Tanzania

Private Health Laboratories (Regulation) Act

Private Health Laboratories (Conditions Pre-requisite to Registration and Management) Regulations, 1998

Government Notice 399 of 1998

Legislation as at 31 July 2002

FRBR URI: /akn/tz/act/gn/1998/399/eng@2002-07-31

There may have been updates since this file was created.

PDF created on 20 April 2024 at 14:04.

Collection last checked for updates: 31 July 2002.

Check for updates

About this collection

The legislation in this collection has been reproduced as it was originally printed in the Government Gazette, with improved formatting and with minor typographical errors corrected. All amendments have been applied directly to the text and annotated. A scan of the original gazette of each piece of legislation (including amendments) is available for reference.

Private Health Laboratories (Conditions Pre-requisite to Registration and Management) Regulations, 1998

Contents

Tanzania

Private Health Laboratories (Regulation) Act

Private Health Laboratories (Conditions Pre-requisite to Registration and Management) Regulations, 1998

Government Notice 399 of 1998

Published in Tanzania Government Gazette

Commenced on 1 July 1998

[This is the version of this document at 31 July 2002.]

[Note: This legislation has been thoroughly revised and consolidated under the supervision of the Attorney General's Office, in compliance with the Laws Revision Act No. 7 of 1994, the Revised Laws and Annual Revision Act (Chapter 356 (R.L.)), and the Interpretation of Laws and General Clauses Act No. 30 of 1972. This version is up-to-date as at 31st July 2002.]

[Sections 18; G.N. No. 399 of 1998]

Part I – Regulations (regs 1-10)

1. Short title

These regulations may be cited as the Private Health Laboratories (Conditions Pre-requisite to Registration and Management) Regulations.

2. Interpretation

In these Regulations, unless the context requires otherwise—

"**the Act**" means the Private Health Laboratories Regulation Act[1];

"**approved person**" means a registered health laboratory technologist or a pathologist approved by the Board to manage a private health laboratory in accordance with the provision of the Act;

"**Board**" means the Private Health Laboratories Board established under section 4 of the Act;

"**commencement date**" means the 1st day of July 1998;

"**group A laboratory**" means a referral health laboratory for group B1 laboratories which is attached to a Tertiary Hospital or may operate as an autonomous Private Health Laboratory;

"**group A multipurpose laboratory**" means any group A laboratory which operates health laboratory services in two or more of the following disciplines of the laboratory speciality:

- Clinical Chemistry
- Haematology and Blood Transfusion;
- Histopathology and Cytology;
- Microbiology and Immunology;
- Parasitology and Medical Entomology;

1

Cap. 136

- Any other speciality as approved from time to time by the Board;

"**group A single purpose laboratory**" means a health laboratory which operates with one discipline of the laboratory speciality;

"**group B1 laboratory**" means the referral health laboratory for group B2 laboratories which is attached to a secondary hospital or may operate as an autonomous private health laboratory;

"**group B2 laboratory**" means the first referral health laboratory for group C laboratories which is attached to a primary hospital or can operate as an autonomous private health laboratory;

"**group C laboratory**" means health laboratory services which is attached to a dispensary or health centre or can operate as an autonomous private health laboratory;

"**health education**" means provision of information on laboratory investigations;

"**private health laboratory services**" means services provided by a health laboratory to an individual and the community and includes clinical chemistry, haematology and blood transfusion, histopathology and cytology, microbiology and immunology, parasitology and medical entomology and research, health education and the provision of laboratory investigation supplies;

"**Registrar**" means the Registrar of the Private Health Laboratories Board appointed under section 9 of the Act.

3. Establishment, operation and management of a private health laboratory

(1) No person shall establish, operate, manage or cause to be managed or operated a private health laboratory facility unless the facility complies with the standard guidelines set out in the First Schedule to these regulations and that the facility has been registered and a certificate issued by the Board.

(2) No person shall render a private health laboratory service in terms of provision of health laboratory supplies whether by—

(a) manufacturing;

(b) selling;

(c) supplying;

(d) importing, exporting or as a representative,

unless the items are included in the national health laboratory services supplies list and application has been approved by the Board and permit certificate granted in accordance with the provisions of the Second Schedule to these regulations.

(3) No person shall manage a private health laboratory unless that person is an approved person.

(4) All dispensaries, health centres or hospitals registered under the Private Hospitals (Regulation) Act[2] shall register their health laboratories and be categorised in groups as provided under regulation 2.

