Republic of the Philippines
Department of Health
**OFFICE OF THE SECRETARY**

JAN 10 2019

**ADMINISTRATIVE ORDER**
No. ~~2018-~~ 2019 - 0001

**SUBJECT:** **Guidelines on the Implementation of Rapid HIV Diagnostic Algorithm (rHIVda)**

## I. RATIONALE

The Philippines registered the fastest growing HIV and AIDS epidemic in Asia Pacific in the past ten years. The reported case of HIV has increased from one case per day in 2007 to 31 newly diagnosed cases per day in 2017. Unprotected sex remains the leading mode of transmission, with men having sex with men comprising 83% of the number of new cases. The HIV infection is also transmitted through male-female sex, needle sharing among injecting drug users, and mother to child transmission.

Until 2015, the country is using Western Blot test as part of the HIV confirmatory algorithm. The average waiting time of confirmatory test result is around seven to ten days, but may reach up to three weeks when referring laboratories pool their specimens before sending to the National Reference Laboratory – San Lazaro Hospital / STD AIDS Cooperative Central Laboratory (NRL-SLH/SACCL)) to lessen the courier service expenses. The long waiting period of confirmatory test leads to delay in HIV treatment initiation.

With increasing trend of HIV cases, there is a need for early recognition of HIV cases. In low prevalence countries, WHO recommends testing algorithms of sequential combinations of two or three tests (immunoassay and/or rapid tests) which can be reliably used to rapidly confirm HIV infection. Thus, the introduction of Rapid Diagnostic Tests (RDT) in other countries has become an important strategy to increase access to HIV testing, reduce long waiting time for laboratory results, reduce undiagnosed cases, prevent HIV transmission, and provide immediate HIV Testing Services (HTS) to prolong and improve quality of life of People Living with HIV (PLHIV).

Hence, the National HIV, AIDS and STI Prevention and Control Program (NASPCP) is introducing the use of rapid HIV diagnostic algorithm (rHIVda) as the new HIV confirmatory test in the Philippines. This issuance is adopting the HIV diagnostic algorithm validated and piloted in eight sites around the country as a collaborative work of the Department of Health - Disease Prevention and Control Bureau (DOH-DPCB), World Health Organization (WHO), and National Reference Laboratory - San Lazaro Hospital/ STD AIDS Cooperative Central Laboratory (NRL-SLH/SACCL) with technical assistance from HIV National Reference Laboratory (NRL)-Australia in 2014 to 2015.

2/F Building 1, San Lazaro Compound, Rizal Avenue, Sta. Cruz, 1003 Manila * Trunkline 651-7800 local 1108, 1111, 1112, 1113
Direct Line: 711-9502; 711-9503; 912-5244 * Fax: 743-1829 • URL: http://www.doh.gov.ph; email: ftduque@doh.gov.ph

## II. OBJECTIVES

### A. General Objective:

To provide implementation policies and guidelines for the use of rapid HIV diagnostic algorithm (rHIVda) as the new HIV confirmatory test in Certified rHIVda Confirmatory Laboratory (CrCL) facilities.

### B. Specific Objectives:

1. To provide standards for the establishment of CrCL;
2. To outline the operational guidelines for rHIVda;
3. To outline the roles and responsibilities of different DOH units and other stakeholders.

## III. SCOPE AND COVERAGE

This policy shall cover Social Hygiene Clinics and HIV testing laboratories except Medical Facilities for Overseas Workers and Seafarers (MFOWS). The rHIVda is intended to be used in both general and key HIV populations.

## IV. DEFINITION OF TERMS

1. **Certified rHIVda Confirmatory Laboratory (CrCL)**- a DOH-licensed clinical laboratory compliant with rapid HIV diagnostic algorithm (rHIVda) laboratory standards and technical requirements set by the National HIV, AIDS and STI Prevention and Control Program (NASPCP) and National Reference Laboratory- San Lazaro Hospital/ STI, AIDS Central Cooperative Laboratory (NRL-SLH/SACCL).
2. **Clinical Laboratory** – a facility where tests are done on specimens from the human body to obtain information about the health status of a patient for the prevention, diagnosis and treatment of diseases. These tests include, but not limited to, the following disciplines: clinical chemistry, hematology, immunohematology, microbiology, immunology, clinical microscopy, histopathology, cytology, toxicology, endocrinology, molecular biology and cytogenetics. Other functions of the clinical laboratory are to provide consultative advisory services covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation. Facilities that are involved in the pre-analytical processes, such as collection, handling and preparation of specimens, or act as mailing or distribution center, such as in a laboratory network or system are also considered to be a part of a clinical laboratory. The total testing process includes pre-analytical, analytical and post analytical procedures (DOH-AO No. 2007-0027).
3. **Enhanced HIV/AIDS and ART Registry of the Philippines (eHARP)** - an electronic case-based reporting and database system maintained by the Epidemiology Bureau for reporting use of HIV treatment hubs, primary HIV care facilities, and CrCL facilities.
4. **HIV Testing** – refers to initial serological test to determine the presence of antigens and/or antibodies against HIV, performed by a HIV-proficient medical technologist (AO No. 2017-0019).
5. **HIV Testing Services (HTS)** – full range of services accompanying HIV testing including counselling (pre-HIV test and post-HIV test); linkage to appropriate HIV prevention, treatment and care services and other clinical and support services with proper coordination with reference laboratories to support quality assurance and delivery of accurate results (AO No. 2017-0019).

