SYLLABUS

CLINICAL PATHOLOGY

MEDICAL TECHNICIANS

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

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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/student technicians 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. 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, two hour, written practical papers which will be based on the contents of this syllabus.

For Medical Technician 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. Whilst candidates are not required to memorize formulae, they must be able to select the appropriate formula from the list provided in the examination paper.

Please refer to:

- 10. Nomenclature / Acronyms
- 11. Appendices
    - 11.1 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/students 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 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 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 Technicians.
- 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 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:

Fire, Flood, Bomb threat	Chemical or bio-hazardous spill

- 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 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. This includes but is not limited to:

Range

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

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

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

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 student should be able to:

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

Venous, capillary and radial arterial blood samples. Urine Stool Sputum Semen	Nail clippings and filings, hair Pus swabs Nasopharyngeal and oropharyngeal swabs for medical pathology purposes.

Note: The physical collection of specimens for analysis are **excluded** from this syllabus.

- 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.
- Identify criteria for the rejection of unsuitable specimens.
- Conduct the pre-analytical check and preparation 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 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.
- 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 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 • Balances – top pan and fine analytical chemical • Stirrer • Hotplates • Fridges • Freezers • Water-baths • Stopwatches/timers • Spectrophotometers • Thermometers – min/max, electronic and mercury	• 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 CO_2. • Centrifuges – micro-haematocrit, safety, temperature controlled and ultra

❁ Bio-hazardous safety cabinets – Class I and II ❁ Fume cupboards	

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:

- 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 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 reagents ❁ Controls	❁ Working solutions ❁ Calibrators ❁ Reagent kits

- ◎ Define terms and solutions used in the laboratory:

Range:

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

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

3.5 STOCK CONTROL

Objective

Outline the processes involved in good materials stock management**.**

Specified outcomes

On completion of this section the 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 vail 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 student to all aspects of quality assurance and accreditation.

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

Specified outcomes

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

- Discuss quality assurance and quality control in the correct context.
- Define 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 verified 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.

Non-conformance Corrective action Preventive action	Root cause analysis Continual improvement of quality assurance and quality control processes Audits – internal, external, onsite, virtual, desktop, horizontal, vertical, witnessing

3.7 QUALITY CONTROL

Objective

Expose the student to all aspects of quality control.

Specified outcomes

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

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

Range

Westgard rules Shift Trend Outlier	Systemic error Random error Delta difference Reference range

❁ Positive and negative bias ❁ Specificity ❁ Sensitivity ❁ Precision ❁ Imprecision ❁ Total allowable error	❁ Linearity ❁ Reportable range ❁ Uncertainty of measurement ❁ Accuracy ❁ Biological variance

- ◎ 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.
- ◎ 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 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.

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

3.8 METHOD VALIDATION

Objective

Expose the student to basic 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).

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 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 'training', competency' and ongoing competency' in terms of the training of all laboratory personnel which falls within the scope of practice of Medical Technicians.

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 student should be able to:

- Demonstrate knowledge of document control requirements.
- Demonstrate basic 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 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

4. LABORATORY RELATED MATHEMATICS

Objective

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

Specified outcomes

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

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

Range:

❁ Calculated osmolality ❁ LDL (Friedewald calculation) ❁ Unconjugated Bilirubin ❁ Uncorrected and corrected creatinine clearance ❁ 24-hour urine excretions ❁ % Saturation (Iron)	❁ 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
❁ 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	❁ Correction for the presence of nucleated red blood cells ❁ INR ❁ Absolute and relative differential white cell counts ❁ Percentage parasitaemia
❁ Percentage solutions ❁ Dilutions - serial and doubling dilutions	❁ Molar solutions ❁ Apply SG and purity in the preparation of molar/molal solutions ❁ Physiological saline
❁ Standard deviation(SD) ❁ Coefficient of variation(CV) ❁ Standard deviation index(SDI)	❁ Mean ❁ Median

5. MOLECULAR BIOLOGY

Objective

Provide 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 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

- 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.
- Demonstrate knowledge of and apply the quality controls used in the assay procedure.
- Identify the potential causes of false positive and negative results.
- Identify potential causes of interference in the PCR process.
- Demonstrate basic practical knowledge and skills of the techniques utilised 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).
- Perform 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).

6. CHEMICAL PATHOLOGY

Objective

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

Range

Blood – timed and random	Urine – timed and random
Aspirates	CSF
Faeces	Body fluids – transudates and exudates

Specified outcomes

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

- Discuss and apply the principles of test methodologies and the tests related to it.

