

**ASSESSMENT TOOL FOR ACCREDITATION OF DRUG TESTING LABORATORY**

Name of Laboratory: \_\_\_\_\_

Address: \_\_\_\_\_

Number & Address

Barangay/Municipality

Province/City

Region

Contact No./Fax No./E-mail Address: \_\_\_\_\_

Application for:  Initial  
 Renewal

Accreditation No: \_\_\_\_\_

Date Issued: \_\_\_\_\_

Expiry Date: \_\_\_\_\_

**GENERAL INFORMATION:**

Name of Owner or Governing Body (if corporation): \_\_\_\_\_

Name of Head of Laboratory: \_\_\_\_\_

Classification according to:

Ownership:  Government  Private  
Institutional Character:  Institution-Based  Free-Standing  
Service Capability:  Screening  Confirmatory

**Instructions:**

- (1) This tool serves as a guide for self-assessment of the facility in preparation for inspection/ monitoring visits.
- (2) Under REFERENCE, indicate name of laboratory document and records where the standards can be found.
- (3) Under FINDINGS, encircle (+) if item indicated is present, and (-) if item indicated is absent/ present but non-functional.
- (4) All items with (\*) shall be posted in a conspicuously designated area.
- (5) To facilitate processing and issuance of the Certificate of Accreditation, make it a point to comply with all standards prior to submission of application.
- (6) For technical assistance:
  - a. Website <http://www.doh.gov.ph/>
  - b. Telephone 711-6982
  - c. Fax 781-4179

STANDARDS	REFERENCE	TYPE OF INDICATOR	FINDINGS
<p><b>1. <u>MANAGEMENT STANDARDS</u></b></p> <p><b>1.1 <u>APPLICATION DOCUMENTS</u></b></p> <p><b>All application documents must be valid and properly filled up.</b></p> <p><b>1.1.1 <u>Documentary Requirements:</u></b></p> <p>1.1.1.1 List of Personnel</p> <ul style="list-style-type: none"> <li>❖ Name</li> <li>❖ Position</li> <li>❖ PRC license number and validity (if applicable)</li> <li>❖ Status: P-Permanent/T-Temporary</li> <li>❖ Educational Attainment</li> <li>❖ Training</li> <li>❖ Signature</li> </ul> <p>1.1.1.2 List of Equipments/Instruments</p> <ul style="list-style-type: none"> <li>❖ Name of Equipment</li> <li>❖ Date acquired with proof of purchase</li> <li>❖ Quantity</li> <li>❖ Functional status</li> </ul> <p>1.1.1.3 Floor Layout</p> <ul style="list-style-type: none"> <li>❖ Properly labeled areas with adequate scaling to include spatial relationship with adjacent units if present.</li> </ul> <p>1.1.1.4 Certificates and Permits:</p> <p><b>The laboratory must comply with the following certificates and permits, which should be valid and current. They should be filled up and posted conspicuously at the reception area.</b></p> <ul style="list-style-type: none"> <li>❖ DTI/SEC registration*</li> <li>❖ Enabling Act (for National Gov't. Lab)</li> <li>❖ Board Resolution (for Local Gov't. Lab)</li> <li>❖ PRC Board Certificate for the following*: <ul style="list-style-type: none"> <li>▪ Head of Laboratory</li> <li>▪ Analyst</li> </ul> </li> <li>❖ Certificate of Proficiency of the Laboratory (for renewal)*</li> <li>❖ Contract of Lease/Proof of ownership of the premises should be valid and notarized to include location map</li> </ul>		<p>Critical</p> <p>Critical</p> <p>Critical</p> <p>Critical</p>	<p>(+) (-)</p> <p>(+) (-)</p> <p>(+) (-)</p> <p>(+) (-)</p>

