Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JUN 11 2021

ADMINISTRATIVE ORDER
No. 2021 - 0037

SUBJECT: New Rules and Regulations Governing the Regulation of Clinical Laboratories in the Philippines

I. RATIONALE

By virtue of Republic Act No. 4688 s. 1966, "An Act Regulating the Operation and Maintenance of Clinical Laboratories and Requiring the Registration of the Same with the Department of Health, Providing Penalty for the Violation Thereof, and for Other Purposes," the Department of Health (DOH) through the Bureau of Medical Services, now known as the Health Facilities and Services Regulatory Bureau (HFSRB), was mandated to ensure public health, safety and welfare through enforcement of the Act and was authorized to issue such rules and regulations as may be necessary to carry out the law. Clinical laboratory services play an important role in the diagnosis, treatment, prevention and control of disease. Thus, it is imperative that the laboratories generate accurate, precise and reliable laboratory test results in a timely manner to aid the physicians in assuring the quality of patient care.

Through the years, several laboratory technological advancements have been introduced. As such, certain provisions in the current Administrative Order (AO) No. 2007-0027, dated August 22, 2007, titled "Revised Rules and Regulations Governing the Licensure and Regulation of Clinical Laboratories in the Philippines," may have become outdated. This policy is being issued to align the laboratory procedures with the requirements of AO 2020-0047 titled "Rules and Regulations Governing the Licensure of Primary Care Facilities in the Philippines."

The necessity to review the current AO and to revise and update the minimum standards and technical requirements for licensing clinical laboratories in the Philippines is aligned with the main objective of Republic Act No. 11223 or the Universal Health Care Act which is to guarantee access to quality and affordable health products, devices, facilities and services.

II. OBJECTIVE

These rules and regulations shall serve as the new guidelines in the licensing of diagnostic clinical laboratories in the Philippines which shall ensure accountability of the laboratory on generation of accurate, precise and reliable laboratory results in a timely manner through continuous compliance.

III. SCOPE OF APPLICATION

This Order shall apply to all individuals, agencies, partnerships or corporations, whether private or government-owned, involved in the application for DOH license to operate and those in the operation of diagnostic clinical laboratories in the Philippines.

This Order shall also apply to the Bangsamoro Autonomous Region in Muslim Mindanao (BARMM) subject to the applicable provisions of RA 11054 or the "Bangsamoro Organic Act" and subsequent rules and policies issued by the Bangsamoro Government.

IV. DEFINITION OF TERMS

A. Applicant – refers to any natural juridical person, government instrumentalities/agencies, partnership, corporation or agency seeking a license to operate and maintain a clinical laboratory.

B. Assessment Tool – the checklist which prescribes the minimum standards and requirements for licensure of a clinical laboratory.

C. Clinical Laboratory (CL) – a facility that is involved in the (a) pre-analytical, (b) analytical, (c) and post-analytical procedures, where tests are done on specimens from the human body to obtain information about the health status of a patient for the prevention, diagnosis and treatment of diseases. These tests include, but are not limited to, the following disciplines: anatomic pathology, clinical chemistry, clinical microscopy, endocrinology, hematology, immunology and serology, microbiology, toxicology, as well as molecular and nuclear diagnostics.

D. Department of Health - License to Operate (DOH-LTO) – a formal authorization issued by the DOH to an individual, partnership, corporation, association or any government agency/unit seeking to perform laboratory tests in compliance with the requirements prescribed in this Order.

E. Department of Health - Permit to Construct (DOH-PTC) – a permit issued by DOH through HFSRB or Center for Health Development-Regulation, Licensing and Enforcement Division (CHD-RLED) to an applicant who will establish and operate a hospital or other health facility, upon compliance with required documents prior to the actual construction of the said facility. A DOH-PTC is also required for hospitals and other health facilities with substantial alteration, expansion, renovation, increase in the number of beds, transfer of site, or for additional services (add-ons) beyond their service capability. It is a prerequisite for License to Operate.

F. External Quality Assessment Program (EQAP) – a program where participating CL are given unknown samples for analysis. These samples should be treated as ordinary human specimens for the usual processing and examination. The quality of performance of the CL shall be assessed through the closeness of its results to the pre-determined value or reference value generated by the participating CL through peer group analysis.

G. Initial Application – refer to applications by newly constructed health facilities, or those with changes in the circumstances of the facility, such as, but not limited to, change of ownership, transfer of site, increase in beds or for additional services beyond their service capability and major alterations or renovations.

H. Mobile Clinical Laboratory (MCL) – a laboratory testing unit capable of performing limited CL diagnostic procedures. It moves from one testing site to another, and it has a DOH-licensed CL as its main laboratory.

I. National External Quality Assessment Scheme (NEQAS) – an EQAP activity conducted by the National Reference Laboratories to assess the quality of performance and accuracy of the results of laboratories.

J. National Reference Laboratory (NRL) – the highest level of laboratory in the country performing highly complex procedures, including confirmatory testing, that is not commonly performed by the lower level of laboratory. It is the responsible entity for facilitating NEQAS to ensure compliance to quality standards for regulation and licensing of all laboratories in the Philippines.

K. Physician's Office Laboratory (POL) – refers to a doctor's office/clinic wherein CL examinations are performed for the purpose of monitoring the doctor's patients only, wherein NO official results shall be issued. In this Order, POL within the premises of a DOH-regulated facility shall be under the supervision of the CL.

L. Point of Care Testing (POCT) – refers to diagnostic testing done at or near the site of patient care rather than in the CL. It may be in the emergency room, operating suites, wards, and ambulances.

M. Satellite Clinical Laboratory (SCL) – refers to an extension of the main CL located within the facility's compound or premises. It shall have the same service capability as the main laboratory.

N. Referral Tests – refers to CL tests that are either sent-out or outsourced to other DOH-licensed CL with the same or higher service capability.

V. GENERAL GUIDELINES

A. All CL shall secure DOH-LTO prior to its operation and must comply with the minimum regulatory standards and requirements at all times.

B. The DOH-LTO shall be secured from the DOH regulatory office in accordance with DOH guidelines.

C. Only DOH-licensed institution-based CL may have a SCL which shall be located within the premises of the regulated health facility.

D. A DOH-licensed CL may have MCL services as listed in Section IV of Annex A, provided, they adhere to the standard testing protocols.

E. The DOH-licensed CL shall not perform any examinations or testing beyond its authorized service capability. However, it may be allowed to offer laboratory services other than the respective stipulated minimum services, such as but not limited to, MCL, SCL, confirmatory testing for Glucose-6-Phosphate Dehydrogenase (G6PD) Deficiency, and Rapid HIV Diagnostic Algorithm (rHIVda), provided that the additional

services have been approved and indicated as add-on services in the DOH-LTO of the CL.

F. Unit/Section of health facilities performing diagnostic CL tests such as, but not limited to, arterial blood gas and/or Radioimmunoassay for thyroid function tests and Prostate Specific Antigen shall be under the DOH-licensed CL.

G. The head of the CL shall be a pathologist certified by a professional organization recognized as the Accredited Professional Organizations/Accredited Integrated Professional Organizations of the Professional Regulation Commission. The head of laboratory shall ensure the optimal overall operations and maintenance of the CL and if applicable, of its SCL and MCL.

H. There shall be an adequate number of competent personnel assigned in the different services provided by the DOH-licensed CL, which includes the MCL, SCL, remote collection activities, if applicable.

I. CLs that are operated and maintained exclusively for research and teaching purposes shall be required to register with the DOH-HFSRB.

J. The DOH designated NRL shall be covered by the license of the CL of the hospital where they are affiliated with. Independent NRLs, or those designated by DOH but are not affiliated with any DOH-regulated health facility, shall secure a DOH-LTO from HFSRB.

K. All CLs shall make their prices for laboratory services accessible to the public as mandated by the UHC law and related DOH issuances.

L. At the Central Office, the Director IV, or in his/her absence or unavailability or when delegated, the Director III of HFSRB, shall approve the issuance of the DOH-LTO of the CL.

M. At the CHD, the Director IV, shall approve the issuance of the DOH-LTO of the CL.

N. In the advent of new technologies or diagnostic platforms that shall affect the current licensing standards for CL, Department Circulars shall be issued, as needed, as supplements to this Order.

O. The CL shall be compliant with the prescribed standards and requirements (Annex A), Assessment Tool for Licensing Clinical Laboratories (Annex B1 and B2) and other relevant laws and issuances. These standards shall also apply to MCL and SCL.

P. The DOH-LTO may be revoked, suspended or modified in full or in part for any false statement by the applicant, or as shown by the record of inspection or for a violation of, or failure to comply with any of the terms and conditions and provisions of these rules and regulations.

VI. SPECIFIC GUIDELINES

A. Classification of Clinical Laboratories

1. Classification by **Ownership**
   a. Government – operated and maintained, partially or wholly, by the national government, a local government unit (provincial, city or municipal), any other political unit or any department, division, board or agency thereof.
   b. Private – privately owned, established and operated with funds through donation, principal, investment or other means, by any individual, corporation, association or organization.

2. Classification by **Institutional Character**
   a. Institution-based – a laboratory that is located within the premises and operates as part of a DOH licensed health facility.
   b. Non-institution based – a laboratory that operates independently and is not attached to any DOH licensed health facility.

3. Classification by **Function**
   a. Clinical Pathology – deals with the chemical and cellular analyses of blood and other body fluids (includes, but not limited to, clinical chemistry, clinical microscopy, toxicology, therapeutic drug monitoring, immunology and serology, hematology and coagulation), identification and examination of microbes and parasites (bacteriology/parasitology/mycology/virology).
   b. Anatomic Pathology – provides processing and examination of surgical specimens as to the physical appearance and microscopic structure of tissues, such as, but not limited to, surgical pathology, cytopathology, immunohistochemical techniques, autopsies and forensic pathology.
   c. Molecular Pathology – deals with the analysis of certain genes, proteins and other molecules in samples from organs, tissues or bodily fluids in order to diagnose disease and/or to guide the prevention and treatment of disease based on the principles, techniques and tools of molecular biology as they are applied to diagnostic medicine in the laboratory.

4. Classification by **Service Capability**
   a. Clinical Laboratory for Clinical and Anatomic Pathology

	Provides the following minimum service capabilities:	*Provides the minimum service capabilities of a primary category, plus the following:*	*Provides the minimum service capabilities of a secondary category, plus the following:*	*Provides one (1) or two (2) specialized tests that are not classified under Anatomic or Molecular Pathology, as exemplified below:* - *Hormones* - *Trace Metals* - *Tumor markers* - *Allergy Panel* - *This classification shall also apply to facilities offering DOH-program related tests, e.g.,*
Clinical Microscopy	- Urinalysis - Fecalysis - Fecal Occult Blood Test - Pregnancy Test (Rapid Test Kits – Lateral Flow) - Wet Smear for Trichomonas			
Clinical Chemistry	- Fasting and Random Blood Sugar - Oral Glucose Tolerance Test - Lipid Profile (Total Cholesterol, HDL, LDL, Triglycerides) - Creatinine - Blood Urea Nitrogen - Blood Uric Acid	- Serum Electrolytes (Sodium, Potassium, Chloride) - ALT - AST	- Other Clinical Chemistry Examinations Hospital-based: Arterial Blood Gases	

	Provides the following minimum service capabilities:	*Provides the minimum service capabilities of a primary category, plus the following:*	*Provides the minimum service capabilities of a secondary category, plus the following:*	*Kato Katz for Schistosomiasis, Malarial Smear, Filaria Smear, Slit-skin Smear, Rapid Plasma Reagin for Syphilis*
Hematology	- Complete Blood Count (Hemoglobin, Hematocrit, Red Blood Cell Count, White Blood Cell Count with Differential Count, Quantitative Platelet Count) - Forward and reverse ABO grouping and Rh (D) typing (tube method)	For Hospital-based - Coagulation studies (PT, aPTT)		
Serology/ Immunology	- Dengue - Syphilis - Hepatitis B (Screening) - HIV (Screening) Using Rapid Test Kits		- Any machine-based serological and immunological testing such as, but not limited to: tumor markers, thyroid function tests and hepatitis profile	
Microbiology	- TB (DSSM) or Nucleic Acid Amplification Test – for government facilities	- Gram Stain - KOH	- Culture and sensitivity (aerobic and anaerobic)	
Anatomic Pathology		- Pap smear	For Hospital-based: - Cytology and Histopathology	

b. Clinical Laboratory for Anatomic Pathology only – provides services for any of the following, but not limited to: cytology and histopathology.
c. Clinical Laboratory for Molecular Pathology only – provides services for genetics, immuno/hematopathology and infectious disease. COVID-19 testing laboratories shall be covered by another Order.

VII. PROCEDURAL GUIDELINES

A. Permit to Construct (PTC)

1. A completely filled out application form for DOH-PTC (downloadable at www.hfsrb.doh.gov.ph), whether manual or online, shall be submitted to the DOH regulatory offices, as specified in Section V. B of this Order.

2. A DOH-PTC shall be required for construction of new CL and for renovation or expansion of existing CL, including change in ownership and transfer of location.

3. The application shall be processed in accordance with the procedural guidelines set forth in A.O. No. 2016-0042, also known as, "Guidelines in the Application for Department of Health Permit to Construct (DOH-PTC)."