Range

Potentiometry/ ISE	Colorimetry
Enzymatic/ kinetic	Nephelometry
Turbidimetry	Lateral flow - Immuno-chromatography
Chemiluminescence	Immuno-assays

- 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.
- Utilize the correct units for reporting the results of the analytes.
- Process samples in accordance with documented laboratory procedures.
- 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).
- Identify and act on critical/panic values/life threatening results for all the analytes and parameters in the range, and describe application of all tests in the range below.

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

Ranges

BLOOD	
Renal • Sodium • Potassium • Chloride • tCO_2 • Anion gap (calculated) • pH	• Urea • Creatinine • Uncorrected and corrected creatinine clearance • Uric acid •
Lungs - Blood Gas Analysis Parameters, Including: • pH • PCO_2 • PO_2 • TCO_2	• O_2 Sat. • Actual and standard bicarbonate • Base excess
Liver • Total Protein • Albumin • Globulin • Total bilirubin • Conjugated bilirubin • Unconjugated bilirubin	• ALP • GGT • LDH • AST • ALT
Lipid • Triglyceride • Low density lipoprotein (LDL) (measured and calculated)	• Cholesterol • High density lipoprotein (HDL)
Pancreas • Amylase(excluding P-type)	• Lipase
Cardiac • CK • CKMB (mass & activity) • Troponin (T and I)	• Myoglobin • pro-BNP or BNP • CKMB Index

Endocrine • βHCG • TSH • Free T_3 • FreeT_4	• FSH • E_2 • Prolactin • Progesterone • Free PSA

❁ LH ❁ PSA	
***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 student must be able to demonstrate the ability to identify and act accordingly on critical/panic values where relevant.	
Miscellaneous ❁ Ionized calcium ❁ Iron, transferrin ❁ Ferritin ❁ % Transferrin saturation ❁ Total iron binding capacity ❁ CRP ❁ PCT ❁ Neonatal bilirubin	❁ Magnesium ❁ Inorganic phosphorous ❁ Total and corrected calcium ❁ Glucose ❁ Glucose tolerance (GTT) ❁ HbA1C (Glycated Haemoglobin) ❁ Cholinesterase
URINE	
Urine ❁ Reducing substances ❁ B-HCG ❁ Urea ❁ Sodium ❁ Potassium ❁ Amylase	❁ Chloride ❁ Creatinine ❁ Calcium ❁ Magnesium ❁ Phosphate ❁ Protein
Dipstick ❁ pH ❁ Leucocytes ❁ Nitrates ❁ Glucose ❁ Ketones	❁ Urobilinogen ❁ Bilirubin ❁ Blood ❁ Haemoglobin ❁ Protein ❁ SG

Faeces	
❁ Occult blood/faecal haemoglobin	❁ Reducing substances

CSF	
❁ Glucose	❁ Protein

FLUIDS	
❁ LDH ❁ Glucose ❁ Protein	❁ Differentiation between exudates and transudates

BLOOD	
Toxicology	❁ Salicylates

• Digoxin • Phenytoin • Phenobarbitol • Carbamazepine • Theophylline • Valproic acid • Alcohol • Vancomycin	• Paracetamol • Tricyclic antidepressants • Lithium • Amikacin • Gentamycin • Organophosphates (cholinesterase) • Cyclosporine • Tacrolimus
***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.	

Miscellaneous
• Basic protein electrophoresis. - **Normal electrophoretic pattern**
• Osmolality - measured and calculated
• Ca15-3
• Ca12-5
	• Lactate
	• Ammonia
	• Tumor markers, including:
	  ○ CEA
	  ○ AFP
	  ○ Ca19-9
	  ○ βHCG

URINE	
Urine – Drugs of abuse (including but not limited to): • Cannabis (TCH) • Barbiturates • Benzodiazepine • Cocaine • Opiates	• Methamphetamine / Amphetamine • Methaqualone • Phencyclidine (PCP) • Tricyclic antidepressants

7. MICROBIOLOGY

7.1 Microscopy and staining technique

Objective

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

Specified outcomes

On completion of this section the 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

Faeces Vaginal swabs	Urine

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

Range

Faeces (flotation OR sedimentation)	Urine

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

Range

Urine	Body fluids

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

Range

Cell counts on CSF, pleural fluid, peritoneal fluid, pericardial fluid and synovial fluid, where applicable (Fuchs-Rosenthal OR Improved Neubauer chamber). Staining technique for *Cryptosporidium* India ink for *Cryptococcus neoformans*	Gram's stain KOH for yeasts and fungal elements Lacto-phenol cotton blue Staining techniques for TB smears

Range TB stains

Ziehl-Neelsen Auramine	Cold Kinyoun

7.2 Processing of specimens

Objective

Provide 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 and the accurate interpretation of the results.

