

#### Republic of the Philippines Department of Health

#### OFFICE OF THE SECRETARY

SEP 15 2017

ADMINISTRATIVE ORDER No. 2017- 0019

**SUBJECT:** 

**Policies** and Guidelines in the Conduct Immunodeficiency Virus (HIV) Testing Services (HTS) in Health Facilities.

#### I. **RATIONALE**

Since 1984, over 39,622 cases of Human Immunodeficiency Virus (HIV) infections have been reported in Philippines. Eighty-five percent (85%) of the total cases (33, 607) were reported in the past five years, from January 2011 to December 2016 (Epidemiology Bureau, HIV, AIDS and ART Registry of the Philippines, 2016.). The unprecedented increase in incidence prompted the Department of Health (DOH) to intensify its prevention and control initiatives in key populations and vulnerable groups by including HIV as one of the 12 Legacy Agenda under the current DOH administration.

The Sixth AIDS Medium Term Plan (2017-2022) recognized HIV counseling and testing strategy as one of the preventive interventions for key populations at risk. HIV testing is being promoted to the key populations because through this intervention, those who have HIV risks are given the opportunity to know their HIV status, and at the same time are provided with information on risk reduction strategies and referred to relevant support facilities. Providing counseling prior to and after HIV testing is mandated by Republic Act No. 8504, "AIDS Prevention and Control Act of 1998".

The policy on HIV Counseling and Testing is updated in order to provide quality standards in the conduct of HIV testing services consistent with the 2015 WHO Consolidated Guidelines on HIV Testing Services. This is also to ensure wider access to HIV treatment in the country.

#### II. **OBJECTIVES**

#### A. General:

To provide policies and guidelines in the conduct of HIV Testing Services (HTS) in health facilities.

#### **B.** Specific Objectives:

- 1. To identify the components of HTS and the protocol for each of them;
- 2. To set the standards/requirements for an HTS facility;
- 3. To define the roles and responsibilities of stakeholders in the implementation of these guidelines.

#### III. SCOPE AND COVERAGE

These guidelines cover all STI and HIV service providers, coordinators, managers of HIV clinics and/or testing laboratories, and all facilities offering HIV testing for diagnostic purposes, in both public and private settings. These guidelines do not include HIV testing for purposes of surveillance, blood donation and research-related activities.

#### IV. DEFINITION OF TERMS

- 1. Community-based HIV screening (CBS) Non-laboratory rapid HIV screening procedure done outside a health facility by a trained member of community-based organizations or groups.
- 2. Confidentiality an ethical duty that maintains the privacy of any personal information revealed during the entire process of HIV Testing Services.
- 3. Confirmed HIV positive test result a series of reactive test using rapid HIV diagnostic algorithm (rHIVda), or Western Blot or Nucleic Amplification Test (NAT) as performed by the National Reference Laboratory/San Lazaro Hospital STD, AIDS Cooperative Central Laboratory (NRL/SLH SACCL) or any of the DOH certified laboratories.
- 4. **Consent** written informed decision of a person based on full information allowing him/her to undergo HIV testing or a verbal decision to go through screening procedure. The information shall be given by a health care provider or a HIV Counselor.
- 5. **HIV Counselor** A person who conducts counseling for HIV testing. He could be a health care provider or a DOH certified HIV Counselor.
- 6. **HIV Counseling** a confidential interactive communication process between a person and HIV counselor that enables a client to make an informed choice about being tested for HIV and assist a client understand and cope with HIV test result.
- 7. **HIV Screening** a procedure using DOH Food and Drug Administration (FDA)-registered HIV test kits performed through finger-pricking by a trained and supervised healthcare workers and lay person.
- 8. **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.
- 9. **HIV Testing Services (HTS)** full range of services accompanying HIV testing including counseling (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.
- 10. **HIV Testing Services (HTS) facility** any health facility (clinics, hospitals) providing HIV testing services which can be a stand-alone, or incorporated into existing health-care services.
- 11. HIV Treatment hub a hospital with an organized HIV and AIDS Core Team (HACT) that facilitates in-patient and out-patient prevention, treatment, care, and 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.
- 12. **Key Population** members of this population are male who are having sex with male, people in prisons and other closed settings, people who inject drugs, sex workers, and transgender men and women.
- 13. 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.

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- 14. **Quality Assessment** processes undertaken by NRL-SLH/SACCL to monitor, evaluate and document the effectiveness of the QA program of testing laboratories (e.g. EQAS, site visit)
- 15. **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.
- 16. rHIVda (rapid HIV diagnostic algorithm) 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.
- 17. **Primary HIV Care Clinic** a private or public health facility that provides out-patient primary care services to PLHIV including but not limited to HTS, clinical management, patient monitoring, and other care and support services. ARV treatment can also be accessed through these facilities.
- 18. **Social Hygiene Clinics** these are clinics of the local government unit (LGU) that specialized in the management of Sexually Transmitted Infections.

#### V. GENERAL GUIDELINES

- A. Consent for HIV Test: All people receiving HTS shall give written informed consent to be tested and counseled. They shall be informed of the process for HIV test and counseling and of their right to decline.
- **B.** Confidentiality: HTS shall be confidential and client's privacy shall be ensured at all times. The counseling session between the HTS provider and the client, including test results shall not be disclosed to anyone else without the written consent of the person being tested except as stipulated in the RA 8504
- C. Counseling: All HIV testing shall be accompanied by appropriate and high quality counseling. Public and private facilities performing HIV test shall provide pre- and post-HIV test counseling to all clients.
- **D.** Correct Results: There shall be accurate tests and prevention of false positive results through continued adherence to quality standards and procedures.
- E. Connection to Care: All clients shall be linked to prevention, treatment and care services. These services shall include effective and appropriate follow-up, including long-term prevention and treatment support.

