FORM 108b

HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

PROFESSIONAL BOARD FOR MEDICAL TECHNOLOGY

GUIDELINES FOR THE APPROVAL OF TRAINING LABORATORIES

1. An approved laboratory must be able to provide the apparatus and working environment considered necessary for Good Laboratory Practice, to the standard determined by the Professional Board and make necessary resources available to all students

2. An approved laboratory must provide practical training in basic routine tests under conditions whereby each employee is given adequate instruction in, and every opportunity to carry out, all the tests and procedures considered by the Professional Board to be consistent with adequate training in the category in which the employee is being trained.

3. An approved laboratory must have in its employ a qualified Medical Technologist or Medical Laboratory Scientist (MLS) who must be registered in the category in which Medical technologists/technicians are to be trained. If a laboratory functioned without such a registered person for longer than 6 months, it will be asked for an explanation and the Professional Board will then reconsider the continued approval of such a laboratory for training of Medical Technology Professionals.

4. An approved training laboratory must maintain the ratio between registered medical technologists and technicians, laboratory assistants and students in all categories as the Professional Board may determine from time to time.

   One (1) Registered Medical Technologist/Medical Laboratory Scientist may only be responsible for the supervision of a combination of five practitioners constituted according to the following six practitioner categories, all of whom must always work under supervision:

   - Registered Medical Technicians
   - Registered Intern Medical Technologists
   - Registered Student Medical Laboratory Scientists / Student Medical Technologist
   - Student Medical Technicians
   - Registered Laboratory Assistants
   - Student Laboratory Assistants

5. The Professional Board reserves the right to inspect the laboratory at any time.

6. The laboratory is required to cover a minimum of 80% of the practical component of the relevant syllabus. Practical training in the remaining sections of the syllabus may be provided at an alternative facility; however, a written agreement indicating the details of such an arrangement must be available.

7. The individual current syllabi of the different disciplines are used in conjunction with this checklist to see if the laboratory has the necessary resources to train students in the specific discipline.

8. In terms of rule 4 of the ethical rules a practitioner must confine himself / herself in the use of a practice name to his / her name or where practitioners practise in partnership or as a juristic person, the names of such practitioners.

9. The approved laboratory must ensure that students are placed on a structured training programme when appointed and provide students with a rotation schedule to cover aspects of the relevant syllabus.

10. Students that are currently in approved training laboratories will be interviewed by HPCSA appointed evaluators as per guide on form and reported to the Professional Board.

11. It is the responsibility of the Laboratory Manager to ensure that students work within their scope of practice.

12. The Laboratory Manager must keep the records of training periods completed by students in relevant disciplines using Form 25 (*available on HPCSA website*)

13. The Laboratory submit an annual report to the PBMT Committee Coordinator during each four-year accreditation cycle- see Appendix C below.

14. Approved laboratories must inform the Professional Board in writing of name changes to the names of such practices. These practices may be re-evaluated for possible continued HPCSA approval.

15. The general information herewith of the practice in your laboratory is required to stimulate a self-evaluation of the procedures applied.

16. While you consider the answer to the various questions on this checklist you may realise that there are certain shortcomings in the organisation of your laboratory or the procedures that are used. As such shortcomings come to light, you will probably wish to take remedial steps. Such changes would be voluntary, of your own design and within the means at your disposal. Any changes instituted should result in improvement in the standard set in your laboratory and cause little or no anxiety to you or your staff. You are also invited to make comments on the contents of this document it

17. Note - The addendum to Form 108 (*found at end of this document*) must be completed from Section 2 onwards when applying for approval as a Phlebotomy training site –Appendix D.

FORM 108b

PROFESSIONAL BOARD FOR MEDICAL TECHNOLOGY

APPLICATION FOR APPROVAL OF TRAINING LABORATORIES

New application ❒ *(Please tick relevant application)*	**Re-application** ❒ *(Please tick relevant application)*
Certificate number	
Category **Medical Laboratory Scientist** **Medical Technologist** **Medical Technician** **Laboratory Assistant**	
Discipline **e.g MT (CLIN Path, Virology)**	
Date of Application	
Name of Organisation / Pathology Providers	
Name of Laboratory	
Owner of Laboratory	
Practice number	
Head of Laboratory	
Contact Person	
Postal Address	
Physical Address	
Phone Number	
Email Address	

FORM 108b

SANAS Accredited Lab *(Please tick as relevant)*	YES ❒ NO ❒
SANAS Accreditation Number	
Name of Applicant	
Signature of Applicant	
Note: In cases where a Laboratory has a SANAS accreditation number then only sections 1, and 3.1 to 3.3 will be evaluated on HPCSA Form108.	

1. PERSONNEL AND ORGANISATION

Relevant Standards: The management of the laboratory must formulate the quality goals with respect to the education and skills of the laboratory. The laboratory must have a policy and procedures for identifying training needs and providing training of personnel. The training program must be oriented on present and future tasks of the laboratory. Personnel performing specific tasks must be qualified on the basis of appropriate education, training, experience and/or skills, as required.

