Kingdom of Cambodia
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Ministry of Health

A Guidance on Establishing HIV-1 Recent Infection Surveillance Using a Rapid Test for Recent Infection (RTRI) among Persons Newly Diagnosed with HIV Infection in Cambodia

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National Center for HIV/AIDS, Dermatology and STD
(NCHADS)

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NCHADS hopes that the Guidance on Establishing HIV-1 Recent Infection Surveillance Using a Rapid Test for Recent Infection (RTRI) among Persons Newly Diagnosed with HIV Infection in Cambodia, will be used at VCCT services, sub-national program, and all implementing partners effectively and successfully.

Phnom Penh, September 15th, 2021

Director of NCHADS

Dr. Ly Penh Sun

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Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Care
ART	Antiretroviral Therapy
CBT	Community Based Testing
CDC	US Centers for Disease Control and Prevention
CQI	Continuous Quality Improvement
DBS	Dried Blood Spot
DGHT	Division of Global HIV and TB
EDTA	Ethylene Diamine Tetra Acetic acid
EIA	Enzyme Immunoassay
EQAS	External Quality Assurance Scheme
EW	Entertainment Workers
HC	Health Center
HIV	Human Immunodeficiency Virus
HIVST	HIV Self-Testing
HTS	HIV Testing Services
HPITC	Hospital Provider Initiative Testing and Counseling
ID	Identification Number
ILB	International Laboratory Branch
KP	Key Population
LAg	Limiting Antigen
LDMS	Laboratory Data Management Systems
MOH	Ministry of Health
NGO	Non-Governmental organization
PMTCT	Prevention of Mother to Child Transmission of HIV
QC	Quality Control
MSM	Men who have Sex with Men
NCHADS	National Center for HIV/AIDS, Dermatology, and STD
PEPFAR	President's Emergency Plan for AIDS Relief
PWID	Persons Who Inject Drugs
RITA	Recent Infection Testing Algorithm
RNA	Ribonucleic Acid
RTRI	Rapid Test for Recent Infection
SOPs	Standard Operating Procedures
TRACE	Tracking with Recency Assay to Control the Epidemic
TRI	Tests for Recent Infection
UNAIDS	Joint United Nations Programme on HIV and AIDS
VCCT	Voluntary, Confidentiality, Counseling and Testing
VL	Viral Load
WHO	World Health Organization

1. Background

To accelerate the impact of the public health response to the HIV epidemic, in 2014, the Joint United Nations Programme on HIV/AIDS (UNAIDS) issued ambitious fast-track treatment targets to eliminate HIV by 2030 (UNAIDS, 2018). Thus, the global goal was set for 95:95:95 by 2030, which is 95% of all people living with HIV (PLHIV) to be diagnosed, 95% of these to be initiated and retained on ART, and 95% of these on ART to be virally suppressed. At the end of 2020, global achieved 84:73:66. Two countries (Eswatini and Namibia) have reached the first 95. Nine countries (Burundi, Cambodia, Denmark, Eswatini, Haiti, Rwanda, Senegal, Switzerland, Zambia) have reached the second 95, and 12 countries (Australia, Botswana, Cambodia, Eswatini, Germany, Ireland, Japan, Myanmar, Netherlands, Switzerland, Thailand, Viet Nam) have reached the third 95 (Global AIDS Update, 2020). Cambodia has made great progress towards these ambitious targets and UNAID estimates that Cambodia has reached the targets at 84%-99%-97% (AEM, March 2020). As Cambodia has reached epidemic control, real-time monitoring of recent HIV infections will allow a targeted public health response. Thus, the rapid test for recent infections (RTRI) has incorporated in routine HIV testing services (HTS) to identify recent HIV-1 infected people from newly HIV-diagnosed populations to deploy prevention measures to block ongoing HIV transmissions, and to track and control the HIV epidemic.

Data from recency implementation in Central American region, Rwanda, Ethiopia, Malawi, Vietnam, Greek, Mexico, Kenya, Eswatini, Lesotho, Malawi, Zambia, and Zimbabwe have revealed that recency testing combined with routinely collected HTS data can detect ongoing HIV transmissions hot spots in real-time, increase HIV diagnostic yield by targeted index testing and deploy timely targeted HIV prevention measures to block ongoing HIV transmission, (Rutherford, July 21-24, 2019).

The Cambodia TRACE program (Tracking with Recency Assays to Control the Epidemic) was initiated under the support of NCHADS and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) Corporative Agreement in Cambodia Country Operation Plan FY19, has been integrated into the national HIV Testing Services (HTS) algorithm as a supplemental test led by NCHADS under the direct technical support from the U.S Centers for Disease Control and Prevention (U.S-CDC) Atlanta and the University of California, San Francisco (UCSF). A year pilot project was successfully been implemented across the entire country of Cambodia in the 68 voluntary, confidentiality, counseling, and testing (VCCT) sites. Since March 2020, 85% of all newly identified HIV-positive individuals (n=2994) accepted recency tests. Of which, 93% confirmed long-term infection and 7% with RTRI-Recent, and 5% with RITA-Recent (VCCT Report, March 2021).

The VCCT sites is designed to provide voluntary, confidentiality, counseling, and testing services to walk-in clients and to perform the confirmatory testing for every reactive client referred from HTS sites including hospital provider initiative testing and counseling (HPITC), community-based testing (CBT), health center (HC), NGO clinics and Military testing sites, HIV self-testing (HIVST) network, and private sectors (NCHADS, 2017). Through a year-long pilot of the TRACE program, 225 counselors and testers from the 68 VCCT sites also received

initial training on TRACE and re-training on the National HIV diagnostic algorithm which has further strengthened the quality of HIV testing service in the country. In addition, all the VCCT counselors and selected testers also underwent refresher training on HIV risk elicitation taking and data management skills. Similarly, the piloting of the TRACE program has strengthened the national supply chain management system and prevented service interruption.

2. Introduction

Real-time data on new HIV infections can help identify populations and geographies with active HIV transmission, which in turn, can be used to inform targeted prevention and treatment interventions. This guidance provides the basis for implementing HIV recency testing in Cambodia. This guidance aims to equip personnel working in VCCT and Antiretroviral Therapy (ART) clinics to provide HIV/AIDS services to newly identified HIV-positive individuals with essential knowledge and detailed procedures on counseling, stepwise and proficiency HIV, and recency testing. It also intends to support the national and sub-national program via a mechanism to timely track recent infection and quickly respond based on demographic and risk characteristics. The guidance is based on the experience gained during the last one-year pilot project in Cambodia, the National Policy on HIV Testing Services (HTS)/recency testing, and the international recommendations.

Antibody-based tests for recent infection (TRI) that distinguish recent from long-term HIV infection have been used since the mid-1990s to estimate population-level HIV incidence and to evaluate the impact of large-scale HIV interventions in preventing HIV infection (Brokmeyer and Quinn, 1995) (Janssen et al, 1998). Interpretation of these assays is challenged, however by several factors that can cause 'false-recent' results on the assay, including variable immune responses at the individual level, variable performance of the assay across diverse HIV-1 subtypes and across populations with naturally low viral loads (VL), current ART use, and advanced HIV disease. Considerable efforts have been made in the last few years to improve the accuracy of the interpretation of these assays through recent infection testing algorithms (RITAs) that incorporate the TRI result with other markers of chronic infection (e.g., low VL for evidence of ART and low CD4 count for AIDS) (Kassanjee et al, 2016).

In recent years, a rapid test for recent infection (RTRI) assay has been developed (Granade et al, 2013). Similar to the enzyme immunoassay (EIA)-based tests for recent HIV infections, the advantage of the RTRI is its capability to be incorporated into routine HTS services as a supplemental test during the HTS services, which makes it possible to conduct population-based surveillance of recent HIV infections to describe shifting dynamics in the HIV epidemic, such as the proportion of recent infections and for tracing active HIV transmission networks (Nikolopoulos et al, 2016) to inform targeted prevention strategies.

The Asanté Rapid HIV-1 Recency Assay is a single-use rapid in vitro immunoassay developed by Sedia BioSciences (Portland, OR) that can simultaneously verify HIV infection and distinguish recent from long-term HIV-1 infection using a single test device. The assay is intended for use with whole blood, serum, or plasma specimens as either in a laboratory or

point of service delivery to detect recent infections. Sedia BioSciences has taken this concept and developed a rapid test for recent infection (RTRI). The performance of the RTRI has been evaluated using a well-characterized panel of cross-sectional specimens with known HIV serology status and recent or long-term status based on comparative Limiting Antigen (LAg) Avidity Enzyme immunoassay (EIA) results, which have been validated to detect recent infections (Duong et al, 2015). The CDC in-house evaluation of the RTRI has provided preliminary data which showed a percent agreement of 93.2% and a Spearman's Rho of 0.83 when compared to results from the LAg Avidity EIA (Parekh et al, 2017). The mean duration of recent infection detected by the RTRI was approximately 6 months (161 days: 95% CI 148-174) (Duong et al, 2015). Preliminary data from ongoing field validations of the RTRI in Vietnam and Malawi have shown similar results with a Spearman's Rho of 0.75 in Vietnam and 0.74 in Malawi when compared to the LAg Avidity EIA (Ageymang et al, 2018). Based on similar tests for recent infection (e.g., LAg-Avidity EIA), CDC expects reported, that on average, there is a one in ten chance that someone who tests recent on the rapid test for recent infection may have been infected over a year ago.

To maintain the quality of HTS and HIV recency testing implementation, including the real-time monitoring across the country, this guidance is developed to mainly describe the use of a rapid test for recent infection to provide continuous epidemiological data on person, place, and time of newly diagnosed individuals to inform HIV prevention and control strategies.

3. Objectives

The objectives of the guidance are to:

- Provide instruction on how to follow testing procedures for the Asanté HIV-1 Rapid Recency test and on the steps to provide recency test results at VCCT and ART sites.
- Provide the management of HTS/recency quality control and the quality assurance programs within the laboratory quality management system (LQMS).
- Outline the processes of data collection, data quality, analysis, and dashboards/visualization.
- Support the national and sub-national programs to routinely share the real-time information regarding the groups of persons with recent infection including their demographic and geographic characteristics and risk characteristics, and to timely respond based on the findings.
- Share results with management to guide future program interventions and decision making.