#### VI. SPECIFIC GUIDELINES

#### A. Informed Consent

Client's consent must be obtained prior to HIV test in the following forms:

- 1. Verbal consent, from clients 18 years old and above, is adequate only in community-based HIV screening services;
- 2. Written informed consent from the client shall be secured first before proceeding to HIV testing for clients of legal age (see Annex I- A).
- 3. For the following conditions, written consent can be provided by persons aside from the client as provided by Philippine laws (RA 8344, RA 10354):
  - a. For infants/children born to HIV positive mothers, persons below 18 years old needing HIV test, and patients who are comatose or mentally incapacitated, consent for HIV test shall be provided by the nearest of kin;
  - b. In addressing serious cases, as defined in RA 8344, that deem HIV test to be a crucial diagnostic test to proceed with clinical management, consent for HIV test can be provided by a licensed social worker for minors, mentally incapacitated,

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and comatose patients only if consent from parents or nearest of kin cannot be obtained, in accordance with the provisions of RA 10354, section 23.

#### **B.** HIV Screening

- 1. HIV screening procedure shall only be regarded as an additional HIV risk screening tool and shall not be considered as first test in the diagnostic algorithm.
- 2. Health care workers (doctors, nurses, medical technologists, midwives) are allowed to perform the procedure.
- 3. Community-based HIV screening, with linkage to prevention, treatment and care, shall be offered to key populations. Trained and supervised lay providers can independently conduct safe and effective HIV screening using rapid diagnostic kits.

#### C. Pre-HIV Test Counseling

- 1. Confidentiality of all data to be gathered from the client shall be emphasized.
- 2. The HIV Counselor shall provide the following information to the client:
  - a. For provider initiated testing, HIV and its relationship with client's current health condition (i.e. STI, Tuberculosis, Hepatitis B and C, and pregnancy) and the benefit of knowing one's HIV status;
  - b. Flow of the HIV test procedures in the clinic.
- 3. The client shall be given chance to express any other concern or needs in relation to HIV and test procedures.
- 4. The HIV Counselor shall review/validate the information provided in the DOH EB Form A / A-MC (see Annex II).
- 5. If necessary, the HIV Counselor shall assist the client in the completion of information in the DOH EB Form A / A-MC.
- 6. The client shall be asked to sign the consent for HIV test.
- 7. The Counselor shall log the information needed in the HTS daily registry, and individual client record (See Annex III and IV respectively).
- 8. The Counselor shall accompany the client to the laboratory for testing.

#### D. Conduct of HIV Testing

All HTS facilities shall adhere to the operational requirements as stated in Annex V and HIV testing standard criteria for laboratories set by NRL-SLH/SACCL (see Annex VI).

- 1. HIV testing shall be routinely offered, prioritized for and promoted to the following:
  - a. Key populations including adolescents
  - b. High risk individuals who have not been tested recently
  - c. Partners, infants and children of PLHIV
  - d. Patients showing signs and symptoms consistent with AIDS defining illness
  - e. Patients with Sexually Transmitted Infections
  - f. Patients with Hepatitis B and C
  - g. Patients with under nutrition not responsive to interventions
  - h. All confirmed tuberculosis patients
  - i. All pregnant women regardless of risk
- 2. HIV testing **shall** be provided to any client who go to the HTS facility with expressed intention or need to undergo the test.
- 3. Only a registered medical technologist with HIV proficiency training certificate shall perform the HIV test procedure using DOH Food and Drug Administration (FDA)-registered test kits. Reactive blood samples from the populations shall be

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sent to NRL-SLH/SACCL or its designated and certified confirmatory rapid HIV diagnostic algorithm (rHIVda) facility sites.

#### 3. Testing procedures

- a. The HIV Counselor shall endorse the client for testing to a licensed and HIV proficient medical technologist and shall submit the DOH-EB Form A / A-MC.
- b. The HIV proficient medical technologist shall ensure that EB Form A / A-MC was properly filled out and signed by the client before performing blood extraction.
- c. The HIV proficient medical technologist shall ensure that HIV testing is performed according to the work instruction or standard procedure.
- d. Alternatively, a nurse phlebotomist may extract blood from the client and shall endorse the specimen to the HIV proficient medical technologist for testing. Nurse phlebotomists are required to undergo training in specimen handling to prevent mislabeling, losing specimens, and other pre-analytical errors.
- e. If the result is nonreactive, the medical technologist and supervising Pathologist or physician shall provide validated official laboratory result to the HIV Counselor or requesting physician for post-HIV test counseling.
- f. If the result is reactive, the medical technologist shall repeat the test on the same blood sample, then send the specimen to NRL-SLH/SACCL or its designated confirmatory rHIVda laboratory for confirmatory testing (see Annex VII Confirmatory Request Form). The reactive specimen must be refrigerated and sent within one week of extraction. However, if the reactive test is done in a confirmatory rHIVda site, then the medical technologist shall proceed to performing the confirmatory rHIVda.
- g. The medical technologist shall maintain a log of all necessary client information including the HIV test result before releasing the result to the HIV Counselor or requesting physician for post-HIV test counseling.

#### E. Post-HIV Test Counseling

- 1. Post HIV Test Counseling: Non-Reactive Result
  - a. The HIV Counselor shall do the following:
    - i. Provide the client an official copy of the HIV nonreactive test result signed by an HIV-proficient medical technologist who performed the test and validated by a pathologist. For Social Hygiene Clinics and TB DOTS facilities without a pathologist, the supervising physician shall review, validate and countersign;
    - ii. Explain that the client may either be non-infected or may have been infected from the most recent exposure but his/her body has not produced sufficient level of antibodies that can be detected by the HIV test kit;
    - iii. Check for the latest or ongoing significant risk. If the client reports of a major significant risk, the Counselor shall:
      - a) Emphasize the importance of knowing the HIV status of sexual partner(s). Counselor shall recommend for the sexual partner(s) to undergo HIV testing.
      - b) Facilitate risk reduction planning, discuss prevention of HIV infection, and the importance of maintaining an HIV negative status;
      - c) Offer retesting after 6 weeks from the last HIV test result;
      - d) Refer the client for continuous support, STI & HIV prevention services and other appropriate services from partner community-based organizations. Provide a referral letter (see Annex I-B).

