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 [ ] Monitoring [ ]

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
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 goals shall be in accordance with Republic Act (RA) No. 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** • Compiled clinical laboratory (CL) Administrative Order (AO), Reports of Inspection/Monitoring **Observe** • Valid DOH-LTO posted in a conspicuous area visible to clients • **The CL operating hours is known to clients**		
4. There is a policy and procedure on management review	**Document Review** • Written policy on management review • Compiled documented minutes of meeting reflecting the date, time, attendance, agenda, and action taken signed and approved by head of laboratory (HOL), held at least twice a year or as needed • 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.		
5. There is policy and procedure for handling complaints and client feedback	**Document Review** • Written policy and procedure for handling complaints/client feedback • Forms for complaints/ client feedback • Records of complaints/client feedback and actions taken • Documented analysis of the client feedback/customer satisfaction survey **Observe** • Suggestion box visible to clients		

CRITERIA	INDICATOR/EVIDENCE	COMPLIED	REMARKS
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/Administrative Personnel Officer/RMT Supervisor/Training 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 • **Written policies and procedures on reporting of workload**		

10. There is an adequate number of qualified personnel with documented training and experience to conduct/perform the laboratory procedures	**Document Review**
	• List of Personnel with designation
	• Area of assignments indicated in the posted work schedule and assignment signed and approved by HOL
	• Written policies and procedures on reporting of workload (whenever there is an increase in workload, there shall be a corresponding increase in the number of personnel)
	• Written 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	**Document Review** • Proof of submission of data to NDHRHIS		

CRITERIA	INDICATOR/EVIDENCE	COMPLIED	REMARKS
Information System (NDHRIS)			
12. 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 • **Notarized list of handled CL/s including the addresses**		
13. Each personnel shall have a record of updated 201 files	**Document Review** • Updated 201 files of all CL 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 qualifications: ◦ Updated Resume/Personnel Data Sheet ◦ Valid PRC ID and Certificate ◦ PSP Board Certificate ◦ Certificate of Good Standing from PSP ◦ Notarized employment contract ◦ Relevant training certificates (e.g., Molecular Pathology) ◦ Annual Health Status (Latest Medical Certificate) ◦ Vaccination record (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	/		

**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

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B. Registered Medical Technologist (RMT)
 	
(At least 1 competent RMT per assigned area)
	Document Review
	• Proof of qualifications:
	  ▪ Updated Resume/ Personnel Data Sheet
	  ▪ Valid PRC ID and Certificate
	  ▪ Relevant training certificates
	  ▪ Notarized employment contract
	  ▪ Annual Health Status (Latest Medical Certificate)
	  ▪ Vaccination record (Hepatitis B and Influenza)		

RMT staff with designated assignments, as applicable:	Additional proof of trainings		
1. HIV Proficiency Testing	• **Certificate of Proficiency (SACCL)**		
2. rHIVda Training	• Certificate of Proficiency (SACCL)		
3. AFB microscopy	• Certificate of training on DSSM (NTRL **and other NTRL recognized institutions)**		
4. Bacteriology	• Certificate of training in bacteriology (RITM and other RITM recognized institutions)		
5. Malaria smear	• Certificate of training in malaria smear (RITM)		
6. Others, as applicable			
C. Biosafety and Biosecurity Officer (May be designated by the HOL)	**Document Review** • Valid PRC ID and Certificate (RMT) • Certificate of training in Biosafety and Biosecurity (RITM or other DOH/RITM recognized training providers)		
D. MCL Personnel	**Document Review** • **Valid PRC ID and Certificate (RMT)**		

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
Clinical 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
Immunology/Serology							1	1	1
Microbiology				1			1		
Histopathology							1		
Total	2	2	2	4	3	3	6	4	4
Overall	**6 for 24-hour shift 1 reliever**			**10 for 24-hour shift 1 reliever**			**14 for 24-hour shift 1 reliever**		

Note: An increase in workload and add-on services shall require a corresponding increase in the number of personnel

- **Limited-Service Capability shall follow the staffing pattern and will depend which services are being provided. There shall be one personnel per section/area**
- **MCL shall have its own set of personnel including RMT and an additional staff will depend on the anticipated workload**

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

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III. PHYSICAL PLANT AND ENVIRONMENTAL MANAGEMENT			
14. There are an adequate and appropriate areas to safely, effectively and efficiently provide the services to clients	**Document Review** • **Approved copy of DOH-PTC, floor plans and checklist for review of floor plan** • **Presence of eyewash and/or handwashing in extraction area** **Observe** • **No smoking signages are visible to patients**		
15. 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 • **Documented records and reports on compliance to biosafety cabinet standards (for those with microbiology section) and other safety practices** **Observe** • Updated proof of actual implementation of maintenance as to structure, ventilation, lighting & water supply • **Adequate lighting shall be provided in all areas**		
16. 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 • **Written guidelines on environmental infection and prevention control** **Observe** • Good Laboratory Practice that includes use of Personal Protective Equipment and other precautionary measures		
17. There is a policy and procedure for the proper waste management including handling and disposal of waste and hazardous/ infectious substances that shall conform to the	**Document Review** • Written policy on disposal of wastes that conform with Healthcare Waste Management Manual, and RA No. 6969 • Written protocols on waste decontamination and disposal • Notarized Memorandum of Agreement (MOA) with **DENR accredited hauler/ EMB Certificate, as**		

