



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

June 5, 2023

DEPARTMENT CIRCULAR

No. 2023 - 0291

FOR : **DIRECTORS OF CENTER FOR HEALTH DEVELOPMENT (CHD); MINISTER OF HEALTH-BANGSAMORO AUTONOMOUS REGION IN MUSLIM MINDANAO (MOH-BARMM); CHIEFS OF CHD-REGULATION, LICENSING AND ENFORCEMENT DIVISION AND REGULATION, LICENSING AND ENFORCEMENT CLUSTER OF BARMM; AND REGULATORY OFFICERS; AND ALL OTHERS CONCERNED**

SUBJECT : **Interim Guidelines in the Regulation of Confirmatory Rapid HIV Diagnostic Algorithm Clinical Laboratory (CrCL)**

I. RATIONALE

Administrative Order No 2019-0001, issued on January 10, 2019, titled "*Guidelines on the Implementation of Rapid HIV Diagnostic Algorithm (rHIVda)*," was amended last October 25, 2022. The amendment updated the process of establishment of a Certified rHIVda Confirmatory Laboratory (CrCL) and removed the process of securing a certification from the National Reference Laboratory – San Lazaro Hospital/STD AIDS Cooperative Central Laboratory (NRL-SLH/SACCL) as part of the efforts to expand rHIVda sites to ensure equitable access to confirmatory HIV testing.

Relative thereto, this Circular is being issued to provide guidelines in the process of establishment of CrCL aligned with the recent changes to ensure compliance of clinical laboratories in the generation of accurate, precise, and reliable results in a timely manner. Moreover, an agile regulatory approach is adopted to streamline and fast track the processing of applications.

II. GENERAL GUIDELINES

1. All existing DOH-licensed clinical laboratories with the intent to apply for a CrCL shall follow the guidelines stated herein, the Administrative Order (AO) No. 2021-0037 titled "*New Rules and Regulations Governing the Regulation of Clinical Laboratories in the Philippines*," and other related laws and DOH issuances at all times.
2. Only existing DOH-licensed clinical laboratories shall be allowed to apply for CrCL as an additional (add-on) service. Annex A. *Process Flow for Initial Application of DOH-License-to-Operate (DOH-LTO) as CrCL* of this Circular provides the process of establishment of CrCL.
3. CrCL applicants shall secure DOH-LTO from the Health Facilities and Services Regulatory Bureau (HFSRB) or Center for Health Development-Regulation

Licensing and Enforcement Division/Bangsamoro Autonomous Region in Muslim Mindanao-Regulation Licensing and Enforcement Cluster (CHD-RLED/BARMM-RLEC).

4. The CrCL may be a section or unit integrated in a DOH-licensed clinical laboratory.
5. The CrCL shall provide room for the pre-test and post-test counseling conducted by a HIV and AIDS counselor trained by a DOH accredited institution/organization or by the DOH.
6. The CrCL shall formulate its Manual of Operations for rHIVda aligned with the current DOH guidelines which shall be strictly enforced and implemented in the clinical laboratory. It shall include but not limited to the following: standard operating procedure; work instruction; internal and external quality assurance program; policies on biosafety and biosecurity: handling, transport, processing, retention, disposal of specimens; decontamination and biological spill response, validation of test results; assurance of patient confidentiality; infection prevention and control; and records management to ensure confidentiality of records.
7. The CrCL shall participate and pass the annual National External Quality Assessment Scheme (NEQAS) implemented by the NRL-SLH/SACCL for rHIVda. Nonparticipation and absence of action to improve the unsatisfactory EQAP results shall be the basis for the revocation of license for rHIVda as an add-on service.
8. Violations of the guidelines stated herein, Annex C of AO No. 2021-0037, and other DOH related policies or laws shall be the basis for the sanctions and penalties for the CrCL.

III. SPECIFIC GUIDELINES

1. There shall be at least one (1) rHIVda trained Registered Medical Technologist (RMT) per 8-hour of operation, which may be designated, to perform rHIVda. The head of laboratory or the associate clinical pathologist shall also undergo rHIVda training.
2. At least one (1) staff/encoder, which may be designated, shall be trained in the use of One HIV-AIDS and STI Information System (OHASIS) as conducted by the DOH Epidemiology Bureau.
3. The DOH-licensed clinical laboratory shall release results signed by the analyst who performed the test, by the RMT knowledgeable in rHIVda (preferably senior RMT) to validate that the test procedure was followed, and by the pathologist to attest the validity of the test result.
4. For application of rHIVda as an additional (add-on) service, complete documentary requirements shall consist of the following:
 - a. Completely filled-out DOH-HFSRB-Form 2 downloadable at hfsrb.doh.gov.ph;
 - b. Duly accomplished Annex B. *Additional Requirements for the Conduct of Rapid HIV Diagnostic Algorithm (rHIVda) in the DOH-licensed Clinical Laboratory* of this Circular;
 - c. List of rHIVda trained personnel who are designated to perform rHIVda with the corresponding training certificate from NRL-SLH/SACCL;
 - d. Certificate of passing result of panel proficiency for rHIVda from NRL-SLH/SACCL;
 - e. Photos of room for HIV counseling (outside of the clinical working area); and