(5) Subject to subregulation (4) of this regulation that dispensary, health centre or hospital shall be exempted from paying the laboratory registration fees but shall be responsible to pay other fees as required by the Board.

(6) No health laboratory technologist or pathologist who is in full time employment in the Government or other employer shall manage any of the group B1, B2 or group A private health laboratory, save that such a health laboratory technologist or pathologist may manage a group C health laboratory and may work only on part time basis in any health laboratory group.

2

Cap. 151

(7) An application to render private health laboratory services under regulation 3 of these regulations shall be made through application form shown in form PHL FORM A and application fees shall be payable to the Board upon collection of the application forms.

(8) Fees for all approved applications for rendering private health laboratory services as shown in the Third Schedule shall be made payable to the Board before rendering any private health laboratory services.

(9) Any person who contravenes or fails or refuses to comply with any of the provision of these regulations commits an offence against the Act.

(10) Subject to subregulation (9) any person convicted of an offence to these regulations is liable to a fine of not less than two hundred thousand shillings or to imprisonment to a term of not less than two years or to both fine and imprisonment.

4. Regional laboratory technologist to become an Assistant Registrar

Subject to subsection (4) of section 9 of the Act, the regional laboratory technologist shall be the Assistant Registrar.

5. Authorized officers to inspect equipment and chemicals

All health laboratory equipment, reagents and chemicals imported or distributed in the country shall be subject to inspection by officers authorized by the Board.

6. Defective equipment, reagents and chemicals to be destroyed

If health laboratory equipment, reagents and chemicals are defective and/or expired, the Board shall cause them to be destroyed at the expense of the owner.

7. Accidents to be recorded

All Private Health Laboratories shall—

(a) record all accidents; and

(b) display standard health laboratory safety rules approved from time to time by the Board.

8. Mechanism of receiving complaints to be set

The Board shall set mechanisms of receiving complaints of poor laboratory investigation services and proper action shall be taken in accordance with provision of subregulation (10) of regulation 3 of these regulations.

9. Appointment of permanent and temporary officers

The Board may from time to time by resolution appoint such permanent or temporary officers as they may deem to be necessary and may remunerate such officers by way of salary.

10. Training for members and staff

The Board shall make sure that its members and staff are trained regularly in order to perfom their duties efficiently.

Part II – The Private Health Laboratories (Material and Supplies (regs 11-27)

11.

Except as otherwise provided in these regulations, no person shall manufacture, sell, supply, import or export any health laboratory supply unless—

(a) the product is in the list of the national health laboratory services supplies or has been approved by the Board;

(b) the person holds the appropriate permit required and issued by the Private Health Laboratories Board.

12.

(1) Subject to regulation 11—

(a) the Board may on application being made in the form PHL FORM B specified in Second Schedule to these regulations, permit any laboratory product subject to such conditions as it may impose;

(b) every application for permit for any laboratory product shall be accompanied by non-refundable application fees provided for under the Third Schedule of these regulations and by such documents, items samples, particulars or information as the Board may require;

(c) the Board may charge any applicant such costs as it may incur, for the purpose of carrying out laboratory investigation prior to the issuing of the permit or inclusion of the product in the national health laboratory services supplies list;

(d) any change in any document, item, sample particulars or information provided under subregulation (b) above shall be notified in writing by the applicant to the Board within fourteen days from the date of such change and shall be accompanied by alteration fee as indicated in the Third Schedule;

(e) subject to subregulation (a) of this regulation, the period of permit of laboratory product shall be specified in the permit certificate issued under subregulation (g) of this regulation and where so specified, the permit shall be valid until the end of the specified period;

(f) upon approval of the laboratory supplies or product or payment of permit fee by the applicant the Registrar shall grant to the applicant a permit certificate;

(g) a permit certificate granted under this regulation shall be issued in the form PHL CERT 3 set out in the Second Schedule to these regulations.

(2) Any person who knowingly supplies false or misleading information to the Board in connection with his application for any health laboratory supplies permit commits an offence.

13.

(1) The Registrar shall keep and maintain a suppliers register of the approved health laboratory products.

(2) Subject to subregulation (1) of this regulation, the register shall contain—

(a) name and address of the supplier;

(b) the name of the product (generic);

(c) the name and address of the manufacturer;

(d) manufacturer's certificate number;

(e) the date of issue and expiry of the permit certificate.

14.

The Board may require any person applying for permit of any imported laboratory supplies to furnish a written declaration made by or on behalf of the manufacturer of the product that all the legal requirements governing the manufacture of such product imposed by the laws of the country of manufacturer have been complied with.

