



Science | Technology | People



SYLLABUS

CLINICAL PATHOLOGY **MEDICAL TECHNOLOGISTS and** **MEDICAL LABORATORY SCIENTISTS**

PBMT approved in July 2022 for training implementation in 2023 for students who write from March 2024 onwards

SYLLABUS 4th YEAR INTERN MEDICAL TECHNOLOGISTS & MEDICAL LABORATORY SCIENTISTS
CLINICAL PATHOLOGY

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1. INTRODUCTION

Clinical Pathology is a term used for a discipline which incorporates the disciplines of Microbiology, Haematology and Chemical Pathology. Wherever the term 'laboratory' is used throughout this syllabus it is implicit that this applies to the three disciplines in Clinical Pathology.

The objective of this syllabus is to provide the intern technologists or student medical laboratory scientists with a guideline on the essential aspects that must be covered in order to adequately prepare themselves for the HPCSA's Professional Board of Medical Technology examination (intern technologists) and final UoT exit examination (student medical laboratory scientists). The candidates are expected to be able to correlate their practical knowledge and laboratory testing with the clinical condition and other disciplines.

The HPCSA's Professional Board of Medical Technology examination is in the form of two, three hour, written papers which will be based on the contents of this syllabus and related theoretical knowledge gained during study at the University of Technology, as well as practical experience gained during the fourth practical year of laboratory bench work.

For the Medical Technologist Board examination, the candidates are required to attain a minimum of 50% overall and a sub-minimum of 50% for each of the disciplines that comprise Clinical Pathology. Emphasis will be placed on the ability to relate practical and theoretical knowledge to clinical conditions with particular reference to those listed in Addendum 1.

Since the final exit exam for Medical Laboratory Scientist is administered by the respective UoT's and pass requirements are determined by UoT, the candidate is urged to familiarise themselves with the pass requirements for the exit examination of their respective UoT.

Please refer to:

- Ⓢ Nomenclature / Acronyms
- Ⓢ Appendices
 - 11.1 Definitions of acronyms contained in the syllabus
 - 11.2 Recommended text books

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 receive appropriate training in the tests contained within the syllabus but which are not routinely performed on site. (Where practical training at an alternate training facility is not feasible, minimum of theoretical and written assessments are compulsory)

2. STATUTORY REGULATIONS AND ETHICS

Objective

Provide the Intern with information on the regulations and ethical principles which apply to 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.
- ⊙ Demonstrate knowledge of the structure and function of the Professional Board for Medical Technology.
- ⊙ Discuss the regulations relating to the scope of practice for Medical Technologists or Medical Laboratory scientists.
- ⊙ Describe the legal and ethical standards related to the professional practice of Medical Technology.
- ⊙ Discuss the application of legal and ethical guidelines with regards to the communication and distribution of patient results via electronic platforms and/or other means.
- ⊙ Demonstrate knowledge of the requirements for the acquisition of continual education units (CEUs).
- ⊙ Demonstrate knowledge on how confidentiality in the workplace is obtained and maintained.
- ⊙ Demonstrate knowledge of National Health Act, 2004 No. 61 of 2003

3. TOTAL QUALITY MANAGEMENT SYSTEM

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.

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	 Compensation for Occupational Injuries and Diseases Act
 Hazardous Substances Act	

- ⊙ Demonstrate knowledge of the procedures to follow in the event of laboratory accident or emergency.

Range:

☀ Fire, Flood, Bomb threat	☀ Chemical or bio-hazardous spill
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- ⊙ Describe the correct procedures for the storage, handling and disposal of laboratory waste.
- ⊙ Describe the application of laboratory safety procedures to the collection, packaging, transport, storage and analysis of biological specimens, including the International Air Transport Association (IATA) regulations.

Range:

☀ Biological specimens	☀ Solid and liquid bio-hazardous waste
☀ Human tissue	☀ 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	☀ First aid officer
☀ Safety representative	

- ⊙ Recognize the international safety symbols used in the laboratory environment. This includes but is not limited to:

Range

☀ Exits	☀ Fire equipment
☀ Electrical	☀ Biohazards, chemical and fire warnings
☀ Assembly point	
☀ First aid fire equipment	

- ⊙ Demonstrate knowledge of all safety and emergency equipment. This includes but is not limited to:

☀ Disposable aprons and laboratory coats	☀ Face shields
☀ Goggles	☀ Face masks
☀ Gloves (various types used in the laboratory environment)	☀ Paper dispensers
☀ Soap dispensers	☀ Respirators
☀ First aid kits	☀ Chemical fume hoods
☀ Biological safety cabinets	☀ Fire blanket
☀ Eye wash bottle	☀ Fire hose
☀ Emergency whistle/ horn	☀ Fire extinguisher
☀ Emergency shower	

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:

- ⊙ Demonstrate knowledge of any required patient preparation for the collection of specimens for individual tests.
- ⊙ **Collect** specimens and identify and describe the related factors which may affect results generated from the analysis of these specimens, as defined within current statutory requirements and limitations.

Range – including but not limited to:

<ul style="list-style-type: none">✿ Venous, capillary and radial arterial blood samples.✿ Urine✿ Stool✿ Sputum✿ Semen	<ul style="list-style-type: none">✿ Nail clippings and filings, hair✿ Pus swabs✿ Nasopharyngeal and oropharyngeal swabs for medical pathology purposes.
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Note: The following are specifically excluded from the scope of practice:

- ✿ Collecting venous or arterial blood from premature neonates; umbilical, internal and external jugular veins; brachial or femoral arteries; anterior fontanelle and central venous pressure or arterial lines.
- ✿ Collection of non-blood aspirates, tissue for histology, PAP smears and swabs requiring specialised knowledge and/or skills.

- ⊙ Describe the mode of action of the various anticoagulants / preservatives.
- ⊙ Select the correct anticoagulant / preservative for the analysis to be performed.
- ⊙ Describe the optimal specimen requirements for the individual tests.
- ⊙ Describe the conditions under which the specimens must be transported to the laboratory including the use of appropriate transport media for micro-organisms.
- ⊙ Display knowledge of the optimal storage conditions should testing be delayed and the stability of the specimen for the individual testing process.
- ⊙ 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 of the specimen, aliquots and documentation.
- ⊙ Describe the process for the rejection of unsuitable specimens.
- ⊙ Conduct the pre-analytical processes required for specimen type and test requested.

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 analyzers used to perform the tests and procedures outlined in this syllabus

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

- ⊙ Describe the principle of operation where applicable.
- ⊙ Operate all equipment optimally in accordance with 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.
- ⊙ Differentiate between calibration, validation and verification.
- ⊙ Conduct applicable decontamination procedures as per manufacturer's recommendation or laboratory SOP.
- ⊙ Discuss and perform 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 an understanding of the approach to the validation and/or verification of new equipment, reagents and testing kits (Qualitative and Quantitative).
- ⊙ Demonstrate full knowledge the maintenance procedures, all equipment records and documentation required for good laboratory practice.

Range:

<ul style="list-style-type: none"> ✱ All glassware – volumetric and graduated ✱ Pipettes – glass, automated, air displacement and disposable ✱ Balances – top pan and fine analytical chemical ✱ Stirrer ✱ Hotplates ✱ Fridges ✱ Freezers ✱ Water-baths ✱ Stopwatches/timers ✱ Spectrophotometers ✱ Thermometers – min/max, electronic and mercury ✱ Bio-hazardous safety cabinets – Class I and II ✱ Fume cupboards 	<ul style="list-style-type: none"> ✱ pH meters ✱ Rotators ✱ Shakers ✱ Rollers ✱ Flat bed and vortex mixers ✱ Pipette aids - rubber teats, pro-pipettes and dispensers ✱ Microscopes – light, phase contrast, inverted and fluorescent ✱ Incubators – aerobic and CO₂. ✱ Centrifuges – micro-haematocrit, safety, temperature controlled and ultra ✱ Equipment for sterilization –autoclaves, hot-air ovens, steamer, filtration, and inspissation and tyndallisation.
<p>Laboratory instrumentation and automated analysers are included in this range – knowledge of the principles and application of instruments in use in the current workplace is required. These include, but are not limited to:</p> <ul style="list-style-type: none"> ✱ Staining instruments ✱ Microbiological automated identification/sensitivity systems (refer to section 7.4 and 7.5) ✱ Automated analyzers ✱ TB and blood culture semi-automated/automated growth indicator equipment ✱ Flow cytometry 	

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 intern/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.