B. License to Operate (LTO)

1. Any person, firm or corporation desiring to establish, operate and maintain CL shall submit an accomplished application form to HFSRB/CHD-RLED in accordance with the current DOH guidelines, whether manual or through the Online Licensing and Regulatory System (OLRS), once it is fully functional.

2. A complete application for DOH-LTO of CL shall consists of the following:
   a. Completely filled out application Form 1 and its attachments (downloadable at www.hfsrb.doh.gov.ph);
      i. Notarized Acknowledgement
      ii. Any of the following proof of ownership and name of health facility
         - DTI/SEC/CDA Registration including Articles of Incorporation/ Cooperation and By-Laws
         - Enabling Act/ LGU Resolution (for government health facility)
      iii. Accomplished Self-Assessment Tool
      iv. Health Facility Geographic Form
   b. Copy of official receipt payment.
   c. Certificate from NRL-SLH/SACCL for rHIVdA Confirmatory, if applicable.
   d. Certificate from Newborn Screening Reference Center (NSRC), if applicable.

3. Upon receipt of the complete application forms, the HFSRB/CHD-RLED representative, in accordance with the current DOH guidelines, reviews the application and conducts an on-site assessment of the laboratory to determine full compliance with the standards and technical requirements.

4. If, upon assessment, the laboratory is not fully compliant with the licensing requirements, the HFSRB/CHD-RLED, in accordance with the current DOH guidelines, shall provide a written report outlining the laboratory's deficiencies. The laboratory must comply with the deficiencies within thirty (30) days. Otherwise, the application shall automatically be denied.

5. The DOH-LTO, whether initial or renewal, shall only be issued after the HFSRB/CHD-RLED, in accordance with the current DOH guidelines, has determined that the laboratory is fully compliant.

6. Submitted complete applications that are not processed within twenty (20) days by the HFSRB/CHD-RLED, in accordance with the current DOH guidelines, due to force majeure, shall automatically be granted the LTO, and a post-licensing visit shall be scheduled.

7. Only DOH licensed CL identified by the program and has already secured a certificate of "Certified rHIVda Confirmatory Laboratory (CrCL)" from the NRL-SLH/SACCL or its designated regional counterpart, shall be allowed to apply for a license CrCL.

8. A DOH-licensed hospital-based tertiary CL, already certified by the NSRC, may apply as a G6PD Deficiency confirmatory laboratory to HFSRB.

9. For institution-based CL, the One-Stop Shop (OSS) Licensing System, pursuant to Administrative Order No. 2018-0016 dated June 4, 2018, titled "Revised Guidelines in the Implementation of the One-Stop Shop Licensing System," shall

10. The DOH-LTO is non-transferable and a new application for DOH-LTO shall be required in case of change of ownership or transfer of location.

11. The HFSRB/CHD-RLED, in accordance with the current DOH guidelines, shall be notified in writing of any change in management name, ownership, or headship or laboratory personnel. Failure to notify of any substantial change in the condition of the laboratory, i.e. changes in the physical plant, equipment, or personnel, in writing within fifteen (15) days, may be a basis for the suspension or revocation of the DOH-LTO.

12. Different branch(es) of a CL, even if owned by the same entity shall secure separate DOH-LTO.

13. Application for DOH-LTO shall be in compliance with AO No. 2019-0004 dated April 30, 2019, titled "Guidelines on the Annual Cut-off Dates for Receipt of Complete Applications for Regulatory Authorizations Issued by the Department of Health."

14. The DOH-LTO shall be placed in an area that can be readily seen by the public, at all times.

C. Certificate of Registration (COR)
   1. COR is required for research and teaching laboratories.

   2. Applicants shall submit an accomplished registration form (downloadable at www.hfsrb.doh.gov.ph) together with the necessary attachments to HFSRB, which includes Annex for services.

   3. The applicant shall be required to pay a non-refundable application fee before submission of the requirements as part of complete application.

   4. The HFSRB shall evaluate and accept applications based on the due execution of forms and completeness of attachments.

D. Validity
   1. The DOH-LTO is valid for one (1) year.

   2. COR for CL that is operated and maintained exclusively for research and teaching purposes shall be required to register with the DOH-HFSRB every three (3) years.

E. Fees
   1. All fees shall follow the prescribed fees by the DOH.

   2. All fees/checks shall be paid to the order of DOH Central Office/ CHD Cashier, whichever is applicable in person, through postal money order or online payments approved by the DOH.

F. Monitoring
   1. Authorized representatives from the HFSRB/CHD-RLED in accordance with the current DOH guidelines, may conduct unannounced on-site visits of licensed CL and registered research and teaching laboratories to monitor and document the continuous compliance of the CL to the set standards.

2. If upon monitoring visit, the CL is found to be violating any of the rules and regulations stated herein relative to its operation, the HFSRB/CHD-RLED in accordance with the current DOH guidelines, may immediately impose preventive suspension.

3. CL that are operated and maintained exclusively for research and teaching purposes shall not issue official results for diagnostic purposes. They may be monitored to ensure that they are not operating beyond allowed capabilities.

VIII. ROLES AND RESPONSIBILITIES

A. Health Facilities and Services and Regulatory Bureau shall;
   1. Set standards for the regulation of CL and strictly enforce the provisions of this Order.

   2. Disseminate regulatory policies, standards and forms for information and guidelines of the DOH-CHDs.

   3. Provide consultation and technical assistance to stakeholders, including regulatory officers from the DOH-CHDs in line with the regulation of CL.

   4. Respond promptly to complaints relative to the operation of CL under its jurisdiction.

B. Center for Health Development – Regulatory, Licensing, and Enforcement Division shall;
   1. Strictly enforce the provisions of this Order.

   2. Submit quarterly report on Suspension/Revocation/ Cease and Desist Order issued on CL not later than the 15th day of the following month after the covered quarter.

   3. Provide consultation and technical assistance to stakeholders in line with the regulation of CL.

   4. Respond promptly to complaints relative to the operation of CL under its jurisdiction.

C. National Reference Laboratories shall;
   1. Provide laboratory reference/referral services for confirmatory testing.

   2. Train laboratory personnel and recognize other training institutions.

   3. Maintain the National External Quality Assessment Scheme (NEQAS).

   4. Perform technical evaluation of reagents and diagnostic kits.

D. DOH-Licensed Clinical Laboratories shall;
   1. Continuously comply with the rules and regulations, licensing standards and requirements for CL, as provided in this Order and related issuances.

2. Participate in EQAP that may be administered by a designated NRL or other local and international EQAP approved by the DOH, surveys and other activities that will be required from them by the DOH.

3. In times of Pandemic of Public Health Event, be mandated to submit timely reports and data.

IX. VIOLATIONS, SANCTIONS AND APPEAL

A. A CL shall be sanctioned and penalized by the HFSRB/CHD Director upon violation of any of these guidelines and its related issuances and laws, or upon committal (commission/omission) of prohibited acts (Annex C) by the persons owning or operating the CL, and/or the persons under their authority.

B. For non-institution-based CL that are not under the OSSOLS, the following are the penalties and sanctions that shall be imposed for the commission of any of the violations in this Order and other relevant issuances:

i. 1st offense: Stern warning
ii. 2nd offense: Thirty thousand pesos (Php 30,000.00)
iii. 3rd offense: Fifty thousand pesos (Php 50,000.00)
iv. 4th offense: Revocation of DOH-LTO

C. For CL that are part of hospitals and other facilities that are subject to comply with the OSS licensure system, AO No. 2007-0022, dated June 6, 2007, titled "Violations under the One-Stop Shop Licensure System for Hospitals," sanctions shall be governed by the aforementioned Order.

D. Any person who operates a CL without securing the necessary DOH-PTC and corresponding DOH-LTO shall be issued a Cease-and-Desist Order (CDO) and shall pay the administrative penalty of Fifty thousand pesos (Php50,000.00).

E. Section 4 of Republic Act No. 4688 shall still be imposable aside from the administrative penalty provided in this Order.

F. In case of complaints, the CL, upon receipt of such by HFSRB/CHD-RLED shall be given due process wherein an investigation shall be conducted and the appropriate sanctions for its violation/s. A 60-day preventive suspension may be given to the CL during the investigation depending on the seriousness of the violation.

G. Any CL or any of its personnel not amenable with the decision of the HFSRB/CHD-RLED may, within ten (10) days after the receipt of notice of decision, file a notice of appeal to the Head of the Health Regulation Team (HRT). All pertinent documents and records of the appellant shall then be elevated by HFSRB/CHD-RLED to the HRT. The decision of the Head of the HRT, if still contested may be brought on a final appeal to the Secretary of Health, whose decision shall be final and executory.

H. CL with revoked licenses can only re-apply after one year from the date of LTO revocation.

I. Any person authorized or licensed to conduct clinical laboratory tests, who issues false or fraudulent laboratory test results knowingly, willfully or through gross negligence shall not be allowed to own, manage, operate, or be an analyst of any DOH-licensed CL.

X. TRANSITORY PROVISIONS

A. All existing licensed CL shall be given three (3) years to comply with the physical plant requirements from the date of effectivity of this Order.

B. All existing licensed CL shall be given two (2) years to fully offer the additional services for each category with corresponding personnel and equipment from the date of effectivity of this Order.

C. For new CL, this Order shall be immediately applicable.

D. For CL currently headed by Anatomic Pathologists with an associate Clinical Pathologist or Clinical Pathologists heading tertiary CL with Anatomic Pathology services, such headships shall be retained until his/her eventual retirement, resignation or replacement. Thereafter, all CL shall be headed by a pathologist certified in Clinical Pathology by the Board of Pathology of the Philippine Society of Pathologists, except for tertiary CL with anatomic pathology service which shall be headed by a pathologist certified in both Anatomic and Clinical Pathology.

XI. REPEALING CLAUSE

These rules and regulations shall rescind Administrative Order No. 2007-0027 titled "Revised Rules and Regulations Governing the Licensure and Regulation of Clinical Laboratories in the Philippines," all administrative orders and previous issuances inconsistent thereof.

XII. SEPARABILITY

In the event that any provision or part of this Order be declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected by such declaration shall remain valid and effective.

XIII. EFFECTIVITY

This Order shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing three (3) copies to the University of the Philippines Law Center.

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

LICENSING STANDARDS FOR CLINICAL LABORATORY

I. PHYSICAL PLANT

Every clinical laboratory (CL) shall have an adequate space for its operation to safely, effectively and efficiently provide services to clients.

A. The CL shall conform to all applicable local and national regulations for the construction, renovation, maintenance and repair of CL.

B. The laboratory shall conform to the required space for the conduct of its activities. Personnel, fixtures, equipment, sink, etc. shall also be considered. Minimum area requirements for each are listed in Annex D.

C. There shall be well-ventilated, lighted, clean, safe and functional areas based on the services provided.

D. There shall be a program of proper maintenance and monitoring of physical plant and facilities.

E. There shall be policy guidelines on laboratory biosafety and biosecurity which includes risk assessment that will serve as the basis of biosafety level required for the specific CL.

F. There shall be an area for confirmatory testing for Rapid HIV Diagnostic Algorithm (CrCL) and Glucose-6-Phosphate Dehydrogenase (G6PD) Deficiency which may be a section, unit, or division integrated in a DOH licensed CL, if applicable.

II. PERSONNEL

Every CL shall have an adequate number of trained personnel, depending on the workload, to provide safe, effective and efficient services to clients.

A. **Head of the Laboratory (HOL)**

1. The head of the laboratory shall be a competent and experienced professional, with a specialized skill set related to and proportionate to the laboratory category, to ensure that the laboratory runs efficiently. The head of the laboratory is essentially responsible for the operation of the entire laboratory, its personnel, functions, and data, all of which shall meet the quality assurance criteria and regulatory requirements.

2. The head of the laboratory shall oversee the operation of the CL and have administrative and technical supervision of the activities including the mobile clinical laboratories (MCL), remote collection activities, and point of care testing (POCT), if applicable.

3. The head of the laboratory shall supervise the staff in accordance to the standards set by the Philippine Society of Pathologists.

4. The head of the laboratory shall visit once a month and at least twice a week of supervisory calls and/or videoconferencing OR at least once a week physical visit. For hospital-based DOH licensed CL, it shall be once a week physical visit. The visits shall have to be well documented.

5. For Geographically Isolated and Disadvantaged Areas (GIDAs) with no clinical pathologists, as certified by the Philippine Society of Pathologists, board certified Anatomic Pathologists or Physicians with complete training in Clinical Laboratory Medicine, Quality Assurance and Laboratory Management, may head one primary DOH licensed CL.

B. **Registered Medical Technologist (RMT)**
   1. There shall be an adequate number of full-time RMTs to conduct the laboratory procedures, including those assigned in MCL. The number of staff shall depend on the workload and the services being provided.

   2. There shall be staff development and continuing education program at all levels of organization to upgrade the knowledge, attitude and skills of staff.

   3. There shall be a designated Biosafety and Biosecurity Officer in-charge primarily of the risk assessment of the DOH licensed CL.

C. **Support Staff**
   1. There shall be an adequate number of support staff such as, but not limited to laboratory technician, laboratory aide, encoders, and receptionists when applicable.