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b. After post-HIV test counseling, clients shall be requested to complete the Client Satisfaction Form (HTS Client Satisfaction Survey Form - Annex I-D).

#### 2. Post - HIV Test Counseling: Reactive Result

No written reactive HIV test results shall be released to clients. Reactive blood samples shall be sent for confirmatory testing to NRL-SLH / SACCL or its designated Confirmatory rHIVda site.

- a. Clients shall be verbally informed of the HIV reactive test result.
- b. Clients shall be appropriately linked to care.
- c. The HIV Counselor shall perform the following:
  - i. Explain to the client that a reactive result means possible HIV infection and the blood sample will be submitted for confirmatory testing. Provide ample time to allow him/her to absorb the information and/or to ask questions for clarifications or further information.
  - ii. Facilitate risk reduction planning and discuss prevention of multiple HIV infection and other STI including Hepatitis B and C. Condoms and lubricants are provided along with information on their correct use;
  - iii. Emphasize the importance of knowing the HIV status of sexual partner(s). Counselor shall recommend for the sexual partner(s) to undergo HIV testing.
  - iv. Advise the client/facilitate screening for TB, Hepatitis B and C, Syphilis and other STI.
  - v. Emphasize the importance of early assessment by a treatment hub physician and provide a referral letter for the client to be linked to a treatment hub or primary HIV care facility chosen by the client.
  - vi. Coordinate with a treatment hub or primary HIV care clinic and ensure that the client will be seen by the physician for further assessment and clinical management.
- d. The receiving treatment hub or primary HIV care clinic provides feedback to the referring HTS facility once the client has reached its facility.

#### Post HIV-Test Counseling: Positive Confirmatory Result

All official confirmatory test results shall ONLY be released to the referring facility by the NRL-SLH/SACCL or by its designated certified Confirmatory rHIVda testing sites. This is to ensure that the release of HIV confirmatory test is accompanied by a post-test Everyone who is diagnosed HIV-positive should receive post-test counseling, including couples where one or both are diagnosed HIV-positive after the PLHIV has disclosed his/her HIV status to the intimate partner.

The NRL-SLH/SACCL and confirmatory rHIVda testing facilities are required to report HIV positive results to the Epidemiology Bureau of the Department of Health.

a. It is an ethical obligation of the HIV Counselor to check the test result if it is consistent with the label on the envelope and with that of the identified client. Upon verification of the result, the HIV Counselor, as previously consented during pretest counseling, shall contact the client for post-HIV test counseling and release of confirmatory test result.

b. During post-HIV test counseling, the HIV Counselor shall release the official copy of the confirmatory test result informing the client of the result simply, clearly, and in an objective manner, and provide ample time to allow him/her to absorb the information. MM \$

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- c. The HIV Counselor shall do the following:
  - i. Help the client cope with emotions arising from the test result;
  - ii. Address significant concerns and assist the client to identify who in her/his network may be available and acceptable to offer immediate support;
  - iii. Reinforce risk reduction planning and other procedures found in sections 2.c.ii iv of Post HIV-Test Counseling: reactive result (see page 6);
  - iv. Discuss importance of disclosure of her/his HIV status to partner(s), family member(s) and/or significant other(s). Help the client in a decision making process to facilitate disclosure by presenting different strategies to do so.
  - v. Encourage and offer referral for counseling and testing of partners and children;
  - vi. Assess the risk of violence or suicide and discuss possible steps to ensure the physical safety of the client;
  - vii. Inform the client of the importance of /or offer early treatment in maintaining health and transmission prevention and management of possible opportunistic infections:
  - viii. Provide the client a referral letter (see Annex I-B) and ensure that the client shall be linked to the treatment hub or primary HIV care clinic of his/her choice for access of antiretroviral therapy, management of possible opportunistic infections, care and support services.

#### 4. Post HIV-Test Counseling: Negative Confirmatory Result

- a. It is an ethical obligation of the HIV Counselor to check the test result if it is consistent with the label on the envelope and with that of the identified client. Upon verification of the result, the HIV Counselor, as previously consented during pretest counseling, shall contact the client for post-HIV test counseling and release of confirmatory test result.
- b. The HIV Counselor shall release the official copy of the confirmatory test result informing the client of the result simply, clearly, and in an objective manner.
- c. Follow section E.1 under Post-HIV Test Counseling: Non-Reactive Result (see page 5).
- d. The sending laboratory shall perform the recommendations of the national reference laboratory as indicated in the confirmatory result, if there is any.

#### 5. Indeterminate results or Inconclusive results

In cases that NRL-SLH/SACCL will release such test result to the sending laboratory, the latter shall perform the recommendations of the national reference laboratory as indicated in the confirmatory result. NO RESULT shall be released to the client at this point. The laboratory should get a fresh plasma sample from the client and send to NRL-SLH/SACCL for further tests.

#### F. Connection to Care

#### 1. Clients with reactive result

a. The treatment hub or primary HIV care clinic who receives referred clients with initial reactive result shall repeat HIV screening for the purpose of validating client's initial HIV test result. Specimen should not be sent to NRL-SLH / SACCL for confirmatory testing.

b. The treatment hub or primary HIV care clinic physician shall assess and manage the clients according to the Enhancing Linkage to Care of PLHIV (DC 2016-0171).

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#### 2. Clients with confirmed positive HIV test result

- a. All clients diagnosed with HIV shall be managed in accordance to the Treatment Guidelines of the Department of Health.
- b. The treatment hub or primary HIV care clinic who receives clients with confirmed positive result may repeat HIV screening if deemed necessary before initiating ART.