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<p><b>1.2 <u>MANAGEMENT RESPONSIBILITY</u></b></p> <p><b>The Laboratory shall be managed effectively, efficiently and in accordance with its mission, vision and objectives.</b></p> <p><b>1.2.1 <u>Mission, Vision and Objectives</u> *</b></p> <p>1.2.1.1 Mission, vision and objectives should be in accordance with the RA 9165 "Comprehensive Dangerous Drugs Act of 2002".</p> <p>1.2.1.2 Known and understood by all personnel.</p> <p><b>1.2.2 <u>Management/Staff Meetings</u></b></p> <p>1.2.2.1 Management/Staff meeting should be held at least 2x a year or as needed with proof of attendance.</p> <p>1.2.2.2 Documented minutes (reflecting the date, time, attendance, agenda and action taken of meeting) should be present and properly filed <u>within</u> the lab.</p> <p><b>1.2.3 <u>Continuing Program for Staff Development and Training</u></b></p> <p>1.2.3.1 There should be a policy/program for continuing program on staff development and training.</p> <p>1.2.3.2 Proof of training through certificates memos, written reports, budgetary allocations, etc.</p> <p><b>1.2.4 <u>Quality Plan</u></b></p> <p>1.2.4.1 A written program/plan of management to assure competence, integrity of drug testing.</p> <p>1.2.4.2 Status of program plan implementation.</p> <p><b>1.2.5 <u>Procedures for handling complaints and laboratory accidents</u></b></p> <p>1.2.5.1 Protocol for handling complaints</p> <p>1.2.5.2 Presence of suggestion box</p> <p>1.2.5.3 Memorandum for Record</p> <p>1.2.5.4 Record book</p>				
		Critical	(+)	(-)
		Non-Critical	(+)	(-)
		Critical	(+)	(-)
		Non-Critical	(+)	(-)
		Critical	(+)	(-)
		Critical	(+)	(-)
		Non-Critical	(+)	(-)
		Critical	(+)	(-)
		Non-Critical	(+)	(-)
		Critical	(+)	(-)
		Non-Critical	(+)	(-)



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STANDARDS	REFERENCE	TYPE OF INDICATOR	FINDINGS	
<p>1.3.3 <b><u>Analyst</u></b></p> <p>1.3.3.1 Proof of qualifications/trainings like:</p> <ul style="list-style-type: none"> <li>❖ PRC ID (valid)</li> <li>❖ PRC Board certificate*</li> <li>❖ Certificate of Training for SDTL* conducted by DOH Certificate No. _____</li> </ul>		Critical	(+)	(-)
<p>1.3.3.2 Written and notarized full time employment contract of the analyst.</p>		Critical	(+)	(-)
<p>1.3.4 <b><u>Authorized Specimen Collector(ASC)</u></b></p> <p>1.3.4.1 Proof of qualifications/training like:</p> <ul style="list-style-type: none"> <li>❖ Educational background</li> <li>❖ Proof of training conducted by the lab regarding specimen collection</li> </ul> <p>1.3.4.2 Written &amp; notarized full time employment contract of the ASC.</p>		Critical	(+)	(-)
<p>1.3.5 <b><u>Personnel Records</u></b></p>				
<p>All records should be within the lab premises.</p>				
<p>1.3.5.1 Curriculum vitae containing:</p> <ul style="list-style-type: none"> <li>❖ Personal background</li> <li>❖ Education</li> <li>❖ Training &amp; experience</li> </ul>		Critical	(+)	(-)
<p>1.3.5.2 Job Description</p> <ul style="list-style-type: none"> <li>❖ Detailed description of tasks, responsibilities and accountabilities</li> </ul>		Critical	(+)	(-)
<p>1.3.5.3 Health Status</p> <ul style="list-style-type: none"> <li>❖ Medical /health certificate</li> <li>❖ Annual drug test report conducted by another accredited DTL.</li> </ul>		Critical	(+)	(-)
<p>1.3.5.4 Work Schedule (to include office hours)</p> <ul style="list-style-type: none"> <li>❖ Monthly schedule of duties and assignment posted within the laboratory.</li> </ul>		Critical	(+)	(-)
<p>1.3.6 <b><u>Policies For Hiring, Orientation and Promotion</u></b></p> <p>1.3.6.1 There should be a written policy for hiring, orientation and promotion for all levels of personnel.</p>		Critical	(+)	(-)