1.1 Person-in-Charge

1.1.1 Name:
1.1.2 Qualifications:
1.1.3 Years of relevant experience:
1.1.4 Hours per week spent in this laboratory:
1.1.5 Is the person-in-charge involved in:

1.1.5.1	Development of training programmes?	**YES**	**NO**
1.1.5.2	Approval of changes in methodology and procedures?	**YES**	**NO**
1.1.5.3	Review of laboratory reports?	**YES**	**NO**
1.1.5.4	Review of quality control programmes?	**YES**	**NO**

1.1.6 Is the person-in-charge readily available for consultation with:

1.1.6.1	Referring medical practitioners?	**YES**	**NO**
1.1.6.2	Medical administrators?	**YES**	**NO**
1.1.6.3	Laboratory personnel?	**YES**	**NO**
1.1.6.4	Computer personnel?	**YES**	**NO**

1.1.7 If the person-in-charge is absent are there suitable relief arrangements? **YES** **NO**

1.2 Laboratory Staff

1.2.1 Are there appropriate and competent qualified staff to perform procedures of the laboratory to acceptable standards? **YES** **NO**

Medical Laboratory Scientist, Medical technologists and Medical technicians must perform any test within their scope of practice provided that there is proof that they have been trained to do so.

1.2.2 Have these persons received formal training in performing these tasks? **YES** **NO**

1.2.3 Please attach total staff complement with appropriate qualifications and HPCSA registration numbers. **Appendix A**

1.2.4 Do staff working in high risk areas have regular medicals? **YES** **NO**

1.2.5 Are there vaccination records available for students and staff members?

1.2.6 Are confidentiality agreements available for all staff? **YES** **NO**

1.3 Staffing Policies

1.3.1 Are records maintained on all current employees? **YES** **NO**

1.3.2 Do these records include:

1.3.2.1 Formal qualifications (or required licenses)? **YES** **NO**

1.3.2.2 Dates of employment, employment contract, copy of ID, work permit if an employee is not a South African Citizen? **YES** **NO**

1.3.2.3 A job description specifying duties/ responsibilities? **YES** **NO**

1.3.2.4 Incident reports where applicable **YES** **NO**

1.3.3 Are records kept on staff participation in Continuing Professional Development programmes

1.3.4 Have all staff been instructed in the safe handling of infected material **YES** **NO**

1.4 Education and Training

1.4.1 Does the laboratory have a structured, documented training programme in place? **YES** **NO**

1.4.2 Does the training programme involve: **YES** **NO**

1.4.2.1 Orientation of new personnel? **YES** **NO**
1.4.2.2 Special attention to laboratory ethics and safety? **YES** **NO**
1.4.2.3 Bench training coordinated by qualified personnel? **YES** **NO**
1.4.2.4 In-service seminars or lectures? **YES** **NO**
1.4.2.5 Use of teaching aids (audio-visual, manuals etc.)?
1.4.2.6 Rotational training program **YES** **NO**

1.4.3 If the laboratory has been approved by HPCSA to offer training, and what level does training take place:

Student Laboratory assistant? **YES** **NO**
Student Medical Technician? **YES** **NO**
Inter Medical Technologist? **YES** **NO**
Student Medical Laboratory Scientist? **YES** **NO**

1.4.4 Is there a documented procedure that outlines the review of the training program which includes: Setting targets against objectives, Review of quality indicators, documented follow-up actions when set targets are not met. Changes to operations are documented, communication of review process? If yes, please provide ***YES NO***

2. ACCOMMODATION AND ENVIRONMENTAL CONDITIONS -

Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to ensure proper performance of calibrations or tests.
The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises. e.g. POCT sites
The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, mains voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned.

There shall be effective separation between neighbouring areas when the activities therein are incompatible.

Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

2.1	Is there adequate uncluttered space provided for:		
	2.1.1 Workbench?	**YES**	**NO**
	2.1.2 Storage (including refrigeration)?	**YES**	**NO**
	2.1.3 Administration (including reporting areas)?	**YES**	**NO**
2.2	Are work areas provided with adequate electrical, water and gas utilities (double adapters long lengths of gas tubing, should be avoided)?	**YES**	**NO**
2.3	Is there an adequate specimen collection area suitably separated from laboratory work areas?	**YES**	**NO**
2.4	Is there a staff library?	**YES**	**NO**
	2.4.1 If no, does the staff have adequate access to current text books/journals or the Internet?	**YES**	**NO**
2.5	Is there a Tea room/ Recreation room?	**YES**	**NO**
2.6	Does the laboratory environment provide:		
	2.6.1 Adequate lighting?	**YES**	**NO**
	2.6.2 Adequate ventilation?	**YES**	**NO**
	2.6.3 Adequate air conditioning (particularly where sensitive instruments are in use)?	**YES**	**NO**
2.7	Is the laboratory cleaned regularly and maintained in good order?	**YES**	**NO**
2.8	Are there adequate facilities for waste disposal consistent with good laboratory practice and local government requirements?	**YES**	**NO**
2.9	Does the laboratory have an emergency power supply to maintain essential services? If not has alternative arrangements been made?	**YES**	**NO**
2.10	Does the laboratory have a direct outside telephone line for emergency use?	**YES**	**NO**
2.11	Are glassware in good condition and properly stored?	**YES**	**NO**
2.12	Are benches decontaminated daily?	**YES**	**NO**
2.13	Are records kept of decontamination procedures?	**YES**	**NO**

3. HEALTH AND SAFETY

Occupational Health and Safety Act covers all statutory aspects of Safety to which all laboratories must conform.

