COMMON SERVICES LABORATORY
INTERNAL SERVICES

1.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:

Complaints – These are alleging deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a health product after release from distribution. High-risk complaints shall be processed for seven (7) working days.

Government Deliveries – These are health products submitted by government agencies like the Department of Health, Local Government Units and government hospitals. Government deliveries for anti-tuberculosis drugs (DOH-LMD) shall be processed for fifteen (15) working days.

Donations – Samples coming from government and private institutions intended for donations.

Referrals – These are health products referred by the FDA Centers or Offices (CDRR, CFRR, CCHUHSRR, CDRRHR, Regulatory Enforcement Unit, FDA Satellite laboratories)

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
Who May Avail:	FDA Centers and Offices
Fees to be Paid:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Duly Accomplished Request for Analysis (RFA) Form	FDA website (https://www.fda.gov.ph/downloadables/)

Actual Sample/s Quantity should be in accordance with FDA Circular No. 2014-014 "Minimum Number of Samples Units required for Each Test Analysis"	Applicant/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
With expiration date at least three (3) months prior to request for analysis	
Actual sample per request should bear the same batch or lot	
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 - For food-borne illness outbreak-related samples, information on the onset of symptoms, time of consumption, and other food consumed must be provided. *e:* 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
Sends Request for Analysis (RFA) per request through email: For Alabang Testing and Quality Assurance Laboratory: atqal.rfa@fda.gov.ph For Cebu Testing and Quality Assurance Laboratory: ctqal.rfa@fda.gov.ph	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,	None	–	*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 Davao Testing and Quality Assurance Laboratory: dtqal.rfa@fda.gov.ph 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*** *Note:* For requests for analysis related to food-borne illness outbreak, pre-assessment and evaluation of RFA will be conducted in-person. For requests for analysis from Regulatory Enforcement Unit (REU), pre-assessment and evaluation of RFA will be conducted through videoconferencing.	indicating that the request is rejected. Consequently, RFA will be returned, for appropriate actions. Revised RFA shall be submitted for pre-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.			
Submits the required number of samples for laboratory analysis, as well as the printed and signed copies of pre-assessed RFA.	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.	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
	If found unacceptable, rejects the RFA and issues Letter for Returned Sample.			
	2 Encodes RFA in CSL database.	None	5 Minutes	*Food-Drug Regulation Officer/Laboratory Technician* CSL – Receiving and Releasing Unit
	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
	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
	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
	Handles and stores samples for testing in designated location.	None	5 Minutes	*Laboratory Technician/ Administrative Aide* Concerned CSL–

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
				Laboratory Section/s
	Pre-evaluates received samples as per label and/or test required.	None	10 Minutes	*Laboratory Technician/ Administrative Aide* Concerned CSL–Laboratory Section/s
	Conducts laboratory testing with corresponding processing timelines: **A. Complaints** High risk Low-medium risk **B. Donations** **C. Post-marketing Surveillance** **D. Referrals** **E. Microbiological Tests *(see notes)*** Sterility testing Commercial sterility Evaluation of antimicrobial protection	None	**(A)** 5 Working Days 18 Working Days **(B)** 18 Working Days **(C)** 18 Working Days **(D)** 18 Working Days **(E)** 18 Working Days 23 Working Days 42 Working Days (note: with pending request to ARTA)	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Records and compute data gathered from laboratory testing.	None	1 Working Day	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s
	Evaluates data and results from laboratory testing.	None	4 Hours	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s
	Prepares Test Reports	None	1 Hour	*Laboratory Technician/ Administrative Aide* Concerned CSL–Laboratory Section/s
	Signs all test reports	None	10 Minutes	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s
	Signs non-conforming test reports	None	10 Minutes	*Director II* CSL
	Forwards signed Test Reports to concerned Office/Center.	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit
	Forwards the Test Report to FDA Records for Test Reports to Regional Field Offices.	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Releasing of Test Reports to Internal Customer.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**20 Working Days except** **<u>(A) High Risk</u>** **7 Working Days** **<u>(E) Antimicrobial Protection</u>** **44 Working Days**	

<u>NOTES:</u>

- 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)*