4. Principle

The RTRI is intended to use as a supplementary test on specimens already diagnosed as an HIV-1 positive. The results obtained from the Asanté Rapid Recency Assay will not change the national-specific guidelines on HIV care and treatment nor change the diagnosis of the client tested. It is for real-time monitoring of the epidemiology of recent HIV infections which

will enhance the countries' ability to target the public health response to sub-populations and locations where high levels of transmission may be occurring. Hence, it is neither intended for use in diagnostic procedures nor for determining clinical outcome or treatment. The RTRI and RITA are integrated into the national algorithm (Figure 2) and VCCT/ART services in order to hone in on epidemic control and improve surveillance.

5. Eligibility Criteria for Recency Testing

- Newly diagnosed HIV-positive (No previous diagnosis and never on ART)
- Aged ≥ 15 years
- Voluntary basis through informed consent (Appendix 1)

6. Implementation

An RTRI will be applied to whole blood samples from persons who are diagnosed as a newly identified HIV-positive and consent to having the RTRI assay performed as part of routine HTS. Persons who tested RTRI-recent will be requested for VL testing to confirm the indication of the recent infection. The result of RITA-recent, defined as RTRI-recent and VL ≥1000 copies/ml will be given to the patients by the trained clinicians at ART clinic.

6.1 Specimen Collection Procedures

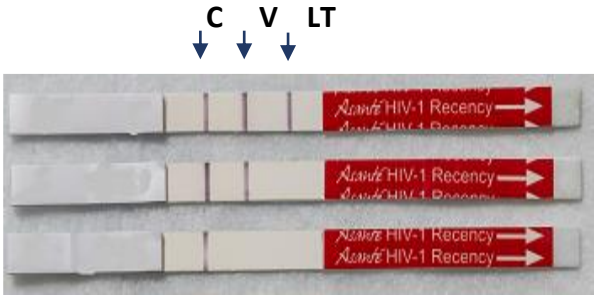
Persons with a new diagnosed HIV-positive through the routine HIV testing according to the national HIV testing algorithm will be offered a recent infection test. Persons who test HIV-reactive initially at one of more than 1,221 HTS locations across Cambodia require a confirmatory test to be performed at a VCCT site. If the persons aged 15 years old and older is confirmed as a newly identified HIV-positive, then they will be given information on the recent and long-term infection (Appendix 1) and asked for their consent to use the 5 ml of blood collected for routine service for RTRI (Appendix 2). The blood sample will be applied directly to the Asanté Rapid Recency Assay administered by a trained VCCT provider. The results of the RTRI are available by examining the testing strip, which has a control line, a positive verification line, and a long-term infection line. VCCT providers will use the VCCT recording form or counseling sheet to record the RTRI test results (e.g., a checkmark for each line that is present), clinic name, and client unique ID (Appendix 3).

Provider at VCCT sites will notify the ART clinic by marking RTRI-Recent on the client' s HIV-testing result's card (Appendix 6). The blood collected for routine services from individuals who are tested RTRI-recent will be used for the VL test. Providers will share counseling messages based on the RITA results (Appendix 4). **Note:** The VL blood test should be drawn before ARV initiation, and ARV can begin rapidly regardless of VL result return.

6.2 Testing Performance Characteristic

The Asanté Rapid Recency assay is formatted as a lateral flow device with three lines, representing a Control line (C), a Positive Verification line (V), and a Long-Term line (LT) (to distinguish recent from long-term infection in 20 minutes (Figure 1). The limitation of antigen amount applied to the LT line form is a basis for the separation of recent (low-avidity antibodies) from long-term (high-avidity antibodies) infection.

The test is interpreted by visual inspection of the band patterns. The presence of only the control line (C), the RTRI test is considered "inconclusive" for the purpose of this guidance testing on the patients' blood specimen (not "non-reactive or negative"), while the presence of C and V lines indicates an HIV-1 positive with a recent infection. The presence of all three lines indicates HIV-1 positive with long-term infection. At the individual level for the detection of new infections, the duration of recent infection is defined as an infection that occurred within the past 12 months (with an average of approximately 6 months). The testing procedures describe the conditions of storage, testing preparation and performance are described in Box 1.



Long-term infection

Recent infection

Inconclusive

Figure 1: Pont-of-care test for recent infection illustration

Viral load testing*:* A venous blood sample (drawn for routine purposes) of those RTRI-recent individuals will be sent to the ART clinic for VL testing in order to confirm the indication of the recent infection test. HIV-1 RNA will be measured using a VL testing platform that has been validated for plasma, such as the Abbott m2000 system according to manufacturer's instructions. Handling, storage, and transportation will be conducted according to the national algorithm and SOPs.

RITA: Specimens that test RTRI-recent will be tested for HIV-1 RNA concentration to improve recent infection status determination. Specimens that test RTRI-recent with a viral load result ≥ 1,000 copies/mL will be noted as a confirmed recent infection result, RITA-recent (Aghaizu et al, 2014) (Granade et al, 2013).

BOX 1: Testing Procedures

Preliminary Statements

- Read the Product Insert completely before using this assay. Follow the instructions carefully as not doing so may result in inaccurate test results.
- Use of this test kit with sample types other than those specifically approved for use with this device may result in inaccurate test results.
- This test should be performed at 15°C to 37°C. If stored refrigerated, allow the Test Set to come to ambient or room temperature before running the test.
- **DO NOT USE** the test device if there is no desiccant packet in the device pouch. Discard the test device and use a new device from a pouch that contains a desiccant. **DO NOT USE** the test device if the device pouch is damaged.
- Each test component (i.e., test strip, sample buffer tube, and collection loop) is intended for a single use. If a test must be repeated, use all new components for the retest.
- **DO NOT USE** the components in any other type of test kits as a substitute for the components in this test kit.
- When removing the specimen collection loop in a pouch, avoid touching the loop. **DO NOT USE** any kit components beyond their stated expiration date.
- Avoid handling the read area (i.e., white membrane) of the test strip to minimize contamination. **DO NOT OPEN** the test strip packaging until ready to perform a test.
- After performing the test, read test strip visually using adequate lighting to ensure accurate results.

Assay Procedure: Specimen Preparation

- Bring all of reagents and specimens to ambient or room temperature (15-37°C) before beginning testing. Allow for at least 30 minutes for warm up. It is essential that all test components and specimens are at ambient or room temperature before use.
- Set a timer for 20 minutes.
- Place the required number of sample buffer tube(s) in a test tube rack, (do not use more than 5 sample tubes in a batch) with the patient ID label facing toward the operator. Remove the cap from the sample buffer tube(s).
- Using the blood collection loop, touch the round end of the loop to the blood, serum, or plasma in the sample tube sufficiently to draw liquid specimen up into the loop, completely filling the loop. Visually inspect the loop to make sure that it is completely filled with specimen without any air bubbles.
- Transfer the loopful of sample directly into the open sample buffer tube. Agitate the loop in the tube to thoroughly mix the sample with the sample buffer.
- Repeat for any remaining specimen and buffer tubes.

Assay Procedure: Test the Specimen

- Once the blood, serum, or plasma has been collected and mixed with the sample buffer, the test can be performed on the diluted specimen.
- Discard the loop from the sample buffer into a biohazard bag/container.
- Open the foil pouch containing the test strip and remove the test strip. Do not touch the middle of the test strip where the results are read nor the red-colored end of the strip. Check to see that there is a desiccant packet inside the foil pouch. If no desiccant packet is present, discard the test strip and obtain another test strip.
- Insert the test strip into the liquid in the sample buffer tube with arrows pointing down toward the liquid.
- Start the timer to count down 20 minutes.
- After 20 minutes, remove the test strip from the tube of sample buffer and blot off extra buffer with blotting paper.
- Read the test results on the test strip immediately. Refer to Interpretation of Results below. (**Note: it is important to read the results at 20 minutes and no more than 25 minutes after placing the test strip into the sample buffer containing the specimen).**
    - RTRI-LT: return result to patient with sufficient counseling
    - RTRI-Recent: consent to refer for VL test
    - RTRI- Inconclusive: repeat HIV diagnosis, and Asante, if the results stay the same, send specimen to NCHDS lab
    - RTRI-Invalid: repeat Asante once, if the result stays the same refer specimen to NCHADS

Reagent Lot-to-Lot Verification

- **Using Participant specimens:** If patient specimens are to be used for verification, duplicate testing is performed with at least two participant samples using both sets of reagents.
- **Using External DTS-QC Controls:** External DTS-QC control materials which have been previously used should be used on the new kit lot for verification purpose.

- Perform HIV recency testing as per the Asanté HIV-1 Rapid Recency Standard Operating Procedure Assay Procedure as mentioned above.
- Results of verification tests are documented on the Reagent Lot-To-Lot Verification worksheet.

