SYLLABUS

GENERALIST LABORATORY ASSISTANT

March 2023 (can only be implemented for 2024 students who write in April 2025 onwards)

CONTENTS

1. INTRODUCTION

Laboratory Assistants (LA's) play an important role in performing many of the routine pre-analytical and post-analytical tasks in a medical laboratory environment, whether in the general pre-laboratory department or in the laboratory which specialises in a specific discipline.

The objective of this syllabus is to provide the student LA with a guideline on the essential aspects that must be covered in order to adequately prepare themselves for the Health Professions Council of South Africa's (HPCSA) Professional Board of Medical Technology (PBMT) examination for LA's. Successful passing of this LA examination and registration with the HPCSA as such will enable the LA to perform the **pre-analytical** and **post-analytical** tasks as outlined in the Generalist section of this syllabus. This will not be restricted to the pre-laboratory or receiving department, but will be permitted in any discipline where the laboratory requires the LA to perform these tasks. Please note that performing tasks which are deemed as part of the analytical processes of the laboratory is out of the scope of practice for LA's. It is imperative that the training laboratory keeps record of all training and competency assessments done, and be able to provide proof thereof should this be requested during an audit.

Board Examination

The HPCSA's PBMT examination for LA's is in the form of one, two hours, written paper which will be based on the contents of this syllabus, and related theoretical knowledge gained during the registration and training year as a LA student. Candidates are required to attain a minimum of 50% for the examination paper in order to pass the examination.

Note that in order for a candidate to be eligible to write the LA examination, HPCSA regulations require that he/she complete 12 months practical training in an HPCSA accredited training laboratory. Laboratories are required to ensure that students receive appropriate exposure and training in the concepts and procedures contained within this syllabus, where relevant.

Specialist LA

Should a qualified LA be required by his/her laboratory of employment to perform additional, discipline specific, pre- and/or post- analytical tasks not covered in this syllabus, he/she would be required to participate in further training and be deemed competent by the training laboratory in these task, and to provide proof thereof as stated above.

2. STATUTORY REGULATIONS AND ETHICS

Objective

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

Specified outcomes

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

- Explain the structure and function of the HPCSA.
- Explain the structure and function of the PBMT.
- Discuss/explain the HPCSA regulations relating to the scope of practice for Medical Laboratory Assistants (MLA).
- Describe the legal and ethical standards related to the professional practice of Medical Technology (MT).
- Explain the national and organisational policy and protocol regarding patient and/or donor rights and the LA's responsibilities with particular regard to confidentiality relating to patient information.
- Discuss the application of legal and ethical guidelines concerning the communication and distribution of patient results via electronic platforms.
- Explain the purpose and importance of maintaining confidentiality of organisational information.
- Explain the ethical and professional rules and regulations regarding patient/donor informed consent for procedures.
- Apply ethical standards in the handling of internal and external customers in accordance with organisational policies and procedures.
- Discuss the requirements for the acquisition of continual education units (CEUs).
- Explain the purpose and fundamental concepts of the Acts, their amendments and other relevant legislature regulating Medical Technology and Medical Laboratory Science:

Range:

Occupational Health and Safety Act	Compensation for Occupational Injuries and Diseases Act
Hazardous Substances Act	Protection of Personal Information Act
Human Tissue Act	International Air Transport Association (IATA) rules and regulations
Transportation of Hazardous Goods	Health Professions Act
Health Professions Council of South Africa Act	Children's Act
National Health Act	
Patient Rights Charter	

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 ✸ Human Tissue Act ✸ Transportation of Hazardous Goods	✸ Compensation for Occupational Injuries and Diseases Act ✸ International Air Transport Association rules and regulations

- Identify Microbe Hazard groups 1, 2, 3, and 4
- Discuss the aetiology, mode of transmission, signs and symptoms, prevention and control of laboratory acquired infections:

Range:

✸ Human Immunodeficiency Virus ✸ Viral Haemorrhagic Fevers ✸ Severe Acute Respiratory Syndrome – Corona Virus Disease 19 (SARS – Cov2)	✸ Viral hepatitis ✸ Tuberculosis ✸ Creutzfeldt-Jakob disease

- Discuss the basic principles of infection control, including but not limited to, the transmission of infectious microbes to humans, and how to break the chain of infection.
- Discuss and motivate Good Laboratory Practice guidelines and accepted industry norms related to laboratory safety, including but not limited to general housekeeping, decontamination of equipment and work areas and suitable agents used therefore, as well as eating, drinking, smoking and application of cosmetics in the laboratory, the use of mobile phones, storage of food and beverages in laboratory areas, proper hand washing techniques, mouth pipetting etc.
- Discuss the requirements for the accepted industry norms for safe and effective use and maintenance (where relevant) of various safety, emergency and personal protective equipment, including but not limited to:

Range:

❁ 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

- ◎ Recognise and describe the dangers posed by receiving fresh, unfixed tissue and body fluids in the laboratory.
- ◎ Discuss how and where to handle fresh, unfixed tissue and body fluids in the laboratory.
- ◎ Discuss the purpose and procedure for conducting fire drills.
- ◎ Identify and discuss the main types of hand-held fire extinguishers, including their uses.
- ◎ Identify and discuss the use of other firefighting equipment such as fire hoses and fire-resistant blankets.
- ◎ Explain the importance of returning materials to proper locations.
- ◎ Distinguish between, and classify Health Care Risk Waste (HCRW) and Health Care General Waste (HCGW).
- ◎ Discuss the prescribed procedures and requirements for the filling, sealing and labelling, transportation, storage, general handling and safe disposal of HCRW and HCGW, including any documentation required.
- ◎ Describe the basic requirements for the labelling, separation, storage, handling and disposal of reagents, chemicals, stains, poisons, gasses and flammable substances used in the laboratory environment.
- ◎ Discuss the use, hazards and safe disposal of laboratory antiseptics and disinfectants, including but not limited to, methylated spirits, chlorhexidine, phenolic disinfectants, hypochlorites, alcohols and aldehydes (formaldehyde (and derivatives) and glutaraldehyde).
- ◎ Describe the purpose and basic content of the material safety data sheets (MSDS) of chemicals and reagents commonly used in the laboratory.
- ◎ Define the roles and responsibilities of designated safety personnel.

Range

❁ Fire marshal ❁ Safety representative	❁ First aid officer

- ◎ Recognise, understand, explain and respond to the international situational 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

- ◎ Describe the required content and effective use of laboratory spill kits, including those used for biological, chemical and mercury spills.
- ◎ Recognise and describe the main types of hazards which may be encountered in the laboratory environment, and explain the risk posed by each.

Range

❁ Physical hazards ❁ Ergonomic hazards ❁ Chemical hazards	❁ Fire hazards ❁ Biological hazards ❁ Electrical hazards

- ◎ Discuss the procedures to follow in the event of a laboratory accident or emergency.

Range:

❁ Fire, Flood, Bomb threat ❁ Specimen breakage within a centrifuge ❁ Injury on duty, including needle stick injuries	❁ Chemical or bio-hazardous spill, including assessment of the spill, spill containment, cleaning of small vs large spills, the correct protocol for dealing with the spill, materials used (including absorbing or neutralising material where relevant), and disposal of soiled materials and sharps.

