

National HIV Testing Guideline 2023



National STD/AIDS Control Programme

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2023



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Foreword

The 95-95-95 targets are a set of global goals established by UNAIDS to help combat the HIV/AIDS epidemic. These targets aim to ensure that, by 2030: 95% of people living with HIV know their HIV status. 95% of people who know their HIV status are on sustained antiretroviral therapy (ART). 95% of people on ART have viral suppression. To achieve the 95-95-95 targets, it's essential to address barriers to HIV testing, including stigma, discrimination, and access to testing services.

This comprehensive resource has been developed to assist healthcare professionals and organizations in the accurate and ethical provision of HIV testing services. The guideline is designed to ensure that individuals at risk for or living with HIV receive the highest quality HIV testing, care, and support.

I would like to express my gratitude to all stakeholders who have contributed to the development of the HIV testing guidelines for 2023, and I hope that the information available in this document will be used to further strengthen the national response to the HIV epidemic in Sri Lanka.

The fight against HIV requires dedication, compassion, and commitment from all those involved. By following these guidelines, we can collectively make a significant impact on reducing HIV transmission and improving the lives of those affected.

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Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Clinics
ART	Antiretroviral Treatment
ARV	Antiretroviral Drugs
ATV/r	Atazanavir and Ritonavir
BB	Beach Boys
CBHTS	Community-Based HIV Testing Services
CBO	Community Based Organizations
CSF	Cerebrospinal Fluid
DNA	Deoxyribonucleic Acid
DU	Drug User
EIMS	Electronic Information Management System
ELISA	Enzyme-Linked Immunosorbent Assay
FBC	Full Blood Count
FSW	Female Sex Workers
FTC	Emtricitabine
HCW	Health Care Workers
HIV	Human Immunodeficiency Virus
HTC	HIV Testing and Counselling
HTS	HIV Testing Services
HIV ST	HIV Self-Testing
ICU	Intensive Care Unit
LFT	Liver Function Test
LPV/r	Lopinavir and Ritonavir
MLT	Medical Laboratory Technician
MO	Medical Officer
MOH	Medical Officer of Health
MSM	Men who have Sex with Men
NGO	Non-Governmental Organization
NRL	National Reference Laboratory
NSACP	National STD/AIDS Control Programme
OI	Opportunistic Infections
OPD	Outpatient Department
PCU	Preliminary Care Unit
PEP	Post Exposure Prophylaxis
PIMS	Prevention Information Management System
PITC	Provider Initiated Testing and Counselling
RFT	Renal Function Test
RNA	Ribonucleic Acid
STD	Sexually Transmitted Diseases
STI	Sexually Transmitted Infections
TB	Tuberculosis
TCP	Trained Care Provider
VCT	Voluntary Testing and Counselling
WHO	World Health Organization

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1. HIV testing services

1.1 Background

Early detection and appropriate interventions improve survival and quality of life of people infected with Human Immunodeficiency Virus (HIV) and reduce the risk of onward transmission. However, a significant proportion of people living with HIV remain undiagnosed until they become symptomatic, therefore, presenting late for treatment. Late presentation diminishes the impact of anti-retroviral therapy (ART) on morbidity and survival and delays adoption of preventive measures by persons living with HIV and their partners.

Promotion of HIV testing services is recognized as an important strategy in both prevention and care for HIV in Sri Lanka. As the country is aiming to end AIDS by 2030, achieving 95-95-95 targets by 2025 is an important milestone. Scaling up of HIV testing services is the most important step to achieve the first 95 (95% of those who are infected know their status). Despite scale-up of HIV testing services across diverse contexts, the current reach of these services (especially for key affected populations) remains low. Even though the availability of HIV testing facilities has improved over the past years, utilization of these services in health care settings remain inadequate. Operational, logistic, and social barriers (including stigma, discrimination, and punitive laws and policies) continue to limit those accessing existing testing services. These barriers have to be overcome to make progress toward universal access to essential services including HIV testing services.

The national HIV testing guidelines is the principal document that sets out the objectives, principles, and arrangements for HIV testing services in Sri Lanka. These guidelines are based on the National AIDS Policy and National Strategic Plan 2023-2027. They provide guidance on HIV testing in the country. The guidelines ensure quality screening and diagnostic testing become readily accessible. This aims to identify HIV infection early for timely initiation of treatment for infected individuals. In all settings where people undergo HIV testing, steps should be taken to ensure the adherence to the basic principles of HIV testing services.

1.2 Objectives

1. Provide comprehensive HIV testing services.
Scale-up of HIV testing service (HTS) approaches, in both facility and community settings, to reach those undiagnosed.
2. Increase access and coverage of HIV testing services of key populations and vulnerable populations.
3. Provide high-quality services and adherence to the guiding principles of 5 Cs in diverse HIV testing service delivery approaches.
4. Encourage integration of HIV testing with other relevant services.
5. Support effective linkage to appropriate prevention, treatment, and care services among those tested.

1.3 Guiding Principles

It is important to deliver HTS with a public health and human rights-based approach. It highlights priority areas, including universal health coverage (UHC), gender equality and health-related human rights such as accessibility, availability, acceptability, and quality of services. All HTS approaches should adhere to the WHO 5 Cs: Consent, Confidentiality, Counselling, Correct test results and Connection.

The 5 Cs are principles that apply to all HTS and in all circumstances.

Table 1 : WHO 5Cs

Consent	Test with informed consent and voluntary participation.
Confidentiality	Steps are taken to ensure confidentiality of information.
Counselling	Testing is accompanied by pre-test information and post test counselling.
Correct results	Steps are taken to provide high-quality testing services. Quality assurance mechanisms are in place to ensure the provision of correct results to the individual.
Connection	Systems are in place to connect individuals to required care, follow-up services including long-term prevention and treatment support.

1.4 HIV testing service package

1. Pre-test information
2. Conducting the HIV test
3. Post- test counselling
4. Follow up counselling and referrals

2. Fundamentals of HIV Testing Services

2.1 HIV Testing Service Delivery Models

2.1.1 Facility-based model

Facility-based HTS encompasses testing in a health facility or laboratory setting. HTS are provided with other services being offered in health care facilities in the public, private, and NGO sectors. Some of the entry points include Antenatal Care (ANC), Tuberculosis (TB), and outpatient clinics and inpatient wards. Services can be offered through Provider-Initiated HIV Testing (PIHT), Client-Initiated HIV Testing (CLHT), index-case testing, and self-testing.

2.1.2 Community-based model

Community-Based HIV Testing and Counselling (CBHTS) refers to HTS provided in community settings. It contributes to reduction in stigma and discrimination by removing social barriers to HTS. Different settings/approaches can be used to provide CBHTC as home based, including index case testing, mobile and outreach, workplace, educational institutions, campaigns, and self-testing.

2.1.3 Self testing

HIV self-testing refers to a process in which a person collects his or her own specimen (oral fluid or blood) and then performs a test and interprets the result, often in private or with someone he or she trusts. HIVST is offered as an additional approach to HIV testing services. HIV self-testing (HIV ST) has been recommended by WHO as an innovative strategy to reach the unreached and people who do not attend HIV testing services. The evidence shows that HIV ST is safe and accurate, highly acceptable, increase access, increase the uptake among those who are at high risk and who may not test otherwise.

2.2 HIV Testing Service approaches

2.2.1 Client initiated HIV testing

Clients who are already aware of HIV and their risk may come voluntarily to health care services for HIV testing. As the process of testing is initiated by the client it is known as client- initiated HIV testing.

These services are available to clients through the government sector free of charge at STD clinics. They can also access HIV testing services from many other government health care settings free of charge. In addition, clients can access HIV testing services through private sector; laboratories/hospitals and general practitioners (GPs) at a cost.

2.2.2 Provider Initiated HIV testing

Provider-initiated testing services denotes HIV testing services (HTS) offered in a health facility by a care provider. It includes providing pre-test information and obtaining consent for testing. However, the option for individuals to decline testing is assured.

Provider initiated HIV testing strategy helps to increase HTS coverage, to provide diagnosis earlier for those attending health facilities, to normalize HIV testing and to remove the need for personal motivation to seek HTS. It saves clients from the possible embarrassment of asking for an HIV test. Provider initiated HIV testing should be offered to all categories mentioned below.

A. HIV testing should be routinely offered in all the following settings:

1. STD clinics
2. Antenatal services
3. TB clinics
4. Drug dependency programmes
5. Healthcare settings where hepatitis B, hepatitis C are diagnosed

B. HIV testing is recommended for the following patients:

1. Patients presenting with clinical features suggestive of primary HIV infection and HIV indicator conditions (see Tables 2 for clinical features of primary HIV infection, Table 3 for clinical indicator diseases for adult HIV infection and Table 5 for indicator diseases for pediatric HIV infection)
2. Patients diagnosed with a sexually transmitted infection
3. Sexual partners of persons known to be HIV positive
4. Key populations [Men who have sex with men (MSM), Female Sex workers (FSW), People who inject drugs (PWID), Beach boys (BB), Prison inmates] and vulnerable groups (Youth, migrant workers, armed forces, and tourism industry workers)
5. Female sexual contacts of men who have sex with men
6. Persons who report sexual contact abroad or locally with individuals from countries of high HIV prevalence
7. Victims of sexual assault
8. Persons who reported to have sex with casual or multiple partners

C. HIV testing should also be routinely performed in the following situations

1. Donor blood
2. Donors of tissues and organs for transplant
3. In-utero insemination
4. Other situations when requested by relevant health care providers

Table 2: Clinical features of primary HIV infection

Symptoms and findings	Percentage of patients
Fever	>80 to 90
Fatigue	>70 to 90
Rash	>40 to 80
Headache	32 to 70
Lymphadenopathy	40 to 70
Pharyngitis	50 to 70
Myalgia or arthralgia	50 to 70
Nausea, vomiting or diarrhea	30 to 60
Night sweats	50
Aseptic meningitis	24
Oral ulcers	10 to 20
Genital ulcers	5 to 15
Thrombocytopenia	45
Leukopenia	40
Elevated hepatic enzyme levels	21