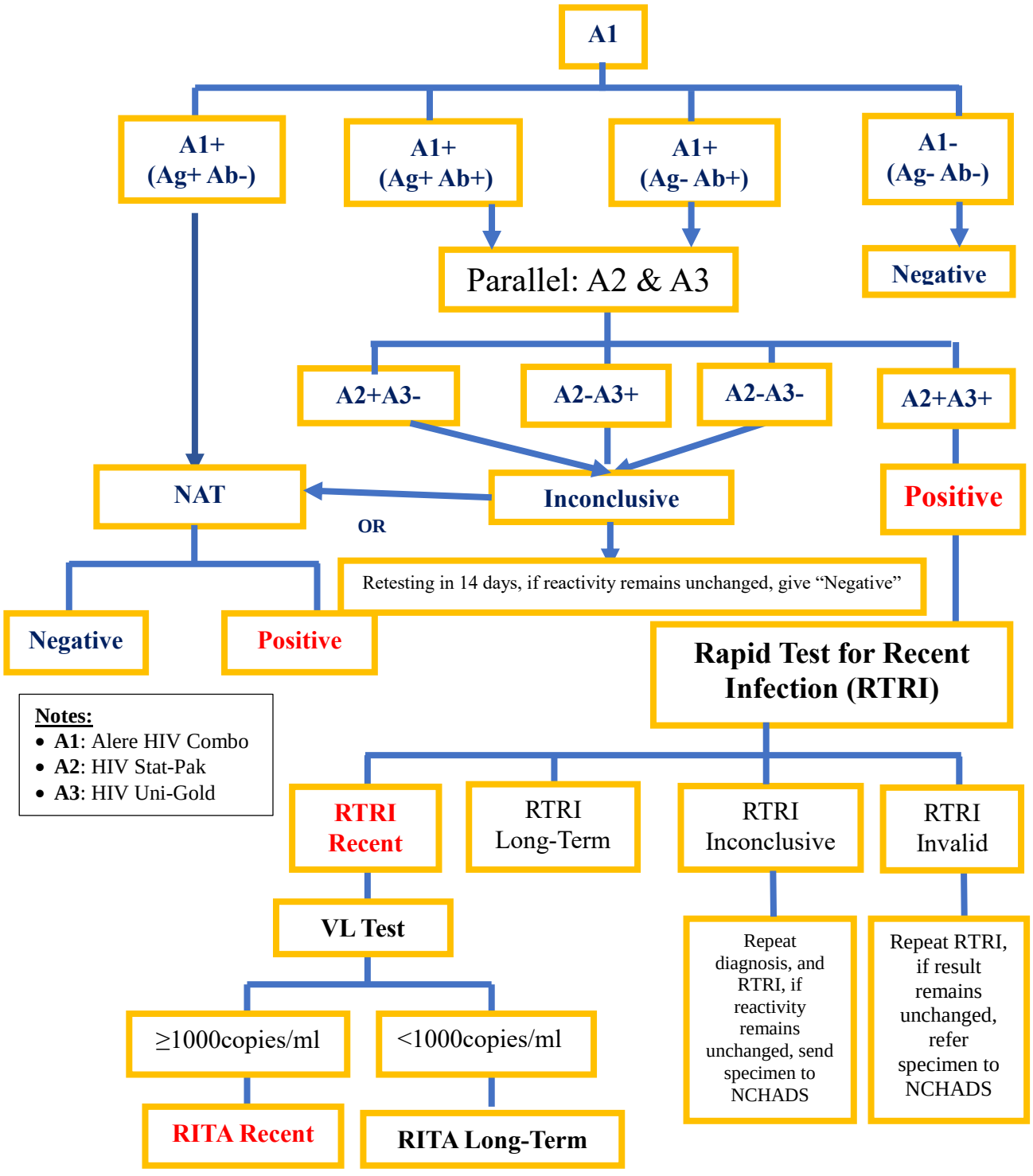


Figure 2: National HIV Testing Algorithm with recency testing incorporation

6.3 Return of HIV Recency Testing Results

The final recent infection testing algorithm (RITA) results will be returned to clients within 2 weeks after VL testing has been completed with appropriate counseling messages by the ART provider (Appendix 4). The counseling messages will include an explanation that the RTRI

assay is under evaluation and considered as a monitoring tool, the interpretation of the test result, the potential for misclassification, and a statement that a recent result will not alter routine standard of care (i.e., diagnosis, treatment, or clinical outcome). A long-term result on the RTRI assay will be the final result for the monitoring and returned to client on same day of testing.

The key procedures and talking points include the following:

- Ascertain patient's readiness to receive test for recent infection results.
- Provide test for recent infection result, including the accuracy of the test result, and give time to process. The counselor should anticipate the emotional reaction from a client who has been told they were recently infected and its implications. A client may express anger, shock, confusion, distrust, etc.
- Use counseling skills: give client plenty of time to talk about the results, ask how the client is feeling about the result and whether they understand the result, listen to client and support accordingly. This may also include talking points to help the person talk about their recent infection with their partners.
    - Ask client what resources are needed, including referrals for psychosocial support. Refer the client to the appropriate referral sources to meet their needs.
- Answer any questions the client may have about the test for recent infection result.

6.4 Data Management

VCCT services collect basic demographics and risk behaviors on a standardized VCCT counseling sheet (Appendix 3). The form has been updated to include RTRI assay result and the final RITA result. Data from the completed forms are entered into VCCT electronic database which will eventually be integrated into the Master Patient Index (MPI) system using District Health Information Software (DHIS2) platform where it can link individual-level data from the time of HIV diagnosis, treatment, and follow-up visits, and it will incorporate automated data quality checks and dashboards.

The algorithm uses VL results to confirm RITA. Once the VL results are available at the ART clinic, data entry clerks with support from case management assistant (CMA) will collect the results and enter them into the VCCT database and complete the counseling sheet of the respective individuals. VCCT data backup files will be sent on monthly basis to the national data management unit (DMU) where the data are aggregated, reviewed, and analyzed for further actions. DMU officers directly communicate with VCCT sites to address the problems including the follow-up of invalid and/or inconclusive RTRI results, low update of RTRI and/or VL results, missing data, ineligible participants, and turnaround times for final RITA results, and conduct site monitoring if the problems cannot be fixed through virtual communication.

After the program results are reviewed and accepted by the national technical bureau (TB), they will be shared with the Provincial AIDS and STI Program (PASP), and prevention program officers who will discuss and timely take appropriate actions with partners. The patients' records will be stored in secure locations (locked cabinets) at the VCCT sites and NCHADS building respectively according to MOH guidelines. Comprehensive data security

measures will be implemented, including human, physical, and electronic procedures and protections at every stage of the activity: data collection, transfer, and storage.

- All databases will be encrypted, password protected and accessible to only appropriate staff.
- The databases will be backed up monthly on a secure external system.
- All staff with access to data were trained in data security and confidentiality and must individually affirm that they will abide by data security and confidentiality principles and procedures.

Box 2: Data review and Data Analysis

Data Review:

Data Management Unit: review, clean, and analyze the data on monthly basis and generate DQC outputs if any data issues, and prepare the progress in pivot table, share the analyzed results with the program team.

The national DMU organizes a list of data quality checks (DQC) consisting of findings with searchable variables including ID, site name, and province. It will be done routinely after receiving all data backup files from all sites and share the DQC outputs with PDMO and work with them to address any data issues. Sub-national data should be done monthly prior to send to NCHADS.

The following minimum variables to review:

- HIV results: missing, following-up of inconclusive
- Referral: HIV-Negative and/or inconclusive but referred to ART clinics,
- VL test and results: missing, pending at either national/Siem Reap lab or ART clinic.
- Age: less than 15 tested for RTRI, age ≤ 4 years old work as EW, age ≤ 14 years married, age too young to be at college or university.
- Sex: confusing selection. Example, female but selected MSM.
- Date: registration came after date counseling.

Data analysis:

- DMU uses STATA software to analyze the data for indicators (Table 1) per required reporting period.
- Then, generate results in an Excel spreadsheet where pivot tables are used to dynamically present the data, example, the total number and percent of patients tested for HIV and test result by sex, age group, patient type, by site, by province, by month/quarter/year.

6.5 Program Indicators

Table 1: HIV Recency Testing Indicators

Indicators	Definition and Disaggregation
% of newly diagnosed HIV-positive aged ≥15 years tested with rapid test for recent infection (RTRI) during the reporting period	Number of newly HIV-positive aged ≥15 years received RTRI test divided by the total number of newly HIV+ aged ≥15 during reporting period, multiply by 100. By province, site, type of patients (MSM, TG, EW, PWID, PPW, GP, partners of KP) etc.
% of newly diagnosed HIV-positive aged ≥15 years had RTRI recent results during the reporting period	Number of newly HIV+ individuals aged ≥15 years diagnosed RTRI Recent divided by total number of newly HIV+ receiving recency tests during the reporting period, multiply by 100. By province, site, age, occupation, education, type of patients (MSM, TG, EW, PWID, PPW, GP, partners of KP) etc.
% of RTRI recent receiving VL test during the reporting period	Number of individuals with RTRI-recent receiving VL tests divided by total number of individuals with RTRI-recent during the reporting period, multiply by 100. By province, site, age, occupation, education, type of patients (MSM, TG, EW, PWID, PPW, GP, partners of KP) etc.
% of RITA recent during the reporting period	Number of RITA recent divided by total number of newly HIV-positive aged ≥15 years received RTRI tests during the reporting period, multiply by 100. By province, site, age, occupation, education, marital status, risk factors, type of patients (MSM, TG, EW, PWID, PPW, GP, partners of KP) etc.
% of RITA Long-Term during the reporting period	Total number of RTRI Long-Term and RITA confirmed Long-Term divided by total number of newly HIV-positive aged ≥15 years received RTRI tests during the reporting period, multiply by 100.
% of reclassified RITA Long-Term during the reporting period	Total number of RITA reclassified Long-Term divided by total number of RTRI recent during the reporting period, multiply by 100.
% of hotspot (s) identified recent infection have contacted for prevention intervention and PNTT services.	Number of hotspot (s) identified recent infection have contacted for prevention intervention and PNTT services divided by total number of sites with RTRI recent during the reporting period, multiply by 100.

The analysis is performed routinely to identify demographic and behavioral factors associated with testing recent versus long-term on the RITA. In addition, a recent infection rate among a population of HTS clients "at risk" for recent infection (e.g., HTS clients tested HIV-negative) over a specified time period may be approximated and monitored over time (e.g., quarterly or annually).

6.6 Training, Monitoring and Quality Control

Trainings, monitoring and quality control measures are applied to ensure that the implementation of program is done with a high degree of quality, accuracy, completeness, and representativeness.

6.6.1 Trainings

Trainings for site-level personnel including VCCT counselors, lab testers, ART clinicians, provincial data management officers and case management assistants (CMA) are properly provided and refreshed.

Training package covers three components:1) Laboratory component, which includes the overview of TRACE, RTRT testing procedure and result interpretation, VL test and EQAS for RTRI; 2) Counseling component, which includes the human subject protections, eligibility criteria, informed consent process and completing the consent form, the flow of recency testing activity and VL testing process, the return of recency result; 3) Data management component, which includes the completion of data collection forms, privacy and confidentiality of data, data entry, cleaning, correcting and sending backup to central level.

6.6.2 Monitoring and Supervision

Monitoring teams will provide regular oversight to VCCT, laboratory, and ART sites to verify procedures are being followed at the site level, including:

- Persons who do not consent to rapid testing for recent infection are not tested.
- VCCT site has an appropriate supply of laboratory consumables.
- Data forms are being completed properly.
- Specimens going to the laboratory are appropriately labeled with the client unique identification number, stored, and transmitted within routine NCHADS timeframes.
- Completing, handing and storage of data and biological specimens is in accordance with procedures and protections to ensure the security and confidentiality of data; and
- Adverse events, including social harm.

The national program and Provincial AIDS and STD Program (PASP) staff will hold monitoring visits on a bi-quarterly basis, at a minimum. A supervision checklist is developed and used to assist supervisors in conducting supervision visits and documenting the findings. Sites where supervision visits document problems will be prioritized for follow-up.

