



SYLLABUS
“Medical Technicians”
“VIROLOGY”

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1. LIST OF ABBREVIATIONS

CEU: Continual Education Units

CMV: Cytomegalovirus

CO₂: Carbon dioxide

CONC: Concentration

CPE: Cytopathic effect

CSF: Cerebrospinal fluid

ELISA: Enzyme Linked Immunosorbent Assay

EQA: External Quality Assurance

HPCSA: Health Professional Council of South Africa

IQC: Internal Quality Control

ISO: International Organisation for Standardisation

MSDS: Material Safety Data Sheet

NHLS: National Health Laboratory Services

OHSA: Occupational Health and Safety

PCR: Polymerase chain reaction

SANAS: South African National Accreditation Systems

SOP: Standard operating Procedure

UV: Ultra violet

2. INTRODUCTION

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

The examination will be based on the contents of this syllabus and related theoretical and practical knowledge gained during study at the HPCSA accredited training facility. The examination consists of two papers, each given two hours. The papers are in a form of written theory and practical.

Please refer to:

- Reference material
- List of abbreviations

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 intern Medical Technicians 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.

Candidates must achieve a minimum mark of **50%** overall and a subminimum of 50% **for each paper**, to pass the examination.

Emphasis will be placed on theoretical knowledge, as expected from any competent laboratory professional. Candidates will not be expected to memories specific details and quantities of reagent preparations. They will however be expected to know the principles of tests

NB: Interns Medical Technicians are reminded that this document is merely a guideline intended to aid the study process. As professionals in a discipline, they are expected to keep their knowledge current and to have an in-depth understanding of their subject.

3. STATUTORY REGULATIONS AND ETHICS

Objective

Provide the intern/student with information on the regulations and ethical principles which underpin the practice of medical laboratory technology.

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Learning outcomes

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

- ✓ Demonstrate knowledge of the structure and function of the HPCSA.
- ✓ Explain the regulations relating to the scope of profession.
- ✓ Describe the legal and ethical standards related to the professional practice of medical technician.
- ✓ Demonstrate knowledge of the requirements for the acquisition of CEUs.
- ✓ Demonstrate knowledge on the practice/ethos of how confidentiality in the workplace is obtained and maintained.
- ✓ Demonstrate knowledge of the National Health Act No. 61 of 2003
- ✓ Demonstrate knowledge of the Health Professions Act No. 56 of 1974
- ✓ Demonstrate knowledge of the Protection of Personal Information Act No. 4 of 2013

Source of information – *Acts, regulations and HPCSA guidelines*

4. TOTAL QUALITY MANAGEMENT SYSTEM

The intern Medical Technician must demonstrate basic knowledge of the principles and practices involving laboratory safety, Quality Management Systems, laboratory accreditation and basic laboratory administration.

Learning outcomes:

On completion of this section, the intern medical technician should be able to:

- ❖ Demonstrate the components involved in a Quality Management System and Laboratory Accreditation (in keeping with the relevant ISO standards) according to the section listed on 3.1 – 3.10.
- ❖ Discuss the concept of laboratory accreditation as defined by the specific standards relevant to medical and public health laboratories.

4.1 LABORATORY HEALTH AND SAFETY

Objective

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

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Learning outcomes

On completion of this section the intern Medical Technician should be able to:

- ✓ Describe the regulations relating to the transport of specimens.
- ✓ Describe the regulations relating to the handling of medico-legal specimens.
- ✓ Explain laboratory safety in relation to the OHSA (1993).
- ✓ List the responsibilities of safety representatives and first aiders as required by the OHSA (1993).
- ✓ Describe the procedures for the storage, handling and disposal of laboratory waste including chemicals, biohazardous waste, human tissue, solid contaminated waste, liquid contaminated waste, sharps and gases.
- ✓ Describe and demonstrate the proper safety precautions while handling and disposing of infectious material including those potentially containing organisms like Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2), Human Immunodeficiency virus (HIV) or Hepatitis Viruses.
- ✓ Describe the safety protocols involved in event of a needle-stick injury and exposure to blood-borne pathogens.
- ✓ Describe the various biosafety level requirements when working with infectious material.
- ✓ Describe the basic concepts from relevant legislation pertaining to laboratory health and safety.
- ✓ List and describe the purpose of each item used for personal protective equipment.
- ✓ Demonstrate knowledge of the procedures to follow in the event of laboratory accident or emergency.
- ✓ Describe the correct procedures for the storage, handling and disposal of laboratory waste.
- ✓ Describe the application of laboratory safety procedures to the collection, transport, storage and analysis of biological specimens including IATA regulations.
- ✓ 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 MSDS.
- ✓ Demonstrate knowledge of the protocols to follow in the event of injuries on duty including needle-stick injury.
- ✓ List and explain the duties of safety personnel.
- ✓ Recognize the international safety symbols used in the laboratory environment.

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- ✓ Demonstrate knowledge of how to use **all** safety and emergency equipment.

Source of information: *Occupational Health and Safety Act, Hazardous Substances Act, Compensation for Occupational Injuries and Diseases Act.*

4.2 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.

Learning Outcomes

On completion of this section the intern Medical Technician should be able to:

- ✓ Demonstrate knowledge of any required patient preparation for the collection of specimens for individual tests.
- ✓ Describe the optimal specimen requirements for the individual tests, i.e., container, quantity, time limits, etc.
- ✓ Describe the conditions under which the specimens must be transported to the laboratory
- ✓ Demonstrate knowledge of the optimal storage conditions should testing be delayed and the stability of the specimen for the individual testing process.
- ✓ Demonstrate knowledge of how to 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, traceability and documentation.
- ✓ Describe the process (identify criteria) for the rejection of unsuitable specimens.
- ✓ Conduct the pre-analytical processes (preparation) required for specimen type and test requested.

4.3 LABORATORY EQUIPMENT

Objective

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

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Learning outcomes – applicable to all equipment, instruments and analyzers

On completion of this section the intern Medical Technician 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 knowledge of performing the correct maintenance, service and calibration requirements within the scope, of the specific instrumentation.
- ✓ Differentiate between calibration, validation and verification.
- ✓ Conduct applicable decontamination procedures.
- ✓ Apply the appropriate functional checks to ensure optimal operation.
- ✓ Describe and implement troubleshooting procedures when optimal operation is not demonstrated by the instrument on-board functional checks.
- ✓ Demonstrate knowledge of the maintenance procedures, all equipment records and documentation required for good laboratory practice.

4.4 LABORATORY REAGENTS

Objective

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

Learning Outcomes

On completion of this section the intern Medical Technician should be able to:

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

Source of information: *Working reagents, controls, calibrators, reagent kits, buffers, physiologically normal saline, molar and molal solutions disinfectants, sterilizers.*

4.5 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:

- ✓ Demonstrate an understanding of the receipt of stock including the required records regarding condition of goods, expiry dates and lot numbers.
- ✓ Demonstrate an understanding of stock rotation with particular reference to expiry dates.
- ✓ Describe the correct storage conditions for all stock.
- ✓ Differentiate between open vial (bottle) stability and expiry date.
- ✓ Demonstrate knowledge of company policy with regard to the use of expired reagents, controls and calibrators.
- ✓ Knowledge of the maintenance of reference Quality Control stock.

4.6 QUALITY ASSURANCE AND ACCREDITATION

Objective

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

Specified outcomes

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

- ✓ Explain 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.
- ✓ Define and explain the terms accreditation, ISO and SANAS.
- ✓ Demonstrate knowledge on the use, performance and evaluation of risk assessments.
- ✓ Define and explain all quality assurance terminology.