D. **POCT Coordinator – if applicable**
   1. A senior staff from the CL shall be designated as a POCT coordinator who shall have the following functions, but not limited to:
      a. Recommends procedures that will ensure the quality of results of POCT in consultation with the pathologist.
      b. Ensures that POCT machines/device and kits are properly maintained.
      c. Supervises the operators of POCT device/machine.
      d. Ensures that the operators have appropriate trainings and checks the competency of the operators regularly.
      e. Ensures that quality control (QC) is implemented and reviews POCT QC results periodically, depending on the number of tests.

E. **POCT Operator – if applicable**
   1. The designated operator of the POCT device/machine and testing kits shall have the following functions, but not limited to:
      a. Ensures accurate results of POCT.
      b. Ensure that POCT machines/device and kits are properly maintained and stored.
      c. Run tests on quality control at least once each day or as recommended by the manufacturer.
      d. Initially, implements quality assurance program or contact the manufacturer's application specialist for assistance, when a POCT machine/device is not properly functioning or the control sample is in out of control range.
      e. Reports to the supervising CL any untoward incidents or problems concerning POCT.

F. **MCL Personnel**

1. MCL shall has its own set of personnel, which includes the following but not limited to:
   a. Registered Medical Technologist – number will depend on the anticipated workload.
   b. Support staff such as, but not limited to, driver and laboratory technician.

III. EQUIPMENT/INSTRUMENTS/REAGENTS/GLASSWARES/SUPPLIES

Every CL shall have an adequate equipment, instruments, reagents, glassware and supplies which are all in good working condition and sufficient for the operations.

A. There shall be available and operational equipment/machines/devices to provide the laboratory examination that the laboratory is licensed for.

B. There shall be a calibration, preventive maintenance and repair program for every equipment/machines/instruments/devices in the DOH licensed CL.

C. There shall be a contingency plan in case of equipment/machines/devices breakdown and malfunction.

D. There shall be adequate available reagents, glassware and supplies for the laboratory examinations.

E. There shall be an inventory control of the reagents, glassware and supplies.

F. The reagents, glassware and supplies shall be properly stored under the required conditions.

G. The machines/devices, reagents and test kits that are used in the CL and MCL as well as POCT shall be approved by the Philippine Food and Drug Administration and validated by the proper government institutions (e.g. National Reference Laboratory).

H. The MCL shall have its own set of functional, and operational equipment, as well as its own set of supplies.

IV. SERVICE DELIVERY

The services provided by the CL shall ensure quality and safety to clients, to its personnel and to the general public.

A. All CL shall ensure that the service being delivered to patients must comply with the standards and other related relevant issuances.

B. Mobile Clinical Laboratory

1. The collection site/area for MCL shall be located within the same region, at a maximum of one hundred (100) kilometer radius, from the address of the DOH licensed CL.

2. Aside from specimen collection for different tests within the service capability of the main CL, the MCL shall be allowed to perform the following on-site tests which shall be declared in the LTO of the main CL:
   a. Urinalysis
   b. Fecalysis
   c. Pregnancy Test (lateral flow)
   d. Basis Serologic Test using Rapid Test Kits – Dengue, Screening of Hepatitis B, RPR/Syphilis Test, and HIV

3. Specimen collected for other test, not mentioned above (Section IV. B. 2), should be properly handled and transported. Serum blood samples for chemistry testing must be separated within four (4) hours from the time of collection.

V. INFORMATION MANAGEMENT

Every CL shall maintain a system of communication, recording, reporting and releasing of results.

A. Administrative Policies and Procedures

1. The CL shall have written policies and procedures for the provision of laboratory services, the operation and maintenance of the CL, which includes satellite laboratories, MCL and POCT, and shall include the accountabilities of every personnel working in the laboratory.

2. There shall be documented technical procedures for services provided in each section of the laboratory, including MCL and POCT, which will ensure the quality of laboratory results.

3. There shall be a risk assessment for every section in the CL.

B. Communication and Records Management

1. The CL shall maintain and ensure the confidentiality of all records.

2. There shall be procedures for the receipt and performance of routine and STAT requests for laboratory examinations.

3. There shall be procedures for the reporting of results of routine and STAT laboratory examinations, including critical values that would impact on patient care.

4. All results shall be released in accordance with DOH guidelines.

5. All laboratory reports on various examinations of specimens shall bear the name, PRC registration number, and original signature of the registered medical technologist(s) who performed the laboratory examinations, and the pathologist who shall be accountable for the reliability of the results.

6. There shall be a policy guideline on the use of digital signature. The use of digital signature for laboratory results shall be permitted only if properly authenticated by the Department of Information and Communication-Philippine National Public Key Infrastructure. The use of digital signature shall also be in accordance with the provisions of the E-Commerce Law.

7. There shall be procedures for the reporting of workload, quality control, inventory control, work schedule and assignments.

8. There shall be procedures for the reporting and analysis of incidents, adverse events, and in handling complaints.

9. The retention of laboratory documents, records, slides and specimens shall be in accordance to the standards promulgated by the DOH or by competent authorities for such purposes.

10. The operating hours of the CL shall be known to its clients.

11. The CL which supervises the POCT shall have a master list of the following, but not limited to:
    a. Name and designation of operators, and,
    b. POCT machines, instruments and kits.

VI. QUALITY IMPROVEMENT

Every CL shall establish and maintain a system for continuous quality improvement activities.

A. There shall be an Internal Quality Assurance Program which shall include:
    1. An Internal Quality Control Program for technical procedures.

    2. An Internal Quality Assurance Program for inputs, processes and outputs.

    3. A Continuous Quality Improvement Program covering all aspects of laboratory performance.

B. The CL shall participate in External Quality Assessment Program (EQAP) that may be administered by a designated NRL or other local and international EQAP approved by the DOH.

C. A periodic assessment shall be conducted by representatives from the top management, clinical laboratory, clinical departments and nursing service, to evaluate the policy of the CL on POCT.

VII. REFERRAL OF LABORATORY EXAMINATIONS

Every CL shall ensure the quality of services provided through an agreement, or its equivalent, to a DOH licensed CL performing the laboratory services needed.

A. The referral laboratory must be a DOH-licensed CL. They shall have a Memorandum of Agreement (MOA) with the referring CL and shall be responsible for the collection, transport and processing of specimens, and releasing of results.

B. A separate MOA is required when referred tests, which are not within the service capability of the CL, unless the referral is part of the contingency plan.

C. A MOA prescribing the accountabilities of each party, shall be secured when laboratory examinations are referred to and provided by another DOH-licensed CL.

D. Referral of examinations to other DOH-licensed CL are only permitted in the following circumstances:
   1. If the laboratory test to be sent out is not part of the service capability expected for the particular category of the referring laboratory; and,

   2. If referral of laboratory test is part of the contingency plan, in cases of equipment breakdown, of the referring CL, this shall be for a certain limited period of time only, which shall not last for more than 3 months. This shall be properly documented.

VIII. ENVIRONMENTAL MANAGEMENT

Every CL shall ensure that the environment is safe for its patients and staff, including the general public.

A. There shall be a program of proper maintenance and monitoring of physical facilities.

B. There shall be procedures for proper disposal of infectious wastes and toxic and hazardous substances in accordance with RA 6969, also known as "Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1990" and other related policy guidelines and/or issuances.

C. There shall be a "No smoking policy" and that the same shall be strictly enforced.

D. There shall be a contingency plan in case of accidents and emergencies.

E. There shall be a policy for biosafety and biosecurity.

F. There shall be policy guidelines on infection prevention and control.

A.O. No. 2021 - 0037
ANNEX B1

Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

ASSESSMENT TOOL FOR LICENSING A GENERAL CLINICAL LABORATORY

INSTRUCTIONS:

1. To properly fill-out this tool, the Licensing Officer shall make use of: INTERVIEWS, REVIEW OF DOCUMENTS, OBSERVATIONS and VALIDATION of findings.
2. If the corresponding items are present, available or adequate, place a (✔) on each of the appropriate spaces under the COMPLIED column or space provided alongside each corresponding item. If not, put an (**X**) instead.
3. The REMARKS column shall document relevant observations.
4. Make sure to fill-in the blanks with the needed information. Do not leave any items blank. Put N/A if Not Applicable.
5. The Team Leader shall ensure that all team members write down their printed names, designation and affix their signatures and indicate the date of inspection/monitoring, all at the last page of the tool.
6. The Team Leader shall make sure that the Head of the facility or, when not available, the next most senior or responsible officer likewise affix his/her signature on the same aforementioned pages, to signify that the inspection/monitoring results were discussed during the exit conference and a duplicate copy also received.

GENERAL INFORMATION:

Name of Facility: _____

Complete Address: _____
Number & Street Barangay/District

_____
Municipality/City Province/Region

Contact Information: _____ E-mail Address: _____

Initial [ ] Renewal [ ]

Existing License Number: _____ Date Issued: _____ Expiry Date: _____

Name of Owner or Governing Body (if corporation): _____

Name of Head of Laboratory: _____

Classification According to:

Ownership:	☐ Government	☐ Private
Function:	☐ Clinical Pathology	☐ Anatomic Pathology
	☐ Molecular Laboratory	
Institutional-Character:	☐ Non-Institution Based	☐ Institution-based Specify Institution: _____
Service Capability	☐ Primary	☐ DOH Based Program Laboratory
	☐ Secondary	☐ Limited-Service Capability
	☐ Tertiary	☐ Mobile Clinical Laboratory

CRITERIA	INDICATOR/EVIDENCE	COMPLIED	REMARKS
I. ORGANIZATION AND MANAGEMENT The organization's management team provides leadership acts according to the organization's policies and has overall responsibility in ensuring effective and efficient operation of the organization (clinical laboratory).			
1. There is an organizational structure that clearly reflects the line of authorities, accountability, communication, interrelationship, hierarchy of functions and flow of referrals	**Observe** • Updated organizational chart is posted/displayed in conspicuous area with the names, latest pictures (at least passport size) and designation		
2. The organization's mission, vision and objectives shall be in accordance with RA 4688	**Document Review** • Written vision, mission, and goals **Observe** • Vision, mission, and goals posted/displayed in a conspicuous area visible to clients		
3. The organization has a valid DOH- LTO and other pertinent documents	**Document Review** • Compilation of Clinical Laboratory AOs, Reports of Inspection/Monitoring **Observe** • Valid DOH-LTO posted in a conspicuous area visible to clients		
4. There is a policy and procedure on management review	**Document Review** • Written policy on management review • Compilation of documented minutes of meeting reflecting the date, time, attendance, agenda, and action taken signed and approved by head of laboratory • Supporting documents for evaluation and monitoring of activities such as records, logbooks, checklist of supplies, inspection report, purchasing or procurement and acceptance of supplies, etc.		

CRITERIA	INDICATOR/EVIDENCE	COMPLIED	REMARKS
5. There is policy and procedure for handling complaints and client feedback	**Document Review** • Written policy and procedure for handling complaints/client feedback • Suggestion box visible to clients • Forms for complaints/ client feedback • Records of complaints/ client feedback and actions taken		
II. HUMAN RESOURCE MANAGEMENT **A. STAFF RECRUITMENT, SELECTION, APPOINTMENT AND RESPONSIBILITIES**			
6. There is policy and procedure for hiring, orientation and promotion for all levels of personnel	**Document Review** • Written policies and procedures on hiring, orientation and promotion of personnel at all levels		
7. There is policy and procedure on continuing program for staff development and training	**Document Review** • Written policies and procedures for staff development and training • Proof of training through relevant certificates, memos, written reports, budgetary allocations **Interview** • Human Resources Management Officer/ Personnel Officer		
8. There is policy and procedure for discipline, suspension, demotion and termination of personnel at all levels	**Document Review** • Written policies and procedures on discipline, suspension, demotion and termination of personnel at all levels		
B. PERSONNEL			
9. The duties and responsibilities shall be clearly stated	**Document Review** • Written job description or duties and responsibilities of all laboratory personnel		
10. There is an adequate number of qualified personnel with documented	**Document Review** • List of Personnel with designation • Area of assignments indicated in the posted work schedule		

CRITERIA	INDICATOR/EVIDENCE	COMPLIED	REMARKS

training and experience to conduct/perform the laboratory procedures	signed and approved by head of laboratory
	• There is a policy whenever there is an increase in workload, there shall be a corresponding increase in the number of personnel
	• There is a policy on hiring or designating additional personnel as:
	  • Proof of attendance
	  • Proof of qualifications (please refer to specific personnel)
	  • Authority to practice signed by the head of the government facility, if applicable (A.O. # 92 s. 2003)		

11. There is policy on the implementation of National Database of Human Resource for Health Information System (NDHRIS)	**Document Review** • Proof of submission of data to NDHRHIS		
12. Each personnel shall have a record of updated 201 files	**Document Review** • Updated 201 files of all laboratory personnel		

A. The Head of the Laboratory (HOL) shall have the overall supervision on technical procedures as well as on the administrative laboratory management	**Document Review**
	• Proof of supervisory visits at least once a week for physical visit OR once a month physical visit with at least twice a week of supervisory calls and/or video conferencing
	• For HOL of hospital-based clinical laboratory: supervisory physical visits of at least once a week
	• Proof of qualifications:
	  • Updated resume
	  • PRC certificate and valid PRC ID
	  • PSP Board Certificate
	  • Certificate of Good Standing from PSP
	  • Notarized employment contract		

CRITERIA	INDICATOR/EVIDENCE	COMPLIED	REMARKS
	• Relevant training certificates (e.g., Molecular Pathology) • Annual medical certificate and proof of immunization (Hepatitis B and Influenza)		

