SYLLABUS

TB

MEDICAL TECHNICIAN

PBMT Approved July 2022 for training implementation Jan 2023

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CONTENTS

1. INTRODUCTION

The objective of this syllabus is to provide the 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 examination is in the form of two, two hours, written practical papers which will be based on the contents of this syllabus.

Candidates are required to attain a minimum of 50% overall and a sub-minimum of 50% for each of the papers.

Please refer to:

- 13. Reference material
- 14. Nomenclature / Acronyms

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

3. TOTAL QUALITY MANAGEMENT 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 relating to laboratory safety procedures.

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 - *Chemical or bio-hazardous spill; Fire; Flood; Bomb threat*

- Describe the correct procedures for the storage, handling and disposal of laboratory waste.
- Describe the application of laboratory safety procedures to the collection, transport, storage and analysis of biological specimens including the International Air Transport Association (IATA) regulations.
    - Range - *Biological specimens; Human tissue; Solid and liquid bio-hazardous waste; Radioactive waste; Sharps*
- Describe the basic principles for the storage, handling and disposal of chemicals; poisons; flammable substances; gases and infectious material.
- Describe procedures to follow for the prevention, control and management of laboratory acquired infections including general housekeeping and decontamination of equipment.
- Describe the purpose and basic content of the material safety data sheets (MSDS).
- Demonstrate knowledge of the protocols to follow in the event of injuries on duty including needle-stick injury.
- Define the role of the designated safety personnel.
    - Range - *Fire marshal; Safety representative; First aid officer*
- Recognise the international safety symbols used in the laboratory environment.
- Demonstrate knowledge of all safety and emergency equipment.
- Understand and explain the various bio-safety levels when working with infectious material.
- Discuss positive and negative pressure in a Bio Safety Level 3 laboratory.

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:

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

- Name the various anatomical sites from which specimens for TB examination may originate.
- Name the various types of specimens obtained from each site.
- Collect specimens as defined within current statutory requirements and limitations.

3.3 LABORATORY EQUIPMENT

Objective

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

Specified outcomes– applicable to all equipment/instruments and analysers

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

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

Laboratory instrumentation and automated analysers are included in this range.

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:

Demonstrate knowledge of the objective, use and retention of package inserts/ instructions for use (IFU's).

- Prepare, store, and safely dispose of laboratory reagents including working reagents
- Define terms and solutions used in the laboratory:
  Range - *Physiologically normal saline; Buffer; Stains – refer to Section 10. Microscopy and staining techniques; Reagents – refer to Section 6. Sterilisation and disinfection; and 8. Media*

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:

- Demonstrate knowledge of the basic principles to apply when managing merchandise stock.
- Demonstrate an understanding of the receipt of stock including the required records regarding condition of goods, expiry dates and lot numbers.
- Demonstrate an understanding of stock rotation with particular reference to expiry dates.
- Describe the correct storage conditions for all stock.
- Demonstrate knowledge of workplace policy with regard to the use of expired reagents, controls.
- Knowledge of the Maintenance of Reference Quality Control stock.

3.6 QUALITY ASSURANCE / ACCREDITATION

Objective

Expose the student to all aspects of quality assurance.

Specified outcomes

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

- Discuss quality assurance and quality control in the correct context.
- Define and apply the appropriate processes of quality assurance in the pre-analytical, analytical and post analytical areas of specimen handling.
- Demonstrate general knowledge on the terms accreditation, International Organisation for Standardisation (ISO).
- Demonstrate general knowledge on the use, performance and evaluation of RISK assessments.
- Have knowledge/understanding of the importance of CLSI guidelines used in the laboratory.
- Define and explain all quality assurance terminology.
    - Range -
        - Non-conformance
        - Corrective action
        - Preventive action
        - Root cause analysis
        - Continual improvement of quality assurance and quality control processes
        - Audits – Internal & External

3.7 QUALITY CONTROL

Objective

Expose the student to all aspects of quality control.

Specified outcomes

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

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

3.8 METHOD VALIDATION

Objective

Expose the student to all aspects of method validation.

Specified outcomes

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

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

3.9 PERSONNEL

Objective

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

Specified outcomes

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

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

3.10 DOCUMENTATION

Objective

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

Specified outcomes

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

- Demonstrate knowledge of document control requirements in terms of relevant ISO standards.
- Demonstrate knowledge of the required content of SOP's including the minimum content of the cover page.
- Know the process on how to render documents obsolete.
- Demonstrate knowledge on the retention and disposal of this documentation.
- Demonstrate knowledge on document control and regular review of prescribed documentation.
- Differentiate between a record and document.
- Explanation/Description of the records needed to prove an audit trail on all procedures performed. This includes knowledge of the time, condition, as well as raw data (paper or electronic storage).
    - 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 to 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.

