CONDUCT OF ROUTINE LABORATORY ANALYSIS

Conduct of Routine Laboratory Analysis, including testing through Accredited Third Party Laboratory

Laboratory testing involves the physico-chemical and microbiological analysis of health products to determine compliance with the standards of safety, efficacy, purity and quality. Samples received by the Common Services Laboratory are categorized as:

a. Complaints – These are alleging deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a health product after release from distribution.
b. Government Deliveries – These are health products submitted by government agencies like the Department of Health, Local Government Units and government hospitals
c. Donations – Samples coming from government and private institutions intended for donations.
d. Referrals – These are health products referred by the FDA Centers or Offices (CDRR, CFRR, CCHUHSRR, CDRRHR, Regulatory Enforcement Unit, FDA Satellite laboratories)
e. Post Market Surveillance (PMS) – These are health products sampled/collected by the FDA Inspectorates and Regulatory Enforcement Officers, as part of monitoring the safety, effectiveness, efficiency and performance after it has been released on the market. This includes Annual Post-Marketing Surveillance (APMSP) and *motu propio*, among others. PMS is an important part of FDA's advocacy in health/pharmacovigilance.

Center/Office/Division:	Common Services Laboratory (CSL) – Office of the Director, Receiving and Releasing Unit, Laboratory Sections FDA Cashier FDA Records
Classification:	Highly Technical Transaction
Type of Transaction:	G2G - Government to Government; G2C - Government to Client (G2C)
Who May Avail:	Government Agencies, FDA Centers and Offices
Fees to be Paid:	AO No. 50 s. 2001 + Legal Research Fee (LRF)

CLASSIFICATION	FEES (PHP)
1. Physico-chemical Analysis	
▪ Drugs and Antibiotics	

CLASSIFICATION	FEES (PHP)
• Visual Examination	300.00
• Assay/Potency (single component)	1,500.00
• Assay/Potency (multi-component)	2,000.00
• Dissolution Test	2,000.00
• Disintegration Test	350.00
• Hardness Test	350.00
• Identification Test	500.00
• Purity Test / Related Substances	500.00
• Moisture Content	300.00
• Loss on Drying	300.00
• pH	300.00
• Vitamins	
○ Vitamin A	1,000.00
○ Vitamin B1, B2, B6	2,000.00
○ Vitamin C (Ascorbic Acid)	500.00
○ Vitamin E	500.00
○ Other Vitamins	500.00
• Minerals	800.00
▪ in vitro Diagnostic Reagents	1,000.00
▪ Medical Devices	1,500.00
▪ Cosmetics	
• Assay	1,200.00
• Identification Test	500.00
• Volatile/Non-volatile Matters	500.00
▪ Food Products	
• Moisture	300.00
• Protein	1,000.00
• Fat/Oil	500.00

CLASSIFICATION	FEES (PHP)
• Starch	500.00
• Glucose	500.00
• Sucrose	500.00
• Lactose	500.00
• Crude Fibers	500.00
• Dietary Fibers	2,000.00
• Total Solids	300.00
• Soluble Solids	300.00
• Water-Insoluble Solids	300.00
• Ash	300.00
• Acid-insoluble Ash	500.00
• Saponification Number	500.00
• Viscosity	300.00
• Refractive Index	300.00
• Peroxide Value	500.00
• Free Fatty Acids	500.00
• Permanganate Oxidation Number (PON)	500.00
• Total Acidity	300.00
• Water Activity	500.00
• Vacuum	300.00
• Minerals	1,000.00
• Amino Acids (LC)	2,000.00
• Proline	500.00
• Additives	
○ Nitrate	500.00
○ Nitrite	500.00
○ Sodium Benzoate	500.00

