledge. Candidates are required to attain a minimum of 50% overall and a sub-minimum of 50% for each of the papers.

HPCSA regulations require that accredited training laboratories perform a minimum of 80% of the tests identified in this syllabus. Laboratories are required to ensure that Interns / Students receive appropriate training in the tests contained within the syllabus but which are not routinely performed on site.

SECTION 1. GENERAL SECTION.

2. STATUTORY REGULATIONS AND ETHICS.

Objective

Provide the Intern / student with information on the regulations and ethical principles which underpin the practice of Medical Laboratory Technology.

Specified outcomes

On completion of this section the intern / student should be able to:

- Demonstrate knowledge of the structure and function of the Health Professions Council of South Africa (HPCSA).
- Demonstrate knowledge of the structure and function of the Professional Board for Medical Technology (PBMT).
- Discuss the regulations relating to the scope of practice for Medical Technology
- Demonstrate knowledge of the requirements for the acquisition of continual education units (CEUs).
- Demonstrate knowledge on the practice/ ethos of how confidentiality in the workplace is achieved and maintained.
- Demonstrate knowledge of No. 61 of 2003: National Health Act, 2004.

3. TOTAL QUALITY MANAGEMENT

3.1. LABORATORY SAFETY

Objective

Provide knowledge of all safety procedures that must be applied in the workplace and an understanding of the relevant legislation relating to laboratory safety procedures.

Specified outcomes

On completion of this section the intern / student should be able to:

- Explain and apply the fundamental concepts of the relevant legislation pertaining to laboratory safety.
 - Range –
Occupational Health and Safety Act;
Hazardous Substances Act; Compensation for Occupational Injuries and Diseases Act
- Demonstrate knowledge of the procedures to follow in the event of laboratory accident or emergency.
 - Range –
Chemical or bio-hazardous spill;
Fire; Flood; Bomb threat
- Describe the correct procedures for the storage, handling and disposal of laboratory waste.
- Describe the application of laboratory safety procedures to the collection, transport, storage and analysis of biological specimens including the International Air Transport Association (IATA) regulations.
 - Range –
Biological specimens; Human tissue; Solid and liquid bio-hazardous waste;
Radioactive waste; Sharps
- Describe the basic principles for the storage, handling and disposal of chemicals; poisons; flammable substances; gases and infectious material.
- Describe procedures to follow for the prevention, control and management of laboratory acquired infections including general housekeeping and decontamination of equipment.

- Describe the purpose and basic content of the Material Safety Data Sheets (MSDS).
- Demonstrate knowledge of the protocols to follow in the event of injuries on duty including needle-stick injury.
- Define the role of the designated safety personnel.
 - Range –
Fire marshal; Safety representative; First aid officer
- Recognize the international safety symbols used in the laboratory environment.
Demonstrate knowledge of all safety and emergency equipment.

3.2. SPECIMENS / PRE-ANALYTICAL REQUIREMENTS

Objective

Provide an understanding of the optimal specimen requirements for the maintenance of the integrity and suitability for all types of laboratory analysis with particular reference to the tests specified throughout this syllabus.

Specified outcomes

On completion of this section the intern / student should be able to:

- Describe the optimal specimen requirements for the individual tests.
- Describe the conditions under which the specimens must be transported to the laboratory.
- Display knowledge of the optimal storage conditions should testing be delayed and the stability of the specimen for the individual testing process.
- Where applicable, capture the data and patient demographics that are required for the registration of the specimens at the laboratory accurately.
- Explain the principle of continuous identification and tracking of the specimen, aliquots and documentation.
- Identify criteria for the rejection of unsuitable specimens.
- Conduct the pre-analytical preparation required for specimen type and test requested.

For clarity include the following:

- Describe the colour codes that are used for the different types of blood samples.
- Describe the mode of action of each additive / preservative.
- Explain why certain anti-coagulants are required for certain investigations.
- List the specimens that must be received within specific time limits.
Describe why these specific time limits apply.
- Demonstrate knowledge of the procedures that are to be followed to ensure continuous correct patient and specimen identification from collection site to analysis with emphasis on the following:
 - The registration process of specimens.
 - The use of a unique laboratory number system.
 - The reception and flow of specimens at receiving in the laboratory.
 - Demonstrate knowledge of system to “track” where a specimen is.
 - Demonstrate knowledge of a system for data retention, as applicable to Pre-analytic procedures.

3.3. LABORATORY EQUIPMENT

Objective

Explain the correct use, principle of operation, maintenance of laboratory equipment and the appropriate troubleshooting procedures to apply where and when indicated.

Specified outcomes

Applicable to all equipment/instruments and analysers

On completion of this section the intern/student should be able to:

- **Operate** all equipment optimally in accordance with the manufacturers recommended operating procedures.
- Apply the correct **safety precautions** during the operation and maintenance of equipment.
- Demonstrate full knowledge of, and apply, the correct **maintenance, service and calibration requirements** within scope, of / for the specific instrumentation.
- Conduct applicable **decontamination** procedures.
- Apply the appropriate **functional checks** to ensure optimal operation.
- Describe and implement **troubleshooting** procedures when optimal operation is not demonstrated by the instrument on-board functional checks.
- Demonstrate full knowledge of the maintenance procedures, all equipment **records and documentation** required for good laboratory practice.
 - Range -
 - All glassware – volumetric and graduated
 - Pipettes – glass, automated, air displacement and disposable
 - Fridges
 - Freezers
 - Stopwatches / timers
 - Thermometers – min/max, electronic and mercury
 - Bio-hazardous safety cabinets – Class I and II
 - Fume cupboards
 - Pipette aids - rubber teats, pro-pipettes and dispensers
 - Centrifuges, safety centrifuges

Laboratory instrumentation and automated analysers are included in this range.

For Immunology also include the following:

External Cleaning:

On completion of this section the student should be able to:

- Perform cleaning of bench tops.
- Perform cleaning of equipment.

At Temperatures:

- Room temperature

At Instruments:

- Balances.
- pH meter.
- Microscopes (refer to Bright field, Fluorescence, Inverted)
- Water baths. Water level and temperature.
- Vortex Mixers and Rotators and Shakers
- Incubators
- Cryo storage units: Liquid Nitrogen levels
- Spectrophotometer

- Specialised equipment i.e. Thermo cyclers, Sequencers.
- Analysers as applicable to each institution i.e. at Immunology: Nephelometers, Flow cytometers, Luminex® etc.

The following is not applicable to Immunology:

- All glassware – volumetric and graduated
- Fume cupboards

3.4. LABORATORY REAGENTS

Objective

Provide details of the correct preparation, storage and disposal of laboratory reagents.

Specified outcomes

On completion of this section the student should be able to:

- Differentiate between controls and calibrators.
- Demonstrate knowledge of the objective, use and retention of package inserts/ instructions for use (IFU's).
- Prepare, store, and safely dispose of laboratory reagents including working reagents
- Define terms and solutions used in the laboratory:

Range:

Physiologically normal saline; Buffers

For Immunology Solutions also refers to:

- Lyophilised reagents

3.5. STOCK CONTROL

Objective

Outline the processes involved in good materials stock management

Specified outcomes

On completion of this section the intern/student should be able to:

- Demonstrate knowledge of the basic principles to apply when managing merchandise stock.
- Demonstrate an understanding of the receipt of stock including the required records regarding condition of goods, expiry dates and lot numbers.
- Demonstrate an understanding of stock rotation with particular reference to expiry dates.
- Describe the correct storage conditions for all stock.
- Differentiate between open vial stability and expiry date
- Demonstrate knowledge of workplace policy with regard to the use of expired reagents, controls and calibrators.

For clarity also refer to:

With specific reference to:

- order stock
- document receipt of stock
- document the condition of the stock at reception
- document the expiry dates and lot numbers of stock
- demonstrate knowledge of the company policy regarding the use of expired reagents
- count and move stock according to GLP

3.6. QUALITY ASSURANCE / ACCREDITATION

Objective

Expose the Intern/student to all aspects of quality control.

Specified outcomes

On completion of this section the intern/student should be able to:

- Discuss quality assurance and quality control in the correct context.
- Define and apply the appropriate processes of quality assurance in the pre-analytical, analytical and post analytical areas of specimen handling.
- Demonstrate general knowledge on the terms Accreditation, International Organisation for Standardisation (ISO) and South African National Accreditation System (SANAS).
- Demonstrate general knowledge on the use, performance and evaluation of RISK assessments.
- Define and explain all quality assurance terminology. Range -
 - Non-conformance
 - Corrective action
 - Preventive action
 - Root cause analysis
 - Continual improvement of quality assurance and quality control processes
 - Audits – Internal & External

3.7. QUALITY CONTROL

Objective

Expose the intern/student to all aspects of quality control.