Supervision visits will utilize a continuous quality improvement (CQI) approach, focusing on creating and monitoring action plans to resolve documented challenges (Appendix 14).

Box 3: For data quality check, the supervisor should:

Randomly select several counseling sheets	Check aggregated numbers at facility level
• Review for completeness • Verify against the entered data in the database. • Note the differences • Notify, discuss, and correct the differences either in database or the sheets as appropriate.	• Define reporting period • Count number of counseling sheets against HTS register and the printed report (paper) • Generate the report in database and compare the numbers to the printed report and the reports at province/ NCHADS. • Note the differences – notify and discuss – correct as needed

6.6.3 Quality Assurance / Quality control

All tests are performed according to manufacturer's instructions including the use of appropriate quality control (QC) specimens, and all tests are interpreted according to manufacturer's instructions, unless stated otherwise.

Quality assurance activities will take place primarily either at VCCT sites or laboratory units where RTRI is conducted.

- RTRI kit verification will be carried out using QC panels at regular intervals, for example at the beginning of each month or upon receiving a new lot and a new consignment at the hub laboratory. QC panels consist of recent, long-term and negative control specimens. Results will be monitored by the national program team.
- All testers using the RTRI must undergo proficiency testing during their training and thereafter twice annually. Corrective action, including refresher training to ensure tests are performed and interpreted correctly, are conducted throughout program implementation.
- Intermittent supervision of the sites conducting recent infection testing is carried out by TRACE Team and/or PASP team and development partners to ensure quality testing standards are maintained.

Box 4: Quality Control Procedure

<u>Dried Tube Specimen (DTS) for External Quality Controls (EQC)</u>

- DTS-QC includes 3 specimens: one HIV long-term infection, one HIV recent infection, and one negative specimen
- It is recommended to perform the DTS-QC under the following circumstances:
    - When a site initiates RTRI testing upon site activation; and
    - Once per month thereafter; and
    - When opening a new test kit lot; and
    - Whenever a new shipment of test kits is received.

In-built Control Feature

- The Asanté Rapid HIV-1 Recency Assay has a built-in procedural control that establishes assay validity.
- A reddish-purple line in the Control line region of the test strip membrane indicates that a proper specimen was collected and run in the test, and that the test strip functioned properly.
- The Control Line will appear on all valid tests whether or not the Long-Term and Verification Lines give a reactive or non-reactive result.

Reagent Lot-to-Lot Verification by National Institute of Public Health (NIPH) Laboratory

- Clinical laboratory reagents and control materials are exposed to many variables due to conditions during transportation and storage environments in different laboratory and health facility settings.
- The verification of new reagents kits with old reagent kits is performed by NIPH lab to ensure that, despite of varying environmental conditions, there are no clinically significant differences in the results obtained when different lot numbers of reagents are used before in-country test kit distributions.

7 The Intervention Framework using HIV Recency Results

Figure 3 presents the flow of HIV recency results and responsibilities of relevant institutions for timely response to contain an HIV outbreak and to tailor prevention strategies and program interventions. The flow will be created at the national and sub-national forums. The networks will help support activities between facilities (ART, VCCT) and communities addressing the approaches and challenges based on the findings of recency infection distribution with their geographic, demographic, and risk characteristics, which will be linked to sexual partners and biological children for HIV testing.

The VCCT TWG forum is convened routinely for meetings at the national level. The Group-of-Champion (GOC) meeting, the Plan-Do-Check-Action (PDCA), the Pro-TWG meeting is considered a forum at the sub-national level to discuss the use of recency results and plan for prevention intervention.

Individual Recent Infection Response

Every HIV infection identified and reported (recent or long-term) on a **continuous basis** should have **immediate response** by health providers **at the time of diagnosis** and receiving standard of care and treatment according to the national guideline.

Recent cases may be prioritized for certain interventions.

Step 1: Identify and characterize site- level recent HIV infection patterns

Above Site Response	**Dashboard review** Of RTRI, RITA and QC data. Identify and characterize sites within in a defined area that have above the threshold #/% of suspected cases/months	Above threshold number of recent HIV infections	**Step 2: Site Investigations** **Using Recent HIV infection Response Form** Gather information about recent cases at sites identified in Step 1 from facility staff. Site level and multi-site analysis and identify gaps. Report findings to stakeholders.	**Step 3: Response** Program (NCHADS, NIPH, DPs) review findings and develop action plans. • **Site level**: Ensure existing or enhanced safe of client are met. • **Program Level**: Provide guidance, training, or allocated resources for improvement of preventive and treatment services.	**Step 4: Close and Document Response** Program (NCHADS, NIPH, DPs and TRACE Team) **follow-up on action plans** **Document and report:** Response activities.	
	Continue steps 1 to 3 every month until site investigation and follow-up are "closed"					
National Response	Dashboard review Identify broad epidemic trends	**National program response:** • Discuss broad epidemic patterns of recent HIV infection • Discuss service gaps that may have contributed to recent cases • Provide guidance on program implementation, policy, and resource allocation				

Figure 3: Intervention Framework at individual, sub-national and national level monthly

8 The Roles and Responsibilities

National Program:

- **NCHADS:**
  - Develop program planning and roadmap,
  - Develop the national training package and build the capacity of site-level staff in HTS/recency testing,
  - Develop guidance for recency implementation, including necessary job aids and SOPs
  - Provide orientation on overview of recency implementation to stakeholders.
  - Develop supportive supervision plan and conduct supervision to sites to track challenges/gaps.
  - Develop guidance for recency implementation, including necessary Job Aids and SOPs.
  - Ensure sufficient tests at site level.
  - Identify and characterize site-level recent HIV infection patterns monthly.
  - Monitor the trends of recency HIV infection and document the response activities regularly.
  - Develop presentation and share results and response activities to VCCT TWG.
  - Join the Sub-TWG of prevention program routinely for prevention intervention and tracking all contacts for HIV testing.

- **NIPH:**
  - Jointly-develop the program planning and roadmap for HTS/recency in its area
  - Jointly-develop the training package and build capacity of site level staff in HTS/recency testing
  - Produce panels (DTS) for internal and external quality control for sites utilization and training needs.
  - Distribute QC panels to all VCCT sites and NCHADS/Siem Reap laboratories
  - Create database for EQAS results for all VCCT sites.
  - Monitor the proficiency testing (PT) results and take corrective actions

- **Development Partners:**
  - Support the procurement plan.
  - Support the development of data systems to support recency.
  - Support the training of staff in public health response and data use for recent HIV infection.
  - Support the availability and use of real-time data for public health action, including monthly analysis, and quarterly reporting to national indicators.
  - Assist in data dashboard development and be available to relevant public health authorities for decision-making and use.
  - Assist in documentation of lesson learned, and best practices for HTS/HIV recency testing program.

- Assist in the development of recency surveillance abstracts and manuscripts evaluating the value of recent infection surveillance by comparing data on negatives, positives, and recent infection using STATA multivariate analysis to see which demographic and geographic risk factors are associated with HIV-positive and also with HIV-recent infection.
- Assist in the development of national policies such as HTS/ HIV recency SOPs, revised HTS consolidated guidelines, and other relevant SOPs.

➢ **Provincial AIDS and STD Program:**
- Coordinate to ensure each VCCT site under its coverage is functioning with an assigned point-of-contact (POC).
- Monitor the progress of HTS/HIV recency testing implementation.
- Coordinate among PDMO, CMA, ART teams to help support VCCT for VL testing arrangement among all RTRI-recent clients.
- PDMO monthly perform data quality review, collaborate with DMU to address data issues and do virtual communication with sites, and conduct site visit if needed to fix data quality issues.
- Develop a slide presentation by PDMO.
- Integrate recency testing topic into the existing meeting forums such as Pro-TWG, GOC, CQI, and/or PDCA meeting to share the recency results, and to track the index's sexual partners for HIV testing. The expectation of meeting shall produce a list of timely actions plan (among whom and where the recent infections have occurred, all inconclusive cases are confirmed, VL tests are requested accordingly, and its results are returned and filled out) with the responsible persons and deadline.
- If clinic staff is absent at the meeting forum, PDMO and CMA loop with clinic staff the meeting results.
- File the minutes, and follow-up actions from previous meetings.
- Conduct supportive supervision as needed.
- CMA monitor the VL testing and the results for the RTRI-recent patients between VCCT, and ART clinics. If the VL testing schedule is not common, the blood drawing for VL test will be flexible by site/province whether it should be taken at VCCT or ART clinic.

➢ **Site level:**

➢ ***VCCT***
- Arrange the workstation (testing and counseling) venue and ensure HTS guidelines, SOPs, Job Aids, and counseling sheets are available onsite.
- Attend trainings and refresher trainings to enhance and/or maintain capacity in HTS/HIV recency testing and counseling.
- Conduct HIV diagnosis and perform the RTRI assay
- Provide quality pretest counseling using the GATHER technique (Appendix 8)
- Follow the national HTS guideline and Recency SOPs.
- Respect clients' rights and keep confidentiality.
- Perform routine QC as recommended by the national program and keep the recording result on QC form (Appendix 9-12).
- Perform PT for maintaining external quality control. Complete the PT forms and send electronic results to NIPH timely.

- Return RTRI Long-Term to the HIV-positive patients
- Take informed consent for VL testing among RTRI-recent patients.
- Enter data into the electronic database on daily basis and do real-time data entry when MPI is fully functioning, and complete counseling sheet for all VCCT clients.
- Send backup files and submit monthly and quarterly VCCT reports to NCHADS DMU using a drag-and-drop tool.
- Aggregate the backup files monthly and generate monthly reports.

➢ ***ART***

- Facilitate for blood drawing for VL tests among RTRI-recent patients.
- Provide RITA recent results using the steps and messages steps (Appendix 4).
- Return VL results to VCCT for filling up on VCCT database and counseling sheet.
- Attend training and refresher training, and/or meeting on HIS/recency testing.

Below is a flow of HIV recency testing between VCCT and ART services.