C. B. All clients diagnosed with HIV shall be linked to prevention, treatment and care services, which include effective and appropriate follow-up, including continuous adherence counseling once enrolled to lifelong treatment

#### G. Retesting

Frequency of retesting shall be recommended to the following:

Population	Frequency
1. Key populations	Every 3 months
2. Pregnant women who belong to key populations or a partner of a PLHIV	1 <sup>st</sup> trimester, 2 <sup>nd</sup> trimester, 3 <sup>rd</sup> trimester, and at least once while breastfeeding
3. Casual or intimate partners of key populations or PLHIV	Annual

#### H. MONITORING AND EVALUATION

All HTS facility shall maintain daily client registry and monthly monitoring report (see Annex III and VIII for the reporting forms). These should be submitted to LGU NASPCP coordinator. The programmatic evaluation of HTS will be covered by the annual Monitoring and Evaluation Plan for the Philippine Health Sector's Strategic Plan for HIV.

All HIV testing laboratories shall be subjected to regular quality assessment and evaluation in compliance to quality management system implementation.

#### I. ROLES AND RESPONSIBILITIES

#### 1. Disease Prevention and Control Bureau shall:

- a. Formulate plans and policies in the improvement of HTS strategy
- b. Review the HTS training programs relative to the implementation of this policy
- c. Develop Operations Guidelines on Community-Based HIV Screening.

#### 2. Epidemiology Bureau (EB) shall:

- a. Maintain and update HIV/AIDS and ART Registry of the Philippines.
- b. Collect required data from sites and provide the status of outcomes of HTS
- c. Provide quarterly updates on the surveillance of HIV/AIDS to National HIV, AIDS and STI Prevention and Control Program (NASPCP).

#### 3. DOH - Regional Offices (DOH-RO) shall:

- a. Advocate the setting up of HTS facilities in local government units
- b. Conduct monitoring and evaluation activities on HTS
- c. Manage HTS related commodities
- d. Facilitate capability-building activities regarding HTS
- e. Strengthen the service delivery network for HTS and regularly update its directory
- f. Ensure testing sites' compliance to certification, licensing and accreditation (laboratories, clinical facilities)
- g. Monitor and supervise implementation of HTS.

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#### 4. NRL-SLH / SACCL shall:

- a. Develop accreditation criteria on HIV confirmatory testing for other agencies
- b. Set-up sub-national referral centers for HIV confirmatory tests
- c. Conduct regular review of the national testing algorithm
- d. Mentor HIV testing facilities on the development of site standard operating procedures (SOP) and job aids
- e. Train clinic physicians on monitoring HIV laboratory procedures while pathologists are still being hired.

#### 5. rHIVda sites shall:

- a. Implement the rHIVda and HTS guidelines accordingly
- b. Comply with the requirements set by NRL-SACCL as stated in the guidelines on the implementation of the rHIVda.
- c. Develop and maintain effective documented SOPs
- d. Maintain close collaboration with NASPCP, EB, Treatment Hubs, Primary HIV care facilities, LGU and NRL-SLH/SACCL in order to promote an overall efficient management system.

#### 6. HIV treatment hubs and DOH hospitals shall:

- a. Integrate HTS in all relevant departments through the coordinative function of HIV and AIDS Core Teams
- b. Provide necessary data to EB for the monitoring of HIV cascade indicators, HTS, etc.

#### 7. Local Government Units shall:

- a. Institutionalize the implementation of the guidelines through a local resolution by the local health board or as may be appropriate;
- b. Implement/conduct HTS in various departments of hospitals, Social Hygiene Clinic, and primary HIV care clinics and other HIV testing facilities;
- c. Ensure that HIV policies are implemented in every workplace, both private and public, within their area of responsibility.
- d. Ensure that infrastructures of the facilities implementing HTS are fully functional
- e. Promote adherence to SOPs at all levels of service providers;
- f. Support implementation of quality control and participate in External Quality Assurance Scheme;
- g. Ensure sufficient test kits and supplies for HTS implementation;
- h. Monitor and evaluate HTS implementation.

# 8. Non-Government/Community-based/Civil Society Organizations are encouraged to:

- a. Assist in the dissemination of this policy through training education and advocacy
- b. Ensure linkage to HTS facility and facilitate client referral and feedback
- c. Provide feedback to NASPCP on the quality of HTS
- d. Coordinate and collaborate on community-based HIV screening implementation.

#### 9. WHO/UNICEF and other bilateral partners are encouraged to:

- a. Provide technical support in ensuring coordinated strategies in HTS implementation
- b. Assist in monitoring and evaluation and provide recommendation.

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#### J. FUNDING

The Disease Prevention and Control Bureau - National HIV, AIDS, and STI Prevention and Control Program shall allocate budget for the implementation of these policies and guidelines including procurement of HIV test kits and funds for monitoring and supervision activities. Other DOH Offices and DOH hospitals shall support financially, as part of their annual budget, the implementation of these policies and guidelines in their respective regions/institutions.

## VII. REPEALING CLAUSE

Administrative Order 2010-0028 entitled "Policies and Guidelines in the Conduct of Human Immunodeficiency Virus (HIV) Counseling and Testing in Community and Health Facility Settings" is hereby repealed.

#### VIII. EFFECTIVITY

This Administrative Order shall take effect immediately.

