SMLTSA
Science I Technology I People

HPCSA
Health Professions Council of South Africa

# SYLLABUS

# CLINICAL CHEMISTRY

# MEDICAL TECHNICIANS

**Effective from October 2024 examinations**

**PBMT approved in September 2022 for training implementation in 2023 for students who write from October 2024 onwards**



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# CONTENTS

# 1. INTRODUCTION

The objective of this syllabus is to provide the students 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, Clinical Chemistry (Chemical Pathology) Technician's examination.
**The candidates are expected to be able to correlate their Practical knowledge and laboratory testing with the Clinical condition.**

**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 and related theoretical and practical knowledge.

Candidates are required to attain a minimum of 50% in each paper.

***Please refer to:***

Section 7: Reference material/ textbooks

Section 8: Definitions of acronyms contained in the syllabus

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 students receive appropriate training in the tests contained within the syllabus but which are not routinely performed on site.

# 2. STATUTORY REGULATIONS AND ETHICS

**Objective**

Provide the student with information on the regulations and ethical principles which apply to the practice of medical Technicians.

**Specified outcomes**

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

a. Demonstrate knowledge of the structure and function of the Health Professions Council of South Africa.
b. Demonstrate knowledge of the structure and function of the Professional Board for Medical Technology.
c. Discuss the regulations relating to the scope of practice for Medical Technicians.
d. Describe the legal and ethical standards related to the professional practice of medical Technicians.
e. Demonstrate knowledge of how confidentiality applies to his/her workplace and all the results obtained.
f. Demonstrate basic knowledge of: National Health Act, 2004: no. 61 of 2003
g. Demonstrate knowledge of the requirements for the acquisition of continual education units (CEUs).

# 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:

a. Explain and apply the fundamental concepts of the relevant legislation pertaining to laboratory safety.
   **Range**, Occupational Health and Safety Act; Compensation for Occupational Injuries and Diseases Act; Hazardous Substances Act.
b. Demonstrate knowledge of the protocols to follow in the event of injuries on duty including needle-stick injury.
c. Demonstrate knowledge of the procedures to follow in the event of laboratory accident or emergency and the use of all safety and emergency equipment.
   **Range:** Chemical or bio-hazardous spill; fire; flood; bomb threat.
d. Demonstrate knowledge of the procedures to follow when handling a suspected case of any of the Viral Haemorrhagic Fevers
e. Describe procedures to follow for the prevention, control and management of laboratory acquired infections including general housekeeping and decontamination of equipment.
f. Describe the application of laboratory safety procedures to the collection, transport, packaging, storage and analysis of biological specimens. Have a basic knowledge of the role / purpose of IATA procedures.
g. Describe the purpose and basic content of the material safety data sheets (MSDS).
h. Describe the basic principles for the storage, handling and disposal of chemicals; poisons; flammable substances; gases and infectious material.
i. Describe the correct procedures for the storage, handling and disposal of laboratory waste.
   **Range:** biological specimens; human tissue; solid and liquid bio-hazardous waste; radioactive waste and sharps.
j. Define the role of the designated safety personnel.
   **Range:** First aid officer; fire marshal; safety representative.
k. Recognize the international safety symbols used in the laboratory environment.
l. Understanding the use of Personal Protective Equipment (PPE) in the Laboratory environment.

## 3.2 SPECIMENS

**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 test specified throughout this syllabus.

**Specified Outcomes**

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

a. Demonstrate knowledge of any required patient preparation for the collection of specimens for individual tests.
b. Describe the mode of action of the various anticoagulants / preservatives.
c. Select the correct anticoagulant / preservative for the analysis to be performed.
d. Describe the optimal specimen requirements for the individual tests.
e. Describe the conditions under which the specimens must be transported to the laboratory.
f. Display knowledge of the optimal storage conditions should testing be delayed and the stability of the specimen for the individual testing process.
g. Capture the data and patient demographics that are required for the registration of the specimens at the laboratory accurately.
h. Explain the principle of continuous identification of the specimen, aliquots and documentation.
i. Describe the process for the rejection of unsuitable specimens.
j. Conduct the pre-analytical processes required for specimen type and test requested.

## 3.3 LABORATORY EQUIPMENT

**Objective**

Provide details of the correct use, maintenance of laboratory equipment and the appropriate troubleshooting procedures to apply when indicated.

**Range:** All glassware – volumetric and graduated; pipettes (glass, automated and disposable); dispensers; balances (top pan and fine chemical); stirrers; hotplates; pH meters; rotators; shakers; roller, flat bed and vortex mixers; pro-pipettes, rubber teats, pipette aids; fume cupboards; bio-hazardous safety cabinets (Class I and II); centrifuges (including micro haematocrit, safety, temperature controlled, ultra-); water-baths; stopwatches and or timers; spectrophotometers; thermometers min/max, electronic and mercury; hot-air ovens; filtration; desiccators; fridges, freezers.