CRITERIA	INDICATOR / EVIDENCE	COMPLIED	REMARKS
standards set by the DOH	**applicable (no hauler)** for infectious waste, toxic, and hazardous substances **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 (Revision 01 Annex D1 and D2)			
IV. EQUIPMENT, INSTRUMENTS, GLASSWARES, REAGENTS AND SUPPLIES			
18. 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		
19. There is program for calibration, preventive maintenance and repair for the equipment.	**Document Review** • Records of regular schedule including the frequency of preventive maintenance and calibration • Updated certificate of calibration and maintenance of equipment • Record of corrective repair maintenance with service reports or logbooks		
20. There is an adequate supply of properly stored and inventoried reagents and supplies for the laboratory examinations to be provided.	**Document Review** • Updated quality records of supplies /reagents with expiration date, their usage/ consumption and disposal • Certificate of Product Registration from FDA, 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		

21. 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
	• Availability of appropriate thermometer
	• Monitoring of room temperature
	• Temperature of refrigerators (2°C to 8°C) and freezers (-20°C to -30°C)		

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22. There is an appropriate storage facilities/area and 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		
NOTE: Please see the Glassware/Supplies/Reagents per Area of Activity (Revision 01 Annex B2)			
V. INFORMATION MANAGEMENT **A. Administrative and Technical Policies and Procedure**			
23. There is an administrative policies & procedures for provision of laboratory services and for the operation and maintenance of the laboratory	**Document Review** • Documented policies, protocols, procedures signed and approved by the HOL, including of the CL, MCL and POCT, as applicable. • Written guidelines in the operation and maintenance of the laboratory including policy on security of supplies, specimens and confidentiality of records and material accountability, inventory control • Written protocols on the operation and maintenance of equipment, machine, including of biosafety cabinet and autoclave (for microbiology section) • **Written policies on Good Laboratory Practice (GLP)** **Observe** • **GLP including the use of personal protective equipment (PPE) and other precautionary measures** • **Provision of appropriate and good quality PPE**		
24. Policy guidelines on laboratory biosafety and biosecurity	**Document Review** • **Local risk assessment reviewed at least annually** • **Documented records of conducted spill response drill** • **Written policies and protocols on information security including database inventory and ensure confidentiality of records** • **List of authorized personnel who can enter the CL** **Observe** • **Limited access control is being implemented in the facility** • **Lock and key features are provided**		
25. The technical procedures of services provided by each section are available	**Document Review** • Updated written policies and procedures of laboratory services in each of the sections/areas.		

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	• Documented policies, protocols, and guidelines in the operation and maintenance of the laboratory		
26. There is contingency plan in case of equipment breakdown	**Document Review** • Written policy on contingency plan in case of equipment breakdown		
B. Communication and Records Management			
27. There is a policy on the conduct of **remote collection, mobile CL (MCL) and satellite CL (SCL)**	**Document Review** • Documented procedures on the conduct of MCL and SCL • **Proof of remote collection permit as applicable** • Proof of vehicle ownership and Land Transportation Office Registration • Notarized Memorandum of Agreement (MOA) between the CL and the facility where the mobile activity is conducted		
28. There is a policy and procedure on the performance of Point of Care Test (POCT)	**Document Review** • **There is a designated POCT coordinator** • Documented list of POCT operators, machines, instruments and kits • **Written policy and procedure on the performance, maintenance, quality control, encoding of results and related processes on POCT** • 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 CL on POCT		
29. There are procedures for the receipt of samples, performance of laboratory tests and reporting/releasing of results **including that of the MCL, SCL and POCT as applicable**	**Document Review** • Written protocols, policies and procedures in specimen handling/transport/receiving and performance of laboratory tests • Written procedures for reporting/releasing of results of laboratory tests • Documented procedures for the validation of laboratory results prior to reporting/releasing • Documented procedures for receipt, performance and reporting of routine and STAT laboratory examinations, including reporting of critical values.		
30. The laboratory report forms on various CL examinations **(CL official results) shall be signed by the analyst and the HOL or his/her associate**	**Document Review** • Updated records of result (logbooks/ electronically stored data with back up) including entry, releasing & endorsement records. • Laboratory report forms (CL official results) bearing the name and original or **digital signature** with PRC ID No. of the HOL or his/her associate		

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pathologist who shall be responsible for the reliability of the results	pathologist and the RMT analyst/s who performed the test • There is a policy guideline on the use of authenticated digital signature that is in accordance with the E-commerce law • Documented policy for Laboratory Information System, if available		
31. There are procedures for quality control, inventory control and related processes	**Document review** • Documented procedures for quality control, inventory control, and related processes. • Updated reports and documents (hard or soft copy with back up) • Worksheets/machine print out per section as proof of actual performance		
32. 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		
33. 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 No. 2021-0226) 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		
C. Access to Price Information			

34. The prices for laboratory services are readily available and accessible to the public as mandated by RA No. 11223 and related DOH issuances	**Document Review**
	• **Updated laboratory services with corresponding prices/price list is readily available and accessible to clients/public which can be in any of the following form:**
	  ◦ **Printed handout**
	  ◦ **Booklet**
	  ◦ **Digital form**
	  ◦ **Poster/tarpaulin**
	  ◦ **Online/website**		

VI. QUALITY IMPROVEMENT ACTIVITIES			

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35. 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 QAP audits / assessments		
36. 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		
VII. REFERRAL AND OURSOURCING OF LABORATORY EXAMINATIONS			
37. There is a policy on referral and outsourcing of examinations	**Document Review** • Documented procedures on referral and outsourcing of examinations to other DOH licensed CL • Records of referred examinations (in the event of e.g., machine breakdown and power interruption) • **List of outsourced examination** • Notarized MOA • DOH-LTO of the CL where specimens are sent-out (referred/outsourced)		