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STANDARDS	REFERENCE	TYPE OF INDICATOR	FINDINGS
<p>1.3.7 <u>Policies For Violations/ Suspension/ Terminations</u></p> <p>1.3.7.1 Written policies for violations/suspensions/terminations for all levels of personnel.</p> <p>1.3.7.2 Records of memos sent, if applicable.</p>		<p>Critical</p> <p>Non-Critical</p>	<p>(+) (-)</p> <p>(+) (-)</p>
<p><b>1.4 <u>PHYSICAL FACILITY</u></b></p> <p>Adequate facility shall be in place for the safe and efficient operation of the laboratory.</p> <p><b>1.4.1 <u>General Floor Area</u></b></p> <p>1.4.1.1 Should be 20 m<sup>2</sup> or more for free standing SDTL or a designated area exclusively for drug testing if institution-based (at least secondary category clinical laboratory SDTL; not applicable for institution-based).</p> <p>1.4.1.2 Receiving Area</p> <ul style="list-style-type: none"> <li>❖ There should be a designated receiving area that can seat at least 5 clients at the same time with a reception table to perform the activity.</li> <li>❖ An information bulletin/poster*detailing the process of drug testing.</li> </ul> <p>1.4.1.3 Specimen Collection Area</p> <p>There should be a designated clean and private stall/toilet for specimen collection.</p> <ul style="list-style-type: none"> <li>❖ For urine collection, any extra water source shall be secured prior to the collection.</li> <li>❖ Control valves for faucets/lavatories/showers/taps should be closed and located outside of the toilet and inaccessible to the client.</li> <li>❖ Removal of all water containers.</li> <li>❖ Toilet water coloring (blue or green) agents should be placed in toilet tanks and in toilet bowls.</li> <li>❖ For urine collection, there shall be a hand washing facility outside the stall/toilet collection area with accessible water source.</li> </ul>		<p>Critical</p> <p>Critical</p> <p><b>Critical</b></p>	<p>(+) (-)</p> <p>(+) (-)</p> <p>(+) (-)</p>

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<p><b>1.4.1.4 Working Area</b></p> <p><b>There should be a working area that shall be exclusively for drug testing. It shall have the following attributes:</b></p> <ul style="list-style-type: none"> <li>❖ At least 10 m<sup>2</sup> for free standing SDTL</li> <li>❖ A clean, well ventilated, well lighted working counter</li> <li>❖ Sink with strong water supply</li> <li>❖ Secured storage cabinet for supplies and documents</li> </ul>		Critical	(+)	(-)
<p><b>1.4.2 <u>Laboratory Utilities</u></b></p> <p>1.4.2.1 Proper ventilation like:</p> <ul style="list-style-type: none"> <li>❖ Functional exhaust fan located at the working area</li> <li>❖ Electric fan/air conditioner unit may be used for improved ventilation.</li> </ul> <p>1.4.2.2 Adequate Lighting</p> <p>1.4.2.3 Adequate Water Supply</p> <ul style="list-style-type: none"> <li>❖ There should be a free flowing water supply from the faucet facility in the working and hand washing areas.</li> </ul>		Critical	(+)	(-)
<p><b>1.4.3 <u>Solid Waste Facility</u></b></p> <p>1.4.3.1 There should be a written protocol for solid waste management following the universal guidelines.</p>		Critical	(+)	(-)
<p>1.4.3.2 Implementation of the protocol</p>		Critical	(+)	(-)
<p><b>1.4.3.3 Practice of waste segregation</b></p>		Critical	(+)	(-)
<p><b>1.4.4 <u>Liquid Waste Facility</u></b></p> <p>1.4.4.1 There should be a protocol for proper disposal of urine specimen either by chemical neutralization or by flushing in the toilet bowl.</p> <p>1.4.4.2 There should be a protocol for proper disposal of used and expired reagents either by neutralization, delay to decay or through the drainage system.</p>		Critical	(+)	(-)