Range:

✿ Stock solutions	✿ Working solutions
✿ Working reagents	✿ Calibrators
✿ Controls	✿ Reagent kits

- ⊙ Define terms and solutions used in the laboratory:

Range:

✿ Molar and Molal solutions	✿ SG
✿ Physiologically normal saline	✿ Calibrators
✿ Buffer	✿ Controls

Note: In addition refer to section 4.0 Laboratory related mathematics.

3.5 STOCK CONTROL

Objective

Outline the processes involved in good stock management.

Specified outcomes

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

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

3.6 QUALITY ASSURANCE / ACCREDITATION

Objective

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

Note: ISO Standard 15189 may be used as a guideline here.

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.
- ⊙ Identify the need for releasing, communicating and reporting urgent/critical/panic value laboratory results, following prescribed protocols.
- ⊙ Discuss the correct protocol to be followed when erroneous laboratory reports are released and amended reports are issued.
- ⊙ Demonstrate general knowledge on the term accreditation.
- ⊙ Demonstrate general knowledge on the use, performance and evaluation of RISK assessments.
- ⊙ Define and explain all quality assurance terminology.

Range:

<ul style="list-style-type: none">✿ Non-conformance✿ Corrective action✿ Preventive action	<ul style="list-style-type: none">✿ Root cause analysis✿ Continual improvement of quality assurance and quality control processes.✿ Audits – internal, external, onsite, virtual, desktop, horizontal, vertical, witnessing
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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:

- ⊙ Define and explain all terminology used in the assessment of quality control results.

Range

<ul style="list-style-type: none">✿ Westgard rules✿ Shift✿ Trend✿ Outlier✿ Positive and negative bias✿ Specificity✿ Sensitivity✿ Precision✿ Imprecision✿ Total allowable error	<ul style="list-style-type: none">✿ Systemic error✿ Random error✿ Delta difference✿ Reference range✿ Linearity✿ Reportable range✿ Uncertainty of measurement✿ Accuracy✿ Biological variance
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- ⊙ Describe and apply the appropriate quality control processes which must be performed
 - In the analysis of all analytes, organisms and parameters,
 - On equipment and analyser operation, and
 - In reagent and media preparation, as contained within this syllabus.
- ⊙ Discuss fundamental concepts of Six Sigma methodologies as relevant to Clinical Pathology Laboratories.
- ⊙ Explain the principles of internal and external quality control procedures in the context of the tests performed.
- ⊙ Understand and interpret LJ and SDI graphs.
- ⊙ Apply a sound knowledge of all the principles, procedures, calculations and interpretation of all related internal and external, **quantitative** quality control data.
- ⊙ Apply a sound knowledge of all the procedures, principles and interpretation of 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.

Note: In addition, refer to section **4.0** Laboratory related mathematics.

3.8 METHOD VALIDATION

Objective

Expose the student to all aspects of method validation.

Note: ISO Standard 15189 may be used as a guideline here.

Specified outcomes

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

- ⊙ Differentiate between validation and verifications.
- ⊙ Demonstrate an understanding of the approach to the validation and/or verification of new equipment, reagents and testing kits (Qualitative and Quantitative).
- ⊙ Differentiate between the terms sensitivity and specificity used in the validation/ verification of qualitative test kits.
- ⊙ Differentiate and explain the different statistical analysis terms in the below range. (No calculations)

Range

<ul style="list-style-type: none"> ✿ Bias (proportional and constant) ✿ Biological variation ✿ Slope ✿ Intercept ✿ r-value 	<ul style="list-style-type: none"> ✿ Reference range / normal range ✿ Analytical range / reportable range ✿ Linearity ✿ Within run and between run precision studies ✿ Correlation
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3.9 PERSONNEL

Objective

Provide knowledge of basic requirements for personnel for Quality Assurance purposes.

Note: ISO Standard 15189 may be used as a guideline here.

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 Technologists and Medical Laboratory Scientists.
- ⊙ Demonstrate an understanding of the terms 'training', 'competency' and 'ongoing competency' in terms of the training of all laboratory personnel which falls within the scope of practice of Medical Technologists and Medical Laboratory Scientists.

3.10 DOCUMENTATION

Objective

Provide knowledge of basic requirements of documentation for Quality Assurance purposes.

Note: ISO Standard 15189 may be used as a guideline here.

Specified outcomes

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

- ⊙ Demonstrate knowledge of document control requirements.
- ⊙ Demonstrate knowledge of the required content of SOP's including the minimum content of the cover page.
- ⊙ Identify the minimum required content of a laboratory report.
- ⊙ Know the process on how to make 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	✿ Equipment records
✿ Procedures(SOPs)	✿ Quality control records
✿ Working instructions	✿ Personnel records
✿ Raw data	✿ Package inserts/IFU's

4. LABORATORY RELATED MATHEMATICS

Objective

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

Specified outcomes

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

- ⊙ Demonstrate proficiency in the use of the correct formula used in the calculation of patient results
- ⊙ Demonstrate proficiency in the calculations required for the preparation of solutions or patient samples.
- ⊙ Calculate parameters used in the assessment of quantitative quality control results.

Range:

<ul style="list-style-type: none"> ✿ Calculated osmolality ✿ LDL (Friedewald calculation) ✿ Unconjugated Bilirubin ✿ Uncorrected and corrected creatinine clearance ✿ 24-hour urine excretions ✿ % Saturation (Iron) 	<ul style="list-style-type: none"> ✿ Anion gap ✿ Globulin estimation ✿ Corrected calcium ✿ Unit conversions – e.g. w/w, w/v and v/v conversions, making use of SI units and their derivatives. Note that this includes molar, molal and % conversions. Normality is excluded. ✿ Protein/Creatinine ratio ✿ CKMB - Index
<ul style="list-style-type: none"> ✿ Red cell parameters - MCV; MCH; MCHC; Hct; RDW ✿ Absolute reticulocyte count ✿ RMI/RPI ✿ Reticulocyte percentage/relative reticulocyte count ✿ Corrected reticulocyte count ✿ Prothrombin ratio and index 	<ul style="list-style-type: none"> ✿ Correction for the presence of nucleated red blood cells ✿ INR ✿ Absolute and relative differential white cell counts ✿ Percentage parasitaemia
<ul style="list-style-type: none"> ✿ Percentage solutions ✿ Dilutions - serial and doubling dilutions 	<ul style="list-style-type: none"> ✿ Molar solutions ✿ Apply SG and purity in the preparation of molar/molal solutions ✿ Physiological saline
<ul style="list-style-type: none"> ✿ Standard deviation(SD) ✿ Coefficient of variation(CV) ✿ Standard deviation index(SDI) 	<ul style="list-style-type: none"> ✿ Mean ✿ Median

5. MOLECULAR BIOLOGY

Objective

Provide intern/student with a foundation of skills and 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 will be able to:

- ⊙ Describe workflow dynamics in a molecular biology laboratory.
- ⊙ Demonstrate and apply knowledge of the methods used for the prevention of contamination in a molecular 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
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- ⊙ 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 lab.
- ⊙ Demonstrate knowledge of and apply the quality controls used in the testing procedure.
- ⊙ Identify the potential causes of false positive and negative results.
- ⊙ Identify potential causes of interference in the PCR process.
- ⊙ 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 singleplex 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, analysis, applicable safety precautions, sources of error.)
- ⊙ Perform basic molecular test procedures (including but not limited to PCR and micro array assays) 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).

6. CHEMICAL PATHOLOGY

Objective

Provide in depth practical knowledge of the screening, quantitative and/or qualitative analytical processes used in the testing of specimens in Chemical Pathology and the clinical significance of the final results.

Range

<ul style="list-style-type: none"> ✿ Blood – timed and random ✿ Aspirates ✿ Faeces 	<ul style="list-style-type: none"> ✿ Urine – timed and random ✿ CSF ✿ Body fluids – transudates and exudates
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Specified outcomes

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

- ⊙ Discuss and apply the principles of the test methodologies in the range.

Range

<ul style="list-style-type: none"> ✿ Potentiometry / ISE ✿ Enzymatic/ kinetic ✿ Turbidimetry ✿ Chemiluminescence 	<ul style="list-style-type: none"> ✿ Colorimetry ✿ Nephelometry ✿ Lateral flow - Immuno-chromatography ✿ High performance liquid chromatography ✿ Immuno-assays
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- ⊙ Practically apply knowledge of principles and demonstrate skill in performing tests based on above test methodologies and combinations thereof to all analytes, parameters and identification of abnormalities and disease processes where relevant, across the disciplines mentioned in this syllabus.
- ⊙ Demonstrate knowledge of the optimum specimen requirements, limitation of the test methods and interfering substances.
- ⊙ Provide the common “street name” for drugs of abuse in the specific range (where applicable).
- ⊙ Process samples in accordance with documented laboratory procedures.
- ⊙ Utilize the correct units for reporting the results of the analytes.
- ⊙ Describe appropriate physiological conditions affecting test results.
- ⊙ Identify and act on critical/panic values/life threatening results for all the analytes and parameters in the range, and correlate abnormal laboratory results with physiological and pathological conditions.

