



NATIONAL HIV TESTING SERVICES POLICY

2025



health

Department:
Health
REPUBLIC OF SOUTH AFRICA







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Dr SSS Buthelezi
Director-General of Health

South Africa has made significant progress towards the UNAIDS 95-95-95 targets reaching 95% of all HIV positive people, however despite these achievements, substantial gaps remain. Many of those at highest risk remain unreached, this includes adolescents and young people (ages 15–24 years) and men. Key populations – men who have sex with men, people who inject drugs, people in prisons or other closed settings, sex workers and transgender people should be prioritized since they are most affected by HIV and at high ongoing risk.

The Global AIDS Strategy 2021-2026 (End Inequalities. End AIDS), is a bold new approach to use an inequalities lens to close the gaps that are preventing progress towards ending AIDS. The Global AIDS Strategy 2021-2026 aims to achieve the Three Zeros: zero new HIV infections, zero AIDS related deaths and zero HIV-related discrimination. The Global AIDS Strategy aims to reduce these inequalities that drive the AIDS epidemic and prioritize people who are not yet accessing life-saving HIV services. The Strategy sets out to end AIDS as a public health threat by 2030.

The strategy has three priorities: 1. Access to HIV services for all, 2. Breaking down barriers and 3. Integrating HIV, securing the resources.

To achieve the new UNAIDS 2030, 95-95 targets, efforts towards HIV testing should focus on:

support implementation and scale-up of a strategic mix of evidence-based HTS approaches, in both facility and community settings, to reach those undiagnosed,
support effective linkage to appropriate prevention, treatment, and care services among those tested,
encourage integration of HIV testing with other relevant services.

In this revised national HIV testing policy, South Africa has aligned with the goals of the National Development Plan to ensure that South African's have a life expectancy of at least 70years for men and women and ensuring the generation of under 20 is free of HIV. The policy is further aligned to World Health Organization (WHO) guidance with regards to elimination of neo-natal syphilis. To close this gap, South Africa has committed to the implementation of dual HIV/Syphilis RDTs in ANC settings and the 3 Test Strategy to ensure accuracy and reliability of diagnosis.

The revision of our national HTS policy is important to keep abreast of international guidance and recommendations. More importantly, I am confident that the implementation of these revised guidelines will be important in achieving the 2023 agenda where HIV is no longer a health threat.

I strongly urge all HTS service implementers to do all that is necessary to adhere to the recommendations outlined herein.

Dr SSS Buthelezi
Director-General
Date: 29/05/2025

ABBREVIATIONS AND ACRONYMS

AGYW	Adolescent girls and young women
AIDS	Acquired immune deficiency syndrome
ANC	Antenatal care
ART	Antiretroviral therapy
ARV	Antiretroviral (drugs)
AGYW	Adolescents Girls and young women
AIDS	Acquired immune deficiency syndrome
ANC	Antenatal care
ART	Antiretroviral therapy
ARV	Antiretroviral (drugs)
AGYW	Adolescents Girls and young women
AIDS	Acquired immune deficiency syndrome
ANC	Antenatal care
ART	Antiretroviral therapy
ARV	Antiretroviral (drugs)
BANC +	Basic Antenatal Care
CALHIV	Children & Adolescents living with HIV
CBO	Community-based organisation
CDC	United States Center for Disease Control and Prevention
CHCT	Couples HIV counselling and testing
CICT	Client-initiated counselling and testing
DIC	Drop-in Centre
DHIS	District Health Information System
DHS	District health system
DNA	Deoxyribonucleic acid
ELISA	Enzyme-linked immunosorbent assay
EMEA	European Medicines Evaluation Agency
EPI	Expanded Programme on Immunisation
EQA	External quality assessment
FDA	United States Food and Drug Administration
FBO	Faith-based organisation
GBV	Gender Base Violence
HBHITS	Home-based HIV testing service
HCT	HIV counselling and testing
HIV	Human immunodeficiency virus
HIVSS	HIV self-screening
HPCSA	Health Professions Council of South Africa HTA High transmission area HTS
IDU	Injection drug user
IVD	In-vitro diagnostic (medical devices)
IEC	Information, education, and communication
IQC	Internal Quality Control
M and E	Monitoring and evaluation
MSM	Men who have sex with men
NAT	Nucleic acid testing
NCD	Non-communicable disease
NDOH	National Department of Health
NGO	Non-governmental organisation
NICD	National Institute for Communicable Disease
NSP	National Strategic Plan
OI	Opportunistic infection
OST	Opioid Substitution Therapy
OVC	Orphans and vulnerable children
PCR	Polymerase chain reaction
PEP	Post-exposure prophylaxis
PITC	Provider-initiated testing and counselling
PLHIV	People living with HIV

PLWHA	People living with HIV and AIDS
PMS	Post-market surveillance
PMTCT	Prevention of mother-to-child transmission
PNC	Post-natal care
OVC	Orphans and vulnerable children
OST	Opioid Substitution Therapy
PT	Proficiency Testing
PrEP	Pre-exposure prophylaxis
PWID	People who inject drugs
PWUD	People who use drugs
QA	Quality assurance
QC	Quality control
QI	Quality improvement
QMS	Quality management system
RDT	Rapid diagnostic test
RNA	Ribonucleic acid
RTCQI	Rapid Test Continuous Quality Improvement
SAHPRA	South African Health Products Regulatory Authority
SANAC	South African National AIDS Council
SAPC	South African Pharmacy Council
SBCC	Social and behaviour change communication
SOP	Standard operating procedure
SPI-RT	Stepwise Process to Improving the quality of HIV Rapid Testing
SRH	Sexual and reproductive health
STI	Sexually transmitted infection
SW	Sex Workers
TB	Tuberculosis
TMC	Traditional medical circumcision
TNA	Total nucleic acid
UHC	Universal health coverage
UTT	Universal test and treat
UNAIDS	Joint United Nations Programme on HIV and AIDS
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VMMC	Voluntary medical male circumcision
VTP	Vertical transmission prevention
WB	Western blot
WBOT	Ward-based outreach teams
WHO	World Health Organization

DEFINITIONS

Active referral	A referral where the person performing an HIV test makes an appointment for the client or accompanies the client to an appointment, including an appointment for co-located services, and enrolment into HIV clinical care.
Acute infection	The period in which an individual becomes HIV-infected and before HIV antibodies can be detected by a serological assay.
Couple HTS	It is when two or more people are in an ongoing sexual relationship or who plan to start such a relationship and therefore wish to test together for HIV and/or mutually disclose their test results. The term includes both heterosexual couples as well as same sex couples as recognized by the Constitution of South Africa.
Discrepant test results	When the test results from two or more in an individual tested do not agree. For example, test 1 reactive, test 2 reactive and test 3 non-reactive. When one HIV test result in an individual is reactive and the other test result using a different HIV assay in the same individual is non-reactive.
Early infant diagnosis	Testing infants to determine their HIV status, given that HIV can be acquired in utero (during pregnancy), peri-partum (during delivery), post-partum (through breastfeeding) or via parental exposure.
Family-based index case testing	When HTS is offered to all biological infants and young children with an HIV-positive parent and whose HIV status is unknown.
HIV self-screening (HIVSS)	A process where a person who wants to know his or her HIV status collects a specimen, performs a test, and interprets the result by him- or herself, often in private. Reactive test results must be confirmed through the national testing algorithm.
HIV status	Result from one or more assays. It refers to reports of HIV-positive, HIV-negative, or HIV-inconclusive.
HTS curricula	This refers to, but is not limited to, i) HIV Testers Training – 10-day initial training every 36 months and the 3-day refresher every 24 months, ii) Rapid Test Continuous Quality Improvement (RTCQI) Training – 2 – 3 days in person or self-paced online and 2-day refresher training every 24 months, iii) Tester Certification – this includes a written exam, observation and sample testing every 24 months to ensure competency of all HIV Testers. Additional HTS curricula include Index Testing, HIV Self-Screening Training and Dual HIV/Syphilis Testing. These are all nationally approved courses and may be offered in-person or online as an approved combination.

Inconclusive HIV test result	The test results cannot lead to a definitive diagnosis as the results is neither positive nor negative using subsequent HIV assays.
Index testing	A case identification approach that focuses on eliciting sexual or needle sharing partners, biological children or siblings and parents of HIV-positive individuals and offering them HIV testing services.
Key populations	Refer to defined groups who, due to higher-risk sexual and/or drug behaviours, have an increased risk for HIV irrespective of the epidemic type or local context. These are men who have sex with men, people who inject drugs, people in correctional facilities and closed settings, sex workers, and transgender people.
Men who have sex with men (MSM)	Men who have sex with men (MSM) refers to males who have sex with males regardless of whether they also have sex with women or have a personal or social gay or bisexual identity. This concept is inclusive of men who self-identify as heterosexual but have sex with other men
Nucleic acid testing (NAT)	Also referred to as molecular technology, for example, polymerase chain reaction (PCR) or nucleic acid sequence—based amplification (NASBA). This type of testing can detect small quantities of ribonucleic acid (RNA), deoxyribonucleic acid (DNA), or total nucleic acid (TNA), qualitatively and quantitatively.
Pre exposure prophylaxis (PrEP)	PrEP is an anti-retroviral drug (ARV) that is used by HIV uninfected people before the potential exposure to prevent the acquisition of HIV.
Post-Exposure Prophylaxis	PEP is an ARV drug that is used to prevent an HIV infection after the virus has potentially entered a person's body (within 72 hours).
Quality assurance (QA)	A part of quality management focused on providing confidence that quality requirements will be fulfilled.
Quality control (QC)	A mechanism which, when used with or as part of a test system (assay), monitors the analytical performance of that test system (assay). It may monitor the entire test system (assay) or only one aspect of it.