Range

✹ Aspirates from normally sterile sites including but not limited to pleural fluid, peritoneal fluid, pericardial fluid, synovial fluid, CSF ✹ Genital specimens ✹ Pus ✹ Stool ✹ Urine	✹ Blood Cultures ✹ Ear, nose & throat swabs ✹ Eye swabs ✹ Respiratory samples ✹ Tissue ✹ IUD ✹ Catheter tips ✹ CVP tips

Specified outcomes

On completion of this section the 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

✹ Atmospheric conditions ✹ Temperature	✹ 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 the preparation and sterilization of culture media necessary for the isolation, identification and sensitivity testing of the micro-organisms listed in this syllabus.

Range

Isolation Media	
✹ McConkey with or without crystal violet ✹ Sorbitol McConkey for EHEC identification ✹ Blood agar ✹ Chocolate/boiled blood agar ✹ XLD	✹ Media for isolation of anaerobes ✹ Naladixic/CN agar ✹ Tellurite agar ✹ TCBS agar ✹ Sabdex agar

❁ Salmonella/Shigella agar ❁ New York City or Thayer Martin ❁ Sabdex & Chlor agar ❁ Thioglycolate Broth	❁ Campylobacter agar OR Blood based agar for Campylobacter isolation ❁ Egg yolk agar
Identification Media	
❁ Bile esculin ❁ DNA ❁ Mannitol salt agar	❁ Carbohydrates (glucose, lactose, sucrose, maltose) ❁ CTA sugars
Antimicrobial sensitivity Testing media	
❁ Mueller Hinton agar ❁ Haemophilus test medium ❁ Mueller Hinton agar with sheep blood	❁ Mueller Hinton agar with laked blood OR Mueller Hinton for Fastidious organisms ❁ Gonococcus sensitivity agar
Chromogenic Media	
❁ Identification of urinary pathogens	

Specified outcomes

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

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

Range

❁ Selective ❁ Non-selective ❁ Enriched	❁ Indicator ❁ Differential

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

Range

❁ Autoclave ❁ Filtration ❁ Tyndallisation	❁ 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 student should be able to:

- Describe 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 and use of automated and semi-automated equipment.

Range

Automated blood culture systems Automated and semi-automated bacterial identification and susceptibility testing systems	Molecular biology amplification and detection systems Automated rapid detection of microorganisms.

- Describe the **application** of the tests as tabulated below.

Range

Glucose, lactose and other carbohydrate utilisation Urea Indole Motility H2S Citrate Decarboxylase Oxidase ONPG Nitrate reduction X and V factors Hippurate Catalase	Coagulase Bile Esculin 6.5% NaCl Bacitracin Optochin Lancefield grouping using Latex kits DNAse Novobiocin CTA sugars Germ tube CAMP Reverse CAMP

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:

Gram stain Colonial morphology on appropriate media Carbohydrate utilisation (glucose, lactose) Oxidase ONPG Basic knowledge of the serotyping of *Salmonella* and *Shigella*	Urea Indole Motility H_2S Citrate Decarboxylase Nitrate

B. Non-fermentative Gram Negative Bacilli

- *Acinetobacter baumannii*
- *Pseudomonas aeruginosa*

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

Gram stain Colonial morphology on appropriate media Carbohydrate utilisation (glucose, lactose)	Motility Citrate Oxidase

C. Miscellaneous Gram Negative Organisms:

- *Campylobacter jejuni*
- *Campylobacter coli*

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

Gram stain Colonial morphology on appropriate media Oxidase Hippurate	Erythromycin Growth conditions

- *Haemophilus influenzae*
- *Haemophilus parainfluenzae*
- *Moraxella catarrhalis*
- *Neisseria gonorrhoeae*
- *Neisseria meningitides*

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

Gram stain, Colonial morphology on appropriate media, Oxidase	Carbohydrate utilization (glucose, maltose) X and V factors

- *Vibrio cholera*

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

Gram stain	Motility

✹ Colonial morphology on appropriate media ✹ Carbohydrate utilization (glucose, lactose, sucrose) ✹ Urea ✹ Indole	✹ H_2S ✹ Citrate ✹ Decarboxylase ✹ Oxidase ✹ ONPG