15.

The Board may without giving any reason, reject any application for permit of any laboratory product.

16.

The Board may at any time and without assigning any reason suspend or cancel the permit certificate of any laboratory supplies and may cancel conditions to which such permit is subject.

17.

The laboratory chemicals or reagents manufacturing laboratory or plant should not be in the same building with living premises, hotel, bar, restaurant, hair salon and other commercial or entertainment activities.

18.

The registration permit for rendering health laboratory services in terms of provisions of laboratory supplies whether as a manufacturer, retail or whole seller, representative, importer or exporter, shall be renewed annually.

19.

Any person who needs to import or export specimens shall make sure that the specimens are put in a sealed and leak-proof container and placed in a polythene bag similarly well sealed. Specimens sent by post shall obey post office regulations and contained in a plastic bag surrounded by absorbent material and then packed in a strong cardboard box or plastic container.

20.

The Board after scrutinizing permit requests shall recommend to the licensing authority whether or not a person may be issued licence for importing, exporting, selling, manufacturing or operating as a company representative for any of the health laboratory supplies.

21.

No person shall be issued a licence to deal with any of the provisions of the health laboratory supplies unless he has received recommendations from the Registrar of the Private Health Laboratories Board.

22.

Where a person is convicted of an offence under the Act, such conviction shall entail automatic revocation of his permit and this shall be a ground of refusal to review the permit after one year.

23.

Every permit shall be personal to the permittee named therein and shall not be transferable to another person.

24.

Every application for permit to import any health laboratory product listed in the national health laboratory supplies list shall be in a form PHL FORM B set out in the Second Schedule to these regulations and shall be accompanied by fees prescribed by the Third Schedule of these regulations.

25.

(1) The Board may issue such directions to any person as it thinks necessary for the better carrying out of the provisions of these regulations and which may in particular relate to the recall of any laboratory product from the market and the disposal of any product.

(2) Any person who contravenes any directions issued by the Board under subregulation 12(2) of these regulations shall be guilty of an offence.

26.

(1) No person or any local manufacturer of health laboratory supplies or products may export any health laboratory supplies or products from the United Republic of Tanzania to a destination outside Tanzania unless authorised by the Board.

(2) Every authorised manufacturer of health laboratory supplies who exports any health laboratory product shall keep a full and accurate record of all his exports to indicate whether the supplies exported were registered and parcel post shall indicate—

(a) name of product;

(b) date of exportation;

(c) batch number, production date and expiry date;

(d) name and address of customer;

(e) mode of exportation if by post or registered;

(f) address of final destination.

27.

Any person convicted of an offence under Part II of these regulations is liable to a fine of not less than two hundred thousand shillings and not exceeding five hundred thousand shillings or to imprisonment for a term not less than six months or both fine and imprisonment.

Part III – Manufacture of health laboratory supplies or products (regs 28-35)

28.

(1) Every application for a permit to manufacture laboratory supplies or products, shall be in the form PHL FORM C set out in the Second Schedule to these regulations.

(2) A permit certificate granted under this regulation shall be issued in the form PHL CERT 2 set out in the Second Schedule to these regulations and shall be valid from 1st April in the year issued to 31st March in the following year.

(3) A permitted manufacturer shall ensure that the personnel employed at all levels of manufacture—

(a) possess suitable qualifications required for their jobs;

(b) have adequate experience and are technically competent;

(c) are regularly trained during their employment for the purpose of keeping up to date with any advancements or changes; and

(d) are regularly medically examined.

29.

(1) A permitted manufacturer shall ensure that the laboratory supplies are manufactured, processed, packed, labelled and tested in the premises which are in accordance with the standards set by the Board.

(2) Subject to subregulation (1) of this regulation a permitted manufacturer shall ensure that—

(a) there is adequate storage space and good sanitation conditions;

(b) manufacturing operations are carried out in accordance with WHO standards of good manufacturing practices, rules and other requirements as may be determined by the Board;

(c) proper records, of every batch of finished products of laboratory materials distributed are maintained to enable information retrieval or for inspection purposes.

(3) A permitted manufacturer may have in his possession or under his control and supply free samples of health laboratory supplies or products for carrying out health laboratory investigations to laboratory which satisfy him that they may lawfully possess those laboratory supplies in accordance with standard guidelines for health laboratory facility.

30.

Every permit shall be personal to the permittee named therein and shall not be transferable to another person.

31.