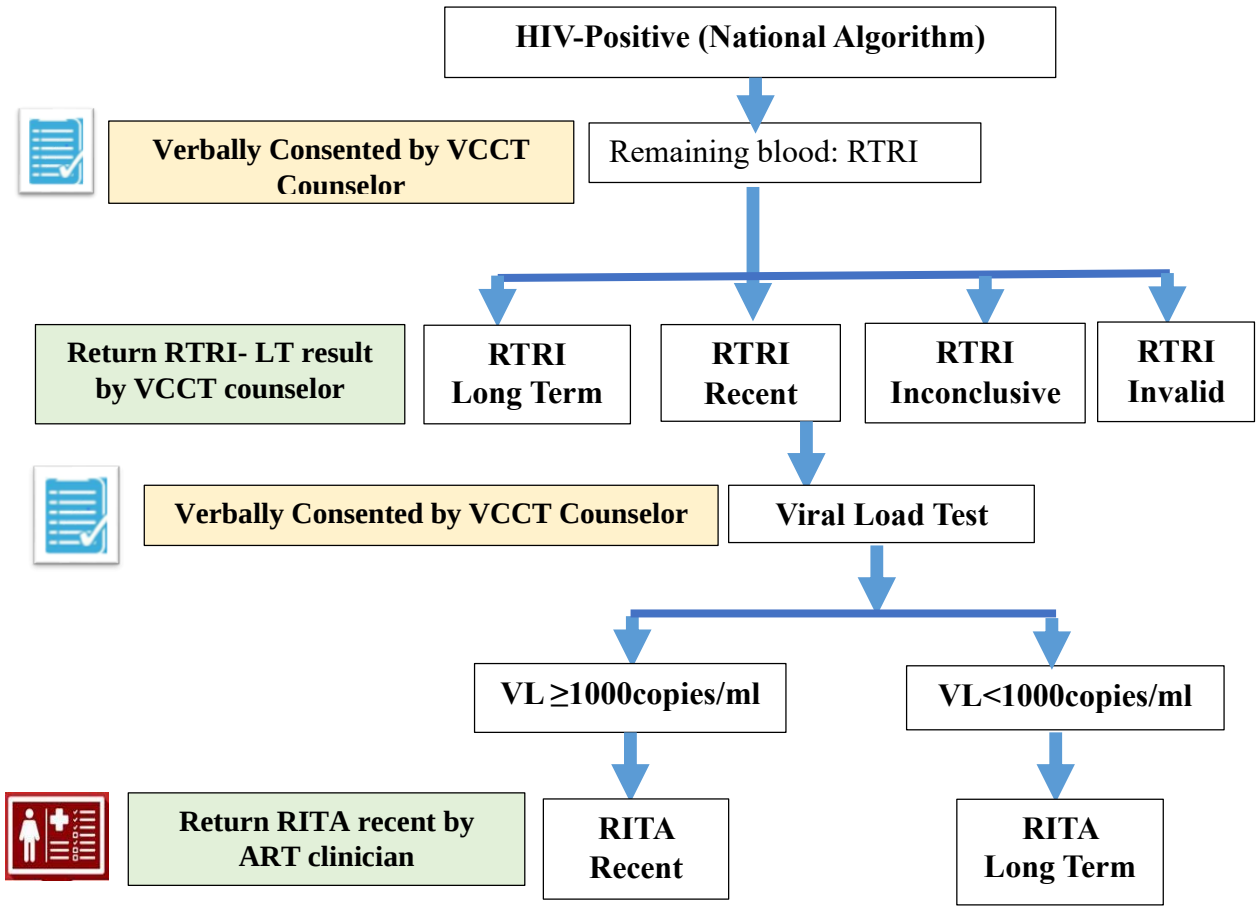


Figure 4: Flow of HIV-1 Recency Activity Management at VCCT and ART clinic

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Appendixes

Appendix 1: Information Sheet on Understanding Recent and Long-term HIV Infection

What does recent HIV infection mean?

Recent HIV infection means a person likely got HIV within the past one year. People with recent HIV infection have high amounts of HIV in their blood. Having more virus means that it is easier to pass on infection to others. HIV medications (antiretrovirals or ARVs) lower the amount of HIV in your body. ARVs help you to stay healthy. ARVs make it less likely for you to pass the infection to others, including unborn and breastfeeding infants and sex partners. ARVs need to be taken every day or as prescribed by a doctor for your health, which is well known as undetectable = untransmittable. This will also lower the risk of passing HIV. There is a small (one in ten) chance that someone who got HIV more than one year ago will test as if they have a recent infection. The test cannot tell exactly when you got HIV. The test cannot tell you who passed the infection to you.

What does long-term HIV infection mean?

A long-term HIV infection means a person likely got HIV more than one year ago. A person with long-term HIV infection can still pass HIV to other people. People with any HIV infection should start and stay on HIV medications (ARVs) as prescribed by your doctor for your health. ARVs lower the risk of passing HIV to others. There is a chance that someone who got HIV within the past one year will test as if they have a long-term infection. The test cannot tell exactly when you got HIV. The test cannot tell you who passed the infection to you.

How can I reduce the risk of transmitting HIV to others?

If you have a recent or long-term HIV infection, you have HIV in your blood. Start HIV medication (ARVs) as soon as possible. Take the pills everyday as prescribed by your healthcare provider. If you forget to take your HIV medicine, take it as soon as you remember. If HIV medications make you feel sick, talk to your healthcare provider.

You can pass HIV to sex partners [and to your unborn or breastfeeding baby or persons you share needles with]. Not having sex is the best way to not pass HIV to your sex partner. If you do have sex, you and your partner need to use a condom the right way every time you have sex. Limit the number of people you have any kind of sex with.

If you have HIV and are pregnant or breastfeeding, it is important to start and stay on HIV medications. It is important for your baby to take HIV medicines for 6-12 weeks after birth. This will lower the chance of passing infection on to your baby**.**

If you inject drugs outside of the clinic or hospital, only use sterile needles or syringes. Do not share the needle or syringe with anyone else.

If you have any questions or concerns, please contact Dr. Chea Chankosalmony, a chief of VCCT unit, NCHADS through 011 627 797 or at NCHADS # 245, national Road #6, Kien Kleing Village, Sangkat Prek Leap, Khan Chhroy Chanva, Phnom Penh.

Appendix 2: Informed Consent Script

Purpose: We are doing an activity with the Ministry of Health to know how many new HIV infections occur each year in this country. This activity will use a new test. The new test can tell if someone got HIV in the past one year. We call this new test "HIV rapid test for recent infection". If you decide not to have this test for recent infection, your normal care will not change. The information that you provide is very important for the Ministry of Health. It will help to improve health services for persons living with HIV and their partners and families.

Procedures: This activity will not require us to take any additional blood from you. If you test positive for HIV, we will use leftover blood from the blood sample you give for the other tests that are part of standard of care. We will test this leftover blood with the HIV rapid test for recent infection and a viral load test. We will return the recent infection result to you at the same time that you receive your viral load result. You will receive the results within 4 weeks. We also need to collect basic information about you and other people tested for HIV. We will not collect your name. This will help keep your information private. This information will help us understand more about HIV in your community and in Cambodia.

Risks: If you take part, your risks are small. There may be a risk that some of your personal information may be disclosed. Every effort will be made to keep your information private. Project staff will set up procedures and protections at every stage of the study to ensure the confidentiality and security of your personal information. We will use a code to identify any sample from you or information about you. The link between your name and code will be kept in a secure location at the clinic only. Any project report will not use your name or identify you. You may have some emotional distress upon learning the test results. Now, the HIV rapid test for recent infection is a research tool and may not have accurate results. There is a small (one in ten) chance that a person who got HIV more than one year ago will test as if they have recent infection. There is a chance that a person who got HIV within the past one year may test as if they have a long-term infection.

Benefits: Your results may help to improve HIV services for persons living with HIV and their partners and families.

Confidentiality: We will keep your information private. A code will be used to identify any sample or information from you. Any paper linking your name and code will be kept in a safe location at the clinic. Your name will not be used in any project reports.

Voluntary participation: Taking part in this activity is voluntary. You do not have to agree to have your leftover blood tested for recent infection, if you do not want to. This will not affect your regular care. There is no cost to you for taking part in this activity.

Appendix 3: VCCT Record: Counseling Sheet

1. Client testing ID: ……....**2**. Date:…….……..
3. PMRS ID:……...**4.** HTS ID:…….....**5**.UUIC ID:…….

Client' information: 6. Sex at birth: 1. □Male 2. □Female 7. Date of birth…../…../……/ or age:……years old
8. Marital status: 1. □single 2. □married 3. □widow/widower
9. Occupation: 1. □entertainment 2.□civil society 3.□uniformed service 4. □private sector 5.□construction workers 6. □garment workers, 7.□casino workers 8.□farmers 9.□student 10. □transportation 11.□housewife 12.□other* (specify)……..
10. Education: 1. □Never study 2. □Primary school 3. □Junior College 4. □ College 5. □University
11. Address: Village…… Commune…… District…… Province/City……
12. Country of birth: 1. □Cambodia 2. □Vietnam 3. □Chinese 4. □Others:……

13. Referred from (tick 1):

1. □Self-refer	5. □ Infectious disease	9. □Dental clinic	13. □STI clinic	17. □ICU
2. □Family planning	6. □IPD	10. □ NGO clinic	14. □TB service	18. □ PNTT/ART
3. □Surgery	7. □ Pediatric service	11. □Maternity ward	15. □ANC service	19. □HIVST
4. □OPD	8. □Dermatology service	12. □ HC	16. □Private clinic	20. □NBTC

14. Reasons for visit (tick >=1):

1. □Has symptom	5. □Parents have HIV-positive	9. □Re-testing before ART initiation	13. □Post PEP
2. □Expose to risk	6. □Partner/husband of PW	10. □ apply job (requested)	14. □ During PrEP
3. □Intended marriage	7. □Confirmatory test (A1+)	11. □Health Checkup	
4. □Partner has HIV-positive	8. □HEI Antibody test	12. □Partner testing	

15. Risk Assessment in the last 12 months:

	Y N		Y N		Y N
1. Had uncontrolled blood transfusion	□ □	7. Sex with men & women	□ □	13. Inject drugs	□ □
2. Self or partners mobile	□ □	8. Sex with transgender	□ □	14. Shared needle	□ □
3. Partners had HIV-positive	□ □	9. Partner has more sex partners (>2)	□ □	15. Had PEP	□ □
4. Former partner(s) died of HIV-positive	□ □	10. Sex without condom (including once)	□ □	16. Had PrEP	□ □
5. Sex only with men	□ □	11. □Parents are HIV-positive	□ □	17. Had STIs	□ □
6. Sex only with women	□ □	12. □had sale or buy sex	□ □	18. □Post rape	□ □