Table 3 : Clinical indicator diseases for adult HIV infection

AIDS defining Conditions		Conditions where HIV testing should be considered
Respiratory	Tuberculosis	Bacterial pneumonia
	Pneumocystis Pneumonia	Aspergillosis
Neurology	Cerebral toxoplasmosis	Aseptic meningitis/encephalitis
	Primary cerebral lymphoma	Cerebral abscess
	Cryptococcal meningitis	Space occupying lesion of unknown cause
		Guillain–Barré syndrome
	Progressive multifocal leukoencephalopathy	Transverse myelitis
		Peripheral neuropathy
		Dementia
Dermatology	Kaposi’s sarcoma	Severe or recalcitrant seborrheic dermatitis
		Severe or recalcitrant psoriasis
		Multi dermatomal or recurrent herpes zoster
Gastroenterology	Cryptosporidiosis	Persistent oral candidiasis
		Oral hairy leukoplakia
		Chronic diarrhoea of unknown cause
		Weight loss of unknown cause
		Salmonella, shigella or campylobacter
		Hepatitis B infection, Hepatitis C infection
Oncology	Non-Hodgkin’s lymphoma	Anal cancer or anal intraepithelial dysplasia
		Lung cancer Seminoma
		Head and neck cancer
		Hodgkin’s lymphoma
		Castleman’s disease
Oncology	Cervical cancer	Vaginal intraepithelial neoplasia
		Cervical intraepithelial neoplasia Grade 2
Haematology		Any unexplained blood dyscrasia including:
		• Thrombocytopenia
		• Neutropenia
Ophthalmology	Cytomegalovirus retinitis	• Lymphopenia
		Infective retinal diseases including Herpesviruses and toxoplasma
		Any unexplained retinopathy
ENT		Lymphadenopathy of unknown cause
		Chronic parotitis
		Lymphoepithelial parotid cysts
Other		Mononucleosis-like syndrome (primary HIV infection)
		Pyrexia of unknown origin
		Any lymphadenopathy of unknown cause
		Any sexually transmitted infection

2.2.3 Facility and community index case testing

Index case testing can be provided at the facility and in the community. The HIV-positive client is the index case. Index testing is an approach whereby the exposed contacts (spouse, children, sexual partners, injecting partners, siblings, and parents) of an HIV-positive person are notified and offered a HIV test on their own initiative or assisted by a doctor, nurse, public health nursing sister, public health inspector, trained community worker, or expert client.

2.2.4 Mobile outreach and HTS campaigns

HTS can be delivered in different forms including service provision through mobile or outreach services.

2.2.5 Social network-based approaches

Social network-based approaches can be offered as an HIV testing approach for key populations as part of a comprehensive package of care and prevention.

2.2.6 Lay provider HIV testing

Lay providers who are trained and supervised can independently conduct safe and effective HIV testing using rapid diagnostic tests.

3. Mobilizing, Demand creation and implementing effective pre-Test services, information, and messaging

3.1 Demand creation

Demand creation is to increase HTS uptake, and its approaches may need to be prioritized, depending on the setting, focus population and available resources. A wide range of demand creation strategies have been identified.

- Peer-led demand creation interventions, including mobilization.
- Digital platforms, such as short, pre-recorded videos, social media
- Advertisement of specific HTS attributes
- Motivational messages
- Personal invitation letters
- Individualized content messaging
- General text messages, including SMS.
- Educational programmes (for example, drama, sport-based and faith-centered);
- Counselling strategies
- Couples-oriented counselling and partner services (including provider-assisted referral and social network-based approaches)
- Pretest information

3.2 Enabling environment

NSACP and other relevant stakeholders are working towards creating an enabling environment for HIV testing services in the country. During training of health staff on HIV, special emphasis is given to addressing issues on human rights, stigma and discrimination and importance of non-judgmental attitudes towards KPs. Advocacy programmes are conducted for policy makers, community leaders, media, and other relevant sectors to create an enabling environment for KPs. Training programmes are conducted for law enforcement officers to sensitize them on human rights and fundamental freedom for all.

- Protecting confidentiality

All HTS providers must remain committed to preserving confidentiality, one of the 5 Cs of HTS. Confidentiality applies not only to the test results and reports of HIV status but also to any personal information, such as information concerning sexual behavior and the use of illegal drugs. HTS should avoid practices that can inadvertently reveal a client's test results, or HIV status, to others in the waiting room or in the health facility.

- Preventing social harm, stigma, discrimination, and criminalization
- Empowering people living with HIV, key populations, and other affected communities
- Ensuring appropriate age-of-consent policy to reduce age-related barriers to HIV services and to empower providers to act in the best interest of the adolescent.

3.3 Pre-test services

The National STD/AIDS Control Programme (NSACP) with the support of Ministry of Health (MoH) uses a variety of methods to promote HIV testing in the county.

Continuous pre-service and in-service training programmes are being conducted by NSACP and peripheral STD clinics for healthcare providers to promote HIV testing for clients who attend health care services. The number of full time and part-time STD clinics are increasing continuously giving more access to STI and HIV services. In addition, STD clinics promote HTS tailor-made to the needs of the districts including training of health care workers, outreach testing and supportive supervision for peer led interventions in the district. Furthermore, accessibility and turnaround time of testing have improved significantly with availability of rapid HIV testing services at STD clinics, hospitals, medical Officer of Health (MOH) clinics, and in several private laboratories.

Print, electronic, and social media are used to promote HIV testing in general as well as among risk groups and vulnerable groups.

In addition, peer led community interventions and outreach HIV testing services are in place to reach previously unreached key affected population, vulnerable populations, and people in geographically difficult areas. A special internet-based peer led intervention was being introduced to promote HIV testing among KPs.

3.3.1 Pretest information

All clients who undergo HIV tests should be provided with adequate pretest information. The information could be provided through individual or group counselling, posters, or leaflets. The depth of provision of pretest information depends on the setting.

Offering or recommending HIV testing to a client or a group of clients includes providing clear and concise information on:

- Meaning of HIV and AIDS
- Modes of transmission and brief natural history
- The benefits of HIV testing
- The meaning of an HIV-positive and an HIV-negative diagnosis
- The services available (including ART)

- The potential for incorrect results if a person already on ART is tested
- A brief description of prevention options and encouragement of partner testing
- Confidentiality of results
- The fact that the client has the right to refuse to be tested and it will not affect the client's access to HIV-related services or general medical care.
- Potential risks of testing to the client in settings where there are legal implications for those who test positive and/or for those whose sexual or other behavior is stigmatized.
- Availability of opportunity to ask questions from the provider.

If a patient refuses a test, the reasons why they have made that choice should be explored to ensure that these are not due to incorrect beliefs about the virus or the consequences of testing.

Special considerations for pregnant or postpartum women

In addition to the pre-test information mentioned above for women who are or may become pregnant or are in postpartum period should also receive following additional information:

- Potential risk of transmitting HIV to the infant
- The benefits of early HIV diagnosis for mothers and infants
- Measures that can be taken to reduce mother-to-child transmission, including having ART for the benefit of the mother and prevent HIV transmission to the infant.
- Counselling on infant feeding practices to reduce the risk of HIV transmission

4. Post-test services

HIV testing services are not complete without effective linkage to appropriate HIV prevention, treatment and care services. The core package of post-test services needs to include:

- Clear and concise counselling messages
- Referral and offer of rapid ART initiation
- Additional linkages to HIV prevention, care, support, and other relevant services

4.1 Post-test counselling following HIV negative screening results

Individuals who test HIV-negative should receive brief health information about their test results.

Counselling for those who test HIV-negative should include the following:

- An explanation of the test result and reported HIV status
- Education on HIV prevention methods
- Emphasis on the importance of knowing the status of sexual partner(s) and information about the availability of partner and couple testing services at STD clinic if relevant.
- Referral and linkage to STD clinics for people at substantial ongoing HIV risk
- A recommendation on retesting based on the client's level of recent exposure and/or ongoing risk of exposure.
- Opportunity for the client to ask questions and request counselling

4.2 Retesting among people who have HIV-negative screening results

Most people who have HIV-negative results will not need retesting. Retesting among people who are HIV-negative or of unknown status has two key purposes:

- (1) Monitoring the effectiveness of HIV prevention interventions and
- (2) Identifying and treating new HIV infections as early as possible when prevention efforts fail

The following describes situations where retesting is needed or may be beneficial.

- Window period retesting
- Individuals who report recent or ongoing risk of exposure
- Key populations (Frequency of the HIV testing will be decided by the level risk behaviour)
- People with a known HIV-positive partner who is not virally suppressed while on ART
- Individuals presenting with a diagnosis or receiving treatment for STIs or viral hepatitis

- Individuals with a confirmed or presumptive TB diagnosis
- Outpatients presenting with clinical conditions or symptoms indicative of HIV
- Pregnant women from key populations or those who have a partner from key populations or with HIV who is not virally suppressed

4.3 Post-test counselling following HIV positive confirmatory test results

The name and other identity details of the client should always be checked before disclosing the results to clients. It should always be ‘client centered’ which means counselling should always be responsive to and tailored to the unique situation of each individual or couple.

- Make sure the client is ready to receive results
- Explain that a positive result means the client is infected with HIV
- Make sure that the client understands the results
- Reinforce confidentiality
- Give the client time to absorb the information before proceeding. Assess the client’s ability to cope with the diagnosis and check the support available to the client immediately.
- Provide brief information on available HIV treatment and care services and refer the clients to nearest STD clinic for further counselling and HIV care.
- Make an active referral to the nearby STD clinic with a specific time and date. (An active referral is one in which the tester makes an appointment for the client or accompanies the client to an appointment and enrolment into HIV clinical care.)
- If the individual refuses to go to a particular clinic, an alternative arrangement should be made
- Assess the risk of suicide, depression, and other mental health consequences of a diagnosis of HIV infection
- Check whether the client has any questions
- Ensure client’s safety in travelling home

Partner and family screening and partner disclosure is best to be discussed and arranged at STD/ HIV clinic later. Most clients will be too distressed for a detailed discussion about ways of transmission and will not be able to absorb information at this point. Thus, may need to be discussed at another counselling session/s. If the care provider is not able to provide a proper post - test counselling, it is always advisable to refer the client to STD clinic for further management.

4.4 Service for Inconclusive/ Indeterminate HIV test results

Receiving an HIV-inconclusive status may be confusing and stressful for the individual or couple and may be difficult for the provider to explain. Therefore, it is always advisable to refer the patient to Venereologist for:

- Proper counselling to avoid unnecessary distress to the patient
- Arranging appropriate testing to arrive at a diagnosis and minimize loss to follow up

In community based / outreach testing, the client should be given an appointment to return in 14days for retesting. If the patient is willing to go to the STD clinic, an active appointment should be arranged for further testing.