(1) A permitted manufacturer shall establish a Quality Control Department under the supervision of a suitably qualified person to control—

(a) materials used in manufacturing process;

(b) manufacturing process; and

(c) the quality and suitability of the finished product.

(2) For the purpose of subregulation (1) of this regulation, a permitted manufacturer shall provide such facilities as may be necessary for the Quality Control Department to discharge its duties.

32.

(1) The Board may certify on any matter relating to any laboratory product where such certification is required by any country importing such product.

(2) Subject to subregulation (1) of this regulation a certification fee prescribed under the Third Schedule of these regulations shall be payable on issued certification.

33.

Any person who refuses or fails to comply with the provisions of Part III of these regulations commits an offence.

34.

Any person convicted of an offence under regulation 33 of these regulations is liable to a fine of not less than two hundred thousand shillings or to imprisonment for a term not less than six months or both fine and imprisonment.

35.

Where a person is convicted of an offence under regulation 33 of these regulations, such conviction shall entail automatic revocation of his permit and it shall be a ground of refusal to review the permit after one year.

Part IV – Medical representative/dealer/retail seller for health laboratory supplies (regs 36-40)

36.

(1) Any person practising as a medical representative/dealer/retail seller for health laboratory products with any engagement in the sale or supply of health laboratory products may have in his possession or under his control free samples of health laboratory supplies or products for carrying out laboratory investigations to laboratories which satisfy him that they may lawfully possess those laboratory supplies in accordance with standard guidelines for health laboratory facilities.

(2) Every medical representative/dealer/retail seller shall within twenty-four hours after supplying any laboratory supply enter the following particulars in a book regularly used for the purpose namely—

(a) the date on which any laboratory product is supplied;

(b) the name and quantity of the laboratory product supplied;

(c) the name and address of the person to whom laboratory products were supplied.

37.

(1) Every application for a permit to operate a medical representative or dealer/retail seller for the laboratory supplies or products, made pursuant to regulation 3(2) of these regulations shall be in a form PHL FORM D set out in the Second Schedule to these regulations.

(2) A permit certificate granted under this regulation shall be issued in the form PHL CERT 4 set out in the Second Schedule to these regulations and shall be valid from 1st April in the year issued to 31st March the following year.

(3) No person shall be a representative/dealer/retail seller for health laboratory products unless that person is approved by the Board.

38.

The Board may issue such directions to any medical representative/retail seller for the health laboratory supplies as it thinks necessary, for the better carrying out of the provisions of these regulations and which may be in particular related to the recall of any laboratory product from the market and the disposal of any product.

39.

Any person who refuses or fails to comply with the provisions of Part IV of these regulations commits an offence.

40.

Subject to regulation 39 any person convicted of an offence is liable to a fine of not less than two hundred thousand shillings or to imprisonment to a term of not less than six months or both fine and imprisonment.

Part V – Importation of health laboratory products (regs 41-42)

41.

(1) Subject to subregulation (2) of regulation 3 of these regulations, no person other than a person issued with a permit under the provisions of these regulations may import to the United Republic of Tanzania any health laboratory equipment, chemicals, reagents or any other laboratory product.

(2) The Board may issue a permit for the importation of materials for new technology trials in the form PHL FORM E set out in the Second Schedule to these regulations authorising the permittee to import any laboratory products for purposes of technology trials notwithstanding that the product is not in the national health laboratory Supplies list.

(3) A new technology import permit will include supplies of only one type of method of any health laboratory investigation.

(4) A new technology import permit shall be reviewed and renewed annually for period not exceeding three years from the date of the issue of the permit and may be specified in the permit.

(5) Every permit shall be personal to the permittee named therein and shall not be transferable to another person.

(6) Any person who refuses or fails to comply with the provisions of these regulations commits an offence.

42.

Any person convicted of an offence under regulation 41(6) of these regulations is liable to a fine of not less than two hundred thousand shillings or imprisonment to a term not less than six months or both fine and imprisonment.

First Schedule (Regulation 4(1))

General standard guidelines for private health laboratory services

1. Any approved person shall not work in another similar health laboratory facility registered under his or her name.

2. The health laboratory facility should have an identified address and should not be in the same building with living premises, hotel, bar and restaurant, hair salon and other commercial or other entertainment activities.

3. The building should be easily accessible by road throughout the year.

4. The premises should have good and properly functioning toilets, shower or bath rooms, sluicing room or washing slab.

5. The premises should have reliable clean running water, effective ventilation, lighting system, incinerator and burial area for sharps after sterilization.