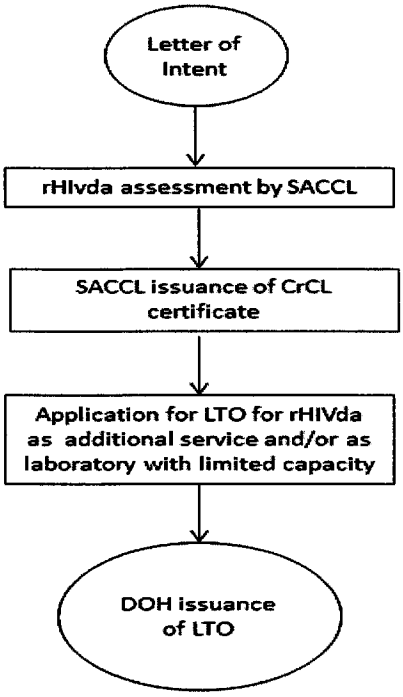
6. **HIV Testing Services (HTS) facility**- any health facility providing HIV testing services. This can offer stand-alone HTS or incorporated into existing health-care support services to People Living with HIV (PLHIV) including but not limited to HIV testing services, clinical management, patient monitoring, and other care and support services. Antiretroviral (ARV) treatment can be accessed through these facilities.
7. **Key population**- members of this population are males who are having sex with males, people in prisons and other closed settings, people who inject drugs, sex workers, and transgender men and women (AO No. 2017-0019).
8. **Non- Certified rHIVda Confirmatory Laboratory (Non-CrCL)** – a clinical laboratory where HIV screening test is performed but is unauthorized to perform HIV confirmatory test (i.e. rHIVda, Western Blot or PCR).
9. **Nonreactive Result**– When an HIV testing or screening procedure indicates absence of HIV antibodies and/or antigens
10. **Quality Assurance (QA)** - a planned and systematic intervention done by testing laboratories that aims to ensure that their services and processes will satisfy given requirements for quality.
11. **Quality Management System (QMS)**- a comprehensive and integrated organizational approach that provides guidance and support to achieve quality in all components of HIV testing using rHIVda.
12. **Rapid HIV diagnostic algorithm (rHIVda)**- uses a combination of 2 or 3 rapid test formats done in parallel or sequence on a sample that had a reactive result in the initial test (AO No. 2017-0019).
13. **Reactive result** – When an HIV testing or screening procedure indicates presence of HIV antibodies and/or antigens. This result should be confirmed using the current diagnostic algorithm.
14. **Regional Laboratory Quality Officer** – a dedicated DOH-Center for Health Development (CHD) personnel to monitor and provide technical support to CrCL in compliance with laboratory standards and technical requirements.
15. **Social Hygiene Clinics** – these are clinics of local government unit (LGU) that specialize in the management of Sexually Transmitted Infections (AO No. 2017-0019).

## V. GENERAL GUIDELINES

1. The Disease Prevention and Control Bureau (DPCB) shall provide overall direction in the nationwide implementation of rHIVda as confirmatory test for HIV.
2. The rHIVda shall be a combination of three WHO prequalified and FDA registered HIV Rapid Diagnostic Tests (RDT).
3. The rHIVda shall be established in government clinical laboratories, HIV Treatment Hubs, Social Hygiene Clinics (SHC), HIV Testing Services (HTS) facilities, private and project-based HIV clinics that passed the laboratory standards and technical requirements of a Certified rHIVda Confirmatory Laboratory (CrCL).
4. Only DOH-licensed and Certified rHIVda Confirmatory Laboratory is allowed to issue an official confirmatory result based on rHIVda algorithm.
5. Confirmatory test results released by CrCL shall be acknowledged for PhilHealth Out-Patient HIV and AIDS Treatment (OHAT) package enrollment.
6. Quality Assurance Program for rHIVda shall include, but not limited to, lot testing, National External Quality Assurance (NEQAS), and validation, monitoring and supervision to ensure correct laboratory testing and diagnosis, appropriate management of specimens, recording and releasing of results.
7. Strong collaboration with LGU shall be developed to ensure compliance of CrCL to laboratory standards and sustain its operations.

## VI. SPECIFIC GUIDELINES

### A. Establishment of Certified rHIVda Confirmatory Laboratory (CrCL)




1. Any public clinical laboratories interested to establish a CrCL shall submit a letter of intent to DOH Regional Director.
2. Areas with high prevalence of HIV and HTS facilities initially supported by Global Fund Project-New Funding Model (NFM) shall be prioritized in the establishment of CrCL.
3. A certificate "Certified rHIVda Confirmatory Laboratory (CrCL)" shall be issued by NRL-SLH/SACCL or its regional counterpart to a public clinical laboratory which met rHIVda laboratory standards and technical requirements. The CrCL certificate is a pre-requisite for the issuance of LTO, which is valid for 2 years, by HFSRB or Centers for Health Development - Regulatory, Licensing and Enforcement Division (CHD-RLED).
4. For laboratory with existing LTO, rHIVda shall be applied as additional service to existing DOH-LTO.
5. For laboratory without existing DOH-LTO, it shall receive a CrCL certificate from SACCL before it can apply to DOH for LTO as laboratory with limited capacity. (Refer to AO. 2007-0027 Revised Rules and Regulations Governing the Licensure and Regulation of Clinical Laboratories in the Philippines).
6. Clinical laboratories which need technical assistance to meet requirements for certification shall be supported by the CHD - HIV/STI Program and/or the designated Quality Laboratory Officer.
7. Licensing of CrCL shall be under the responsibility of the Health Facilities and Service Regulatory Bureau (HFSRB) as defined in Administrative Order. No. 2018-0016 or the Revised Guidelines in the Implementation of the One-Stop Shop Licensing System.