Specified outcomes

On completion of this section the intern/student should be able to:

- Describe and apply the appropriate quality control processes which must be performed and applied to all the analyses as well as equipment and reagents in this syllabus.
- Explain the principles of internal and external quality control procedures in the context of the tests performed.
- Apply a sound knowledge of all the principles, procedures and interpretation of all related internal and external, quantitative quality control data.
- Apply a sound knowledge of all the principles, procedures and interpretation of all related internal and external, qualitative quality control data.
- Describe the potential causes and apply appropriate troubleshooting procedures in the event of failed Internal and External, quantitative and qualitative quality control.

Also refer to:

Inter-laboratory QC

Also define and explain the following:

- Westgard rules
- LJ graph with reference to:
Mean, Standard Deviation, % Coefficient of Variation, Trend, Shift, and Outlier.

3.8. METHOD VALIDATION

Objective

Expose the Intern/student to all aspects of method validation.

Specified outcomes

On completion of this section the intern/student should be able to:

- Differentiate between validation and verifications in terms of relevant ISO standards.
- Demonstrate an understanding of the approach to the validation and/or verification of new equipment, reagents and testing kits (Qualitative and Quantitative).

Also define the following terms:

- Specificity
- Sensitivity
- Precision
- Imprecision
- Systemic error
- Random error
- Uncertainty of measurement
- Accuracy
- Bias
- Biological variance
- Total allowable error
- Linearity
- Delta difference

3.9 PERSONNEL

Objective

Provide knowledge of basic requirements for personnel in terms of relevant ISO standards.

Specified outcomes

On completion of this section the intern/student should be able to:

- Describe the personal documents and records which are required for all laboratory personnel which falls within the scope of practice of Medical Technicians.
- Demonstrate an understanding of the terms 'competency' and 'ongoing competency' in terms of the training of all laboratory personnel which falls within the scope of practice of Medical Technicians.

Also refer to:

- Demonstrate an understanding of Job profiles.

3.10 DOCUMENTATION

Objective

Provide knowledge of basic requirements of documentation in terms of relevant ISO standards.

Specified outcomes

On completion of this section the intern/student should be able to:

- Demonstrate knowledge of document control requirements in terms of relevant ISO standards.
- Demonstrate knowledge of the required content of SOP's including the minimum content of the cover page.

- Know the process on how to render documents obsolete.
- Demonstrate knowledge on the retention and disposal of this documentation.
- Demonstrate knowledge on document control and regular review of prescribed documentation.
- Differentiate between a record and document.

Range –

Policies; Procedures(SOPs);

Working instructions;

Raw data; Equipment records;

Quality control records; Personnel records;

Package inserts/IFU's

Also refer to:

- List the steps that must be followed for approval or edit or review of an SOP.

4. LABORATORY RELATED MATHEMATICS

Objective

Provide the intern/student with instruction on the application of the correct mathematical formulae to relevant calculations.

Specified outcomes

On completion of this section the intern/student should be able to:

- Demonstrate proficiency in the calculations required for the preparation of solutions.

Range –

Physiological saline; Percentage solutions

Also refer to:

- Dilution of patient samples
- Reporting of results of diluted patient samples

5. MOLECULAR BIOLOGY

Objective

Provide intern/student with a foundational knowledge of basic molecular biology as applied to techniques throughout the Medical Laboratory Technology disciplines.

Specified outcomes

At the end of this training the intern/student should be able to:

- Describe workflow dynamics in a molecular biology laboratory.
- Demonstrate a fundamental knowledge of the function of DNA in terms of structure, replication, transcription and translation.
- Discuss the principle of the polymerase chain reaction (PCR) and the steps involved.
 - Range –
Denaturation; Annealing; Extension
- Demonstrate knowledge of the quality controls used in the assay procedure.
- Identify the potential causes of false positive and negative results.

Also refer to the following:

- Demonstrate and apply knowledge of the methods used for the prevention of contamination

in a molecular laboratory.

- List the components of a PCR master mix and explain the purpose and action of each component.
- Discuss the role of primers used within a PCR laboratory.
- Discuss what probes are and how they are used in real-time PCR.
- Provide a basic explanation of the PCR graph and Ct values including construction and interpretation of variables presented on the graph, and how the Ct values are used in quantitative and semi-quantitative PCR's.
- Discuss the difference between conventional PCR and Real-time PCR.
- Discuss the principle and purpose of reverse transcription PCR (cDNA synthesis).
- Explain the difference between multiplex and single-plex PCR's.
- Demonstrate basic practical knowledge and skills of the techniques utilized for the automated extraction, amplification and detection.
- Explain the principle and basic introductory level information of agarose gel electrophoresis (principle, materials and their purpose, applicable safety precautions, sources of error).

Understand basic molecular test procedures (including but not limited to PCR) for the identification of the disease states and abnormalities indicated in this syllabus, where applicable (including but not limited to the identification of infectious agents).

e.g. with Immunology apply this to:

- SSP
- SSOP
- rSSOP
- SBT
- NGS

SECTION II: IMMUNOLOGY SYLLABUS

RANGE STATEMENTS:

The following RANGE STATEMENT applies to all DISORDERS:

- Explain the **aetiology**.
- Describe the **pathophysiology**.
- List the **treatment** options.
- List the **diagnostic laboratory tests** that can be used to diagnose the disorder.

The following RANGE STATEMENT applies to all LABORATORY TESTS:

- Explain the **principle**.
- List the **steps in the method**.
- List the **normal values**.
- **Perform the test**, where possible.
- **Interpret the results** of the test.
- List the **associated disorders** that can be diagnosed by this test.
- Analyse **case studies** that refer to the laboratory results and to diagnosis of a disorder.

MODULE 1: PRIMARY IMMUNO-DEFICIENCIES (PID)

The student should understand that PIDs may be classified according to the nature of the deficiency and the consequent laboratory analysis.

6. NEUTROPHILS

6.1 BACKGROUND KNOWLEDGE AND CRP OBJECTIVE

Provide students with introductory knowledge of the innate immune response with regards to the following:

- The characteristics, components and functions of the innate immune response.
- Their origin of the cells of the Innate immune response
- The morphology of the cells of the innate immune response.
- The receptors of neutrophils and monocytes.
- The functions of the cells of the innate immune response.
- The cardinal signs of the Acute Inflammatory Response (AIR).
- The cascade (steps / phases) of the Acute Inflammatory Response (AIR).
- The characteristics of CRP (C-Reactive Protein) as an example of an APP (Acute Phase Protein).
Nephelometry as the preferred method of testing for CRP.
Interpretation of CRP results and analysis of case studies.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Describe the characteristics, components and functions of the innate immune response
- Describe the origin of the cells of the Innate immune response
- Illustrate (by labelled sketches) the morphology of the following cells of the innate immune response: Neutrophils / Monocytes and Macrophages / Dendritic Cells (DCs) / Eosinophils / Basophils
- List the receptors of Neutrophils and Monocytes
- Describe the functions of the following cells: Neutrophils / Monocytes and Macrophages / Dendritic Cells (DCs) / Eosinophils / Basophils
- Describe the cardinal signs of the AIR
- Give a detailed description of all the phases of AIR. Refer to the following steps: the Cytokines that mediate the response / Margination / Pavementing / Diapedesis / Chemotaxis / Phagocytosis / Killing by OB (Oxidative Burst), MPO (Myelo Peroxidase system) and NETs (Neutrophil Extracellular Traps)
Describe the characteristics of CRP, as an example of an APP
- Describe the principle of Nephelometry as used to measure CRP
- List the steps in the method of Nephelometry as used to measure CRP
- List the Normal ranges of CRP
- Interpret results and analyse case studies of CRP with bacterial and viral infections and as risk factor for Myocardial Infarction

6.2 THE DISORDERS ASSOCIATED WITH NEUTROPHILS OBJECTIVE

Provide students with knowledge of the following PIDs associated with neutrophils:

- Disorders of Phagocyte NUMBERS:
Severe Congenital Neutropenia / Cyclic Neutropenia
- Disorders of Phagocyte FUNCTION:
 - Adhesion / Chemotaxis disorder: LAD 1 / LAD 2 (Leukocyte Adhesion Deficiency)
 - Phagocytosis disorders owing to abnormal Morphology:
Chediak Higashi syndrome / SGD (Specific Granule Deficiency)
 - Killing disorders:
Disorder of the OB (Oxidative Burst): CGD (Chronic Granulomatous Disease).
Disorder of MPO (MyeloPerOxidase): Myeloperoxidase disorder
- Disorders associated with CYTOKINES:
MSMD (Medelian Susceptibility to Mycobacterial Disease)
CMC (Chronic Muco-cutaneous Candidiasis)
AD (Autosomal Dominant) HIES (Hyper IgE Syndrome)

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the Aetiology of each disorder
- Describe the Pathophysiology of each disorder
- List the treatment options for each disorder
- List the laboratory tests that can be used to diagnose each disorder

6.3 LABORATORY TESTS THAT ARE USED TO DIAGNOSE DISORDERS ASSOCIATED WITH NEUTROPHILS OBJECTIVE

Provide students with knowledge and skills relating to the following laboratory tests:

- The Chemotaxis tests: Boyden Chamber and/or Migratest.
- The Phagotest.
- The NBT screening test (Nitro Blue Tetrazolium) and/or the Oxidative Burst test by Flow Cytometry
- The Luminex method to determine Cytokine levels
- The NGS test to detect the abnormal genes

SPECIFIED OUTCOMES

On completion of this section the student should be able to show a clear understanding of the laboratory analyses appropriate for dysfunction of Phagocytic cells (Neutrophils) by the following:

- Explain the Principle of the tests
- List the Steps in the method of the tests
- List the Normal values of the tests
- Perform the tests, where possible
- Identify the results of the tests
- List the disorders that can be diagnosed by the tests
- Analyse case studies that refer to the laboratory results and to diagnosis of a disorder

7. NK-CELLS (Natural Killer Cells)

7.1 BACKGROUND

KNOWLEDGE OBJECTIVE

Provide students with introductory knowledge relating to NK-cells with regards to the following:

- The Morphology of the NK-cells
- The CD(Cluster of Differentiation) markers on NK-cells
- The Subsets of NK-cell types
- The Functions of NK-cells
(with reference to Fas-FasLigand mediated and Perforin-Granzyme mediated Killing)
- Apoptosis and Necrosis

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Illustrate (by labelled sketch) the morphology of an NK-cell
- List the CD markers on NK-cells
- Describe the subsets of NK-cells
- List the functions of NK-cells
- Describe Fas-FasLigand mediated and Perforin-Granzyme mediated killing
- Compare Apoptosis and Necrosis

7.2 THE DISORDERS ASSOCIATED WITH NK-CELLS OBJECTIVE

Provide students with knowledge of the following disorders associated with NK-cells:

Infertility and Spontaneous abortion

Recurrent re-activation of the following Herpes infections:

HSV (Herpes Simplex Virus) and HVZV (Herpes Varicella Zoster Virus)

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the aetiology of each disorder
- Describe the pathophysiology of each disorder
- List the treatment options for each disorder
- List the laboratory tests that can be used to diagnose each disorder

7.3 THE LABORATORY TESTS THAT ARE USED TO DIAGNOSE DISORDERS ASSOCIATED WITH NK-CELLS OBJECTIVE

Provide students with knowledge and skills relating to the following laboratory tests:

- Phenotyping and Enumeration of NK-cells.
- NK-cell killing test.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the principle of the tests.
- List the steps in the method of the tests.
- List the normal values of the tests.
- Perform the tests, where possible.
- Identify the results of the tests.
- List the disorders that can be diagnosed by the tests.
- Analyse case studies that refer to the laboratory results and to diagnosis of a disorder.

8. COMPLEMENT

8.1 BACKGROUND

KNOWLEDGE OBJECTIVE

Provide students with introductory knowledge relating to the Complement system with regards to the following:

- The characteristics and functions of complement.
- The 3 complement pathways and the regulators of the 3 complement pathways.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Describe the characteristics of complement
- Describe the functions of complement
- Describe the Complement pathways and the regulators of complement

8.2 THE DISORDERS ASSOCIATED WITH

COMPLEMENT OBJECTIVE

Provide students with knowledge of the following disorders associated with complement:

- HAE (Hereditary angioedema)
- SLE (Systemic Lupus Erythematosus)
- Hypo-Complementemic MCGN (Mesangio capillary glomerulonephritis)
- HUS (Hereditary Uremic Syndrome)
- Recurrent pyogenic infections leading to sepsis
- PNH (Paroxysmal Nocturnal Haemoglobinuria)
- Neisserial infections (Non-recurrent and Recurrent)
- Anaphylaxis owing to excessive Anaphylatoxins

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the aetiology of each disorder.
- Describe the pathophysiology of each disorder.
- List the treatment options for each disorder.
- List the laboratory tests that can be used to diagnose each disorder.

8.3 THE LABORATORY TESTS THAT ARE USED TO DIAGNOSE DISORDERS ASSOCIATED WITH COMPLEMENT OBJECTIVE

Provide students with knowledge and skills relating to the following laboratory tests:

The FUNCTIONAL SCREENING tests:

- **The Classical Pathway Haemolytic Complement test (CPHC 100).**
- **The Alternative Pathway Haemolytic Complement test (APHC 100).**

Tests to measure the LEVELS of Complement Components, Factors and Complement Regulators:

- **Nephelometry** for C4 and C3.
- **Single immune-diffusion and precipitation** in gel.

SPECIFIC TESTS to aid in the diagnosis of certain disorders:

- **Crossed Immuno-Electrophoresis** to detect C3 and C3c.
- **ELISA functional test for C1-inhibitor.**
- **Phenotyping and enumeration of CD55 and CD59** for PNH.

SPECIFIED OUTCOMES

On completion of this section the student should be able to show a clear understanding of the laboratory analyses appropriate for dysfunction of the Complement system by the following:

- Explain the principles of the tests.
- List the steps in the method of the tests.
- List the normal values of the tests.
- Perform the tests, where possible.
- Identify the results of the tests.
- List the disorders that can be diagnosed by the tests.
- Analyse case studies that refer to the laboratory results and to diagnosis of a disorder.

9. T-CELLS

9.1 BACKGROUND

KNOWLEDGE OBJECTIVE

Provide students with introductory knowledge relating to T-cells with regards to the following:

- The characteristics, components and functions of the adaptive immune response.
- The function of T-cells
- The CD markers on T-cells.
- The structural composition of the thymus.
- The origin of and education of T-cells in the thymus.
- The structural composition of mucosal associated lymphoid tissue (MALT), lymph nodes and spleen.
- Lymphocyte trafficking.
- The activation of T-cells.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Describe the characteristics, components and functions of the adaptive immune response.
- Describe the function of T-cells
- List the CD markers of T-cells
- Illustrate (by labelled sketch) the structural composition of the thymus, MALT, lymphnode, spleen.
- Describe the origin of and education of T-cells in the thymus.
- Describe lymphocyte trafficking
- Describe the activation of T-cells by Exogenous antigen, Endogenous antigen, Co-stimulatory molecules and Cytokines.

9.2 THE PIDs ASSOCIATED WITH T-CELLS OBJECTIVE

Provide students with knowledge of the following PIDs associated with T-cells:

- Disorders associated with Cytokine receptors or Cytokine signalling:
 - SCID IL-2 RG (Interleukin-2 Receptor Gamma).
 - SCID IL-7 RA (Interleukin-7 Receptor Alpha).
 - SCID JAK3 (Janus Kinase 3).
- Disorders associated with V(D)J recombination
 - SCID RAG1 / RAG2 (Recombinase Activating Genes).
 - SCID Omenn's syndrome.
 - SCID RS (Radiation Sensitivity).
- Disorders associated with abnormalities of the thymus:
 - SCID Di George syndrome.
- Disorders associated with abnormalities of MHC (Major Histocompatibility Complex).
 - Absence of MHC Class I.
 - SCID Absence of MHC Class II.
- Disorder associated with abnormalities of a Co-stimulatory molecule:
 - Hyper IgM Type I.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the aetiology of each disorder.
- Describe the pathophysiology of each disorder.
- List the treatment options for each disorder.
- List the laboratory tests that can be used to diagnose each disorder.