Source of information: ISO 15189 – Management requirement (*Non-conformance, corrective action, preventive action, root-cause analysis, continual improvement, audits – internal & external*)

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4.7 QUALITY CONTROL

Objective

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

Learning Outcomes

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

- ✓ Describe and apply the appropriate quality control processes which must be performed and applied in the analysis of all analytes, parameters, reagents, equipment and analysers operation as contained within this syllabus.
- ✓ Explain the principles of IQC and EQA procedures in the context of the tests performed.
- ✓ Demonstrate knowledge and understanding of monitoring, calculations and interpretation of qualitative IQC data.
- ✓ Demonstrate knowledge and understanding of monitoring, calculations and interpretation of quantitative IQC data.
- ✓ Describe the potential causes and apply appropriate troubleshooting procedures in the event of failed IQCs and EQAs for quantitative and qualitative assays.
- ✓ Define and explain all terminology used in the assessment of quality control results.

4.8 PERSONNEL

Objective

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

Learning Outcomes

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

- ✓ List and describe the personal documents and records which are required for all laboratory personnel.
- ✓ Demonstrate an understanding of the terms 'competency' and ongoing competency' in terms of the training of all laboratory personnel.

4.9 DOCUMENTATION

Objective

- ✓ Demonstrate knowledge of basic requirements of documentation in terms of relevant ISO 15189 standard.

Specified outcomes

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

- ✓ Demonstrate knowledge of document control requirements in terms of relevant ISO 15189 standard.
- ✓ Demonstrate knowledge of the required content of SOP's including the minimum content of the cover page.
- ✓ Demonstrate knowledge on document control
- ✓ Differentiate between a record and document.

Source of information: *Policies, procedures (SOPs), working instructions, raw data, equipment records, quality control records, personnel records, package inserts.*

5. LABORATORY RELATED MATHEMATICS

Objective

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

Specified outcomes

- ✓ Demonstrate proficiency in the calculations required for accuracy, specificity, sensitivity, precision, mean, standard deviation, co-efficient of variance:
- Demonstrate proficiency in the calculations required for the preparation of reagents and solutions.

Source of information: Basic calculations using formulas in making laboratory solutions

$$C1V1 = C2V2$$

$$\#moles = \text{mass/molar mass} \text{ (mg, g, kg)}$$

$$\text{Conc.} = \#moles/volume \text{ (ul, ml, l)}$$

Key: # = number of

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6. EQUIPMENT AND AUTOMATION

Objective

To obtain a basic knowledge and understanding of laboratory equipment and other automated systems in-use in the laboratory environment.

Learning Outcomes

On completion of this section, the intern Medical Technician should be able to:

- Describe the use of the following types of laboratory equipment / instrumentation under the following headings:
 - ❖ Principles of use
 - ❖ Operation, Maintenance and Trouble-shooting
 - ❖ Quality Control
 - ❖ Record-keeping
 - ❖ Calibration, where applicable
- ✓ Demonstrate knowledge of the makes and models in-use in the current workplace such as the following:
 - ❖ Laboratory instrumentation
 - ❖ Automated and semi-automated testing
- ✓ Describe the use of the following - **Standard laboratory equipment:**
 - Fridges
 - Freezers
 - Stopwatches/timers
 - Centrifuges
 - Bio-hazardous safety cabinets – Class I and II
 - Fume hood/cupboard
 - Balances – top pan and fine analytical chemical
 - Magnetic and non-magnetic stirrers
 - Pipettes – glass, disposable, adjustable & fixed volume pipettes, automated and air displacement
 - Pipette aids – rubber teats, pro-pipettes and dispensers
 - Water baths
 - pH meters
 - Rotators shakers

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- Flat bed and vortex mixers
- Thermometers - min/max, electronic and mercury
- Immunoassays incubators and washers used in Virology
- Molecular biology amplification and detection systems
- Spectrophotometers
- Automated rapid detection of Viruses

(The systems have been listed generically, to allow for inter-laboratory differences between specific types/makes of instruments used. The student is expected to have a basic understanding **of one example of each**).