## B. Capability-building

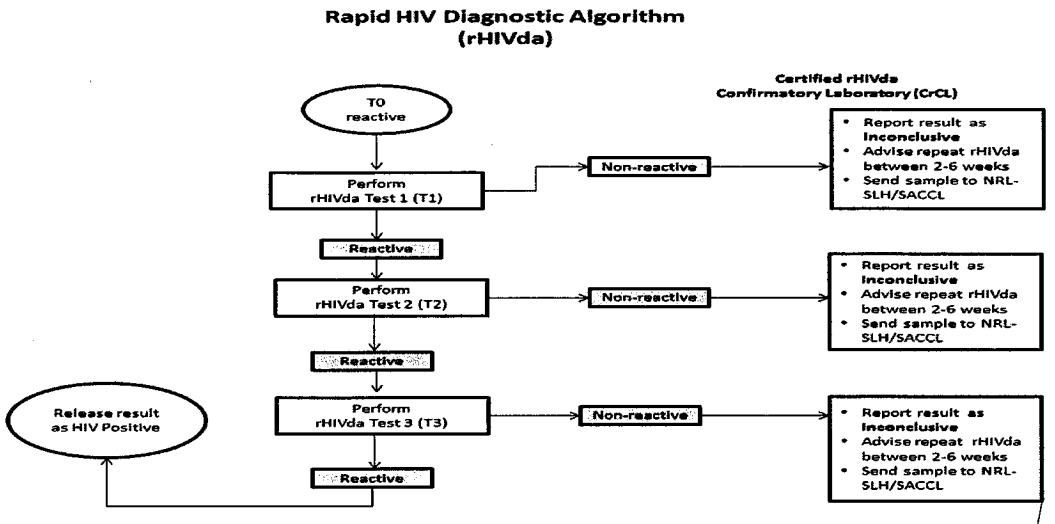
1. For the first 2 years of implementation, training on rHIVda for medical technologists of CrCL shall be provided by the NRL-SLH/SACCL.
2. The NRL shall accredit training institutions to provide accessible and sustainable HIV proficiency training for medical technologists in different regions.
3. A pool of trainers shall be established by NRL-SLH/SACCL to cascade rHIVda training and provide continuing technical support to CrCL.

## C. Human Resource

1. HIV proficiency certification shall be required to any medical technologist who will perform rHIVda.
2. There shall be adequate number of medical technologists in a CrCL. The standard number of medical technologists shall be based on the ratio of one medical technologist to manually perform 50 laboratory tests per eight hours. Additional staff depends on workload (10 minutes/test). (Refer to AO. No. 2007-0027 Revised Rules and Regulations Governing the Licensure and Regulation of Clinical Laboratories in the Philippines.)

## D. Laboratory Testing

1. The rHIVda algorithm shall be done in sequence of three WHO pre-qualified and FDA registered HIV Rapid Diagnostic Tests (RDTs) pre-selected by NRL-SLH/SACCL in coordination with NASPCP.
2. Test 0 (T0) reactive blood specimens from Non-CrCL shall be sent to CrCL for confirmatory test along with the Laboratory Request Form for HIV Testing (See Annex 4). Only reactive blood specimen referred from Non-CrCL facility shall be accepted by CrCL facility.
3. Walk-in clients in CrCL facility without T0 result shall be tested using rHIVda Test 1 (T1). If **T1** result is **non-reactive**, release result as **non-reactive**. If T1 result is **reactive**, test specimen using rHIVda Test 2 (T2). If **T2** result is **reactive**, test specimen using rHIVda Test 3 (T3). If **T3** result is **reactive**, release result as **HIV positive.**



4. Clients with **T0 reactive** results from Non-CrCL facility shall be tested using rHIVda Test one (T1). If **T1** result is **reactive**, test specimen using rHIVda test 2 (T2). If **T2** result is **reactive**, test specimen using rHIVda Test 3 (T3). If **T3** result is **reactive**, release result as **HIV positive.**
5. If rHIVda result is **Inconclusive** or there is any inconsistency with T1, T2 and T3 results, follow recommendations in Annex 1. Interpretation and Release of Inconclusive Results.

## E. Interpretation and Release of Result

1. **HIV POSITIVE** result shall be released if three rHIVda RDT results are all reactive (T1+, T2+, T3+).
2. **HIV NEGATIVE** result shall be released if the following conditions are satisfied:
   a. T0 test is not done and T1 result is non-reactive for walk-in clients in CrCL.
   b. If repeated T1 is non-reactive for second time (Two T1 non-reactive results).
3. **HIV INCONCLUSIVE** result shall be reported if there is any inconsistency with screening and/or rHIVda RDT results. Combinations are as follows:
   a. T0 result is reactive, T1 result is non-reactive (T0+, T1-)
   b. T1 result is reactive, T2 result is non-reactive (T1+, T2-)
   c. T1 result is reactive, T2 result is reactive, T3 result is non-reactive (T1+, T2+, T3-)
4. The confirmatory test result released by CRCL shall be signed by HIV-proficient medical technologist and pathologist.
5. All results shall be released to client during post-test counselling sessions. (Refer to AO No. 2017-0019 Policies and Guidelines in the Conduct of Human Immunodeficiency Virus (HIV) Testing Services (HTS) in Health Facilities).

## F. Data Management

1. All CrCL shall have a designated data management point person.
2. All rHIVda-related processes must be properly documented and recorded, including errors and gaps in the processes in the laboratory workbook/ registry.
3. All CrCL shall maintain daily client registry and shall submit monthly monitoring report to NASPC Coordinator of their respective LGU every last Friday of the month. These collected reports shall be submitted by the DOH Regional Coordinator to the Disease Prevention and Control Bureau (DPCB) every three months.
4. All CrCL shall report all rHIVda clients' data to the Epidemiology Bureau using the eHARP software. *(See Forms in Annex 2 and 3).*

## G. Quality Assurance

1. **Lot Testing**
   a. The NRL-SLH/SACCL shall subject samples per lot number of rHIVda RDTs to evaluation prior to shipment to CrCL.
   b. Consolidated report shall be submitted by NRL to DPCB every lot number tested.