Laboratory instrumentation and automated analyzers are included in this range – knowledge of the use and maintenance of instruments in use in the current workplace is required.

**Specified outcomes – applicable to all equipment/instruments and analyzers**

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

a. Operate all equipment optimally in accordance with recommended operating procedures.
b. Apply the correct safety precautions during the operation and maintenance of equipment.
c. Demonstrate full knowledge of, and apply, the correct maintenance, service and calibration requirements.
d. Conduct applicable decontamination procedures in accordance to manufacturers recommended operational procedures/SOP's.
e. Apply the appropriate functional checks to ensure optimal operation.
f. Describe and implement troubleshooting procedures when optimal operation is not demonstrated by the functional checks.
g. Demonstrate full knowledge of, and maintain, all equipment records and documentation required for good laboratory practice.

## 3.4 LABORATORY REAGENTS

**Objective**

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

**Range:** Stock solutions; working solutions; working reagents; controls; calibrators; reagent kits.

**Specified outcomes**

a. Define terms and solutions used in the laboratory:

**Range:** Molar and Molal solutions, physiologically normal saline, buffer, SG, calibrators, controls

b. Prepare, store, and safely dispose of laboratory reagents.
c. Demonstrate knowledge of the objective, use and retention of package inserts.

***Note:*** In addition refer to **Section 4**: Laboratory related mathematics.

### 3.5 STOCK CONTROL

**Objective**

Provide details of the processes involved in good stock management**.**

**Specified outcomes**

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

a. Demonstrate an understanding of the receipt of stock including the required records regarding condition of goods, expiry dates and lot numbers.
b. Demonstrate an understanding of stock rotation with particular reference to expiry dates.
c. Describe the correct storage conditions of stock.
d. Differentiate between open vial stability and expiry date.
e. Demonstrate knowledge of 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.

**Specified outcomes**

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

a. Discuss quality assurance and accreditation in the correct context.
b. Define and apply the appropriate processes of quality assurance in the pre-analytical, analytical and post analytical areas.
c. Demonstrate an in depth knowledge of principles and practice of laboratory Quality Assurance and Good Laboratory Practice (GLP).
d. Demonstrate knowledge of the Accreditation system and process, related to ISO 15189.
e. Define and explain all quality assurance terminology.

**Range**: Non-conformance, Corrective action, Preventive action, Root cause analysis, Continual improvement and Audits: Internal and External, Onsite, virtual, desktop, horizontal, vertical, witnessing etc

## 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:

a. 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.
b. Explain the principles of internal (daily / inter lab correlation / pooled sera) and external quality control procedures in the context of the tests performed.
c. Apply a sound knowledge of all the principles, procedures, calculations and interpretation of all related internal and external, ***quantitative*** quality control data. – Maths
d. Apply a sound knowledge of all the procedures, principles and interpretation of internal and external ***qualitative*** quality control data.
e. Describe the potential causes and apply appropriate troubleshooting procedures in the event of failed Internal and external, quantitative and qualitative quality control
f. Define all terminology used in the assessment of quality control results.
   **Range**: Westgard rules; shift; trend; outlier; positive and negative bias; specificity; sensitivity; systemic error; random error; delta difference; control limits / acceptable range; linearity; reportable range / analytical range, %CV, SD, LJ Charts, %Error, %D, accuracy, precision
g. Describe and apply the appropriate quality control for all testing procedures included in this syllabus.

***Note:*** In addition refer to **Section 4**: Laboratory related mathematics.

## 3.8 METHOD VALIDATION

**Objective**

Expose the student to all aspects of method validation.

**Specified outcomes**

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

a. Demonstrate basic knowledge of Validation and verification requirements in terms of relevant ISO standards. Differentiate between validation and verifications
b. Differentiate between quantitative, semi-quantitative and qualitative validation and verifications
c. Basic knowledge of the following statistical analysis
   **Range:** Bias (proportional and constant), Biological variation, Slope, Intercept, r-value, Upper and Lower limit of acceptance, reference range / normal range; analytical range / reportable range; linearity, specificity; sensitivity, within run and between run precision studies, correlation

### 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:

a. Describe the personal documents and records which are required for all personnel.
b. Demonstrate an understanding of the terms 'competency' and 'ongoing competency' in terms of the training of all laboratory personnel.

### 3.10 DOCUMENTATION

**Objective**

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

**Range:** Policies; SOPs; equipment records; quality control records; personnel records; package inserts; patient records

**Specified outcomes**

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

a. Demonstrate knowledge of document control requirements in terms of relevant ISO standards.
   **Range:** Issue of new documents; frequency of review; process for obsolete documentation; document retention and disposal.
b. Demonstrate knowledge of the required content of SOPs.
c. Demonstrate knowledge of record retention in terms of relevant ISO standards.
d. Differentiate between a record and document.