3.1 Safety Personnel

3.1.1	Does the laboratory have a designated safety officer?	**YES**	**NO**
3.1.2	Name the designated person		
3.1.3	Does the laboratory have a safety committee?	**YES**	**NO**
	If yes:		
3.1.3.1	How often do they meet?		
3.1.3.2	Are minutes kept of the meetings?	**YES**	**NO**
3.1.4	Does the laboratory have written safety manual?	**YES**	**NO**
	If yes:		
3.1.4.1	Is this available in each laboratory?	**YES**	**NO**
3.1.5	Has all staff been trained in the correct safety procedures?	**YES**	**NO**
3.1.6	Are records of this training kept?	**YES**	**NO**
3.1.7	Have policies regarding "Injury on duty" and "Diseases contracted through exposure at work" been developed?	**YES**	**NO**

3.2 Fire

3.2.1	Is an operational Fire Alarm system installed in the building housing the laboratory?	**YES**	**NO**
3.2.2	Is there a backup system?	**YES**	**NO**
3.2.3	Is the fire alarm audible in all sections of the laboratory?	**YES**	**NO**
3.2.4	Are fire drills held periodically?	**YES**	**NO**
3.2.5	Is smoking prohibited in all areas except in designated smoke area?	**YES**	**NO**
3.2.6	Are there sufficient and appropriate fire extinguishers (not the powder type) in the laboratory?	**YES**	**NO**
	If yes:		
3.2.6.1	Are these serviced and inspected on a regular basis?	**YES**	**NO**
3.2.6.2	Are records kept?	**YES**	**NO**
3.2.7	Are there fire blankets available in the laboratory?	**YES**	**NO**
3.2.8	Are there sufficient fire hoses in the passages?	**YES**	**NO**
	If yes:		
3.2.8.1	Are these checked regularly to ensure that they are in good working order and, that hoses reach all areas?	**YES**	**NO**
3.2.8.2	Are records kept?	**YES**	**NO**
3.2.9	Are all staff familiar with the correct use of appropriate extinguishers?	**YES**	**NO**
3.2.10	Are there clear evacuation route/s?	**YES**	**NO**
3.2.11	Are evacuation routes diagrammed and posted?	**YES**	**NO**
3.2.12	Are volatile chemicals and flammable solutions appropriately stored?	**YES**	**NO**

3.2.13	Does the laboratory comply with the local fire regulations?	**YES**	**NO**

3.3 Accidents and First Aid

3.3.1	Are detailed records of laboratory accidents kept?	**YES**	**NO**
3.3.2	Are policies altered to prevent recurrences?	**YES**	**NO**
3.3.3	Are first-aid facilities available?	**YES**	**NO**
	If yes:		
3.3.3.1	Are first-aid boxes available in the laboratory?	**YES**	**NO**
3.3.3.2	Are the first-aid boxes regularly checked against an inventory kept inside?	**YES**	**NO**
3.3.3.3	Do these boxes comply with the OHS Act?	**YES**	**NO**
3.3.3.4	Is the person in charge of the First Aid boxes qualified in First Aid?	**YES**	**NO**
3.3.4	Is there an eyewash facility available in each laboratory?	**YES**	**NO**
3.3.5	Is there an emergency shower available?	**YES**	**NO**
3.3.6	Is there a protocol for the management of accidental injury following exposure to blood or body fluids?	**YES**	**NO**
3.3.7	Is there a policy on needle stick injury?	**YES**	**NO**