7. VIRUSES and the CLINICAL DIAGNOSTIC LABORATORY

Learning Outcomes

On completion of this section, the intern Medical Technician should be able to:

- Compare the sizes of viruses
- Describe structure and compositions of viruses
- Be familiar with species names and nucleic acid composition
- Be familiar with viral replication
- Be familiar with routes of transmission and mechanisms for pathogenesis
- Describe approaches for diagnosing viral disease

8. CELL CULTURE and VIRUS ISOLATION

Learning Outcomes

On completion of this section, the intern Medical Technician should be able to:

- Describe the storage and transport of clinical samples for virus isolation
- Describe viral transport media, listing components and their purpose.
- Define cytopathic effects (CPE) for common viruses isolated in cell culture such as Respiratory viruses, Herpesviruses and Enteroviruses.
- Name the various cell types used for diagnostic virology.

9. VIRAL IMMUNOLOGY

Learning Outcomes

On completion of this section, the intern Medical Technician should be able to:

- Explain the concept of vaccination.

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- Compare attenuated vaccines and inactivated vaccines.
- For the following serological principles give an overview of the procedural steps: direct haemagglutination, passive haemagglutination, viral haemagglutination, haemagglutination inhibition, direct and indirect immunofluorescence, and virus neutralisation.

10. SEROLOGICAL DIAGNOSIS of VIRAL INFECTION

Learning Outcomes

On completion of this section, the intern Medical Technician should be able to:

- Give an overview of the steps required for Indirect and Direct ELISAs.
- List and explain the mechanical factors affecting ELISA assays.
- Discuss the reasons for having controls and calibrators.
- Discuss the mechanical factors affecting ELISA's
- List and explain the purpose each reagent reagents used in ELISA's
- Describe the proper collection and storage of blood samples that will be tested for viral antibodies.
- Illustrate with a labelled diagram the structure of HIV
- List and explain the properties, characteristics and classification of HIV
- Outline the precautions taken in your laboratory to minimise HIV infection.
- Describe and perform the screening and confirmatory tests done in your laboratory for HIV and explain their significance in the diagnosis of HIV/AIDS

11. MOLECULAR DIAGNOSTIC VIROLOGY

Learning Outcomes

On completion of this section, the intern Medical Technician should be able to:

- Describe the principle of a PCR.
- Explain controls necessary for a PCR.
- List and explain the purpose of each reagent used in PCR.
- Explain factors that can affect a PCR.
- Describe the workflow dynamics in a PCR laboratory.
- List and explain the steps required to prevent PCR contamination.
- Describe the safety aspects of working with specimens, reagents and equipment in the PCR laboratory.

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- Explain the procedures necessary to discard PCR products.
- Explain the role the detector chemicals such as Gel Red/ Green in gel electrophoresis.

12. DNA VIRUSES

Objective

To obtain a basic knowledge and understanding of virus that cause human infection and disease.
Examples:

- *Adenoviridae*: e.g. Adenovirus
- *Hepadnaviridae*: e.g. Hepatitis B virus
- *Herpesviridae*: e.g. Herpes simplex virus type 1 and 2, Varicella-zoster virus, Cytomegalovirus; Epstein-Barr virus; Human herpes virus 6 and 7; Kaposi sarcoma virus
- *Papillomaviridae*: e.g. Papillomaviruses types 16 and 18
- *Polyomaviridae*; e.g. JC virus
- *Parvoviridae*: e.g. Human parvovirus B19

Learning Outcomes

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

- ✓ Name the DNA viruses associated with human viral infection.
- ✓ List disease or syndromes and transmission dynamics for each virus.
- ✓ Indicate which types of clinical samples should be collected and submitted for diagnosis.