6. There should be an effective communication system between the laboratory and other health care facilities to ensure early management and referral of patients.

7. Each health laboratory facility shall keep records on specimens from patients and or public sources including examination results, such records shall be kept for 5 years before throwing them away, and shall be accessible for inspection by required authority.

8. There should be adequate space for all rooms offering different kinds of health laboratory services, minimum size for reception room should be floor area 2 x 2 metres, working room floor area 5 x 4 metres.

9. Any professional malpractice, misconduct or gross negligence may result in closure of the premises and the Board may take any disciplinary action.

10. (1) The health laboratory facility shall be allowed to operate after—

(a) the premises have been inspected by the regional laboratory technologist who may be accompanied by any other person(s) approved by the Board;

(b) an application has been approved by the private health laboratory Board and a certificate of registration issued by the Registrar of the Private Health Laboratory Board.

(2) The registration shall be renewed annually.

11. There shall be an inspection fee for re-registration charged yearly by the Private Health Laboratory Board to any private health laboratory facility.

12. The approved person should always be available at the health laboratory facility in case of the Group B2, Group B1 and Group A laboratories and must always personally be present at the Group C laboratory for a minimum of 2 hours twice a week.

13. The Manager or owner of the laboratory facility must employ at least the minimum number of workers in accordance with the standard guidelines for a health laboratory facility.

14. The operation of the private health laboratory will be done in accordance with the guidelines issued from time to time by the Ministry of Health.

15. The private health laboratory facility shall have appropriate standard equipment and other supplies according to the laboratory groups before offering different kinds of service.

16. The equipment shall have a regular system of maintenance and operational and service manuals should be available.

17. (1) The costing mechanisms for various health laboratory services provided shall be made available to the Board or its inspectors on demand.

(2) Patients or clients have full right to get an invoice with details on how the total cost was arrived at.

(3) Each charged component must be shown separately.

18. There shall be no advertising either in mass media or through posters or signs. Any sign should be made no more than 300 metres from the private health laboratory facility itself and shall only be for directional purposes.

19. Private health laboratories are not allowed to undertake clinical examinations or prescribe or provide prescriptions or medicines to patients.

20. The health laboratories facility should make use of the standard bench work manuals provided for or approved by the Ministry of Health.

21. Walls and floors of the health laboratory should be impervious to water and have smooth washable surfaces.

22. The windows should readily be opened to allow adequate ventilation and sufficient light.

23. The bench tops should be smooth without cracks by using formica or similar hard material allowing easily cleaning and disinfection.

24. The roof should be of corrugated sheets or concrete roofing or tiles.

25. It is mandatory for a private health laboratory to participate in National Quality Assurance programs and a fee set out in the Third Schedule shall be paid annually for this activity.

Standard guidlines for each health laboratory group

1. **Group C Laboratories**

The Group C laboratories should have the following:

1.1 **Premises:**

- Reception and one working room;
- Two washing sinks, one at the reception and another at working room;
- Two bench and wall shelves one for working reagents and another for manuals and record files;
- Two wastebins (a) one for sharp and (b) another for disposable waste.

1.2 **Furniture:**

- One table for reception;
- One chair for reception;
- One bench for patients at reception;
- Two stools at the working room;
- Two working benches.

1.3 **Essential major equipment:**

- Binocular powered microscope (electrical or light);
- Centrifuge machine electrical or manual;
- Haemoglobinometer/Lovibond comparator;
- Weighing scale;
- Timer;
- Kerosene stove;
- Spirit lamp/bunsen burner;
- Staining rack;
- Tally counter;
- Boxes for microscope slides;
- Cover glass for haemoglobinometer;
- Differential counter;
- One refrigerator with freezing compartment for reagents and/or vaccines;

- Glucometer;
- Improved Neubauer's chamber.

1.4 **Essential tests and methods:**

Specimen	Test	Method
1. Blood	Haemoglobin	Haemoglobincyanide method
	Blood film	Romanowsky and field stain
	Total leucocyte count	Turk's method
	Differential leucocyte count and cell morphology	Romanowsky stain
	Sickle cell	Sodium metabisulphite slide test
	screening test	
	Syphilis screening	RPR
	Glucose	Glucometry
2. Urine	Glucose	Glucostix/Benedict's test
	Protein	Albustix/Sulphosalicylic acid
	Sediment	Direct microscopy
3. Stool	Protozoa/Ova	Direct microscopy saline and iodine preparation
4. Sputum	AFB	Ziehl Neelsen stain
5. Skin	AFB	Ziehl Neelsen stain
	Fungal elements	Direct potassium hydroxide preparation
	Onchocerca volvulus	Direct saline preparation
		Romanowsky staining microscopy

6. Pus/ Exudates	Trichomonas	Direct saline preparation miocroscopy
	Bacteria	Gram staining
7. Any other essential tests and methods as may be approved by the Board.		