3.4 Equipment

3.4.1	Are written safety procedures available for all equipment?	**YES**	**NO**
3.4.2	Does apparatus conform to acceptable safety standards?	**YES**	**NO**
3.4.3	Is the laboratory on an earth leakage system?	**YES**	**NO**
3.4.4	Are measures taken to minimise formation and dissemination of aerosols when centrifuging blood or bacterial specimens?	**YES**	**NO**
3.4.5	Are biohazard cabinets used in the laboratory when hazardous bacteria, fungi, or viruses are handled?	**YES**	**NO**
3.4.6	Are adequate fume cupboards provided where necessary?	**YES**	**NO**
3.4.7	Are adequate laminar flow provided where necessary?	**YES**	**NO**
3.4.8	Are the surrounding areas of instruments disinfected at least once a day?	**YES**	**NO**
3.4.9	Is effluent disinfected before being discarded directly into the municipal waste?	**YES**	**NO**
3.4.10	Are safety pipettes available for handling of:		
	3.4.10.1 Acids and corrosive chemicals?	**YES**	**NO**
	3.4.10.2 Infected material?	**YES**	**NO**
3.4.11	Are facilities adequate for disinfection of contaminated pipettes?	**YES**	**NO**
3.4.12	Are containers for sharp instruments available in all laboratories?	**YES**	**NO**
3.4.13	Are SOPs written regarding the prevention of injury of personnel by cutting instruments?	**YES**	**NO**
3.4.14	Is the condition of each piece of equipment satisfactory?	**YES**	**NO**
3.4.15	List any defective apparatus.		
3.4.16	Are defective equipment clearly marked	**YES**	**NO**
3.4.17	Is equipment serviced regularly?	**YES**	**NO**
	3.4.17.1 By whom.		
3.4.18	Are records available of instrument services and operation checks?	**YES**	**NO**
3.4.19	Are operating manuals including calibration instructions available for all the types of equipment?	**YES**	**NO**

3.5 Prevention of laboratory-acquired infection

3.5.1	Are the appropriate signs available and in use?	**YES**	**NO**
3.5.2	Is eating, drinking, smoking and application of cosmetics prohibited in all laboratories/areas where specimens are handled?	**YES**	**NO**
3.5.3	Is storage of food in laboratory refrigerators or cupboards prohibited?	**YES**	**NO**
3.5.4	Is mouth pipetting prohibited?	**YES**	**NO**
3.5.5	Are suitable laboratory coats worn in all laboratories?	**YES**	**NO**
3.5.6	Are laboratory coats supplied to all staff members and laundered by the laboratory?	**YES**	**NO**
3.5.7	Are laboratory staff prohibited to leave the laboratory wearing their laboratory coats?	**YES**	**NO**
3.5.8	Are suitable gloves provided in the laboratory for use where necessary?	**YES**	**NO**
3.5.9	Are hand wash facilities with elbow taps provided in every laboratory?	**YES**	**NO**
3.5.10	Is there an SOP for decontamination of all spillage? If yes:	**YES**	**NO**
3.5.10.1	Are staff well informed about these procedures?	**YES**	**NO**
3.5.11	Are detailed SOPs available for the proper transportation of specimens to avoid breakage and spills?	**YES**	**NO**
3.5.12	Are there detailed SOPs available on the receipt of broken specimens?	**YES**	**NO**
3.5.13	Are SOPs written to prevent exposure of personnel to unfixed/partially fixed, biohazardous material?	**YES**	**NO**
3.5.14	Are SOPs written to prevent exposure to noxious fumes and reagents in the laboratory?	**YES**	**NO**
3.5.15	Are SOPs available for the proper handling of specimens?	**YES**	**NO**
3.5.15.1	Do these include criteria for rejection of specimens?	**YES**	**NO**
3.5.16	Are the arrangements for preservation of specimen quality satisfactory?	**YES**	**NO**

4. PROCEDURES

The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of samples. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

4.1 Specimens

4.1.1	Has a fully comprehensive specimen collection and handling manual been created?	**YES**	**NO**
4.1.2	Are there SOPs covering:	**YES**	**NO**
4.1.2.1	Method of collection?	**YES**	**NO**
4.1.2.2	Positive identification of the patient?	**YES**	**NO**
4.1.2.3	Preparation of the patient?	**YES**	**NO**
4.1.2.4	Nature of the sample to be collected?	**YES**	**NO**
4.1.2.5	Need for special timing for collection?	**YES**	**NO**
4.1.2.6	Appropriate preservation or anticoagulant blood is adequately mixed before sampling (e.g. sequential testing of the same specimen)?	**YES**	**NO**
4.1.2.7	Safety precautions in the handling of specimens?	**YES**	**NO**
4.1.2.8	Appropriate preservative or anti-coagulant?	**YES**	**NO**
4.1.2.9	Need for special handling between time of collection and time received (e.g. refrigeration)?	**YES**	**NO**
4.1.2.10	Instructions for labelling?	**YES**	**NO**
4.1.2.11	A system in use by which damaged or unsuitable specimens can be rejected or partially tested?	**YES**	**NO**
4.1.2.12	Action steps to follow when specimens are lost?	**YES**	**NO**
4.1.3	What provision is made for storage of specimens prior to testing or referral?	**YES**	**NO**
4.1.4	For how long and what storage conditions are specimens retained after testing?		