Note: Knowledge of normal ranges for analytes within the range is not required, as these vary between laboratories.

Ranges

BLOOD	
Renal <ul style="list-style-type: none"> ✿ Sodium ✿ Potassium ✿ Chloride ✿ tCO₂ ✿ Anion gap (calculated) ✿ pH 	<ul style="list-style-type: none"> ✿ Urea ✿ Creatinine ✿ Uncorrected and corrected creatinine clearance ✿ Uric acid

<p>Lungs – Blood Gas Analysis Parameters, Including:</p> <ul style="list-style-type: none"> * pH * PCO₂ * PO₂ * TCO₂ 	<ul style="list-style-type: none"> * O₂ Sat. * Actual and standard bicarbonate * Base excess
<p>Liver</p> <ul style="list-style-type: none"> * Total Protein * Albumin * Globulin * Total bilirubin * Conjugated bilirubin * Unconjugated bilirubin 	<ul style="list-style-type: none"> * ALP * GGT * LDH * AST * ALT
<p>Lipid</p> <ul style="list-style-type: none"> * Triglyceride * Low density lipoprotein (LDL) (measured and calculated) 	<ul style="list-style-type: none"> * Cholesterol * High density lipoprotein (HDL)
<p>Pancreas</p> <ul style="list-style-type: none"> * Amylase (excluding P-type) 	<ul style="list-style-type: none"> * Lipase
<p>Cardiac</p> <ul style="list-style-type: none"> * CK * CK-MB (mass& activity) * Troponin (T and I) 	<ul style="list-style-type: none"> * Myoglobin * Pro-BNP or BNP * CK-MB Index
<p>Endocrine</p> <ul style="list-style-type: none"> * βHCG * TSH * Free T₃ * FreeT₄ * LH 	<ul style="list-style-type: none"> * FSH * E₂ * Prolactin * Progesterone
<p>Note: Knowledge of normal ranges of female hormones during the different stages of gestation and the various stages of the menstrual cycle is not required. The intern/student must be able to demonstrate the ability to identify and act accordingly on critical/panic values where relevant.</p>	
<p>Miscellaneous</p> <ul style="list-style-type: none"> * Ionized calcium * Iron, transferrin * Ferritin * % Transferrin saturation * Total iron binding capacity * CRP * PCT * Neonatal bilirubin 	<ul style="list-style-type: none"> * Magnesium * Inorganic phosphorous * Total and corrected calcium * Glucose * Glucose tolerance (GTT) * HbA1C (Glycated Haemoglobin) * Cholinesterase

URINE	
Urine <ul style="list-style-type: none"> ☀ Reducing substances ☀ B-HCG ☀ Urea ☀ Sodium ☀ Potassium ☀ Amylase 	<ul style="list-style-type: none"> ☀ Chloride ☀ Creatinine ☀ Calcium ☀ Magnesium ☀ Phosphate ☀ Protein
Dipstick <ul style="list-style-type: none"> ☀ pH ☀ Leucocytes ☀ Nitrates ☀ Glucose ☀ Ketones 	<ul style="list-style-type: none"> ☀ Urobilinogen ☀ Bilirubin ☀ Blood ☀ Haemoglobin ☀ Protein ☀ Specific Gravity

Faeces	
☀ Occult blood/faecal haemoglobin	☀ Reducing substances

CSF	
☀ Glucose	☀ Protein

FLUIDS	
<ul style="list-style-type: none"> ☀ LDH ☀ Glucose ☀ Protein 	☀ Differentiation between exudates and transudates

Ranges

BLOOD	
Toxicology <ul style="list-style-type: none"> ☀ Digoxin ☀ Phenytoin ☀ Phenobarbital ☀ Carbamazepine ☀ Theophylline ☀ Valproic acid ☀ Alcohol ☀ Vancomycin ☀ Tacrolimus 	<ul style="list-style-type: none"> ☀ Salicylates ☀ Paracetamol ☀ Tricyclic antidepressants ☀ Lithium ☀ Amikacin ☀ Gentamycin ☀ Organophosphates (cholinesterase) ☀ Cyclosporine
<p>Note: Although knowledge of normal or therapeutic ranges is not required, the intern/student must be able to demonstrate the ability to identify and act accordingly on critical/panic values where relevant.</p>	

<p>Miscellaneous</p> <ul style="list-style-type: none"> ✿ Basic protein electrophoresis. - Normal electrophoretic pattern; pattern of plasma cell myeloma/multiple myeloma ✿ Osmolality - measured and calculated ✿ Rheumatoid factor ✿ Anti-streptolysin O titre 	<ul style="list-style-type: none"> ✿ Lactate ✿ Ammonia ✿ Tumor markers, including: <ul style="list-style-type: none"> ○ CEA ○ AFP ○ Ca19-9 ○ Ca15-3 ○ Ca12-5 ○ βHCG ○ Total and free PSA
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URINE	
<p>Urine – Drugs of abuse (including but not limited to):</p> <ul style="list-style-type: none"> ✿ Cannabis (TCH) ✿ Barbiturates ✿ Benzodiazepine ✿ Cocaine ✿ Opiates 	<ul style="list-style-type: none"> ✿ Methamphetamine / Amphetamine ✿ Methaqualone ✿ Phencyclidine (PCP) ✿ Tricyclic antidepressants

- ⊙ Describe the appropriate application of the confirmatory tests.
- ⊙ Demonstrate an understanding of the expected findings and correlation with the appropriate clinical implications.

7. MICROBIOLOGY

7.1 Microscopy and staining technique

Objective

Provide in depth practical knowledge in the methods, use and application of microscopy techniques in a clinical microbiology setting.

Specified outcomes

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

- ⊙ Describe and perform the methods of wet preparations of specimens used in the identification of microorganisms and cellular elements.

Range

<ul style="list-style-type: none">✿ Faeces✿ Vaginal swabs	<ul style="list-style-type: none">✿ Urine
--	---

- ⊙ Describe and perform the concentration methods utilized for the identification of the presence of parasites.

Range

<ul style="list-style-type: none">✿ Faeces (flotation OR sedimentation)	<ul style="list-style-type: none">✿ Urine
---	---

- ⊙ Describe and apply the methods used for the identification of casts and/or crystals.

Range

<ul style="list-style-type: none">✿ Urine	<ul style="list-style-type: none">✿ Body fluids
---	---

- ⊙ Demonstrate a sound knowledge of the principles and techniques, and perform the stains and microscopy procedures commonly employed in a clinical microbiology laboratory.

Range

<ul style="list-style-type: none">✿ Cell counts on CSF, pleural fluid, peritoneal fluid, pericardial fluid and synovial fluid, where applicable (Fuchs-Rosenthal OR Improved Neubauer chamber).✿ Staining technique for <i>Cryptosporidium</i>✿ India ink for <i>Cryptococcus neoformans</i>	<ul style="list-style-type: none">✿ Gram's stain✿ KOH for yeasts and fungal elements✿ Lacto-phenol cotton blue✿ Staining techniques for TB smears
--	--

Range TB stains

<ul style="list-style-type: none">✿ Ziehl-Neelsen✿ Auramine	<ul style="list-style-type: none">✿ Cold Kinyoun
--	--

7.2 Processing of specimens

Objective

Provide in depth practical knowledge of the pre-analytical and analytical processing of specimens through the selection and performance of the appropriate procedures that can result in the growth and identification of pathogens present.

Range

<ul style="list-style-type: none"> ✿ Aspirates from normally sterile sites, including but not limited to pleural fluid, peritoneal fluid, pericardial fluid, synovial fluid, CSF ✿ Genital specimens ✿ Pus ✿ Stool ✿ Urine 	<ul style="list-style-type: none"> ✿ Blood Cultures ✿ Ear, nose & throat swabs ✿ Eye swabs ✿ Respiratory samples ✿ Tissue ✿ IUD ✿ Catheter tips ✿ CVP tips
---	--

Specified outcomes

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

- ⊙ Describe and correctly apply the documented procedures for the processing of the specimens in the range.
- ⊙ Demonstrate knowledge of optimum growth requirements for the optimum growth of micro-organisms listed in this syllabus.