PAULYN JEAN B. ROSELL-UBIAL, MD, MPH, CESO II

Secretary of Health

## **Annex I-A HTS Counselling Form**



### National HIV, AIDS & STI Prevention and Control Program HIV Testing Services (HTS) Form 1 HIV Test Counseling Form

Clients Name:	Clients Name:			
UIC:		e, two-digit birth		D-YYYY)
PRE-TEST counselling interventions: Date of Pretest Counseling:			Client's C	Contact Details:
Confidentiality and privacy offered to the clie Basic information about HIV Basic information about the test and result p Any other special needs expressed by the cl Informed consent to undergo HIV test obtain Others:	provision procedu i <b>ent</b> ned	ure	of communication p me when my test re Phone no: Email add.:	ounsellor to use all means orovided here to contact esult is available.
	Informed	Consent		
I was given information about HIV, process and was given the opportuquestions.  I agree to undergo HIV Testing.	HIV testing	Client's Sig Client's Na		
ragice to undergo my resting.		Date:	$\frac{1}{\sqrt{D}} \frac{1}{\sqrt{Y}} \frac{1}{\sqrt{Y}$	
POST TEST Counselling: It is an ethical obligation envelope and with that of the identified client before given Please check the box if the following are perfo	ving the official co	elor to check the	e test result if it is consist esult.	ent with the label on the
For <u>NEGATIVE</u> Screening / Confir	matory Test		Schedu	le for Retest
Latest or ongoing significant risk Risk reduction planning Condoms and lubricants Referral for continuous support, STI & HIV pro	evention services	s	Annual After six (6) weeks Others:	Date (mm/dd/yy):///
HIV Screening REACTIVE			HIV POSITIVE	
Risk reduction planning STI, Hep B, HIV prevention messages Condoms and lubricants Referral to treatment hub for early assessment  Remarks (use back side for additional notes):	Assessment for risk for suicide / self-harm / violence to others Immediate support for client Risk reduction planning STI, Hep B, HIV prevention messages Condoms and lubricants ART Initiation, OI management Disclosure to partner(s)/family Partner(s) / children for HIV Testing Other Referral needs Consent for Release of Information Other Interventions:			
Name & Signature of Counselor:				/ /
Name of Facility:			1	$\overline{M}$ $\overline{M}$ $\overline{D}$ $\overline{D}$ $\overline{D}$ $\overline{Y}$ $\overline{Y}$ $\overline{Y}$

### **Annex I-B. HTS Client Referral Form**



# National HIV, AIDS & STI Prevention and Control Program HIV Testing Services (HTS) Form 2 HTS Client Referral Form

rev. April 7, 2017

MENT	HTS Client Referral Form	1ev. April 7, 20
Client's Name:	Date of Referral:	
Referred by:		
Sending Facility:		
Referred to:	Contact No.:	
Receiving Facility:	Address:	
Dear		
	t who has received confidential HIV Testing Services in our HTS fa	acility for the
(Please check as necessary)	Specific Details	
Medical Management		
Surgical Management		
Laboratory Services		
Psychological / Psychiatric		
services		
Financial support /		
Livelihood assistance  Psychosocial support / care group		
DSWD services		
Temporary Shelter		
Legal assistance		
Others		
REMARKS:		
If you have any questions or concerns on this accommodated. Thank you very much.	s referral, please do not hesitate to contact us. Kindly inform us once	e the client is
Respectfully yours,		
(printed name over signature)		
	ACTIONS TAKEN (To be returned to Referring Facility)	
	(To be returned to Kererring Facility)	
Special Instructions (If any):		_
If you have any questions or concerns, please do	not hesitate to contact us.	
Staff Name and Signature	Contact Number	
Date///		
(M M / D D / Y Y)	Address	

# Annex I -C. HTS Consent for Release of Information



# National HIV, AIDS & STI Prevention and Control Program HIV Testing Services (HTS) Form 3 Consent for Release of Information

Client Details		
Name :		UIC:
Contact Details:		Date of Birth:
UIC: First two letters of moth	er's name, first two letters of father's n	ame, two-digit birth order, birthdate (MM-DD-YYYY)
Consent for Release of Inf		
After being made aware	of the health care services that	I need that can be provided by another facility and the
necessary referral proc	ess, I,	
,		(Name of Client / Parent / Guardian)
years old, f	reely give my consent to	
(Age)	- · ·	(Name of Counselor / Attending Physician)
	(C. 1)	to release the following information:
	(Sending Facility)	•
HIV Test Result	Medical Abstract	Summary of issues and concerns disclosed during counseling sessions
Contact Details	Others:	
he above specified informati	ion will be released to:	(Receiving Physician / Personnel)
	(Receiving Facility)	·
understand that I can withdr		my confidential information at any time.
(Client's Signature)	·	IMin and C
Date://		(Witness' Signature over Printed Name)
(M M/DD/YY)		Date: / / / / / / / /
Vithdrawal of Consent		
hereby withdraw the consen- pecified information.	t given to above mentioned counse	lor / attending physician to release the details of the previously
		·
(Client's Signature)		(Witness' Signature over printed name)
ate:/// (M_M/D_D/Y_Y)		Date:///
, ,		\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\

# Annex I-D. HTS Client Satisfaction Survey Form



#### National HIV, AIDS & STI Prevention and Control Program HIV Testing Services (HTS) Form 4 Client Satisfaction Survey

(Please check one)	Strongly Disagree	Disagree	Agree	Strongly Agree
The staff are friendly and				
supportive				
The staff / counselor took time				
to explain the processfor the				
service/s I needed				
The counselor made me				
comfortable to ask questions				
The counseling session had a				
relaxed and safe atmosphere				
I was satisfied to the services				
provided				
I will come back to this facility				
for another counseling session /				
other services				
Remarks:				

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in the Philippine planning activiti	nt of Health (DOH) has an existing program for the prevention and control of the Human Immunodeficiency Virus es. The Epidemiology Bureau (EB) of DOH is mandated by Republic Act 8504 to collect information that will be u les to help stop the spread of HIV and to support and treat those diagnosed to have HIV. Your full cooperation is s program. Please answer all questions as honestly as possible.	used in
ABOUT THE T	EST	
If the first test (	testing? 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 screening) is reactive, another test (confirmatory) will be done to make sure that the first test is confirmed to be positive. A polynome been infected with HIV, a negative test means you are probably not infected because it takes time for the body to propose think you have been exposed recently, you need to be re-tested after 6 weeks to make sure you are not infected.	sitive
	IIV testing test is voluntary. Under Republic Act 8504, you cannot be tested without your knowledge and consent. If you do not want te the right to refuse the test.	to be
	lity of Test Results t 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.