4.2 Reception

4.2.1	Are the procedures in this area documented?	**YES**	**NO**
4.2.2	Is an SOP for this area e.g. use of gloves, procedures for handling leaking specimens and contaminated forms written?	**YES**	**NO**
4.2.3	Is there an SOP for specimens received after hours?	**YES**	**NO**

4.3 Specification Identification

4.3.1	Is the specimen given a unique identification on receipt (Laboratory Requisition Number)?	**YES**	**NO**
4.3.2	Is this identification used through all steps of the test procedure?	**YES**	**NO**
4.3.3	Is this identification quoted on all documentation pertaining to that specimen?	**YES**	**NO**

4.4 Rejection of Unsuitable Specimens

4.4.1	Is there an SOP on the handling of unsuitable/inadequately labelled specimens?	**YES**	**NO**
4.4.2	Are suitable records kept of the dispatch of and return of referred test results	**YES**	**NO**

4.5 Methods

4.5.1	Are there SOPs covering detailed instructions for each test procedure where no kit is used?	**YES**	**NO**
4.5.2	Are current package inserts available for all reagents and kits used in the laboratory?		
4.5.3	Are the SOPs in 4.5.1 validated?	**YES**	**NO**

4.6 Quality Assurance Programme

4.6.1	Does the laboratory have a documented quality management program (quality manual) that covers all the areas of the laboratory as well as the beneficiaries of the service?	**YES**	**NO**
4.6.2	Are there written in-house safety guidelines?	**YES**	**NO**

4.7 Reports

4.7.1 Does the report form contain the following:

4.7.1.1	Name of laboratory which performed the tests?	**YES**	**NO**
4.7.1.2	The name and identification of the patient ?	**YES**	**NO**
4.7.1.3	Name of clinician (with the HPCSA /or SANC number requesting the work?	**YES**	**NO**
4.7.1.4	Laboratory accession number?	**YES**	**NO**
4.7.1.5	References values for each test?	**YES**	**NO**
4.7.1.6	Date/time of specimen collection?	**YES**	**NO**
4.7.1.7	Comment on inadequate/unsuitable specimen?	**YES**	**NO**
4.7.1.8	Date/time of issue of report?	**YES**	**NO**

4.7.2 Do records of the original results identify:

4.7.2.1	Who did the work?	**YES**	**NO**
4.7.2.2	Who reviewed and validated the results?	**YES**	**NO**
4.7.2.3	Who made any amendments	**YES**	**NO**
4.7.3	Is there a SOP written to minimise transcription errors?	**YES**	**NO**
4.7.4	Are records retained on the computer or other storage system?	**YES**	**NO**
4.7.5	Are there SOPs in use for the handling of clerical errors and unusual laboratory results?	**YES**	**NO**
4.7.6	Are SOPs written for the timeous correction of mistakes?	**YES**	**NO**

4.8 Records

4.8.1	Is an SOP written to ensure that laboratory reports are treated as confidential, and are they only reported to the referring practitioner or to such person(s) as he/she nominated?	**YES**	**NO**
4.8.2	Is there an SOP for accelerated communication of seriously abnormal results?	**YES**	**NO**
4.8.3	Are all reports given in writing (or where given verbally for specific reasons, later confirmed in writing)?	**YES**	**NO**
4.8.4	Is there an SOP regarding conveying results, telephonic reports and records kept?	**YES**	**NO**

4.9 Equipment

It is not the purpose of this evaluation to specify the type of equipment that must be used by a laboratory. However, it is essential that all equipment in use is suitable for the tests being performed.

4.9.1	Is there an up-to-date maintenance record for all items of equipment?	**YES**	**NO**
4.9.2	Are there operating manuals available for:		

4.9.2.1	Water baths?	YES	NO
4.9.2.2	Incubators	YES	NO
4.9.2.3	Hot air ovens	YES	NO
4.9.2.4	Autoclaves?	YES	NO
4.9.2.5	Biological safety cabinets?	YES	NO
4.9.2.6	Anaerobic workstations?	YES	NO
4.9.2.7	Centrifuges?	YES	NO
4.9.2.8	Microscopes?	YES	NO
4.9.2.9	Test Instrumentation?	YES	NO
4.9.2.10	Other small equipment?	YES	NO
4.9.3	Is there a schedule or system for the regular checking of the critical operating characteristics for all instruments?	YES	NO
4.9.4	Are the equipment manufacturer's operator manuals readily available to testing staff, and where possible, available in the language understood by staff?	YES	NO
4.9.5	Are function checks documented in a convenient manner to detect trends or malfunctions?	YES	NO
4.9.6	Are tolerance limits for acceptable function written for specific instruments wherever appropriate?	YES	NO
4.9.7	Are instruments provided with methods for minor troubleshooting and repairs?	YES	NO
4.9.8	Are records maintained for each instrument to document all repairs and service procedures?	YES	NO
4.9.9	Are adjustable automatic pipettes/dispensers checked for accuracy and reproducibility at regular intervals and the results recorded?	YES	NO

4.10 Reagents

4.10.1	Are all reagents and standards properly labelled as to content and concentration?	YES	NO
4.10.2	Are reagents dated on receipt, preparation and/or when placed in service?	YES	NO
4.10.3	Are expiry dates indicated on the reagent containers?	YES	NO
4.10.4	Are reagents stored properly (i.e. refrigerated when necessary?	YES	NO
4.10.5	Are fresh reagents checked against old reagents or other reference material prior to being placed in service?	YES	NO

5 QUALITY ASSURANCE

Relevant Standard:

The laboratory must establish, implement and maintain a quality management system appropriate to the scope of its activities including the type, range and volume of testing and/or calibration activities it undertakes. The laboratory must document all of its policies, systems, programmes, procedures, instructions and findings, to the extent necessary to enable the laboratory to assure the quality of the test and/or calibration results it generates. Documentation used in this quality management system must be communicated to, understood by, available to and implemented by the appropriate personnel.