Quality improvement (QI)	Part of quality management focused on increasing the ability to fulfil quality requirements.
Quality management system (QMS)	A system to direct and control an organisation with regards to quality.
Retesting for HIV	In certain situations, individuals should be retested after a defined period to rule out errors and sero-conversion. These include: <ul style="list-style-type: none"> • HIV-negative people with recent or ongoing risk of exposure • HIV-inconclusive result • HIV-positive people before antiretroviral treatment (ART) initiation if there is no proof of a previous documented HIV positive result.
Sero-discordant couple	A couple in which one partner is HIV-positive, and the other is HIV-negative.
Sex Worker (SW)	Sex Worker refers to consenting male, female, and transgender adult, and young people (18 years or older) who work in different settings with the primary intention of exchanging money, goods and/or services for sexual services, either regularly or occasionally. Sex work is consensual sex between adults. As defined in the Convention on the Rights of the Child (CRC), children, and adolescents under the age of 18 who exchange sex for money, goods or favors are sexually exploited and not defined as Sex Workers.
Transgender (TG)	Transgender is an umbrella term to describe people whose gender identity and expression does not conform to the norms and expectations traditionally associated with their sex at birth. Transgender people include individuals who have received gender reassignment surgery, individuals who have received gender-related medical interventions other than surgery (e.g., hormone therapy).
Unconfirmed HIV test results	Refers to an HIV-positive test result without a confirmatory test.
Window period	The period between HIV infection and the detection of HIV-1/2 antibodies using serological assays, this signals the end of the seroconversion period.

PART 1 - INTRODUCTION

1.1 Background

South Africa has reached 96-79-94 across the general population towards the UNAIDS 95-95-95 targets as of October 2024, however, these targets are lagging among children and key populations. Of those who know their HIV status, only 77% of female sex workers and 60% of men who have sex with men are receiving antiretroviral treatment (ART) (Thembisa, 2023). HIV prevalence has decreased slightly; however, it remains high at 17% amongst people between 15 and 49 years (Thembisa, version 4.7). In 2024 an estimated 141,808 people were newly infected with HIV – a 59% reduction from 2010; and 55 000 of these infections occurred among adolescents and young people aged 15-24 years – a 66% reduction from 2010 (Thembisa, 2024).

Despite the decrease in new infections, the country did not achieve some of the targets of the National Strategic Plan on HIV, STIs and TB, 2017-2022 (NSP). Goal 1 (Accelerate prevention to reduce new HIV and tuberculosis (TB) infections and sexually transmitted infections (STIs) aimed at reducing new HIV infections by more than 60% – from an estimated 270 000 in 2016 to below 100 000 by 2022, including the elimination of mother-to-child HIV transmission and a reduction in new HIV infections among adolescent girls and young women (AGYW) from 2 000 a week to less than 800. South Africa reduced new HIV infections to 164 000 and averted 40 000 new HIV infections from mother-to-child in 2022.

South Africa has demonstrated strong commitment to reducing the persisting high rate of new HIV infections in the country through a combination of prevention services. HIV prevention services were made available to millions of adolescent and young adults through demand creation, HIV prevention, and other community-led sensitization campaigns. To achieve treatment adherence that improves retention rates for overall health outcomes of people living with HIV (PLHIV), a dolutegravir-based regimen was adopted as the preferred first line HIV treatment regimen.

To identify the remaining undiagnosed PLHIV, HIV testing services (HTS) should be expanded to reach all people in need of appropriate quality HTS with effective linkage to prevention, treatment, and support services. HTS should be provided and include the World Health Organization (WHO) five Cs: Consent, Confidentiality, Counselling, Correct test results, and Connection/linkage to prevention and treatment services. The five Cs should always be adhered to in the provision of HTS, as follows:

1. **Consent:** is verbal or written informed permission that should be provided prior to being tested. Clients should be informed of the process for HIV testing and their right to decline or withdraw at any point in the process.
2. **Confidentiality:** HIV testing and counselling services are confidential, and therefore healthcare implementers have an obligation to keep all information, documents, and data collection tools private. Clients should be notified regarding shared confidentiality amongst the multi-disciplinary teams
3. **Counselling:** HIV testing services must be accompanied by appropriate and high-quality brief pre-test information (which can be provided as group pre-test information in some settings) and appropriate post-test counselling, depending on the HIV test results. Quality assurance mechanisms, supportive supervision and mentoring systems should be in place to ensure the provision of high-quality counselling.
4. **Correct result:** HIV testing and counselling implementers should provide high-quality testing services by adhering to the appropriate steps required to make a correct HIV diagnosis. Quality assurance may include support from the national reference laboratory as needed.
5. **Connection:** linkage to prevention and treatment services should include the provision of effective referral to appropriate follow-up services, including long-term engagement of clients in prevention and treatment services. Linkage remains the responsibility of all healthcare workers providing demanding creation and testing services.

HTS encompasses the full range of services that should be provided together with HIV testing, including:

pre-test information and post-test counselling,
linkage to appropriate HIV prevention, treatment, management services, and other clinical support services,
coordination with laboratory services to support quality assurance and the delivery of correct HIV results.

A human rights-based approach to HTS ensures that the essential elements of the programme are aimed towards the realization of rights and that those rights are used as standards.

1.2 Rationale for an HTS Policy

This updated National HTS Policy combines existing and new guidance on HTS across different settings and populations, and was guided by the following:

Guidelines on Quality Assurance for HIV Rapid, 2025
National Development Plan, 2030,
National Institute for Communicable Diseases (NICD) five-year (2015/2016 - 2019/2020) trend analysis of HIV positivity rate in HIV testing services in South Africa for consideration to transition to a three tests strategy,
The 2024 WHO HTS recommendations,
The National Strategic Plan for HIV, TB and STI, 2023-2028.
The South African National Health Sector HIV Prevention Strategy 2020-2025,

1.3 Goals and objectives

HIV testing remains a key entry point to both HIV prevention and treatment services and is critical to the success of the country's HIV response. To maximise individual and public health benefits, it is important that HTS programme provides a strategic mix of modalities that will identify and diagnose PLHIV and link these individuals to treatment. Individuals who test HIV negative and are at substantial risk of HIV acquisition should be offered and linked to appropriate prevention services.

The programme also seeks to expand coverage in areas and among populations with the most significant coverage gaps and the main objective of this document is to provide guidance to health care implementers to ensure:

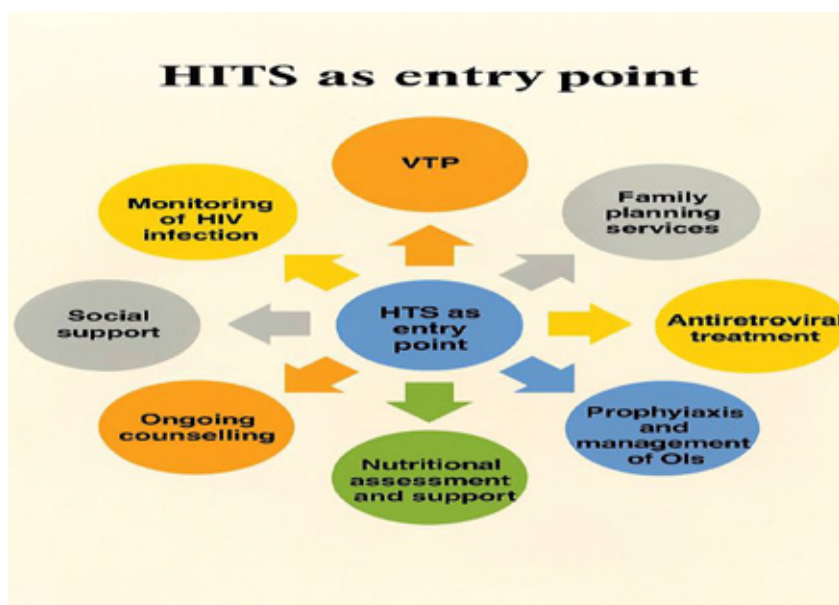
appropriate use of differentiated HTS approaches to reach different populations in different settings,
strengthening linkages to prevention and treatment services,
closing the HIV testing gap by reaching and testing the remaining undiagnosed PLHIV.
strengthening quality assurance and consistent delivery of accurate results.

1.4 Target audience

This document is intended for HIV programme managers and service implementers at national, provincial, district levels, health facilities, and community-based services. These managers and service implementers are responsible for the national health sector response to HIV, including HIV testing, as well as prevention, treatment, and care services for the entire population.

1.5 HTS continuum of care

WHO recommends a strategic mix of HIV testing approaches which are informed by the local dynamics of the changing HIV epidemic. The HTS continuum of care is aimed at reaching the remaining PLWHIV who are still undiagnosed and to ensure that they are initiated on HIV treatment and remain engaged in care. It is critical to note that HTS will continue to provide the necessary support to those who test negative for HIV, individuals at continuous risk for HIV, to link them to appropriate HIV prevention services and contribute to the prevention of new HIV infections. This can be achieved through the scale up of differentiated HIV testing services.



PART 2 – PRE-TEST SERVICES

Several pre-test activities should take place before testing takes place in all settings, and for all prioritized populations.

2.1 Demand creation

Concise education prior to HIV testing, that is informative, encouraging and motivating is an effective way to create demand for testing among people who do not know their status and to engage those at high risk without increasing stigma and discrimination. An enabling environment that removes barriers such as stigma, discrimination, and criminalisation is important for increasing access and uptake of HTS, particularly among those at high risk and key populations.

Demand creation and mobilisation strategies include activities intended to directly improve an individual's knowledge, attitudes, motivations, and intentions to test and to inform the decision to obtain HIV testing services. Such interventions may include:

- targeted promotions, advertisements, and messaging
- educational programmes
- brief motivational messages and counselling strategies
- couples-oriented counselling and partner services

These strategies can be implemented using peer-based or community-led approaches as well as digital tools (such as videos or text messages (SMS), and other m-health and e-health mass media). Existing technological options such as MomConnect and Be-Wise must be used to encourage individuals to test for HIV.