2. **National External Quality Assessment Scheme (NEQAS)**
   a. The CrCL shall participate in the annual National External Quality Assessment Scheme (NEQAS) implemented by NRL-SLH/SACCL.
   b. The CrCL passing the NEQAS shall receive certificate valid for 1 year.
   c. The CrCL that will not pass the NEQAS shall be subjected to onsite assessment, retraining and close monitoring of performance until all recommendations are satisfactory met; and/or cancellation of CrCL certificate.
   d. An annual report on NEQAS shall be submitted by NRL to DPCB and HFSRB, to be used as reference in renewing DOH-LTO of clinical laboratories.

3. **Monitoring and Supervision**
   a. The CrCL shall comply with Quality Management System (QMS) policies and procedures.
   b. Monitoring of the CrCL performance shall be assessed regularly by the Quality Assessment Team composed of NRL-SLH/SACL, CHD and/or DOH Central Office- HIV Program.
   c. Technical laboratory supervision shall be provided as necessary or upon CrCL request.

**H. Monitoring and Evaluation**

1. Program performance indicators shall be used as basis for the conduct of monitoring and evaluation activities.
2. Monitoring of rHIVda programmatic outcomes shall be covered by the annual Health Sector Strategic Plan for HIV of the NASPCP.

## VII. ROLES AND RESPONSIBILITIES

**A. Disease Prevention and Control Bureau (DPCB)**

1. Together with NRL-SHL/SACCL, develop standards and technical requirements for a CrCL;
2. Endorse the list of potential CrCL laboratories to NRL-SLH/SACCL;
3. Oversee the creation of rHIVda pool of trainers to implement decentralize training and other capability building activities for health workers;
4. Provide rHIVda commodities to government CrCL through CHD;
5. Support NRL-SLH/SACCL in preparation of budget proposal in the implementation of rHIVda and NEQAS;
6. Collaborate with the National Voluntary Blood Donation Safety Program (NVBSP) to provide constant supply of blood for NEQAS implementation in the CrCL;
7. Conduct health promotion and advocacy activity for rHIVda service;
8. Conduct monitoring, supervision and evaluation activities of rHIVda implementation.

**B. Epidemiology Bureau (EB)**

1. Integrate rHIVda reporting in the current HIV surveillance system;
2. Conduct training on Data Management and Encoding for rHIVda;
3. Ensure all CrCL submission of reports to HIV surveillance system;
4. Provide HIV surveillance report to DPCB.

**C. Health Facilities and Services Regulatory Bureau (HFSRB)**

1. Set minimum licensing standards for HIV testing laboratories;
2. Issue License to Operate (LTO) to compliant laboratories applying for rHIVda;
3. Disseminate regulatory policies and standards for information and compliance;
4. Provide list of licensed CrCL sites to PhilHealth and DPCB.

**D. National Reference Laboratory-San Lazaro Hospital-STD AIDS Cooperative Central Laboratory (NRL-SLH/SACCL)**

1. Assess and certify clinical laboratories and clinics as "Certified rHIVda Clinical Laboratory (CrCL)" based on certification requirements;
2. Validate inconsistent rHIVda results;
3. Develop proficiency training program, training modules, monitoring and supervision tools for pool of trainers pursuant to the implementation of this guidelines;
4. Continually assess diagnostic kits with potential use for rHIVda and shall provide updated list of in-vitro diagnostic kits and combination of rapid tests;
5. Provide proficiency training and certificates to medical technologists and rHIVda trainers;
6. Provide technical assistance, mentorship and supervision to CrCL in the development of site standard operating procedures (SOPs), job aids (work instructions) and internal quality assurance procedures;
7. Oversee the implementation of Quality Assurance Program (QAP) together with NASPCP and CHD;
8. Conduct regular National External Quality Assurance Scheme (NEQAS);
9. Provide list of certified facilities to HFSRB and DOH-RLED regularly for validation of certificates submitted by the facility when they apply for LTO.
10. Provide feedback and recommendations on the performance of CrCL to NASPCP regularly.

**E. Center for Health Development (CHD) - HIV/STI Program**

1. Coordinate and disseminate rHIVda guidelines to HIV stakeholders and partners;
2. Lobby with Local Chief Executives (LCEs) in setting up CrCL in identified areas with high prevalence of HIV;
3. Endorse to Disease Prevention and Control Bureau (DPCB) the list of potential CrCL facilities;
4. Support the compliance of CrCL to required technical and standard requirements /Quality Management System (QMS) of rHIVda laboratories;
5. Designate Regional Quality Officer and provide support and technical assistance to clinical laboratories and facilities to ensure readiness to comply with laboratory standards and technical requirements in establishing CrCL;
6. Lead the creation of rHIVda pool of trainers;
7. Together with NRL-SLH/SACCL, organize training, mentoring and coaching activities for CrCL health workers following NASPCP policies and direction;

8. Provide rHIVda testing kits and other consumables to CrCL;
9. Conduct monitoring, supervision and evaluation activities of rHIVda implementation;
10. Regularly collect and analyze regional supply inventory reports, monitoring and supervision reports; and provide feedback to DPCB.

**F. PhilHealth**

1. Inform and provide list of accredited CrCL facilities for OHAT claims;
2. Coordinate with HFSRB for regular updates of CrCL list.

**G. DOH Hospitals and HIV Treatment Hubs**

1. Establish CrCL in their respective laboratories;
2. Accept and manage clients with HIV positive results from CrCL and/or NRL-SLH/SACCL.

**H. Local Government Units**

1. Support the establishment and maintenance of CrCL in their respective areas, including but not limited to, provision of laboratory space, additional funds for hiring of human resource, additional commodities, and other logistical needs;
2. Institutionalize the implementation of rHIVda in HIV testing facilities in their area of jurisdiction;
3. Support CrCL to comply with standards and requirements for rHIVda.