9.3 THE LABORATORY TESTS THAT ARE USED TO DIAGNOSE DISORDERS ASSOCIATED WITH T-CELLS OBJECTIVE

Provide students with knowledge and skills relating to the following laboratory tests:

- Phenotyping and Enumeration of T-cells.
- *In vivo* T-cell function test
- *In vitro* T-cell function test by measuring proliferation of cells
- The Luminex® method to determine Cytokine levels
- The FISH and NGS test to detect the abnormal genes
- The TREC test to detect abnormal V(D)J recombination of T-cells

SPECIFIED OUTCOMES

On completion of this section the student should be able to show a clear understanding of the laboratory analyses appropriate for dysfunction of T-cells by the following:

Explain the principle of the tests.

List the steps in the method of the tests.

List the normal values of the tests.

Perform the tests, where possible.

Identify the results of the tests.

List the disorders that can be diagnosed by the tests.

Analyse case studies that refer to the laboratory results and to diagnosis of a disorder.

9.4 ACQUIRED DISORDERS OF T-CELLS

9.4.1 HIV (Human Immunodeficiency Virus) and AIDS (Acquired Immunodeficiency Disorder)

OBJECTIVE

Provide students with knowledge of HIV and AIDS with regards to the following:

- The types and sub-types of HIV.
- The lifecycle of HIV.
- The phases of HIV infection.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the aetiology of HIV with reference to the types and sub-types of HIV.
- Describe the pathophysiology of HIV / AIDS with reference to the lifecycle of HIV and the phases of the infection.
- List the treatment options.
- List the laboratory tests that can be used to diagnose HIV and to monitor progression of the disease.

9.4.2 THE LABORATORY TESTS THAT ARE USED FOR HIV / AIDS

OBJECTIVE

Provide students with knowledge and skills relating to the following laboratory tests:

Laboratory tests to DIAGNOSE HIV infection:

- Screening test: 4th generation Chemiluminescence
- Confirmatory tests: HIV Western blot and Qualitative PCR

Laboratory tests to MONITOR progression of the infection:

- Phenotyping, enumeration and ratio of CD4 / CD8
- Quantitative PCR

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

Explain the principle of the tests.

List the steps in the method of the tests.

List the normal values of the tests.

Perform the tests, where possible.

Identify the results of the tests.

Analyse case studies that refer to the laboratory results and to diagnosis of HIV / AIDS

10. B-CELLS

10.1 BACKGROUND KNOWLEDGE

OBJECTIVE

Provide students with introductory knowledge relating to B-cells with regards to the following:

- The origin of B-cells
- The functions of B-cells and the function of antibody-antigen interaction
- The CD markers of B-cells.
- The development of B-cells (Primary and Secondary Phase).
- The activation of B-cells
(refer to Thymus dependent, Thymus-independent, co-stimulatory molecules and cytokines).
- Class-switching (refer to the structure and functions of the different isotypes).
- Somatic hyper-mutation.
- Definitions associated with antigens.
Refer to the following terms: immunogen / antigen / requirements for immunogenicity / hapten / super antigen / naive antigen / epitope / allelic exclusion / isotypes / allotypes / idiotypes.
- Definitions associated with antibodies.
Refer to the following terms: antibody / primary and secondary response / affinity and avidity / lock and key metaphor of antigen-antibody interaction / specificity / cross-reactivity / associative recognition / monoclonal and polyclonal / natural antibodies (active and passive) and artificial antibodies (active and passive).
- Vaccines. Refer to the following types of vaccines:
live attenuated / inactivated / sub-unit / toxoid / conjugated / and to the use of adjuvants

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Describe the functions of B-cells the functions of antibody-antigen interaction.
- List the CD markers of B-cells.
- Describe the development of B-cells (primary and secondary phase).
- Describe the activation of B-cells.
(Thymus dependent and Thymus Independent, Co-stimulatory molecules and Cytokines)
- Describe class-switching.
- Describe and illustrate (by labelled sketch) the structure of the different Isotypes.
- Describe the functions of the different Isotypes and subtypes.
- Describe Somatic hyper-mutation.
- Explain the meaning of the following terms: antibody / primary and secondary response / affinity and avidity / lock and key metaphor / specificity / cross-reactivity / associative recognition / monoclonal and polyclonal / natural antibodies (active and passive) and artificial antibodies (active and passive).
- Describe the following types of vaccines:
live attenuated / inactivated / sub-unit / toxoid / conjugated / and the use of adjuvants.

10.2 THE PIDs ASSOCIATED WITH B-CELLS

OBJECTIVE

Provide students with knowledge of the following PIDs associated with B-cells:

- Disorders of decreased B-cell numbers:
 - A-gammaglobulinemia.
- Disorders associated with V(D)J recombination:
 - SCID RAG1 / RAG2.
 - SCID Omenn's syndrome.
 - SCID RS (Radiation sensitivity).
- Disorders associated with abnormalities of Co-stimulatory molecules:
 - Hyper IgM
 - CVID (Common variable immune deficiency).
- Disorder associated with slow development of antibody synthesis:
 - Transient hypo-gammaglobulinemia.
- * Disorders associated with selective antibody deficiency.
 - Selective IgA deficiency.
 - Selective IgG subclass deficiency.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

Explain the aetiology of each disorder.

Describe the pathophysiology of each disorder.

List the treatment options for each disorder.

List the laboratory tests that can be used to diagnose each disorder.

10.3 THE LABORATORY TESTS THAT ARE USED TO DIAGNOSE DISORDERS ASSOCIATED WITH B-CELLS

The student must show a clear understanding of the laboratory analyses appropriate for dysfunction of B-cells.

OBJECTIVE

Provide students with knowledge and skills relating to the following laboratory tests:

- **Nephelometry** for quantitation of immunoglobulins (Total IgM / IgG / IgA) and IgG sub-classes.
- **ELISA** for quantitation of secretory IgA.
- **Immuno-fixation electrophoresis** for quantitation of serum proteins.
- **ELISA for IgG Vaccination response tests** as follow up to IgG subclass deficiency.
- **Phenotyping** and enumeration of B-cells.
- ***In vitro* B-cell function** test by measuring proliferation of cells.
- **The FISH and NGS test** to detect the abnormal gene.
- **The KREC test** to detect abnormal V(D)J recombination of B-cells.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the principle of the tests.
- List the steps in the method of the tests.
- List the normal values of the tests.
- Perform the tests, where possible.
- Identify the results of the tests.
- List the disorders that can be diagnosed by the tests.
- Analyse case studies that refer to the laboratory results and to diagnosis of a disorder.

10.4 ACQUIRED DISORDERS OF B-CELLS

10.4.1 MULTIPLE MYELOMA

OBJECTIVE

Provide students with knowledge of Multiple Myeloma.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the aetiology of multiple myeloma.
- Describe the pathophysiology of multiple myeloma.
- List the treatment options for multiple myeloma.
- List the laboratory tests that can be used to diagnose multiple myeloma.

10.4.2 THE LABORATORY TESTS THAT ARE USED TO DIAGNOSE MULTIPLE MYELOMA

OBJECTIVE

Provide students with knowledge and skills relating to the following laboratory tests:

- **Nephelometry** for quantitative determination of immunoglobulins
- **Immuno-fixation electrophoresis** for detection of the immunoglobulins

SPECIFIED OUTCOMES

On completion of this section the intern/student should be able to:

- Explain the principle of the tests.
- List the steps in the method of the tests.
- List the normal values of the tests.
- Perform the tests, where possible.
- Identify the results of the tests.
- Analyse case studies that refer to the laboratory results and to diagnosis of Multiple myeloma.

MODULE 2:

11. AUTO-IMMUNITY

11.1 BACKGROUND KNOWLEDGE AND CLASSIFICATION

OBJECTIVE

Provide students with introductory knowledge relating to Auto-immunity with regards to the following:

- The principle of fluorescent microscopy.
- Tolerance and breakdown of tolerance.
- Protection against tumours and immunological escape by tumour cells.
- Provide the student s with information to understand that the different autoimmune diseases are classified according Organ Non Specific and Organ Specific disorders.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Describe and illustrate (by labelled sketch) the principle of fluorescent microscopy
- Describe tolerance and breakdown of tolerance
- Describe protection against tumours and immunological escape by tumour cells
- Describe how Auto-immune disorders are classified as Organ Non Specific and Organ Specific and tabulate the Non Organ Specific and Organ Specific diseases and their associated antibodies.