Qualification of Head of Laboratory	Certified CP	Certified AP	Remarks
A. Clinical Laboratory			
1. Primary	/		
2. Secondary	/		
3. Tertiary	/		
4. Limited*			
B. Anatomic Laboratory		/	
C. Molecular Laboratory			
1. Genetics**			
2. Immunohematology	/		
3. Infectious	/		

* It will depend on the limited services to be provided

**A pathologist or a licensed physician who is trained in the management, principles and methodology of these specialized services that are being provided shall head this type of laboratory

CRITERIA	INDICATOR/EVIDENCE	COMPLIED	REMARKS

B. Registered Medical Technologist (RMT)
 	
(**At least** 1 competent RMT per assigned area)
	Document Review
	• Proof of qualifications:
	  • Updated resume
	  • PRC certificate and valid PRC ID
	  • Relevant training certificates
	  • Notarized employment contract
	  • Annual medical certificate
	  • Proof of immunization (Hepatitis B and Influenza)		

RMT staff with designated assignments, as applicable:	Additional proof of trainings		
1. rHIVda	• Certificate of proficiency (SACCL)		
2. AFB microscopy	• Certificate of training on DSSM (NTRL)		
3. Bacteriology	• Certificate of training in bacteriology (RITM and other RITM recognized institutions)		
4. Malaria smear	• Certificate of training in malaria smear (RITM)		

5. Others			
C. Biosafety and Biosecurity Officer (May be designated by the HOL)	**Document Review** • PRC certificate and valid PRC ID (RMT) • Certificate of training in Biosafety and Biosecurity (RITM and/or UP-NTCBB)		

Staffing Pattern for RMT Analysts

1. Clinical Laboratory for Clinical and Anatomic Pathology

SERVICES	PRIMARY			SECONDARY			TERTIARY		
	1st Shift	2nd Shift	3rd Shift	1st Shift	2nd Shift	3rd Shift	1st Shift	2nd Shift	3rd Shift
Microscopy	1	1	1	1	1	1	1	1	1
Hematology	1	1	1	1	1	1	1	1	1
Clinical Chemistry	1			1	1	1	1	1	1
Immunology/Serology	1			1			1		
Microbiology				1			1		
Histopathology							1		
Total	8 (7+1 reliever) without Microbiology 9 (8+1 reliever) for Government Facilities			12 (11+1 reliever)			12 (11+1 reliever) without Histopathology 13 (12+1 reliever) for Hospital-Based		
Note: An increase in workload shall require a corresponding increase in the number of personnel									

2. Clinical Laboratory for Anatomic Pathology – At least one RMT per section
3. Clinical Laboratory for Molecular Pathology – Will depend on the services offered

CRITERIA	INDICATOR / EVIDENCE	COMPLIED	REMARKS
III. PHYSICAL PLANT, FACILITIES, AND WORK ENVIRONMENT			
13. There is program of proper maintenance and monitoring of physical plant and facilities	**Document Review** • Written policy and program for the proper maintenance and monitoring of physical plant and facilities • Proposed schedule for preventive maintenance **Observe** • Updated proof of actual implementation of maintenance as to structure, ventilation, lighting & water supply		
14. There are policy guidelines on laboratory biosafety and biosecurity	**Document Review** • Local risk assessment reviewed at least annually • Written protocols on laboratory biosafety and biosecurity **Observe** • Good Laboratory Practice that includes use of Personal		

CRITERIA	INDICATOR / EVIDENCE	COMPLIED	REMARKS
	Protective Equipment and other precautionary measures		
15. There is a policy and procedure for the proper disposal of waste and hazardous/infectious substances that shall conform to the standards set by the DOH	**Document Review** • Policy on disposal of wastes that conform with Healthcare Waste Management Manual, and RA No. 6969 • Notarized Memorandum of Agreement (MOA) with infectious waste, toxic, and hazardous substances hauler **Observe** • Proof of proper management of wastes from point of generation, segregation (color-coded waste bins), disinfection, up to the final disposal		
NOTE: Please see the reference plan/physical plant (Annex D1 and D2)			
IV. EQUIPMENT /INSTRUMENTS			
16. There is an adequate number of operational equipment to provide the laboratory examinations that the laboratory is licensed for	**Document Review** • List of available and functional laboratory equipment **Observe** • All laboratory equipment and instruments are operational		
17. There is program for calibration, preventive maintenance and repair for the equipment.	**Document Review** • Regular schedule including frequency of preventive maintenance and calibration • Updated certificate of calibration and maintenance of equipment • Record of repair reports		
18. There is contingency plan in case of equipment breakdown	**Document Review** • Written policy on contingency plan in case of equipment breakdown		
V. REAGENTS AND SUPPLIES			
19. There is an adequate supply of properly stored and inventoried reagents and supplies for the	**Document Review** • Quality records of supplies /reagents with expiration date, their usage/ consumption and disposal are available • Certificate of Product Registration from FDA,		

CRITERIA	INDICATOR / EVIDENCE	COMPLIED	REMARKS
laboratory examinations to be provided.	including the reagents, supplies, and equipment used for POCT and MCL **Observe** • Availability and completeness of reagents and supplies • Validate the expiration dates of reagents		

20. The reagents and supplies are stored under the required conditions with adequate storage facilities such as refrigerators for perishable reagents and supplies	**Document Review**
	• Records of temperature monitoring as follows:
	  ◦ Room temperature reading
	  ◦ Refrigerator and freezer temperature reading
	
	Observe
	• Monitoring of room temperature
	• Temperature of refrigerators (2°C to 8°C) and freezers (-20°C to -30°C)		

21. There is an appropriate storage area/technique for flammable, combustible and hazardous chemical/reagents	**Document Review** • Material Safety Data Sheet (MSDS) available for all reagents/supplies and accessible to all personnel at all times **Observe** • Organized per section with National Fire Protection Association (NFPA) Label or its equivalent		
VI. ADMINISTRATIVE AND TECHNICAL POLICIES AND PROCEDURES			
22. There is an administrative policies & procedures for provision of laboratory services and for the operation and maintenance of the laboratory	**Document Review** • All documented policies, protocols, procedures are signed and approved by the head of laboratory • Guidelines in the operation and maintenance of the laboratory including policy on security of supplies, specimens and confidentiality of records • Laboratory services and corresponding prices are accessible to the public		
23. The technical procedures of services provided by	**Document Review** • Documented and updated policies and procedures of laboratory services in each of the sections/areas.		

CRITERIA	INDICATOR / EVIDENCE	COMPLIED	REMARKS
each section are available	• Documented policies, protocols, and guidelines in the operation and maintenance of the laboratory		
A. Communication and Records			
24. There are procedures for the receipt and performance of laboratory tests	**Document Review** • Documented procedures for receipt and performance of laboratory tests		
25. There are procedures for reporting of results of laboratory tests	**Document Review** • Documented procedures for reporting of results of laboratory tests • Documented procedures for the validation of laboratory results prior to reporting		
26. The laboratory reports on various examinations of specimens: A. shall bear the name of the pathologist or designated associate who shall be responsible for the reliability of the results B. The reports shall also bear the name of the RMT(s) who performed the examinations and duly signed by that/those person(s)	**Document Review** • Laboratory report forms bearing the name and original/digital signature with PRC ID No. of the head of the laboratory and the RMT analysts • Updated records of result (logbooks/ electronically stored data with back up) including entry, releasing & endorsement records. • There is a policy guideline on the use of authenticated electronic/digital signature that is in accordance with the E-commerce law • Documented policy for Laboratory Information System, if available		
27. There are procedures for reporting of workload, quality control, inventory control, etc.	**Document review** • Documented procedures for reporting of workload, quality control, inventory control, etc. • Updated reports and documents (hard or soft copy with back up) • Worksheets/machine print out per section as proof of actual performance		

CRITERIA	INDICATOR / EVIDENCE	COMPLIED	REMARKS
28. There is a procedure for reporting and analysis of incidents, adverse events, and other related process.	**Document review** • Documented procedures for reporting and analysis of incidents, adverse events, etc. • Compiled of written reports with resolutions		
29. There is a documented procedure on the retention of documents, records, slides, and specimens of the clinical laboratory which shall follow standards promulgated by the DOH (DC# 70 s. 1996) and/or competent professional organizations	**Document review** • Documented procedure for the retention of records which follows standards promulgated by the DOH • Compiled laboratory tests results, whether logbook or electronically stored		
B. Quality Assurance			
30. There is a policy on Quality Assurance Program (QAP) and Continuous Quality Improvement	**Document review** • Documented Internal QAP including Internal Quality Control and Continuous Quality Improvement • Updated Quality Control reports conducted per tests and filed accordingly • Availability of reference materials and appropriate reagents & equipment used • Results/findings of Quality Assurance audits / assessments		
31. There is a proof of participation in External QAP (EQAP) that may be administered by a designated NRL or other local and international EQAP approved by the DOH	**Document review** • Documented procedure in the actual performance of EQAP activities • Certificate of Performance in EQAP with passing rate		
C. Referral or Outsourcing of Laboratory Tests			

CRITERIA	INDICATOR / EVIDENCE	COMPLIED	REMARKS
32. There is a policy on referral and outsourcing of examinations	**Document Review** • Documented procedures on referral and outsourcing of examinations to other DOH licensed clinical laboratory • Records of outsourced examinations (in the event of machine breakdown) • Notarized Memorandum of Agreement • DOH-LTO of referral testing laboratory		
VII. POINT OF CARE TESTING (POCT)			
33. There is a policy on POCT	**Document Review** • Documented list of POCT operators, machines, instruments and kits • Documented procedure on the conduct of periodic assessment by representatives from the top management, clinical laboratory, clinical departments and nursing service, to evaluate the policy of the clinical laboratory on POCT		
VIII. MOBILE CLINICAL LABORATORY			

34. There is a policy on Mobile Clinical Laboratory	**Document Review**
	• Documented Procedures on
	  ▪ Collection of specimens
	  ▪ Processing of specimens
	• Land Transportation Office Registration (proof of ownership)
	• File of Memorandum of Agreement between the clinical laboratory and the facility where the mobile activity is conducted		

Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

Name of Facility: _____

Date of Inspection: _____

RECOMMENDATIONS:
For Licensing Process

[ ] For Issuance of License to Operate as: _____
Validity from _____ to _____

[ ] Issuance depends upon compliance to the recommendations given and submission of the following within _____ days from the date of inspection.

[ ] Non-issuance.

Specify reason/s: _____

_____

_____

Inspected by: _____ _____ _____
Printed Name | Signature | Position/Designation

_____

_____

_____

_____

_____

Received by:

Signature: _____

Printed Name: _____

Position/Designation: _____

Date: _____

Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

Name of Facility: _____

Date of Monitoring: _____

RECOMMENDATIONS:
For Monitoring Process

[ ] Issuance of Notice of Violation.

_____
_____
_____

[ ] Non-issuance of Notice of Violation.

_____
_____
_____

[ ] Others. Specify:

_____
_____
_____

Monitored by: _____ _____ _____

Printed Name | Signature | Position/Designation

_____
_____
_____
_____
_____

Received by:

Signature: _____

Printed Name: _____

Position/Designation: _____

Date: _____

Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

EQUIPMENT/INSTRUMENTS/GLASSWARE/SUPPLIES/REAGENTS PER AREA OF ACTIVITY/SERVICE CAPABILITY OF GENERAL CLINICAL LABORATORY *(Place a ✓on spaces provided before each item if available and* **X** *if not; or NA for Not Applicable)*

ACTIVITY	SERVICES	GLASSWARE AND SUPPLIES	REMARKS
SPECIMEN COLLECTION	Blood Extraction	__ 70% Alcohol __ Cottons __ Tourniquet __ Lancet __ Capillary Tubes __ Labeling Materials __ Test Tubes __ Sterile Medical tape __ Syringe and Needle-any gauge **(Expiration Date)** __ Puncture Proof Sharps Container	
	Other Body Fluids (Urine, Stool, Sputum, etc.)	__ Applicator Stick __ Specimen container w/ cover or Screw Cap (50mL) __ Sterile Screw Cap Specimen Container, if applicable __ Plastic calibrated loop and other necessary materials, if applicable	
OTHER EQUIPMENT		__ Non-Mercurial Thermometer: (Room and storage refrigerator)	
		__ Refrigerator (samples/reagents)	
		__ Fire Extinguisher (Class B)	
		__ Spill Kits	

SERVICES	EQUIPMENT / INSTRUMENT / GLASSWARE/SUPPLIES	REAGENT/S (Take Note of Expiry)	REMARKS (Quality Improvement)
Clinical Microscopy			
URINALYSIS	**Supplies** __ Slides __ Test tubes (10ml) __ Cover Slips __ Test Tube Rack __ Applicator sticks __ **Manual** __ Clinical Centrifuge (2,000 rpm) __ Microscope (Binocular Compound) __ **Automated** __ Strip Reader __ Urine Analyzer	Urine Strips __ 4 - parameter __ 10 - parameter Control/s __ Normal __ Pathologic	