16. Type of Clients (tick 1):
1. □FEW 2. □MSM 3. □TG 4. □MEW 5. □PWUD 6. □PWID 7. □GP 8. □PPW

17. Testing history:	If tested in last 12 month:	Partner testing history:
1. □Never tested	1.□Reactive 2. □Negative	Partner 1. □Negative 2. □positive 3. □unknown
2. □Have been tested	3. □Inconclusive 4. □Unknown	Partner 2. □Negative 2. □positive 3. □unknown

18. Testing performance:	Alere Combo test result:	HIV Diagnosis:
1□Accepted 2□Refuse	1.□Negative 2.□ Reactive: 2.1.□Ag 2.2.□Ab	1.□Negative 2. □Positive 3. □Inconclusive

19. RTRI performance (if HIV+):	RTRI line (Tick box if line appear on tests strip)	1.□Control 2. □Verification 3. □Long Term
1□Accepted 2□Refuse test	RTRI Result	1.□Long Term 2. □Recent 3. □Inconclusive 4. □Invalid 4.1 □tick if have done for first inconclusive

20. VL performance (if RTRI Recent):	VL test results	1.□ <1000copies/ml 2. □ ≥1000copies/ml
1□Accepted 2□Refuse test	RITA result	1.□Long Term (<1000copies/ml) 2. □Recent (≥1000copies/ml)

21. Post-test counseling: 1. □Not done 2. □Done Date: / /

22. Referred to: 1. □ART clinic 2. □STI service 3. □TB service 4. □others (specify):……

Name of counselor:…….Signature:……..

Note: *Others: street venders, maid, baggers, waste collectors, monks, homeless, businessmen etc. Deliveries: motorbike drivers, bike drivers, PassApp drivers, bus drivers, truck drivers. Sex without condom even missing once is counted on.

Appendix 4: Steps and Messages for Return of RTRI/RITA Results

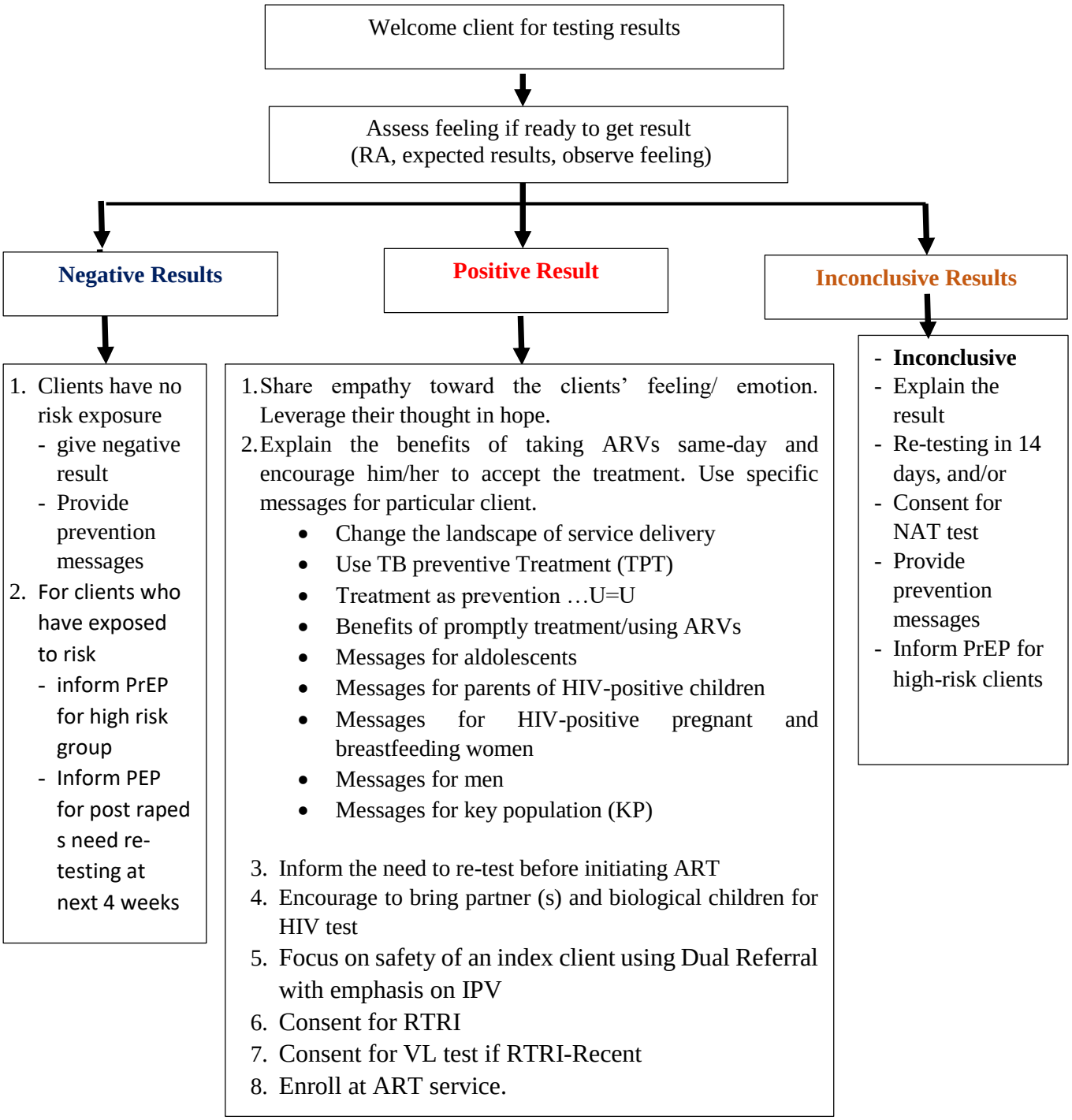
Step	Message
1	Ask client whether he/she has any questions about his/her care, specifically the new HIV diagnosis and treatment. Ask whether he/she has any questions regarding test for recent infection and if ready to receive test for recent infection results.
2	Provide test for recent infection result and allow time to process. The counselor should anticipate the emotional reaction from a client who has been told they were recently infected and its implications. A client may express anger, shock, confusion, distrust, etc. Use counseling skills to listen to client and support accordingly.
2.1	If **RTRI long-term**, state the following: *We tested your blood sample, and the test indicates you may have long-term infection. You were most likely infected with HIV more than 12 months ago and possibly several years ago. The test cannot tell exactly when you were infected or who infected you.* *There is a small chance that the result is not correct and that you have been infected within the past 12 months.* • *Take your time we have plenty of time to talk about your results.* • *How do you understand this result?* • *How are you feeling about this result?* • *How can I help support you?*
2.1a	If **RTRI Recent**, state the following: Your result has not finalized yet, to measure your result, you will need to go with another test, a vial load (VL). It is beneficial for you to see how much your viral load are in your body before take medication, and then in 6 months after your medication taken, you can observe if the VL will have decreased, your treatment is successful. The test will be conducted at ART service where you will be enrolled for the treatment. The result will be returned by ART clinician to you. To maintain your health, I would recommend you get treatment today. • Will you accept the VL test? • Do you have any questions/clarification? • How can I help support you?

2.2	If **RITA Recent,** state the following:
	
	We tested your blood sample and RITA results indicate:
	
	• For those who have VL≥1000c/ml*: you may have recent infection. You were likely infected with HIV within the past 12 months. The test cannot tell exactly when you were infected or who infected you.*
	• For those who have VL<1000c/ml*: you have been infected for more than 12 months and possibly for several years. The test cannot tell exactly when you were infected or who infected you. If you were ever on treatment for HIV, this test result is not correct.*
	  o *Take your time we have plenty of time to talk about your results.*
	  o *How do you understand this result?*
	  o *How are you feeling about this result?*
	  o *How can I help support you?*

3	Answer any questions the client may have about test for recent infection test result.

4	Discuss and reinforce HIV prevention messages and partner testing for all HIV infected persons: • *Your result does not reflect your partner(s) HIV status. You need to ask your partner(s) to get tested whether you tested as having a recent infection or a long-term infection. We have many options on how to do so and we can discuss further. You do not need to tell your partners the results from your test for recent infection, the important thing is to share your HIV status and that you are on treatment.* • *You can pass HIV on to your loved one(s) by having unprotected sex. Disclosing your HIV status to your loved ones may help you discuss ways that you can use to protect them from HIV.* • *A good practice to prevent transmission to unborn or newborn children and partner(s) is to be on treatment, and with partner(s) using a condom during sex* • *The best way to keep yourself healthy and to keep your partner(s) healthy is to start taking ART. Once you start HIV treatment, it is critical that you continue taking it every day as prescribed by your nurse or doctor.*

Appendix 5: Flow of HTS Post-Test Counseling



Appendix 6: HIV Testing Result's Form

ក្រសួងសុខាតិបាល

បណ្ណាលទ្ធផលតេស្តមេរោគអេដស៍ - ស្វាយ (HIV / Syphilis Test Result)

១.សេវា: ☐ VCCT ☐STI ☐TB ☐ANC ☐Maternity ☐OPD ☐IPD ☐NGO ☐NBTC ☐**Others**.....

២.ឈ្មោះទីកន្លែងធ្វើតេស្ត: .....លេខកូដទីកន្លែង.....លេខកូដអតិថិជន.....

លេខកូដអតិថិជនប្រតិកម្មដែលបញ្ជូនមកធ្វើតេស្តបញ្ជាក់: .....

ថ្ងៃ ខែ ឆ្នាំ

៣.ថ្ងៃខែឆ្នាំធ្វើតេស្ត: ☐☐ ☐☐ ☐☐☐☐

៤.លទ្ធផលតេស្តមេរោគអេដស៍ (HIV)				៥.លទ្ធផលតេស្តមេរោគស្វាយ (Syphilis)			៦.លទ្ធផលតេស្ត Recency
លទ្ធផលតេស្តរហ័សទី១	SD HIV/Syphilis Duo	NR	R	SD HIV/Syphilis Duo	NR	R	៦.១. RTRI តេស្ត:
	Alere HIV Combo ☐Ag ☐Ab	NR	R	តេស្តបញ្ជាក់ RPR	-	+	☐ LT ☐ Recent ☐ Inconclusive ☐ Invalid
លទ្ធផលតេស្តទី២ : Stat-Pak HIV 1/2		NR	R	តេស្តបែបបរិមាណ (Titer):.....			៦.២. Viral Load តេស្ត: ☐ Yes ☐ No
លទ្ធផលតេស្តទី៣ : Uni GoldHIV 1/2		NR	R				៧. ឈ្មោះ និងហត្ថលេខាអ្នកធ្វើតេស្ត:
រោគវិនិច្ឆ័យមេរោគអេដស៍		±	- +				ឈ្មោះ: .....
❖ លទ្ធផលកំណត់មិនបាន ± : ☐ ណាត់ធ្វើតេស្ត១៨ថ្ងៃបន្ទាប់ ☐ បញ្ជូនសំណាកធ្វើ NAT តេស្ត							ហត្ថលេខា : .....