1.5 **Preservation and posting of:**

(a) Swab specimens — culture: use Stuarts transport medium;

(b) Sputum — TB culture: use empty sterile container.

1.6 **Human resources:**

- Licensed Laboratories Technologist
- Laboratory Attendant

2. **Group B2 Laboratories**

The Group B2 Laboratories should have the following:

2.1 **Premises:**

- Reception and two working rooms
- One room for stool, urine examinations, Gram staining and Z/N staining
- Another room for Haematology and Clinical Chemistry

[N.B. If the laboratory is going to perform Blood Group Serology (B/T) then separate rooms for blood donation and blood group serology are required.]

- Three washing sinks: one at reception and others one at each working room
- Lockable cupboards
- Laboratory store with shelves for reagents/chemical
- Wall/bench shelves for reagents
- Three working benches.

2.2 **Furniture:**

- Wall/bench shelves for reagents
- Lockable cupboards
- Reception to have one table, one chair, one bench for patients, one sink and pigeonholes for the laboratory results
- Each working room to have one table, one chair, one sink and 2 stools
- Donation room to have donation beds, one bench, a compartment for resting, room to which will have one set of couches, one coffee table, wall shelf/cupboard and one fan in area with hot climate
- Laboratory store with shelves for reagents/chemicals.

2.3 **Essential major equipment:**

All equipment found at the Group C Laboratories plus the following:

- VDRL rotator
- Fuchs-Rosenthal chamber
- Autoclave/Pressure cooker
- Waterbath
- Hot air oven
- Distiller
- Maximum/Minimum thermometer
- Sterilizer/kerosene stove
- Electrical stabilizer for sensitive equipment
- Westergren stand
- ELISA reader or optional
- ELISA washer.

2.4 Essential tests and methods—

All tests and methods of Group C Laboratories plus the following:

Specimen	Test	Methods
Urine	Bile pigments	Fouchet's test
	Ketone bodies	Rothera's test
	Urobilinogen	Ehrlich's test
	Blood	Reagent tablet
	Pregnancy test	Slide latex agglutination
Stool	Occult blood	Reagent tablet
Blood/Serum	ESR	Westergren
	Platelet count	Ammonium oxalate
	Reticulocytes count	Brilliant cresyl blue test
	Bleeding time	IV
	Clotting time	Lee and White
	ABO and Rhesus grouping	Tile and tube method
	Compatibility testing	Tube bovine albumin
	Syphilis	VDRL
	HIV tests	Visual or ELISA
	Glucose	O-toluidine method
	Total protein	Biuret reaction
	Creatinine	Jaffé
	Bilirubin	Jendrassik - Grof

	Urea	Reagent strips
	Alkaline phosphatase	PNPP
	ALAT/ASAT	Commercial Kit
CSF	Total protein	Coomassie brilliant blue
	Glucose	O-toluidine
	Cell count	Fuchs-Rosenthal counting chamber
	Differential cell count	Romanowsky stain
	Deposit: direct with preparation organisms	Gram stain and Z/N stain

2.5 **Human resources:**

- Registered laboratory technologists
- Licensed laboratory technologist
- Laboratory attendants
- A full time Pathologist may replace one registered laboratory technologist

3. **Group B1 Laboratories**

Group B1 Laboratories should have the following—

3.1 **Premises:**

- Reception and three working rooms
- One room for stool, urine, gram stain and Z/N stain
- Another room for haematology, B/S and Clinical Chemistry and another room for Serology and Bacteriology

N.B. If the laboratory is going to perform Blood Group Serology (B/T) then separate rooms for blood donation and blood group serology are required.