SERVICES	EQUIPMENT / INSTRUMENT / GLASSWARE/SUPPLIES	REAGENT/S (Take Note of Expiry)	REMARKS (Quality Improvement)
WET SMEAR FOR Trichomonas	**Supplies** ___ Slides ___ Test tubes (10ml) ___ Cover Slips ___ Test Tube Rack ___ Applicator sticks ___ Microscope (Binocular Compound)	___ Normal Saline Solution ___ Lugol's Iodine	
STOOL ANALYSIS			
PREGNANCY TEST	___ Pregnancy test kit		
FECAL OCCULT BLOOD	___ Occult blood test kit		
Special Tests: For DOH identified endemic areas only(e.g., Kato Katz, Schistosomiasis, Malaria smear, Filaria smear, slit-skin smear, rapid plasma regain for syphillis)	Indicate the Test		
Hematology			
HEMOGLOBIN	___ **Manual** ___ Spectrophotometer or its equivalent ___ Cuvettes/test tubes ___ Sahli/micropipette	___ Hemoglobin Reagent (Cyanmet Hemoglobin) ___ Standard	
HEMATOCRIT	___ **Manual** ___ Hematocrit Centrifuge ___ Hematocrit Reader ___ Capillary Tube ___ Sealer		
RED BLOOD CELLS (Optional)	___ **Manual** ___ Microscope (Binocular Compound) ___ Pipette Shaker ___ Tally Counter ___ RBC / micropipette ___ Counting Chamber w/ Cover Slips ___ WBC / micropipette ___ Petri Dish (as applicable)	___ RBC Diluent ___ Other reagent	
WHITE BLOOD CELLS		___ WBC Diluent	
PLATELET COUNT (Quantitative)		___ Platelet Diluent	
DIFFERENTIAL COUNT	___ **Manual** ___ Differential Counter ___ Slides ___ Staining Glasses ___ Microscope (Binocular Compound)	___ Hematology Staining Kit ___ Oil immersion	

SERVICES	EQUIPMENT / INSTRUMENT / GLASSWARE/SUPPLIES	REAGENT/S (Take Note of Expiry)	REMARKS (Quality Improvement)
COMPLETE BLOOD COUNT	__ **Automated** ___ Hematology Analyzer	___ Diluents ___ Lyse ___ Cleanse Solution ___ Other Reagents Controls ___ Low ___ Normal ___ High	
FORWARD AND REVERSE ABO GROUPING AND Rh (D) TYPING (Tube Method)	__ Serofuge or its equivalent __Test Tubes __ **Manual** __ **Semi-automated machine** __ **Automated**	__ Normal Saline Solution __ Gel-type based blood typing reagents __ Blood Typing Sera	
Additional Services for Secondary Category			
COAGULATION STUDIES – for hospital-based	__ Coagulation Machine __ Calibrated Pipettes __ Cuvettes or its equivalent	__ Coagulation Reagents __ Controls	
Clinical Chemistry			
ROUTINE: **Blood Glucose** (FBS / RBS / OGTT) **Total Cholesterol** **Triglycerides** **HDL** **Blood Uric Acid** **Blood Creatinine** **Blood Urea Nitrogen**	__ Refrigerator (sample and reagents) __ Clinical Centrifuge __ Water Bath or its equivalent __ Calibrated Pipettes __ Pipette tips __ Other Pipettes __ Timer __ Cuvettes __ Test Tubes __ Test Tubes Rack __ **Manual** __ Spectrophotometer or its equivalent __ **Automated** __ Chemistry Analyzer	__ Distilled Water __ Standard/ Calibrator Controls __ Normal __ Pathologic Test Reagents __ Glucose __ Total Cholesterol __ Triglycerides __ HDL __ Uric Acid __ Creatinine __ Urea __ Oral Glucose Tolerance Drink	
Additional Services for Secondary Category			
ELECTOLYTES (Na, K, Cl)	__ **Manual** __ **Automated Analyzer**	__ Standard/ Calibrator Controls __ Normal __ Pathologic	

SERVICES	EQUIPMENT / INSTRUMENT / GLASSWARE/SUPPLIES	REAGENT/S (Take Note of Expiry)	REMARKS (Quality Improvement)
AST **ALT**		__ Test Reagents __ Na __ K __ Cl __ AST __ ALT	
Additional Services for Tertiary Category			
Other Clinical Chemistry Examinations	__ **Manual** __ **Automated Analyzer** (Indicate the name of machine)	__ Standard/ Calibrator Controls __ Normal __ Pathologic __ Test Reagents	
ARTERIAL BLOOD GASES (ABG) – for hospital-based			
Immunology / Serology			
BASIC SEROLOGIC TESTING using Rapid Test Kits – Dengue, Hepatitis B, Syphilis, HIV	__ Cuvettes __ Test Tubes __ Test Tubes Rack __ Glass Pipettes __ Pipettes & Pipette tips __ Rapid test kits __ Dengue __ Syphilis __ Hepatitis B (screening) __ HIV (screening) __ Microscope or agglutination viewer	__ Standard/ Calibrator, if applicable Controls, if applicable __ Normal __ Pathologic __ Test Reagents, if applicable	
Additional Services for Tertiary Category			
MACHINE-BASED SEROLOGICAL AND IMMUNOLOGICAL TESTING	__ **Automated Analyzer** (Indicate the name of machine) __ **Manual** __ Spectrophotometer or its equivalent	__ Distilled Water __ Standard/ Calibrator Controls __ Normal __ Pathologic Test Reagents __ Tumor Markers __ Thyroid Function __ Hepatitis Profile	
Microbiology			
TB DIRECT SPUTUM SMEAR MICROSCOPY for government facilities	__ Microscope (Binocular Compound) __ Staining Rack __ Bunsen Burner or Electric Loop Incinerator __ Isolation Hood with exhaust fan (Improvised) __ Timer __ Slides __ Cover Slips __ Inoculating Loops	__ Acid-Fast Bacilli Stain Kit	

SERVICES	EQUIPMENT / INSTRUMENT / GLASSWARE/SUPPLIES	REAGENT/S (Take Note of Expiry)	REMARKS (Quality Improvement)
	__ Applicator Sticks __ Forceps		
NUCLEIC ACID AMPLIFICATION TEST (NAAT) for government facilities	__ NAAT for TB	__ Test kits for NAAT	
Additional Services for Secondary Category			
KOH	__ Centrifuge __ Refrigerator	__ 10% KOH	
GRAM STAIN		__ Gram's stain kit	
Additional Services for Tertiary Category			
CULTURE AND SENSITIVITY (aerobic and anaerobic)	__ Biosafety cabinet (Class II Type A with certification) __ Incubator __ Drying Oven __ Autoclave __ Weighing Scale __ Water Bath __ Table Lamp __ Electric/Gas Stove __ Refrigerator with freezer __ Sterile Swabs __ Candle Jar __ Caliper/Ruler __ Graduated Cylinder __ Beaker __ Erlenmeyer flask __ Petri dish __ Glass Pipettes __ Calibrated Inoculating Loops __ Laboratory Thermometer __ **Automated System / Blood Automated Card System** (Indicate the name of machine)	Culture Media: __ BHI __ BAP __ MAC __ CAP __ GBA __ BCA __ SSA __ TSA __ MHA __ TSB __ SFB __ APW __ TCBS __ Thio broth __ MHA w/ 5% sheep Blood __ Biochemical Reaction (Conventional Method/ Commercially Prepared) __ Sensitivity Disk/Antimicrobial Disk __ Mac Farland Standard (0.5) Control Strains (ATCC): __ *Pseudomonas aeroginosa* __ *Staphylococcus aureus* __ *Escherichia coli*	
Anatomic Pathology			
For Secondary Category			
PAP SMEAR	__ Microscope (Binocular Compound) __ Timer __ Slides __ Cover Slips __ Adhesive or its equivalent __ Forceps __ Staining Glasses	__ Papanicolaou stain	

SERVICES	EQUIPMENT / INSTRUMENT / GLASSWARE/SUPPLIES	REAGENT/S (Take Note of Expiry)	REMARKS (Quality Improvement)
Additional Services for Tertiary Category			
SURGICAL PATHOLOGY	__ Paraffin Oven __ Microtome __ **Manual Technique** __ Water Bath __ **Automatic tissue processor**	__ Formalin __ Paraffin wax __ Xylene __ Chloroform __ Benzene __ Toluene __ Carbon tetrachloride __ Hematoxylin & Eosin Stain __ Alcohol (50%, 70%, 80% 90%, 100%)	
CYTOLOGY			
FROZEN SECTION, if applicable	__ Cryostat __ Block holder	__ Isopentane __ Hematoxylin & Eosin Stain __ Alcohol (70%, 80%, 90%)	
AUTOPSY, if applicable	__ Ruler __ Autopsy Table __ Bone Saw __ Scalpel __ Scissors __ Rib Shears __ Toothed Forceps __ Weighing Scale		
Molecular Pathology			
Indicate Services	__ Clinical Centrifuge __ Refrigerator __ PCR __ Other Machines/Equipment/ Supplies	__ Distilled Water __ Standard/ Calibrator Controls __ Normal __ Pathologic Test Reagents	

***Note**: These are the list of minimum requirements as to **equipment, reagents/culture media, supplies & glassware's**. Additional services are acceptable provided that appropriate items mentioned with technical procedures, space and personnel are available, if necessary. (Please use additional sheet of paper, if needed.)*

A.O. No. 2021 - 0037
ANNEX C

Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

PROHIBITED ACTS IN THE OPERATIONS OF CLINICAL LABORATORIES

Sanctions and penalties will be based on Section IX. B of the Administrative Order

A. The Clinical Laboratory (CL) may be sanctioned or penalized upon commission of the following prohibited acts and violations:

1. Refusal to allow HFSRB/CHD-RLED authorized personnel to conduct inspection or monitoring visits of the clinical laboratory at any appropriate time;

2. Refusal or nonparticipation of any CL in an External Quality Assessment Program (EQAP) provided by a designated NRL or other local and international EQAP approved by the DOH;

3. Absence of action to improve the unsatisfactory or failed EQAP administered by a designated NRL or other local and international EQAP approved by the DOH;

4. Demonstrating incompetence or making consistent errors in the performance of CL examinations and procedures;

5. Deviation from the standard test procedures including use of expired reagents;

6. Issuance of a laboratory report without the approval of the head of the laboratory;

7. Transferring of laboratory results done by another laboratory to the result form of the referring laboratory;

8. Performing laboratory procedures beyond their authorized service capability; and,

9. Giving and receiving any commission, bonus, kickback or rebate or engaging in any split-fee arrangement in any form whatsoever with any facility, physician, organization, agency or person, either directly or indirectly, for patients referred to a CL licensed by the DOH.

10. Violation of provisions in the Republic Act No. 10173 or the Data Privacy Act of 2021.

B. The DOH_LTO will be revoked immediately after commission of the following prohibited acts and violations:

1. Permitting unauthorized or unregistered personnel to perform technical procedures and access to laboratory records/data;

2. Lending or using the name of the DOH-licensed CL or the head of the laboratory or medical technologist to an unlicensed CL;

3. Unauthorized use of the name and signature of the pathologist and RMT to secure LTO;

4. Issuance of fraudulent laboratory results, or tests not actually done or inaccurate results;

5. Change in the ownership, location, and head of the laboratory or laboratory personnel without informing the HFSRB/CHD-RLED; and,

6. Any material false statement in the application of LTO.

C. Other violations similar or analogous to the above will be sanctioned and penalized accordingly.

Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

PLANNING AND DESIGN GUIDELINES FOR GENERAL CLINICAL LABORATORY

I. GENERAL CONSIDERATIONS

1. ***Location.*** The clinical laboratory shall be situated in an area that is accessible both to clients and staff.

2. ***Privacy.*** The design shall also provide appropriate levels of the client audible and visual privacy and dignity throughout the diagnosis process, from specimen collection to the releasing of results.

3. ***Conformance with Building Laws.*** The clinical laboratory shall conform to all applicable local and national regulation for the planning and design, construction, renovation, maintenance and repair of its facilities.

4. ***Ventilation.*** Adequate ventilation with the acceptable air changes per hour shall be maintained for each specific area of the clinical laboratory.

5. ***Spaces Required.*** The clinical laboratory shall have adequate space or area provided for its various space/room requirements in order to attain the effective and efficient operation of its activities and functions.

   5.1 The spaces/areas of the clinical laboratory shall be zoned into the following areas, if applicable, and planned based on the functionality of the space and the activity workflow of the laboratory:

   5.1.1 General Administrative Services and Public Areas;
   5.1.2 Clinical Working Area;
   5.1.3 *Support Services Area.*

   5.2 The *General Administrative and Public Areas* shall be comprised of the following spaces:

   5.2.1. *Business Area*, provided with:

   5.2.1.1 A Reception area, for information and business transactions, receiving of specimen and releasing of results;
   5.2.1.2 Sufficient waiting area for clients.

   5.2.2. *Collection Area.* There shall be a collection area/s for specimens which is located outside the clinical working area.

   5.2.3. *Toilet Facilities,* may be within the premises of the facility but shall not within the clinical working area, or may be adjacent to the clinical laboratory.

   5.2.3.1 Conveniently accessible toilet for the public.
   5.2.3.2 A separate toilet for the staff.

5.3 *The Clinical Working Area.* The clinical working area shall be sufficient to accommodate its activities and allow for smooth and coordinated workflow. Areas and rooms intended for its sections shall be planned to meet the workload described in the functional program.

5.4 The *Support Services Area(s)* shall be composed of the following spaces:

5.4.1 Sufficient storage for records and supplies;
5.4.2 Sterilization area / room;
5.4.3 Waste holding area;
5.4.4 Staff Pantry;
5.4.5 Other spaces for staff such as offices, conference room, lockers and changing room (gender-sensitive) and the like, are optional.