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*

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

✹ Gram stain ✹ Colonial morphologyon appropriate media ✹ Catalase ✹ Bacitracin	✹ Optochin ✹ Bile esculin ✹ 6.5%NaCl ✹ Lancefield grouping using latex kit tests ✹ CAMP

B. Staphylococci:

- ◎ *Staphylococcus aureus*
- ◎ *Coagulase negative staphylococci*
- ◎ *Staphylococcus saprophyticus*

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

✹ Gram stain ✹ Colonial morphology on appropriate media ✹ Catalase ✹ DNase	✹ 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:

✹ Gram stain ✹ Colonial morphology on sheep blood agar, ✹ Clinical significance	✹ Catalase ✹ Motility ✹ Lecithin

B.Non-Spore-forming gram positive bacilli

- *Corynebacterium diphtheriae*
- *Listeria monocytogenes*

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

Gram stain Colonial morphology on blood agar and tellurite media Motility	Catalase Esculin CAMP

7.4.4 Anaerobic organisms

A.Gram Negative Organisms

- *Bacteroides fragilis* group

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

Gram stain Colonial morphology on appropriate media	Presumptive identification by use of special potency disks: Penicillin (2U), Rifampicin (15ug), Kanamycin (1000µg), Colistin (10µg) Vancomycin (5µg) and Erythromycin (60µg).

B.Gram Positive Organisms

Gram Positive cocci*:*

- *Peptostreptococcus anaerobius*

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 Reverse CAMP
Note: The Nagler test is excluded from this syllabus

7.5 Mycobacteria

Objective

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

Specified outcomes

On completion of this section the 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 *Mycobacterium spp.*

- Detail and accurately apply the IUATLD (ZN & Auramine) and WHO guidelines for the reading and reporting of TB sputum direct smears.

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 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:

Colonial morphology on Sabdex and blood agar Germ tube	Urease

7.7 Susceptibility Testing

Objective

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

Specified outcomes

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

- Apply the correct methods and interpretation for susceptibility testing (either EUCAST or CLSI)
- Demonstrate understanding and application of resistance mechanisms and test procedures.

Range

β-lactamase testing

- Demonstrate an understanding of the methodology of the susceptibility testing methods.

Range

Disk (Kirby Bauer) and breakpoint Minimum Inhibitory Concentration (MIC) by E test	Automated methods

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 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/s of the parasites within the range and the mode of transmission to the human.

Range

Cestodes: *Echinococcus granulosus* (O or H) *Hymenolepis nana* (OO) *Taenia* species (O)	***Nematodes:*** *Ascaris lumbricoides* (O) *Enterobius vermicularis* (O) Hookworms: *Necator americanus* and *Ancylostoma duodenale* (O) *Trichuris trichiura* (O)
Protozoa: *Cryptosporidium parvum* (OO) *Entamoeba histolytica* and *Entamoeba coli* (O) *Giardia lamblia* (C), (T) *Trichomonas vaginalis* (T)	***Trematodes:*** *Schistosoma haematobium* (O) *Schistosoma mansonii* (O)

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 student should be able to:

- Describe the methodology in the below range.

Range of methodologies:

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

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

8. SEMEN ANALYSIS

Objective

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

Specified outcomes

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

- Perform post vasectomy analysis on semen, and limited to commenting on the presence/absence of spermatozoa.

9. HAEMATOLOGY

Objective

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

9.1 Full Blood Count (FBC)

Range

Red cell count	Basophils
White cell count	Haemoglobin
Platelet count	Haematocrit
Neutrophils	MCV
Lymphocytes	MCH
Monocytes	MCHC
Eosinophils	RDW

Specified outcomes

At the end of the training the 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 impedence counting (Coulter principle), and the interpretation of the histograms and scatter plots generated by the auto-analyzer in use at the workplace.
- Describe the relevant changes in the FBC results which could be expected in various clinical states and haematological conditions.

Range of conditions:

Hypochromic microcytic anaemias (Fe deficiency, Anaemia of chronic disorders)	Viral infection, including but not limited to HIV/AIDS, Infectious mononucleosis
Oval Macrocytic anaemias (B12 and Folate deficiency)	Leukaemoid reactions
Hypoproliferative disorders - Aplastic anaemia and Red cell aplasia	Acute and chronic blood loss
Haemolytic anaemias	Acute lymphoblastic and myeloid leukaemias
Plasmodium infection	Chronic myelocytic leukaemia and chronic lymphocytic leukaemia

- Identify and act on critical/panic values/life threatening results for all the parameters in the range, and describe application of all tests in the range.