4.5 Special considerations for people with a reactive test for triage or self- test result

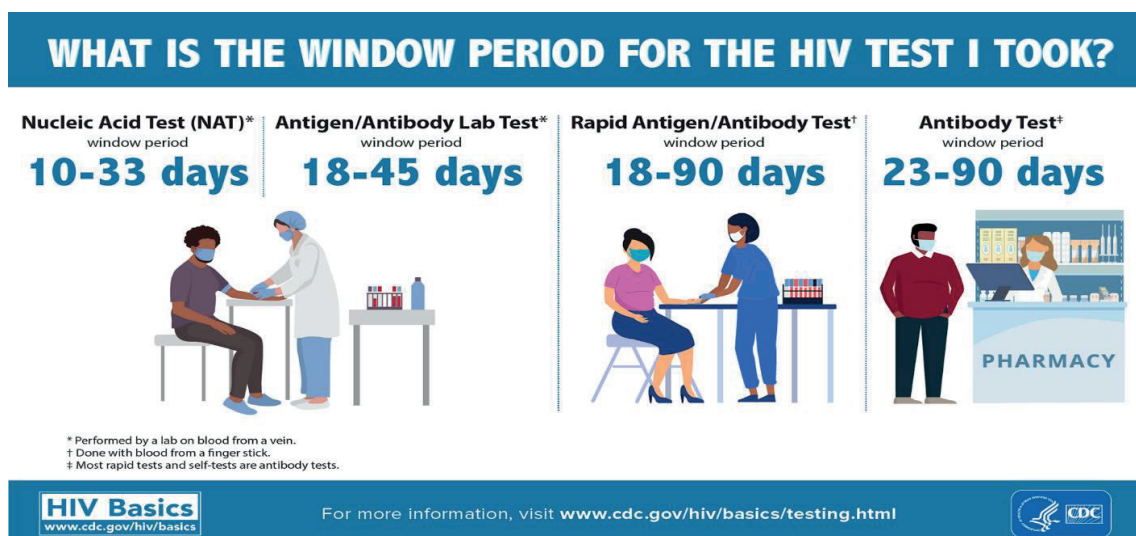
No single HIV test can provide an HIV-positive diagnosis. In many settings people are tested for HIV by a lay provider using a single rapid test (that is, test for triage) or are testing themselves using an HIV Self-Test Kit (HIVST) kit. When such a test result is reactive (positive), the person needs further testing, beginning with the first test (A1) in the national testing algorithm (see Chapter 5 for further discussion). Providers distributing HIVST (HIV Self Test) kits or following up with self-testers need to refer clients who disclose that they had a reactive self-test result to the nearest STD clinic.

5. HIV testing strategies in response to HIV epidemic

Providing correct HIV diagnoses, as quickly as possible, is critical to all HIV testing services. To achieve accurate results, NSACP uses HIV testing strategy/algorithm whereby a combination of rapid diagnostic tests (RDTs) and/or enzyme immunoassays (EIAs), together with other supplementary tests when necessary to achieve at least a 99% positive predictive value (that is, less than one false positive per 100 people diagnosed with HIV).

5.1 Screening tests

The recommended first-line assay must detect HIV p24 antigen and antibodies for HIV 1 and HIV 2 (4th generation assay). It is advice to use a test with 99.5 % sensitivity and 100 % specificity. The advantage of using a 4th generation assay is to identify the infection earlier than assays of prior generation. In 4th generation tests infections are caught with capturing of antigens. Different methods can be used based on the place of testing whether laboratory or in the field, eg: ELISA, RDT respectively. For all private sector testing centers, it is recommended to use 4th generation assays.

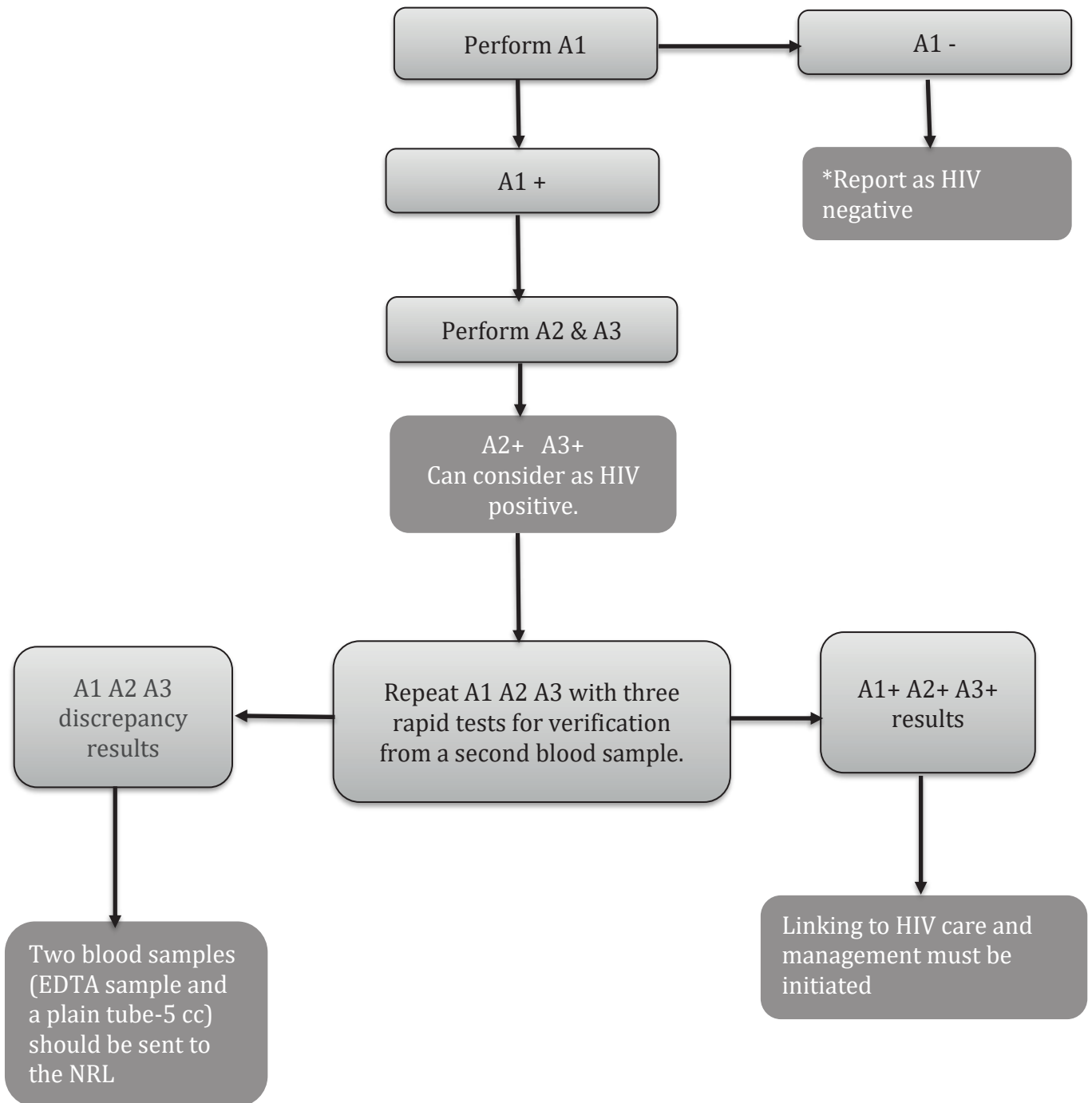


5.2 Confirmatory assays

Fourth-generation screening tests require confirmation with a supplemental test, such as an HIV-1/HIV-2 antibody differentiation assay. Single HIV test cannot confirm the HIV positive diagnosis and screening test should always be followed by confirmatory test or tests. HIV confirmation should be conducted by a qualified and trained health care worker. HIV is confirmed using WHO prequalified tests within a nationally approved testing strategy and algorithm. The epidemiological form should be filled out by the medical officer and completed epidemiological (Annexure 1) form should be sent with the HIV confirmatory blood sample to the NRL.

5.3 HIV testing algorithm (For individuals above 18 months)

Figure 1: Three test algorithm (Scenario 1)



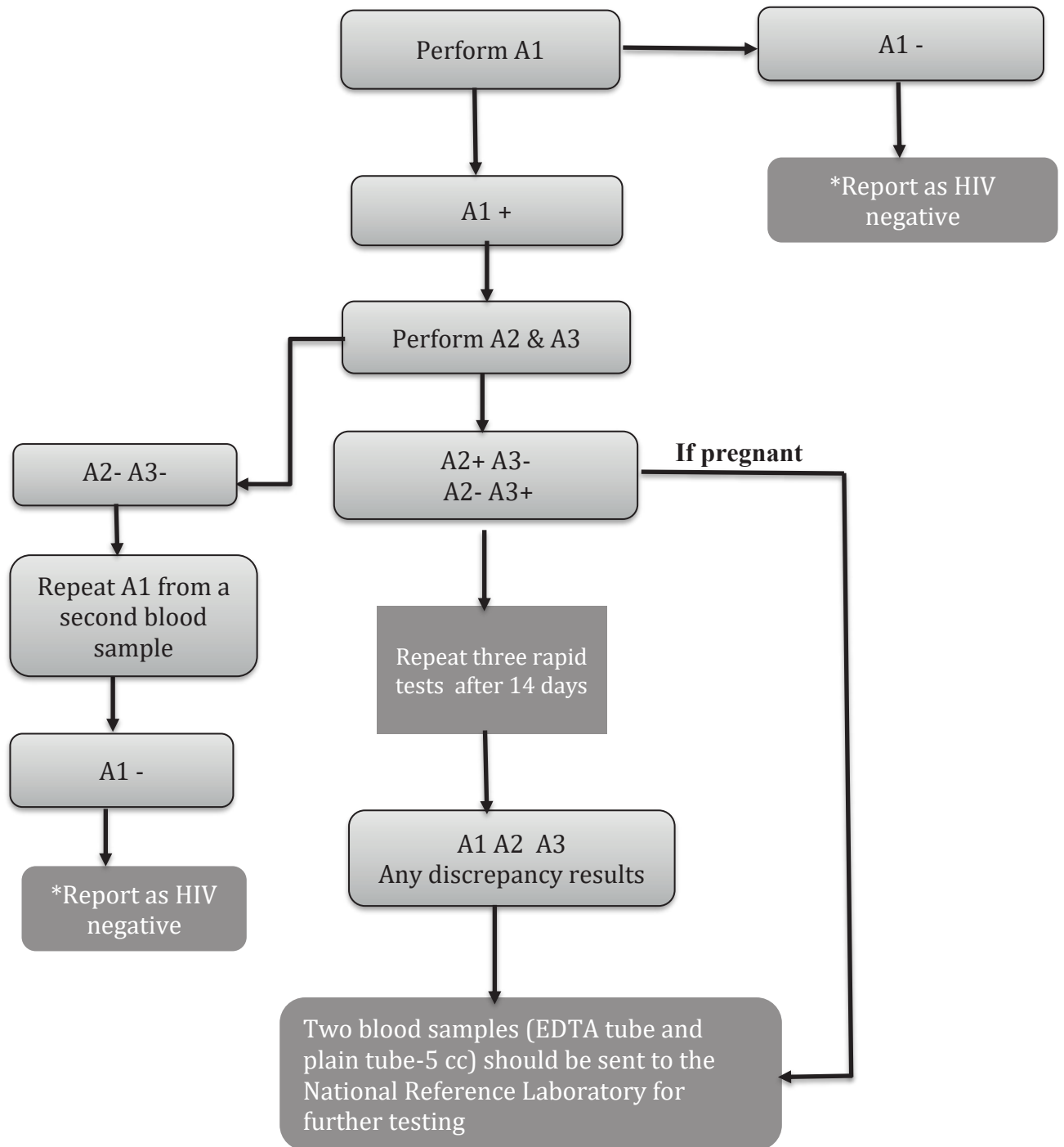
A1- HIV 1 & 2 Ag/Ab combo rapid /ELISA (Ag/Ab test)