5.5 Business area and support services areas may be optional for One Stop Shop (OSS) Facility, provided it is identified and accessible from the clinical laboratory.

6. ***Functional and Planning Considerations***

6.1 The different areas of the clinical laboratory shall be planned functionally related to each other to attain efficient workflow.

6.2 The clinical laboratory shall have space allocated for the performance of its work, and is designed to ensure the quality, safety and efficiency of the service provided to the user and the health, safety and comfort of laboratory personnel, patients and visitors. The laboratory shall evaluate and determine the sufficiency and adequacy of the space allocate for the performance of the work to accommodate its activities and allow for smooth and coordinated work flow.

6.3 There shall be sufficient and appropriate storage spaces and conditions provided for laboratory specimens, documents, records, manuals, equipment, reagents, supplies, slides and tissue blocks.

6.4 The clinical working area shall be sufficient to accommodate its activities and allow for smooth and coordinated workflow. Areas and rooms intended for its sections shall be planned to meet the workload described in the functional program. A dedicated room or area for each sections of the laboratory shall be provided inside the clinical working area.

II. SPECIFIC TECHNICAL REQUIREMENTS

____ 1. Collection area for blood extraction shall provide space, equipment and furniture appropriate for its activity performed. The area shall have work counter/tray, space for patient seating, and handwashing stations.

____ 2. Specimen collection toilet for urine and feces shall be equipped with water closet and/or urinal and lavatory. This facility may be located outside the main clinical laboratory, a designated cubicle for specimen collection in a toilet facility, or a dedicated toilet solely for specimen collection.

____ 3. A Pathologist's area may be provided and shall be located adjacent to or within the clinical working area so that he/she may have easy access to clinical working area of the

laboratory. Its location shall permit the pathologist to observe the clinical working area. It can be a separate room or a cubicle within the clinical working area.

____ 4. Entrance to clinical working area must not be directly located to high traffic areas that might cause unwanted air current drafts which may cause potential damage to equipment and possible contamination of specimen. A hand washing area (with designated dressing area is recommended) at the entry and exit points of the clinical working area is required.

____ 5. Sections of the clinical laboratory shall be provided with stainless steel sink with a depth of at least 8" and a gooseneck faucet.

____ 6. Each sections of the laboratory shall be properly identified in the clinical working area. Separate rooms for both Histopathology and Microbiology sections and for molecular pathology, if provided, shall be provided.

____ 7. Provision of toilets and other amenities for staff (e.g. lockers, lounge, pantry and changing room) shall be located outside the clinical working area to prevent contamination.

8. Biosafety Cabinets and isolation hoods shall be located so that fluctuations in air supply and exhaust or the operations of equipment do not alter the performance standard of the cabinet/hood.

____ 9. ***Fire Safety.*** The clinical laboratory shall conform to the applicable provisions of the 2019 Revised Implementing Rules and Regulations (IRR) of Republic Act (RA) 9514 or the Fire Code of the Philippines. In addition, there is no more than 23 meters of travel distance to any exit door from any point of the clinical working area.

____ 10. ***Corridors.*** The minimum width for corridor for clinical laboratory shall be at least but not limited to 1.20 meters or four (4) feet. Wider corridors shall be provided taking into consideration of passage of large equipment, movement of people and the activity involved.

____ 11. ***Clearances.*** Adequate clearances intended for working space in the clinical working area shall be provided. Clearance from work counter in the clinical working area from a wall shall be at least 1.2 meters or four (4) feet and 1.52 meters or five (5) feet for a work counter to another work counter, to allow passage of staff while others are working. Other consideration shall also be given for adequate clearances, such as size and type of equipment, activity involved, ergonomics and anthropometrics.

____ 12. Suitable facilities for quick drenching or flushing of the eyes and body parts shall be provided within the clinical laboratory for immediate emergency use. Such unit must be within 30 meters of work access, hands-free eyewash unit with hand wash unit is preferred.

____ 13. ***Lighting.*** All areas be well-lighted by providing appropriate luminaire with no exposed or dangling electrical wires and unwanted glare shall be avoided. Also, convenience outlets shall be provided within the facility.

____ 14. ***Ceiling Height.*** Ceiling height of the clinical laboratory shall conform to the provisions of the National Building Code of the Philippines. The floor-to-ceiling height of rooms containing biosafety cabinet and fume hoods shall be at least 2.60 meters. For rooms containing tall and ceiling-mounted equipment, the ceiling shall be of sufficient height in order to accommodate the equipment and/or fixtures.

____ 15. ***Plumbing.*** Continuous and sufficient supply of water shall be made available at all times in both working and hand washing areas. Piping systems shall be kept concealed as possible yet should be located where they will be easily accessible for service and repairs with a minimum of disruption of normal laboratory services.

____ 16. ***Ventilation.*** Artificial Air Conditioning shall be provided in the clinical working area to attain required HVAC requirements (i.e. exhaust fan, fume hood, air conditioning). Exhaust fan shall be provided in the clinical working area and its sections as a minimum requirement, with dedicated exhaust fans for rooms in the Microbiology and Histopathology sections.

Exhaust in the clinical working area shall be directed to the outside and air from clinical working area must not be recirculate within the facility. Directional airflow in the laboratory is recommended, wherein air should move form clean to less clean areas, with specific exceptions, based on the functional program of the laboratory and its sections.

There should be a sufficient air exchanges in the clinical working area, depending on the use and contents of the space.

____ 17. **Space.** Adequate area shall be provided for the people, activity, furniture, equipment and utility.

Space	Area in square meters
GENERAL ADMINISTRATIVE AND PUBLIC AREAS	
Business Area	
Reception Area	5.02 m²/staff
Waiting Area	0.65 m²/person
Collection Area	
Extraction Area *(for blood)*	6.00 m²/chair or couch
Specimen Collection Toilet *(for stool and urine)*	1.67 m²
Public Toilet	3.06 m²
Staff Toilet	1.67 m²
Pathologist Area	5.02 m²/staff
SUPPORT SERVICES AREA	
Storage Area for Supply and Records	4.65 m² or 1.2 m²/storage unit
Sterilization Unit / Room	4.65 m²
Waste Holding Area	4.65 m²
Staff Pantry	1.40 m²/person
Conference Room *(Optional)*	1.40 m²/person

____ 18. ***Material Specification***

____ 18.1. *Walls and partition.* All walls of the Clinical Laboratory in general shall be structurally sound, safe, and sturdy with minimum fire resistant rating as prescribed by the Fire Code of the Philippines for this type of occupancy. Wall finish shall be with impervious, smooth, less terminations, and easy to clean.

Interior walls or partitions and walls of the clinical working area and its sections shall be constructed from floor to ceiling.

Cubicle curtains and draperies if used for the clinical laboratory shall be non-combustible or flame-retardant.

18.2. *Flooring.* Floors in general shall be made of durable, and shall be readily cleanable and wear-resistant. Floors subject to traffic while wet (i.e. entrance porch, toilet facilities) shall have a non-slip surface. Floors in the clinical working area shall be seamless and self-coving to a height of 6 inches (152.4 millimeters) towards the wall.

18.3. *Work counters.* Work counters shall be provided with finish that does not support bacterial growth, durable, non-porous, smooth and easy to clean, stain and dirt resistant, preferably seamless finish. Sink or lavatory, preferably stainless steel, with faucet, preferably gooseneck, with adequate supply of water shall be provided. The width of the work counter shall be at least 600mm (750mm or 30 inches is preferred).

Backsplash or wainscoting shall be provided in the work counter, preferably with the same material with the countertop finish or its equivalent with at least 400mm high.

18.4. *Windows.* Windows and openings shall be in compliance with the requirements of Rule VIII of the National Building Code of the Philippines. If operable window is utilized in the clinical working area, it should be fitted with arthropod-proof screens.

18.5. *Doors.* The minimum clear opening for the main door/s of the clinical laboratory and the clinical working area and exit doors shall be at least 900mm. There shall also be at least one door with a minimum width of 900mm for rooms/sections housing large instruments and equipment. No doors in the clinical working area shall be less than 800mm. The main door of the clinical laboratory and doors to the clinical working area shall have appropriate fire ratings, and preferably be self-closing.

18.6. Carpeting, fabrics, wood and other similar finishes shall be avoided.

19. ***Additional Requirement/s***

The clinical laboratory shall provide for additional requirements depending on the type of pathogens handled in the facility and biosafety level required based on the conducted risk assessment, in adherence with the requirements of laboratory biosafety and biosecurity.

III. REFERENCES

A. Relevant Laws and Standards

a) Batas Pambansa Blg. 344. An Act to Enhance the Mobility of Disabled Persons.
b) PD 1096.The National Building Code with its revised Implementing Rules and Regulations.
c) 2019 Revised Implementing Rules and Regulations of RA 9514 Fire Code of the Philippines.
d) *Laboratory Biosafety Manual. 3rd Edition.* World Health Organization. 2004
e) *Laboratory Design: Approved Guideline. 2nd Edition.* Clinical and Laboratory Standards Institute. 2007.

B. DOH Issuances and Manuals

a) A.O. 2016-0042- *Guidelines in the Application for Department of Health Permit to Construct (PTC).* Department of Health. Manila. 2016.
b) *Manual of Standards on Quality Management System in the Clinical Laboratory*, Health Facility Development Bureau, Department of Health. Manila. 2019.
c) *Manual of Standards on Laboratory Biosafety and Biosecurity*, Health Facility Development Bureau, Department of Health. Manila. 2018.

d) *Manual on Healthcare Waste Management. 4th Edition.* Department of Health. December 2020.

C. Books and Publication

a) De Chiara, Joseph. (2001). *Time-Saver Standards for Building Types (4th edition).* McGraw-Hill Book Company.
b) McPherson R.A. & Pincus M.R. (2017). *Henry's Clinical Diagnosis and Management Laboratory Methods (23rd Edition).* Missouri, USA. Elsevier Inc.
c) *Guidelines for Design and Construction of Hospital and health Care Facilities.* American Institute of Architects. 2001.
d) Fajardo (2002). *Planning and Designers Handbook*, Second Edition. Quezon City. 5138 Merchandising.

Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

CHECKLIST FOR REVIEW OF FLOOR PLANS
GENERAL CLINICAL LABORATORY

Name of Health Facility: _____
Address: _____
Date: _____ Review: 1st _____ 2nd _____ 3rd _____

1.1 General Administrative and Public Areas

____ 1.1.1 Business Area
____ 1.1.1.1 Reception Area (Receiving of specimen / Releasing of laboratory results) *
____ 1.1.1.2 Waiting Area (commensurate 0.65 m² per person) *
____ 1.1.2 Collection Area
____ 1.1.2.1. Extraction Area (for blood)
____ 1.1.2.2. Specimen Collection toilet (for urine and stool)
____ 1.1.3 Public Toilet (PWD toilet is preferred; provide urinal if common toilet) *
____ 1.1.4 Staff Toilet (1 toilet for every 15 personnel) *

1.2 Clinical Working Area

____ CLINICAL PATHOLOGY
____ 1.2.1 Microscopy Section
____ 1.2.2 Hematology Section
____ 1.2.3 Clinical Chemistry Section
____ 1.2.4 Immunology/Serology Section [2]
____ 1.2.5 Microbiology Section (room type) [1]
____ 1.2.5.1 Culture & Sensitivity Room/ Processing Room
____ 1.2.5.2 Media Preparation Room
____ 1.2.5.3 Decontamination Room
____ 1.2.5.4 Sterilization Unit / Room

____ ANATOMIC PATHOLOGY
____ 1.2.6 Cytology Section [1]
____ 1.2.7 Histopathology Section (room type) [3]
____ 1.2.8 Frozen Section [3]
____ 1.2.9 Autopsy Room (room type) [3]

____ MOLECULAR PATHOLOGY *(if applicable)*
____ 1.2.10 Infectious Disease Section (room type)
____ 1.2.11 Genetics Section (room type)
____ 1.2.12 Oncology Section (room type)

OTHER AREAS
____ 1.2.13 Section for additional diagnostic tests for DOH-identified endemic areas *(if applicable)*
____ 1.2.14 Pathologist Office / area (may be within or adjacent to the clinical working area)

Note: each section shall be provided with stainless steel sink with a depth of at least 8" and a gooseneck faucet.

1.3 Support Services Area

____ 1.3.1 Storage Area for Supply and Records *
____ 1.3.2 Staff Lockers and Changing rooms (gender-sensitive) (Optional)
____ 1.3.3 Sterilization Unit / Room *
____ 1.3.4 Conference Room (Optional)
____ 1.3.5 Waste Holding Area *
____ 1.3.6 Staff Pantry*

[1]- *not required for primary Clinical laboratories (CL);*
[2]- *required for tertiary CLs only;*
[3]- *required for Level III Hospital-based CLs only;*
*- *optional for One Stop Shop (OSS) Facility, provided it is identified and accessible from the CL.*

Notes:
1. Floor plans properly identified and completely labelled.
2. Doors, windows, fixtures, furniture, and equipment are properly laid out.
3. Floor plans and drawings shall be in conducive scale (e.g. 1:100 m, 1:50 m) and with appropriate dimensions.

