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

ASSESSMENT TOOL FOR ACCREDITATION OF DRUG TESTING LABORATORY

I. FACILITY INFORMATION

Name of Laboratory : _____

Complete Address : _____

No. & Street Barangay

_____

City/Municipality Province Region

Contact Number : _____ E-mail Address _____

Name of Owner/Corporation : _____

Name of Head of Laboratory : _____

Application for: ☐ Initial ☐ New ☐ Existing with change/s. Specify _____

☐ Renewal Accreditation No.: _____

Expiry Date: _____

Classification: Ownership: ☐ Government ☐ Private

Institutional Character: ☐ Institution-based ☐ Free-standing

Service Capability: ☐ Screening ☐ Confirmatory

II. TECHNICAL REQUIREMENTS ☐ Inspection ☐ Monitoring

Instruction: In the appropriate box, place a check mark (√) if the drug testing laboratory is compliant or x mark (X) if it is not compliant.

STANDARDS AND REQUIREMENTS	INSPECTION	MONITORING	REMARKS
A. PERSONNEL **Every DTL shall have an adequate number of qualified, trained, and competent staff to ensure efficient and effective delivery of services.**			
ORGANIZATIONAL CHART The organizational chart shall be clearly structured indicating the name and designation of all personnel with corresponding picture.			
HEAD OF THE LABORATORY ➢ For SDTL ☐ Free-standing ❒ Clinical Pathologist ❒ Physician trained in Laboratory Management ❒ Chemist ☐ Institution-based ❒ Clinical Pathologist/Trained Physician ❒ Chemist ❒ Medical Technologist ❒ Pharmacist ❒ Chemical Engineer			

STANDARDS AND REQUIREMENTS	INSPECTION	MONITORING	REMARKS
➢ For CDTL ❒ Clinical Pathologist ❒ Chemist			
ANALYST ❒ Chemist ❒ Medical Technologist ❒ Pharmacist ❒ Chemical Engineer			
201 FILES (All records should be within the laboratory premises) ➢ HEAD OF LABORATORY Name: _____ ❒ Resume ❒ PRC ID (Valid) ❒ PRC Board Certificate ❒ Written & notarized employment contract/appointment as head of lab. ❒ For Clinical Pathologist, certificate from Philippine Society of Pathologist ❒ For Non-Pathologist, Certificate of Laboratory Management for DTL conducted by DOH Certificate No. _____ ❒ Job description (detailed description of tasks, responsibilities and accounta-bilities) ❒ Complete, updated and notarized list of DTLs handled to include each address and work schedule <u>For CDTL only:</u> ❒ 2 years of active laboratory experience in analytical toxicology ❒ If chemist, master's degree in chemistry/Biochemistry/other fields of chemistry			
➢ ANALYST ❒ Resume ❒ PRC ID (Valid) ❒ PRC Board Certificate ❒ Written & notarized employment contract/appointment as analyst ❒ Certificate of training for SDTL conducted by DOH Certificate No. _____ ❒ Certificate of training for CDTL conducted by DOH Certificate No. _____ ❒ Job description (detailed description of tasks, responsibilities & accountabilities)			
➢ AUTHORIZED SPECIMEN COLLECTOR (ASC) *Applicable for SDTL only ❒ Resume ❒ Written & notarized employment contract/appointment as ASC ❒ Certificate of training conducted by the Laboratory signed by HOL ❒ Job description (detailed description of tasks, responsibilities & accountabilities)			