5.1 General

5.1.1 Name the designated staff member responsible for monitoring QC?

5.1.2 To whom does the person report?

5.1.3	Is there an internal Quality Control Programme to cover all tests performed? If yes, please state which IQC system is used for each test procedure.	**YES**	**NO**
5.1.4	Is there an external Quality Control (EQA) programme?	**YES**	**NO**
5.1.4.1	If yes, please state which EQA system is used for each test procedure.		
5.1.5	Is there intra-laboratory control procedure for results checking within the laboratory group? If so, please specify.	**YES**	**NO**
5.1.6	Are Quality Control records kept?	**YES**	**NO**
5.1.7	If yes:		
5.1.7.1	For how long?		
5.1.7.2	Are these records readily available?	**YES**	**NO**
5.1.8	Is the archive system in operation?	**YES**	**NO**
5.1.9	Are results used for:		
5.1.9.1	Evaluating performance?	**YES**	**NO**
5.1.9.2	Identifying problems?	**YES**	**NO**
5.1.9.3	Method development?	**YES**	**NO**
5.1.10	Are the results from internal and external QC programmes available to all laboratory staff?	**YES**	**NO**
5.1.11	Is an SOP written for preparing and handling control materials for each procedure?	**YES**	**NO**
5.1.11.1	State the frequency of which QC are run.		
5.1.11.2	Is there an SOP to follow when the QC results fall outside the acceptable limits?	**YES**	**NO**
5.1.11.3	Is there a record of what corrective action was taken (and by whom)?	**YES**	**NO**
5.1.12	Are there SOPs for validation and verification of new methods, procedures and equipment?	**YES**	**NO**

5.2 Controls and Standards

5.2.1	Are all controls labelled properly i.e. contents, concentration etc.?	**YES**	**NO**
5.2.2	Do all calibrators have labels showing dates of receipt, opening for use and expiry?	**YES**	**NO**
5.2.3	Are controls used at different levels (i.e. intermediate and low)?	**YES**	**NO**
5.2.4	Are quality control data:		
5.2.4.1	Evaluated daily?	**YES**	**NO**
5.2.4.2	Is data charted?	**YES**	**NO**
5.2.4.3	Is this displayed prominently?	**YES**	**NO**
5.2.5	Are ongoing and updated records kept?	**YES**	**NO**
5.2.6	Is frequency of calibration in accordance with instruments and/or reagent manufactures recommendations?	**YES**	**NO**
5.2.7	Is calibration traceable to QC results?	**YES**	**NO**
5.2.8	Are QC results used to determine process failure?	**YES**	**NO**

6.	LABORATORY COMPUTER SYSTEM (If Applicable)		
6.1	Do computer manuals exist which includes the following aspects of the computer operation and maintenance?	**YES**	**NO**
6.1.1	Is the computer system protected against unauthorised access?	**YES**	**NO**
6.1.2	Preservation of data in case of fire, flooding etc.	**YES**	**NO**
6.1.3	Fire fighting equipment in the computer room?	**YES**	**NO**
6.1.4	Are there defined levels of programme access for various staff members?	**YES**	**NO**
6.1.5	Is there a documented stated policy for correction of test request errors?	**YES**	**NO**
6.1.6	Is there a procedure for the changes of any **results** entries and errors?	**YES**	**NO**
6.1.7	Is there a documented policy for the verification of results coming online from instruments before final entry into the patient files?	**YES**	**NO**
6.1.8	Is there a documented policy for final verification for results before they are reported and are accessed or accessible by the wards and **clinics/or** sent out to private practitioners?	**YES**	**NO**
6.1.9	Is there a special library or other system to allow comment on unsuitable specimens (haemolysis, delayed specimen)?	**YES**	**NO**
6.1.10	Is the staff member who entered the results identifiable and traceable?	**YES**	**NO**
6.1.11	Is a system in existence for the timeous retrieval of results?	**YES**	**NO**
6.1.12	Is there a procedure for the daily **back-up data?**	**YES**	**NO**
6.1.13	Do instructions exist and where relevant a schedule for the maintenance of hardware?	**YES**	**NO**
6.1.14	Are there records of all hardware and software changes and repairs?	**YES**	**NO**
6.1.15	Are all changes to hardware and software validated prior to acceptance?	**YES**	**NO**
6.1.16	Are changes to hardware and software done by qualified persons?	**YES**	**NO**
6.1.17	Is there a procedure for the shutdown of the computer, for software and/or hardware failure?	**YES**	**NO**
6.1.18	Is there an audit trail within the system permitting the identification of data input and/or editing for all stages of the analytical process?	**YES**	**NO**
6.1.19	Is there an emergency after-hours service for software and hardware problems and telephone numbers displayed in an area where they are freely accessible to the staff?	**YES**	**NO**
6.1.20	Is there a hardcopy file of all patient data (results of tests and test process hard copy) maintained?	**YES**	**NO**
6.1.21	At the end of each working day is a housekeeping exercise constituted, recorded and performed to make sure that all requested test results are in fact sent out or where there are test batches done on certain days, these test batches are checked to make sure that the results have gone out or will be going out?	**YES**	**NO**
6.1.22	When computers are used to capture data directly or to control test runs, is the laboratory able to demonstrate the adequacy of the total system.	**YES**	**NO**

