

STANDARDS AND REQUIREMENTS	INSPECTION	MONITORING	REMARKS
<ul style="list-style-type: none"> ➤ For CDTL <ul style="list-style-type: none"> <input type="checkbox"/> Clinical Pathologist <input type="checkbox"/> Chemist 			
<p>ANALYST</p> <ul style="list-style-type: none"> <input type="checkbox"/> Chemist <input type="checkbox"/> Medical Technologist <input type="checkbox"/> Pharmacist <input type="checkbox"/> Chemical Engineer 			
<p>201 FILES (All records should be within the laboratory premises)</p> <ul style="list-style-type: none"> ➤ HEAD OF LABORATORY Name: _____ <ul style="list-style-type: none"> <input type="checkbox"/> Resume <input type="checkbox"/> PRC ID (Valid) <input type="checkbox"/> PRC Board Certificate <input type="checkbox"/> Written & notarized employment contract/appointment as head of lab. <input type="checkbox"/> For Clinical Pathologist, certificate from Philippine Society of Pathologist <input type="checkbox"/> For Non-Pathologist, Certificate of Laboratory Management for DTL conducted by DOH Certificate No. _____ <input type="checkbox"/> Job description (detailed description of tasks, responsibilities and accountabilities) <input type="checkbox"/> Complete, updated and notarized list of DTLs handled to include each address and work schedule <u>For CDTL only:</u> <ul style="list-style-type: none"> <input type="checkbox"/> 2 years of active laboratory experience in analytical toxicology <input type="checkbox"/> If chemist, master's degree in chemistry/Biochemistry/other fields of chemistry 			
<ul style="list-style-type: none"> ➤ ANALYST <ul style="list-style-type: none"> <input type="checkbox"/> Resume <input type="checkbox"/> PRC ID (Valid) <input type="checkbox"/> PRC Board Certificate <input type="checkbox"/> Written & notarized employment contract/appointment as analyst <input type="checkbox"/> Certificate of training for SDTL conducted by DOH Certificate No. _____ <input type="checkbox"/> Certificate of training for CDTL conducted by DOH Certificate No. _____ <input type="checkbox"/> Job description (detailed description of tasks, responsibilities & accountabilities) 			
<ul style="list-style-type: none"> ➤ AUTHORIZED SPECIMEN COLLECTOR (ASC) *Applicable for SDTL only <ul style="list-style-type: none"> <input type="checkbox"/> Resume <input type="checkbox"/> Written & notarized employment contract/appointment as ASC <input type="checkbox"/> Certificate of training conducted by the Laboratory signed by HOL <input type="checkbox"/> Job description (detailed description of tasks, responsibilities & accountabilities) 			

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<ul style="list-style-type: none"> ➤ HEALTH STATUS <ul style="list-style-type: none"> <input type="checkbox"/> Medical/Health Certificate (valid) <input type="checkbox"/> Annual drug test report conducted by another accredited DTL 			
<p>WORK SCHEDULE</p> <ul style="list-style-type: none"> ➤ Monthly schedule of duties and assignment posted within the laboratory 			
<p>B. PHYSICAL FACILITIES The laboratory has adequate space for conduct of its activities.</p>			
<ul style="list-style-type: none"> ➤ FLOOR AREA <input type="checkbox"/> SCREENING LABORATORY <ul style="list-style-type: none"> ❖ FREE-STANDING <ul style="list-style-type: none"> <input type="checkbox"/> Approved PTC (for new facility) <input type="checkbox"/> Floor Area (20 sq.m.) ❖ INSTITUTION-BASED <ul style="list-style-type: none"> <input type="checkbox"/> Working Area of Secondary/Tertiary Clinical Lab. (designated area Exclusive for drug testing) <input type="checkbox"/> CONFIRMATORY LABORATORY <ul style="list-style-type: none"> <input type="checkbox"/> Floor Area (60 sq.m.) <input type="checkbox"/> Stock Room <input type="checkbox"/> Instrumentation Room <p>A laboratory of whatever category shall have within its premises the following:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Receiving Area (can accommodate at least 5 clients at a given time) <ul style="list-style-type: none"> • Suggestion box for Client's Feedback <input type="checkbox"/> Toilet Facility 			
<ul style="list-style-type: none"> ➤ POSTED IN CONSPICUOUS AREA <ul style="list-style-type: none"> <input type="checkbox"/> For SDTL, poster detailing the process flow of drug testing <input type="checkbox"/> Vision, mission and objectives <input type="checkbox"/> Organizational Chart <input type="checkbox"/> Local Permits <input type="checkbox"/> Licenses and Certificates of personnel <input type="checkbox"/> NO SMOKING Signage 			
<ul style="list-style-type: none"> ➤ SPECIMEN COLLECTION AREA (SDTL) <ul style="list-style-type: none"> <input type="checkbox"/> Waterless urinal <input type="checkbox"/> Handwashing Facility <ul style="list-style-type: none"> <input type="checkbox"/> Outside the toilet <input type="checkbox"/> Within, provided with partition <input type="checkbox"/> With free flowing water supply from the faucet 			
<ul style="list-style-type: none"> ➤ WORKING AREA <ul style="list-style-type: none"> <input type="checkbox"/> At least 10sq.m. for free standing SDTL <input type="checkbox"/> At least 30sq.m. for Confirmatory Lab. <input type="checkbox"/> Sink (with countertop and faucet with adequate water supply) <input type="checkbox"/> Functional exhaust fan <input type="checkbox"/> Electric fan/air conditioner unit may be used for improved ventilation 			
<ul style="list-style-type: none"> ➤ PERIODIC SIGNAGE PER AREA 			