STANDARDS AND REQUIREMENTS	INSPECTION	MONITORING	REMARKS
➢ HEALTH STATUS ❒ Medical/Health Certificate (valid) ❒ Annual drug test report conducted by another accredited DTL			
WORK SCHEDULE ➢ Monthly schedule of duties and assignment posted within the laboratory			
B. PHYSICAL FACILITIES **The laboratory has adequate space for conduct of its activities.**			
➢ FLOOR AREA ▭ SCREENING LABORATORY ❖ FREE-STANDING ❒ Approved PTC (for new facility) ❒ Floor Area (20 sq.m.) ❖ INSTITUTION-BASED ❒ Working Area of Secondary/Tertiary Clinical Lab. (designated area Exclusive for drug testing) ▭ CONFIRMATORY LABORATORY ❒ Floor Area (60 sq.m.) ❒ Stock Room ❒ Instrumentation Room A laboratory of whatever category shall have within its premises the following: 🗀 Receiving Area (can accommodates at least 5 clients at a given time) • Suggestion box for Client's Feedback 🗀 Toilet Facility			
➢ POSTED IN CONSPICUOUS AREA ❒ For SDTL, poster detailing the process flow of drug testing ❒ Vision, mission and objectives ❒ Organizational Chart ❒ Local Permits ❒ Licenses and Certificates of personnel ❒ NO SMOKING Signage			
➢ SPECIMEN COLLECTION AREA (SDTL) ❒ Waterless urinal ❒ Handwashing Facility 🗀 Outside the toilet 🗀 Within, provided with partition 🗀 With free flowing water supply from the faucet			
➢ WORKING AREA ❒ At least 10sq.m. for free standing SDTL ❒ At least 30sq.m. for Confirmatory Lab. ❒ Sink (with countertop and faucet with adequate water supply ❒ Functional exhaust fan ❒ Electric fan/air conditioner unit may be used for improved ventilation			
➢ PERIODIC SIGNAGE PER AREA			

STANDARDS AND REQUIREMENTS	INSPECTION	MONITORING	REMARKS
➢ WASTE MANAGEMENT AND HOUSEKEEPING ❒ Solid Waste – Practice of waste Segregation ❒ Liquid Waste ▪ Proper disposal of urine specimen ▪ Proper disposal of used and expired reagents either by neutralization, delay to decay or through the drainage system (Applicable for CDTL only) ❒ Housekeeping ▪ Facility is kept clean, safe and odor-free ▪ There should be a program for pest and vermin control ▪ Supplies are kept and secured			
➢ PROGRAM FOR THE PROPER MAINTENANCE AND MONITORING OF PHYSICAL PLANT AND FACILITIES			
C. EQUIPMENT, SUPPLIES AND FIXTURES ❒ Schedule of preventive maintenance of equipment ❒ Inventory relative to the workload and procurement receipts of supplies			
➢ REFRIGERATOR/FREEZER ❒ Properly maintained & functional, strictly for urine specimen ❒ Laboratory thermometer inside refrigerator/freezer (non-mercurial) ❒ Daily monitoring temperature record posted on the unit			
➢ INFORMATION TECHNOLOGY REQUIREMENTS ▪ Windows XP operating system ▪ 1.5 GHz processor ▪ 4GB HDD ▪ ISP 128Kbps CIR ▪ Fingerprint Biometric Scanning Device ▪ Webcam (For SDTL only) ▪ Megamatcher License Dangle ▪ Ink or Laser printer ▪ DOH-IDTOMIS			
➢ SUPPLIES ❒ Specimen Container (For SDTL only) - 60ml polyethylene, wide mouth with screw cap ❒ Plastic Bag (For SDTL only) - Transparent, self-sealing/sealable and leak proof, capable of containing the specimen & pertinent documents (CCF) ❒ Gloves - disposable			