11.2 DISORDERS ASSOCIATED WITH AUTOIMMUNITY

11.2.1 PIDs ASSOCIATED WITH AUTO-IMMUNITY

OBJECTIVE

Provide students with knowledge of the following autoimmune disorders:

- APECED (Auto-immune Poly-Endocrinopathy Candidiasis Ectodermal Dystrophy)
- IPEX (Immune dysregulation Poly-EndocrinopathyEnteropathy X-linked syndrome)
- ALPS (Auto-immune Lympho-Proliferative Syndrome)
- Defective CTLA-4 (Cytotoxic T-Lymphocyte Antigen 4)

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the aetiology of each disorder.
- Describe the pathophysiology of each disorder.
- List the treatment options for each disorder.
- List the laboratory tests that can be used to diagnose each disorder.

11.2.2 NON ORGAN SPECIFIC DISORDERS

OBJECTIVE

Provide students with knowledge of the following NON-ORGAN SPECIFIC autoimmune disorders:

- Sjogren's syndrome
- Scleroderma (Scl 70 and CREST)
- MCTD (Mixed Connective Tissue Disorder)
- Polymyositis
- RA (Rheumatoid Arthritis)
- SLE (Systemic Lupus Erythematosus)
- APLS (Anti Phospholipid Syndrome)
- Churg-Strauss Syndrome
- Wegener's Granulomatosis
- IBD (Inflammatory Bowel Disease): Ulcerative Colitis and Crohn's disease

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the aetiology of each disorder.
- Describe the pathophysiology of each disorder.
- List the treatment options for each disorder.
- List the laboratory tests that can be used to diagnose each disorder.

11.2.3 ORGAN SPECIFIC DISORDERS

OBJECTIVE

Provide students with knowledge of the following ORGAN SPECIFIC autoimmune disorders:

- PBC (Primary Biliary Cirrhosis)
- Pernicious anaemia
- Coeliac disease
- Goodpasture's syndrome
- IDDM Type I (Insulin Dependent Diabetes Mellitus Type I)
- Hashimoto's Thyroiditis
- Graves' disease
- Myasthenia Gravis
- Multiple Sclerosis
- Auto-immune Haemolytic anaemia (Warm and Cold)
- Rheumatic Fever

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the aetiology of each disorder.
- Describe the pathophysiology of each disorder.
- List the treatment options for each disorder.
- List the laboratory tests that can be used to diagnose each disorder.

11.3 THE LABORATORY TESTS THAT ARE USED TO DIAGNOSE AUTO-IMMUNE DISORDERS

11.3.1 LABORATORY TESTS FOR HEREDITARY CAUSE OR PREDISPOSITION TO AUTO-IMMUNITY

OBJECTIVE

Provide students with knowledge and skills relating to the following laboratory tests:

- NGS to detect the genes
- HLA typing to detect HLA alleles that are associated with certain Auto-immune disorders.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the principle of the tests.
- List the steps in the method of the tests.
- List the normal values of the tests (if applicable).
- Perform the tests, where possible.
- Identify the results of the tests.

The student must be able to describe the clinical significance of the different ANA and CB patterns

- List the disorders that can be diagnosed by the tests.
- Analyse case studies that refer to the laboratory results and to diagnosis of a disorder.

11.3.2 LABORATORY TESTS FOR ORGAN NON SPECIFIC DISORDERS

OBJECTIVE

Provide students with knowledge and skills relating to the following laboratory tests:

- **SCREENING TEST:**
The ANA test (Anti-Nuclear Antibodies) utilising HEp-2 cells (Human Epithelium carcinoma)
Refer to the following patterns: Homogenous / Speckled / Scl-70 / Centromere / Nucleolar /Jo-1.
- **CONFIRMATORY TEST:**
EIA (automated ELISA), **ELISA or FEIA**(Fluorescence Enzyme Immuno-Assay) for detection of ENAs (Extractable Nuclear Antigens), Cytoplasmic antibodies, Non-soluble nuclear antigens or other antigens
Refer to the following antibodies:
 - ENAs: SS-A (Ro) / SS-B (Ra) / Sm / RNP / Scl-70 / CENP-B
 - Cytoplasmic antibody: Jo-1
 - Non-soluble nuclear antigen: dsDNA
 - Antibodies to other antigens: CCP (Cyclic-Citrullinated peptide)
- **Tests to detect free CIC** (Circulating Immune Complexes)
Refer to precipitation and solubility in PEG (Polyethylene Glycol) and Affinity for C1q by ELISA
- **ANCA** (Anti Neutrophil Cytoplasmic Antibodies)
Refer to the following patterns: Anti-MPO / Anti-PR3 / Atypical
- **Specific tissue IFA**(Indirect Fluorescence Assay)
Refer to the following tissue: Parotid / Oesophagus / Umbilical vein / Pancreas / Colonic Goblet cells / Crithidia luciliae / ASCA (Anti Sacchromyces Cerevisiae Antibody).
- **Nephelometry** for RF (Rheumatoid Factor) to aid in screening for Rheumatoid Arthritis.
- **EIA** (automated ELISA), **ELISA or FEIA** for Cardiolipin and β 2 Glycoprotein.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the principle of the tests.
- The student should be able to describe
 - the HEp2 cells used on the ANA test slide.
 - the following ANA patterns (and the antibodies that lead to each pattern):
Homogenous / Speckled / Scl-70 / Centromere / Nucleolar /Jo-1.
- List the steps in the method of the tests.
- List the normal values of the tests (if applicable).
- Perform the tests, where possible.
- Identify the results of the tests.
The student must be able to describe the clinical significance of the different ANA patterns
- List the disorders that can be diagnosed by the tests.
- Analyse case studies that refer to the laboratory results and to diagnosis of a disorder.

11.3.3 LABORATORY TESTS FOR ORGAN SPECIFIC DISORDERS

OBJECTIVE

Provide students with knowledge and skills relating to the following laboratory tests:

- **SCREENING TEST:**
The CB test (Composite Block)
Refer to the following patterns (and the antibodies that lead to each pattern):
Anti-smooth muscle antibody / Anti-parietal ab / Anti-mitochondrial ab / Anti-liver kidney microsomal ab.
- **CONFIRMATORY TEST**
Specific tissue IFA
Refer to the following tissues: Intestine / Pancreas / Kidney / Thyroid / Skeletal muscle / Optic nerve
- **ELISA** for
 - Thyroid auto-antibodies (Tg and TPO) and antibody to TSH-receptor
 - Anti-Acetylcholine receptor (AChR).
- **Direct Coombs** for the Warm auto-immune Haemolytic anaemia
- **Nephelometry** of ASL and anti-DNAse to aid in the diagnosis of Rheumatic fever.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the principle of the tests.
- The student should be able to describe
 - the tissue used on the CB slides
 - the following CB patterns:
Anti-smooth muscle antibody / Anti-parietal ab / Anti-mitochondrial ab / Anti-liver kidney microsomal ab.
- List the steps in the method of the tests.
- List the normal values of the tests (if applicable).
- Perform the tests, where possible.
- Identify the results of the tests.
The student must be able to describe the clinical significance of the different ANA and CB patterns
- List the disorders that can be diagnosed by the tests.
- Analyse case studies that refer to the laboratory results and to diagnosis of a disorder.

12. HYPERSENSITIVITY TYPE I (ALLERGY)

12.1 BACKGROUND KNOWLEDGE

OBJECTIVE

Provide students with introductory knowledge of Hypersensitivity Type 1 (Allergy), with reference to the following:

- The Coombs and Gell Classification of hypersensitivities.
- The causes of allergy (include atopy, the hygiene hypothesis and environmental factors).
- The definition, characteristics and routes of exposure of allergens.
- The most common food allergens and inhalant allergens in adults and infants.
- The different phases (i.e. induction and effector: early, late, secondary) and mechanism of damage of Hypersensitivity type I (allergy).
- The structure of IgE.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Describe the Coombs and Gell Classification of Hypersensitivities.
- Explain the following causes of allergy: atopy, the hygiene hypothesis, and environment.
- Describe the definition, characteristics and routes of exposure of allergens.
- List the most common food allergens and inhalant allergens in adults and infants.
- Describe the different phases (i.e. induction and effector: early, late, secondary) and mechanism of damage of Hypersensitivity Type I (Allergy)
- Describe and illustrate (by labelled sketch) the structure of IgE

12.2 DISORDERS ASSOCIATED WITH HYPERSENSITIVITY TYPE I (ALLERGY)

OBJECTIVE

Provide students with knowledge of the following Hypersensitivity Type I disorders (Allergy):

Localized allergic reactions to food.