7. DEFINITIONS

7.1 GLP - “Good Laboratory Practice” and all the rules and regulations which apply.
7.2 HOD - Head of department
7.3 SOP - Standard operating procedures or Work instructions
7.4 QC - Quality Control

8. REFERENCES

8.1 Interim South African Medical and Dental Council Pilot Study on Accreditation of Pathology Laboratories, 1995.
8.2 Good Laboratory Practice, The United Kingdom Compliance Programme, Department of Health (UK), 1989.
8.3 ISO/IEC 17025 Standard
8.4 ISO 15189 (2012) Standard

9. APPENDICES

9.1 **Appendix A**: Staff Complement Record
9.2 **Appendix B:** Student Interview Guide
9.3 **Appendix C**: Annual Report by Laboratories Accredited by HPCSA PBMT for Training in Medical Technology
9.4 **Appendix D** : Aaddendum to Form 108 for Phlebotomy Training Sites

FORM 108b

Appendix A*:* Staff Complement Record

MT/MLS: GT/ LA/Interns/Students Ratio = ……

Surname, Initials and Title	Qualifications	HPCSA Registration Number & Registered categories	Year of registration

Appendix B*:* Student Interview Guide

Name:
Laboratory:
Discipline:
Date:

NB! Please give details wherever possible.

1. Describe your internship experience (mention both positive and negative experiences)
2. Do you receive training in your department? *E.g. discussions on test method, principle and result interpretation*
3. Are you free to consult qualified staff members in the laboratory? -
4. Tell me about your theoretical training? When/how is this done? (May be e-learning, self-study, lectures, tutorials etc.) Does this work for you? Explain.
5. How do you know that what you are learning will be tested in the exam (check if training aligned to syllabus)?
6. There may be procedures required for your exam that is not performed in this lab. How will you learn this?
7. Are there any challenges (personal or otherwise) hindering your preparation for the final summative exam?
8. Are there aspect/s of training you think should be done differently?
9. Have you written any tests (excl bench competency tests)? What tests/How often? How have you done in them? Do you know how to improve on these marks? Discuss your improvement plan that will allow you to get back on track with your preparation towards the Final Exam?
10. What recommendations can you make to help future learners training at this lab?
11. How many days were you absent since commencement of Internship? *Please state reasons*.
12. Are you on shift work/ overtime? (i.e. night duty and over weekends)
13. Do you intend to work as a qualified MT/GT/MLS in this lab after exams? Tell me why? (Probe to establish if quality/safe/ structured and supportive learning and work environment in place.
14. When did you participate in a fire drill/building evacuation?
15. Who is the first aider/SHE rep in this lab

Thank you for the feedback

FORM 108b

Appendix C: ANNUAL REPORT BY LABORATORIES APPROVED BY HPCSA PBMT FOR TRAINING IN MEDICAL TECHNOLOGY (TO BE SUBMITTED ON 30 NOVEMBER EACH YEAR)

LABORATORY DETAILS- *Please submit any changes*		
LABORATORY NAME:		
ADDRESS:		
TEL.:	FAX:	EMAIL:
CONTACT PERSON/S:		

STAFF COMPLEMENT- *Please submit all changes using Form 108 - Appendix A*

TEST PROCEDURES- *provide details of any changes to testing performed by laboratory*

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……

TRAINING PROGRAMME- *provide details of any changes to the training programme*

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……

SUCCESSES: *Comment on goals and objectives met*

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……
……

CHALLENGES: *Comment on barriers and problems encountered*

……
……
……

Other general comments:

……
……

Prepared by: …… (Name) ……..…….…. (Job Title)

Signature: …… Date:……..…..