CLASSIFICATION	FEES (PHP)
○ Sorbic Acid	500.00
○ Food Color	300.00 per color
○ Sodium metabisulfite	500.00
○ Bromates	500.00
○ BHT	500.00
○ BHA	500.00
○ Aspartame	500.00
○ Saccharin	500.00
○ Monosodium Glutamate	500.00
• Micronutrients	
○ Vitamin A	1,000.00
○ Vitamin E	1,000.00
○ Beta Carotene	1,000.00
○ Vitamin C	500.00
○ Vitamin B1, B6	1,000.00
○ Vitamin B1, B6, Niacin	1,000.00
○ Iodine	500.00
○ Iron	500.00
• Contaminants	
○ Borax	300.00
○ Aflatoxin	2,000.00
○ Total heavy metals	500.00
○ Lead	500.00
○ Cadmium	300.00
○ Chromium	300.00
○ Arsenic	300.00
○ Mercury	300.00
○ Tin	300.00
○ Cyanide	300.00

CLASSIFICATION	FEES (PHP)
○ Histamine	1,500.00
○ Filth	500.00
○ Formalin	500.00
○ Pesticide residue	2,000.00
○ Alcohol content	1,000.00
○ Gas volume	300.00
○ Total Soluble Solids (Brix)	300.00
○ pH	300.00
○ Caffeine	500.00
▪ Food Supplements	4,000.00
▪ Beverages	
• Alcohol Content	1,000.00
• Gas Volume	300.00
• Total Soluble Solids (Brix)	300.00
• pH	300.00
• Caffeine	500.00
▪ Bottled Water	2,000.00
▪ Food Chemicals/Additives	
• Direct	1,000.00
• Indirect	500.00
▪ Containers/Wrappers	
• Migratable Substances	1,000.00
• Plastic Additives	500.00
• Cellulosic Materials for Pesticide Residue	1,500.00
• Materials Testing	500.00
2. Microbiological Assay	
▪ Potency of Antibiotics	2,500.00
3. Sterility Tests	

CLASSIFICATION	FEES (PHP)
▪ Injectables, Medical Devices, and Large Volume Parenterals	2,500.00
4. Microbial Limit Tests	
▪ Aerobic Plate Count	500.00
▪ Aerobic Halophilic Count	500.00
▪ Aerobic Thermophilic Count	500.00
▪ Coliform Plate Count	500.00
▪ Coliform / *Escherichia coli* (MPN)	500.00
▪ Fecal Streptococci	600.00
▪ Yeast and Mold Count	500.00
▪ Halophilic Yeast Count	500.00
▪ *Staphylococcus aureus* Count	600.00
▪ *Pseudomonas aeruginosa*	600.00
▪ Identification of Microorganisms (*Salmonella* sp.)	
• Presumptive Test	600.00
• Confirmatory Test (complete biochemical reaction)	2,000.00 per organism
• Commercial sterility of thermally processed foods in hermetically sealed containers	1,000.00
5. Bioassay Tests	
▪ Bacterial endotoxin test (LAL)	4,000.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Duly Accomplished Request for Analysis (RFA) Form	FDA website (https://www.fda.gov.ph/downloadables/)
2. Actual Sample/s a. Quantity should be in accordance with FDA Circular No. 2014-014 "Minimum Number of Samples Units required for Each Test Analysis"	Customer/Requesting Party https://www.fda.gov.ph/wp-content/uploads/2021/06/FC2014-014-Minimun-Numbers-of-Samples-Units-Required-for-Each-Test-Analysis.pdf
b. With expiration date at least three (3) months prior to request for analysis	
c. Actual sample per request should bear the same batch or lot	