## 4. LABORATORY RELATED MATHEMATICS

**Objective**

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

**Specified outcomes**

a. Demonstrate ability to accurately apply the correct formula used in the calculation of patient results.

   **Range:** Calculated osmolality; LDL ; Unconjugated Bilirubin ;anion gap; globulin estimation; corrected calcium; uncorrected and corrected creatinine clearance; 24hr Urine (DU); unit conversions; GFR, Manual test calculations

b. Demonstrate proficiency in the calculations required for the preparation of solutions or patient samples.
   **Range:** Physiological normal solutions; percentage solutions; dilutions; serial and doubling dilutions.

c. Calculate parameters used in the assessment of quantitative quality control results.
   **Range:** %CV; SD; %Error; %D, mean; median; Bias (proportional and constant), Slope, Intercept, r-value, Upper and Lower limit of acceptance.

## 5. MOLECULAR BIOLOGY

**Objective**

Provide the student with the foundation knowledge of basic molecular biology as applied to techniques used in the testing of specimens in Clinical Chemistry.

**Specified outcomes**

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

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

# 6. MODULES

## 6.1 QUANTITATIVE ANALYSIS

**Objective**

Provide theoretical and practical knowledge of the quantitative analytical processes used in the testing of specimens in Clinical Chemistry.
**Range**: Blood / Serum / Plasma: timed, fasting and random; Urine: timed and random; CSF; body fluids; aspirates; Faeces.

**Specified outcomes**

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

a. Demonstrate knowledge of any preparation steps required for the analytes listed below on all appropriate specimen types, either on automated instruments or by manual methods.
b. Process samples in accordance with documented laboratory procedures.
c. Demonstrate basic knowledge of the test methodologies and the tests related to the following:
d. **Range:** Colorimetry, Enzymology, Turbidimetry, Nephlometry, Chemiluminescence, and ISE
e. Demonstrate knowledge of limitations of the methods including interfering substances, detection limits / analytical range, dilutions
f. Apply any calculations that may be required
g. Demonstrate knowledge of units reported, reference ranges, critical results and procedures to follow when abnormal and life-threatening results are obtained.
h. Demonstrate basic knowledge of clinical significance of test results.
i. Demonstrate knowledge of the clinical significance/purpose of other tests requested:
**Range:** HbA1c, Fructosamine, Protein electrophoresis, Immunoglobulins, Ferritin, CA 125, CA 19-9, CEA, CA15-3.

j. Understand the concept of Turn Around Time (TAT).

**Range of Analytes:**

**Renal/ other related analytes:** Sodium, potassium, chloride, TCO2, anion gap (calculated), urea, creatinine, uncorrected and corrected creatinine clearance (calculated), uric acid, calcium, Corrected Calcium (calculated,) magnesium, inorganic phosphate, glucose

**Lung / Acid Base:** pH, PCO2, PO2, TCO2, $O_2$ Sat, actual and standard bicarbonate and base excess, Co-oximetry, Ionized Calcium.

**Diabetes:** Glucose, Glucose Tolerance Test

**Lipids:** Total Cholesterol, High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL) (measured and calculated), Triglyceride.

**Liver:** Total Protein, Albumin, Globulin (calculated), Total Bilirubin, Conjugated and Unconjugated Bilirubin (calculated), ALP, GGT, AST, ALT and LDH.

**Pancreas:** Amylase, Lipase,

**Cardiac:** CK, CKMB (mass), Troponin (T/I), Myoglobin, Pro-BNP/ BNP

**Iron Studies:** Iron and Transferrin,

**Poisoning:** Cholinesterase (serum).

**Therapeutic Drugs**: Digoxin, Phenytoin, Phenobarbitol, Carbamazapine, Theophylline, Valproic Acid, Lithium, Paracetamol, Salicylates, Tricyclic Antidepressants

**Antibiotic Assays**: Amikacin, Gentamycin and Vancomycin.

**Endocrine:** TSH, T3, T4 (Free), Quantitative βhCG, FSH, LH, Estradiol (E2), Progesterone, Prolactin

**CA markers**: PSA, free PSA, AFP

**Septicaemia and Inflammation:** CRP and PCT (procalcitonin).

**Fluids:** Differentiation between exudates and transudates

**Miscellaneous**:

Lactate, Ammonia

Osmolality (measured and calculated),

Neonatal Bilirubin,

### 6.2 QUALITATIVE AND SEMI-QUANTITATIVE ANALYSIS

**Objective**

Provide theoretical and practical knowledge of the qualitative and semi-qualitative screening processes used in the testing of specimens in Clinical Chemistry.
**Range**: Urine: timed and random; Faeces and Calculi.
**Specified outcomes**