Range

<ul style="list-style-type: none"> ✿ Atmospheric conditions ✿ Temperature 	<ul style="list-style-type: none"> ✿ Time
---	--

- ⊙ Differentiate between normal flora, commensals and pathogens in each of the specimen types in the range.
- ⊙ Determine the suitability of specimens for processing.
- ⊙ Apply and discuss the sterile techniques employed in the processing of specimens.
- ⊙ Comply with all required safety precautions when processing specimens.

7.3 Media

Objective

Provide knowledge of culture media necessary for the isolation, identification and sensitivity testing of the micro-organisms listed in this syllabus.

Range

Isolation Media	
<ul style="list-style-type: none"> ✿ McConkey with or without crystal violet ✿ Sorbitol McConkey for EHEC identification ✿ Blood agar ✿ Chocolate/boiled blood agar ✿ XLD; ✿ Salmonella/Shigella agar ✿ New York City or Thayer Martin 	<ul style="list-style-type: none"> ✿ Media for isolation of anaerobes ✿ Naladixic/CN agar ✿ Tellurite agar ✿ TCBS agar ✿ Sabdex agar ✿ Campylobacter agar OR Blood based agar for Campylobacter isolation

<ul style="list-style-type: none"> ☀ Sabdex & Chlor agar ☀ Thioglycolate Broth 	<ul style="list-style-type: none"> ☀ Egg yolk agar
Identification Media	
<ul style="list-style-type: none"> ☀ Bile esculin ☀ DNA ☀ Mannitol salt agar 	<ul style="list-style-type: none"> ☀ Carbohydrates (glucose, lactose, sucrose, maltose) ☀ CTA sugars
Antimicrobial sensitivity Testing media	
<ul style="list-style-type: none"> ☀ Mueller Hinton agar ☀ Haemophilus test medium ☀ Mueller Hinton agar with sheep blood 	<ul style="list-style-type: none"> ☀ Mueller Hinton agar with laked blood OR Mueller Hinton for Fastidious organisms ☀ Gonococcus sensitivity agar
Chromogenic Media	
<ul style="list-style-type: none"> ☀ Identification of Methicillin Resistant Staphylococcus aureus (MRSA) ☀ Carbapenem Resistant Enterobacteriaceae (CRE) 	<ul style="list-style-type: none"> ☀ Identification of urinary pathogens

Specified outcomes

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

- ☉ Describe the different types of media used for the optimum growth of micro-organisms.

Range

<ul style="list-style-type: none"> ☀ Selective ☀ Non-selective ☀ Enriched 	<ul style="list-style-type: none"> ☀ Indicator ☀ Differential
--	---

- ☉ Select Appropriate media for the isolation and identification of the organisms listed in this syllabus.
- ☉ Demonstrate knowledge of the principles and techniques of sterilisation techniques for culture media.

Range

<ul style="list-style-type: none"> ☀ Autoclave ☀ Filtration ☀ Tyndallisation 	<ul style="list-style-type: none"> ☀ Hot-air ovens ☀ Steamer ☀ Inspissation
---	--

- ☉ Demonstrate knowledge of the main ingredients and their function in the different media.
- ☉ Describe and apply the appropriate procedures for the quality control of the media preparation.

7.4 Identification of organisms

Objective

Provide knowledge of the tests used in the differentiation and final identification of the listed organisms. Many of the species given are merely the most common representative organisms in that genus, in most cases there are many more; however, for examination purposes, only the species listed in this syllabus need to be studied.

Specified outcomes

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

- ⊙ Describe in detail the methods, reagents and results obtained for the biochemical identification of the organisms listed.
- ⊙ Accurately report on findings according to established laboratory protocols.
- ⊙ Perform the appropriate tests for the identification of the organisms listed.
- ⊙ Describe the principle of biochemical identification tests.

Range

<ul style="list-style-type: none">✱ Glucose, lactose and other carbohydrate utilisation✱ Urea✱ Indole✱ Motility✱ H₂S✱ Citrate✱ Decarboxylase✱ Oxidase✱ ONPG✱ Nitrate reduction✱ X and V factors✱ Hippurate✱ Catalase	<ul style="list-style-type: none">✱ Coagulase✱ Bile Esculin✱ 6.5% NaCl✱ Pyruvate OR Arabinose for Group D Enterococcus identification✱ Bacitracin✱ Optochin✱ Lancefield grouping using Latex kits✱ DNase✱ Novobiocin✱ CTA sugars✱ Germ tube✱ CAMP✱ Reverse CAMP
---	---

- ⊙ Describe the principle and use of automated and semi-automated equipment.

Range

<ul style="list-style-type: none">✱ Automated blood culture systems✱ Automated and semi-automated bacterial identification and susceptibility testing systems	<ul style="list-style-type: none">✱ Molecular biology amplification and detection systems✱ Automated rapid detection of microorganisms.
--	--

7.4.1 Gram negative organisms

A. Enterobacterales

- ⊙ *Enterobacter cloacae*
- ⊙ *Escherichia coli*
- ⊙ *Klebsiella pneumonia*
- ⊙ *Klebsiella aerogenes*
- ⊙ *Morganella morganii*

- ⊙ *Proteus mirabilis*
- ⊙ *Proteus vulgaris*
- ⊙ *Providencia rettgeri*
- ⊙ *Salmonella typhi*
- ⊙ *Salmonella species*
- ⊙ *Serratia marcescens*
- ⊙ *Shigella flexnerii*
- ⊙ *Shigella boydii*
- ⊙ *Shigella sonnei*
- ⊙ *Shigella dysenteriae*

Differentiation of above organisms by the use of the following tests:

<ul style="list-style-type: none"> ✿ Gram stain ✿ Colonial morphology on appropriate media ✿ Carbohydrate utilisation (glucose, lactose) ✿ Oxidase ✿ ONPG ✿ Basic knowledge of the serotyping of <i>Salmonella</i> and <i>Shigella</i> 	<ul style="list-style-type: none"> ✿ Urea ✿ Indole ✿ Motility ✿ H₂S ✿ Citrate ✿ Decarboxylase ✿ Nitrate reduction
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B. Non-fermentative Gram Negative Bacilli

- ⊙ *Acinetobacter baumannii*
- ⊙ *Pseudomonas aeruginosa*

Differentiation of above organisms by the use of the following tests:

<ul style="list-style-type: none"> ✿ Gram stain ✿ Colonial morphology on appropriate media ✿ Carbohydrate utilisation (glucose, lactose) 	<ul style="list-style-type: none"> ✿ Motility ✿ Citrate ✿ Oxidase
---	--

C. Miscellaneous Gram Negative Organisms:

- ⊙ *Campylobacter coli*
- ⊙ *Campylobacter jejuni*

Differentiation of above organisms by the use of the following tests:

<ul style="list-style-type: none"> ✿ Gram stain ✿ Colonial morphology on appropriate media ✿ Oxidase ✿ Hippurate 	<ul style="list-style-type: none"> ✿ Erythromycin ✿ Growth conditions
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- ⊙ *Haemophilus influenzae*
- ⊙ *Haemophilus parainfluenzae*
- ⊙ *Moraxella catarrhalis*
- ⊙ *Neisseria gonorrhoeae*
- ⊙ *Neisseria meningitides*

Differentiation of above organisms by the use of the relevant tests:

<ul style="list-style-type: none">Gram stainColonial morphology on appropriate mediaOxidase	<ul style="list-style-type: none">Carbohydrate utilization (glucose, maltose)X and V factors
---	---

© *Vibrio cholera*

Identification of the above organism by the use of the following tests:

<ul style="list-style-type: none">Gram stainColonial morphology on appropriate mediaCarbohydrate utilization (glucose, lactose, sucrose)UreaIndole	<ul style="list-style-type: none">MotilityH₂SCitrateDecarboxylaseOxidaseONPG
--	--

7.4.2 Gram positive cocci

A. Streptococcus

- © Lancefield group A (*S. pyogenes*)
- © Lancefield group B (*S. agalactiae*)
- © Lancefield group D (*S. bovis* & *S. equinus*)
- © *Streptococcus pneumoniae*
- © Viridans group of streptococci (to group level only)
- © *Enterococcus faecalis*
- © *Enterococcus faecium*

Differentiation of Streptococci organisms by the use of the following biochemical tests:

<ul style="list-style-type: none">Gram stainColonial morphology on appropriate mediaCatalaseBacitracinPyruvate OR Arabinose OR Cefuroxime/Imipenem to distinguish between Group D Enterococci	<ul style="list-style-type: none">OptochinBile esculin6.5%NaClLancefield grouping using latex kit testsCAMP
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B. Staphylococci:

- © *Staphylococcus aureus* including Methicillin Resistant *Staphylococcus aureus* (MRSA)
- © Coagulase negative staphylococci
- © *Staphylococcus saprophyticus*

Differentiation of above Staphylococci with the use of the following tests:

<ul style="list-style-type: none">Gram stainColonial morphology on appropriate mediaCatalaseDNase	<ul style="list-style-type: none">Coagulase,Novobiocin susceptibility and any commercially prepared identification system.
--	---

7.4.3 Gram positive bacilli

A. Spore-forming gram positive bacilli:

- ⊙ *Bacillus cereus*
- ⊙ *Bacillus anthracis*

Differentiation of above organisms by the following tests:

<ul style="list-style-type: none"> ✿ Gram stain ✿ Colonial morphology on sheep blood agar, ✿ Clinical significance 	<ul style="list-style-type: none"> ✿ Catalase ✿ Motility ✿ Lecithin
---	--

B. Non-Spore-forming gram positive bacilli

- ⊙ *Corynebacterium diphtheriae*
- ⊙ *Corynebacterium jeikeium*
- ⊙ *Listeria monocytogenes*

Differentiation of above organisms by the use of the following biochemical tests:

<ul style="list-style-type: none"> ✿ Gram stain ✿ Colonial morphology on blood agar and tellurite media ✿ Glucose ✿ Maltose ✿ Sucrose 	<ul style="list-style-type: none"> ✿ Lactose ✿ Nitrate ✿ Urea ✿ Motility ✿ Catalase ✿ Esculin ✿ CAMP
--	---

B. Gram positive branching bacilli

- ⊙ *Nocardia asteroides*

Differentiation of above organisms by the use of the following tests:

<ul style="list-style-type: none"> ✿ Gram stain, ✿ Modified Kinyoun 	<ul style="list-style-type: none"> ✿ Colonial morphology on blood agar.
---	--

7.4.4 Anaerobic organisms

A. Gram Negative Organisms

- ⊙ *Bacteroides fragilis* group

Differentiation of above organisms by the use of the following tests:

<ul style="list-style-type: none"> ✿ Gram stain ✿ Colonial morphology on appropriate media 	<ul style="list-style-type: none"> ✿ Presumptive identification by use of special potency disks: Penicillin (2 μ), Rifampicin (15ug), Kanamycin (1000μg), Colistin (10 μg) Vancomycin (5μg) and Erythromycin (60μg).
--	---

B. Gram Positive Organisms

Gram Positive cocci:

- ⊙ *Peptostreptococcus anaerobius*
- ⊙ *Peptostreptococcus assacharolyticus*

Differentiation of above organisms by the use of the following biochemical tests:

☀ Gram stain, ☀ Colonial morphology on appropriate media	☀ SPS (sodium polyanethol sulphonate) disc
---	--

C. Spore-forming gram positive bacilli:

- ☉ *Clostridium perfringens*

Differentiation of above organisms by the use of the following biochemical tests:

☀ Gram stain ☀ Colonial morphology on appropriate media ☀ Catalase ☀ Motility ☀ Lecithinase	☀ Lipase ☀ H ₂ S ☀ Indole ☀ Esculin ☀ Reverse CAMP
Note: The Nagler test is excluded from this syllabus	

D. Non-spore forming gram positive bacilli:

- ☉ *Actinomyces israelii*

Differentiation of above organisms by the use of the following biochemical tests:

☀ Gram stain ☀ Modified Kinyoun	☀ Colonial morphology on appropriate media
------------------------------------	--

7.5 Mycobacteria

Objective

Provide a thorough knowledge of the microscopy and reporting of microscopy findings, culture and identification of Mycobacteria.

Specified outcomes

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

- ☉ Decontaminate specimens for culture.
- ☉ Isolate *Mycobacterium tuberculosis* using appropriate media.

Range

- | |
|---|
| ☀ Conventional Lowenstein-Jensen OR
☀ Middlebrook media OR
☀ Mycobacterial index growth indicator tube (MGIT) |
|---|

- ☉ Describe the principle and use of automated and semi-automated equipment:

Range

- | |
|--|
| ☀ Automated TB culture and mycobacterial susceptibility systems;
☀ Molecular biology amplification and detection systems;
☀ Automated rapid detection of <i>Mycobacterium</i> spp. |
|--|

- ⊙ Detail and accurately apply the IUATLD (ZN & Auramine) and WHO guidelines for the reading and reporting of TB sputum direct smears.
- ⊙ Define MDR and XDR TB in relation to the relevant antimicrobial agents reported as sensitive or resistant.

7.6 Mycology

Objective

Provide a basic knowledge and understanding of microscopy and culture methods for the detection and identification of yeasts and fungi.

Specified outcomes

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

- ⊙ Process specimens including skin, hair and nail specimens for yeasts and fungi using recognized SOPs.

Identify the following organisms:

- ⊙ *Candida albicans*
- ⊙ *Cryptococcus neoformans*

Differentiation of above organisms by the following biochemical tests:

<ul style="list-style-type: none"> ✿ Colonial morphology on Sabdex and blood agar ✿ Germ tube 	<ul style="list-style-type: none"> ✿ Urease
---	--

Differentiation of the below organisms by microscopy to genus level only

- ⊙ *Aspergillus*
- ⊙ *Penicillium*

7.7 Susceptibility Testing

Objective

Provide an understanding of antimicrobial susceptibility testing principles and procedures in a clinical setting.

Specified outcomes

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

- ⊙ Apply the correct methods and interpretation for susceptibility testing (either EUCAST or CLSI)
Note: Memorising inhibition zone sizes or MIC levels and their interpretations for the various microbes and related antibiotics is not required.
- ⊙ Demonstrate understanding and application of resistance mechanisms and test procedures.

Range

<ul style="list-style-type: none"> ✿ Inducible- clindamycin resistance (D-test) ✿ Extended spectrum β -lactamase testing (ESBL) ✿ Carbapenem resistant Enterobacteriaceae (CRE) 	<ul style="list-style-type: none"> ✿ β-lactamase testing ✿ Inducible β -lactamase (AmpC)
---	--

- ⊙ Discuss intrinsic microbial resistance and identify the antimicrobial agents which are routinely reported as resistant for the microbes in this syllabus.
- ⊙ Demonstrate an understanding of the principles of the susceptibility testing methods.

Range

<ul style="list-style-type: none"> ✿ Disk (Kirby Bauer) and breakpoint ✿ Minimum Inhibitory Concentration (MIC) by E test 	<ul style="list-style-type: none"> ✿ Automated methods
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- ⊙ Demonstrate a basic knowledge of the mode of action of antibiotics.

Range:

Class	Groups included in Class
Beta-lactams	Penicillin's, Cephalosporin's, Monobactams, Carbapenems and Beta lactam-inhibitor combinations
Aminoglycosides	Amikacin, Gentamycin, Tobramycin
Macrolides	Erythromycin
Lincosamides	Clindamycin
Glycopeptides	Vancomycin, Linezolid
Quinolones	Ciprofloxacin, Levofloxacin
Sulfa-drugs	Co-trimoxazole
Tetracyclines	N/A

7.8 Parasitology

Objective

Provide training in the recognition and identification of parasite stages and structures which may be detected in routine clinical specimens, using appropriate microscopy and staining techniques.

Specified outcomes

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

- ⊙ Identify the ova (O), oocysts (OO), cysts (C), trophozoites (T), hooklets (H) and adult forms microscopically and macroscopically from the appropriate specimen.
- ⊙ Demonstrate knowledge of the natural host/sof the parasites within the range and the mode of transmission to the human.

Range

<p>Cestodes:</p> <ul style="list-style-type: none"> ✿ <i>Echinococcus granulosus</i> (O or H) ✿ <i>Hymenolepis nana</i> (O) ✿ <i>Taenia</i> species (O) 	<p>Nematodes:</p> <ul style="list-style-type: none"> ✿ <i>Ascaris lumbricoides</i> (O) ✿ <i>Enterobius vermicularis</i> (O) ✿ Hookworms: <i>Necator americanus</i> and <i>Ancylostoma duodenale</i> (O)
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	☀ <i>Trichuris trichiura</i> (O)
Protozoa:	Trematodes:
☀ <i>Cryptosporidium parvum</i> (OO)	☀ <i>Schistosoma haematobium</i> (O)
☀ <i>Entamoeba histolytica</i> and <i>Entamoeba coli</i> (O)	☀ <i>Schistosoma mansoni</i> (O)
☀ <i>Giardia lamblia</i> (C), (T)	
☀ <i>Trichomonas vaginalis</i> (T)	

7.9 Serology

Objective

Provide a sound knowledge and understanding of serological tests employed by the bacteriology laboratory in the diagnosis of disease.