MI I	PERSONAL INFORMATION SHEET (FORM A)  Information given will be STRICTLY CONFIDENTIAL. Please fill out this form COMPLETELY and as honestly as possible
	se write in CAPITAL LETTERS and CHECK the appropriate boxes.
	DEMOGRAPHIC DATA
1	PhilHealth Number: - Not enrolled in PhilHealth
	Name (Full name)
2	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: Age in months (for less than 1 year old):
5	Sex (at birth):
	Current Place of Residence: City/Municipality: Province:
6	Permanent Residence: City/Municipality: Province:
	Place of Birth: City/Municipality: Province:
7	Nationality: ☐ Filipino ☐ Other, please specify:
8	Highest Educational Attainment:
•	☐ Elementary ☐ College ☐ Post-Graduate
9	Civil Status: Single Married Separated Widowed
10	Are you currently living with a partner?
11	Are you currently pregnant? (if female only)
	OCCUPATION
12	Current Occupation (please specify main source of income):  If no current work, please specify previous occupation:
13	Currently in school? ☐ No ☐ Yes; please indicate level: ☐ High school ☐ Vocational ☐ Other ☐ College ☐ Post-graduate
	Did you work overseas/abroad in the past 5 years?   No Yes  If yes, when did you return from your last contract?
14	Year
	Where were you based? ☐ On a ship ☐ Land
	What country did you last work in?

# Annex III. HTS Daily Client Registry

			. :		HIV Testing Services Daily Re	gistry	· ·				
			-	Name o	f Institution:			<del></del>			
Date of Consult	Name	Age	Gender	Date of	Address / Contact Information	Type of Client	Pre-test Counselling (Y/N)	Tested	HIV Test Result (N/R)	Post-test Counselling and HIV result(Y/N)	Date of Follow up
	<u></u>			<u> </u>							
		-						:			
				-		<del></del>					
-											
				-							
						-					

## Annex IV - Individual Client Record Form

	First	: Name:	Mid	dle Initial:	DATE o	f Visit:		
ge: Birthday:								
ome Address:								
lace/ Address of Wo								
HIEF COMPLAINT: _								
Purpose of visit:	( )Routine ch ( )Referred fi	eck-up ( om other facilit	) STI S/Sx cy: specify	( ) HIV testi	ng ( ()Othe	Contact of	STI/HIV cas	e
SIGNS / SYMPTOMS	C if propert /Dis	Charle ( () :			:£	11		
Vaginal Urethral		enital Dysuria		Genital	Scrotal	Lower	Vaginal	Others,
Discharge Discharge	,	ster	rash	itching	swelling/ pain	Abdominal pain	bleeding	specify
						<u> </u>		
PAST HISTORY OF STI	s and other Gen	ital Tract Infect	ions: (past 3 m	onths)				
SEXUAL HISTORY (pas								
						c sexuel coll		
	f partners:							
Sexua	ol activity (check a	il that apply):	( ) Oral	( ) Vagi	nal ()	Anal	( ) Other	s
MENSTRUAL HISTORY	r: Age at menar	che:	LMP:		Interval: _		Duration:	
OB-GYNE HISTORY:								
AMILY PLANNING M								
PHYSICAL EXAMINAT		r ( ) DIVIFA	( )	/ Condoni	( ) NFP	( ) 101	) ( ) Otr	iers:
/ital signs:	B.D.	uр	DD	Tamm	147	-(1\	LIT	
yes :	( ) Pallor	HR ( ) lcteresia	( ) Discharg	e ()Redn	VV	Others sne	nı	-
Dropharynx:	( ) Redness	( ) Swelling	( ) Ulcer	( ) Exud	ates (	Others, spe	cify:	
Neck:		( ) Lymphad		, ,			,.	
kin :		ify				Others		
ungs:		s: ( ) Clear		( ) Wh	eezes			
leart:		( ) Irregular						
Abdomen: nguinal Nodes:		s ()R		ness	( ) Mass	( ) Oti	ners	
_		ss ()E						
Male Genital Exam:	( ) Lice	( ) Rash	( ) Blisters	( ) Ulce	r ()	Warts	() Mass	
	( ) Urethral d	_	( ) Tendern	ess				
emale Genital Exam:	External:	( ) Lice	( ) Rash	( ) Red	ness ( )	Ulcer	( ) Blister	
		( ) Wart	( ) Swelling	( ) Mass	s ()	Abnormal [	Discharge	
	Vaginal wall:	( ) Abnorma	discharge	( ) Foul-	smell ( )	Wart		
		( ) Bleeds ea					( )Others	(specify
								,-,- 35117
		( ) Enlarged			- 1			
	Pelvic Exam:	( ) Enlarged						
Anus/Pactum	Pelvic Exam:	( ) Motion to	enderness			141	/ \ T.	
nus/Rectum :	Pelvic Exam:	( ) Motion to ( ) Redness	enderness ( ) Blisters	( ) Ulce		Wart	( ) Fissure	•
Inus/Rectum :	Pelvic Exam:	( ) Motion to	enderness ( ) Blisters	( ) Ulce		Wart	( ) Fissure	•
	Pelvic Exam:  ( ) Swelling ( ) Discharge	( ) Motion to ( ) Redness ( ) Abcess	enderness ( ) Blisters ( ) Others, s	( ) Ulce				
Anus/Rectum : SPECIMEN COLLECTEI DIAGNOSIS:	Pelvic Exam:  ( ) Swelling ( ) Discharge	( ) Motion to ( ) Redness ( ) Abcess	enderness ( ) Blisters	( ) Ulcer	QUESTED:			

#### Annex V: Operational Requirements for Facility-Based HTS

HIV Testing Services may be stand alone or integrated into existing services of hospitals, social hygiene clinics/reproductive health centers, outpatient clinics, drug treatment and rehabilitation centers, family planning clinics, health centers, and a diverse range of health outreach or community-based programs

#### 1. Human Resources

- a. Trained HIV Counselor
  - The HIV counselor always introduces him/herself and the purpose of the activity
  - The counselor who provided the pre-test counseling ideally, should also be the same person to provide post-test counseling.
- b. HIV proficient medical technologist
- c. Licensed Pathologist or a NRL-SLH/SACCL trained clinic physician on monitoring quality HIV laboratory management

#### 2. Structural requirements

- a. HIV testing and counseling rooms should well be ventilated, with adequate lighting and privacy (i.e., discussions within the room should not be discernibly overheard from the outside or the adjoining rooms) to ensure confidentiality.
- b. Counseling rooms should have a minimum of two chairs, at arms' length to create an informal, relaxed environment for HIV counseling and testing.
- c. Directory of partners and services should be updated twice a year.