A2- 2nd generation antibody rapid

A3- 2nd generation antibody rapid

* Consider retesting if the patient is in the window period or presence of symptoms of acute HIV infection or HIV Seroconversion

Figure 2: Three test algorithm (Scenario 2)



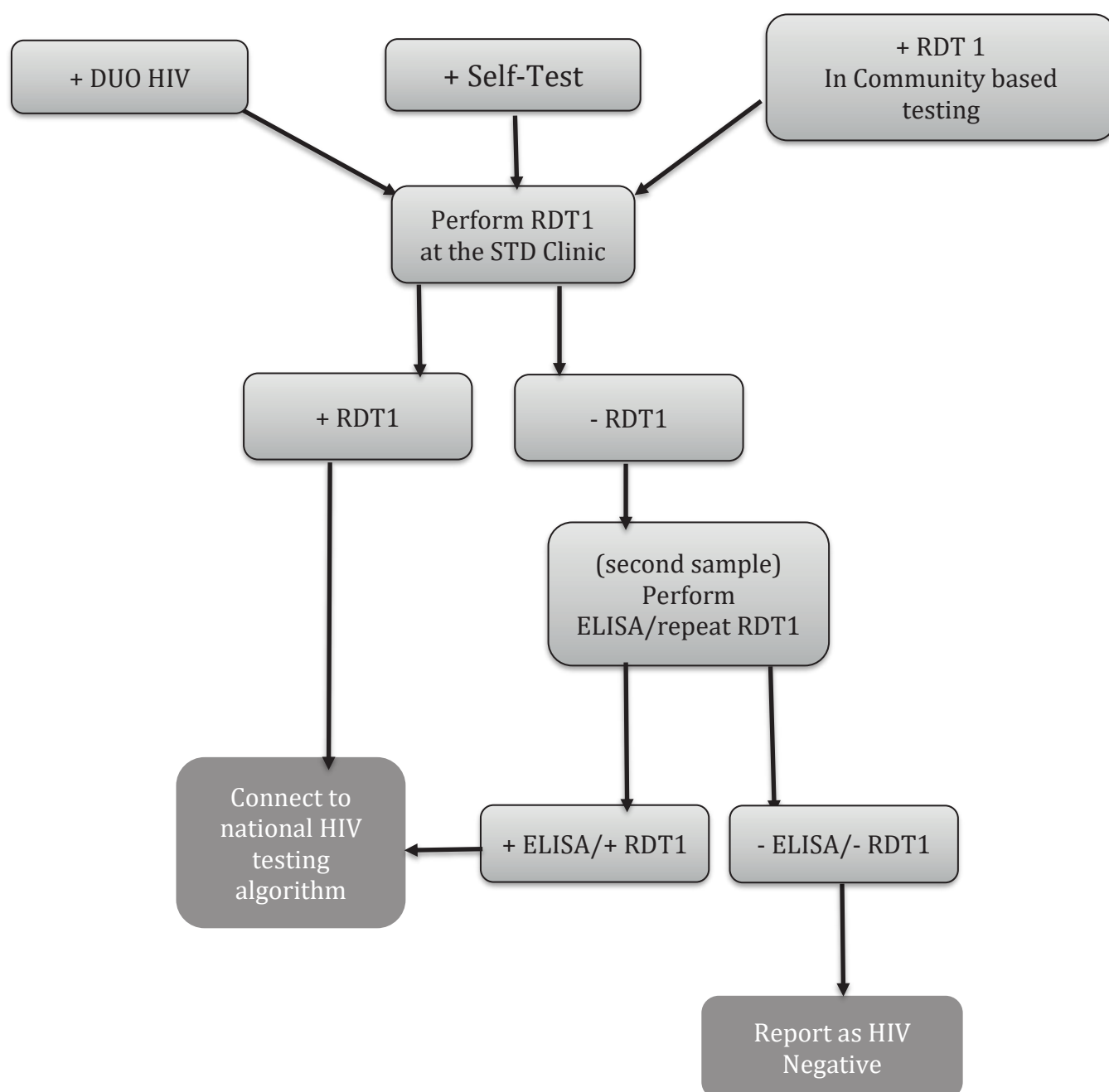
A1- HIV 1 & 2 Ag/Ab combo rapid /ELISA (Ag/Ab test)

A2- 2nd generation antibody rapid

A3- 2nd generation antibody rapid

* Consider retesting if the patient is in the window period or presence of symptoms of acute HIV infection or HIV Seroconversion

Figure 3 : Test of triage



5.3 HIV Point of care testing

HIV point-of-care testing (POCT) refers to the rapid and convenient diagnostic approach that allows healthcare providers or trained people to test individuals for HIV infection outside of traditional clinical laboratory settings. This testing method has significantly impacted the field of HIV diagnosis, treatment, and prevention, particularly in areas with limited access to healthcare infrastructure. HIV point-of-care testing has revolutionized HIV diagnosis by making it faster, more accessible, and more convenient. This approach has proven instrumental in identifying new cases, linking individuals to care, and advancing efforts to control the HIV epidemic. However, ensuring the quality and accuracy of these tests remains a critical consideration in the broader strategy of HIV prevention, treatment, and care.

Rapid and On- Site test: HIV POCT provides results in a much shorter time frame compared to conventional laboratory testing. The tests are designed to be administered on-site, often in community health centers, clinics, outreach programs, and even non-clinical settings like mobile testing vans, making testing accessible to individuals who may not otherwise seek healthcare services.

Types of POCT available in SL: Various types of HIV POCTs are available, including rapid antibody tests (HIV Self-test), rapid antigen/antibody combination test and HIV syphilis DUO test.

Challenges and considerations: While HIV POCT offers numerous advantages, there are challenges to consider, such as test accuracy, quality assurance, and training of healthcare workers.

However, POCT positive results can be confirmed by normal adult algorithm (Figure 1) by STD clinic laboratory staff. All other POCT positive clients should be referred to the nearest STD clinic or Consultant venereologist (Test of triage).

WHO /FDA recommended POCT kits should be used, and quality assurance of the testing process should always be followed.

POCT is recommended in the following contexts:

- Clinical settings where a rapid turnaround of test results is desirable
- For Key population groups
- Community based testing sites
- Outreach testing programmes
- Urgent source testing in cases of exposure incidents (PEP/PrEP services)
- Circumstances in which venipuncture is refused

6. HIV testing in different settings

6.1 Facility based testing settings

HIV testing services are provided to clients from various government, non-government, and private sector institutions.

Table 4 : Facility based testing settings

Facility based testing settings	
STD Clinics	HIV and STI co-infection are common. STI clinics provide an important entry point for HTS that should be prioritized. HIV screening is offered to clients who attend STI services during the first consultation following pre-test information. HIV Ag/Ab RDT should be offered to high-risk clients whereas ELISA can be offered to low risk clients.
TB /Chest clinics	TB is a leading cause of death among people with HIV. Early detection and prompt linkage to TB treatment along with ART can prevent deaths among people with HIV. HIV screening is offered to all persons diagnosed with TB with pre-test information. Blood samples are drawn at the TB clinics and sent to the local STD clinic laboratory for testing. Screening test results are sent to the referring physician. HIV rapid tests kits are available at some chest clinics and HIV testing is offered and done at those chest clinics. In the event of a positive screening test result, either the client or a second sample of blood is sent to the local STD clinic for confirmation. In case a sample has been sent for confirmatory test, result is sent to the referring TB physician. He/she will refer the patient to a local STD clinic for further management where HIV is confirmed.

ANC Services	All pregnant women are offered HIV testing following pretest information, with the option to ‘opt out’. Blood samples are drawn at the antenatal clinics and sent to the local STD clinic laboratory for testing. Dual HIV/syphilis RDT test is used for ANC screening. Results are sent to the relevant obstetrician or Medical Officer of Health (MOH). It is planned to evaluate the possibility of performing DUO HIV syphilis at ANC clinic settings. Pregnant mothers with the positive screening test result is referred to the local STD clinic to arrange confirmation (refer algorithm). It is recommended to offer a repeat HIV test during third trimester to pregnant women who are at risk of acquiring HIV.
Viral hepatitis services	HIV screening should be offered to all patients diagnosed with hepatitis B/C. HTS should be integrated into viral hepatitis services. Integration should be prioritized for populations most affected by both HIV and hepatitis, such as people who inject drugs and prison population. Blood samples are drawn in the wards/clinics and sent to local STD clinic laboratory for testing. But HIV point of care testing is strongly recommended in this setting.
Outpatient, in patient and emergency services in hospital settings	In all settings, HTS should be offered in inpatient and outpatient hospital settings to clients with symptoms and clinical conditions indicative of or related to HIV infection. Samples are sent to local STD clinic laboratory or hospital laboratory for testing. Point of care tests should be scaled up in these settings.

Private Sector (Private hospitals/laboratories/ general practitioners)	In private sector, either client initiated, or provider-initiated HIV testing can be arranged following provision of pre - test information. Both positive and negative screening test results are given to the individual with post - test counselling. Following a positive screening test result, it is strongly recommended to send the positive individual to nearest government STD clinic for confirmatory tests. However, failing that option a second sample of blood could be sent to NRL for confirmatory test. Confirmatory test is done at the National Reference Laboratory. Result of the confirmatory test is sent to the referring clinician or laboratory in case where a sample has been sent for confirmation. It is recommended that confirmatory test result is provided to client with post - test counseling as mentioned above. When patients are referred to STD clinics for confirmatory tests, both positive and negative confirmatory test results are given during post - test counselling at STD clinic. In addition, any general practitioners can also arrange HIV testing for clients. It could be either client initiated or provider-initiated testing. Results should be given to patients with post-test counselling.
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6.2 Outreach / Community based HIV Testing

Community based HIV testing services are carried out by STD clinics as well as through peer led interventions. It is done either with serology, using rapid HIV tests or self-tests. In addition to MLTs, selected health staff and NGO staff (trained care providers - TCP) are trained to perform rapid HIV testing at field level. Outreach testing is promoted for following groups / situations.

6.2.1 Key Affected Populations

Peer-led targeted intervention programme in collaboration with STD clinics provide outreach HIV testing services for key populations on regular basis. HIV testing services are provided through outreaching to key populations by STD clinic staff on their own initiative. MSM, TG, FSW, beach boys, PWID, and prisoners are the identified KPs in Sri Lanka.