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

a. Demonstrate knowledge of patient preparation, specimen requirements and precautions for the qualitative chemistry tests.
b. Perform the qualitative and semi-quantitative chemistry tests and quality control according to documented laboratory procedures.
c. Demonstrate knowledge of the limitations of the methods including interfering substances.
d. Demonstrate knowledge with regards to the reporting of results and expected values of the tests listed below:

**Range of Analytes:**

**Drugs of Abuse screen**: Cannabis and Methamphetamine

**Miscellaneous:** Urine βhCG and Dry Chemistry (dipstick and ketostix),

Faecal and urine reducing substances,

Porphobilinogen, Porphyrin,

Occult Blood / Faecal Haemoglobin

## 7. REFERENCE MATERIAL

CLINICAL CHEMISTRY, PRINCIPLES, PROCEDURES AND CORRELATIONS M.L. Bishop
INTROUDUCTION TO MEDICAL LABORATORY TECHNOLOGY Baker and Silverton

QUALITY CONTROL AND ACCREDITATION REFERENCE SITES:

www.iso.org, www.clsi.org, www.sanas.co.za; www.westgard.com

HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA (HPCSA):

www.hpcsa.co.za

SOCIETY OF MEDICAL LABORATORY TECHNOLOGY OF SOUTH AFRICA (SMLTSA):

www.smltsa.org.za

## 8. NOMENCLATURE / ACRONYMS

| | |
|---|---|
| **ALT**: | Alanine Transaminase |
| **ALP:** | Alkaline Phosphatase |
| **AST:** | Aspartate Transaminase |
| **AFP:** | alpha-fetoprotein; α-fetoprotein |
| **βhCG:** | Beta Human Chorionic Gonadotrophin |
| **BE:** | Base excess |
| **BV:** | Biological Variation |
| **CA-125:** | Tumor marker protein is present in greater concentration in ovarian cancer |
| **CA 1-53:** | CA-Breast; Cancer Antigen-Breast |
| **CA 19-9:** | Carbohydrate Antigen 19-9; Cancer Antigen-GI; CA-GI |
| **CK:** | Creatine Kinase |
| **CKMB:** | creatine kinase MB |
| **CLSI:** | Clinical and Laboratory Standards Institute |
| **CRP:** | C-reactive protein |
| **CSF:** | Cerebrospinal Fluid |
| **CV:** | Coefficient of variation |
| **CVR:** | Coefficient of variation Ratio |
| **COIDA:** | Compensation for Occupational Injuries and Diseases Act |
| **DOA/ DAU:** | Drugs of Abuse/ Drugs of Abuse in Urine |
| **E2:** | Estradiol |
| **FSH:** | Follicle Stimulating Hormone |
| **GGT:** | Gamma Glutamyl Transferase |
| **GLP:** | Good Laboratory Practice |
| **GFF:** | Glomerular filtration rate |

| | |
|---|---|
| **GTT:** | Glucose Tolerance Test |
| **HbA1c:** | Hemoglobin A1c |
| **HDL:** | High density Lipoprotein |
| **HPCSA:** | Health Professions Council of South Africa |
| **IATA:** | International Air Transport Association |
| **ISO:** | International Organization for Standardization |
| **kPa** | Kilopascal |
| **LDL:** | Low density lipoprotein |
| **LDH:** | Lactate Dehydrogenase |
| **LH:** | Luteinizing Hormone |
| **LJ:** | Levy-Jennings |
| **MSDS:** | Material Safety Data Sheet |
| **NHA**: | National Health Act |
| **O2:** | Oxygen |
| **OSHACT:** | Occupational Safety and Health Act |
| **PCO2:** | Partial Pressure Carbon Dioxide |
| **PCT:** | Procalcitonin |
| **PO2:** | Partial Pressure Oxygen |
| **PSA:** | Prostate-specific antigen |
| **%D:** | Percentage Deviation |
| **Q.A**.: | Quality Assurance |
| **Q.C:** | Quality Control |
| **SABS:** | South African Bureau of Standards |
| **SANAS:** | South African National Accreditation System |
| **SMLTSA:** | Society of Medical Laboratory Technicians of South Africa |
| **SOP:** | Standard operating procedure |
| **SD:** | Standard deviation |
| **SDI:** | Standard deviation Index |
| **TEa% :** | Total Allowable Error |
| **T3:** | Triiodothyronine |
| **T4:** | Thyroxine |
| **TCO2:** | Total CO2 |
| **TQM:** | Total Quality Management |
| **TSH:** | Thyroid Stimulating Hormone |
| **VHF:** | Viral Haemorrhagic Fever |
| **WHO:** | World Health Organisation |