2.1.1 Digital platforms, online outreach workers, and peer navigators can promote HTS among key populations

Use of digital and online platforms can successfully generate demand for HTS among men who have sex with men and transgender people who are not otherwise connected with services.

Online outreach workers use social media, networking and dating apps to encourage the use of HIV services, including HIVSS, community-based testing by lay implementers and prevention services, for users who benefit from them.

Outreach community workers provide HTS to clients or support them to link to testing services. Peer navigators support those diagnosed with HIV to link them to treatment and care.

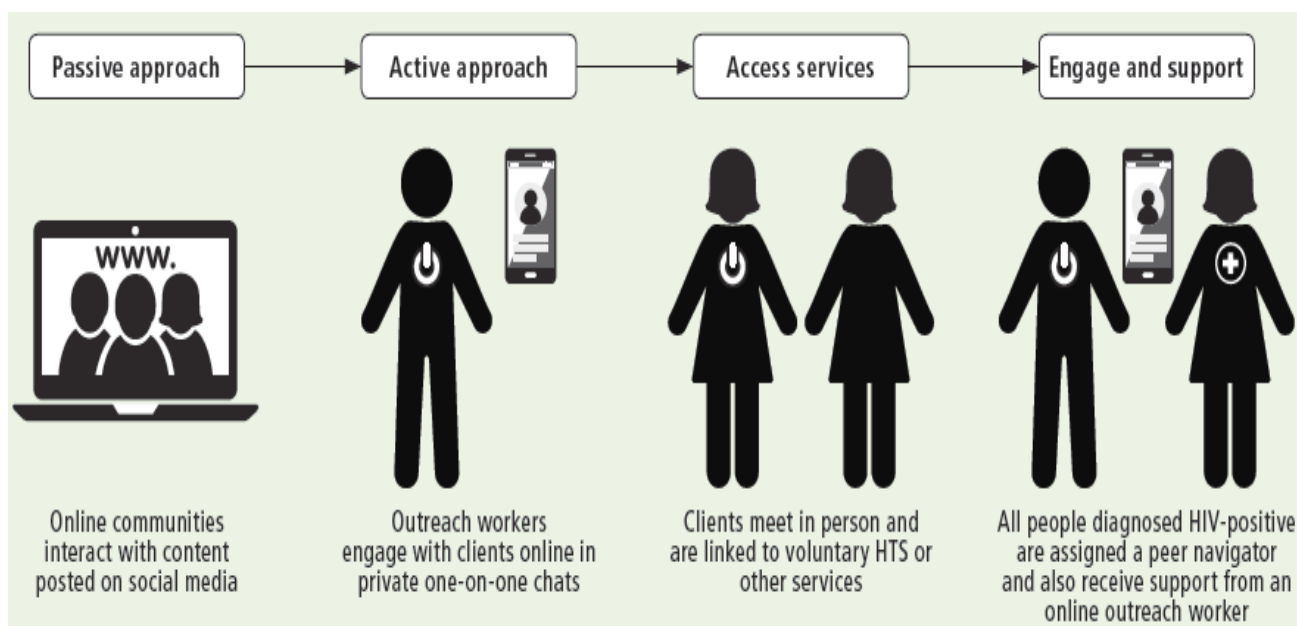


Figure 1: Digital online platforms as demand creation approaches for key populations.

2.2 The pre-test information session

Comprehensive pre-test information is recommended and individual risk assessment and person-focused counselling during the pre-test information sessions should be presented in an age- appropriate manner.

In public health facilities and other high volume HTS settings, pre-test information and education sessions may be conducted in a group rather than individually. Information sessions and print materials should be available in the local language.

The pre-test information session for an individual or for a group must include clear information on:

- the benefits of HIV testing,
- the testing process,
- the meaning of an HIV-positive and HIV-negative diagnosis and discrepant results
- services - including ART provision and prevention services,
- the potential for an incorrect result if a person is already on ART,
- benefits of partner testing and potential sero-discordancy,
- index testing for sexual/ needle sharing partner(s) and children,
- the confidentiality of the test result and any other information shared by the client,
- the right to refuse to be tested and that declining testing will not affect the client's access to HIV services or general medical care, and
- benefits of viral load suppression.

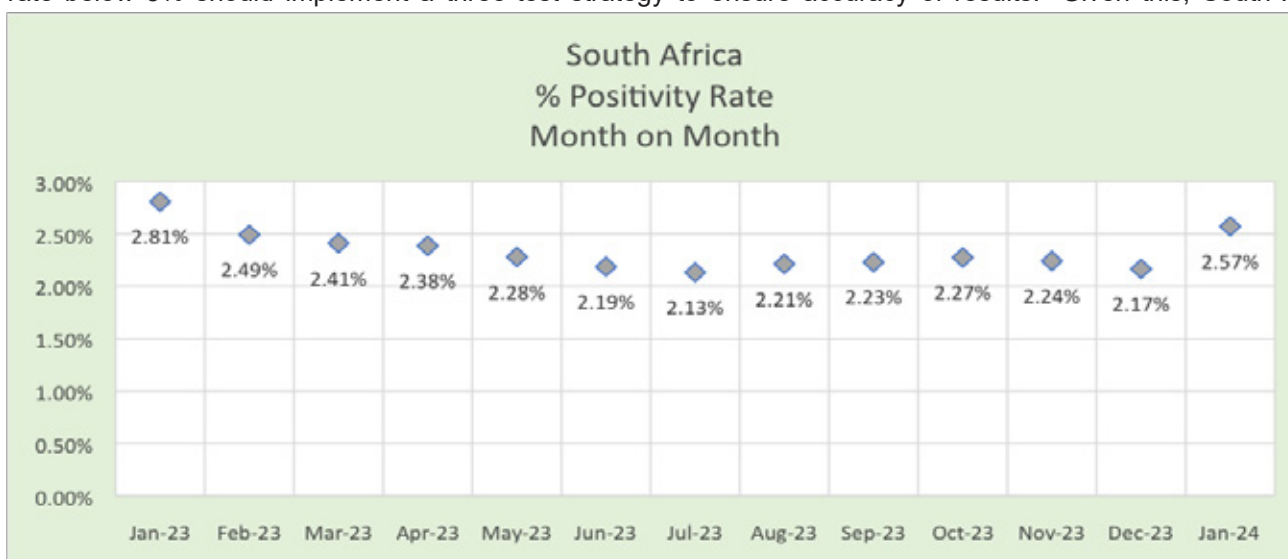
Pregnant or post-partum women require additional pre-test information including:

- the potential risk of transmitting HIV to the unborn child and infant,
- counselling on infant feeding practices,
- how to reduce mother-to-child transmission, including the use of ART to benefit the mother and prevent HIV transmission to the infant,
- benefits of early HIV diagnosis for mothers and infants, and
- importance of syphilis and hepatitis B testing during pregnancy.

PART 3 – HIV TESTING PROCESS

3.1 Rationale for the 3 Test Strategy

Access to accurate and reliable HIV testing services is crucial. WHO recommends that all countries with HIV positivity rate below 5% should implement a three-test strategy to ensure accuracy of results. Given this, South Africa has



adopted the WHO recommendation since the positivity rate is below 5% as of 2023.

Figure 2: DHIS 2023/2024 Data

3.2 Three consecutive HIV reactive tests

This testing strategy aims to ensure that at least 99 % of the positive predictive value (PPV) is maintained thus reducing the chances of a false-positive misdiagnosis. To achieve at least a 99 % PPV, it is critical that:

A screening test must be able to identify all HIV-reactive individuals and have the highest sensitivity.

Anyone with a non-reactive test result is reported to be HIV negative.

Individuals whose test results are reactive on both screening test and confirmatory test 1 should then be tested using confirmatory test 2

Confirmatory test 1 and confirmatory test 2 must be able to rule out any false HIV-reactive test results.

Report HIV positive if confirmatory test 2 is also reactive (screening test reactive; confirmatory test 1 reactive; confirmatory test 2 reactive).

Report as HIV discrepant if confirmatory test 2 is non-reactive (screening test reactive; confirmatory test 1 reactive; confirmatory test 2 non-reactive). Request for ELISA reflex testing.

If the screening test is reactive and confirmatory test 1 is non-reactive, repeat the screening test only. Do not repeat the algorithm.

- If repeat screening test is non-reactive, report HIV negative (screening test reactive; confirmatory test 1 non-reactive; repeat screening test non-reactive).