COMMENTS:

RECOMMENDATIONS:

Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

Name of Health Facility: _____
Address: _____

COMMENTS:

_____
_____
_____
_____
_____
_____
_____

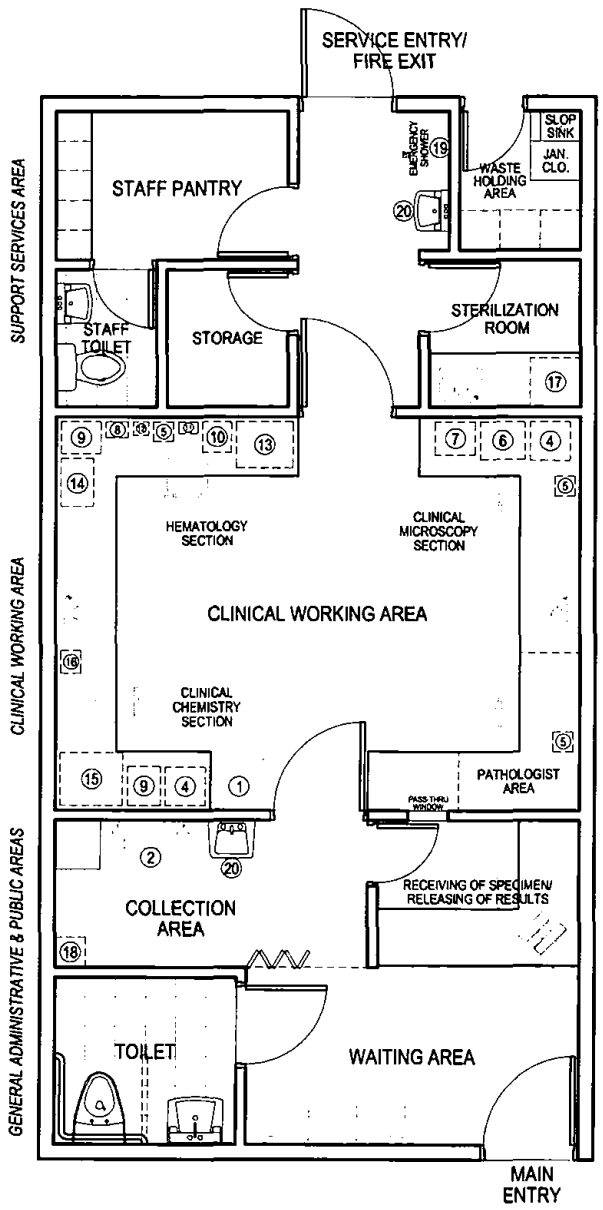
HEALTH FACILITIES EVALUATION AND REVIEW COMMITTEE (HFERC)
[ ] Approved [ ] Disapproved

_____
Chairperson, HFERC

_____
Vice-Chairperson, HFERC

_____	_____	_____
Member	Member	Member
_____	_____	_____
Member	Member	Member

_____
_____
_____



LEGEND:

1. REFIGERATOR
2. PHLEBOTOMY CHAIR
3. COMPUTER SET
4. CLINICAL CENTRIFUGE
5. MICROSCOPE
6. STRIP READER
7. URINE ANALYZER
8. HEMOCYTOMETER
9. SPECTROPHOTOMETER
10. HEMATOCRIT CENTRIFUGE
11. HEMATOCRIT READER
12. PIPPETTE SHAKER
13. HEMATOLOGY ANALYZER
14. SEROFUGE
15. CHEMISTRY ANALYZER
16. WATER BATH
17. AUTOCLAVE
18. TRASH BIN
19. EMERGENCY SHOWER AND EYE WASH
20. HANDWASHING SINK

NOTES:

- SCHEME APPLICABLE FOR NON-INSTITUTION-BASED PRIMARY CLINICAL LABORATORIES WITH MINIMUM SERVICE CAPABILITY. IF ADDITIONAL SERVICES AND TESTS WILL BE INTRODUCED, APPROPRIATE AREAS/SPACE INTENDED FOR SUCH SERVICES, AND ITS CORRESPONDING EQUIPMENT, FIXTURE AND SPACE FOR STAFF, SHALL BE ADDED.
- THE SIZE OF THE CLINICAL WORKING AREA AND ITS SECTION MAY VARY, DEPENDING ON THE TESTS PERFORMED, EQUIPMENT, FURNITURES, FIXTURES, INSTRUMENTS AND SUPPLIES, AND PERSONNEL INVOLVED.
- FOR INTITUTION-BASED CLINICAL LABORATORIES, BUSINESS AREA AND SUPORT SERVICES AREAS MAY BE OPTIONAL, PROVIDED THOSE ARE IDENTIFIED AND ACCESSIBLE FROM THE CLINICAL LABORATORY.
- THE TOILET FOR CLIENT/PATIENT, IF NOT WITHIN THE LABORATORY, SHALL BE ACCESSIBLE FROM THE LABORATORY (ADJACENT OR NEAR).
- THE SPECIMEN COLLECTION TOILET, MAY BE A SEPERATE TOILET OR DESIGNATED CUBICLE FOR SPECIMEN COLLECTION OF URINE AND STOOL, IF NOT WITHIN THE PREMISES OF THE CLINICAL LABORATORY, SHALL BE ACCESSIBLE FROM THE LABORATORY (ADJACENT OR NEAR).
- BASIC SEROLOGIC TESTING USING RAPID TEST KITS MAY BE PERFORMED IN THE HEMATOLOGY SECTION OR IN OTHER APPLICABLE SECTION, PROVIDED THE NECESSARY INSTRUMENTS AND SUPPLIES FOR THE CONDUCT OF TEST WILL BE PROVIDED.

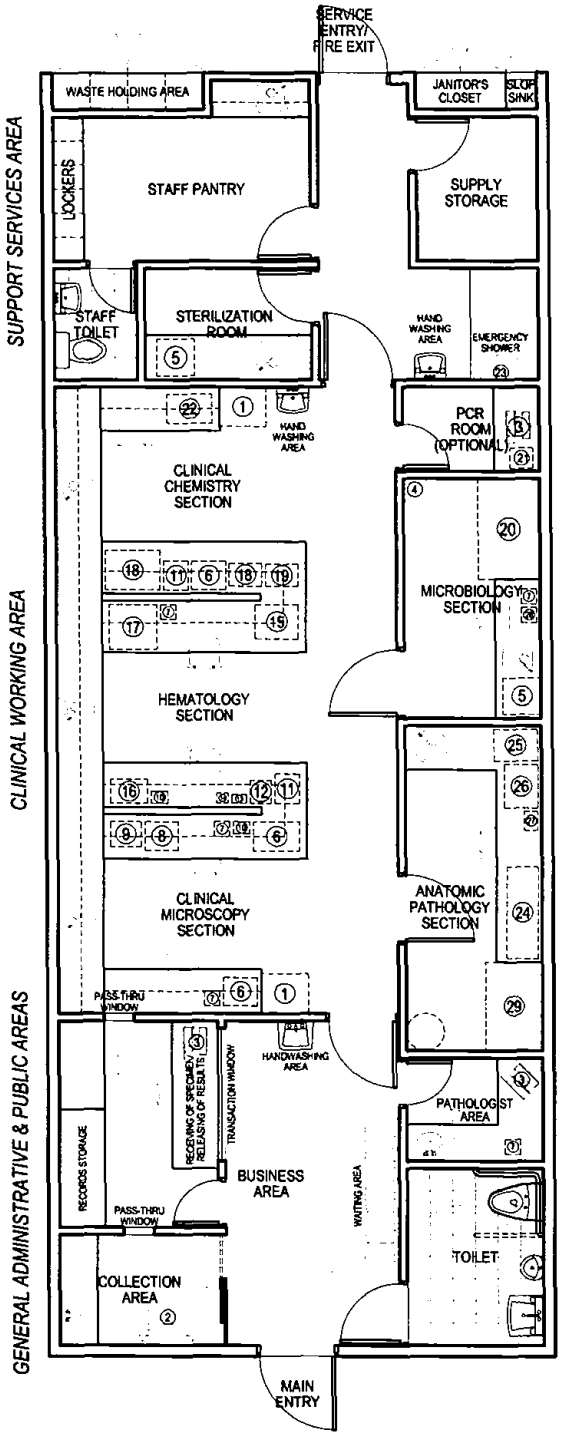
SAMPLE FLOOR PLAN

SCALE 1:75 m **GROSS FLOOR AREA: 62 m²**

0 1 2 4 6

Republic of the Philippines DEPARTMENT OF HEALTH CENTRAL OFFICE San Lazaro Compound, Rizal Avenue, Sta. Cruz, Manila City	TITLE / SHEET CONTENT: SAMPLE FLOOR PLAN FOR GENERAL CLINICAL LABORATORY (PRIMARY SERVICE CATEGORY)	APPROVED BY: GERARDO V. BAYUGO, MD, MPH, CESO I UNDERSECRETARY OF HEALTH, HEALTH REGULATION TEAM, DEPARTMENT OF HEALTH	SHEET NO. 1 OF 1 REVISION 0.0 MM/DD/2021 PREPARED BY: HFSRB-SDD

ANNEX D3b
AO 2021- 0037



LEGEND:

1. REFIGERATOR
2. PHLEBOTOMY CHAIR
3. COMPUTER SET
4. WASTE BIN
5. AUTOCLAVE
6. CLINICAL CENTRIFUGE
7. MICROSCOPE
8. STRIP READER
9. URINE ANALYZER
10. HEMOCYTOMETER
11. SPECTROPHOTOMETER
12. HEMATOCRIT CENTRIFUGE
13. HEMATOCRIT READER
14. PIPPETTE SHAKER
15. HEMATOLOGY ANALYZER
16. SEROFUGE
17. COAGULATION MACHINE
18. CHEMISTRY ANALYZER
19. ELECTROLYTE ANALYZER
20. ISOLATION HOOD / BIOSAFETY CABINET
21. PCR MACHINE (CARTRIDGE-BASED)
22. WATER BATH
23. EMERGENCY SHOWER AND EYE WASH
24. AUTOTECHNICON TISSUE PROCESSOR
25. MICROTOME
26. PARAFFIN OVEN
27. TISSUE PROCESOR
28. STAINING RACK
29. BACKDRAFT TABLE

NOTES:

- SCHEME APPLICABLE FOR NON-INSTITUTION-BASED SECONDARY CLINICAL LABORATORIES WITH MINIMUM SERVICE CAPABILITY. IF ADDITIONAL SERVICES AND TESTS WILL BE INTRODUCED, APPROPRIATE AREAS/SPACE FOR SUCH SERVICES, EQUIPMENT AND SPACE FOR STAFF, SHALL BE ADDED.
- THE SIZE OF THE CLINICAL WORKING AREA AND ITS SECTION MAY VARY, DEPENDING ON THE TESTS PERFORMED, EQUIPMENT, FURNITURES, FIXTURES, INSTRUMENTS AND SUPPLIES, AND PERSONNEL INVOLVED.
- FOR INTITUTION-BASED CLINICAL LABORATORIES, BUSINESS AREA AND SUPORT SERVICES AREAS MAY BE OPTIONAL, PROVIDED THOSE ARE IDENTIFIED AND ACCESSIBLE FROM THE CLINICAL LABORATORY.
- TOILET FOR PATIENT, IF NOT WITHIN THE LABORATORY, SHALL BE ACCESSIBLE FROM THE LABORATORY (ADJACENT OR NEAR).
- THE DEDICATED SPECIMEN COLLECTION TOILET, MAY BE A SEPERATE TOILET OR DESIGNATED CUBICLE FOR SPECIMEN COLLECTION OF URINE AND STOOL, IF NOT WITHIN THE PREMISES OF THE CLINICAL LABORATORY, SHALL BE ACCESSIBLE FROM THE LABORATORY (ADJACENT OR NEAR).
- STAFF LOCKERS AND CHANGING ROOMS ARE OPTIONAL.
- BASIC SEROLOGIC TESTING USING RAPID TEST KITS MAY BE PERFORMED IN THE HEMATOLOGY SECTION OR IN OTHER APPLICABLE SECTION, PROVIDED THE NECESSARY INSTRUMENTS AND SUPPLIES FOR THE CONDUCT OF TEST WILL BE PROVIDED.
- HISTOPATHOLOGY IS OPTIONAL FOR SECONDARY LABORATORY(IF OPTED OUT, THE LABORATORY MAY NOT PROVIDE CORRESPONDING EQUIPMENT, FURNITURES, FIXTURES, INSTRUMENTS AND SUPPLIES FOR HISTOPATHOLOGY ONLY).