**I. Certified rHIVda Confirmatory Laboratories (CrCL)**

1. Release accurate laboratory result on the same day the specimen is received;
2. Ensure confidentiality of laboratory results;
3. Develop, update, sustain and strictly implement standard operating procedures (SOP), job aids (work instructions), and Quality Management System (QMS) for a CrCL facility;
4. Establish and maintain good coordination with CHD, NRL- SLH/SACCL, HIV testing and treatment facilities, LGU, CBO, NGO and other agencies to facilitate efficient rHIVda implementation and service delivery;
5. Participate in NEQAS by NRL-SLH/SACCL;
6. Advocate for logistical and human resource supports to rHIVda;
7. Submit reports to CHD and DOH-Epidemiology Bureau.

## VIII. FUNDING

The DOH-DPCB shall allocate budget for the implementation of these guidelines, including but not limited to, augmentation of rHIVda test kits and consumables, conduct of capacity building activities, monitoring, supervision and evaluation activities. The Local Government Units (LGU) shall be tapped to provide financial support for the implementation of these guidelines that shall be included in their respective annual budgets.

## IX. REPEALING CLAUSE

Provisions in previous issuances inconsistent and contrary to this Administrative Order are hereby rescinded and repealed.

## X. EFFECTIVITY CLAUSE

This Administrative Order shall take effect immediately. All implementing agencies are required to strictly follow this directive.

**FRANCISCO T. DUQUE III, MD, MSc.**
Secretary of Health

**Annex 1. Interpretation and Release of Inconclusive Results**

| Test Result in CrCL | Interpretation of HIV Status | Recommendation | Remarks |
|---|---|---|---|
| 1.T1 Non-reactive | Inconclusive | Repeat rHIVda after 2-6 weeks<br><br>(Send specimen to SACCL for data collection) | To come back after 2-6 weeks |
| Same result after Return 1 | Negative | -Release **negative result**<br><br>(Send specimen to SACCL for data collection) | Post-test counselling |
| 2.T1 Reactive<br>T2 Non-reactive | Inconclusive | Repeat rHIVda after 2-6 weeks<br><br>(Send specimen to SACCL for data collection) | To come back after 2-6 weeks |
| Same result after Return 1 | Inconclusive | Repeat rHIVda after 2-6 weeks<br><br>(Send specimen to SACCL for data collection) | To come back after 2-6 weeks |
| Same result after Return 2 | Inconclusive | Request final result from SACCL<br><br>(Send specimen to SACCL for data collection) | Release final result from SACCL |
| 3.T1 Reactive<br>T2 Reactive<br>T3 Non-reactive | Inconclusive | Repeat rHIVda after 2-6 weeks<br><br>(Send specimen to SACCL for data collection) | To come back after 2-6 weeks |
| Same result after Return 1 | Inconclusive | Repeat rHIVda after 2-6 weeks<br><br>(Send specimen to SACCL for data collection) | To come back after 2-6 weeks |
| Same result after Return 2 | Inconclusive | Request final result from SACCL | Release final result from SACCL |

# Annex 2. DOH EB Form A

**HIV TESTING** **A**

The Department of Health (DOH) has an existing program for the prevention and control of the Human Immunodeficiency Virus (HIV) in the Philippines. The Epidemiology Bureau (EB) of DOH is mandated by Republic Act 8504 to collect information that will be used in planning activities to help stop the spread of HIV and to support and treat those diagnosed to have HIV. Your full cooperation is very important to this program. Please answer all questions as honestly as possible.

**ABOUT THE TEST**

**1. What is HIV testing?**
An HIV test is a blood test. It will show if you have antibodies to HIV– the virus that causes AIDS. A sample of blood will be taken from your arm. If the first test (screening) is reactive, another test (confirmatory) will be done to make sure that the first test is confirmed to be positive. A positive test means you have been infected with HIV, a negative test means you are probably not infected because it takes time for the body to produce antibodies. If you think you have been exposed recently, you need to be re-tested after 6 weeks to make sure you are not infected.

**2. Voluntary HIV testing**
Taking an HIV test is voluntary. Under Republic Act 8504, you cannot be tested without your knowledge and consent. If you do not want to be tested, you have the right to refuse the test.

**3. Confidentiality of Test Results**
Your test result is confidential. It will only be given to you personally.

**Please fill up this form after you have signed the informed consent to be tested for HIV.**

**PERSONAL INFORMATION SHEET (FORM A)**

**All information given will be STRICTLY CONFIDENTIAL. Please fill out this form COMPLETELY and as honestly as possible. Please write in CAPITAL LETTERS and CHECK the appropriate boxes.**

**DEMOGRAPHIC DATA**

| | |
|---|---|
| 1 | **PhilHealth Number:** ☐☐ - ☐☐☐☐☐☐☐☐☐ - ☐ ☐ Not enrolled in PhilHealth |
| 2 | **Name (Full name)**<br>First Name ____ Middle Name ____ Last Name ____ Suffix (Jr, Sr, III, etc) ____ |
| 3 | **First 2 letters of mother's real name** ☐☐ **First 2 letters of father's real name** ☐☐ **Birth order** ☐☐ |
| 4 | **Birth date:** ☐☐ Month ☐☐ Day ☐☐☐☐ Year **Age:** ☐☐ Age in months (for less than 1 year old): ☐☐ |
| 5 | **Sex** *(at birth)*: ☐ Male ☐ Female **Self-identity:** ☐ Male ☐ Female ☐ Other: _____ |
| 6 | **Current Place of Residence:** City/Municipality: _____ Province: _____<br>**Permanent Residence:** City/Municipality: _____ Province: _____<br>**Place of Birth:** City/Municipality: _____ Province: _____ |
| 7 | **Nationality:** ☐ Filipino ☐ Other, please specify: _____ |
| 8 | **Highest Educational Attainment:** ☐ None ☐ Highschool ☐ Vocational ☐ Elementary ☐ College ☐ Post-Graduate |
| 9 | **Civil Status:** ☐ Single ☐ Married ☐ Separated ☐ Widowed |
| 10 | **Are you currently living with a partner?** ☐ No ☐ Yes |
| 11 | **Are you currently pregnant?** *(if female only)* ☐ No ☐ Yes **Number of children:** ☐☐ |