- Laboratory store with shelves for reagents
- Preparation and washing room (2 x 2m)
- Office for the laboratory head
- Lockable cupboards
- Walls/bench shelves for working reagents

3.2 **Furniture:**

- Reception to have one table, one chair, one bench for patients, and a pigeon hole for the laboratory results
- Each working room to have one table, one chair and two stools and two working benches
- Donation room to have donation bed, one bench and compartment for resting room to which will have one set of couches, one coffee table wall self/cupboard and one fan in areas with hot climate
- Lockable cupboards
- Walls/bench shelves for working reagents

3.3 **Essential major equipment:**

All equipments found at the Group B2 laboratories plus the following:

- Analytical balance
- Incubator
- Flame photometer or any other appropriate equipment
- Gas cylinders
- Vacuum pump
- Anaerobic jars
- pH meter
- ELISA reader or any other appropriate equipment
- ELISA washer
- Voltage stabilizer
- Spectrophotometer
- Blood cell counter

3.4 **Essential test and methods:**

All tests and methods of group B2 laboratories plus the following:

Specimen	Test	Methods
Blood Serum	Prothrombin time	Manufacturer's manual
	Partial Thromboplastin time	Manufacturer's manual
	Full Blood Picture	Automation method
	Bone marrow aspiration	Romanowsky stain and microscopy
	Widal test	Screening and titration method
	Uric Acid	Caraway
	Albumin	Bromocresol green
	Electrolytes	Flame emission or any other approved method
Bacteriological Blood	Culture and sensitivity	Approved Standard Inoculation
Pus	Culture and sensitivity	Approved Standard Inoculation
Urine	Culture and sensitivity	Approved Standard Inoculation
CSF	Culture and sensitivity	Approved Standard Inoculation
Other body fluid	Culture and sensitivity	Approved Standard Inoculation
Stool	Culture and sensitivity	Approved Standard Inoculation
Skin scrapings or other tissues	Specific test for fungus	Approved method

3.5 **Human resources:**

• Registered Specialist Laboratory Technologists or Pathologists	
• Haematology/Blood transfusion	1
• Clinical Chemistry	1
• Microbiology	1
• Registered laboratory technologist	4
• Licensed laboratory technologist	5
• Laboratory Attendants	5

4. **Group A Laboratories**

4.1 **Single purpose group A laboratory**

This type of laboratory operates with one speciality as:

- Group A single purpose Haematology Laboratory
- Group A single purpose Clinical Chemistry Laboratory
- Group A single purpose Blood Group Serology
- Group A single purpose Histopathology Laboratory
- Group A single purpose Parasitology Laboratory
- Group A single purpose TB Laboratory
- Group A single purpose Microbiology Laboratory
- Group A single purpose Laboratory for any specific health problem

Each single purpose group A laboratory should have the following:

4.1.1 **Premises:**

Reception and two working rooms and store

4.1.2 **Furniture:**

As for B2 Laboratory

4.1.3 **Essential major equipment:**

As per speciality according to standard guidelines for health laboratory facility

4.1.4 **Essential tests and methods:**

According to laboratory discipline, all tests at B1 level

4.1.5 **Human resources:**

- Registered specialist health laboratory technologist
- Laboratory attendant

4.2 **Multipurpose group A laboratory**

The specification of the laboratory will be same as that of Group B1 with additional space depending on additional specialised activities

4.2.1 **Premises:**

The laboratory building shall have adequate rooms for each of the required specialities (departments)

- Haematology
- Blood group serology
- Microbiology
- TB laboratory
- Clinical Chemistry
- Parasitology
- Histopathology
- Office room for the laboratory head
- Sluice
- Weighing room
- Collection of blood for transfusion
- Media preparation (microbiology)
- Cold room
- Staff room
- Toilet rooms for staff, male patients and female patients
- Incinerator and closed drainage facility

4.2.2 **Furniture:**

As for B1 Laboratory

4.2.3 **Essential major equipment**

(a) **Haematology**

- Voltage stabilizer
- Haemoglobinometer
- Haematocrit centrifuge
- Binocular microscope
- Dark ground/phase microscope
- Improved Neubauer's chamber
- Differential counter

- Blood mixer
- Electrophoretic tank
- Electrophoretic power
- Slide cabinet
- Counter
- Coagulometer
- Refrigerator with freezer
- Hot air oven
- Sterilizer
- Analytical balance

(b) **Blood transfusion (Blood Group Serology)**

- Voltage stabilizer
- Binocular microscope
- Blood cabinet with alarm
- Centrifuge refrigerator
- Vacuum pump
- Platelet shaker
- Electric sealer
- ELISA reader
- Haemoglobinometer
- Safety cabinet
- Freeze-drier
- VDRL rotator
- Cold room
- Incubator (air)
- Waterbath
- Sterilizer
- ELISA washer
- Manual balance
- Refrigerator
- Deep freezer -20°C