13. RNA VIRUSES

Objective

To obtain a basic knowledge and understanding of virus that cause human infection and disease.
Examples:

- *Coronaviridae*: e.g. SARS-CoV-2
- *Orthomyxoviridae*: e.g. Influenza virus A, B, and C
- *Paramyxoviridae*: e.g. Measles; Mumps; Parainfluenza 1,2,3, and 4; Respiratory syncytial virus (RSV); Human Metapneumovirus (hMPV)
- *Picornaviridae*: e.g. Enterovirus; Coxsackie A and B; Echovirus; Poliovirus; Hepatitis A; Rhinovirus
- *Retroviridae*: e.g. HIV type 1
- *Rhabdoviridae*: e.g. Rabies virus

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- *Togaviridae*: e.g. Rubella virus
- *Flaviviridae*: Hepatitis C virus, Dengue fever Virus, Yellow fever Virus
- Other RNA viruses
 - Diarrhoeal associated viruses: e.g. Rotavirus, Astroviruses, Caliciviruses e.g. Norovirus and Sapovirus
 - Viral haemorrhagic fever viruses:
 - *Filoviridae*: e.g. Ebola virus),
 - *Arenaviridae*: e.g. Lassa fever virus,
 - *Flaviviridae*: e.g. Dengue fever virus, Yellow fever Virus, and
 - *Bunyaviridae*: e.g. Crimean-Congo haemorrhagic fever virus, Rift valley fever viruses
 - Hepatitis E.

Learning Outcomes

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

- ✓ List disease syndromes and vector to which each virus is commonly associated.

14. REFERENCE MATERIAL

- Fenner and White' Medical Virology. Eds Christopher J. Burrell, Colin R. Howard, Frederick A. Murphy. 5th edition. Elsevier. 2016.
- Lennettes Laboratory Diagnosis of Viral Infections. Ed Keith R. Jerome. Routledge Taylor and Francis group. 4th Edition. 2010.
- Virology: An Illustrated Colour Text. Eds. Stephen N J Korsman, Gert Van Zyl, Wolfgang, Louise Nutt, Andersson Monique. Churchill Livingstone Elsevier. 2012

15. ASSESSMENTS EXPLANATORY WORDS LIST

In order to assist the trainer and examiner to capture a specific level of knowledge and the intern/student with the interpretation of questions, a list is provided which gives a description of what is needed for a specific verb during questioning in assessment.

Explanatory list of words

Classify	Arrange information in categories.
Correct	Identify and remedy mistakes, identify false statements and correct them.
Define	Give a clear, systematic and authoritative explanation (description of concepts to reflect the precise meaning thereof).
Describe	Write the basic facts/results down in a logical, systematic and well-structured manner.
Give an explanation	Make a summary of the main facts of a subject in clear, logical sequence so that differences, similarities and points of reference are clearly indicated.
Give an outline	Give a framework consisting of main facts and relevant information in support of these facts. It is not necessary to write down a detailed discussion.
Identify	Reproduce the essential characteristics (main facts).
Name	Make short notes of the required information, but do not discuss it in detail
Summarize / Give a summary	Give a resume of the most important facts without detail, illustrations, critical analysis or discussion.
Use	Make use of information or subjects supplied to illustrate/explain a specific viewpoint.
Write notes on	Comment in short explanation (clarification) on a given subject.
Contrast	Emphasize the differences, contrasts and anomalies of facts or events by using analysis, discussion, and examples.
Determine	Calculate, compare

Determine	Prove, make a diagnosis by using facts and commentary.
Explain	Give a clear explanation (exposition). Elucidate by means of examples and/or illustrations and give reasons for pronouncements or results.
Illustrate	Use a sketch, diagram, graph or concrete item to explain a concept or solve a problem. It can also mean to give examples in well chosen, descriptive words.
Apply	Show the application of acquired knowledge or given information in practice; or in relation to what is asked. Use the knowledge to reach an answer to the question.
Calculate	Use the information given to reach a sensible and acceptable answer/result.
Demonstrate	Explain by using a sketch, model, picture, graph or a concrete subject. It may also imply a well-thought out and well-formulated description.
Interpret	Comment on available facts, with reference to applicable examples. Give a clear indication of own interpretation.
Solve	Explain, prepare well thought-out answers/recommendations.

Approved		Date:	Comments:
Not Approved		Date:	Comments:

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