STANDARDS AND REQUIREMENTS	INSPECTION	MONITORING	REMARKS
➢ FIXTURES ❒ Cabinet - With lock to secure and store records & supplies ❒ Tables/Chairs/Bench - Tables and chairs allotted for personnel - Chairs/bench that can accommodate at least 5 clients at the same time			
D. STANDARD OPERATING PROCEDURES The DTL shall have a Manual of Standard Operating Procedures containing documented policies, protocols, guidelines in the operation and maintenance of the laboratory.			
• **Administrative Policies and Procedures**			
➢ Vision, Mission and Objectives (should be in accordance with RA 9165 "Comprehensive Dangerous Drug Act of 2002")			
➢ Policy for hiring, orientation and promotion for all levels of personnel			
➢ Duties and Responsibilities of personnel			
➢ Continuing Education/Training Program for Staff			
➢ Policy for discipline, suspension, demotion and termination of all personnel at all levels			
➢ Procedures for handling complaints and laboratory accidents			
➢ Quality Plan A written program/plan of management to assure competence, integrity of drug testing			
➢ Policy for waste management and housekeeping			
➢ Policy for equipment maintenance and repair			
• **Technical Policies and Procedures**			
➢ Specimen Collection/ Sampling (within the laboratory)			
➢ Receiving, Accessioning and Releasing of Specimen			
➢ Specimen Rejection/ Cancellation			
➢ Referral to Confirmatory Laboratory when positive results was obtained			
➢ Remote Collection			
➢ Reagents, Standards and Controls			
➢ Analytical Procedure			
➢ Mechanism of Reporting Results			
➢ Procedure for Security and Confidentiality of Records, Supplies and Specimen			
➢ Storage and Disposal of Specimen *For CDTL, include storage and disposal of chemicals			
➢ Internal Quality Assurance Program			
➢ External Quality Assurance Program			
➢ Good Laboratory Practice			

STANDARDS AND REQUIREMENTS	INSPECTION	MONITORING	REMARKS
E. RECORDS/FILES ➢ Systematic filing and safekeeping of records			
For SDTL ❒ Laboratory file copy of results with corresponding attached test kit membrane (For Renewal) ❒ File of letters of request for confirmatory drug test received by CDTL/with attached copy of receipt from courier (For Renewal) ❒ File of submitted MFR through IDTOMIS (For Renewal) ❒ Memorandum of Agreement with Confirmatory Drug Testing Laboratory Name of CDTL: _____			
➢ FORMS (For SDTL) For renewal, completely and properly filled-out. o Custody and Control Form (CCF) o Consent Form			
➢ LOGBOOKS Properly labeled. For renewal, with updated entries o Remote Collection o Receiving, Accessioning and Releasing o Confirmatory Test (For SDTL only) o Test Results o Quality Control Results o Equipment Preventive Maintenance o Storage and Disposal of Specimen o Visitor's Logbook			
F. QUALITY IMPROVEMENT ACTIVITIES The drug testing laboratory shall practice Quality Assurance Program (QAP) and Continuous Quality Improvement (CQI) reviewed periodically. • Client Satisfaction Survey (e.g. comments, feedback) • Records of complaints and laboratory accidents • Corrective Actions Taken (For renewal) • Management/staff meetings conducted at least twice a year (with minutes of meetings) – For Renewal			
➢ EXTERNAL QUALITY ASSURANCE PROGRAM (For Renewal of Accreditation) ❒ Application for proficiency test ❒ Record of receipt of samples for EQAS from NRL ❒ Logbook/Record of PT Results ❒ Certificate of PT ❒ Record of corrective action taken when evaluation of performance is below satisfactory			

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Name of Health Facility: _____

Date of Inspection: _____

RECOMMENDATIONS:

A. For Licensing Process:

[ ] For issuance of Certificate of Accreditation as Drug Testing Laboratory

Classification: _____

Validity from _____ to _____

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

_____

_____

_____

_____

[ ] Non-Issuance : Specify _____

_____

_____

_____

Inspected by:

Name	Position/Designation	Signature

Received by:

Signature _____
Name _____
Position/Designation _____
Date _____

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Name of Health Facility: _____

Date of Monitoring: _____

RECOMMENDATIONS:

B. For Monitoring Process:

[ ] Issuance of Notice of Violation

_____

_____

_____

[ ] Non-issuance of Notice of Violation

_____

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_____

_____

[ ] Others (Specify) _____

_____

_____

_____

Monitored by:

Name	Position/Designation	Signature

Received by:

Signature _____
Name _____
Position/Designation _____
Date _____