d. Properly handled	
Additional Requirements	
• If purpose of collection is **scheduled/planned PMS** - compliance to the current approved APMSP.	
• **For Complaint Samples** - Copy of Medical certificate or any document that will serve as a guide to the laboratory on the analyte that has to be checked - Copy of Report on the interview conducted, if any - Endorsement from the concerned FDA Center, if applicable *Note:* Sample that will be submitted to the CSL for analysis should be from the same batch or lot number as the subject product of the complaint.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends Request for Analysis (RFA) per request through email: a. For Alabang Testing and Quality Assurance Laboratory: atqal.rfa@fda.gov.ph b. For Cebu Testing and Quality Assurance Laboratory: ctqal.rfa@fda.gov.ph c. For Davao Testing and Quality Assurance Laboratory: dtqal.rfa@fda.gov.ph	1.1. Pre-assessment and evaluation of the RFA based on the following requirements: • If the above requirements are not met, the Customer shall be informed by email response and/or by telephone communication, indicating that the request is rejected. Consequently, RFA will be returned, for appropriate actions. Revised RFA shall be submitted for pre-	None	15 Minutes	*Food-Drug Regulation Officer/Health Program Officer/Laboratory Technician* CSL – Receiving and Releasing Unit

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
• For Internal Customers (FDA Centers/Offices), email subject shall be: ***Purpose of Collection [space] Center/Region*** • For External Customers (other Government Agencies), email subject shall be: ***Name of Agency [space] RFA***	assessment prior to acceptance. • If the above requirements are met, the request is accepted. *Note:* For External Customers, a reference number will be issued during pre-assessment.			
2. Submits the required number of samples for laboratory analysis, as well as the printed and signed copies of pre-assessed RFA.	2.1. Receives, and assesses accuracy of information indicated in the RFA vis-a-vis the actual sample. Likewise, checks if compliant with the required handling conditions. • If found acceptable, issues Laboratory Number. • If found unacceptable, rejects the RFA and issues Letter for Returned Sample.	None	15 Minutes	*Food-Drug Regulation Officer/Health Program Officer/Laboratory Technician* CSL – Receiving and Releasing Unit
	2.2. Encodes RFA in CSL database.	None	5 Minutes	*Food-Drug Regulation Officer/Laboratory Technician*

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
				CSL – Receiving and Releasing Unit
	2.3. Forwards the following to the concerned Section: • RFA • Sample • Transmittal Sheet	None	5 Minutes	*Food-Drug Regulation Officer/Laboratory Technician* CSL – Receiving and Releasing Unit
	2.4. Receives and updates the FDA Inventory System (FIS), as well as the Database: • RFA • Sample • Transmittal Sheet	None	10 Minutes	*Laboratory Technician/ Administrative Aide* Concerned CSL–Laboratory Section/s
	2.5. Records received samples in respective Section's Database and schedules decking of samples for testing.	None	10 Minutes	*Laboratory Technician/ Administrative Aide* Concerned CSL–Laboratory Section/s
	2.6. Handles and stores samples for testing in designated location.	None	5 Minutes	*Laboratory Technician/ Administrative Aide* Concerned CSL–Laboratory Section/s
	2.7. Pre-evaluates received samples as per label and/or test required.	None	10 Minutes	*Laboratory Technician/ Administrative Aide* Concerned CSL–

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
				Laboratory Section/s
	2.8. Conducts laboratory testing[1] with corresponding processing timelines: **A. Complaints** • High risk • Low-medium risk **B. Government deliveries** • Anti-tuberculosis (TB) drugs (DOH-LMD) • DOH-LMD, other than TB drugs • Other government agencies (LGUs, etc.) **C. Donations** **D. Post-marketing Surveillance** **E. Referrals** **F. Microbiological Tests *(see notes)*** • Sterility testing • Commercial sterility • Evaluation of antimicrobial protection	None	**(A)** • 5 Days • 18 Days **(B)** • 13 Days • 18 Days • 18 Days **(C)** 18 Days **(D)** 18 Days **(E)** 18 Days **(F)** • 18 Days • 23 Days • 42 Days	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	2.9. Process samples that will be referred to third-party laboratory testing[2].	None	Processing timeline following RA No. 9184	*BAC Secretariat* FDA BAC
	2.10. Records and compute data gathered from laboratory testing. *Note:* This step is excluded if request for analysis is conducted by third-party laboratory.	None	1 Day	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s
	2.11. Evaluates data and results from laboratory testing.	None	4 Hours	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s
	2.12. Prepares Test Reports	None	1 Hour	*Laboratory Technician/ Administrative Aide* Concerned CSL–Laboratory Section/s
	2.13. Signs all test reports	None	10 Minutes	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s
	2.14. Signs non-conforming test reports	None	10 Minutes	*Director II* CSL
	2.15. For Test Reports requested by Internal Customers,	None	10 Minutes	*Laboratory Technician*