During outreach testing, pre-test information is provided on an individual or group basis. If requested, individual pre-test counseling should be provided by a trained care provider. People who consent for testing should be provided with an HIV rapid screening test or assisted HIV self-test by a trained care provider.

Testing frequency

- ❖ Optimum – once in 6 months for FSW, TG, MSM, PWID and beach boys
- ❖ Minimum– annual

Please refer Figure 3, for the protocol for community-based HIV testing.

6.2.2 HIV testing for Vulnerable populations

- Migrant workers – HIV testing needs to be included in a general health screening package for external migrant workers who have returned. The services will be provided through a provider-initiated approach in collaboration with other relevant stakeholders.
- Youth and adolescents in vulnerable settings
- Tourism industry workers
- Inbound health assessment for foreign labor migrant workers
- Annual testing is recommended for the members of these population groups.

6.2.3 People living in difficult geographical and urban low-socioeconomic areas

The testing services are promoted among estate sector workers and people living in urban low-socioeconomic areas through provider-initiated approach. However, the accessibility for HIV testing services is limited in these groups. Therefore, outreaching for them with relevant services is recommended.

6.2.4 People who find it difficult to attend services during working hours

This guideline recommends that the members of population groups such as three-wheeler drivers, fishermen, and long-distance drivers etc. to be provided with HIV testing services through provider-initiated approach.

6.2.5 Special events-based HIV testing (World AIDS day, special exhibitions)

HIV testing promotional campaigns could be integrated into other related events such as world AIDS day or other health promotion exhibitions etc.

6.2.6 HIV testing in prisons

Voluntary testing through provider-initiated approach is offered to inmates while they are in prison. If the prisoner has been tested within the preceding three months, he/she need not be offered testing. Peer educator training programmes for prison inmates on HIV/STI are being carried out by the prison welfare officers who are trained by NSACP. The peer educators conduct both formal and informal education for prison inmates. This is followed by group discussions and one-to-one discussion when required. During these sessions group pre-test information / counseling is given, and HIV testing is promoted. Monthly outreach HIV testing is conducted by the staff attached to central and district STD clinics of the National STD/AIDS Control programme for prisons with the support of prison staff covering HIV testing in 30 prisons island wide. Some prisons have continued to do tests by trained prison staff at the prison premises.

6.3 HIV testing through virtual reaching

A special internet -based outreach testing programme is in place in some of the STD clinics by online outreach workers. This programme is mainly targeting KPs who find partners through social media. Internet peer-educators encourage them through social media to carry out HIV risk assessment and facilitates to have HIV test. “know4sure.lk” online platform is available for online clients to have the risk assessment, information, education communication and book an appointment for HIV testing.

HIVST kits are couriered for those who request HIV ST through this online plat form or through online outreach workers.

6.4 HIV screening for donor blood

Blood collected for transfusion or for manufacture of blood products are screened for HIV and other blood borne viruses (All donors are informed during donor counseling that a sample of the given blood is tested for HIV and other blood borne viruses).

All confirmed HIV positive blood donors are traced and referred to district STD clinics for HIV care after a post- test counselling while maintaining confidentiality.

6.5 HIV screening in organ donors

- Donors involving in transfer of bodily fluids or body parts, such as artificial insemination, corneal grafts, and organ transplant are screened for HIV prior to procedures.
- Antigen and antibody combo test/fourth generation ELISA is recommended prior to organ transplant.
- Pre-donation NAAT testing may help reduce the residual risk of infection during the serological window period and may be done on an individual basis.
- If the donors are found to be HIV positive, they should be referred to STD clinics for further evaluation and HIV care.

6.6 HIV screening before major invasive surgical procedures

HIV screening is done before major surgical procedures, and the HIV positives should have been referred to nearest STD clinic for HIV care.

7. HIV testing in special situations

7.1 Testing infants and other children for HIV

Any infant/child/young person thought to be at significant risk of HIV infection, including all those with parents or siblings who are HIV-infected, should be tested. It is in the best interest of the infant/child/young person to be tested in these circumstances although this only needs to be undertaken urgently in infants who are at risk of rapid disease progression.

7.1.1 Indications for HIV testing among children

1. Infants and children whatever their age where the mother has HIV or may have died of an HIV associated condition
2. Infants born to mothers known to have HIV in pregnancy
3. Infants born to mothers who have refused an HIV test in pregnancy
4. Infants and children with signs and symptoms consistent with an HIV diagnosis (See table 5 for indicator conditions among infant and children)
5. Infants and children are being screened for congenital immunodeficiency
6. Infants and children in circumstances of post-exposure prophylaxis
7. Infants and children in cases where there has been sexual abuse

7.1.2 Obtaining consent for HIV testing from children <10 years old

As the child is unable to give consent, consent is taken from one parent or caregiver following provision of pretest information. However, in the circumstances where a caregiver or parent is not available, the caring doctor should seek advice from Venereologist and venereologist can consider ordering HIV test for the best interest of the infant or child.

Table 5 : Clinical indicator diseases for pediatric HIV infection

AIDS-defining conditions		Other conditions where HIV testing should be offered
ENT		Chronic parotitis
		Recurrent and/or troublesome ear infections
Oral		Recurrent oral candidiasis
		Poor dental hygiene
Respiratory	Pneumocystis pneumonia	Recurrent bacterial pneumonia
	CMV pneumonitis	Lymphoid interstitial pneumonitis
	Tuberculosis	Bronchiectasis
Neurology	HIV encephalopathy	Developmental delay
	meningitis/encephalitis	Childhood stroke
Dermatology	Kaposi's sarcoma	Severe or recalcitrant dermatitis
		Multi dermatomal or recurrent herpes zoster
		Recurrent fungal infections
		Extensive warts or molluscum contagiosum
Gastroenterology	Wasting syndrome	Unexplained persistent hepatosplenomegaly
	Persistent cryptosporidiosis	Hepatitis B infection
		Hepatitis C infection
Oncology	Lymphoma	
	Kaposi's sarcoma	
Haematology		Any unexplained blood dyscrasia including:
		• Thrombocytopenia
		• Neutropenia
		• Lymphopenia
Ophthalmology	Cytomegalovirus retinitis	Any unexplained retinopathy
Other	Recurrent bacterial infections (Meningitis, Sepsis, Osteomyelitis, Pneumonia etc.)	
	Pyrexia of unknown origin	

7.1.3 Testing of children of known HIV-positive parents

Testing should be offered in all cases at risk of vertical transmission. Increasing evidence shows that children infected vertically can survive into their teenage years without being diagnosed. Therefore, it can't be assumed that older children of mothers with HIV do not require testing. This raises difficult issues of informed consent for these young people, particularly if they are unaware of the mother's diagnosis. Testing of neonates, children, and young people where the mother refuses consent and/or disclosure of her HIV status is a complex area. The overriding consideration must be the best interests of the child, and multidisciplinary decision-making and expert advice should be sought, including legal advice where appropriate. It is not acceptable to simply accept the mother's refusal. Referral to NSACP with experience in managing HIV-infected children is strongly recommended. Parents may need to be supported in making the decision to go ahead with testing their children.

What do children need to know about having an HIV test?

One of the main reasons that parents do not want to test their children for HIV is because they are afraid to share the diagnosis with them. It should be explained to parents that developmentally and age-appropriate explanation of the test should be given to children and ~~it~~ does not necessarily mean using the term HIV.

- Older children (usually those older than 11) should be asked to give consent for an HIV test.
- Younger children (usually five to ten years of age) can be told they are being tested for a 'bug' in the blood.
- Pre-school children and infants do not need any formal explanation of why they are having a blood test.

Appropriate HIV tests for infants and children

- **Children older than 18 months of age:** HIV antigen antibody assays, as same as for adults. Please follow the adult HIV testing algorithm.
- **Infants younger than 18 months of age:** infants born to mothers with HIV receive trans placental maternal HIV antibodies which can usually be detected in the infant blood until about 18 months of age. Therefore, molecular diagnostics (HIV DNA/ RNA nucleic acid tests) are the investigation of choice for diagnosis of HIV in infants and children younger than 18 months.

Diagnosis of a baby born to HIV positive pregnant mother

- **When a mother is known HIV positive, and the baby is formula fed:**

Molecular diagnostics (DNA or RNA nucleic acid tests)

1. At birth (within 48 hours)
2. At 8 weeks
3. At 4-6 months – babies who have negative nucleic acid test at 8 weeks and 4-6 months are considered HIV negative

HIV Ag/Ab type 1 & 2 ELISA

- This test is performed at 9 and 18 months to confirm sero-conversion of maternal antibodies.
- If HIV ELISA is negative at 9 months, it should be repeated immediately with a repeat blood sample to confirm sero- conversion.
- Children with perinatal HIV exposure aged 18-24 months may rarely have residuals maternal antibodies.
- In such cases, confirmation should be based on nucleic acid test.

Definitive exclusion of HIV infection in non-breast-fed infants

Definitive exclusion of HIV infection in non-breast-fed infants is based on two or more negative virologic tests, with one obtained at age ≥ 1 month and one at age ≥ 4 months or two negative antibody tests from separate specimens obtained at age ≥ 6 month.