**OCCUPATION**

| | |
|---|---|
| 12 | **Current Occupation** (please specify main source of income): _____<br>If no current work, please specify previous occupation: _____ |
| 13 | **Currently in school?** ☐ No ☐ Yes; please indicate level: ☐ High school ☐ Vocational ☐ Other ☐ College ☐ Post-graduate |
| 14 | **Did you work overseas/abroad in the past 5 years?** ☐ No ☐ Yes<br>If yes, when did you return from your last contract? ☐☐☐☐ Year<br>Where were you based? ☐ On a ship ☐ Land<br>What country did you last work in? _____ |

## HISTORY OF EXPOSURE

15 Did your birth mother have HIV when you were born? ☐ No ☐ Yes

16 *Answer all*. Have you ever experienced any of the following? Please check the appropriate column for each item.

| | No | Yes; the most recent time was within the past 12 months | Yes; the most recent time was more than 12 months ago |
|---|---|---|---|
| Sex with a female with no condom | ☐ | ☐ | ☐ |
| Sex with a male with no condom | ☐ | ☐ | ☐ |
| Sex with someone whom you know has HIV | ☐ | ☐ | ☐ |
| Paying for sex | ☐ | ☐ | ☐ |
| Regularly accepting payment for sex | ☐ | ☐ | ☐ |
| Injected drugs without doctor's advice | ☐ | ☐ | ☐ |
| Received blood transfusion | ☐ | ☐ | ☐ |
| Occupational exposure (needlestick/sharps) | ☐ | ☐ | ☐ |
| Gotten a tattoo | ☐ | ☐ | ☐ |
| Sexually transmitted infection (STI / STD) | ☐ | ☐ | ☐ |

17 Age at first sex: ☐☐ ☐ Not applicable Age at first injecting drug use: ☐☐ ☐ Not applicable

18 *If you have ever had sex, please answer this section.* If the answer is none, write "0" in the box.

How many FEMALE sex partners have you ever had? ☐☐☐☐☐ Year of last sex with a female: _____

How many MALE sex partners have you ever had? ☐☐☐☐☐ Year of last sex with a male: _____

## MEDICAL HISTORY

19 Please check all that apply.

☐ Current TB patient ☐ With hepatitis B ☐ CBS reactive

☐ Currently pregnant ☐ With hepatitis C ☐ Taking PreP

## REASONS FOR HIV TESTING

20 Please check all that apply.

☐ Possible exposure to HIV ☐ Employment - Overseas/Abroad ☐ No particular reason

☐ Recommended by physician ☐ Employment - Local/Philippines ☐ Other (please specify):

☐ Re-testing ☐ Requirement for insurance _____

## PREVIOUS HIV TEST

21 Have you ever been tested for HIV before? ☐ No ☐ Yes

If yes, when was the most recent test? ☐☐ Month ☐☐☐☐ Year

Which testing facility did you have the test? _____ City/Municipality: _____

What was the result? ☐ Positive ☐ Negative ☐ Indeterminate ☐ Was not able to get result

## To be filled up by PHYSICIAN, CLINIC STAFF or COUNSELOR only

22 Clinical Picture: ☐ Asymptomatic

☐ Symptomatic Describe S/Sx: _____

World Health Organization (WHO) Staging: _____ ☐ No physician available to do staging

Patient type: ☐ Inpatient ☐ Outpatient ☐ Mobile HTS client

## To be filled up by TESTING FACILITY only

23 Name of Testing Facility: _____

Complete Mailing Address: _____

Contact Numbers: _____ Email address: _____

Referred by (if referral):

☐ TB-DOTS/PMDT facility

☐ Antenatal/Maternity clinic

24 Name of Counselor (with signature): _____

## To be filled up by RHIVDA Facility only

25 RHIVDA code: _____ Date tested: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

Result: ☐ Non-reactive ☐ Positive ☐ Negative ☐ Indeterminate

## To be filled up by SACCL only

26 SACCL Laboratory Code: ☐☐☐☐☐☐☐☐☐☐ Date HIV Confirmed: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

HIV Results Confirmed by: _____ Test: ☐ Western Blot ☐ PCR for infants

END

## Annex 3. DOH EB Form AMC

**SUPPLEMENTAL FORM FOR MOTHERS AND CHILDREN** — **A-MC**

**Demographics**

1 **Patient's name:** First Name | Middle Name | Last Name

**UNIQUE IDENTIFIER CODE**

2

| First 2 letters of mother's real name | First 2 letters of father's real name | Birth Order | Month of Birth | Day of Birth | Year of Birth |
|---|---|---|---|---|---|
| ☐☐ | ☐☐ | ☐☐ | ☐☐ | ☐☐ | ☐☐☐☐ |

**FOR PREGNANT MOTHERS ONLY**

**Pregnancy History**

M-1 **Number of Alive Children:** ☐☐

M-2

| HIV Testing Status | Child #1 | Child #2 | Child #3 | Child #4 |
|---|---|---|---|---|
| HIV Status | ☐ Positive ☐ Negative ☐ Don't know | ☐ Positive ☐ Negative ☐ Don't know | ☐ Positive ☐ Negative ☐ Don't know | ☐ Positive ☐ Negative ☐ Don't know |
| Place Tested | | | | |
| Date Tested | | | | |