- f. Copy of official receipt.
- 5. Application for CrCL shall be approved and licensed based on the evaluation of the documentary requirements unless an inspection is warranted. However, newly licensed CrCL shall be prioritized for the scheduled monitoring visit.
- 6. The payment for initial application for DOH-LTO CrCL shall follow the current schedule of fees
- 7. DOH-LTO CrCL shall be renewed annually as part of the DOH-licensed clinical laboratory.

This Order shall take effect immediately.

By Authority of the Secretary of Health:
Digitally signed by Mercado-
Grande Charade Ballucanag
Date: 2023.07.07 11:11:57 +08'00'
ATTY. CHARADE B. MERCADO-GRANDE, MPSA
Assistant Secretary of Health
Health Facility and Patient Support Team

ANNEX A. Process Flow for Initial Application of DOH-License-to-Operate (DOH-LTO) as Confirmatory Rapid HIV Diagnostic Algorithm Clinical Laboratory (CrCL)

Stage 1. Self-Assessment

1. The DOH-licensed clinical laboratory (CL) shall conduct a self-assessment to determine its readiness to perform rHIVda as confirmatory. Self-assessment will include consideration for the laboratory design, process workflow, trained personnel, trained counsellor/s, manual of procedures, logistics and supplies, biosafety and biosecurity measures.

Stage 2. Personnel Training

1. The head of laboratory and Registered Medical Technologist (RMT) who will perform the confirmatory shall undergo rHIVda training provided by the NRL-SLH/SACCL.
2. The RMT must undergo integrated rHIVda proficiency training provided by NRL-SLH/SACCL.
3. The DOH-licensed CL shall have a trained HIV and AIDS counsellor/s. HIV Counseling training may be coordinated with the DOH Disease Prevention and Control Bureau and/or Centers for Health Development Offices.

Stage 3. Proficiency Testing

1. The DOH-licensed CL shall receive the rHIVda external quality assessment scheme (EQAS) panel for initial proficiency testing after the rHIVda training. The CL must obtain a score of 100%.
 - a. If the CL failed the initial panel, corrective measures must be undertaken before receiving the second panel.
 - b. If the CL failed the second panel, the personnel for rHIVda shall undergo re-training.
2. The DOH-licensed CL shall submit to NRL-SLH/SACCL the test results within five (5) calendar days after receipt of the EQAS panel.
3. The DOH-licensed CL may submit application for DOH-LTO for CrCL as an additional service after passing the proficiency panel testing.

Stage 4. Secure DOH-LTO

1. Apply for an additional service using FORM 2 downloadable at hfsrb.doh.gov.ph and submit to HFSRB or CHD-RLED/BARMM RLEC including the documentary requirements.
2. The DOH-licensed CL shall also fill out Annex B. of this Circular, *Additional Requirements for the Conduct of Rapid HIV Diagnostic Algorithm (rHIVda) in the DOH-licensed Clinical Laboratory* and Annex B1 and B2 of AO No. 2021-0037 as applicable.
3. Pay the appropriate fees.
4. The DOH assessment team shall review and evaluate the submitted documents for technical completeness and correctness.
5. If fully compliant, a DOH-LTO CrCL shall be issued.
6. If not fully compliant, the clinical laboratory shall be given thirty (30) days to comply. However, in the event that the applicant cannot comply within the given period, the application shall be automatically denied and the payment shall be forfeited.