(c) **Microbiology/Immunology:**

- Voltage stabilizer
- Binocular microscope
- Incubator

- Waterbath
- Centrifuge, electrical
- VDRL rotator
- Fuchs-Rosenthal chamber
- Fluorescent microscope
- Cabinet (safety)
- Centrifuge refrigerator
- Deep freezer -70°C
- Hot blocks
- Microserology equipment
- Microfiltration apparatus
- ELISA reader
- ELISA washer - manual
- Freeze-drier
- Carbon dioxide incubator
- Analytical balance
- Manual balance

(d) **TB Laboratory**

- Voltage stabilizer
- Binocular microscope
- Incubator
- Shielder centrifuge
- Inspissator
- Safety cabinet — Class II
- Fluorescent microscope
- Walk-in incubator (37°C)

(e) **Clinical Chemistry**

- Voltage stabilizer
- Electric centrifuge
- Spectrophotometer
- Waterbath
- Flame photometer
- Electrophoretic tank
- Electrophoretic power supply
- pH meter

- Blood mixer
- Hot plate with magnetic stirrer
- Reflux flask
- Pipette washer
- Blood gas analyzer
- Chloride meter
- Osmometer
- Freeze-drier
- Enzyme analyzer
- Hot air oven
- Electrophoretic scanner

(f) **Parasitology:**

- Voltage stabilizer
- Binocular microscope
- pH meter
- Slide cabinet
- Mechanical shaker
- ELISA reader
- ELISA washer
- Dissection microscope
- Fluorescent microscope
- Fume cupboard
- Incubator
- Electrical balance
- Freeze-drier (small)
- Analytical balance
- Hot air oven
- Refrigerator with freezer

(g) **Histopathology**

- Voltage stabilizer
- Automatic knife sharpener
- Embedding machine
- Vacuum filtration machine
- Automatic tissue processor
- Microtome

- Hot plate with magnetic stirrer
- Waterbath
- Cryostat
- Binocular microscope
- Safety cabinet
- Automatic staining equipment
- Freeze-drier (small)
- Analytical balance

4.2.4 **Essential tests methods:**

According to laboratory disciplines all tests at B1 level.

4.2.5 **Human resources:**

• Registered specialist health laboratory technologist or pathologist	1
• Registered health laboratory technologists	1
• Laboratory attendant	1

Second Schedule

Forms

[Editorial note: The forms have not been reproduced.]

Third Schedule (Section 6(3))

Fees

The following fees shall be paid in respect of matters arising under the Act.

1.	Application fees		T.Shs. 5,000/-
2.	Registration fees		
	1.	Group C laboratory	T.Shs. 30,000/
	2.	Group B2 laboratory	T.Shs. 40,000/
	3.	Group B1 laboratory	T.Shs. 50,000/
	4.	Group A single purpose laboratory	T.Shs. 50,000/
	5.	Group A multipurpose laboratory	T.Shs. 80,000/
	6.	Health laboratory attached to private dispensary health centre or hospital	NIL
3.	Inspection fee for re-registration fees		
	1.	Group C laboratory	T.Shs. 15,000/-
	2.	Group B2 laboratory	T.Shs. 20,000/-
	3.	Group B1 laboratory	T.Shs. 25,000/-
	4.	Group A single purpose laboratory	T.Shs. 25,000/-
	5.	Group B multipurpose laboratory	T.Shs. 40,000/-
4.	Payment for Quality Assurance Activity:		
	1.	Group C laboratory	T.Shs. 5,000/-
	2.	Group B2 laboratory	T.Shs. 5,000/-
	3.	Group B1 laboratory	T.Shs. 10,000/-
	4.	Group A single purpose laboratory	T.Shs. 10,000/-

	5.	Group B multipurpose laboratory	T.Shs. 15,000/-
5.	Other Fees:		
	1.	Importation permit	T.Shs. 2% of Free on Board
	2.	Exportation permit	T.Shs. 60,000/-
	3.	Manufacturing permit	T.Shs. 120,000/-
	4.	Manufacturing certificate fees	T.Shs. 30,000/-
	5.	Medical representative for health laboratory supplies and products	T.Shs. 120,000/-
	6.	Dealer or wholesaler of health laboratory supplies/products	T.Shs. 100,000/-
	7.	Retail seller or health laboratory supplies or products	T.Shs. 30,000/-
	8.	Alteration fee	T.Shs. 30,000/-
	9.	Importing materials for new technology trial	T.Shs. 50,000/-