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	forwards signed Test Reports to concerned Office/Center.			CSL – Receiving and Releasing Unit
	2.16. For Test Reports requested by External Customers, issues assessment slip and/or order of payment for fees for the tests/ parameters conducted.	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit
3. Proceeds to their preferred payment channel; submits clear copy of the proof of payment to cashierposting@fda.gov.ph and copy furnish (cc:) to concerned laboratory email: Alabang (atqal.rfa@fda.gov.ph); Cebu (ctqal.rfa@fda.gov.ph); or Davao (dtqal.rfa@fda.gov.ph).	3.1. Posting of payment.	Fee for Test/ Parameters Conducted + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
	3.2. Upon confirmation of payment, forwards the Test Report with assessment slip and/or order of payment to FDA Records.	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit
	3.3. Releasing of Test Reports to External Customer.	None	Refer to	*Records Staff* FDA Records

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
			FDA Records Citizen's Charter	
	TOTAL		**20 Working Days**	

[1]Specific processing timelines for samples classified to the following shall be maintained: 1. High-risk complaints (7 working days); 2. Government deliveries for anti-tuberculosis drugs (DOH-LMD) (15 working days); and 3. Samples requiring the following microbiological tests – sterility testing (20 working days); commercial sterility (23 working days); evaluation of antimicrobial protection (44 working days).
[2]Processing for samples forwarded for third-party laboratory testing will have a separate timeline following the procedures stipulated in the implementing rules and regulations of RA No. 9184, The Government Procurement Reform Act.

NOTES:

- Samples subject for **Sterility Testing** requires a total number of **twenty-eight (28) calendar days** (equivalent to **twenty (20) working days**), which includes: (1) 1-day media preparation; (2) 2-days preparation of reference culture; (3) 5 days Growth Promotion Test and Method Suitability Test; (4) 14 days Incubation period; (5) 4 days Confirmatory Test and (6) a total of 2 days for receiving, data recording and computation, evaluation, reporting and releasing to RRU. *(Reference: United States Pharmacopeia and the National Formulary USP/NF <71> Sterility Test)*
- Samples subject for **Commercial sterility** of thermally processed foods in hermetically sealed containers requires approximately **thirty-three (33) calendar days** (equivalent to **twenty-three (23) working days**), which includes: (1) 1-day media preparation; (2) 10-days sample pre-incubation; (3) 5-days sample culturing; (4) 15-days (as needed) Sub-culturing, morphological characterization and Confirmatory tests; (5) a total of 2 days for receiving, data recording and computation, evaluation, reporting and releasing to RRU. *(Reference: Bacteriological Analytical Manual (BAM) Chapter 21A: Examination of Canned Foods 8th Edition by AOAC International)*
- Samples subject for **Evaluation of the Antimicrobial Protection** of a Cosmetic Product requires a total number of **sixty (62) calendar days** (equivalent to **forty-four (44) working days**), which includes: (1) 1 day media preparation; (2) 16 days preparation of inoculate; (3) 5 days of demonstration of the neutralizer efficacy, additional 5 days for modification of the neutralizer (if necessary); (4) 33 days of determination of the Preservation Efficacy of the Formulation; and (6) a total of 2 days for receiving, data recording and computation, evaluation, reporting and releasing to RRU. *(Reference: ASEAN Cosmetic Method: Evaluation of the Antimicrobial Protection of a Cosmetic Product ACM No. 008; ISO 11930:2019 – Evaluation of the Antimicrobial Protection of a Cosmetic Product)*