Refer to the following:

- Allergic gastro-intestinal reactions.
- Allergic urticaria.
- Allergic angioedema.
- Allergic eczema.

Localized allergic reactions to inhalants.

Refer to the following:

- Allergic rhinitis.
- Allergic asthma.

Systemic allergic reaction.

- Allergic anaphylaxis

IgE Negative allergic disorders.

Refer to the following:

- Allergy mediated by Basophils
- Allergy mediated by T-cells

Non-Allergy disorders, associated with a very high IgE.

Refer to the following:

- Multiple Myeloma
- Autosomal Dominant Hyper IgE Syndrome
- Omenn's syndrome
- IPEX (Immuno-dysregulation Poly-endocrinopathy Enteropathy X-linked syndrome)

Non-Allergy disorders, associated with increased tryptase.

Refer to the following:

- Mastocytosis
- MCAS (Mast Cell Activation Syndrome)

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

Explain the aetiology of each disorder.

Describe the pathophysiology of each disorder.

List the treatment options for each disorder.

List the laboratory tests that can be used to diagnose each disorder.

12.3 THE LABORATORY TESTS THAT ARE USED TO DIAGNOSE HYPERSENSITIVITY TYPE I DISORDERS

OBJECTIVE

Provide students with knowledge and skills relating to the following clinical and laboratory investigations:

- Patient history.
- Clinical examination.
- The oral food challenge test.
Also refer to the use of this test to desensitize a patient
- The skin prick test.
- Testing of Total IgE, allergen mixes and specific IgE using FEIA
- Additional tests for allergic rhinitis and allergic asthma:
Nasal and bronchial mucus smear /ECP (Eosinophil Cationic Protein).
- Additional tests for anaphylaxis:
Tryptase /ISAC®(Immuno Solid-phase Allergen Chip) test for essential confirmatory components.
- Additional tests for IgE Negative allergies:
The CAST (Cellular Allergen Stimulation Test) test for basophil activation.
The MELISA (Memory Lymphocyte Immuno-Stimulation Assay) for T-cell activation.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the principle of the tests.
- List the steps in the method of the tests.
- List the normal values of the tests (if applicable).
- Perform the tests, where possible.
- Identify the results of the tests.
Explain the relationship between
positive Total IgE levels, positive Screen tests (mixes) and positive individual allergens
- List the disorders that can be diagnosed by the tests.
- Analyse case studies that refer to the laboratory results and to diagnosis of a disorder.

13. HYPERSENSITIVITY TYPE II

13.1 BACKGROUND KNOWLEDGE

OBJECTIVE

Provide students with introductory knowledge of Hypersensitivity Type II

(as well as the subtype sometimes referred to as Hypersensitivity Type V)

Refer to the definition, time to onset and mechanism of damage of Hypersensitivity Type II and distinguishing traits of Type V

(i.e. ab. bind to cell surface receptors instead of cell surface components thus blocking or impairing cell signalling).

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Describe the definition, time to onset and mechanism of damage of Hypersensitivity Type II.

13.2 DISORDERS ASSOCIATED WITH HYPERSENSITIVITY TYPE II

OBJECTIVE

Provide students with knowledge of the following Hypersensitivity Type II disorders:

Transfusion reactions

Refer to the following:

- Intra-vascular haemolysis (The ABO System)
- Extra-vascular haemolysis (Other Systems e.g. Rhesus / Kidd / Kell / Duffy)
- HDNB (Haemolytic Disease of the New Born)
- Type V: Graves' disease and Myasthenia gravis

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the aetiology of each disorder.
- Describe the pathophysiology of each disorder.
- List the treatment options for each disorder.
- List the laboratory tests that can be used to diagnose each disorder.

3.2.2. THE LABORATORY TESTS THAT ARE USED TO DIAGNOSE HYPERSENSITIVITY TYPE II DISORDERS

OBJECTIVE

Provide students with knowledge and skills relating to the following laboratory test:

The Coombs test (Direct and Indirect)

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the principle of the test.
- List the steps in the method of the test.
- List the normal value of the test (if applicable).
- Perform the test, where possible.
- Identify the results of the test.
- List the disorders that can be diagnosed by the test.
- Analyse case studies that refer to the laboratory results and to diagnosis of a disorder.

14. HYPERSENSITIVITY TYPE III

14.1 BACKGROUND KNOWLEDGE

OBJECTIVE

Provide students with introductory knowledge of Hypersensitivity Type III.

Refer to the following: Clearance of immune complexes, definition, time to onset and mechanism of damage of Hypersensitivity Type III.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Describe the clearance of immune complexes and the factors that influence the process.
- Describe the definition, time it takes to occur and mechanism of damage of hypersensitivity Type III.

14.2 DISORDERS ASSOCIATED WITH HYPERSENSITIVITY TYPE III

OBJECTIVE

Provide students with knowledge of the following Hypersensitivity Type III disorders:

- Serum Sickness.
- The Arthus Reaction.
Refer to repeated injections of therapeutic drugs or vaccinations.
- Persistent infections
Refer to the following infections:
 - Syphilis (refer to the different stages of the disease).
 - APSGN (Acute Post Streptococcal Glomerulonephritis).
 - EAA (Extrinsic "Allergic" Alveolitis). Refer to Bird Fancier's disease and Farmer's lung disease.

Refer to the initial uncomplicated disease and the later Hyper Type III complications.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the aetiology of each disorder.
- Describe the pathophysiology of each disorder.
The student must be able to tabulate the stages of Syphilis.
- List the treatment options for each disorder.
- List the laboratory tests that can be used to diagnose each disorder.

14.3 THE LABORATORY TESTS THAT ARE USED TO DIAGNOSE HYPERSENSITIVITY TYPE III DISORDERS

OBJECTIVE

Provide students with knowledge and skills relating to the following laboratory tests:

- Tests to detect CICs (Circulating Immune Complexes).

Refer to the following tests:

- PEG (Polyethylene glycol) solubility and precipitation.
- ELISA to detect CICs affinity for the C1q complement component.

- Specific test to diagnose EAA.

Refer to the following test:

- **FEIA** (Fluorescent Enzyme Immunoassay) on the Immunocap.

- Specific tests to diagnose Syphilis.

Refer to the Reverse algorithm.

Non Treponemal Screening tests. Refer to the following tests:

- RPR (Rapid Plasma Reagin) test.

The student must demonstrate understanding of Antibody-Antigen interaction in Agglutination tests

- VDRL (Venereal disease Research Laboratory) test.

Treponemal Confirmatory tests. Refer to the following tests:

- TPHA (Treponema Pallidum Haem-Agglutination) test.
- TPA Poly (Treponema Pallidum Antibody) by Chemiluminescence.
- FTA-Abs (Fluorescence Treponemal Assay) test for IgM and IgG.
- ELISA test for IgM and IgG.

The student must be able to indicate the expected result for the different tests at the different stages of Syphilis and tabulate factors that could lead to a false result.

- Specific test to diagnose APSGN.

Refer to the following test: Nephelometry for ASL and Anti-DNAse B.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the principle of the tests.
- List the steps in the method of the tests.
- List the normal values of the tests (if applicable).
- Perform the tests, where possible.
- Identify the results of the tests.
- List the disorders that can be diagnosed by the tests.
- Analyse case studies that refer to the laboratory results and to diagnosis of a disorder.

15. HYPERSENSITIVITY TYPE IV

15.1 BACKGROUND KNOWLEDGE

OBJECTIVE

Provide students with introductory knowledge of Hypersensitivity Type IV (and the subtype VI)
Refer to the definition, time to onset and mechanism of damage.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Describe the definition, time to onset and mechanism of damage

15.2 DISORDERS ASSOCIATED WITH HYPERSENSITIVITY TYPE IV & TYPE VI

OBJECTIVE

Provide students with knowledge of the following Hypersensitivity Type IV disorders:

- Granulomatous lesions in leprosy.
- Cavitation and caseation (in the lung) in tuberculosis.
- Skin damage in contact hypersensitivity reactions to dyes, metals and chemicals.
- Bronchial obstruction in asthmatic individuals (in this condition TH₂ and Eosinophils dominate).
- Poison Ivy Contact Dermatitis

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the aetiology of each disorder.
- Describe the pathophysiology of each disorder.
- List the treatment options for each disorder.
- List the laboratory tests that can be used to diagnose each disorder

15.3 THE LABORATORY TESTS THAT ARE USED TO DIAGNOSE HYPERSENSITIVITY TYPE IV DISORDERS

OBJECTIVE

Provide students with knowledge and skills relating to the following laboratory tests:

- The Patch test to diagnose contact dermatitis.
- The Tuberculin test for Tuberculosis.
- IFN- γ tests (Interferon gamma) to diagnose tuberculosis.