#### 3. Quality Requirements

- a. Test kits to be used shall be FDA-registered.
- b. The blood extraction place shall be well lit, standard precaution, proper waste segregation and disposal must be observed
- c. Maintenance of Daily HTS Registry, individual counseling form, and eHARP forms
- d. ALL DOH licensed laboratories shall ensure quality management system
- e. Compliant participation to the EQAS conducted by NRL-SLH/SACCL

#### Annex VI. HIV Testing Center Standard Criteria

#### 1.0 MANAGEMENT REQUIREMENTS

- 1.1 Organizational structure headed by a Pathologist \*\*
- 1.2 Legal entity of the Laboratory Facility
- 1.3 Quality policy and Objectives
- 1.4 Quality Management System\*\*\*
  - 1.4.1 Documented Standard Operating Procedures (SOPs)
    - 1.4.1.1 Pre-analytical phase
    - 1.4.1.2 Analytical phase
    - 1.4.1.3 Post-analytical phase
  - 1.4.2 Identification of Non-conformities or Deviations from SOPs
  - 1.4.3 Corrective Actions/ Preventive Actions Procedure
  - 1.4.4 Resolution of Complaints Procedure
  - 1.4.5 Continuing Quality Improvement
  - 1.4.6 Management Review

#### 2.0 TECHNICAL REQUIREMENTS

- 2.1 Personnel Qualifications
  - 2.1.1 Personnel: \*\*\*
    Pathologist: 1\*\*

Chief MT: 1\*\*\*

Designated Proficient Medical Technologists\*\*\*: 1-6 [load-dependent]

Encoder: 1\*\*\*
Lab Aide: 1

- 2.1.2 Trainings\*\*\* / continuing education
- 2.1.3 Competence of staff
- 2.1.4 Staff performance review and evaluation
- 2.2 Laboratory Facility Requirements \*\*\*
  - 2.2.1 Sufficient space at least 20 sq meters
  - 2.2.2 Controlled access to laboratory examination area
  - 2.2.3 Organized laboratory work space
  - 2.2.4 Separate storage space for laboratory stocks and supplies
  - 2.2.5 Well-lighted and ventilated
  - 2.2.6 Sufficient electricity power for equipment and water supply
- 2.3 Laboratory Equipment
  - 2.3.1 Required laboratory equipment in place CD4 machine, Biological refrigerator\*\*\* and freezer, Computer\*\*\*, printer, centrifuge\*\*\*, Autoclave\*\*\*
  - 2.3.2 Record of identity, description, location, performance, maintenance, damages of equipment
  - 2.3.3 Calibration of equipment\*\*\*
  - 2.3.4 Preventive maintenance of equipment and repair if required \*\*\*
- 2.4 Reagents, Consumables & Supplies \*\*\*
  - 2.4.1 Reception and storage
  - 2.4.2 Record and inventory

- 2.5 Pre-Examination Processes and Procedures
  - 2.5.1 Available information for patients, clients and users
  - 2.5.2 Appropriate Laboratory request form\*\*\*
  - 2.5.3 Primary sample collection
  - 2.5.4 Sample transport \*\*\*
  - 2.5.5 Receiving of samples \*\*\*
  - 2.5.6 Pre-examination handling, processing, storage of specimens \*\*\*
  - 2.5.7 Referral system for rHIVda \*\*\*
- 2.6 Examination Processes and Procedures
  - 2.6.1 Documented procedures of all laboratory examinations \*\*\*
  - 2.6.2 Internal Quality controls implementation and data analysis \*\*\*
  - 2.6.3 Documented laboratory performance according to monitored corrective actions
- 2.7 Post-Examination Processes and Procedures
  - 2.7.1 Recording and reporting of results and data output \*\*\*
  - 2.7.2 Confidentiality and security of laboratory results \*\*\*
  - 2.7.3 Laboratory results data include \*\*\*
    Name of Laboratory & logo
    Lab result value and interpretation, method of examination
    Signature of Medical technologist, Chief MT and Pathologist\*\*\*
- 2.8 Proper Pre and Post Test Counseling \*\*\*
- 2.9 Client satisfaction survey\*\*\*
- 2.10 Laboratory data/information management
  - 2.10.1 Record of all data from all stages of laboratory operations\*\*\*

Receiving/collection of specimens

Examination process

Post-examination process

Incident reports/Non-compliances

Survey results

- \*\*\* Required criteria now
- \*\* Physician Certified Training in Laboratory Management Course Others will be required later