Annex B. Additional Requirements for the Conduct of Rapid HIV Diagnostic Algorithm (rHIVda) in the DOH-licensed Clinical Laboratory – Supplemental to Annex B1 and B2 of AO No. 2021-0037 “New Rules and Regulations Governing the Regulation of Clinical Laboratories in the Philippines”

GENERAL INFORMATION:

Name of Facility:			
Complete Address:			
	Number & Street	Barangay/District	
	Municipality/City	Province/Region	
Contact Information:		E-mail Address:	
Existing DOH-License Number:		Date Issued:	
		Expiry Date:	
Name of Owner or Governing Body (if corporation): 			
Name of Head of Laboratory: 			

CRITERIA	INDICATOR / EVIDENCE	COMPLIED	REMARKS
HUMAN RESOURCE MANAGEMENT			
Additional records in the personnel's 201 files	Document Review Updated 201 files		
A. The Head of the Laboratory (HOL) or the associate clinical pathologist shall have the overall supervision on technical procedures as well as on the administrative laboratory management	Additional Qualification: rHIVda Certificate of Training (NRL-SLH/SACCL)		
B. Registered Medical Technologist (RMT) – may be designated	Additional Qualifications: Integrated rHIVda Certificate of Proficiency (NRL-SLH/SACCL)		
C. HIV and AIDS Counselor	Document Review Proof of training from DOH accredited institution/ organization or by the DOH		
EQUIPMENT/INSTRUMENT			
Hardware for encoding and reporting of conducted test/OHASIS reporting	Observe - Laptop or PC with password encryption for access - Stable internet connection		

CRITERIA	INDICATOR / EVIDENCE	COMPLIED	REMARKS
REAGENTS AND SUPPLIES			
All HIV rapid diagnostic test kits being used are validated by NRL/SLH-SACCL and FDA registered (list issued and approved by the Disease Prevention and control Bureau)	Observe List down the test kits currently being used for rHIVda Test 1 - _____ Test 2 - _____ Test 3 - _____		
ADMINISTRATIVE AND TECHNICAL POLICIES AND PROCEDURES			
The manual of procedures for rHIVda covers all testing phases and is in accordance with DOH guidelines (i.e., AO No. 2019-0001 and its amendment, AO No. 2022-0035)	Document Review - Documented Standard Operation Procedures (SOP) signed and approved by the HOL which includes procedures on the following: Pre-testing Phase - Conduct of counselling and filling of forms - Proper patient identification; specimen collection, labeling, handling, encoding, forwarding of specimen to the appropriate section, as applicable - Criteria for specimen acceptance and rejection Testing Phase - Quality control assurance program - Specimen testing and analysis in accordance with DOH guidelines Post-Testing Phase - Test reporting and releasing of results - Conduct of post-test counseling and referral (if applicable) - Documented procedure on proper encoding of data to One HIV, AIDS, STI Information System (OHASIS) - Documented procedures on referral of inconclusive test results, as applicable - Documented procedures for data and specimen retrieval and sample banking for quality assurance and future verification purposes		

CRITERIA	INDICATOR / EVIDENCE	COMPLIED	REMARKS
	- Documented procedures to ensure patient's safety and confidentiality of tests results and records - Records of pre-test and post-test counseling Observe - Presence of HIV Test Forms (HTS Form – Form A) - Protocols for the conduct of the test and reporting of results based on the SOP are strictly being followed - Room for counselling		
There is proper documentation on clients' records, received and processed specimens, and released test results with strict adherence to data privacy and confidentiality	Document Review - Records, logbooks or computer data entries of specimens received, test results including inconclusive and invalid tests; and released results - Proof of reporting to DOH (One HIV, AIDS, STI Information System-OHASIS) - Records of monthly census on samples tested, inconclusive tests results, referred samples - Use of worksheet with the following identifiers as recommended by NRL-SLH/SACCL: - Kit Name - Lot Numbers - Expiration Dates - Unique Patient ID - Tester Name - QC results - Test Validity - Test Results - Date of Testing Observe - Utilize requisition form adapted from NRL-SLH/SACCL - Files are stored in a secured, well-kept, and maintained area and/or backed up properly		

Annex C. Relevant Laws and Issuances

1. Republic Act No. 4688: Clinical Laboratory Act dated June 18, 1966
2. Republic Act No. 11166: Philippine HIV and AIDS Policy Act dated December 20, 2018
3. Administrative Order No. 2019-0001: Guidelines on the Implementation of Rapid HIV Diagnostic Algorithm (rHIVda) dated January 10, 2019, and its amendment
4. Administrative Order No. 2021-0037: New Rules and Regulations Governing the Regulation of Clinical Laboratories in the Philippines dated June 11, 2021
5. Administrative Order No. 2022-0035: Guidelines in the Implementation of Differentiated HIV Testing Services dated August 22, 2022
6. Department Memorandum No. 2023-0094: Interim Guidelines for the Transition of Disease-Based Programs to the Implementation of Integrated Primary Care Services for UHC dated February 20, 2023
7. Department Memorandum No. 2021-0381: Interim Guidelines on the use of One HIV, AIDS, STI Information System (OHASIS) as the reporting platform of HIV, AIDS, Viral Hepatitis and Other Sexually Transmitted Infections (STI) in the Philippines