Appendix 7: HIV Laboratory requisition form for Viral Load

Ministry of Health

Referral Hospital: ……

Laboratory Requisition Form for Viral Load

Name of patient:……Age:…… Sex: ……..……

Patients' ID:

Barcode:

Date blood collection: …… Time blood collection: ……

RTRI Recent

Type of Tests

□ CD4 □ HIV-1 Viral Load: □ First line patient □ Second line patient

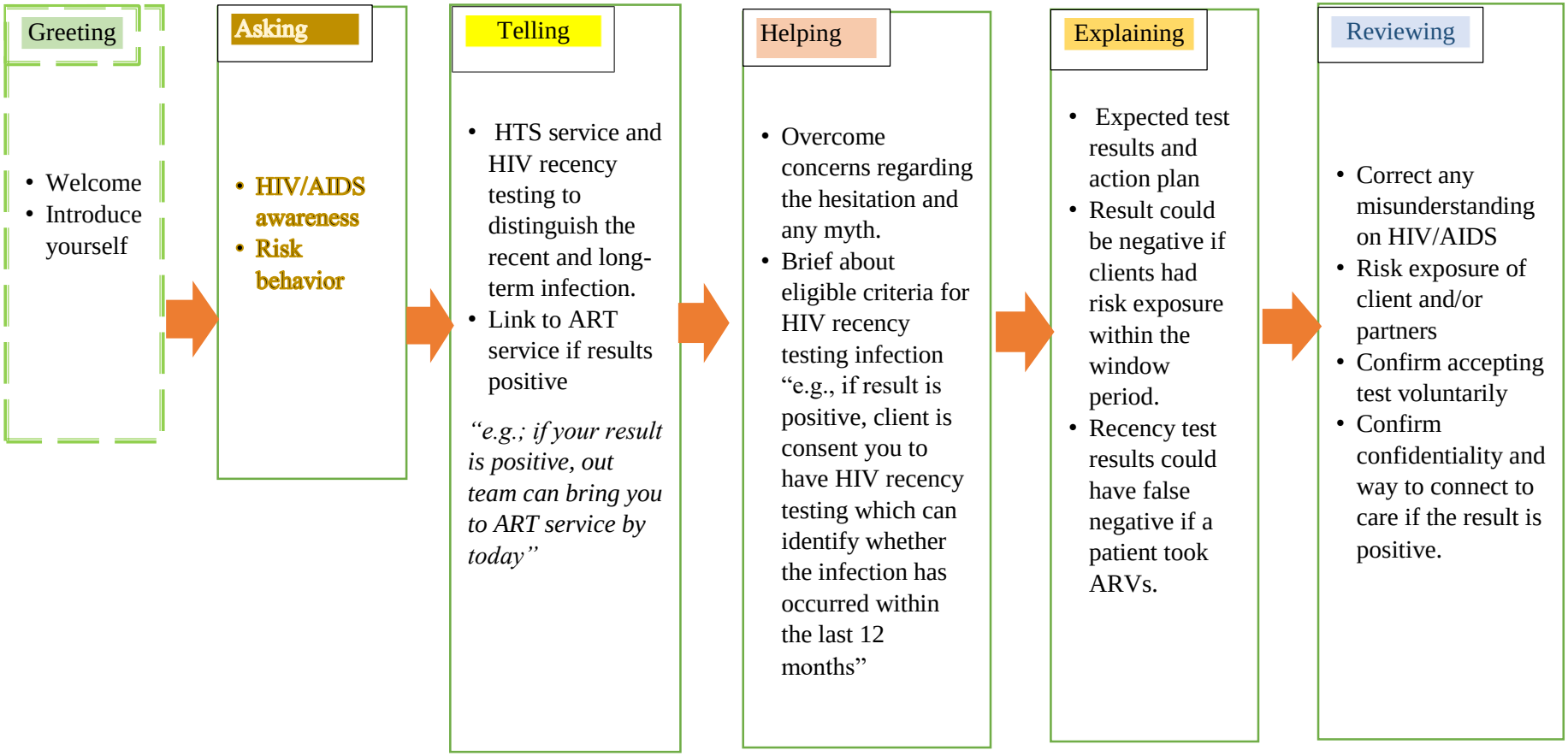
□ HCV-Viral Load: □ 1st test □ 2nd test □ others:……..……

□ DNA PCR: □ at birth □ at 6weeks of age □ at 6 weeks after stop weaning □ confirmed test

□ Date: ……

Signature and name of blood collector Signature and name of requester

Appendix 8: Pre-test counseling steps using GATHER Technique



Appendix 9: QC recording forms for Alere Combo, Stat-Pak, Uni-Gold HIV and Asante HIV-1