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<ul style="list-style-type: none"> ➤ WASTE MANAGEMENT AND HOUSEKEEPING <ul style="list-style-type: none"> <input type="checkbox"/> Solid Waste – Practice of waste Segregation <input type="checkbox"/> Liquid Waste <ul style="list-style-type: none"> ▪ 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) <input type="checkbox"/> Housekeeping <ul style="list-style-type: none"> ▪ Facility is kept clean, safe and odor-free ▪ There should be a program for pest and vermin control ▪ Supplies are kept and secured 			
<ul style="list-style-type: none"> ➤ PROGRAM FOR THE PROPER MAINTENANCE AND MONITORING OF PHYSICAL PLANT AND FACILITIES 			
<p>C. EQUIPMENT, SUPPLIES AND FIXTURES</p> <ul style="list-style-type: none"> <input type="checkbox"/> Schedule of preventive maintenance of equipment <input type="checkbox"/> Inventory relative to the workload and procurement receipts of supplies 			
<ul style="list-style-type: none"> ➤ REFRIGERATOR/FREEZER <ul style="list-style-type: none"> <input type="checkbox"/> Properly maintained & functional, strictly for urine specimen <input type="checkbox"/> Laboratory thermometer inside refrigerator/freezer (non-mercurial) <input type="checkbox"/> Daily monitoring temperature record posted on the unit 			
<ul style="list-style-type: none"> ➤ INFORMATION TECHNOLOGY REQUIREMENTS <ul style="list-style-type: none"> ▪ 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 			
<ul style="list-style-type: none"> ➤ SUPPLIES <ul style="list-style-type: none"> <input type="checkbox"/> Specimen Container (For SDTL only) <ul style="list-style-type: none"> - 60ml polyethylene, wide mouth with screw cap <input type="checkbox"/> Plastic Bag (For SDTL only) <ul style="list-style-type: none"> - Transparent, self-sealing/sealable and leak proof, capable of containing the specimen & pertinent documents (CCF) <input type="checkbox"/> Gloves - disposable 			