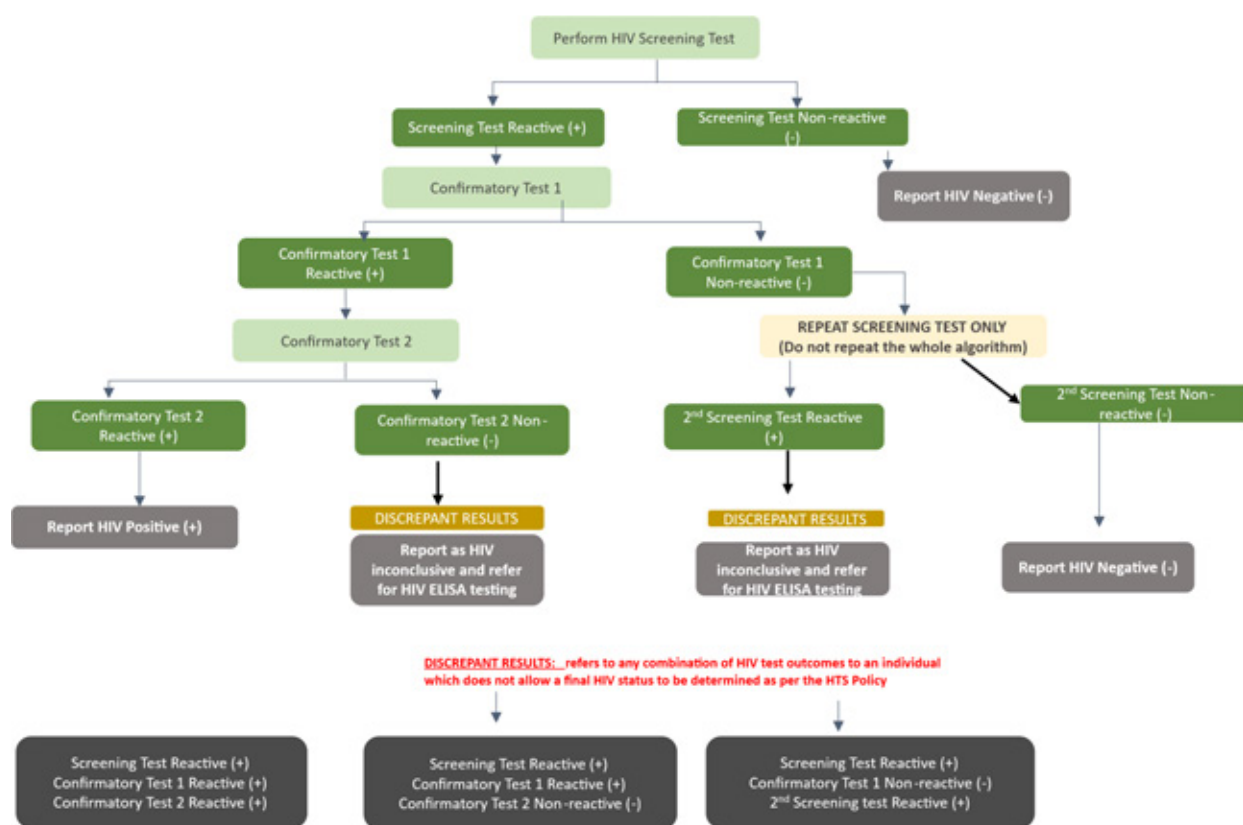
If repeat screening test is reactive, report HIV as HIV discrepant (screening test reactive; confirmatory test 1 non-reactive; repeat screening test reactive). Request for ELISA reflex testing.

- If ELISA reflex testing result is positive, report HIV positive. Individuals whose ELISA test result is inconclusive, should be asked to return in 14 days for additional testing.

When implementing HIV rapid testing, a serial testing algorithm should be followed. The selection of rapid test kits used in the testing algorithm should be guided by the National Reference Laboratory and approved by the National Department of Health.

If the initial test result is reactive (18 – 24 months) please complete the National Algorithm below and refer for PCR for confirmatory.

Figure 3: Three-test kit HIV testing algorithm (among people ≥18 months of age)



3.3 HIV and syphilis dual testing

Individuals can be infected with both HIV and syphilis simultaneously, and having a syphilis infection can increase the risk of HIV acquisition and transmission. In recent years, the clinical utility of rapid diagnostic tests (RDTs) that detect antibodies for *Treponema pallidum* (the cause of syphilis infection) has increased. In 2015 the WHO prequalified a dual HIV syphilis rapid diagnostic test, which is able to detect both anti-HIV and anti-*Treponema pallidum* antibodies in one test device.

Treponemal antibodies will be detected when syphilis is both current/active and when syphilis has been treated/resolved because treponemal antibodies persist for some time after successful treatment (depending on the stage of syphilis when treatment was given). The dual HIV syphilis RDT supports an integrated approach to sexual health, ensuring that individuals receive appropriate treatment, counselling, and support for both infections.

In South Africa, the dual HIV syphilis RDT is only used in antenatal care settings to test pregnant women and their partners. Refer to the Vertical Transmission Prevention and Sexually Transmitted Infections Guideline for detailed information on using the dual HIV syphilis RDT during ANC. For syphilis treatment in the general population refer to the most recent standard treatment guidelines.

3.4 Perinatal HIV testing and early infant diagnosis

In the 2023 Guideline for Vertical Transmission Prevention (VTP) of Communicable Infections the requirements for HIV testing during the different perinatal service points are stipulated. This includes testing during antenatal care, labour and delivery, postpartum care, and care for the HIV-exposed infant. Refer to the 2023 Guideline for Vertical Transmission Prevention of Communicable Infections for detailed information on perinatal HIV testing.

Early infant diagnosis and timely treatment are critical in reducing mortality under 1 year; hence HIV-exposed infants must be tested at birth, 10 weeks, and six months. The HIV test at 18 months of age is universal, meaning all infants, regardless of HIV exposure, must be tested for HIV.

Table 1: Recommended frequency of testing

Circumstance	When to re-test (to rule out window period)
Post sexual exposure	At four weeks and 12 weeks per relevant guidelines.
Occupational exposure & person exposed issued with PEP	At four weeks and 12 weeks per guidelines.
Presenting with clinical conditions (e.g., STI)	At six weeks.

PART 4 – POST-TEST-SERVICE

All clients, regardless of the outcome of the HIV test, should be offered and should receive post-test counselling based on their test result. All results must be communicated clearly.

4.1 Post-test services for people testing HIV negative

Individuals who test HIV-negative should receive HIV prevention information, including guidance on if and when they should undergo their next HIV test (refer to Table 2 for recommended retesting frequencies by population). The health information should also include risk reduction counselling and recommendations of preventive behaviours and uptake of prevention interventions such as consistent condom use, PrEP, PEP, and risk reduction counselling. Active linkage to appropriate services is strongly recommended.

Table 2: Testing frequency by population

Who	When
Pregnant women	As per the 2023 Guideline for Vertical Transmission Prevention (VTP) of communicable Infections.
Breastfeeding women (to detect HIV sero-conversion)	As per the 2023 Guideline for Vertical Transmission Prevention (VTP) of communicable Infections.
HIV-exposed babies	As per 2023 VTP guidelines - at birth, at ten weeks, at the 6-month integrated well-child visit and at 18 months
18-month- 24 months	Once as per the 2023 Guideline for Vertical Transmission Prevention (VTP) of communicable Infections (universal testing).
Children (25 months – 14 years)	Once post 18 months old if no documented 18-month HIV test OR sick AND testing is indicated using the screening algorithm below
12-14 years*	Immediately and annually if presents at FP/ANC/TOP services OR at any other service if sexually active
15-19 years	Annually** or more frequently based on recent exposure.
Adults	Annually or more frequently based on recent exposure.
Key populations	Every 6 months
Clients on PrEP	At one month then every three months (as per the PrEP guidelines).
Known Discordant partner (known HIV positive partner)	Annually Positive partner should be on continuous ART and negative partner should offered PrEP and tested as per the PrEP guidelines
All above individuals presenting with a diagnosis or receiving treatment for sexually transmitted infections or viral hepatitis, a confirmed or presumptive TB diagnosis, outpatients presenting with clinical conditions or symptoms indicative of HIV	Immediately

*Children under 12 years old who attend ANC/FP/TOP services should be evaluated to determine if they are mature enough to give consent for HIV testing. If the child is not deemed sufficiently mature to provide consent, testing should still be conducted. In such cases, the consent process should involve a caregiver or another designated person, as outlined in the Children’s Act.

**HIV testing should be offered annually to adolescents, with the assumption that they may be engaging in sexual activity. Healthcare workers should avoid conducting sexual risk assessments, as these are known to exclude adolescents who are sexually active and at risk of HIV infection. If an adolescent chooses to self-report that they are not sexually active, they are considered to have opted out of testing and do not need to be tested until their situation changes.

4.2 Services for people testing HIV positive

People who test HIV positive should receive related health information about their test results. All post-test counselling should be client-centered, responsive, and tailored to the unique situation of each individual or couple. Health workers, professional counsellors, social workers and trained lay implementers can provide relevant counselling.

The post-test counselling information must include:

- an explanation of the test results and diagnosis,
- clear information on ART and its benefits,
- where and how to obtain ART, in case of out of facility testing (e.g., community or workplace)
- in cases where ART is not initiated immediately, make an active referral for a specific time and date,
- how to prevent transmission of HIV, information on viral suppression, condoms & lubricants, and guidance on their use,
- how to encourage and offer HIV testing to sexual partners, children, and other family members of the client.
- the importance of adhering to ART once initiated
- enhanced counselling may be needed for clients re-engaging to treatment

This can be done individually, through couples testing, index partner testing, or partner notification. However, the shock of learning one's positive status may make it difficult for the client to absorb a lot of information at one time.

The counsellor should provide the necessary emotional support by:

- giving the client time to consider the results,
- helping the client cope with emotions arising from the diagnosis of HIV infection,
- discussing immediate concerns and help the client decide who in her or his social network may be available to provide immediate support,
- discussing barriers to linkage to care, same-day enrolment, ART clinical eligibility assessment and arrange for any follow-up of clients,
- discussing possible disclosure of the result and the risks and benefits of disclosure,
- assessing the risk of intimate partner violence and discussing possible steps to ensure the physical safety of the client, particularly women, who are diagnosed HIV positive,
- assessing the client's mental health and possible consequences of a diagnosis of HIV infection
- providing additional appropriate referrals for prevention, counselling, and support, and
- encouraging and allowing the client to ask additional questions.

4.2.1 HIV status disclosure

Disclosure of HIV status is an important part of the process of people living with HIV and is crucial to continuum of HIV care. Deciding about disclosure is a significant issue for a person who has been diagnosed with HIV. Three acceptable disclosure conditions are discussed below:

Disclosure to a sexual partner, family member, or friend: When people learn their HIV-positive status, they may need time to absorb and accept the diagnosis before they are ready to share it with another person. As such, they require ongoing counselling for disclosure. Disclosure does benefit sexual partners, but the social context of an individual must be taken into consideration. For example, HTS implementers and counsellors should assess the risk of intimate partner violence and make appropriate referrals if necessary.