Specified outcomes

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

- ☉ Describe the principles of the methodologies in the range.

Range of methodologies:

☀ Agglutination	☀ Immunofluorescence - Indirect antibody detection
☀ Haemagglutination - indirect	☀ Neutralization reactions
☀ Immunofluorescence - direct antigen detection	☀ Precipitation
☀ ELISA	
☀ Lateral Flow immunoassay	

- ☉ Demonstrate a basic knowledge of the application of the tests within the range.
- ☉ Apply the appropriate methodology to the correct test.

Range of tests

☀ SARS-CoV-2	☀ Weil Felix
☀ RPR, CLAT	☀ Brucella
☀ TPHA and Amoeba	☀ HIV
☀ Pneumocystis and/or Chlamydia	☀ Hepatitis
☀ FTA - ABS, ANF	☀ Rubella
☀ ASOT	☀ Rota
☀ VDRL	☀ Adeno
☀ Widal	

8. SEMEN ANALYSIS

Objective

To provide a basic knowledge and understanding of the procedures and interpretation involved in semen analysis according to the WHO manual.

Specified outcomes

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

- ⊙ Describe normal and abnormal sperm
- ⊙ Describe a method to distinguish between viable and non-viable sperm
- ⊙ Define terms associated with semen analysis

Range:

<ul style="list-style-type: none">✿ Aspermia✿ Zoospermia✿ Azoospermia✿ Oligozoospermia✿ Hypospermia✿ Hyperspermia✿ Haemospermia✿ Leucospermia	<ul style="list-style-type: none">✿ Asthenozoospermia✿ Teratozoospermia✿ Necrozoospermia✿ Globozoospermia✿ Combinations of these terms where applicable.
--	--

- ⊙ Interpret the results of the semen analysis.
- ⊙ Report the results using the correct terminology.

Range:

<ul style="list-style-type: none">✿ pH✿ Staining✿ Concentration of sperm	<ul style="list-style-type: none">✿ Pre- and post-vasectomy✿ Primary infertility
--	---

9. HAEMATOLOGY

Objective

Provide in depth practical knowledge of the screening, quantitative and/or qualitative analytical processes used in the testing of peripheral blood specimens in Haematology and the clinical significance of the final results.

9.1 Full Blood Count (FBC)

Range

<ul style="list-style-type: none"> ☀ Red cell count ☀ White cell count ☀ Platelet count ☀ Neutrophils ☀ Lymphocytes ☀ Monocytes ☀ Eosinophils 	<ul style="list-style-type: none"> ☀ Basophils ☀ Haemoglobin ☀ Haematocrit ☀ MCV ☀ MCH ☀ MCHC ☀ RDW
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Specified outcomes

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

- ☉ Process specimens with the use of an automated full blood count analyzer.
- ☉ Utilize the correct units for reporting the results of the parameters/cell lines.
- ☉ Demonstrate knowledge of impedance counting (Coulter principle), and the interpretation of the histograms and scatter plots generated by the auto-analyzer in use at the workplace.
- ☉ Identify, troubleshoot and action on errors, factors and specimen characteristics which may cause false low/high and abnormal FBC, histogram and scatter plot results.

Range (including but not limited to):

<ul style="list-style-type: none"> ☀ Clotted sample ☀ Old sample ☀ Storage artefacts; ☀ Improperly mixed sample ☀ Incorrect sample ☀ Insufficient sample and short sampling; ☀ Haemolysed, lipemic and icteric samples 	<ul style="list-style-type: none"> ☀ Presence of nucleated red blood cells (NRBC's); ☀ Presence of red cell fragments and large/giant platelets; ☀ Presence of lysis resistant red cells; ☀ Presence of abnormal cells. ☀ Red cell auto agglutination; ☀ Platelet clumping and satellitism
---	--

- ☉ Describe the relevant changes in the FBC results which could be expected in various clinical states and haematological conditions.

Range (including but not limited to):

<ul style="list-style-type: none"> ☀ Hypochromic microcytic anaemias (Fe deficiency, Anaemia of chronic disorders, Sideroblastic anaemia, Pb poisoning, Thalassemia). ☀ Oval and Round Macrocytic anaemias ☀ Thyroid disorder 	<ul style="list-style-type: none"> ☀ Pregnancy, Pre-eclampsia, eclampsia and HELLP syndrome ☀ New-borns ☀ Renal failure and liver disease ☀ Splenectomy/splenic atrophy ☀ Hypersplenism ☀ Bone marrow infiltration and failure
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<ul style="list-style-type: none"> ☀ Hypoproliferative disorders - Aplastic anaemia and Red cell aplasia ☀ Haemolytic anaemias ☀ Plasmodium infection ☀ Viral infection, including but not limited to HIV/AIDS, Infectious mononucleosis, SARS-CoV-2 etc. ☀ Dehydration ☀ Cardiac and respiratory disease ☀ Bacterial and fungal infections ☀ Leukaemoid reactions ☀ Chronic inflammatory disorders ☀ Acute and chronic blood loss 	<ul style="list-style-type: none"> ☀ Myeloproliferative disorders (excluding mastocytosis) ☀ Myelodysplastic syndromes ☀ Myelodysplastic/myeloproliferative disorders ☀ Acute lymphoblastic and myeloid leukaemias ☀ Mature B cell and T cell neoplasms (refer to section 9.7 - Classifications). ☀ Plasma cell neoplasms
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- ⊙ Identify and act on critical/panic values/life threatening results for all the parameters in the range, and correlate abnormal laboratory results with physiological and pathological conditions.
Note: Knowledge of normal ranges for analytes within the range is not required, as these vary between laboratories.

Note: In addition, refer to section 4.0 Laboratory related mathematics.

9.2 Coagulation Tests

Range

<ul style="list-style-type: none"> ☀ PT ☀ INR ☀ PTT ☀ Fibrinogen ☀ Platelet count ☀ FVIII assay; ☀ FIX assay 	<ul style="list-style-type: none"> ☀ Thrombin time ☀ D-dimers ☀ Bleeding time (manual) ☀ Fibrin degradation products ☀ Platelet Factor Assay 100 (PFA-100) OR equivalent
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Specified outcomes

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

- ⊙ Demonstrate a sound understanding of the haemostatic system.
- ⊙ Discuss the principle, interpretation and limitations of the test parameters and assays in the range.
- ⊙ Describe and utilize manual and automated methodology for the determination of the tests in the range.
- ⊙ Perform and interpret Correction/Mixing studies.
- ⊙ Identify and apply the appropriate technical precautions in the testing process.
- ⊙ Utilize the correct units for reporting the results of the tests.
- ⊙ Identify and act on critical/panic values/life threatening results for all the parameters and tests in the range.
- ⊙ Demonstrate knowledge of the interpretation and clinical significance of the test results.
- ⊙ Describe the mode of action of heparin and warfarin anticoagulant therapy.
- ⊙ Demonstrate knowledge of the therapeutic reference ranges for INR and PTT when used to monitor anticoagulant therapy.

- ⊙ Describe the basic pathogenesis and expected changes to the normal values of the tests within the range, where relevant, in bleeding and thrombotic disorders.

Range

<ul style="list-style-type: none"> ✿ Conditions with failure of platelet production ✿ Thrombocytopenia due to drugs/toxins ✿ Immune thrombocytopenic purpura (ITP) ✿ Thrombotic Thrombocytopenic purpura (TTP) ✿ Haemolytic uraemic syndrome ✿ Disseminated intravascular coagulation (DIC) ✿ HELLP syndrome ✿ Hereditary platelet function disorders (Glanzman's thrombasthenia, Bernard Soulier syndrome; Storage pool disease) 	<ul style="list-style-type: none"> ✿ Acquired disorders of platelet function ✿ Haemophilia A and B ✿ Von Willebrand's disease ✿ Liver disease and Vit K deficiency ✿ Factor V Leiden ✿ Antithrombin deficiency ✿ Protein C and S deficiency ✿ Prothrombin G20210A
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Note: In addition, refer to section **4.0** Laboratory related mathematics.

9.3 Miscellaneous Haematology Tests

Range

<ul style="list-style-type: none"> ✿ ESR ✿ Reticulocyte count 	<ul style="list-style-type: none"> ✿ Buffy layer preparations ✿ CD4 count
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Specified outcomes

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

- ⊙ Perform the tests and relevant staining techniques within the range in accordance with laboratory procedures.
- ⊙ Describe and apply the appropriate technical precautions during the testing process.
- ⊙ Utilize the correct units for the reporting the results of the tests.
- ⊙ Describe the principles of the test processes.
- ⊙ Demonstrate knowledge of the interpretation and clinical significance of the final result of the test requested.