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STANDARDS	REFERENCE	TYPE OF INDICATOR	FINDINGS
<p><b>1.5.3 Refrigerator/Freezer</b></p> <p>1.5.3.1 Properly maintained and functional refrigerator/freezer <b>strictly</b> for urine specimen and kits used for drug testing.</p> <p>1.5.3.2 Lab. Thermometer inside refrigerator/freezer.</p> <p><b>1.5.3.3</b> A daily temperature record monitoring of the refrigerator (for refrigerator: 2-8 °C; for freezer: -20 °C to 0 °C) is posted on the unit.</p>		<p>Critical</p> <p>Critical</p> <p>Critical</p>	<p>(+) (-)</p> <p>(+) (-)</p> <p>(+) (-)</p>
<p><b>1.5.4 Information Technology Requirements</b></p> <p>1.5.4.1 Computer System</p> <p>There should be a functional computer with the following requirements:</p> <ul style="list-style-type: none"> <li>❖ 600 MHz processor</li> <li>❖ 128 MB memory</li> <li>❖ 4 GB HDD</li> <li>❖ 56K Modem</li> </ul> <p>1.5.4.2 Printer (Fully Functional)</p> <p>1.5.4.3 Account with an Application Service provider (ASP)</p> <ul style="list-style-type: none"> <li>❖ Should be connected to a DOH accredited ASP</li> </ul>		<p>Critical</p> <p>Critical</p>	<p>(+) (-)</p> <p>(+) (-)</p>

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STANDARDS	REFERENCE	TYPE OF INDICATOR	FINDINGS
<p>1.5.5 <b><u>Other Laboratory Equipments/ Supplies/ Fixtures</u></b></p> <p><b>1.5.5.1 Cabinets (Records, etc.)</b></p> <ul style="list-style-type: none"> <li>❖ Cabinet with locks to secure and store records and supplies.</li> </ul> <p><b>1.5.5.2 Tables/Chairs/Bench</b></p> <ul style="list-style-type: none"> <li>❖ Minimum of 3 tables or its equivalent with minimum of 3 chairs for personnel and chairs/bench that can accommodate at least 5 clients at the same time</li> </ul> <p><b>1.5.5.3 Functional Calculator</b></p> <p><b>1.5.5.4 Specimen container (as applicable)</b></p> <ul style="list-style-type: none"> <li>❖ Urine (60 ml polyethylene, wide mouth with screw cap) container adequate for workload</li> <li>❖ Sweat (BFAD approved patch)</li> <li>❖ Tissue</li> <li>❖ Scalp Hair</li> <li>❖ Saliva (oral fluid)</li> <li>❖ Fingernail</li> <li>❖ Blood</li> </ul> <p><b>Note:</b> For other types of specimen container, please refer to manual of operations for drug testing.</p>		<p>Critical</p> <p>Critical</p> <p>Non-Critical</p> <p>Critical</p>	<p>(+) (-)</p> <p>(+) (-)</p> <p>(+) (-)</p> <p>(+) (-)</p>