Disclosure of HIV in children: Disclosure of HIV status in children is not a single event, but rather a process, involving ongoing discussions about the disease as the child matures cognitively, emotionally, and sexually. Disclosure should occur whenever a child is clinically and emotionally stable and the caregiver is ready. Although the process should not be rushed, disclosure should happen before the child enters adolescence. The timing will depend on the caregiver's acknowledgment of the disease and readiness to disclose, the child's cognitive skills and emotional maturity and an ability to maintain confidentiality. *(Refer to the Adherence Guidelines Disclosure SOP 3)*

Disclosure among children may be beneficial to the child, as it may:

- provide developmentally appropriate and truthful explanations of the disease and help the child understand the illness,
- validate the child's concerns and clarify misconceptions, and
- increase the child's willingness to adhere to ART and consequently improve his or her social functioning and school performance by decreasing stress.

Shared confidentiality or disclosure by a health worker to other health workers involved in the client's care is a third type of disclosure. Clients and patients who test positive must be informed that their diagnosis may be shared with other healthcare implementers to ensure appropriate medical care from the different health care implementers. The disclosure process should include respect of the client's basic right to privacy and confidentiality of all their medical information.

Disclosure by a health worker to employers, the police or other legal authorities is unlawful and unethical unless the client has given written consent for his or her HIV status to be disclosed. All clients, regardless of the outcome of the HIV test, should be offered and should receive post-test counselling based on their test result. All results must be communicated clearly.



PART 5– LINKAGE TO CARE

Linkage or connection to HIV care is defined as a process of action and activities that support people testing for HIV and people diagnosed with HIV to engage into appropriate services depending on their status (prevention, treatment, and care)

The impact of HTS depends on linkage to services - and vice versa. Prioritising linking and emphasizing follow-up services is necessary to provide an entire spectrum and to ensure clients' responsiveness to meeting their unique needs. Strong linkages to high-quality prevention, treatment, and care services are integrated into all plans to expand HTS. HIV testing alone is of limited value unless it is linked with appropriate services.



5.1 Differentiated linkage approaches

	WHEN	WHERE	WHO	WHAT
To prevention with focus on individuals who will benefit substantially	Offer linkage on the same day as a negative HIV test	Link from testing site to prevention site (ideally same service/site) Facility-based or community-based HIV prevention services	Healthcare provider performing the HIV test links to prevention	Physical escort where appropriate Use referral form in the community and where services are not provided on site HIV Prevention service package (e.g.: PrEP, PEP, VMMC, harm reduction services and condoms/lubricant) and SRH services Referrer should follow up with the client in 7-14 days to ensure they have linked to appropriate prevention services
To treatment	Offer linkage on the same day as a positive HIV test	Link from testing site to treatment site (ideally same service/ site) Facility-based or Community-based ART initiation	Healthcare worker performing the HIV test links to treatment	Physical escort where appropriate Use referral form in the community and where services are not provided on site TB testing and on-site same day ART initiation and unless excluded by clinician Provide condoms, lubricants, refer to SRH or other appropriate services Referrer should follow up in 7-14 days to ensure they have linked to treatment services

Table 3: Differentiated linkage approaches

5.2 Integration of PrEP across various entry points

PrEP refers to the use of antiretroviral drugs by HIV-negative people before potential exposure to prevent the acquisition of HIV. South Africa recommends PrEP for all people at greater risk of HIV infection including: -

Adolescent girls, boys, young women and men, men who have sex with men, individuals with more than one sexual partner, people who inject drugs, people with a recent history of STI(s), individuals who recognize their own risk and request PrEP, sero-discordant couples, sex workers, migrant workers, and pregnant and breastfeeding women. PrEP can be integrated with existing health services and should not be offered as a vertical programme, in conjunction with other appropriate prevention methods. It should be promoted as an additional prevention choice among people for whom it is suitable and their communities.

5.3 Integration of PEP across various entry points

PEP refers to the administering of antiretroviral (ARV) medication after potential HIV exposure to prevent infection. Timely access to PEP is the most crucial factor in PEP effectiveness. PEP is most effective when initiated as soon as possible, ideally within 24 hours and no later than 72 hours after exposure.

PART 6 – PRIORITY AND KEY POPULATIONS

6.1 Priority populations

6.1.1 Infants and children

In all settings, HTS should be offered to all biological infants and children with an HIV-positive parent and whose HIV status is unknown (often termed index testing services). Additional support may be required for orphans and vulnerable children (OVC), where one or both parents may have died. Health care implementers who deliver testing through community outreach may be particularly important for increasing coverage among HIV-exposed children ages 18 months and older. Therefore, it is important to integrate HIV testing into other child health programmes and to develop a systematic process to identify and prioritise testing among infants and children.

Routine HIV testing of HIV-exposed infants (born to mothers living with HIV), prompt return of test results and immediate treatment for those with HIV are critical. Early treatment among infants has demonstrated improved survival and overall clinical outcomes, with substantial impact on reducing HIV reservoirs and future disease progression. Polymerase chain reaction (PCR) is required for exposed infants under 24 months, due to the persistence of maternal antibodies, nucleic acid testing (NAT)

Every child whether exposed to HIV or not should be tested at 18 months, as South Africa still has many undiagnosed and untreated children living with HIV. It is therefore imperative that children who access health services both at facility and community level should be screened and tested for HIV.

6.1.2 Adolescents and young people

Adolescents (10 to 19 years) and young people (20 to 24 years) remain particularly vulnerable to HIV acquisition. This vulnerability stems from social and contextual factors such as:

- Age
- Sex
- Gender
- social and cultural norms
- value systems about sexual activity
- location (where the adolescent or young person lives, learns, and earns)
- economic and educational status and,
- sexual orientation.

Adolescents and young people can benefit from HTS as part of broader HIV prevention, sexual and reproductive health interventions as well as part of focused outreach efforts to reach those with undiagnosed HIV infection.

Among adolescents and young people HTS should be prioritised for:

perinatally HIV-infected persons who were not diagnosed, initiated, and retained on antiretrovirals in early infancy and childhood who survived adolescence,
young (20 – 24 years) key populations
adolescents and young people who are vulnerable and need special attention, such as those who are homeless, orphans, adolescents in child-headed households, girls engaging in sex with older men or in multiple or concurrent sexual partnerships and adolescents and young people who are sexually exploited.
all adolescent girls and young women including those that are pregnant and breastfeeding.

Prevention interventions for girls and young women are a high priority among health authorities and services at every level. Emphasis should be put on girls and young women in- and out-of-school, as part of the broader community with special attention to those living in informal settlements. HIV prevention among girls and young women demands special and innovative attention in terms of national social and behaviour change communication (SBCC) strategies and linkage to prevention services.

6.1.3 Pregnant and postpartum women

Providing HTS early in pregnancy enables pregnant women to benefit from all the relevant prevention interventions. For those who test HIV positive this includes treatment and care, which will reduce the risk of HIV transmission to their infants.

The package of care for pregnant women with HIV includes systematic screening for TB and STIs, and referral for treatment, as necessary. South Africa has committed to the triple elimination of HIV, syphilis and hepatitis, and greater emphasis and efforts should be made on the process of screening and effectively treating mothers, their partners, and their infants affected by syphilis. It is also a priority to test all HIV positive pregnant women for TB as undetected and untreated TB amongst HIV-positive pregnant women increases morbidity and mortality among mothers and infants. Pregnant women testing HIV positive must be linked to ART, TB, and HIV management.

Pregnant women with an HIV-negative test result exposed to ongoing risk of HIV exposure should be linked to comprehensive HIV prevention services. It is safe for women to start or continue taking oral PrEP during pregnancy and breastfeeding. Women taking PrEP during pregnancy and whilst breastfeeding should receive HIV testing and STI screening aligned with BANC+ visits during pregnancy and EPI schedule post-natal as set out in Annexure 4 of the VTP guidelines.

6.1.4 Couples and partners

Couples HIV counselling and testing (CHCT) occurs when two or more partners are jointly counselled, tested, and receive their test results together. This approach has shown to increase uptake of interventions to prevent vertical transmission, to improve infant outcomes, and to improve uptake of and adherence to HIV treatment services. CHCT services are especially important for identifying HIV sero-discordant couples, where one member is HIV infected, and the other is not. Providing ongoing services to sero-discordant couples can prevent HIV transmission to the negative partner. Testing partners of people with HIV is an effective way to reach people at high risk of HIV infection.

It efficiently identifies additional people with HIV not yet diagnosed or on ART— particularly male partners who are substantially less likely to test than women. HTS creates the opportunity to link couples to prevention interventions including PrEP and to safer conception or contraception. It can also facilitate uptake of and adherence to ART among HIV-positive partners and VTP among HIV-positive pregnant women. As with all HTS approaches, couples, and partner HTS must be voluntary and not forced, and implementers must recognize that some clients will not want to involve partners.

Partner testing may occur with or without disclosure. Whenever appropriate, feasible, and safe, mutual disclosure of HIV test results under the guidance of an HTS provider should be encouraged and facilitated with explicit consent from both partners. Programmes that particularly serve key populations should provide and encourage partner testing but may find better uptake of social network testing thereby creating a broader social network. Couples and partner HTS can be conducted in various settings, including ANC and community-based services.

6.1.5 Men

Fewer men than women report ever testing for HIV and consequently, men are more likely to start ART at later stages of HIV infection therefore greater emphasis should be placed on reaching them through HTS. They are also less likely than women to use clinical health services, making focused community based HTS approaches important. These include targeted mobile HTS at community settings frequented by men and as well as workplaces dominated by men. Additional modalities include primary and secondary distribution of HIVSS, and implementation of index testing increases HTS coverage for men.

As part of men's health services, HTS should be offered for both prevention services and treatment access (e.g.: in VMMC, TMC and chronic care settings)

6.1.6 Healthcare providers and workers exposed to HIV

In the case where a healthcare provider is accidentally exposed to blood and/ body fluids of an HIV infected person, it is important to establish the HIV status of the health care provider post exposure. If the healthcare provider has an HIV-negative test result, post-exposure prophylaxis (PEP) should be administered immediately or within 72 hours of exposure to minimise the risk of sero-conversion to HIV. Such exposure should be reported to the employer as per the organisation's occupational health and safety guidelines.