3.2 SPECIMENS/PRE-ANALYTICAL REQUIREMENTS

Objective

Provide an understanding of the optimal specimen requirements for the maintenance of the integrity and suitability for ***the specimens in the following range***:

Range:

❁ Venous, capillary and radial arterial blood ❁ Bone marrow and trephine ❁ Blood culture bottles ❁ Urine ❁ Stool ❁ Sputum ❁ Tracheal aspirates ❁ Broncho-alveolar lavages ❁ Semen ❁ Pleural fluids ❁ Pericardial fluid ❁ Synovial fluid ❁ Peritoneal fluid	❁ Cerebrospinal fluid ❁ Gastric washings ❁ Amniotic fluid ❁ Nail clippings and filings, hair, skin scrapings ❁ Swabs, including but not limited to pus, genital, rectal swabs, nasal swabs, nasopharyngeal and oropharyngeal swabs ❁ Pap smear ❁ Tissue samples/Biopsies/Whole organs ❁ Fine needle aspirations ❁ Catheter tips ❁ Intra-uterine contraceptive devices (IUCD) ❁ Slides

Specified Outcomes

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

- ◎ Describe the site and method of sample collection at a basic level.
- ◎ Explain the purpose and fundamental concepts of the IATA regulations for the transport and receipt of biological/medical samples, chemicals and reagents.
- ◎ Discuss the requirements for sample collection and transportation between the site of collection and sample testing site, with particular focus on factors that may influence sample integrity during this process. These include but are not limited to:

Range:

❁ The effects of time delay in sample collection and transportation ❁ Suitable temperature (frozen, on ice, cool, ambient)	❁ Exposure of the sample to unsuitable temperatures and light, air, ❁ Primary, secondary and tertiary containers used

- ◎ Discuss the use and purpose of additives, anti-coagulants and preservatives, fixatives and transport media for the various specimen types.

  Note: Knowledge of the mode of action of the additives, anti-coagulants and preservatives, fixatives and transport media is not required. The candidate only needs to identify the correct one for the required analysis to be performed.

- Outline the optimal storage conditions and sample stability should testing be delayed, for the individual samples and tests requested on them.
- Describe the optimal specimen requirements for the individual tests.
- Assess sample suitability for requested test(s). The criteria may include but are not limited to sample type, volume, age, haemolysis, icterus (jaundice), lipaemia, clotted samples, preserved samples vs fresh samples etc.
- Perform the pre-analytical processes required for the specimen type and tests requested. This may include but is not limited to the following:

Range:

• Continuous identification of specimens, aliquots and documentation • Sorting of priority and routine specimens • Labelling of specimens • Centrifugation of specimens • Measuring of pH of solutions and samples, and correcting where necessary • Measuring and recording the volume of 24-hour urine samples • Aliquoting of specimens • Handling of leaked samples as per laboratory protocol.	• Accurate logging of patient data and demographics, as well as tests requested, on the Laboratory Information System (LIS). • Creating specimen batches for departments • Dispatching specimens to internal departments • Creating shipping batches and dispatching specimens to external testing sites. • Receiving specimens and slides from external testing sites into the laboratory.

- Discuss the purpose of and perform the printing and resolving of outstanding specimen lists by locating these specimens and forwarding to the responsible person.
- Load suitable, pre-programmed and logged samples on automated instruments.
  Note: This excludes the manual programming of and offloading of samples from instruments (except for automated blood cultures).

- Handle samples which do not fully meet test requirements as per laboratory protocol, including rejecting and requesting recollection of samples.
- Discuss manual and automated sample filing and retrieval systems.

3.3 LABORATORY EQUIPMENT

Objective

Explain and demonstrate the correct functional checks and operation (where indicated), cleaning, maintenance and decontamination of laboratory equipment.