Range - *Physiological saline; Percentage solutions*

5. MOLECULAR BIOLOGY

Objective

Provide student with a foundation 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 should be able to:

- Describe workflow dynamics in a molecular biology laboratory.
- Demonstrate a fundamental knowledge of the function of DNA in terms of structure, replication, transcription and translation.
- Discuss the principle of the polymerase chain reaction (PCR) and the steps involved.
    - Range - *Denaturation; Annealing; Extension*
- Demonstrate knowledge of the quality controls used in the assay procedure.
- Identify the potential causes of false positive and negative results.
- Discuss DNA extraction from biological samples.
- Describe the polymerase chain reaction (PCR) under the following headings:
    - Applications, advantages and disadvantages.
    - Understanding of the function of each component of a PCR mix.
    - Inhibiting factors.
- Prepare and process specimens according to the algorithm of the National Tuberculosis Program (NTBP)
- Have knowledge of the South African national protocol for diagnosis and treatment of Mycobacterium tuberculosis, with specific reference to section 4.1 (XPERT diagnostic algorithm)

- Discuss the applications of molecular probe assays.
- Demonstrate an understanding of agarose gel electrophoresis by discussing the following:
    - Procedure and applications.
    - Preparation and loading of a gel.
    - Quality control.

- Describe real-time PCR under the following headings:
    - Procedure and applications
    - Advantages and disadvantages

6. STERILIZATION AND DISINFECTION

Objective

To obtain a basic knowledge of the applications of sterilization and disinfection procedures in the clinical laboratory setting.

Specified outcomes

At the end of this section the candidate should be able to:

- Name the applications of sterilization in the laboratory under the following :
  - Autoclaves
  - Gas sterilization (formaldehyde)

- Discuss the sterilization methods under the following:
  - Heat
  - Filtration
  - Irradiation
  - Chemical disinfection

- Discuss the use of disinfectants used in a laboratory environment regarding the following compounds:
  - Chlorines
  - Alcohols
  - Phenolics
  - Aldehydes
  - Peracetic acid

7. GENERAL BACTERIOLOGY

Objective

To provide the candidate with an overview of classification of organisms and understand how Mycobacterium species is classified.

Specified outcomes:

At the end of this section the candidate should be able to :

- Provide a simple classification of micro-organisms of medical importance regarding:
  - The organism group
  - An example of the group
  - Microscopic description
  - Disease/s caused by the organism

For example:

Organism group	Example	Microscopic description	Disease
Fungi	Candida Dermatophytes	Gram positive, round/oval bodies on wet preparation Various structural forms stained with LPCB	Thrush Ringworm
Protozoa	P. falciparum	Various forms stained with Giemsa stain	Malaria
Viruses	Hep B virus HIV	- -	Viral hepatitis AIDS
Bacteria	*E. coli* *S. aureus* *N. gonorrhoeae* *S. typhi* *T. pallidum* *M. tuberculosis* *M. leprae*	Gram negative bacilli Gram positive cocci Gram negative cocci Gram negative bacilli - Acid fast bacilli Acid fast bacilli	UrinaryTract Infection(UTI) Boils Gonorrhoea Typhoid fever Syphilis Tuberculosis (TB) Leprosy

- Define the following terms:
    - Saprophyte
    - Parasite
    - Commensal
    - Pathogen
    - Infection

- Describe the different modes of transmission of infection
- Discuss host defence mechanisms
- Describe the pathogenesis of *M .tuberculosis* and contributing risk factors.
- Differentiate between *M. tuberculosis* complex and Bacillus Calmette Guerin (BCG)
- *M. bovis* intended as a vaccine strain.

8. MEDIA

Objective:

To enable the candidate to understand the use of media available for the isolations, identification and susceptibility testing of *Mycobacterium species*.

Learning outcomes

At the end of this section the candidate should be able to:

- Discuss the preparation and sterilization of media necessary for the isolation, culture and susceptibility testing of *Mycobacterium species*.
    - Physiological saline
    - Phosphate buffered saline
    - Sodium hydroxide
    - Sodium Citrate
    - N-acetyl L-cysteine
    - Middlebrook 7H9
    - Middlebrook 7H11
    - Lowenstein-Jensen medium
    - TB broth
    - Tween 80

- List the main ingredients and describe their purpose.
- Discuss quality control procedures employed to ensure quality of media.

9. PROCESSING OF SPECIMENS

Objective:

To enable the candidate to understand proper processing of various specimens.

Learning outcomes

At the end of this section the candidate should be able to:

- Prepare and process samples including the decontaminating methods.
- Discuss the use of aseptic techniques during processing of specimens for TB culture
    - Sterile pipetting
    - Avoiding contamination of the work area while decanting
    - Sterile transfer of live cultures to media etc.
- Process direct AFB positive samples using molecular technology according to the algorithm of the NTBP (National Tuberculosis Program) requirements
    - *See section 5 on Molecular Biology*

10. MICROSCOPY AND STAINING TECHNIQUES

Objective

To enable the candidate to understand the principles of the methods, use and application of microscopy techniques in a diagnostic TB laboratory.