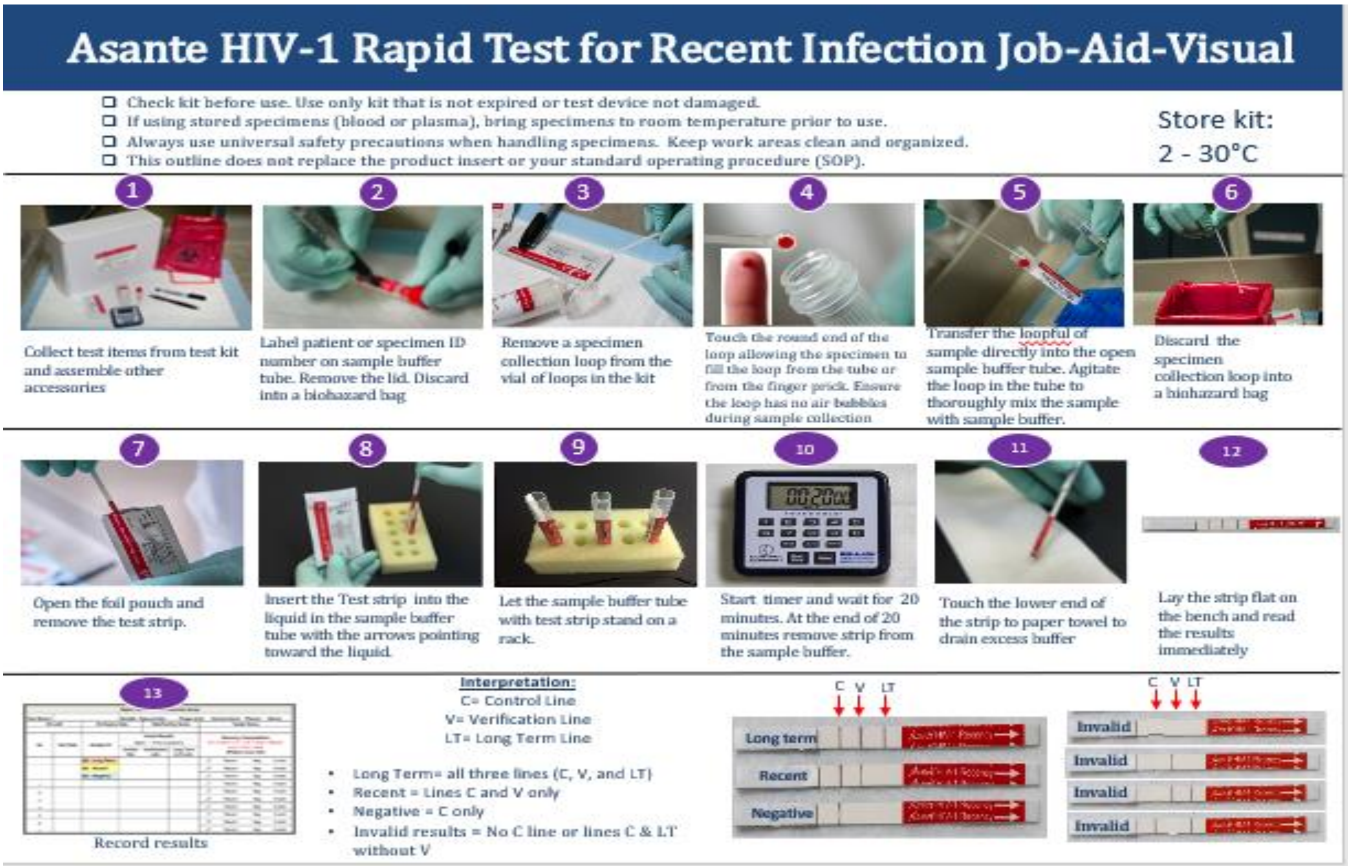
QC recording form for Asante HIV-1

Rapid Test for Recent Infection QC LogBook										
Panel Lot#:						**Inclusive Months:**				
Month	**Tester and Test Date**	**Kit Information**	**Sample ID**	**Visual Results** (Mark "√" if line is present)			**Recency Interpretation** *[All 3 lines = LT; C & V lines = Recent only C line = Neg]* **(Please circle one)**			
				Control (C) Line	**Verification (V) Line**	**Long Term (LT) Line**				
1		Kit Lot #:	QC - Long Term				LT	Recent	Neg	Invalid
		Date Received:	QC - Recent				LT	Recent	Neg	Invalid
		Exp. Date:	QC - Negative				LT	Recent	Neg	Invalid
2		Kit Lot #:	QC - Long Term				LT	Recent	Neg	Invalid
		Date Received:	QC - Recent				LT	Recent	Neg	Invalid
		Exp. Date:	QC - Negative				LT	Recent	Neg	Invalid
3		Kit Lot #:	QC - Long Term				LT	Recent	Neg	Invalid
		Date Received:	QC - Recent				LT	Recent	Neg	Invalid
		Exp. Date:	QC - Negative				LT	Recent	Neg	Invalid
4		Kit Lot #:	QC - Long Term				LT	Recent	Neg	Invalid
		Date Received:	QC - Recent				LT	Recent	Neg	Invalid
		Exp. Date:	QC - Negative				LT	Recent	Neg	Invalid
5		Kit Lot #:	QC - Long Term				LT	Recent	Neg	Invalid
		Date Received:	QC - Recent				LT	Recent	Neg	Invalid
		Exp. Date:	QC - Negative				LT	Recent	Neg	Invalid
6		Kit Lot #:	QC - Long Term				LT	Recent	Neg	Invalid
		Date Received:	QC - Recent				LT	Recent	Neg	Invalid
		Exp. Date:	QC - Negative				LT	Recent	Neg	Invalid
7		Kit Lot #:	QC - Long Term				LT	Recent	Neg	Invalid
		Date Received:	QC - Recent				LT	Recent	Neg	Invalid
		Exp. Date:	QC - Negative				LT	Recent	Neg	Invalid
8		Kit Lot #:	QC - Long Term				LT	Recent	Neg	Invalid
		Date Received:	QC - Recent				LT	Recent	Neg	Invalid
		Exp. Date:	QC - Negative				LT	Recent	Neg	Invalid
9		Kit Lot #:	QC - Long Term				LT	Recent	Neg	Invalid
		Date Received:	QC - Recent				LT	Recent	Neg	Invalid
		Exp. Date:	QC - Negative				LT	Recent	Neg	Invalid
10		Kit Lot #:	QC - Long Term				LT	Recent	Neg	Invalid
		Date Received:	QC - Recent				LT	Recent	Neg	Invalid
		Exp. Date:	QC - Negative				LT	Recent	Neg	Invalid
11		Kit Lot #:	QC - Long Term				LT	Recent	Neg	Invalid
		Date Received:	QC - Recent				LT	Recent	Neg	Invalid
		Exp. Date:	QC - Negative				LT	Recent	Neg	Invalid
Results Reviewed By/Date:				**Comments:**						

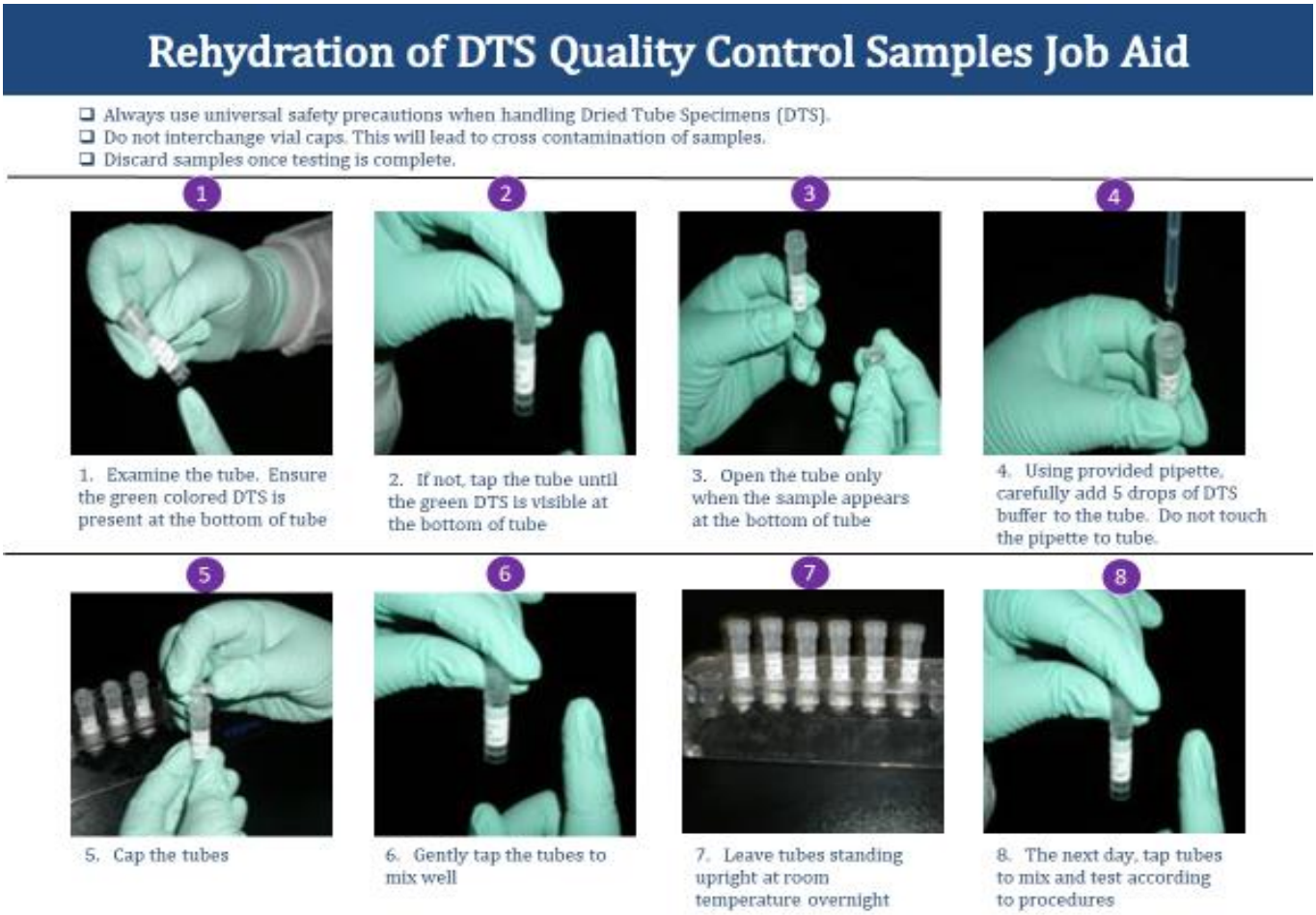
Alere Combo, Stat-Pak, Uni-Gold HIV ½

Date	QC(+/-)ID	Test Name	Lot. No.	Expired Date	Results		Final Results	Performed by		Reviewed by		Remarks
					T	C		Initial Name	Signature	Initial Name	Signature	
	Reaction				R NR I	Yes No	P N I					
	Non Reaction				R NR I	Yes No	P N I					
	Reaction				R NR I	Yes No	P N I					
	Non Reaction				R NR I	Yes No	P N I					
	Reaction				R NR I	Yes No	P N I					
	Non Reaction				R NR I	Yes No	P N I					
	Reaction				R NR I	Yes No	P N I					
	Non Reaction				R NR I	Yes No	P N I					
	Reaction				R NR I	Yes No	P N I					
	Non Reaction				R NR I	Yes No	P N I					
	Reaction				R NR I	Yes No	P N I					
	Non Reaction				R NR I	Yes No	P N I					

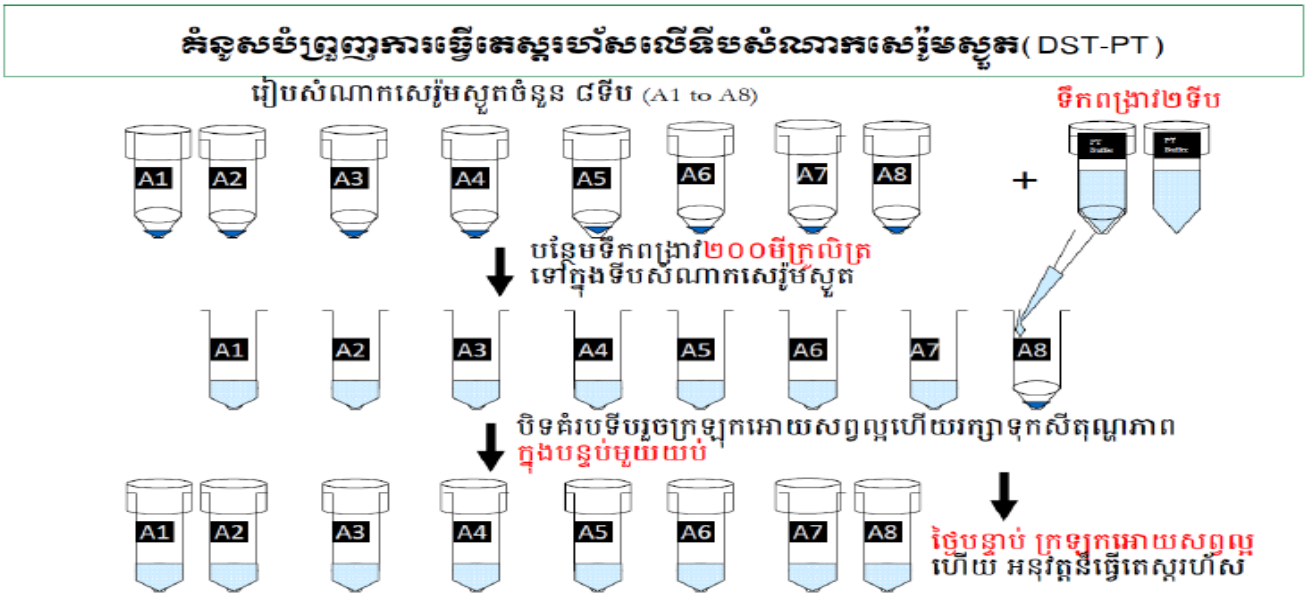
Appendix 10: Asante HIV-1 Rapid Test for Recent Infection Job-Aid Visual



Appendix 11: Rehydration of DTS Quality Control Sample Job Aid



Appendix 12: Flow of Rehydration of DTS-PT Sample



Appendix 13: The list of accessible and available SOP/job aid/forms:

Items	Items
1. HIV Testing Algorithm with Recency assay	2. Asante testing SOP
3. Instruction of QC performance	4. QC HTS log form
5. QC Asante log form	6. PT testing performance and DTS flow
7. PT result sheet	8. DTS rehydration flow
9. Finger prick flow	10. HIV Combo
11. HIV Stat-Pak	12. HIV Uni-Gold
13. Flow of HIV Asante Performance	14. Cleaning testing area
15. Bleach solution preparation	16. Safety practice
17. Waste management	18. Workstation setup
19. Spill management	20. PEP
21. HIV/Syphilis result final	22. Informed consent
23. Pretest counseling technique_ GATHER	24. Posttest counseling steps
25. Message for RTRI results	26. Counseling sheet final
27. Instruction counseling sheet	28. Data management, data flow
29. VL requested form	30. VL results form
31. Stock card form	32. Inventory request form
33. Instruction inventory management	34. Temperature log for refrigerator
35. Salakabat form	36. DBS job aid