Specified outcomes

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

- Discuss and perform functional checks on and operate, clean and dry, decontaminate and perform routine maintenance (where applicable) on the following laboratory equipment:

Range:

All glassware – volumetric and graduated Glass slides Pipettes – glass, automated, air displacement and disposable Centrifuges – micro-haematocrit, safety, temperature controlled and ultra Thermometers – min/max, electronic and mercury Balances – top pan and fine analytical chemical Fridges Freezers Water-baths Flotation baths	pH meters – manual pH strips or automated pH meters. Pipette aids - rubber teats, pro-pipettes and dispensers Scanners Photocopiers Computers Fax machines Stopwatches/timers Bio-hazardous safety cabinets Fume cupboards Stirrers Rotators Vortex mixers

- Discuss and perform basic troubleshooting procedures when optimal operation of the above equipment is not demonstrated by the on-board functional checks.
- Discuss the purpose and operation of water distillers and deionisers as per laboratory protocol.
- Measure and record temperatures of relevant equipment and areas as per laboratory protocol, describing the correct procedure to follow in the case where unsuitable temperature is measured.
- Identify document and report errors on all the above equipment as per laboratory protocol.
- Apply the correct safety precautions during the operation and maintenance of above equipment, where applicable.

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:

- Distinguish between stock solutions and working solutions.
- Define and explain what normal physiological saline is.
- Prepare reagents for laboratory use which can be quality controlled and verified by a senior qualified staff member. This includes but is not limited to physiological saline.

3.5 STOCK CONTROL

Objective

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

Specified outcomes

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

- Explain the basic principles of stock management, stock counting and stock rotation.
- Perform stock counts as per laboratory protocol.
- Order and receive stock, including the completion of accompanying documentation as per laboratory protocol.
- Assess ordered stock received for correct item, quantity, lot numbers, damaged/leaking containers, expiry dates and correct transportation and storage temperature maintained. Correctly action on and report any non-conformities.
- Store received stock items as per manufacturer's instructions.
- Replenish consumables on benches for processing.
- Differentiate between open vail stability and expiry date.
- Apply company policy with regard to the use of expired reagents, controls and calibrators.

3.6 ACCREDITATION, QUALITY ASSURANCE AND QUALITY CONTROL

Objective

Expose the student to basic concepts and principles of Total Quality Management (TQM) in the medical laboratory environment.

Specified outcomes

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

- Distinguish between quality assurance (QA) and quality control (QC) (both internal and external) in the correct context, explaining what each refers to and why it is performed.
- Discuss the reasons for implementation of a QC and QA system.

- Explain the importance of being able to manage sample receipt, registration, relevant preparation and dispatching of samples, as well as resolution of outstanding requests and discrepancies, within acceptable Turn Around Time (TAT).
- Explain the principle of continuous identification of the specimen, raw data and documentation.
- Define and explain quality assurance terminology.

Range:

Non-conformance Corrective action Preventive action Policies Standard operating procedures (SOP's) or Work Instructions (WI's)	Root cause analysis Continual improvement of quality assurance and quality control processes. Audits – Internal & External

- Outline internal and external laboratory audits and accreditation requirements at basic level, including the purpose, processes, role players involved and possible outcomes.
- Discuss and complete the documentation procedure and reporting of damaged equipment and apparatus **(See Laboratory Equipment).**
- Discuss the importance of compliance to all SOP's and WI's, including reading and acknowledgement of SOP's (electronic and manual).
- Measure and record temperatures of relevant equipment and areas as per laboratory protocol, describing the correct procedure to follow in the case unsuitable temperature is measured **(See Laboratory Equipment).**
- Discuss and demonstrate acceptable face to face, email, fax, phone or text message etiquette, as required by laboratory protocol, including meeting and greeting of patients and other clients, and referring requests for laboratory results from clients via any of the aforementioned or others mediums, to a suitable, qualified senior staff member, as per laboratory protocol.
- Confirm receipt of urgent/critical/panic value laboratory results by clients, as per laboratory protocol.
- Handle customer complaints and queries where applicable and within scope, or escalate to the correct person, as per laboratory protocol.

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3.7 PERSONNEL

Objective

Provide knowledge of basic requirements for personnel in terms of relevant International Standards Organisation (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 Biomedical Technology.
- Explain the terms 'competency' and ongoing competency' in terms of the training of all laboratory personnel which falls within the scope of practice of Biomedical Technology
- Explain and apply "line of accountability" in the workplace, and the hierarchical structure of the laboratory.