Specified outcomes:

At the end of this section the candidate should be able to:

- Demonstrate sound knowledge of the following staining techniques(including quality control):
  - Gram stain
  - Ziehl-Neelsen stain
  - Auramine stain
  - Kinyoun stain
- Describe the microscopic identification of *Mycobacterium species*.
- Discuss the IUALTD (International Union Against Tuberculosis and Lung Diseases) and WHO (World Health Organization) guidelines for the reading and reporting of TB sputum direct smears.
- Know the component parts of the following microscopes and the paths of the optical rays.
  - Light
  - Fluorescent

- Describe with the aid of a diagram, the components and light path of each of these microscopes
- Discuss the use and application in a clinical laboratory setting of each of these microscopes
- Describe/discuss the maintenance of each type of microscope.

11. CULTURE

Objective

To enable the candidate to identify the genus *Mycobacteria* by using various cultural techniques.

Specified outcomes

The candidate should be able to discuss the identification of *M. tuberculosis* and Non-tuberculous Mycobacteria (NTMs) in detail under the following headings:

- Cultural morphology

- Growth requirements
- Incubation temperature
- Incubation periods
- Isolation (culture) of Mycobacteria using conventional (solid and liquid media) and automated systems (e.g. MGIT)
- Theoretical difference between *Mycobacterium tuberculosis complex* and the Bacillus Calmette-Guerin (BCG) (*M.bovis*) vaccine strain.
- Basic identification of Non-tuberculous Mycobacteria (NTMs)

Niacin, PNBA (para-nitro-benzoic acid), ZN stain

Runyoun Classification of NTM's and differentiation using biochemical tests, growth temperature and other growth requirements (one example from each group):

Nonchromogens: M. avium- intracellulare group

Photochromogens: M. kansasii

Rapid growers: M. fortuitum group and M. chelonei

Scrotochromogens: M. scrofulaceum

Have knowledge of the South African national protocol for diagnosis and treatment of Mycobacterium tuberculosis, with specific reference to **section 4.1 XPERT diagnostic algorithm.**

12. DRUG SUSCEPTIBILITY TESTING (DST)

Objective

To enable the candidate to gain an understanding of the principles and procedures of drug susceptibility testing.

Specified outcomes

At the end of this section the candidate should be able to:

- Name the antibiotics used in TB treatment (first line, second line and third line)
- Describe what is meant by multi-drug resistant (MDR) and extensive-drug resistance (XDR).
- Know the principles of the following drug susceptibility testing methods:
    - Phenotypic method (proportion method)
    - Molecular method

13. REFERENCE MATERIAL

The following list of books is included merely as a guide; there are many other suitable textbooks available.

- **Bailey & Scott's Diagnostic Microbiology.** 12th Edition- 2007.Betty A Forbes Daniel F Sahm and Alice S Weissfeld

- **Colour Atlas Textbook of Diagnostic Microbiology**. 7th Edition-2017. Procop,G.W, Church,D.L,Hall,G.S, Janda,W.M, Koneman,E.W, Screckenberger,P.C,Woods,G.L. (Wolters Kluwer)

- **Manual of Clinical Microbiology.** (Eds) Albert Balows, William Hausler et al. American Society of Microbiology.

- **Medical Microbiology: A guide to Microbial Infections: Pathogenesis, Immunity, Laboratory Investigation and control**. Nineteenth edition-2018. Barber,M.R , Irving, W, Swann, A, Perera,N.

- **Introduction to Medical Laboratory Technology** – Eds. F J Baker, R E Silverton and C J Pallister. 7th edition, 1998. Hodder Arnold publication

Other Learning material

- **SA National TB protocol : https://www.tbonline.info/media/uploads/documents/national_tuberculosis_management_guidelines_%282014%29.pdf**

- https://www.who.int

- https://www.cdc.gov

- **MGIT manual : https://www.finddx.org/wp-content/uploads/2016/02/mgit_manual_nov2006.pdf**

- **TB training manual** PDF published 2005 : https://www.westerncape.gov.za

- **Statistics South Africa :** https://www.tbfacts.org

14. NOMENCLATURE/ACRONYMS

AFB	Acid-fast bacilli
BCG vaccine	Bacillus of Calmette and Guerin vaccine
CEU	Continuous Educational units
DNA	Deoxyribonucleic Acid
EQC	External quality control
GLP	General Laboratory Practice
HPCSA	Health Professions Council of South Africa
ISO standards	International Organization for Standardization
IQC	Internal quality control
IUALTD	International Union Against Tuburculosis and Lung Diseases
MDR	Multi-drug resistance
MGIT	Mycobacteria Growth Indicator Tube
MOTT	Mycobacteria Other Than Tuberculosis
NTM	Non-tuberculous Mycobacterium
NTBP	National Tuberculosis Program
NTM	Non-tuberculous Mycobacteria
OHS Act (1993)	Occupational Health and Safety Act of 1993
PBMT	South African Professional Board for Medical Technology
PCR	Polymerase chain reaction
RNA	Ribonucleic Acid
SABS	South African Bureau of Standards
SOP	Standard operating procedure
TB	Tuberculosis
UTI	Urinary Tract Infections
WHO	World Health Organization
XDR	Extensive-drug resistance
ZN	Ziehl-Neelsen