Refer to the following tests: The TB spot test / ELISA Quantiferon TB gold in-tube test

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the principle of the tests.
- List the steps in the method of the tests.
- List the normal values of the tests (if applicable).
- Perform the tests, where possible.
- Identify the results of the tests.
- List the disorders that can be diagnosed by the tests.
- Analyse case studies that refer to the laboratory results and to diagnosis of a disorder.

MODULE 4:

16. TRANSPLANT IMMUNOLOGY

16.1 RED BLOOD CELL ANTIGENS

16.1.1 BACKGROUND KNOWLEDGE

OBJECTIVE

Provide students with introductory knowledge of the red blood cell antigens. Include the following:

- Characteristics of the ABO blood group system.
Refer to preformed antibodies / the Landsteiner rule / Universal donor and Universal recipient.
- Characteristics of the Rhesus blood group system.
Refer to development of specific antibodies after sensitisation.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Describe the characteristics of the ABO Blood group system with reference to preformed antibodies, the Landsteiner rule and Universal donor and Universal recipient.
- Describe the characteristics of the Rhesus group system with reference to development of antibodies after sensitisation.

16.1.2 APPLICATION OF ABO AND RHESUS GROUPING

OBJECTIVE

Provide students with knowledge of where ABO and Rhesus grouping is applied e.g.:

- Blood transfusion.
- Organ transplants.
- Pre and post natal care (to prevent and diagnose HDNB).
- Paternity testing (would include grouping of the “other systems” as well).
- Forensic investigations (would include grouping of the “other systems” as well).

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- List situations where ABO and Rhesus grouping is applied.

16.1.3 THE LABORATORY TESTS THAT ARE USED TO PERFORM RED BLOOD CELL GROUPING

OBJECTIVE

Provide students with knowledge and skills relating to the following laboratory tests:

- Forward and Reverse grouping for ABO. Grouping for Rh (Rhesus)
Refer to the following methods: Slide Agglutination / Tube Agglutination.
- Additional test for Discrepancies. Refer to the following: Anti-H / Anti-A1 or Anti-A2.
- Cross-matching of Recipient and Donor.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the principle of the tests.
- List the steps in the method of the tests.
- List the normal values of the tests (if applicable).

- Perform the tests, where possible.
- Identify the results of the tests.
- Analyse case studies that refer to the laboratory results and an application of the test.

16.2 WHITE BLOOD CELL (HLA) ANTIGENS

16.2.1 BACKGROUND KNOWLEDGE

OBJECTIVE

Provide students with introductory knowledge of the White Blood Cell (HLA) antigens.

Include the following:

- Composition of the MHC System (Major Histocompatibility Complex).
- The structure of MHC Class I and MHC Class II (refer to the heavy and light chains and the peptide grooves).
- Cells on which MHC Class I and MHC Class II are expressed.
- Inheritance of the MHC with reference to co-dominance.
- The functions of the MHC in the immune system.
- Include the following definitions:
Gene polymorphism / Phenotype / Genotype / Haplotype / Heterozygous / Homozygous / Linkage disequilibrium.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Describe the composition of the of the MHC system.
- Illustrate (by labelled sketches) the structure of MHC Class I and MHC Class II.
- List the immune cells on which MHC Class I and MHC Class II are expressed.
- Describe the functions of the MHC in the immune system
- Explain the following definitions:
Gene polymorphism / Phenotype / Genotype / Haplotype / Heterozygous / Homozygous / Linkage disequilibrium

16.2.2 APPLICATION OF HLA.

OBJECTIVE

Provide students with knowledge of application of HLA e.g.:

- Organ transplants.
- Paternity testing.
- Forensic investigations.
- Disease associations with HLA alleles.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- List the applications of HLA Class I & II typing.

4.2.1 THE LABORATORY TESTS FOR HLA.

OBJECTIVE

Provide students with knowledge and skills relating to the following laboratory tests:

A. Tests for HLA TYPING:

Refer to the following methods:

Serological Method

- CDC(Complement Dependent Cytotoxicity) HLA antigen test with reference to:
 - Preparation of a lymphocyte suspension utilising Ficoll density gradient separation.
 - Separation of cells using nylon wool / immune-magnetic beads (IMB).
 - Operation of an inverted microscope.
 - The use of fluorescent microscopy stains (A stain to stain live cells / A stain to stain dead cells).

Molecular methods

The student must be given the basic principles of the specific molecular biology application as applicable in the Immunology laboratory.

Emphasis must be placed on:

- GLP in the molecular laboratory (i.e. pre-and post PCR workspace, decontamination).
- Structure of Deoxyribonucleic acid (DNA).
- Different extraction methods of DNA and RNA.
- The Polymerase chain reaction (PCR).
- Visualising and interpreting PCR products.
- How the genetic / molecular testing relates to the theory of molecular biology and the human genome.
- Refer to the following methods that are used for HLA-typing:
 - SSP (Sequence specific primers)
 - SSOP (Sequence specific oligonucleotide probes)
 - rSSOP (reverse Sequence specific oligonucleotide probes)Refer to Luminex
- SBT (Sequence Based Typing) by Sanger method and New generation SBT

B. Tests for PRA (Panel Reactive Antibodies) methods

Refer to the following methods:

- CDC.
- Luminex® solid-phase bead array

C. Tests for DSA (Donor Specific Antibodies) methods

Refer to the following methods:

- CDC
- Solid-phase bead arrays (i.e. Luminex®)
- MLC (Mixed Lymphocyte Culture)

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Describe the preparation of a lymphocyte suspension using Ficoll density gradient centrifugation.
- Describe the separation of T & B lymphocytes using nylon wool / Magnetic beads.
- Illustrate (by labelled sketch) an Inverted Microscope.
- Explain the principle of the tests.
- List the steps in the method of the tests.
- Perform the tests, where possible.
- Identify the results of the tests.
- Compare the advantages and shortcomings of each method.
- Differentiate between: low-, medium- and high-resolution typing of HLA alleles.
- Analyse case studies that refer to the laboratory results of transplant patients

17. REJECTION OF TRANSPLANTED TISSUE

OBJECTIVE

Provide students with knowledge relating to the rejection of transplanted tissue and underlying immunological pathways with reference to:

- Types of rejection: Hyper-acute / Acute / Chronic / GVH (Graft Versus Host).
- Strategies to prevent rejection pre- and post-transplantation.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Describe the types of rejection with reference to the underlying immunological pathways causing the rejection.
- Describe strategies to prevent rejection pre- and post-transplantation with reference to post treatment modalities.

18. AUTOIMMUNE DISORDERS ASSOCIATED WITH HLA

A. DISORDERS

OBJECTIVE

Provide students with knowledge relating to the following disorders:

- Ankylosing spondylitis.
- Celiac disease.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- List these and other autoimmune disorders associated with HLA.
- Link these disorders to the HLA groups that they are associated with.

B. LABORATORY TESTS

OBJECTIVE

Provide students with knowledge of laboratory tests that are used for determining HLA groups that are associated with certain Auto-immune disorders.

Refer to the following tests:

Flow Cytometry for HLA-B*27 of Ankylosing spondylitis

PCR for HLA-B*27 of Ankylosing spondylitis

rSSOP on a Slide e.g. for Celiac and other disorders.

SPECIFIED OUTCOMES

On completion of this section the student should be able to

- Explain the principle of the tests.
- List the steps in the method of the tests.
- Perform the tests, where possible.
- Identify the results of the tests.
- Compare the advantages and shortcomings of each method.
- Differentiate between: low-, medium- and high-resolution typing of HLA alleles.
- Analyse case studies that refer to the laboratory results of these disorders.

MODULE 5:

19. OTHER INFECTIOUS DISORDERS (SEROLOGY)

A. DISORDERS

Provide students with knowledge of the following disorders:

- Syphilis (Note that Syphilis was included at Hyper III)
- Typhoid fever
- Brucellosis
- Tick bite fever
- Yersinia enterocolitica and Yersinia pseudo-tuberculosis
- Cryptococcus infection
- Toxoplasmosis
- Amoebiasis
- Echinococcus granulosus infection
- Taenia solium infection
- Pneumocystis jirovecii infection
- Chlamydia trachomatis infection
- Hepatitis A / B / C infections.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the aetiology of each disorder.
- Describe the pathophysiology of each disorder.
- List the treatment options for each disorder.
- List the laboratory tests that can be used to diagnose each disorder.