M-3 **Last Menstrual Period** *(mm-dd-yyyy)*: ☐☐ - ☐☐ - ☐☐☐☐

M-4 **Number of months and weeks pregnant:** ☐☐ months and ☐☐ weeks

M-5 **Expected Date of Delivery** *(mm-dd-yyyy)*: ☐☐ - ☐☐ - ☐☐☐☐

M-6 **Where do you seek prenatal care?** _____ ☐ No prenatal clinic visit

M-7 **Where do you plan to deliver the baby?**
☐ Hospital, specify: _____ ☐ Home ☐ Others, specify: _____
☐ Lying-in clinic, specify: _____ ☐ No plans yet

**Partner's HIV History and Tx**

M-8 **Partner tested for HIV?**
☐ Yes, when *(mm-dd-yyyy)*? _____ Facility? _____
**Result:** ☐ Positive ☐ Negative ☐ Don't know ☐ Did not get result
☐ No
☐ Don't know

M-9 **Partner taking ARV medication/s?** ☐ Yes ☐ No ☐ Don't know
☐ Stopped, (reason: _____)

**FOR CHILDREN ONLY**

**Mother's HIV History**

C-1 **Sex:** ☐ Male ☐ Female

C-2

| **Full name of mother:** | **Full name of father:** |
|---|---|
| **HIV Status:** ☐ Positive ☐ Negative ☐ Don't know | **HIV Status:** ☐ Positive ☐ Negative ☐ Don't know |
| **If positive,** date of diagnosis (mm-dd-yyyy)? | **If positive,** date of diagnosis (mm-dd-yyyy)? |
| SACCL Code: | SACCL Code: |
| **Status:** ☐ Alive ☐ Dead (when? ) | **Status:** ☐ Alive ☐ Dead (when? ) |

C-6 **Mother took ARV medication/s during pregnancy?** ☐ Yes, ☐ No, (reason: ) ☐ Don't know

C-7 **Did mother breastfeed the baby?** ☐ Yes ☐ No

**TO BE FILLED OUT BY SACCL PERSONNEL ONLY**

**HIV Testing Status**

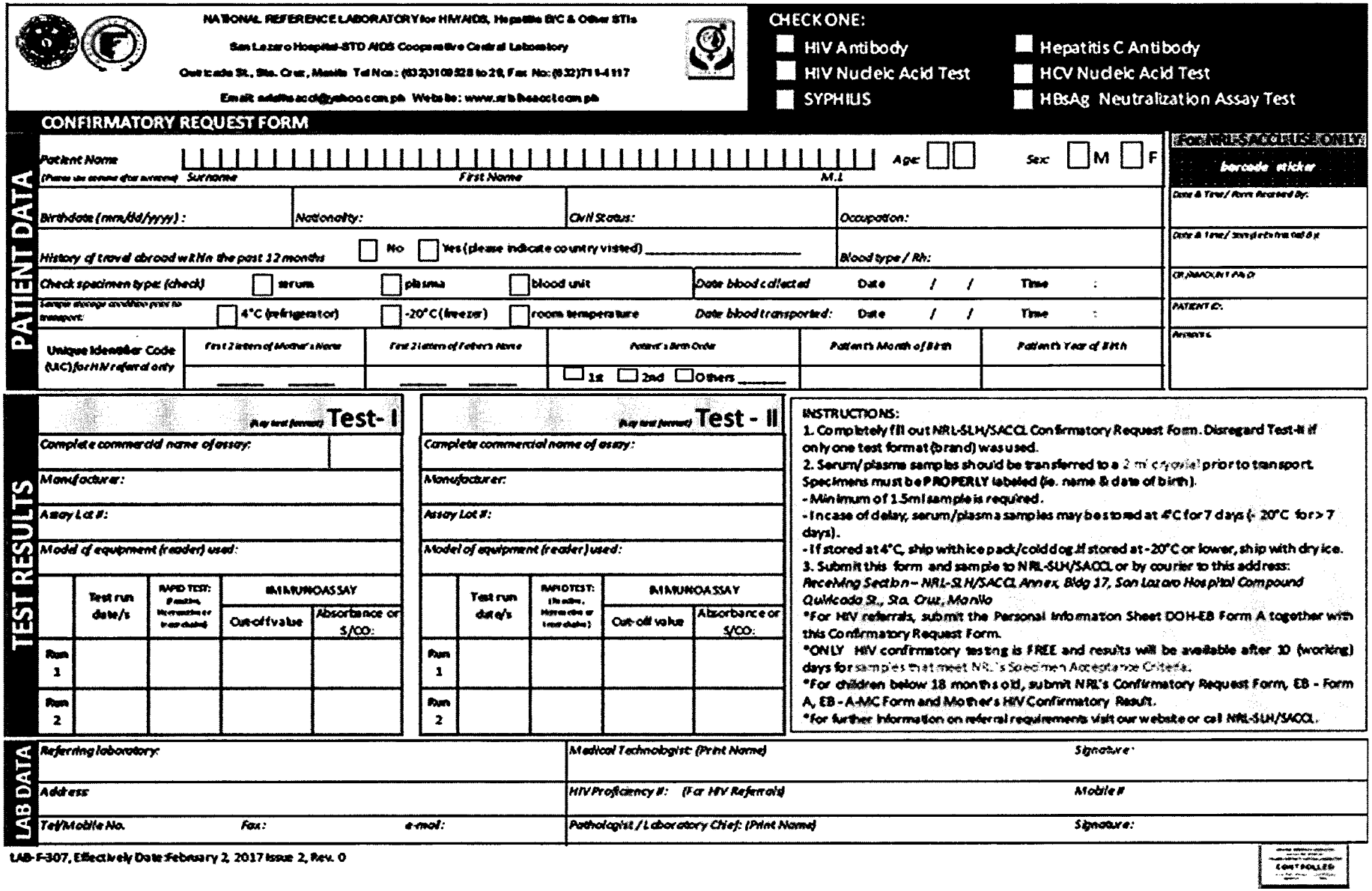
C-9 ☐ PCR 1 Date: ☐☐ Mo - ☐☐ Day - ☐☐☐☐ Year
Result: ☐ Detected ☐ Not detected