- **When a mother is known to be HIV positive and breast feeding**

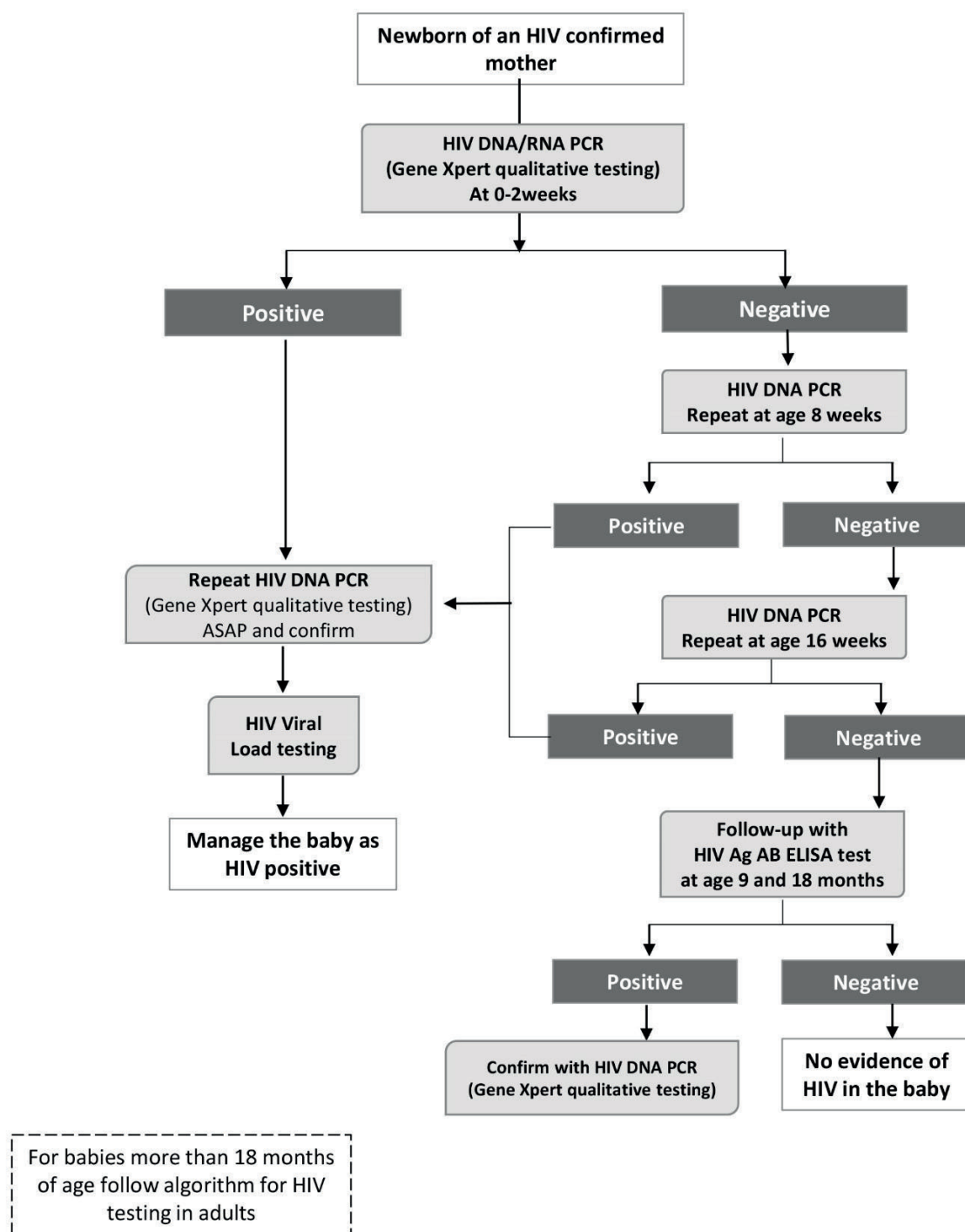
In addition to the testing mentioned for non-breast-fed infants, monthly molecular testing is recommended until cessation of breast feeding and repeat testing should be performed 6 weeks after stopping breast feeding.

- **Confirmation of HIV positive results**

If any of the above molecular tests becomes positive, it is recommended to repeat testing using a separate sample immediately and confirm the diagnosis.

Infants whose serological assays are reactive at 9 months should undergo virological test to rule out the infection.

Figure 4 : HIV testing algorithm for early infant diagnosis



Source: Adopted from Antiretroviral therapy for HIV infection in infants and children: towards universal access. Recommendations for a public health approach. 2010 revision. Geneva, WHO 2010

7.1.4 HIV testing in babies whose mother's HIV status is unknown

Babies of unknown mothers (when mother is not available for testing) can be tested with serological tests for exclusion of HIV infection, but if they become positive it should always be confirmed by molecular assays.

Children less than 18 months of age with a reactive screening test should undergo molecular assays for confirmation.

On the other hand, definitive exclusion of perinatally acquired HIV infection in children whose mothers HIV status is unknown, and mother is not available for testing is only possible by two negative antibody tests from separate specimens obtained at age ≥ 6 month, if they are not breastfed during last 6 weeks.

Children of 18 months of age or older with suspected HIV infection or HIV exposure should undergo HIV serological testing performed according to the validated national testing algorithm used in adults.

7.2 Adolescents (10-19 years)

Two groups of adolescents need HIV testing:

- Adolescents who had the risk of perinatal transmission of HIV and who were not diagnosed in infancy.
- Adolescents who are vulnerable to HIV through early sex or injecting drug use, particularly adolescents from key populations and those with other vulnerabilities.

7.2.1 Age of consent in children less than 16 years

HIV testing in children is conducted on case-by-case basis, in consultation with relevant authorities within the health system. It has to be done adhering to the principles of “five Cs”. Consent of the parent or legal guardian following counseling should be sought prior to testing children below the age of 16 years. If a parent or caregiver refuses HIV testing, the health-care provider should offer additional counselling on the rationale for testing and the potential benefits to the child. When counseling of a child below 16 years is required, preferably it should be done with parent's consent.

When all efforts to obtain parental consent have failed, health care provider has an ethical responsibility to act in the best interest of the child as the treatment available is lifesaving. In the given context, the provider should test the child and initiate treatment.

In situations that child presents for the services alone, the health care provider can perform the HIV test, whenever he/she is satisfied with the child's understanding of the test.

Additionally, HIV testing and the status of the child tested must not be used to deny other rights to a child. This means that a child's HIV status should not be used to discriminate against them in any way, including in education, healthcare, or employment.

In instances where there is no parent or legal guardian to give consent (eg: orphans, abandon children, street children) decision to test should be made by the health care provider and it should be done in the best interest of the child.

7.3 Partners of HIV infected people

Partner HIV testing services with support for mutual disclosure is offered to all individuals who are diagnosed with HIV. Uptake of HIV test by the partner must be voluntary. When a sero-discordant couple is under care, health care provider must explain the positive person about healthcare provider's responsibility towards the health of negative partner and by doing so to persuade for regular HIV testing services for negative partner. Negative partners should be tested once in six months.

7.4 HIV testing related to post exposure prophylaxis (PEP)

Testing both healthcare provider and source person for HIV is required during management of healthcare workers following occupational exposure to blood and other body fluids.

7.5 International migrant workers

HIV testing and counselling should be considered among international migrant workers who come from countries with high HIV prevalence. HIV testing services should adhere to the "Five Cs".

7.6 Surveillance Purposes

In situations of various surveillance / research where HIV testing is required, voluntary participation is essential and needs to be in conformity with National HIV testing guidelines. Sri Lanka being a country with low level HIV epidemic, regular HIV biological surveillance is confined to key population groups. It is recommended to use a linked testing approach during HIV sero- surveillance.

7.7 Victims of sexual assault and non-occupational injuries

Testing victims of child sexual abuse - Testing of victims of child sexual abuse should be considered in every case according to risk factors. Testing should always be performed if post- exposure prophylaxis is to be given.

In situations of sexual assaults and non-occupational injuries HIV testing services should be offered on case-by-case basis.

8. Monitoring and Evaluation of HIV testing

The monitoring of HIV testing involves various processes and activities aimed at ensuring the accuracy, quality, and effectiveness of HIV testing services. Effective monitoring is essential to detect and prevent the spread of HIV, provide timely treatment and support to those affected, and evaluate the impact of prevention and treatment programs.

- **Quality Assurance** : Quality assurance of testing done by adhering to internal quality control measures on day-to-day basis and by participating external quality assurance programme on a regular basis. The NRL is conducting a national quality assurance (NEQUAs) programme.
- **Laboratory Accreditation** : HIV testing laboratories should meet national and international standards for accreditation. Accreditation ensures that testing facilities meet specific quality and competence criteria. It is advised to laboratory to get accredited to the test if possible. If not, laboratories must try and achieve ISO15189 standards for medical laboratories.
- **Training and Competency assessment** : Healthcare workers responsible for conducting HIV tests and outreach testing workers are trained properly and undergo regular competency assessments. This ensures that testing is performed correctly.
- **Documentation and record keeping** ; Proper documentation and record-keeping are maintained for tracking the results of HIV tests, maintaining patient confidentiality, and ensuring traceability.
- **Data Management** : Data is essential for monitoring trends and evaluating the impact of prevention and treatment programs. It is managed by Strategic Information Management (SIM) Unit NSACP.

8.1 Data management

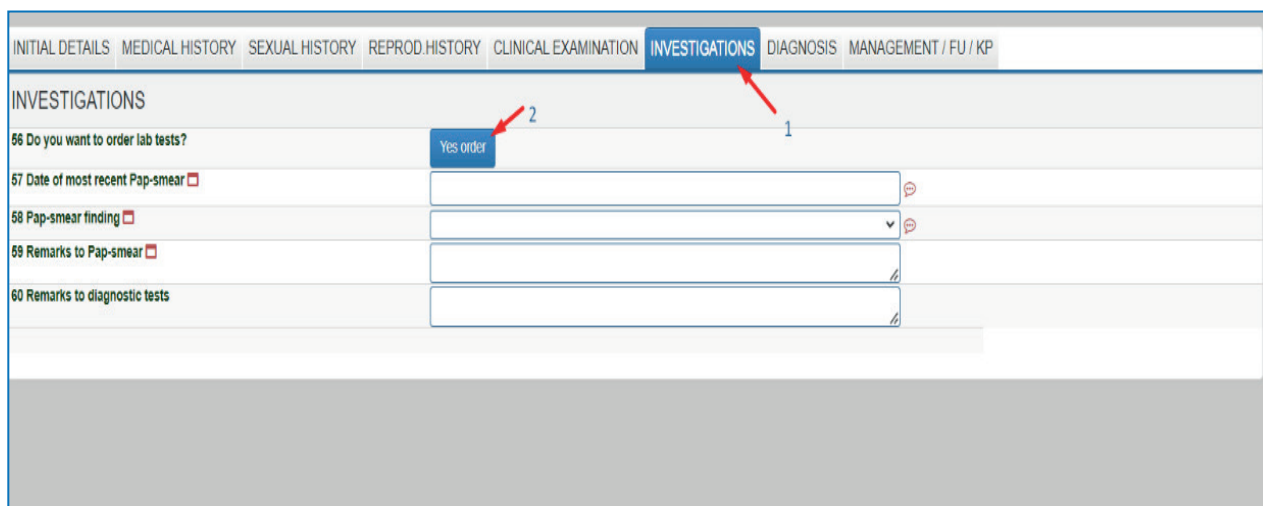
Monitoring and evaluation (M&E) of HIV testing involves several systems e.g. Electronic Information Management System (EIMS), Prevention Information Management System (PIMS), Know4sure.lk and reported via the quarterly returns using Google sheets from STD clinics. In addition, paper-based formats are still used in several STD clinics.

Electronic Information Management System (EIMS) is a medical record system used to record, manage, and analyze data related to patient data across the country. It allows for the efficient collection and storage of patient information, test results, and other pertinent data.

Prevention Information Management System (PIMS) manages outreach key population coverage data related to HIV testing performed on key population by outreach staff such as peer educators, online and physical outreach workers etc. It assists in coordinating data between the field and at national level by key population programme implementing staff.

Google sheets are used to collect Quarterly returns/reports submitted by the relevant staff of STD clinics to the SIM Unit of NSACP once every three months. These returns contain aggregated data including number of HIV tests conducted, test outcomes, demographic information of patients, and any trends or observations noted during the period.