- ❖ In the case where a healthcare provider is accidentally exposed to blood and/ body fluids of an HIV infected person, it is important to establish the HIV status of the health care provider post exposure. If the healthcare provider is HIV negative, post-exposure prophylaxis (PEP) should be administered immediately within 72 hours of exposure to minimise the risk of sero-conversion to HIV. Such exposure should be reported to the employer as per guidelines.

6.1.7 All individuals exposed to HIV

- ❖ Refer to the PEP Guidelines for detailed information.

6.1.8 Survivors of sexual assault

Survivors of sexual assault require an empathetic approach by healthcare professionals. The routine offer of HIV testing is recommended as part of the comprehensive clinical management offered to sexual assault survivors. Survivors who test HIV negative should be offered PEP immediately but within 72 hours of the assault in accordance with the 2020 PEP Guidelines. In addition, screening, and management of STIs and possible pregnancy should be considered. All processes should follow relevant legislation (Criminal Law (sexual offences and related matters Amendment Act)).

6.1.9 Migrant and mobile populations

Mobile populations such as truck drivers, farm workers, miners, and migrant workers are at high risk for acquiring and transmitting HIV. In addition, refugees and migrants are vulnerable to HIV infection due to their economic and social insecurity.

To reach these populations with HTS services, the following should be considered:

- provide outreach/mobile HTS services to migrant and refugee populations to increase access to health care,
- offer HTS and other prevention programs at convenient locations such as truck stops, harbours, and work-places to reach mobile populations,
- address cultural issues by providing culturally specific education videos about HIV and AIDS and other STIs in the refugees' local language, and
- refer all sexual assault survivors to appropriate services as described in Section 2.1.7 of this document. It is important to ensure that HTS for these groups are delivered within a human rights framework.

6.2 Key populations

Local data in South Africa demonstrate that key populations are disproportionately affected by HIV and that they account for a large proportion of new HIV infections and HIV prevalence rate, compared to the overall South African population. This suggests the need to increase HIV prevention efforts for this population.

Due to experiences of stigma, key populations and their clients, partners and children often have poor access to health services and are at high ongoing risk of HIV in all settings. HTS should be routinely offered to all key populations in health care facilities, community, designated high transmission areas (HTAs), correctional facilities, and other closed settings. Provision of HTS will enable linkage to prevention and treatment services for those who have either tested HIV negative or positive. HTS and other HIV services should operate on the principles of medical ethics, avoidance of stigma, non-discrimination, and the right to health.

6.2.1 Men who have sex with men (MSM)

MSM refers to men who engage in sexual activity with members of the same sex, regardless of how they identify themselves. Often these males may identify as gay, homosexual, bisexual, heterosexual, or they may not give any consideration to their sexual orientation.

Differentiated HTS approaches, using a mix of facility-based and focused community-based approaches, are important for reaching MSM. Accessible and confidential HTS are crucial for MSM, therefore regular testing should be encouraged to ensure early detection for linkage to prevention and treatment services (see frequency of re-testing recommendations in Table 2). Partnering with community organizations and peer networks can enhance awareness, reduce stigma, and expand reach into hidden MSM networks. Integrating HTS into existing health care facilities catering to MSM, like drop-in centres, is critical. Pre-test information, post-test counselling and index testing services should be provided. Leveraging social network strategies serves as an effective means to encourage testing uptake. Modalities such as HIVSS should be integrated into index and social network testing approaches. Targeted awareness campaigns through online platforms and events educate MSM about the significance of testing.

6.2.2 Sex workers

The term 'sex worker' is intended to be non-judgmental and focuses on the working conditions under which sexual services are sold. Sex workers include consenting female, male, and transgender adults, and young people over the age of 18 who receive money or goods in exchange for sexual services, either regularly or occasionally. Numerous factors increase the risk of exposure to HIV among sex workers, including multiple, non-regular partners and more frequent sexual intercourse. However, sex workers can substantially reduce the risk of HIV transmission, both from clients and to clients, by consistently and correctly using prevention methods (e.g., condoms, PrEP). Sex workers are more at risk

of acquiring HIV infection compared to the general population, due to an increased likelihood of being economically vulnerable, unable to negotiate consistent condom use, and experiencing violence, criminalisation, and marginalisation. HIV prevention services that are peer led, and community based are proven to be most effective when they address the legal and social barriers that affect sex workers.

Tailoring HTS to the vulnerabilities of sex workers is vital, considering factors like gender, norms, and their social & economic status. Integrating testing into comprehensive HIV prevention strategies, including sexual and reproductive health interventions, is important. Focused outreach efforts are essential to engage sex workers, educate about testing benefits, and identify undiagnosed and/or unlinked sex workers living with HIV. Creating safe, non-discriminatory, and key populations-friendly spaces for testing while upholding confidentiality and privacy rights is crucial both through sex worker specific services and within general population health facilities. Immediate linkage to treatment, care, and support for those testing positive and prevention strategies including PrEP, PEP, condoms, and VMMC for those testing negative is necessary. Collaboration with community organizations and youth networks strengthens testing service effectiveness for sex workers. Social network strategies can be employed to expand testing reach for this population and empowering sex workers with education and accessible testing options fosters informed decision-making for HIV prevention and overall better health outcomes.

6.2.3 Transgender populations

The transgender population is defined as people whose gender identity or gender expression does not correspond with their sex assigned at birth. There is evidence to suggest the HIV prevalence rate of the transgender population, is significantly higher than those among other key populations. This population should be prioritized for HTS and linked to both prevention and treatment services.

Providing differentiated HTS tailored to the unique needs of transgender individuals is important because of their heightened vulnerability to HIV because of societal stigma and limited healthcare access. Targeted outreach campaigns should provide regular HIV testing (see frequency of re-testing recommendations in Table 1), while trans-friendly testing facilities through centres of excellence will ensure privacy and comfort. Comprehensive pre- information and post-test counselling, along with non-discrimination policies and confidentiality standards, are integral both at key population specific services and general health facilities. Empowering transgender individuals within healthcare systems as advocates further enhances communication and understanding. Index testing and social networking strategies can be employed through the integration of HIVSS in this population.

6.2.4 Introduced People using/injecting drugs (PWUD/PWID)

Drugs increase behaviours that are associated with increased rates of HIV transmission. Populations who abuse alcohol and other drugs often suffer worse health problems than the general population, but due to stigmatization these populations often have difficulty accessing quality health services.

To ensure that these populations have access to HTS services, HIV testing should be provided as a standard part of medical care for all clients attending specialised health facilities for substance abuse (e.g., drop-in centres, needle/syringe programmes, opioid substitution therapy (OST) programmes, alcohol/drug dependence treatment services). Outreach initiatives should target drug-using communities, promoting the benefits of regular testing (see frequency of re-testing recommendations in Table 1) and early detection. Creating accessible, non-judgmental, safe, and confidential spaces for testing is crucial to ensure individuals feel comfortable seeking services both within PWUD/PWID specific services and within general population health facilities. Implementing harm reduction strategies (offering syringe exchange programs, counselling, and linkage to care) within testing programs can further engage this population. Social network strategies can be used to help increase testing, including the use of HIVSS. HTS for PWUD/PWID should prioritize linking to treatment services if diagnosed with HIV or an appropriate prevention service if tested negative.

Implementation must include measures to prevent compulsory testing and unauthorised disclosure of HIV status. Employees at these services should also receive training to enable them to enquire sensitively about risk behaviours and to recognise the early symptoms of HIV-related diseases. In addition, involving members of this population in the development of HIV testing and counselling protocols will help to ensure that the most appropriate and acceptable practices are followed.

6.3 Inmates

HTS should be offered to inmates and link all with an HIV-positive test result to ART services and inmates with an HIV-negative test result to prevention services. No inmate should be forced or coerced into having an HIV test, instead inmates should be routinely offered HTS services at the time they enter and leave a correctional facility.



PART 7 - HTS DELIVERY APPROACHES

HTS must focus on people living with HIV who (i) remain undiagnosed (ii) unlinked to treatment services (iii) those re-engaging back to care and (iv) people who would substantially benefit from prevention services. To maximise the impact of HTS, programmes need to consider specific local epidemic contexts and resources available and determine a strategic mix of differentiated HTS approaches for an effective and efficient HTS programme.

The HTS approaches include the following:

- Facility-based HTS by entry/ service point,
- Community-based HTS,
- HIV self-screening (HIVSS),
- Index testing and
- Social network -based HIV testing approaches.

7.1 Facility-based HIV testing services

Facility-based HTS encompasses testing in a health facility within standard operating hours and can be routinely offered by clinicians, all nursing cadres, and counsellors.

Client-initiated counselling and testing should also continue to be supported at all health care facility entry/service points.

ANC and Post Natal Care (PNC) services All pregnant clients must be tested during their first ante-natal visit and at every succession visit (as per VTP guidelines).

SRH services provide an opportunity for HTS as part of SRH services and HIV prevention packages especially for adolescent girls and young women of reproductive age and their partners. Integration of HTS and HIV prevention with SRH may help address the diverse needs of sexually active adolescents.

Child and adolescent health services all children should receive an 18-month test and routinely screen for additional testing at all entry/service points for children and adolescents (EPI, IMCI, acute care, nutrition, TB, AYFS). In all settings, testing of HIV- exposed, sick, or hospitalised children and those with a biological parent with HIV remains an important strategy for identifying additional HIV infections.

TB services TB is the most common presenting illness among people living with HIV and therefore it is important to prioritize the referral of testing at all entry points especially in PLHIV. Routinely offering HTS to all people with presumptive or confirmed TB is the key for early detection and prompt linkage to TB treatment along with ART can prevent unnecessary deaths. Noting that HIV positive asymptomatic clients must be put immediately on TPT while they wait for GeneXpert results. HIV positive clients with WHO stage 3 or 4 disease can be tested with LF-LAM (refer to TB guidelines)

Clinical services providing STI testing and treatment. HIV and STI co-infections are common. STI services provide an important entry point for HTS that should be prioritised. Routinely offering HTS to all people who are screened and tested for STIs.