C-10 ☐ PCR 2 Date: ☐☐ Mo - ☐☐ Day - ☐☐☐☐ Year
Result: ☐ Detected ☐ Not detected

C-11 ☐ PCR 3 Date: ☐☐ Mo - ☐☐ Day - ☐☐☐☐ Year
Result: ☐ Detected ☐ Not detected

Please send this accomplished form to hivregistry.nec@gmail.com or to National Epidemiology Center - Department of Health, 2/F Rm. 209 Building 19, San Lazaro Compound, Rizal Avenue, Sta. Cruz, 1003 Manila.

## Annex 4. Laboratory Request Form for HIV Testing



NATIONAL REFERENCE LABORATORY for HIV/AIDS, Hepatitis B/C & Other STIs

San Lazaro Hospital-STD AIDS Cooperative Central Laboratory

Quiricada St., Sta. Cruz, Manila Tel Nos.: (632)3109328 to 29, Fax No: (632)711-4117

Email: nrlslhsaccl@yahoo.com.ph Website: www.nrlslhsaccl.com.ph

CHECK ONE:

- ☐ HIV Antibody
- ☐ HIV Nucleic Acid Test
- ☐ SYPHILIS
- ☐ Hepatitis C Antibody
- ☐ HCV Nucleic Acid Test
- ☐ HBsAg Neutralization Assay Test

**CONFIRMATORY REQUEST FORM**

**PATIENT DATA**

Patient Name (Please use surname after surname) Surname / First Name / M.I — Age: ☐☐ Sex: ☐ M ☐ F

Birthdate (mm/dd/yyyy): | Nationality: | Civil Status: | Occupation:

History of travel abroad within the past 12 months: ☐ No ☐ Yes (please indicate country visited) _____ | Blood type / Rh:

Check specimen type: (check) ☐ serum ☐ plasma ☐ blood unit | Date blood collected: Date / / Time :

Sample storage condition prior to transport: ☐ 4°C (refrigerator) ☐ -20°C (freezer) ☐ room temperature | Date blood transported: Date / / Time :

| Unique Identifier Code (UIC) for HIV referral only | First 2 letters of Mother's Name | First 2 letters of Father's Name | Patient's Birth Order | Patient's Month of Birth | Patient's Year of Birth |
|---|---|---|---|---|---|
| | _____ _____ | _____ _____ | ☐ 1st ☐ 2nd ☐ Others _____ | | |

FOR NRL-SLH/SACCL USE ONLY

barcode sticker

Date & Time/ Form Received By:

Date & Time/ Sample Received by:

OR NUMBER PAID

PATIENT ID:

REMARKS

**TEST RESULTS**

(Kit/ test format) **Test- I**

Complete commercial name of assay:

Manufacturer:

Assay Lot #:

Model of equipment (reader) used:

| | Test run date/s | RAPID TEST: (Reactive, Non-reactive or Invalid/Indet) | IMMUNOASSAY: Cut-off value | IMMUNOASSAY: Absorbance or S/CO: |
|---|---|---|---|---|
| Run 1 | | | | |
| Run 2 | | | | |

(Kit/ test format) **Test - II**

Complete commercial name of assay:

Manufacturer:

Assay Lot #:

Model of equipment (reader) used:

| | Test run date/s | RAPID TEST: (Reactive, Non-reactive or Invalid/Indet) | IMMUNOASSAY: Cut-off value | IMMUNOASSAY: Absorbance or S/CO: |
|---|---|---|---|---|
| Run 1 | | | | |
| Run 2 | | | | |

INSTRUCTIONS:

1. Completely fill out NRL-SLH/SACCL Confirmatory Request Form. Disregard Test-II if only one test format (brand) was used.
2. Serum/ plasma samples should be transferred to a 2 ml cryovial prior to transport. Specimens must be PROPERLY labeled (ie. name & date of birth).
   - Minimum of 1.5ml sample is required.
   - In case of delay, serum/plasma samples may be stored at 4°C for 7 days (- 20°C for > 7 days).
   - If stored at 4°C, ship with ice pack/cold dog. If stored at -20°C or lower, ship with dry ice.
3. Submit this form and sample to NRL-SLH/SACCL or by courier to this address: *Receiving Section – NRL-SLH/SACCL Annex, Bldg 17, San Lazaro Hospital Compound Quiricada St., Sta. Cruz, Manila*

*For HIV referrals, submit the Personal Information Sheet DOH-EB Form A together with this Confirmatory Request Form.

*ONLY HIV confirmatory testing is FREE and results will be available after 10 (working) days for samples that meet NRL's Specimen Acceptance Criteria.

*For children below 18 months old, submit NRL's Confirmatory Request Form, EB - Form A, EB - A-MC Form and Mother's HIV Confirmatory Result.

*for further information on referral requirements visit our website or call NRL-SLH/SACCL.

**LAB DATA**

Referring laboratory: | Medical Technologist: (Print Name) | Signature:

Address: | HIV Proficiency #: (For HIV Referrals) | Mobile #

Tel/Mobile No. | Fax: | e-mail: | Pathologist / Laboratory Chief: (Print Name) | Signature:

LAB-F-307, Effectively Date: February 2, 2017 Issue 2, Rev. 0

CONTROLLED