Note: In addition, refer to section **4.0** Laboratory related mathematics.

9.4 Immunohaematology

Range

<ul style="list-style-type: none"> ✿ ABO and Rh blood groups ✿ Direct Antiglobulin Test (Direct Coombs) 	<ul style="list-style-type: none"> ✿ Indirect Antiglobulin Test (Indirect Coombs)
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Specified outcomes

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

- ⊙ Demonstrate understanding of forward and reverse grouping techniques.
- ⊙ Correctly identify patient ABO and Rh blood groups from the final test results.
- ⊙ Describe potential causes of false positives and false negative test results.
- ⊙ Demonstrate a sound knowledge of the test methods of the direct and indirect Coomb's test.

- ⊙ Correlate laboratory results with physiological and pathological conditions.

9.5 Peripheral Blood Smear Examination

Specified outcomes

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

- ⊙ Prepare and stain an optimal peripheral blood smear for microscopic examination.
- ⊙ Demonstrate knowledge of the principle of the Romanowsky staining technique.
- ⊙ Apply the correct technique for the examination of the stained slides.
- ⊙ Describe and identify the normal morphology of all stages of maturation of all cell lines.
- ⊙ Describe and identify abnormal platelet morphology.
- ⊙ Confirm the automated results of white cell and platelet counts microscopically.
- ⊙ Demonstrate knowledge of the interpretation of the histograms and scatter plots generated by the auto-analyzer in use at the workplace
- ⊙ Identify the inclusion bodies and define the clinical conditions in which the inclusion bodies may be seen.
- ⊙ Demonstrate the ability to screen peripheral blood smears and identify abnormal morphological features.

Range

<ul style="list-style-type: none"> ✿ Howell Jolly bodies ✿ Pappenheimer bodies ✿ Basophilic stippling ✿ Punctuate basophilia ✿ Heinz bodies ✿ HbH inclusions ✿ Toxic granulation ✿ Döhle bodies ✿ Auer rods ✿ All stages of malaria parasites (see below); ✿ Shuffner's dots ✿ Maurer's clefts ✿ Cabot rings ✿ Russell bodies ✿ Cytoplasmic vacuolization ✿ Platelet clumping 	<ul style="list-style-type: none"> ✿ Presence of fibrin ✿ Presence of any stage of immature white cells with particular reference to blasts ✿ Atypical and reactive lymphocytes ✿ Platelet satellitism ✿ Relate red cell morphology to the MCH, MCV, MCHC and RDW ✿ Presence and relevance of clinically significant poikilocytes such as acanthocytes, echinocytes sickle cells, spherocytes, schistocytes, bite cells, eliptocytes/pencil cells, macrocytes, microcytes, stomatocytes, teardrop cells and target cells. ✿ Rouleaux formation ✿ Red cell agglutination
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- ⊙ Identify special staining techniques used for the identification and/or confirmation of the inclusion bodies where relevant.
- ⊙ Describe the relevant morphological characteristics of the white cell anomalies.

Range

<ul style="list-style-type: none"> ✿ Pelger Huet ✿ Chediak-Higashi 	<ul style="list-style-type: none"> ✿ Alder-Reilly ✿ May-Hegglin
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- ⊙ Perform accurate differential counts demonstrating the ability to identify and describe abnormal morphological features associated with the specified clinical conditions.

Range of clinical conditions:

<ul style="list-style-type: none">✿ Hypochromic microcytic anaemias (Fe deficiency, Anaemia of chronic disorders, Sideroblastic anaemia, Pb poisoning, Thalassemia).✿ Oval and Round Macrocytic anaemias✿ Thyroid disorder✿ Hypoproliferative disorders - Aplastic anaemia and Red cell aplasia✿ Haemolytic anaemias✿ Plasmodium infection✿ Viral infection, including but not limited to HIV/AIDS, Infectious mononucleosis, SARS-CoV-2 etc.✿ Dehydration✿ Cardiac and respiratory disease✿ Bacterial and fungal infections✿ Leukemoid reactions vs. malignancy✿ Chronic inflammatory disorders✿ Acute and chronic blood loss✿ Pregnancy, Pre-eclampsia, eclampsia and HELLP syndrome✿ New-borns	<ul style="list-style-type: none">✿ Renal failure and liver disease✿ Splenectomy/splenic atrophy✿ Hypersplenism✿ Bone marrow infiltration and failure✿ Myeloproliferative disorders (excluding mastocytosis)✿ Myelodysplastic syndromes✿ Myelodysplastic/myeloproliferative disorders✿ Acute lymphoblastic and myeloid leukaemias✿ Mature B cell and T cell neoplasms (refer to section 9.7 - Classifications).✿ Plasma cell neoplasms
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NOTE: Lymphomas are excluded from this syllabus.

- ⊙ Identify appropriate additional laboratory tests and/or stains for diagnostic confirmation.

9.6 Confirmatory Tests and Stains

Specified outcomes

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

- ⊙ Describe the appropriate application of the confirmatory tests for blood and bone marrow.

Range

<ul style="list-style-type: none">✿ Hb electrophoresis – describe the relevant changes to the Hb fractions in disease.✿ Immunophenotyping<ul style="list-style-type: none">○ Range –<ul style="list-style-type: none">▪ Basic lymphoid and myeloid panels▪ Mature B cell neoplasms (including CLL, Prolymphocytic leukaemia and Hairy cell leukaemia - Most common surface markers▪ Plasma cell leukaemia/multiple myeloma - CD38, CD138▪ Large granular lymphocytic leukaemia - Most common surface markers

- Acute myeloid leukaemia and related precursor neoplasms - Most common surface markers
- Acute lymphocytic leukaemia - Most common surface markers
- ☀ Basic cytogenetics with particular reference to the application in the WHO classification of haematological malignancies.
 - **Range** –
 - Myeloproliferative neoplasms - JAK2; BCR/ABL1; MPL
 - T-cell Prolymphocytic leukaemia - Inv 14
 - Large granular lymphocytic leukaemia - T cell receptor (TCR) genes
 - Acute myeloid leukaemia and related precursor neoplasms - t(8;21); t(15;17); inv16; del(11q23); t(9;22)
- ☀ Perl's Prussian blue iron stain.

9.7 Classifications

Specified outcomes

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

- ⊙ The morphological criteria, types and sub-types of the below range in accordance with the FAB classification system.
- ⊙ Demonstrate a sound knowledge of the morphological criteria as defined in the FAB classification system.
- ⊙ Demonstrate **basic knowledge** of the grouping of heamatological dyscracias using the WHO classification system.
- ⊙ Demonstrate an understanding of the difference between the WHO and FAB classifications.

Range

<ul style="list-style-type: none"> ☀ Myeloproliferative neoplasms – excluding mastocytosis ☀ Myelodysplastic syndromes ☀ Myelodysplastic/myeloproiferative neoplasms ☀ Mature B cell neoplasms <ul style="list-style-type: none"> ▪ <u>CLL</u> ▪ <u>Prolymphocytic leukaemia</u> ▪ <u>Hairy cell leukaemia</u> 	<ul style="list-style-type: none"> ☀ Plasma cell neoplasms <ul style="list-style-type: none"> ▪ Plasma cell myeloma ☀ Mature T cell neoplasms <ul style="list-style-type: none"> ▪ Prolymphocytic leukaemia ▪ Large granular lymphocytic leukaemia. ☀ Acute myeloid leukaemia and related precursor neoplasms ☀ Acute lymphocytic leukaemias
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NOTE: Lymphomas are excluded from this syllabus

9.8 Blood Borne Parasites

Specified outcomes

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

- ⊙ Demonstrate an understanding of the life cycle of the malaria parasites in the human host.

Range

Plasmodium species		
<ul style="list-style-type: none"> ✿ Malariae ✿ Falciparum 	<ul style="list-style-type: none"> ✿ Vivax ✿ Knowlesi 	<ul style="list-style-type: none"> ✿ Ovale

- ⊙ Prepare slides and use appropriate staining techniques for the microscopic identification of blood borne parasites.

Range

<ul style="list-style-type: none"> ✿ Staining techniques for thin and thick smear preparations – Romanowsky or Field's.
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- ⊙ Describe the advantages and disadvantages of the use of thick smears for microscopy.
- ⊙ Describe the relevant full blood count changes that are commonly associated with Plasmodium infection.
- ⊙ Perform parasitaemia count
- ⊙ Describe the relevant morphological changes of all cell lines that are commonly associated with Plasmodium infection.
- ⊙ Describe and identify microscopic features of parasitaemia.