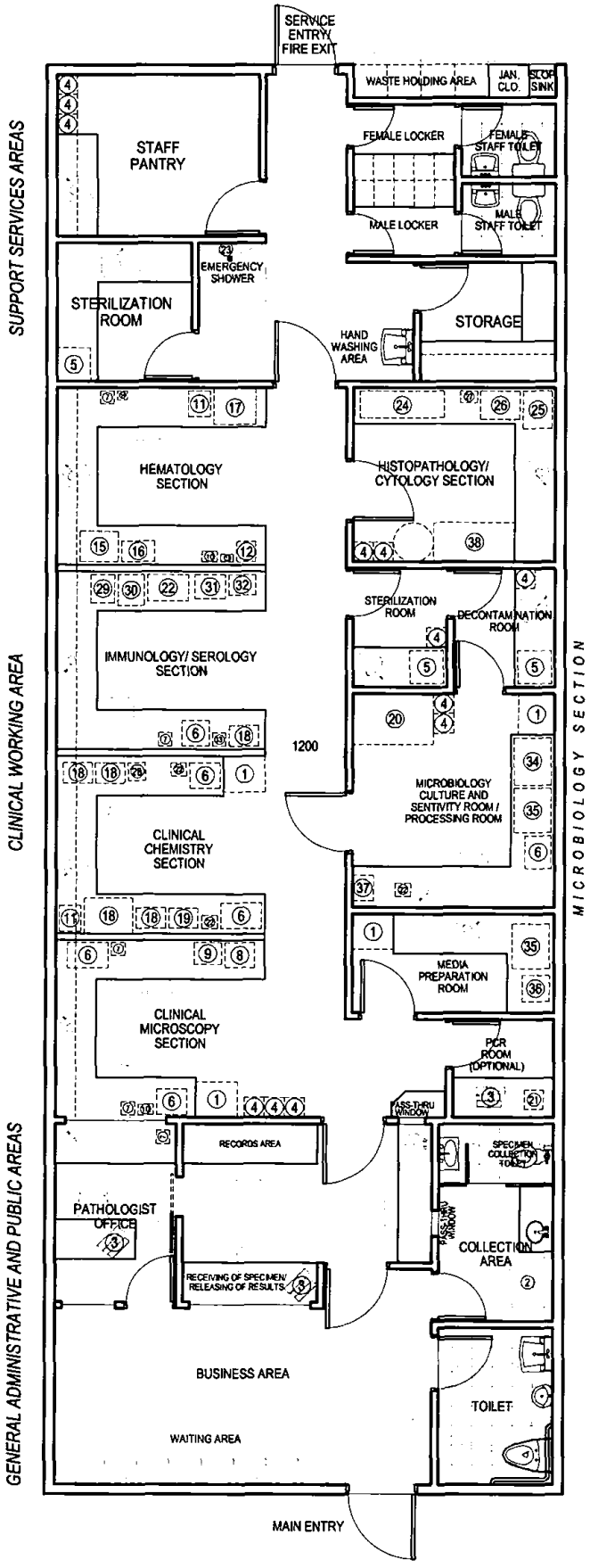
SAMPLE FLOOR PLAN

SCALE 1:100 m **GROSS FLOOR AREA: 110 m²**

0 1 2 4 8

Republic of the Philippines DEPARTMENT OF HEALTH CENTRAL OFFICE San Lazaro Compound, Rizal Avenue, Sta. Cruz, Manila City	TITLE / SHEET CONTENT: SAMPLE FLOOR PLAN FOR GENERAL CLINICAL LABORATORY (SECONDARY SERVICE CATEGORY)	APPROVED BY: GERARDO V. BAYUGO, MD, MPH, CESO I UNDERSECRETARY OF HEALTH, HEALTH REGULATION TEAM, DEPARTMENT OF HEALTH	SHEET NO. 1 OF 1 REVISION 0.0 MM/DD/2021 06 11 PREPARED BY: HFSRB-SDD

ANNEX D3c
AO 2021- 0037



LEGEND:

1. REFIGERATOR
2. PHLEBOTOMY CHAIR
3. COMPUTER SET
4. WASTE BIN
5. AUTOCLAVE
6. CLINICAL CENTRIFUGE
7. MICROSCOPE
8. STRIP READER
9. URINE ANALYZER
10. HEMOCYTOMETER
11. SPECTROPHOTOMETER
12. HEMATOCRIT CENTRIFUGE
13. HEMATOCRIT READER
14. PIPPETTE SHAKER
15. HEMATOLOGY ANALYZER
16. SEROFUGE
17. COAGULATION MACHINE
18. CHEMISTRY ANALYZER
19. ELECTROLYTE ANALYZER
20. BIOSAFETY CABINET
21. PCR MACHINE (CARTRIDGE-BASED)
22. WATER BATH
23. EMERGENCY SHOWER AND EYE WASH
24. AUTOTECHNICON TISSUE PROCESSOR
25. MICROTOME
26. PARAFFIN OVEN
27. TISSUE PROCESOR
28. BLOOD GAS ANALYZER
29. MICROPLATE WASHER
30. MICROPLATE READER
31. ELISA WASHER SET
32. BEAD SYSTEM
33. CRP ANALYZER
34. INCUBATOR
35. DRYING OVEN
36. MICRO CENTRIFUGE
37. ELECTRIC / GAS STOVE
38. BACKDRAFT TABLE

NOTES:

- SCHEME APPLICABLE FOR NON-INSTITUTION-BASED TERTIARY CLINICAL LABORATORIES WITH MINIMUM SERVICE CAPABILITY. IF ADDITIONAL SERVICES AND TESTS WILL BE INTRODUCED, APPROPRIATE AREAS/SPACE FOR SUCH SERVICES, EQUIPMENT AND SPACE FOR STAFF, SHALL BE ADDED.
- FOR INTITUTION-BASED CLINICAL LABORATORIES, BUSINESS AREA AND SUPORT SERVICES AREAS MAY BE OPTIONAL, PROVIDED THOSE ARE IDENTIFIED AND ACCESSIBLE FROM THE CLINICAL LABORATORY.
- THE SIZE OF THE CLINICAL WORKING AREA AND ITS SECTION MAY VARY, DEPENDING ON THE TESTS PERFORMED, EQUIPMENT, FURNITURES, FIXTURES, INSTRUMENTS AND SUPPLIES, AND PERSONNEL INVOLVED.
- TOILET FOR PATIENT, IF NOT WITHIN THE LABORATORY, SHALL BE ACCESSIBLE FROM THE LABORATORY (ADJACENT OR NEAR).
- THE DEDICATED SPECIMEN COLLECTION TOILET, MAY BE A SEPERATE TOILET OR DESIGNATED CUBICLE FOR SPECIMEN COLLECTION OF URINE AND STOOL, IF NOT WITHIN THE PREMISES OF THE CLINICAL LABORATORY, SHALL BE ACCESSIBLE FROM THE LABORATORY (ADJACENT OR NEAR).
- STAFF LOCKERS AND CHANGING ROOMS ARE OPTIONAL.

SAMPLE FLOOR PLAN

SCALE 1:100 m **GROSS FLOOR AREA: 160 m²**

0 1 2 4 8

Republic of the Philippines
DEPARTMENT OF HEALTH
CENTRAL OFFICE
San Lazaro Compound, Rizal Avenue, Sta. Cruz, Manila City

TITLE / SHEET CONTENT:	APPROVED BY:	SHEET NO. 1 OF 1
SAMPLE FLOOR PLAN FOR GENERAL CLINICAL LABORATORY (TERTIARY SERVICE CATEGORY)	GERARDO V. BAYUGO, MD, MPH, CESO I UNDERSECRETARY OF HEALTH, HEALTH REGULATION TEAM, DEPARTMENT OF HEALTH	REVISION 0.0 MM/DD/2021 PREPARED BY: HFSRB-SDD

Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

GUIDELINES IN SECURING FOR REMOTE COLLECTION PERMIT FOR CLINICAL LABORATORIES

1. Only DOH-licensed clinical laboratories (CL), without mobile clinical laboratory (MCL) shall be required to apply for Remote Collection Permit-CL (RCP-CL).

2. Remote collection can only be done in the following non-clinical laboratory settings such as but not limited to:
   2.1. Schools;
   2.2. Offices;
   2.3. Churches; and
   2.4. Other areas used for community-based activities.

3. The remote collection facility should have a proper area for specimen collection (e.g. clean toilet for urine and stool collection).

4. Only employed Registered Medical Technologists (RMTs) of the applicant's CL shall be allowed to collect blood samples/specimens.

5. The activity at the remote collection facility shall only last for four (4) to six (6) hours.

6. No testing or processing of specimens shall be done in the temporary collection facility.

7. Specimens should be properly handled and transported.
   7.1. Samples for routine urinalysis and routine fecalysis shall be stored at refrigerated temperature within one (1) hour from the time of collection.
   7.2. The serum from blood samples for chemistry must be separated within four (4) hours from the time collection.

8. The remote collection facility shall be located within the same region, at a maximum of one hundred (100) kilometre radius, from the address of DOH licensed CL.

9. RCP-CL shall be secured from the DOH at least seven (7) working days prior to the scheduled activity.

10. RCP-CL shall be secured from the DOH regulatory office in accordance with DOH guidelines.

11. RCP-CL shall be signed by the Director IV of HFSRB or Center for Health Development (CHD), or his designate.

12. The following are the documentary requirements:
    12.1. Letter of request, signed by the Head of Clinical Laboratory, to conduct remote collection with the following information:

12.1.1. Name of facility with DOH-LTO number
12.1.2. Address of facility
12.1.3. Date of collection
12.1.4. Time of collection
12.1.5. Venue
12.1.6. Estimated number of clients
12.1.7. Specimen to be collected

12.2. Notarized Memorandum of Agreement or contract between the contracting parties.
12.3. Technical or operational procedures for remote collection including specimen handling and transportation.

12.4. List of laboratory supplies/equipment to be used during remote collection including the transport materials.

13. A remote collection permit fee of Php500.00 for each site shall be collected from the clinical laboratory.

14. The RCP-CL shall be valid only up to the date of collection. In case of failure to conduct the collection at the specified date, the laboratory shall inform the HFSRB or CHD-Regulation, Licensing and Enforcement Division (CHD-RLED) in writing, at least within 48 hours before the scheduled date of remote collection and shall be informed of the new schedule which should be within the validity period. Otherwise, another RCP-CL shall be secured.

15. A copy of the RCP-CL shall be posted in conspicuous area of the remote collection facility.

16. The clinical laboratory shall maintain records of all remote collection performed.

17. The HFSRB or CHD-RLED may inspect the remote collection site prior to the issuance of the permit or monitor during the actual collection.

18. In case of failure to conduct the collection at the specified date, the laboratory shall inform the HFSRB or CHD-RLED in writing, at least within 48 hours before the scheduled date of remote collection, and shall be informed of the new schedule which should be within the validity period. Otherwise, another RCP-CL shall be secured.

19. Home service blood collection shall be exempted from securing RCP-CL provided, that it is upon the patient's doctor request, and the area of collection must be within (1) hour travel time, under normal circumstances, from the licensed clinical laboratory. To ensure proper specimen collection and handling, provision nos. 4, 5, 7.1, and 8 of this guidelines should be followed.

20. Violations of the guidelines stated herein, and related policies or laws shall be the basis for suspension/revocation of the RCP-CL and the LTO of the main clinical laboratory.

A.O. No. 2021 - 0037
ANNEX F

Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

APPLICATION FORM FOR CERTIFCATE OF REGISTRATION FOR RESEARCH AND TEACHING CLINICAL LABORATORY

Name of Facility _____

Complete Address _____
Number & Street Barangay/District

_____
Municipality/City Province/Region

Contact Information _____ Email Address _____

Head of the Facility _____

Owner _____

Status of Application [ ] New [ ] Renewal

I. Classification According to:
A. Ownership:

☐ Government
- ☐ Provincial
- ☐ District
- ☐ City
- ☐ Municipal
- ☐ DOH-Retained
- ☐ University
- ☐ Others: Specify:_____

☐ Private
- ☐ Corporation
- ☐ Partnership
- ☐ Proprietorship
- ☐ Cooperative
- ☐ Foundation
- ☐ Others; Specify: _____

B. Institutional-Character: ☐ Hospital ☐ Non-Hospital Based

II. Certificate of Registration:
Please specify services offered: _____

Instruction: Please check the appropriate boxes below and provide necessary documents
Note: Please refer to www.hfsrb.doh.gov.ph. for other details of the requirements.

Documents	New	Renewal
1. Notarized Acknowledgement		
2. Proof of Ownership and Name of Health Facility: 2.1. DTI/SEC/CDA Registration including Articles of Incorporation/Cooperation and By-Laws 2.2. Enabling Act/ LGU Resolution (for government health facility)		
3. Health Facility Geographic Form (Geographic Coordinates)		

_____ _____
Name and Signature of Approving Authority Date of Application

Acknowledgement

REPUBLIC OF THE PHILIPPINES) CITY/
MUNICIPALITY OF _____) S.S.

I, _____, _____ of legal age, _____,a resident
Name Civil Status Age

of _____, after having been sworn in accordance with law,
Address

Hereby depose and say that I am executing this affidavit to attest to the completeness and truth of the foregoing information and the attached documents required for the establishment/operation of health facility pursuant to existing rules and regulations. That the undersigned is aware and informed that any misrepresentation, falsification/deception herein can cause the denial of my application.

_____
Signature

Before me, this _____ day of _____ 20___ in the City/Municipality of _____, Philippines, personally appeared the above affiant with Community Tax Certificate No. _____ issued on _____ at _____, Known to me to be the same person/s who executed the foregoing instrument and they acknowledge to me that the same is their free act and deed.

Owner	*Community Tax Number*	*Issued at/on*
_____	_____	_____

Known to me to be the same person/s who executed the foregoing instrument and they acknowledge to me that the same is their free act and deed.

IN WITNESS WHEREOF, I have hereunto set my hands this _____day of _____, 20___

Doc No. _____
Page No. _____
Book No. _____
Series of _____

NOTARY PUBLIC
My Commission Expires
Dec. 31, 20____