1 # Appendix D: ADDENDUM TO FORM 108 FOR PHLEBOTOMY TRAINING SITES

2. ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

2.1 Is adequate space provided for:		
2.1.1 Reception area for receiving patients?		
2.1.2 Separate private room/s for the collection of specimen from patients	**YES**	**NO**
2.1.3 Furniture suited to the patient's comfort and safety both in the bleeding rooms and in the reception area?	**YES**	**NO**
2.2 Does the specimen collection area provide:		
2.2.1 Adequate lighting?	**YES**	**NO**
2.2.2 Adequate ventilation and/or air-conditioning?	**YES**	**NO**
2.2.3. Facilities for hand washing?	**YES**	**NO**
2.3 Is the area cleaned regularly and maintained in good order?	**YES**	**NO**
2.4 Are there adequate facilities for waste disposal consistent with good laboratory practice and local government regulatory requirements?	**YES**	**NO**
2.5 Is there a Tea room / Recreation room?	**YES**	**NO**
2.6 Does the laboratory have a direct outside telephone line for emergency use?	**YES**	**NO**
2.7 Are effective procedures in place for cleaning and decontamination of equipment and surfaces in procedure rooms?	**YES**	**NO**
2.8 Are records kept of decontamination procedures?	**YES**	**NO**

3. HEALTH AND SAFETY

3.1 Accidents and First Aid

3.3.1 Does the blood collection area have an emergency bag containing the necessary equipment to aid the nurse/ First Aid officer in the resuscitation of a patient when the collection area is not located near an emergency or trauma unit of a hospital or health clinic?	**YES**	**NO**

3.2 Equipment

3.2.1 Does the phlebotomy chair have a back rest and arms or sides to prevent the patient from falling should they faint?	**YES**	**NO**
3.2.2 Is there a suitable bed or reclining chair for patients with fainting tendencies or for use when drawing blood from babies and children?	**YES**	**NO**
3.2.3 Are there suitable hand-held equipment bags or trays adequately stocked with sufficient supplies for collecting specimens from patients?	**YES**	**NO**
3.2.4 Are the phlebotomy supplies appropriate for collecting blood from adults, children and babies using the closed evacuated system and the open system?	**YES**	**NO**
3.2.5 Are there leak-proof specimen bags with separate pockets for request forms available for the transportation of specimens?	**YES**	**NO**
3.2.6 Are containers for sharps within easy reach so that the phlebotomist can discard needles immediately after removal from sampling site?	**YES**	**NO**
3.2.7 Are there suitable medical waste containers for non-sharp biohazardous waste?	**YES**	**NO**

3.2.8 Are there instructions for the monitoring of expiry dates of tubes, drugs and agents used in specimen collection? **YES NO**

3.3 Prevention of laboratory-acquired infection

3.3.1 Is the storage of food in refrigerators or cupboards containing specimens, reagents or equipment prohibited? **YES NO**

3.3.2 Are suitable gloves provided and freely available for use during specimen collection? **YES NO**

3.3.3 Are there suitable hand washing facilities in the rooms used for specimen collection? **YES NO**

4. PROCEDURES

4.1 Specimen collection

4.1.1 Are there SOPs or manuals covering:

- Venipuncture on adults and paediatric patients? **YES NO**
- The collection of capillary blood specimens? **YES NO**
- The collection of arterial blood specimens (where relevant)? **YES NO**
- The collection of non-blood specimens e.g. urine, stools, semen, sputum, swabs, skin scrapings, nail clippings and hair? **YES NO**
- The performance of specialized procedures e.g. blood culture, bleeding time Mantoux test and glucose tolerance tests? **YES NO**
- The handling and rejecting of unsuitable specimens? **YES NO**
- The handling and processing of urgent specimens? **YES NO**
- The preparations of specimens for transportation to the laboratory? **YES NO**

4.1.2 Are there instructions, electronic or paper, regarding:

- The specimen type required for each test and the minimum volume of specimen needed to process the test? **YES NO**
- The appropriate container or anticoagulant of choice required for the requested test? **YES NO**
- The preferred order for drawing multiple blood specimens to prevent cross-contamination of specimens by additives in the collection tubes? **YES NO**

4.1.3 Is the person who collected the specimen identifiable in laboratory records? **YES NO**

4.1.4 Are there written instructions for patients for the self-collection of non-blood specimens? **YES NO**

4.2 Point of care tests (POCT)

4.2.1 Are there written procedures in place for the following tests? **YES NO**

- HIV screen **YES NO**
- Malaria screen **YES NO**
- Glucose using glucometer **YES NO**
- Haemoglobin using haemoglobinometer **YES NO**
- Rhesus antibody testing **YES NO**

- TB Microscopy **YES NO**
- RPR testing **YES NO**

4.2.2 Do these procedures include safety precautions to be observed during testing where applicable? **YES NO**

4.2.3 Are training and competency records available for all staff performing POC tests? **YES NO**

4.2.4 Are reagents used for testing within expiry date, properly labelled and stored correctly? **YES NO**

4.2.5 Is QC performed, verified for acceptability and corrective actions documented where necessary? **YES NO**

4.2.6 Are maintenance and functional checks performed on POCT instruments? **YES NO**

4.2.7 Is proficiency testing or method comparison testing performed for all POC tests? **YES NO**

4.2.8 Are POCT results recorded accurately and reported correctly? **YES NO**

4.2.9 Are these results traceable to the person who performed the test? **YES NO**

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