Range

<ul style="list-style-type: none"> ✿ Plasmodium (all species listed) ✿ Trypanosoma brucei (Gambiense, Rhodesiense) ✿ Babesia species 	<ul style="list-style-type: none"> ✿ Blood borne Filariasis, including Wuchereria bancrofti, Brugia malayi, Loa loa, Mansonella perstans
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- ⊙ Describe and recognize the morphological differences of the different stages of the Plasmodium species.
- ⊙ Perform and interpret the antigen test demonstrating an understanding of the principle of the test in use.

Note: In addition, refer to section **4.0** Laboratory related mathematics.

10. NOMENCLATURE / ACRONYMS

AIDS	=	Acquired immune deficiency syndrome
ALT	=	Alanine Transaminase
ALP	=	Alkaline Phosphatase
ANAE	=	Alpha, Naphthol Acetate Esterase
ANF	=	Anti-nuclear factor
ASOT	=	Anti-streptolysin O titre
AST	=	Aspartate Transaminase
b-HCG	=	Beta Human Chorionic Gonadotrophin
CAMP	=	Christie Atkins Munch-Petersen
CK	=	Creatine Kinase
CLAT	=	Cryptococcal latex antigen test
CLL	=	Chronic lymphocytic keukaemia
COAD	=	Chronic obstructive airways disease
CRP	=	C-reactive protein
CSF	=	Cerebrospinal Fluid
Ct	=	Threshold cycle
CV	=	Coefficient of variation
CVP	=	Central venous pressure (Catheter tip)
DIC	=	Disseminated intravascular coagulation
DOT	=	Direct observation of treatment
DOA/ DAU	=	Drugs of Abuse/ Drugs of Abuse in Urine
ELIZA	=	Enzyme Linked Immunosorbent Assay
ESR	=	Erythrocyte sedimentation rate
FAB	=	French, American and British
FBC	=	Full blood count
FSH	=	Follicle Stimulating Hormone
FTA-Abs	=	Flourescent treponemal antibody absorbed
GGT	=	Gamma Glutamyl Transferase
GLP	=	Good Laboratory Practice
GTT	=	Glucose Tolerance Test
Hct	=	Haematocrit
HIV	=	Human immunodeficiency virus
HPCSA	=	Health Professions Council of South Africa
INR	=	International normalized ratio
IUATLD	=	International union against tuberculosis and lung disease
IUD	=	Intra-uterine device
KOH	=	Potassium hydroxide
LAP/NAP	=	Leucocyte/neutrophil alkaline phosphatase
LDH	=	Lactate Dehydrogenase
LH	=	Luteinizing Hormone
LJ	=	Levy-Jennings
MCH	=	Mean corpuscular haemoglobin concentration
MCHC	=	Mean corpuscular haemoglobin concentration
MCV	=	Mean corpuscular volume
PAS	=	Periodic acid Schiff
PCO₂& PO₂	=	Partial Pressure Carbon Dioxide & Oxygen
PCV	=	Packed cell volume

PI	=	Prothrombin index
PTH	=	Parathyroid Stimulating Hormone/ Parathormone
PT	=	Prothrombin time
PTT	=	Partial thromboplastin time
QA	=	Quality Assurance
QC	=	Quality Control
RDW	=	Red cell distribution width
RPI/RMI	=	Reticulocyte production index/Reticulocyte maturation index
RPR	=	Rapid plasmin reagin
SABS	=	South African Bureau of Standards
SOP	=	Standard operating procedure
SD	=	Standard deviation
T₃	=	Triiodothyronine
T₄	=	Thyroxine
TB	=	Tuberculosis
TCO₂	=	Total CO ₂
TPHA	=	<i>Treponema pallidum</i> haemagglutination test
TQM	=	Total Quality Management
TRAP	=	Tartrate resistant acid phosphatase
TSH	=	Thyroid Stimulating Hormone
VDRL	=	Venereal disease research laboratory
WHO	=	World Health Organisation
TCBA	=	Thiosulfate Citrate Bile Salts Sucrose Agar

11. APPENDICES

11.1 GUIDELINE TO CLINICAL APPLICATION

The list of conditions below is a guideline; however, assessment will cover all other clinical conditions relevant to the contents of this syllabus.

1. Septicemia
2. Meningitis
3. Urinary tract infection
4. Post-operative sepsis
5. Wound sepsis
6. Nosocomial infection
7. Warfarin and heparin therapy monitoring
8. Deep vein thrombosis
9. Pre-eclamptic toxemia
10. DIC
11. Dehydration
12. Gastro enteritis/Diarrhoea
13. Renal disease: renal failure; nephritis; nephrotic syndrome
14. Cardiac disease: myocardial infarction; ischemia; angina.
15. Liver disease: obstructive jaundice; cirrhosis; infective hepatitis.
16. Respiratory disease: Cor pulmonale; pulmonary embolism; TB; COAD; pneumonia, respiratory viruses, including but not limited to SARS-CoV-2 etc.
17. Pancreatic disease
18. Lipid disorders
19. Diabetes – Type 1 & Type 2; ketoacidosis
20. Organophosphate and salicylate poisoning
21. Syphilis: congenital; primary; secondary; tertiary; latent and neurosyphilis.
22. HIV: congenital; seroconversion; AIDS.
23. Thyrotoxicosis
24. Infectious mononucleosis
25. Primary infertility: post vasectomy
26. Gonococcal urethritis

Students are advised to learn how results from all disciplines are integrated into these and other clinical conditions.

HAEMATOLOGY

- Ⓢ WHO TUMOURS of HAEMATOPOIETIC and LYMPHOID TISSUES
- Ⓢ PRACTICAL HAEMATOLOGY, Dacie and Lewis
- Ⓢ ESSENTIAL HAEMATOLOGY , A.V. Hoffbrandt and J.E. Pettit
- Ⓢ INTRODUCTION TO HAEMATOLOGY, Rappaport
- Ⓢ BLOOD CELLS A PRACTICAL GUIDE, Barbara.Bain
- Ⓢ POSTGRADUATE HAEMATOLOGY, Hoffbrandt and Lewis
- Ⓢ Any atlas of Haematology

MICROBIOLOGY

- Ⓢ COLOR ATLAS AND TEXTBOOK OF DIAGNOSTIC MICROBIOLOGY, E.W. Koneman, S.Allen et al. (5th Edition)
- Ⓢ BAILEY & SCOTT'S DIAGNOSTIC MICROBIOLOGY. Betty A. Forbes, Danel F. Sahn and Alice S. Weissfeld(Eds). Mosby.
- Ⓢ MANUAL OF CLINICAL MICROBIOLOGY. Patrick R. Murray, Ellen Jo Baron et al (Eds) American Society for Microbiology
- Ⓢ MICROBIOLOGY WITH DISEASES and TAXONOMY. International edition. Robert W. Bauman (Ed). Pearson education
- Ⓢ BIOCHEMICAL TESTS FOR IDENTIFICATION OF MEDICAL BACTERIA J.F. Macfaddin (Third Edition)
- Ⓢ ATLAS OF HUMAN PARASITOLOGY, L.R.Ash and T.C. Orihel (Second Edition)
- Ⓢ ATLAS OF CLINICAL FUNGI. (Eds) G.S. Hoog and J.Guarro
- Ⓢ MEDICAL MYCOLOGY-THE PATHOGENIC FUNGI AND THE PATHOGENIC ACTINOMYCETES. (Eds) John Willard Rippon.
- Ⓢ PARASITES: A GUIDE TO LABORATORY PROCEDURES AND IDENTIFICATION. (Eds) Lawrence R. Ash and Thomas C. Orihel.
- Ⓢ ATLAS OF MEDICAL HELMINTHOLOGY AND PROTOZOOLOGY. (Eds) Jeffrey and Leach.
- Ⓢ EUCAST-standardising antimicrobialsusceptibility testing in Europe - Derek Brown - www.eucast.org/

CHEMICAL PATHOLOGY

- Ⓢ CLINICAL CHEMISTRY, PRINCIPLES, PROCEDURES AND CORRELATIONS, M.L. Bishop
- Ⓢ TEXTBOOK OF CLINICAL CHEMISTRY AND MOLECULAR DIAGNOSTICS, Teitz

OTHER:

- Ⓢ QUALITY CONTROL AND ACCREDITATION REFERENCE SITES:
 - www.iso.org
 - www.clsi.org
 - www.sanas.co.za.
- Ⓢ HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA (HPCSA):
 - www.hpcsa.co.za