STANDARDS	REFERENCE	TYPE OF INDICATOR	FINDINGS	
<p><b>1.5.5.5 Label/Seal</b></p> <ul style="list-style-type: none"> <li>❖ Labeling/sealing material should adhere securely to the containers specified, should be water-resistant and can be readily marked with any writing material.</li> </ul>		Critical	(+)	(-)
<p><b>1.5.5.6 Plastic Bag</b></p> <ul style="list-style-type: none"> <li>❖ The plastic bag should be transparent, self-sealing/sealable and leak proof, capable of containing the specimen and pertinent documents (CCF).</li> </ul>		Critical	(+)	(-)
<p><b>1.5.5.7 Gloves</b></p> <ul style="list-style-type: none"> <li>❖ There should be disposable, latex gloves.</li> </ul>		Critical	(+)	(-)
<p><b>1.5.5.8 Pipettes/droppers</b></p> <ul style="list-style-type: none"> <li>❖ All pipettes/droppers for dispensing urine specimens during the testing process should be disposable.</li> <li>❖ Lab thermometer with readability from 0 °C–100 °C.</li> </ul>		Critical	(+)	(-)
<p><b>Note:</b> There should be a readily available inventory relative to the workload and procurement receipts of the above supplies during the inspection/monitoring.</p>				
<p><b>2. <u>TECHNICAL STANDARDS</u></b></p>				
<p><b>2.1 <u>LABORATORY FORMS</u></b></p> <p>There shall be an adequate system for management of laboratory forms.</p>				
<p><b>2.1.1 <u>Custody and Control Form (CCF)</u></b></p>				
<p>2.1.1.1 DOH-prescribed Custody and Control Forms in triplicate (unfilled).</p>		Critical	(+)	(-)
<p>2.1.1.2 Properly filled-up CCF, Lab copy (steps 1 – 6 complete with original signatures).</p>		Critical	(+)	(-)
<p><b>2.1.2 <u>Result Form</u></b></p>				
<p>2.1.2.1 Properly filled-up result forms, signed by analyst and head of the laboratory (printed name and signature).</p>		Critical	(+)	(-)
<p>2.1.2.2 All CCF with (+) results shall bear the original signature of the head of lab.</p>		Critical	(+)	(-)

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STANDARDS	REFERENCE	TYPE OF INDICATOR	FINDINGS
<p><b>2.1.3 <u>Request for Confirmatory Drug Test</u></b></p> <p>2.1.3.1 DOH-prescribed result forms (unfilled).</p> <p>2.1.3.2 Signed by the Analyst and/or the head of the Screening Drug Testing Laboratory.</p> <p>2.1.3.3 Duplicate copy of the letter request received by CDTL containing the following data: date of collection, code number, and description of status of specimen sent (manner of sealing, markings, volume &amp; physical characteristics).</p> <p><b>2.1.4 <u>Memorandum for Record (MFR)</u></b></p> <p>2.1.4.1 DOH-prescribed copy of MFR.</p> <p>2.1.4.2 Properly filled-up and signed by the responsible person.</p> <p>2.1.4.3 Review CCF for errors and check if there is corresponding MFR.</p> <p><b>2.1.5 <u>Drug Testing Consent Form</u></b></p> <p>2.1.5.1 DOH-prescribed copy of consent form (unfilled).</p> <p>2.1.5.2 Properly filled-up forms signed by requesting party.</p>		<p>Critical</p> <p>Critical</p> <p>Critical</p> <p>Critical</p> <p>Critical</p> <p>Critical</p> <p>Critical</p>	<p>(+) (-)</p> <p>(+) (-)</p> <p>(+) (-)</p> <p>(+) (-)</p> <p>(+) (-)</p> <p>(+) (-)</p> <p>(+) (-)</p>
<p><b>2.2 <u>TECHNICAL PROCEDURES</u></b></p> <p>There shall be a system for receiving, accessioning and releasing of specimen.</p> <p><b>2.2.1 <u>Specimen Collection/Sampling (within the laboratory)</u></b></p> <p>2.2.1.1 Protocol for specimen collection as prescribed in the DOH-NRL manual of operations.</p> <p>2.2.1.2 Review Custody and Control Form.</p> <p>2.2.1.3 Interview the designated ASC on the process of collection.</p>		<p>Critical</p> <p>Critical</p> <p>Critical</p>	<p>(+) (-)</p> <p>(+) (-)</p> <p>(+) (-)</p>