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<ul style="list-style-type: none"> ➤ FIXTURES <ul style="list-style-type: none"> ☐ Cabinet <ul style="list-style-type: none"> - With lock to secure and store records & supplies ☐ Tables/Chairs/Bench <ul style="list-style-type: none"> - Tables and chairs allotted for personnel - Chairs/bench that can accommodate at least 5 clients at the same time 			
<p>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.</p>			
<ul style="list-style-type: none"> • Administrative Policies and Procedures 			
<ul style="list-style-type: none"> ➤ Vision, Mission and Objectives (should be in accordance with RA 9165 "Comprehensive Dangerous Drug Act of 2002") 			
<ul style="list-style-type: none"> ➤ Policy for hiring, orientation and promotion for all levels of personnel 			
<ul style="list-style-type: none"> ➤ Duties and Responsibilities of personnel 			
<ul style="list-style-type: none"> ➤ Continuing Education/Training Program for Staff 			
<ul style="list-style-type: none"> ➤ Policy for discipline, suspension, demotion and termination of all personnel at all levels 			
<ul style="list-style-type: none"> ➤ Procedures for handling complaints and laboratory accidents 			
<ul style="list-style-type: none"> ➤ Quality Plan A written program/plan of management to assure competence, integrity of drug testing 			
<ul style="list-style-type: none"> ➤ Policy for waste management and housekeeping 			
<ul style="list-style-type: none"> ➤ Policy for equipment maintenance and repair 			
<ul style="list-style-type: none"> • Technical Policies and Procedures 			
<ul style="list-style-type: none"> ➤ Specimen Collection/ Sampling (within the laboratory) 			
<ul style="list-style-type: none"> ➤ Receiving, Accessioning and Releasing of Specimen 			
<ul style="list-style-type: none"> ➤ Specimen Rejection/ Cancellation 			
<ul style="list-style-type: none"> ➤ Referral to Confirmatory Laboratory when positive results was obtained 			
<ul style="list-style-type: none"> ➤ Remote Collection 			
<ul style="list-style-type: none"> ➤ Reagents, Standards and Controls 			
<ul style="list-style-type: none"> ➤ Analytical Procedure 			
<ul style="list-style-type: none"> ➤ Mechanism of Reporting Results 			
<ul style="list-style-type: none"> ➤ Procedure for Security and Confidentiality of Records, Supplies and Specimen 			
<ul style="list-style-type: none"> ➤ Storage and Disposal of Specimen *For CDTL, include storage and disposal of chemicals 			
<ul style="list-style-type: none"> ➤ Internal Quality Assurance Program 			
<ul style="list-style-type: none"> ➤ External Quality Assurance Program 			
<ul style="list-style-type: none"> ➤ Good Laboratory Practice 			

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E. RECORDS/FILES ➤ Systematic filing and safekeeping of records			
<u>For SDTL</u> <input type="checkbox"/> Laboratory file copy of results with corresponding attached test kit membrane (For Renewal) <input type="checkbox"/> File of letters of request for confirmatory drug test received by CDTL/with attached copy of receipt from courier (For Renewal) <input type="checkbox"/> File of submitted MFR through IDTOMIS (For Renewal) <input type="checkbox"/> Memorandum of Agreement with Confirmatory Drug Testing Laboratory Name of CDTL: _____			
➤ FORMS (For SDTL) For renewal, completely and properly filled-out. <ul style="list-style-type: none"> ○ Custody and Control Form (CCF) ○ Consent Form 			
➤ LOGBOOKS Properly labeled. For renewal, with updated entries <ul style="list-style-type: none"> ○ Remote Collection ○ Receiving, Accessioning and Releasing ○ Confirmatory Test ○ Test Results ○ Quality Control Results ○ Equipment Preventive Maintenance ○ Storage and Disposal of Specimen ○ Visitor's Logbook } (For SDTL only)			
F. QUALITY IMPROVEMENT ACTIVITIES The drug testing laboratory shall practice Quality Assurance Program (QAP) and Continuous Quality Improvement (CQI) reviewed periodically. <ul style="list-style-type: none"> • 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) <ul style="list-style-type: none"> <input type="checkbox"/> Application for proficiency test <input type="checkbox"/> Record of receipt of samples for EQAS from NRL <input type="checkbox"/> Logbook/Record of PT Results <input type="checkbox"/> Certificate of PT <input type="checkbox"/> Record of corrective action taken when evaluation of performance is below satisfactory 			



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

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 _____



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

Name of Health Facility: _____

Date of Monitoring: _____

RECOMMENDATIONS:

B. For Monitoring Process:

Issuance of Notice of Violation

Non-issuance of Notice of Violation

Others (Specify) _____

Monitored by:

Name	Position/Designation	Signature
_____	_____	_____
_____	_____	_____
_____	_____	_____

Received by:

Signature _____
Name _____
Position/Designation _____
Date _____