Figure 5 : HIV testing is ordered by consulting doctor when ordering blood tests



The screenshot shows the 'INVESTIGATIONS' tab in a medical record system. The tab is highlighted in blue. Below the tab, there is a form with the following fields:

- 66 Do you want to order lab tests? (Arrow 2 points to this button)
- 67 Date of most recent Pap-smear (Arrow 1 points to the 'INVESTIGATIONS' tab)
- 68 Pap-smear finding
- 69 Remarks to Pap-smear
- 60 Remarks to diagnostic tests

Analysis of this information helps to identify the achievements in the targets and gaps in service delivery. Regular monitoring of HIV testing services supports evidence-based decision-making and facilitates adjustments to policies and strategies to enhance the effectiveness of HIV prevention services.

8.1.1 Monitoring of HIV testing through EIMS

Electronic Information Management System (EIMS) is the medical record system used in STD clinics in Sri Lanka. The EIMS system is used to record, manage, and analyze data related to patient data on real-time basis. All the clients seeking care at STD clinics will be registered to the EIMS system.

There are two types of registrations relevant to HIV testing.

Figure 6 : Opening investigation in EIMS

Available Groups/Subgroups			
01 Routine screening	☐ Select all test		
03 Anal discharge			
04 Genital ulcer			
06 Eye infection			
07 Skin infections			
08 CNS infection			
09 Newborn of mother with HSV			
10 Suspected ophthalmia neonatorum			
11 Newborn of mother with syphilis			
12 Newborn of mother with HIV			
13 Haematology			
14 Blood & Urine glucose			
15 Biochemistry - all			
15.1 Liver			
15.2 Renal			
15.3 Lipids			
15.4 Bilirubin			
16 ART therapy related			
17 TB screening sputum			
18 Microscopy			
20. Visa screening			
55. PrEP clinic lab-tests			
External tests			
HIV testing by RDT			
HIV testing by RDT			

Section/Department	Priority	Test
☒ Serology-HIV	Routine	Syphilis / HIV Duo tests
☐ Microscopy	On site	Smear for N. gonorrhoeae, urethral
☐ Microscopy	Routine	Smear for Cand, Clue Cells, Lactob., vaginal
☐ Microscopy	On site	Wet smear for Candida (KOH), lat vaginal wall
☐ Microscopy	On site	Saline smear, post fornix
☐ Microscopy	On site	Smear for N. gonorrhoeae, cervical
☐ Microbiology	On site	Culture for N. gonorrhoeae, urethra
☐ Microbiology	On site	Culture for N. gonorrhoeae, cervical
☐ Serology-SY	Routine	VDRL (serum)
☐ Serology-SY	Routine	TPPA (serum)
☒ Serology-HIV	Routine	HIV Ag+Ab/Abs screening test
☐ Molecular biology	Additional	HIV - RNA PCR
☒ Serology-HIV	Routine	HIV Rapid tests
☐ Serology-SY	Routine	Syphilis Rapid test
☐ Serology-HIV	Routine	HIV-Particle agglutination test
☐ Microscopy	On site	Smear for N. gonorrhoeae, high vaginal
☐ Microscopy	On site	Smear for N. gonorrhoeae, oropharyngeal

HIV testing can be ordered by public health staff after the short registration process for needy clients.

Figure 7 : Ordering HIV test in EIMS via short registration

Patient short registration

Title

* First name

* Last name

Current address

Current District, Division, GN Division

Contact Number

National ID

* Sex - at birth

* Date of birth

Age of patient

Old clinic ID

UIC

Remarks

Save

Cancel

Saving options

Save

Create visit

Order lab

Once HIV test is ordered, blood samples will be collected by a nursing officer after generating a sample number with a barcode and pasted onto the tube, before the sample is sent to the laboratory for testing. HIV testing will be performed by an MLT and results are entered to the system. The technical verification and clinical verification will be done by relevant laboratory staff.

Figure 8 : Entering HIV test in the laboratory

#	Performed at	Section	Test name	Result	Ref. value	Tech. Verification	Clinic. Verification	Print
1	Colombo	Serology-HIV	HIV-rapid test -1	negative	non-reactive	Yes Verified Dr. D. J. Pole @ 2021-12-04 12:50:07	Yes Verified Dr. D. J. Pole @ 2021-12-04 12:50:31	

Figure 9 : HIV test results viewing in EIMS medical record

Date	Test name	Status
21.12.04	HIV-rapid test -1	✓✓✓
20.01.11	Darkground microscopy leptospirosis (CSF)	✓✓✓
20.01.07	HIV confirmatory test (WB/LB)	✓✓✓

8.1.2 Generating reports of HIV tests via EIMS

Report generation on HIV testing is available in EIMS. Users need to indicate the date range for the report. Then a report will be generated. This report can be downloaded in Excel format for further analysis.

Figure 10 : Selection of the report to be generated.

Figure 11 : HIV test report generation in EIMS

Colombo Laboratory report for lab tests samples received or rejected for 2023-11-02								Download	Close
CLINIC	SAMPLE ID	ORDER	TEST	STATION	RES. STATUS	RESULT	Active		
			hiv						
STD male clinic	SXMIXC	01 Routine screening	HIV Ag+Ab/Abs screening test	Colombo			Active		
STD female clinic	SXGLFE	01 Routine screening	HIV Ag+Ab/Abs screening test	Colombo			Active		
STD female clinic	SXBRDV	01 Routine screening	HIV-rapid test -3	Colombo			Active		
STD female clinic	SXBRDV	01 Routine screening	HIV-rapid test -2	Colombo			Active		
STD female clinic	SXBRDV	01 Routine screening	HIV-rapid test -1	Colombo		negative	Active		
STD female clinic	SXJXH0	01 Routine screening	HIV-rapid test -3	Colombo			Active		
STD female clinic	SXJXH0	01 Routine screening	HIV-rapid test -1	Colombo		negative	Active		
STD female clinic	SXOF2X	01 Routine screening	HIV Ag+Ab/Abs screening test	Colombo			Active		
STD female clinic	SXJXH0	01 Routine screening	HIV-rapid test -2	Colombo			Active		
STD male clinic	SXV4NW	01 Routine screening	HIV Ag+Ab/Abs screening test	Colombo			Active		
STD female clinic	SXRWJ5	01 Routine screening	HIV-rapid test -2	Colombo			Active		
STD female clinic	SXRWJ5	01 Routine screening	HIV-rapid test -1	Colombo		negative	Active		

8.1.3 Monitoring of HIV testing through PIMS

Prevention Information Management System (PIMS) is used by the Key Population (KP) intervention staff to enter the clients who are reached and tested in addition to other services given.

The Management Assistant (MA), Physical Outreach Worker (ORW) and the Online Outreach Worker (OOW) of the key population unit are the main users of the system. STD clinic consultant, medical officers, and administrative staff of NSACP (SIM unit) are monitoring the testing progress using the system.

8.1.4 Steps in using PIMS

1. Registration of a client of key population and service provision using PIMS is shown in the below figures.

Figure 12 : Client Registration in PIMS

- Transactions
- Clients
- Service Statistics
- Stock Management
- Components
- Reports

Powered by K-SOFT

Home

Clients / New

Save Check Duplicates New UIC & Save Discard

New

Reg Date * 01-November-2022 UIC * Nickname Name * NIC 1stName1stL * X NIC 2ndName1stL * X

Sex at birth * --None-- Is transgender * No Date of birth * dd-month-yyyy Age 0 District of birth --None-- NIC Checked No

Marital status --None-- Mobile No. Mobile No. District * --None-- STD Clinic * --None-- Sub-population * --None-- Hotspot --None--

Address Description

Address Description

2. Creation of a unique identifier code (UIC): Each client entered to PIMS is registered with a given Unique Identifier Code (UIC) which is the primary identifying code for a client. Once a UIC is created in PIMS, services and commodities offered can be given and recorded under the relevant UIC.

Figure 13 : Service statistics in PIMS

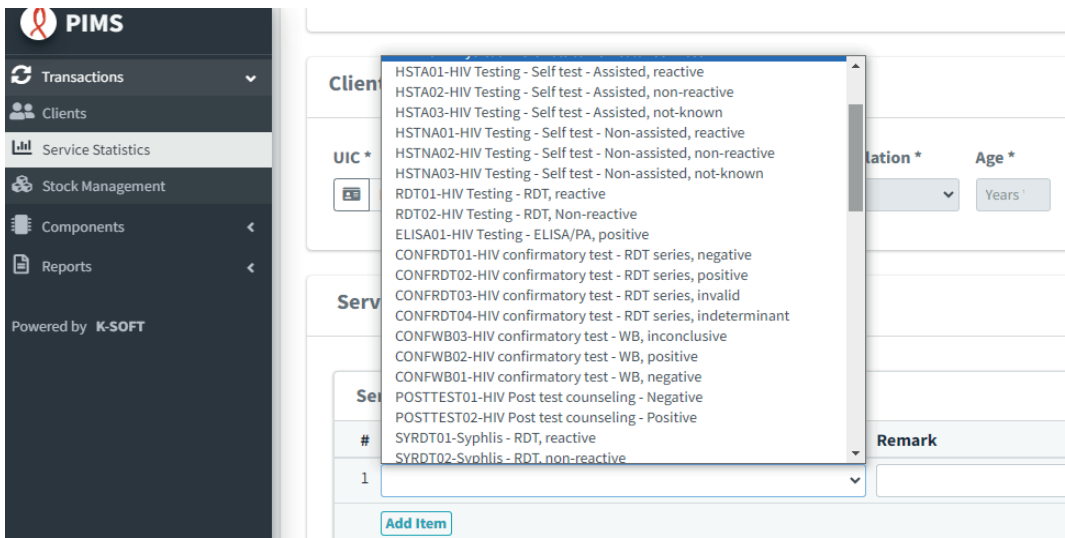
The screenshot shows the 'Service Statistics / New' form in the PIMS application. The form is titled 'New' and has a 'Save' button at the top left. It is organized into three main sections:

- Programme Specific Data:** This section contains four dropdown menus: 'STD Clinic *' (with a '--None--' option), 'Project *' (with a '--None--' option), 'Method of service delivery *' (with a '--None--' option), and 'Date of service provision' (with a date field showing '01-November-2023' and a calendar icon).
- Client Specific Data:** This section contains six dropdown menus: 'UIC *' (with a 'Load' button and a text input for 'Enter UIC/Barcode'), 'District *' (with a '--None--' option), 'Sub Population *' (with a '--None--' option), 'Age *' (with a 'Years *' label), 'Sex at birth *' (with a '--None--' option), and 'Transgender *' (with a 'No' option).
- Service Provision Data:** This section contains a table with two columns: '# Service' and 'Remark'. Below the table is an 'Add Item' button.

3. Provision of services: these can be entered (Figure 12) on each client by the UIC in “Service statistics”. Services are selected from the drop-down menu. Such as.