Viral hepatitis services. Major opportunities also exist to integrate HTS into viral hepatitis services. Integration should be prioritised for populations most affected by HIV and hepatitis, such as people who inject and use drugs and inmates.

Men's Health (VMMC) services. HTS is part of VMMC and men's health services. HTS uptake is usually high when offered in circumcision settings.

Outpatient, inpatient, and emergency services. In hospital settings, HTS should be routinely offered to inpatient, emergency department, and outpatient settings, especially to clients with symptoms and other clinical conditions.

7.2 Community-based HIV testing services

Community-based testing refers to HTS offered outside of a health care facility. Community-based HTS can be delivered in various ways and settings. These include but are not limited to HTS at fixed locations, mobile

outreach in hotspots, household testing, places of worship, workplaces, and educational establishments.

Community-based HTS can be delivered alone or in combination with testing and screening for other infections such as TB, viral hepatitis and STIs or as part of other community services such as maternal and child health, and family planning. Appropriate training and supervision of implementers is needed when combining HTS with other infections and services.

Community-based HTS is a practical approach for reaching people who may be less likely to test at a health care facility. It should be used to reach specific populations that remain under tested or poorly linked to treatment or prevention services.

7.2.1 Implementation considerations for community based HTS

There are several issues to consider when implementing community-based HTS or selecting community-based HTS models for differentiated HTS:

Timing and frequency: community-based HTS can be offered continuously, on a regular schedule or as a one-time service at events and campaigns. Continuous services may be appropriate for men and young people in high HIV burden settings or key populations, who typically have low uptake of HTS. Providing community-based outreach at convenient times for priority populations is important – for example, “moonlight” referred to evening testing for members of key populations, weekends or after hours for the working population.

While dedicated events or campaign-style HTS may reach large numbers of people in a short period, it is likely to be not a useful strategy for identifying people with undiagnosed HIV infections or those at ongoing risk of HIV, unless the events particularly attract a priority population.

Targeted services: for the greatest impact, community based HTS needs to focus on populations and settings with the greatest unmet testing need. It is also essential to engage communities when designing community-based HTS. Services are likely to succeed when they have the community’s buy-in or are community-led.

Workplace HTS: HTS in the workplace is an effective strategy for reaching populations like men in high burden settings, such as mining operations, the transport and logistics sector, the military & other uniformed sectors, as well as workers in the informal sector, such as in taxi ranks and markets. Any HTS in the workplace should be implemented within a framework of workplace policies that ensure confidentiality and protect workers who are diagnosed with HIV positive from losing their jobs and from other discrimination.

Mobile outreach: when focused on key populations and men, mobile outreach can complement facility-based HTS in areas of poor accessibility.

Home-based HTS: HTS offered in the home has the potential to reach undiagnosed people or people not linked to treatment or prevention services. This strategy is resource-intensive, and its use should be targeted. It should be prioritized for partners and contacts of people with HIV, TB contacts, and social networks of key populations.

Community campaigns: these may be designed to serve rural and remote populations with limited access to facility based HTS, as well as men in high burden settings.

School-based & Higher Institutions of Learning HTS: these based programmes offer opportunities for HIV testing in the context of broader HIV prevention, SRH education and other interventions. Adolescents and young adults often have limited access to health facilities. Therefore, HTS at these institutions may provide an entry point for a range of health services for adolescents and young adults

Combination services: community based HTS in combination with testing and screening for other infections and conditions is feasible and effective, mainly when offering HTS with STI testing for key populations. This strategy can be considered for optimizing the use of community-based testing resources and improving efficiency, where feasible.



PART 8 – INDEX TESTING SERVICES

Index testing is a voluntary process where trained health care implementers ask people (i) diagnosed with HIV, (ii) client with an unsuppressed viral, (iii) ART clients missed by index testing services and (iv) re-engaging ART clients about their sexual partners, children, or drug injecting partners. Index testing should be offered to all people living with HIV as part of a comprehensive voluntary package of testing, care, and prevention. Offering voluntary HTS to sexual and/or drug injecting partners of people with HIV, effectively identifying additional people with HIV.

Partners and children who are diagnosed with HIV can be linked to treatment services, and those who are HIV-negative and at ongoing risk of HIV acquisition can be linked to effective HIV prevention services. Index testing is also an opportunity to identify untested children of parents living with HIV. These children, who are at a higher risk of living with HIV, can then be tested in the health care facility, or in the community.

Trained implementers should offer index testing services appropriately and safely. Associated counselling and support services, such as helplines and intimate partner violence screening tools are available and should be utilised to reduce the potential risk of harm. HIV-positive clients should be offered multiple options for index testing and the approach selected should be based on the client preferences. Clients should also be allowed to decline index testing services.

Index testing should be implemented in all facility and community-based HTS. Index testing services should always be voluntary and conducted in a safe and ethical manner. Mandatory or coercive approaches to index testing are never justified. Clients should always be screened for the risk of intimate partner violence and counselled about the benefits and risks so that they can make safe and informed choices.

8.1 All index testing sites should take steps to implement safe and ethical index testing services by:

- i. **Complying with minimum standards** for index testing.
- ii. **Obtaining informed consent** prior to the elicitation interview and before contacting partners.
- iii. Conducting an **IPV risk assessment** for each named partner and providing appropriate services for clients experiencing or at risk of violence.
- iv. Utilizing continuous **quality improvement** to identify and address any gaps in the provision of index testing services; and
- v. Implementing a robust mechanism for detecting, monitoring, reporting, and following up on any
- vi. **adverse events** associated with index testing services

8.1.1 Ten steps for conducting Index testing Services

Step 1: Introduce Index Testing Services during the pre-testing session, re-engagement to care and ART visit.

Step 2: Offer Index Testing as a voluntary service to all eligible clients.

Step 3: When the client accepts Index Testing, obtain consent from the client.

Step 4: Obtain a list of sexual and needle-sharing partners, biological children/ siblings <19 years and parents with unknown HIV status.

Step 5: Conduct an Intimate Partner Violence (IPV) risk assessment/ LIVES screening for each named partner/ child(ren)

Step 6: Determine the preferred approach of contacting each named sexual and needle-sharing partner(s), biological children/ siblings under the age of 19 years and parents.

Step 7: Contact all named sexual and needle-sharing partners, biological children/ siblings <19 years and parents with unknown status using the index client's preferred approach and record outcomes.

Step 8: Record testing of all named elicited contacts.

Step 9: Provide appropriate services to all named elicited contacts based on HIV status.

Step 10: Follow up with the index client to assess any adverse events associated with index testing

8.1.2 Social network-based testing

Social network-based testing involves facility and community testing of social networks through providing testing services at facilities and communities provided by health care implementers.

Social network-based HIV testing approaches are effective for reaching the sexual or drug-injecting partners and social contacts of the members of key populations or specifically identified high prevalence sub-population groups. It is a complementary approach to address some of the challenges in scaling up Index testing, particularly challenges of confidentiality. By addressing confidentiality concerns and broadening the reach to include both HIV-positive and HIV-negative clients, their partners, social contacts, and networks. Social network-based HIV testing approaches can improve the acceptability and reach more people who may not otherwise test for HIV.

Social network-based approaches are safe, acceptable, and feasible and may identify additional people living with HIV.

Social network-based HIV testing approaches also tend to reach more first-time testers.



HIV SELF SCREENING (HIVSS)

8.2 HIVSS

HIVSS is a screening test and does not provide a definitive HIV-positive diagnosis. A reactive HIVSS result is not equivalent to an HIV- positive diagnosis. All reactive HIVSS results need to be confirmed through the national testing algorithm.

Non-reactive HIVSS results should be considered to be HIV-negative, with no need for immediate further testing.

HIVSS can also be used to link clients to PrEP, continuation and re-engagement for those already initiated on PrEP, and this is only applicable if conducted in healthcare facilities

Those with invalid HIVSS results must repeat the test using a new test device or seek testing from a trained provider. Any person uncertain about their HIVSS result should be encouraged to seek testing from a trained provider. HIVSS is not recommended for people with HIV who are on ART, as false-negative HIVSS results can occur. Those who are HIV positive but not on ART should be encouraged and supported to initiate ART. Everyone who test non-reactive should test again six weeks after the time of possible risk. However, retesting is necessary for those at ongoing risk, such as key and vulnerable populations, and should be tested every 12 weeks.

8.2.1 Objectives

HIVSS objectives include the following:

- Improve testing uptake among under tested and test adverse populations - including men, key populations, and young people
- Improve couples testing among pregnant women and lactating mothers, in order to reach male partners with unknown HIV status
- Provide an option for regular repeat HIV testing in key populations, such as sex workers, MSM, transgender people, people who inject drugs and mobile populations (truck drivers, miners, and farm workers)
- Provide an additional modality for testing and retesting clients on PrEP

8.3 Key considerations for HIVSS

This section will highlight the most important considerations for the implementation of HIV self-screening:

Programmes implementing HIV self-screening must use quality-assured products that have been approved for use in South Africa, e.g., a WHO pre-qualified product

There must be appropriate, validated, clear and concise instructions for the use of HIV self-screening kits to minimise errors and maximise performance. Pictures can support the correct use and interpretation or in-person demonstrations for people with low literacy

A reactive (positive) self-screening result always requires further confirmatory testing from a trained healthcare provider starting from the beginning of a full national validated HIV testing algorithm. Clear messages are essential to ensure self-screener are aware of what to do after a reactive self-test

Those with a non-reactive (negative) self-screening result should retest after 6 weeks (as indicated on the HIV self-screening information for use (IFU) insert if they might have been exposed to HIV in the preceding six weeks, or are at high ongoing HIV risk

PLWHIV on ARVs and people in HIV-related clinical trials should not conduct an HIVSS test as this may result in a false non-reactive outcome

If a person is uncertain about how to correctly perform the self-screening test, or interpret the self-screening result, he or she should be encouraged to access the health care facility or community-based HIV testing.