# **Annex VII. Confirmatory Request Form**

1		/	NATIONAL RE	NATIONAL REFERENCE LABORATORY for HIVIAIDS, Hepatitis BIC & Other STIS	RATORY IO	r HIVIAIDS	. Hepatitis	BIC & Other	K STI8	C	CHECK ONE:			
5.00			San Lazan	San Lazaro Hospital-STD AIDS Cooperative Central Laboratory	AIDS Coope	rative Cen	frai Laborat	lory		<b>9</b>	HIV Antibody	Hepatitis C Antibody	Antibo	γþ
/		ð	Quiricada St., Sta. Cruz, Maniia Tel Nos: (\$32)\$109528 to 29, Fax No: (\$32)7114117	Cruz Manila Te	I NOB: (532);	3109528 to	29, Fax No.	: (632)711-	4117		HIV Nucleic Acid Test		c Acid	lest
			Email: nrisil	Email: nrisitiesacci@yahoo.com.ph Website: www.nrisitiesacci.com.ph	om.ph We	Delie: ww	v.nrtsiheac.	d.com.ph			SYPHILIS	HBsAg Neu	ıtraliza	HBsAg Neutralization Assay Test
	CONFIRMATORY REQUEST FORM	TORY R	EQUEST FO	RIM										
U	Patient Name (Please we commo after	S (second	Surname			First Name	- ome				First Name Mil.	Sec M	<u>"</u>	For NRL-SACCL USE ONLY
	Birthdate (mm/dd/yyyy) :	: (1111/)pp		Nationality:				Civil Status:	tus:		Occupation:			Date & Time/ Form Received By:
	History of travel abroad within the past 12 months	obroad wi	thin the past 12 i	months	] No [	Yes (plea	Yes (please indicate country visited)	country vi	sited)		Blood type / Rh:			Date & Time/ Sample Extracted By:
洭	Check specimen type: (check)	type: (chec		serum	emseld		- A	blood unit		Date blood collected	Date /	/ Time :	0	OR/AMOUNT PAID:
17	Sample storage condition prior to transport:	don prior to	4°C (refi	4°C (refrigerator)	-20.0	-20°C (freezer)	200	room temperature	ture	Date blood transported:	sported: Date / /	Time ::	2	NTENTIDE
d	Unique Identifier Code	er Code	First 2 letters of Mother's Name	other's Name	First 2 lette	First 2 letters of Fother's Name	Nome		Potent's Birth Order	A Order	Patient's Month of Sirth	Patient's Year of Birth		Senaris:
	(UIC) for HIV referral only	rral only						124	2nd Others	Others			T	
			(Any test	(Any test formet) TeSt-	-				(Any test format	(Any test format) Test - II	INSTRUCTIONS:			
	Complete commercial name of assay:	ercial nam	e of assay:		Š	mplete co	Complete commercial name of assay:	ame of as	soy:		Completely mison interesting about commission weight in each only not test format (brand) was used.     Commission a smaller should be readed to a smal	) was used.	doese ro	m. Disregato rest-ii ii
S	Monufacturer				¥	Monufacturer	2				Section by passing samples should be uninstelled to a 2 ml cryonal appropriate must be PROPERLY labeled (ie. name & date of birth).  Micromomo of 4 cml remains in required.	ILY labeled (ie. name & dat	te of bird	nei prior to transport.
111	Assay Lot #:				<del> </del>	Assay Lot #:					- In case of delay, serum/plasma samples may be stored at 4°C for 7 days (- 20°C for > 7 days)	isma samples may be store	ed at 4°C	for 7 days (- 20°C for > 7
B	Model of equipment (reader) used:	nent (reads	er) used:		18	del of equ	Model of equipment (reader) used:	oder) uses	+		of 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 NRI-SHASACCI or by courier to this address:	ce pack/cold dog.if stored in mole to NRI-SLH/SACCI or	at -20°C	or lower, ship with dry ice.
1	Test run	RAVIO TEST.		IMMUNOASSAY		Test run	-	PAMPO TEST:	IMMI	MMUNOASSAY	Receiving Section – NRL-SLH/SACCL Annex, Bldg 17, San Lazaro Hospital Compound Outlineads St. Sto. Cruz. Manija	/SACCL Annex, Bldg 17, Sar	n Lazaro	Hospital Compound
<b>S3</b>	date/s	Nonactus or Incatclastwi	owe Cut-off value	lue Absorbance or 5/CO:	ا ا ا	date/s		8 8	Cut-off value	Absorbance or S/CO:	*For HIV referrals, submit the Pethis Confirmatory Request Form.	the Personal Information 5	Sheet DO	*For HIV referrals, submit the Personal Information Sheet DOH-EB Form A together with this Confirmatory Reuest Form.
	Run 1				Run 1	£ .					*ONLY HIV confirmatory testing is FREE and results will be available after 10 (working) days for samples that meet NRL's Specimen Acceptance Criteria.	esting is FREE and results NRL's Specimen Acceptanc othe old culturis NBL's Con	will be	*ONLY HIV confirmatory testing is FREE and results will be available after 10 (working) days for samples that meet NRU's Specimen Acceptance Criteria.
	Run 2				Run 2	5					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.	her's HIV Confirmatory Res rferral requirements visit ou	sult. r website	or call NRL-SLH/SACCL.
AT	Referring laboratory:	tory:						Medical	Technologist	Medical Technologist: (Print Name)		Signature:		
8 DY	Address:							HIV Prof	iciency#: (	HIV Proficiency#: (For HIV Referrals)		Mobile #		
M	Tel/Mobile No.		Fax:		e-mail.	4.		Patholog	ist / Laborat	Pathologist / Laboratory Chief. (Print Name)	(ame)	Signature:		
LAB	LAB-F-307, Effectively Date:February 2, 2017 Issue 2, Rev. 0	Date:Febr	uary 2, 2017 Issu	e 2, Rev. 0										SETTONAL MOO

Annay VIII HIV Councelling and Testing Monthly Deport

	MONTHLY	HIV TES	TING SERVICE	CE FORM		
Name of Reporting Unit :						
Reporting Period:	Month			Year		
Type of Clients	No. of clients who underwent pre-test counselling	No. of clients tested	No. of clients with REACTIVE results	No. of clients who received results and underwent post-test counselling	No. of clients diagnosed with HIV during the reporting month	Remarks
Males having Sex with Males						
Registered Female Sex Worker						
Freelance Female Sex Worker						
Transgender		-				
Drug Users						
Person Who Inject Drugs (PWID)						
Migrant Worker (MW)						
Health Care Worker with Occupational						
Exposure						
Pregnant						
TB Clients						
Adolescents (10-14 years old)						
(15-17 years old)						
(18-19 years old)						
Children (1-9 years old)						
Infants (< 1 year old)						
Others						
TOTAL						
Prepared by:	<del>- 1</del>			Approved by:		

Infants (< 1 year old)				
Others				
TOTAL				
Prepared by:	Approved by:			
Name and Signature	Name and Signature			
Designation	Designation			
Date	Date			