3.8 DOCUMENTATION AND COMMUNICATION

Objective

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

Range:

✸ Policies ✸ SOP's ✸ WI's ✸ Raw data	✸ Equipment records ✸ Quality control records ✸ Personnel records ✸ Package inserts

Specified outcomes

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

- ◎ Discuss document control requirements in terms of relevant ISO standards.
- ◎ Outline the required content of SOP's including the minimum content of the cover page.
- ◎ Identify the minimum required content of a laboratory report according to ISO standards.
- ◎ Demonstrate knowledge on the retention and disposal of laboratory documentation.
- ◎ Differentiate between a record and document.
- ◎ Transcribe verified information, provided that this transcribed information will be verified at some stage by a senior qualified person.
- ◎ Discuss the purpose and importance of, and create and/or access shipping lists, management reports and worksheets.
- ◎ Discuss the importance of and be able to access and search patient, sample, dictionary, test and result information
- ◎ Receive, record (as required) and transfer laboratory related information through appropriate verbal, written and electronic (LIS AND fax OR email OR telephone OR WhatsApp or SMS or other) medium, as per laboratory protocol **(See Confidentiality)**.
- ◎ Assist in the filing and archiving of raw data, worksheets, documents, reports, samples etc. as per laboratory protocol.

3.9 MEDICAL AND LABORATORY RELATED TERMINOLOGY

Objectives

Provide knowledge of the meaning and correct use of terminology commonly used within the medical and laboratory environments.

Specified outcomes

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

- Provide an outline of the medical and pathology laboratory environment, as well as its staff, including the various departments, sub-departments, their purposes and the tests performed in these departments.
- Define and correctly use terminology commonly used within the medical and pathology laboratory environment. This includes, but is not limited to:

Range:

Abscess Acquired condition/disease Acute Allergen/allergy Analyse Anatomy Andrology Anticoagulant Ascitic/ascites Autopsy Benign Biology/biologic Biopsy Calculus Carcinogen/carcinogenic Cardiac Chronic Clinical chemistry/Chemical pathology Clinical pathology Coagulate Contaminate/contaminant Cyst Cytogenetics Cytology	Decontaminate/decontaminant Diagnosis Disease Effusion Electrolyte Endocrinology Enzyme Erythrocyte Extracellular Haemorrhage Haematology Haemolysis/haemolysed Hepatic Histology Histopathology Icterus/icteric (see Jaundice) Immune/Immunity Immunocompromised Immunohaematology Immunology/Serology Infection Infectious disease Jaundice	Leucocyte Lipaemia/lipaemic Malignant/malignancy Microbe/micro-organism Microbiology Molecular Biology Morphology Mycobacteriology Mycology Occult Pathology Polymerase Chain Reaction (PCR) Physiology Plasma Protein Reagent Renal Sample/specimen Serum Sterilise/sterilant Thrombocyte Toxicology/Toxin Tumor Ulcer Virology

4. RECOMMENDED TEXT BOOKS/ REFERENCES

- QUALITY CONTROL AND ACCREDITATION REFERENCE SITES:
  - http://www.iso.org
  - http://www.clsi.org
  - http://www.sanas.co.za.
- HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA (HPCSA):
  - http://www.hpcsa.co.za
- Society of Medical Laboratory Technologists of South Africa (SMLTSA):
  - http://www.smltsa.org.za
- Newmans' Medical Laboratory Assistants Study Guide: A Laboratory Synopsis (Laboratory series) [Authors: Xaiver R.S. Newman AHI (Author), Tiffany Holloway-Clark - contributor] ISBN 13- 978-1481825344
- Basic Medical Laboratory Techniques. Barbara Estridge [Product Code: 0766812065]
- Laboratory Biosafety Manual, WHO, 1993.
- Government Gazettes