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STANDARDS	REFERENCE	TYPE OF INDICATOR	FINDINGS
<p><b>2.2.2 <u>Remote Specimen Collection (if applicable)</u></b></p>			
<p>2.2.2.1 Protocol for remote collection as prescribed in the DOH-NRL manual of operations.</p>		Critical	(+) (-)
<p>2.2.2.2 Permit from DOH-BHFS.</p>		Critical	(+) (-)
<p>2.2.2.3 Logbook for remote collection (see Annex A).</p>		Critical	(+) (-)
<p><b>2.2.3 <u>Receiving, Accessioning and Releasing of Specimen</u></b></p>			
<p><b>2.2.3.1 Protocol for receiving, accessioning and releasing of specimen.</b></p>		Critical	(+) (-)
<p>2.2.3.2 Duly accomplished logbook for receiving, accessioning and releasing of specimen (see Annex B).</p>		<b>Critical</b>	(+) (-)
<p><b>2.2.4 <u>Analytical Procedures for Drug Testing</u></b></p>			
<p>2.2.4.1 Protocol on analytical procedure with corresponding work instructions.</p>		Critical	(+) (-)
<p>2.2.4.2 Review results of test run:</p> <ul style="list-style-type: none"> <li>❖ Kits: result form with attached membrane</li> <li>❖ Instrumented: result form with attached <ul style="list-style-type: none"> <li>▪ Chromatogram (e.g. TLC)</li> <li>▪ Computerized print out of results (e.g. EIA)</li> </ul> </li> </ul>		Critical	(+) (-)
<p>2.2.4.3 Logbook of results (see Annex C).</p>		Critical	(+) (-)
<p><b>2.2.5 <u>Revision of Analytical Protocol or Method ( if applicable )</u></b></p>			
<p>2.2.5.1 Protocol for new or revised analytical method with validation.</p>		Critical	(+) (-)
<p>2.2.5.2 Document in the form of Memo or circular indicating its effectivity/application.</p>		Critical	(+) (-)







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**RESULT:**

- Compliance - Comply with CRITICAL standards
- Non-Compliance - Does not comply with CRITICAL standards

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**NAME OF DTL:** \_\_\_\_\_  
**ADDRESS:** \_\_\_\_\_  
**TEL. NO.:** \_\_\_\_\_

**ANNEX A**

**LOGBOOK FOR REMOTE COLLECTION**

Date: \_\_\_\_\_  
Collection Site: \_\_\_\_\_  
Name of Authorized Specimen Collector: \_\_\_\_\_  
Requesting Party: \_\_\_\_\_  
PRC-DTL\* No.: \_\_\_\_\_

Time of Collection	Specimen No.	Donor's Name	Age	Sex	Signature of Donor/Client	Remarks e.g. Volume – Qty Appearance – Color Temperature

Date and Time Transported: \_\_\_\_\_

\_\_\_\_\_  
Signature over Printed Name of Authorized Specimen Collector

\_\_\_\_\_  
Signature over Printed Name of Requesting Party

*\*PRC-DTL: Permit for Remote Collection – Drug Testing Laboratory*

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**ANNEX B**

**RECEIVING/ACCESSIONING/RELEASING LOGBOOK**  
(at the reception area)

SPECIMEN			Donor's Name	Age	Sex	Requesting Party	RESULT		Remarks
Date & Time Collected	Accession * No.	Code* No.					Released by (LAB)	Received by (DONOR)	

\* maybe one and the same

**ANNEX C**

**RESULTS LOGBOOK**  
(at the working area)

Date & Time		Accession* No.	Code* No.	Result			Signature of Analyst	Donor's Name	Date & Time Released	Signature of Receiving Clerk
Received	Analyzed			THC	MET	Others				

\*maybe one and the same

**ANNEX D**

**SPECIMEN VALIDITY TEST RESULT**

Date & Time		Accession* No.	Code* No.	Validity Test Conducted (pH, creatinine, sp. gravity, nitrites, adulterants & others)	Result	Recommendation	Analyst	Donor's Name
Received	Analyzed							

\* maybe one and the same

**ANNEX E**

**LOGBOOK OF CONFIRMATORY TESTS**

Date & Time Transported	Accession No.	Messenger/Courier (Name)	Name of CDTL	Received by (CDTL):	Remarks	Date Confirmatory Result Received/Signature



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**ANNEX H**

**LOGBOOK OF STORAGE AND DISPOSAL**

Date Collected	Accession * No.	Code* No.	Date of Disposal	Signature

*\* maybe one and the same*