B. THE LABORATORY TESTS THAT AID IN THE DIAGNOSIS OF THESE DISORDERS

OBJECTIVE

Provide students with knowledge and skills relating to the following laboratory tests:

- The tests for Syphilis (Note that this was included at Hyper III)
- The TMX test to aid in screening for Typhoid fever, Brucellosis and Tick Bite fever.
- The Tube agglutination or ELISA tests to aid in the diagnosis of *Yersinia enterocolitica* or *Yersinia pseudo tuberculosis* infection.
- The agglutination test to detect *Cryptococcus* in CSF.
- Specific tests to diagnose Toxoplasmosis.
Refer to the following tests:
 - ELISA for IgM and IgG.
 - ELISA for Avidity / Affinity.
- Passive Haemagglutination to diagnose *Entamoeba histolytica*, *Echinococcus granulosus* and *Taenia solium*.
- DFA to diagnose *Pneumocystis jirovecii* and *Chlamydia trachomatis*.
- Specific test to diagnose Hepatitis A / B / C.
Refer to the following tests:
 - Rapid Lateral flow Screening tests.
 - Chemiluminescence tests.

SPECIFIED OUTCOMES

On completion of this section the student should be able to:

- Explain the principle of the tests.
The student must demonstrate understanding of Antibody-Antigen interaction in Agglutination tests
- List the steps in the method of the tests.
- List the normal values of the tests (if applicable).
- Perform the tests, where possible.
- Identify the results of the tests.
The student must be able to indicate the expected Widal result of a confirmed Typhoid infection and tabulate factors that could lead to a false result.
- List the infections that can be diagnosed by the tests.
- Analyse case studies that refer to the laboratory results and to diagnosis of an infection.

20. RECOMMENDED TEXT BOOKS

The following books are recommended:

- At the Bench. A laboratory Navigator.
Kathy Barker. Cold Spring Harbour press.
- Immunobiology, Latest edition. Janeway.
- Good Laboratory Practice (GLP) Handbook, Latest edition. WHO
- Occupational Health and Safety Act, 1993 (Act No. 85 of 1993)
- Education and Training requirements in Medical Technology in South Africa,
Professional Board for Med Technology (Med Tech Training 2001-11-14)

NOMENCLATURE / ACRONYMS

Acronym	Meaning
ABO	Red blood cell groups A, B and O
AD	Autosomal Dominant
ADA	Adenosine Deaminase Deficiency
ADCC	Antibody Dependant Cell mediated Cytotoxicity
AIDS	Acquired Immuno-Deficiency disorder
AIR	Acute Inflammatory Response
ALPS	Autoimmune Lympho-Proliferative Syndrome
ANA	Anti-Nuclear Antibodies
ANCA	Anti-Neutrophil Cytoplasmic Antibodies
APECED	Autoimmune Poly-Endocrinopathy Candidiasis Ectodermal Dystrophy
APHC 100	Alternative Pathway Haemolytic Complement test
APLS	Anti-Phospho-Lipid Syndrome
APP	Acute Phase Protein
APSGN	Acute Post-Streptococcal Glomerulo-Nephritis
ASL	Anti-Streptolysin
CAST	Cellular Allergen Stimulation Test
CB	Composite Block
CCP	Cyclic-Citrullinated Peptide
CD	Cluster of Differentiation
CDC	Complement Dependent Cytotoxicity
CEUs	Continuous Educational Units
CGD	Chronic Granulomatous Disease
CIC	Circulating Immune Complexes
CLA	Chemiluminescence assay
CMC	Chronic Mucocutaneous Candidiasis
CPD	Continuous Professional Development
CPHC 100	Classical Pathway Haemolytic Complement test
CREST	Calcinosis, Raynaud phenomenon, Esophageal dysmotility, Sclerodactyly, and Telangiectasia
CRP	C-Reactive Protein
CTLA-4	Cytotoxic T-Lymphocyte Antigen 4
CVID	Common Variable Immuno-Deficiency
DCs	Dendritic Cells
DNA	Deoxyribonucleic acid
DNase	Deoxyribonuclease
DSA	Donor Specific Antibodies
EAA	Extrinsic "Allergic" Alveolitis
ECP	Eosinophil Cationic Protein
EDTA	Ethylene Diamine Tetra Acetic acid
EIA	Enzyme Immuno-Assay (this acronym is used to refer to some AUTOMATED ELISA instruments)
ELISA	Enzyme-Linked Immuno-Sorbent Assay
ENAs	Extractable Nuclear Antigens

FEIA	Fluorescence Enzyme Immuno Assay
FISH	Fluorescence in situ hybridisation
FTA-Abs	Fluorescence Treponemal Assay-Absorption
GLP	Good Laboratory Practice
GVH	Graft-Versus-Host
HAE	Hereditary Angio-Edema
HEp-2	Human Epithelium carcinoma-2
HIES	Hyper IgE Syndrome
HIV	Human Immunodeficiency Virus
HLA	Human Leucocyte Antigen
HPCSA	Health Professions Council of South Africa
HSV	Herpes simplex virus
HUS	Hereditary uremic syndrome
HVZV	Herpes varicella zoster virus
IBD	Inflammatory Bowel Disease
IDDM1	Insulin Dependent Diabetes mellitus type i
IFA	Immuno Fluorescence Assay
IFN- γ	Interferon-gamma
IL	Interleukin
IL-2 RG	Interleukin-2 receptor gamma
IL-7 RA	Interleukin-7 receptor alpha
IMB	Immuno magnetic beads
IPEX	Immune dysregulation Poly-endocrinopathy Enteropathy X-linked syndrome
ISAC [®]	Immuno Solid-phase Allergen Chip
ISO	International Organization for Standardization
JAK3	Janus kinase 3
LAD	Leukocyte Adhesion Deficiency
MALT	Mucosal Associated Lymphoid Tissue
MCAS	Mast Cell Activation Syndrome
MCGN	Mesangio Capillary Glomerulo-Nephritis
MCTD	Mixed Connective Tissue Disorder
MELISA	Memory Lymphocyte Immune-Stimulation Assay
MHC	Major Histocompatibility Complex
MLC	Mixed Lymphocyte Culture
MPO	Myeloperoxidase
MSDS	Materials Safety Data Sheets
MSMD	Medelian Susceptibility to Mycobacterial Disease
MW	Molecular weight
NBT	Nitro blue tetrazolium
NETs	Neutrophil Extracellular Traps
NHLS	National Health Laboratory Services
NK	Natural Killer
OB	Oxidative Burst

PBC	Primary Biliary Cirrhosis
PBMC	Peripheral Blood Mono-nuclear Cells
PCR	Polymerase Chain Reaction
PEG	Polyethylene glycol
PIDs	Primary Immuno-Deficiencies
PM	Polymyositis
PNH	Paroxysmal Nocturnal Haemoglobinuria
PNP	Purine Nucleoside Phosphorylase enzyme
PPE	Personal Protective Equipment
QA	Quality Assurance
QC	Quality Control
RA	Rheumatoid arthritis
RAG1/2	Recombination Activating Gene 1 & 2
RBCs	Red Blood Cells
RCF	Relative Centrifugal Force
RF	Rheumatoid factor
Rpm	Revolutions per minute
RPR	Rapid Plasma Reagin
RS	Radiation Sensitivity
rSSOP	reverse Sequence Specific Oligonucleotide Probes
SBT	Sequence Based Typing
SCID	Severe Combined Immuno-Deficiency
Scl-70	Scleroderma-70
SFLC	Serum free light chains
SGD	Specific Granule Deficiency
SLE	Systemic Lupus Erythematosus
SOPs	Standard Operating Procedures
STS	Serological Tests for Syphilis
SSOP	Sequence Specific Oligonucleotide Probes
SSP	Sequence Specific Primers
TB	Tuberculosis
TE	Triss EDTA
TPA	Treponema Pallidum Antibody
TPHA	Treponema Pallidum Haem-Agglutination
TREC	T-cell Receptor Excision Circles
UV	Ultra-violet
VDRL	Venereal Disease Research Laboratory
WIs	Working Instructions