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

PT INR PTT Fibrinogen	Thrombin time D-dimers Fibrin degradation products

Specified outcomes

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

- Demonstrate understanding of the haemostatic system, including the extrinsic, intrinsic and common pathways, and the factors involved.
- Perform the manual and automated methods for the determination of the tests in the range.
- Describe and utilize manual and automated methodology for the determination of the tests in the range.
- 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 application and significance of the test results.
- Describe the mode of action of heparin and warfarin anticoagulant therapy.
- Demonstrate knowledge of the therapeutic ranges for INR and PTT when used to monitor anticoagulant therapy.

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

9.3 Miscellaneous Haematology Tests

Range

ESR Reticulocyte count	Buffy layer preparations CD4 count

Specified outcomes

At the end of this training the 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.
- Demonstrate knowledge of the application and significance of the final result of the test requested.

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

9.4 Immunohaematology

Range

ABO and Rh blood groups Direct Coombs	Indirect Coombs

Specified outcomes

At the end of this training the 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.

9.5 Peripheral Blood Smear Examination

Specified outcomes

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

- Prepare and stain an optimal peripheral blood smear for microscopic examination, using appropriate methods.
- Demonstrate knowledge of the methodology of a 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 the intracellular inclusions bodies which may be seen in erythrocytes and leucocytes.
- Describe and identify abnormal platelet morphology.
- Confirm the automated results of white cell and platelet counts microscopically.
- Demonstrate knowledge of the application of the histograms and scatter plots generated by the auto-analyzer in use at the workplace
- Identify the below 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

Howell Jolly bodies Pappenheimer bodies Basophilic stippling Punctuate basophilia Heinz bodies Cytoplasmic vacuolization Toxic granulation Döhle bodies Auer rods All stages of malaria parasites (see below); Shuffner's dots Maurer's clefts Cabot rings Platelet clumping 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, mcarcrocytes, microcytes, stomatocytes, teardrop cells and target cells. Rouleaux formation Red cell agglutination

- Demonstrate a basic understanding of the significance of the morphological findings within the range.
- Perform accurate differential counts demonstrating the ability to identify and describe abnormal morphological features associated with the specified conditions.

Range of heamatological conditions:

Hypochromic microcytic anaemias (Fe deficiency, Anaemia of chronic disorders) Oval Macrocytic anaemias (B12 and Folate deficiency) Hypoproliferative disorders - Aplastic anaemia and Red cell aplasia Haemolytic anaemias	Viral infection, including but not limited to HIV/AIDS, Infectious mononucleosis Leukaemoid reactions Acute and chronic blood loss Acute lymphoblastic and myeloid leukaemias Chronic lymphocytic leukaemia Myeloproliferative disorders Myelodysplastic syndromes

9.8 Blood Borne Parasites

Specified outcomes

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

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

Range

Plasmodium species		
Malariae Falciparum	Vivax Knowlesi	Ovale

.

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

Range

Staining techniques for thin and thick smear preparations **–** Romanowsky or Field's.

- 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.
- Describe the relevant morphological changes of all cell lines that are commonly associated with Plasmodium infection.
- Describe and recognize the morphological differences of the different stages of the Plasmodium species and the relevant changes of the infected red cell.
- Perform and interpret (positive, negative, invalid) the antigen test.
- Identify the presence of blood borne parasites other than Plasmodium and take appropriate action (identification of actual genus and species is not required).

Range

Plasmodium (all species listed) Trypanosoma brucei (Gambiense, Rhodesiense)	Blood borne Filariasis, including Wuchereria bancrofti, Brugia malayi, Loa loa, Mansonella perstans

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
CK	=	Creatine Kinase
CAMP	=	Christie Atkins Munch-Petersen
CLAT	=	Crytococcal latex antigen test
CLL	=	Chronic lymphocytic leukaemia
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
ELISA	=	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
PCO_2& PO_2	=	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
T_3	=	Triiodothyronine
T_4	=	Thyroxine
TB	=	Tuberculosis
TCO2	=	Total CO2
TPHA	=	*Treponema pallidum* haemaglutination 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 RECOMMENDED TEXT BOOKS

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
- POSTGARDUATE 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. Sahm 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. Onhel.
- ATLAS OF MEDICAL HELMINTHOLOGY AND PROTOZOOLOGY. (Eds) Jeffrey and Leach.
- EUCAST-standardising antimicrobial susceptibility 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