- Self-testing – assisted and non-assisted
- RDT testing
- HIV testing for ELISA/PA
- HIV confirmatory test – RDT series and WB

Figure 14 : List of testing services in PIMS



8.2 Know4sure.lk

The public can order HIV self-test kit or book a clinic appointment for HIV testing services. HIV self-test kits are sent via courier service to client's preferred address. An online outreach worker will virtually support the client to do the test correctly and arrange a physical visit to a clinic in case of positive or doubtful test result.



8.3 Quarterly returns using Google sheets

The STD clinic quarterly return capture aggregated data from each STD clinic comprising of twenty-five (25) tables. The STD Quarterly return is segregated into three parts. For reporting HIV testing, the tables below need to be used in the Google sheet on STD quarterly returns.

Table 6 : HIV testing data tables in the quarterly return

Part	Table & Number
Part I	Table 6: Number of samples tested for HIV infection Table 10: No. of new KPs tested for HIV by STD clinic staff and staff of KP unit within STD clinic or by outreach events Table 14: HIV and syphilis tests performed by private laboratories in the area of STD clinic
Part II	Table 22: No. of new KPs tested for HIV by KP unit within STD clinic or by outreach events* during the quarter (<i>Table 03</i>)
Part III	Table 25: Virtual HIV self-testing by online outreach workers during this quarter by age (<i>Table 04</i>)

Table 6. Number of samples tested for HIV infection					
		Number screened for HIV (ELISA, PA, Rapid)	Number positive	Number tested by a confirmatory test (WB, LB), PCR	Number of confirmatory test positives
6.1	STD patients' samples	139			
6.2	Antenatal samples	912			
6.3	Pre-employment samples	134			
6.4	Other samples	64			
	Total	1249	0	0	0

Table 10 No. of new KPs tested for HIV by STD clinic staff and staff of KP unit within STD clinic or by outreach events* during the quarter													
		Total tested for HIV by STD_outreach <25 y	Total tested for HIV by STD_outreach ≥25 y	Received positive results by STD_outreach <25 y	Received positive results by STD_outreach ≥25 y	Received negative results by STD_outreach <25 y	Received negative results by STD_outreach ≥25 y	Total tested for HIV by KPU_outreach <25 y	Total tested for HIV by KPU_outreach ≥25 y	Received positive results by STD_outreach <25 y	Received positive results by STD_outreach ≥25 y	Received negative results by KPU_outreach <25 y	Received negative results by KPU_outreach ≥25 y
10.1	FSW												
10.2	MSM (non TG)												
10.3	Transgender												
10.4	Beach boys												
10.5	Male IDU												
10.6	Female IDU												
10.7	Male prisoners												
10.8	Female prisoners												
10.9	Others (DU)												

Table 14: HIV and syphilis tests performed by private laboratories in the area of STD clinic (No of private laboratories.....)				Male	Female	Total
14.1	No. HIV screening tests done					0
14.2	No. HIV screening positive					0
14.3	No. sent for confirmation					0
14.4	No VDRL tests done					0
14.5	No VDRL positive					0
14.6	No TPPA/TPHA tests done					0
14.7	No TPPA/TPHA positive					0

Table 22 No. of new KPs tested for HIV by KP unit within STD clinic or by outreach events* during the quarter							
		Total tested for HIV by KPU_outreach or within STD clinic <25 y	Total tested for HIV by KPU_outreach or within STD clinic ≥25 y	Received positive results by STD_outreach or within STD clinic <25 y	Received positive results by STD_outreach or within STD clinic ≥25 y	Received negative results by KPU_outreach or within STD clinic <25 y	Received negative results by KPU_outreach or within STD clinic ≥25 y
22.1	FSW						
22.2	MSM (non-TG)						
22.3	Transgender						
22.4	Beach boys						
22.5	Male IDU						
22.6	Female IDU						
22.7	Prison* - Male						
22.8	Prison* - Female						
22.9	Other (e.g.DU etc)						

Table 25: Virtual HIV self-testing by online outreach workers during this quarter by age						
		Total V-HIV-tested by OOW_outreach/within STD clinic <25 y	Total V-HIV-tested by KPU_outreach ≥25 y	Received positive results by V-HIV-tested <25 y	Received positive results by STD_V-HIV-tested ≥25 y	Received negative results by KPU_V-HIV-tested <25 y
25.1	FSW					
25.2	MSM (non TG)					
25.3	Transgender					
25.4	Beach boys					
25.5	Male DU/IDU					
25.6	Female DU/IDU					

9. Annexures

Request for HIV Confirmatory testing from the Reference Laboratory of the National STD/AIDS Control Programme

(VERSION: 7.4.2017)

Instructions: To be completed by referring doctor/healthcare worker at the time of requesting HIV confirmatory test from the reference laboratory of the National STD/AIDS Control Programme, No. 29, De Saram Place, Colombo 10, Sri Lanka. Patient should be informed that all questions contained in this questionnaire are strictly confidential and will become part of their medical record)		Part I: TO BE FILLED BY THE REFERENCE LABORATORY Date of Receipt Day Month Year Date of Confirmation Day Month Year		
PART II – TESTING DETAILS AND DEMOGRAPHIC INFORMATION				
PATIENT/CLIENT IDENTIFICATION INFORMATION If STD clinic patient fill A otherwise fill B	1A. STD Clinic Registration Number (For STD Clinic Clients) Gender Sequential No Year Clinic Code		1B. Sample Details Institute/Hospital : Ward/ Clinic : BHT/ Clinic No :	
HIV SCREENING TEST DETAILS	2. Type of Screening Test ☐ a. ELISA Test ☐ b. Particle Agglutination Test ☐ c. Rapid Diagnostic Test ☐ d. Other		3. Date of Screening Test: Day Month Year	
HIV TESTING HISTORY	4. Has patient/client ever been tested for HIV previously ☐ a. Yes (date of last negative test) Day Month Year ☐ b. No ☐ c. Not Known			
DEMOGRAPHIC INFORMATION	5. Name and address of Patient/Client Name : _____ Address : _____ _____		6. Gender ☐ M ☐ F ☐ Other	7. Date of Birth Day Month Year
	8. Marital status ☐ a. Single/Never Married ☐ b. Currently Married ☐ Living Together ☐ c. Widow/Sep./Divor. & Living with spouse			
	9. Occupation ☐ a. Unemployed ☐ b. Student ☐ c. Employed as: _____ ☐ d. NA			
	10. District of Residence:		11 Nationality ☐ a. Sri Lanka ☐ b. Other (specify) _____	
	12. Ethnicity ☐ a. Sinhalese ☐ b. Tamil ☐ c. Moore ☐ d. Other (specify) _____ ☐ e. Not Sri Lankan			
13. Reason for HIV Testing (More than one option possible)				
☐ a. Voluntary Testing ☐ b. STD Screening ☐ c. Provider Initiated Testing (asymptomatic) ☐ d. Clinical symptoms suggestive of HIV	☐ e. Accompanied by NGO outreach worker or peer ☐ f. Partner/spouse or family member diagnosed ☐ g. Blood Donor Screening ☐ h. ANC Screening	☐ i. Visa Screening ☐ j. Foreign Job Screening ☐ k. Screening for Legal/Insurance purposes ☐ l. Screening before Medical/Surgical Procedure	☐ m. Screening as part of a Survey ☐ n. TB clinic screening ☐ o. Prison ☐ p. Other (Specify): _____	

14. Clinical status at the time of diagnosis/testing ☐ a. Asymptomatic ☐ b. Symptomatic HIV ☐ c. AIDS	
PART III: INFORMATION ON EXPOSURE TO HIV	
15. Sexual Exposure (Multiple Responses Possible) ☐ a. Sexual Contact with Regular Partner of Opposite Sex ☐ b. Sexual Contact with Non-Regular Partner of Opposite Sex ☐ c. Sexual Contact with Person of Same Sex ☐ d. Sexual Contact with Both Sexes ☐ e. No Sexual Contact	16. Ever sold sex to clients ☐ a. Yes ☐ b. No
17. Ever bought sex from a sex worker ☐ a. Yes ☐ b. No	18. Ever gone abroad? ☐ a. Yes, countries: ☐ b. No
19. Ever had sex with a foreigner? (In Sri Lanka or abroad) ☐ a. Yes ☐ b. No ☐ c. Not Applicable (Foreign Nationality)	20. History of Blood Exposure ☐ a. No ☐ b. Injecting Drug Use ☐ c. Receipt of Blood/Tissue/Organ/Sperm year: ☐ d. Needle stick injury/mucosal splash year:
21. Acquired from mother to child transmission ☐ a. No ☐ b. Yes ☐ c. Not Known	
INFORMATION ABOUT SPOUSE/LIVE-IN PARTNER EXPOSURE TO HIV	
22. HIV status of spouse ☐ a. Positive ☐ b. Negative ☐ c. Not Known ☐ d. Not Applicable	23. Has spouse ever gone abroad? ☐ a. Yes, countries ☐ b. No ☐ c. Not Known ☐ d. Not Applicable
24. Risk factors for HIV in spouse ☐ a. None ☐ b. MSM ☐ c. Sex Worker (now or former) ☐ d. Multiple Sex Partners ☐ e. Injecting drug user (now or former) ☐ f. Not Known ☐ g. Not Applicable	
DETAILS OF THE REFEREING DOCTOR/HEALTHCARE WORKER	
A. Name : B. Signature : C. Designation :	D. Institution : E. Telephone No.: F. Date :

10. References

1. Consolidated Guidelines on HIV Testing Services, WHO 2019
2. WHO encourages countries to adapt HIV testing strategies in response to changing epidemic policy brief November 2019
3. Comprehensive list of HTS approaches and considerations by epidemic setting WHO/HIV/2015.31
4. Prevention and treatment of HIV and other sexually transmitted infections among men who have sex with men and transgender people. Recommendations for a public health approach WHO 2011
5. https://providers.sonoraquest.com/media/1140/hiv_4th_gen_test_summary_0416.pdf
6. Prevention and treatment of HIV and other sexually transmitted infections for sex workers in low- and middle-income countries. Recommendations for a public health approach. WHO 2012
7. Guidance on provider-initiated HIV Testing and counselling in health facilities, WHO 2007
8. Service delivery approaches to HIV testing and Counselling: A strategic HTC programme framework, WHO 2012
9. Delivering HIV test results and messages for re-testing and counselling in adults, WHO 2010
10. Guidance on couple HIV testing and counselling, WHO 2012
11. Policy requirements for HIV testing and counselling of infants and young children in healthcare settings, WHO/UNICEF 2010
12. Policy Statement on HIV Testing and Counselling for Refugees and other persons of concern to UNHCR, UNHCR 2014
13. Using human rights to advance sexual and reproductive health of youth and adolescence in Sri Lanka, Report of Sri Lanka Field tests 2012
14. Sample collection manual for STI/HIV testing. National STD/AIDS Control Programme, 2019

