



ACCREDITATION OF PRIVATE TESTING LABORATORY

Application for Laboratory Accreditation for Private Testing Laboratories

Center/Office/Division:	Common Services Laboratory (CSL) – Office of the Director, Receiving and Releasing Unit, Laboratory Accreditation Team FDA Cashier
Classification:	Highly Technical Transaction
Type of Transaction:	G2B - Government to Business
Who May Avail:	Private Testing Laboratory
Fees to be Paid:	1) Audit of Testing Laboratory (per visit) a) Within Metro Manila - PHP 10,000.00 + transportation cost b) Outside Metro Manila - PHP 10,000.00 + per diem/per auditor + transportation cost 2) Accreditation of Testing Laboratory Fee (per year) – PHP 20,000.00 3) Legal Research Fee (LRF)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Duly Notarized Accomplished Petition Form (FDA Order No. 2012-001 Annex A)	FDA Website (www.fda.gov.ph)
2. Copy of valid ISO 17025 Certificate of Accreditation with defined scope of accreditation issued by Philippine Accreditation Bureau (PAB) within the last six months prior to date of application with FDA	Applicant
3. Copy of Laboratory Quality Manual and List of SOPs	Applicant
4. List of PAB Approved Signatories for the particular test or types of test covered by the Scope of Accreditation	Applicant
5. Location Map of the Laboratory	Applicant
6. Copy of latest PAB assessment findings with corresponding corrective action	Applicant
7. Floor layout with appropriate scale reflecting laboratory areas	Applicant



CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
<p>1. Submits scanned copy of requirements to info@fda.gov.ph with the email subject:</p> <p>CSL_Accreditation of Testing Laboratory [space] Name of Laboratory</p> <p><i>Note:</i> Printed copies of the requirements may be forwarded to FDA Central Office, Alabang, Muntinlupa City, through courier.</p>	<p>1.1. Receives and acknowledges receipt of the email inquiry and forwards to the CSL.</p>	<p>None</p>	<p>Refer to FDAC Citizen's Charter</p>	<p><i>Information Officer II</i> FDAC</p>
	<p>1.2. Receives application requirements and provides Document Track Number (DTN). Pre-evaluates submitted documents as to completeness:</p> <ul style="list-style-type: none"> • If found non-compliant, application is rejected and Applicant is informed of the noted discrepancies on the submitted documents. • If found compliant, a tentative date for audit will be scheduled. 	<p>None</p>	<p>–</p>	<p><i>Laboratory Accreditation Secretariat</i> CSL – Laboratory Accreditation Team</p>
	<p>1.3. Sends Notice of Audit to the Applicant through email.</p>	<p>None</p>	<p>1 Day</p>	



CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	1.4. Reviews submitted document as pre-audit assessment.	None		Laboratory Accreditation Member CSL – Laboratory Accreditation Team
2. Confirms the proposed date of audit within seven (7) working days after receipt of Notice of Audit. <i>Note:</i> Non-receipt of confirmation to the scheduled assessment within the stipulated timeline shall mean forfeiture of application.	2.1. Conducts audit (remote or on-site) and provides audit report with findings and recommendations.	None	3 Days	Laboratory Accreditation Member CSL – Laboratory Accreditation Team
3. Submits signed first corrective action plan through email or courier.	3.1. Receives documents sent through courier and forwards to assigned auditors.	None	6 Days	Laboratory Technician CSL – Receiving and Releasing Unit
	3.2. Evaluates first corrective action plan and sends prepared report to the Applicant.	None		Laboratory Accreditation Member CSL – Laboratory Accreditation Team
4. Submits second and/or third corrective action plan through email or courier.	4.1. Receives documents sent through courier and forwards to assigned auditors	None	8 Days	Laboratory Technician CSL – Receiving and Releasing Unit
	4.2. Evaluates second and/or third corrective action plan	None		Laboratory Accreditation Member



CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	and sends prepared report to the Applicant.			CSL – Laboratory Accreditation Team
	4.3. Provides Final Evaluation Report and notifies Applicant that accreditation is granted or denied.	None		
	4.4. Issues assessment slip to the Applicant.	None		<i>Laboratory Technician</i> CSL – Receiving and Releasing Unit
5. Proceeds to their preferred payment option; submits clear copy of proof of payment to cashierposting@fda.gov.ph and copy furnish (cc:) to csl@fda.gov.ph .	5.1. Posting of payment.	PHP 10,000 (x no. of visit) + PHP 20,000 (x year) + LRF	Refer to FDA Cashier Citizen's Charter	<i>Cashier Staff</i> FDA Cashier
	5.2. Upon confirmation of payment from FDA Cashier, prepares Certificate of Accreditation and Scope and prints on security paper and plain A4 paper with the official receipt no./reference number.	None	2 Days	<i>Laboratory Accreditation Member</i> CSL – Laboratory Accreditation Team
	5.3. Signs Certificate of Accreditation and Scope.	None		<i>Director II</i> CSL



CLIENT STEPS	AGENCY ACTION	FEEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	5.4. Releases signed Certificate of Accreditation and Scope to the Applicant.	None		<i>Laboratory Accreditation Member</i> CSL – Laboratory Accreditation Team
	TOTAL		20 Working Days	