8.3.1 Targeted population

The NSP (2023-2028) emphasises “high yield” HIV testing and leaving no one behind. HIVSS is not intended to replace current HIV testing modalities, but rather to complement HTS and enable more people to know their HIV status, particularly those that are not reached by existing services. It is important to carefully position this service such that it is highly efficient and effective at reaching the undiagnosed people with ongoing risk. It should be noted that anyone who requests self-screen should not be denied the opportunity to do so. However, HIVSS may not be for everyone, and it is important that individuals and communities are aware of how and where to access facility- and community-based testing options.

8.3.2 HIVSS implementation process

At a minimum, HIV self-screening should be offered with the following:

- The application of the 5Cs
- Detailed step-by-step instructions (included in the self-screening kit)
- The HIV self-screening kit must meet the specified minimum standards
- Referral and linkage to confirmatory and prevention services
- Support for partner testing and disclosure

8.4 Assistance with using HIVSS

8.4.1 Directly assisted HIV self-screening

Over and above the manufacturer's supplied instruction, an individual using directly assisted HIV self-screening receives a direct in-person demonstration. This can be done by a trained provider, peer educator, or community health worker before or during self-screening to guide the person on how to perform any of the steps in the self-screening procedure, or to interpret the screening result. Like all other forms of self-screening, additional support such as hotlines, videos and brochures may be provided.

Directly assisted HIV self-screening is recommended for:

- any individual who requests assistance during self-screening
- a person who is using the HIV self-screening kit for the first time and is unsure of the procedure, or those with low literacy levels until they are confident to self-screen
- adolescents from 12 to <18 years old
- individuals who screen HIV negative using HIVSS and require continuation for PrEP, post 4 months following initiation of oral PrEP
- Follow-up HIV testing after PEP



8.5 Unassisted HIV self-screening

This approach refers to individuals who self-screen for HIV independently, without the help of a trained provider or peer, using only manufacturer-provided instructions for use. As with all self-screening, users may be provided with access to additional support such as telephone hotlines, brochures, or instructional videos. Unassisted HIVSS is recommended for anyone who is 18 years and above.



Unassisted HIV self-screening: when individuals self-screen for HIV independently using only manufacturer-provided instructions for use. As with all self-screening, users may be provided with links or contact details to access additional support, such as telephone hotlines, information leaflets or instructional videos.

- HIVSS can contribute to filling gaps in HIV programs by:
 - Improving access and reaching people with high HIV risk and the undertested. HIVSS has been found to increase testing uptake and frequency.
 - Improving testing coverage through integrating HIVSS into clinical services where testing is needed but not routinely provided or where testing is poorly implemented.
 - Facilitating index partner testing through primary and secondary distribution

8.6 HIVSS distribution

8.6.1 Distribution methods for HIV self-screening kits

- HIV self-screening tests can be delivered through primary or secondary distribution methods:
 - The primary distribution method occurs when a self-screening kit is delivered directly to the end-user.
 - Secondary distribution occurs when one or more self-screening kits are given to an individual, not for their own use, but to distribute to their sexual partner, family member, or anyone in their network

8.6.2 Distribution channels for HIV self-screening

HIVSS can be utilized within facility or community based HTS and it can be offered through online ordering and delivery systems. It can also be provided through pharmacies, vending machines, workplace settings, or other public and private sector channels.

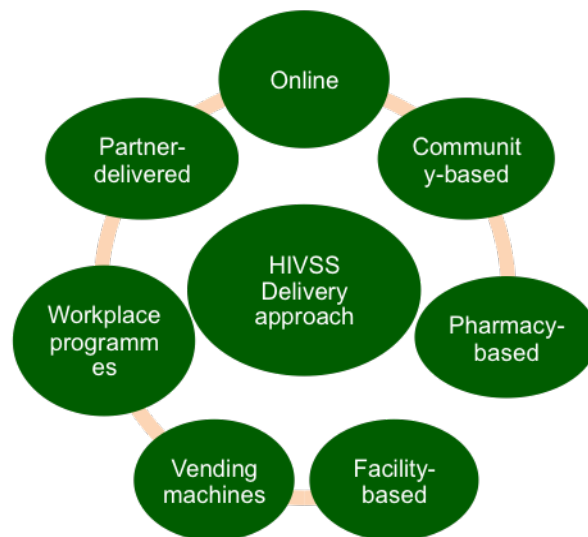


Figure 7: Differentiated HIVSS service delivery approaches

8.6.3 Specific considerations for pharmacy distribution of HIV self-screening kits as outlined by the SA Pharmacy Council (SAPC)

Pharmacists must only sell HIV self-screening kits approved by either SAPHRA, the WHO, other regulatory health authorities recognised by SAPHRA (FDA, European Medicines Evaluations Agency (EMA)) or self-screening kits with CE marking.

Pharmacists and/or pharmacy support personnel must ensure that they have adequate knowledge of the relevant aspects of HIV and HIVSS test kits as well as the ability to demonstrate the use of the test kit to any person as the need arises.

A pharmacist must ensure that the person buying the HIVSS kit has access to the following information:

- Information leaflet

- Guidance on interpretation of all three possible outcomes of the HIVSS test (Reactive, Non-Reactive, Invalid)

- Information on referral and linkage to care

8.7 Linkage strategies after HIV self-screening

- Information material, such as manufacturer's instructions for use, brochures and flyers distributed with HIV self-screening kits should have information on linkages for all possible outcomes.

- A telephone hotline that self-screeners can use before, during or after self-screening for psychosocial and/or technical

- Support can help with referral and linkage information.

- Short Message Services (SMS) or a smartphone application can provide information, reminders, videos, and messages that encourage linkage following HIVSS

- Proactive, community-based follow-up by peer and/or outreach workers

- Community health workers can provide additional post-screen counselling where appropriate and support with referral to confirmatory testing services

- Couples and partner/s self-screening can promote linkage and should be encouraged, including partner delivered self-screen kits with information on linkage.

For further linkage guidance see Part 5.



PART 9 – HUMAN RIGHTS AND ETHICS

9.1 Human rights and rights to access

People living with HIV and AIDS and their families are entitled to full and equal enjoyment of all rights and freedoms in the Bill of Rights. The right to have access to healthcare services, which is guaranteed in Section 27 of the Constitution, is but one of the basic human rights to which people living with HIV and AIDS are entitled.

A human rights-based approach to public health highlights priority areas, including universal health coverage (UHC), gender equality and health-related human rights such as accessibility, availability, acceptability, and quality of services. HTS must be offered in a way that is consistent with the rights described in the Constitution of South Africa, 1996 the National Health Act, 2003, and the Children's Act, 2005. It must be ethical and conducted within a supportive and safe environment.



9.1.1 Right to dignity and non-discrimination

Section 10 of the Constitution provides that everyone has inherent dignity and the right to have their dignity respected and protected. The right to dignity of people living with HIV and AIDS cannot be infringed upon based on their HIV status. Violations to a person's dignity may occur either by action, words, or both forms of conduct. The South African constitution recognises that dignity is not only a basic right that must be protected, but also a value that must guide our actions and interpretations of rights.

Stigma can lead to discrimination and other violations of human rights which affect the well-being of people living with HIV in fundamental ways. HIV-related discrimination is a human rights violation, and it is necessary to address such discrimination and stigma to achieve public health goals and overcome the epidemic. The stigma and discrimination associated with HIV and AIDS also mean that people living with HIV and AIDS are much less likely to seek and receive care and support. Internalised stigma is the negative attitude and beliefs that individuals with HIV may have towards themselves because of the social stigma and discrimination associated with the virus.

It can lead to feelings of shame, guilt, and low self-esteem, which can result in a range of negative outcomes, such as social isolation, depression, anxiety, and reduced access to care. Support groups and counselling services can provide a safe space for individuals living with HIV to share their experiences, emotions, and concerns with others who are going through similar experiences. Additionally, healthcare implementers can play a critical role in reducing internalised stigma by providing compassionate care and treatment that is free from judgment and discrimination. Overall, creating a supportive and inclusive environment can go a long way in helping individuals living with HIV to overcome internalised stigma and live fulfilling lives.

The national HTS programme in collaboration with all stakeholders should help reduce stigma and discrimination by creating knowledge and competence about HIV in communities. All people tested require access to information to make informed choices about their health and the best available treatment and prevention services. The information must be clear, scientifically valid, and non-judgmental.

9.1.2 Right to privacy and confidentiality

All personal information concerning a client, his or her health status, treatment or stay in a health care facility must be kept confidential, unless ordered by a court of law or done so for the advancement of the client's care and treatment after following the necessary procedure.

Section 10 of the Constitution provides that everyone has the right to privacy which includes the right not to have the privacy of their communications infringed. No one, including an employer, health professional, family member, partner, or friend of a person living with HIV and AIDS is allowed to reveal a person's HIV status without his/her permission to do so. The personal information of people, including their health information is protected by the Protection of Personal Information Act, 2020

9.1.3 Right to equality

The right to equality and protection from unfair discrimination are protected in terms of Section 9 of the Constitution and in the law through the Promotion of Equality and Prevention from Unfair Discrimination Act, 2000 (Act 4 of 2000). The right to equality provides that everyone is equal before the law and has the right to equal protection and benefit of the law. No person, including the government or private companies, may unfairly discriminate, directly or indirectly, against anyone on any grounds. No person may be unjustifiably discriminated against because of their HIV status. In the employment sphere potential employees cannot be discriminated against because they are HIV positive.

In the workplace, HIV- positive employees are protected from being dismissed or discriminated against based on their HIV status. Prospective employers cannot request evidence of HIV-negative status as a condition of an employment and cannot insist on a disclosure of HIV status. The Employment Equity Act, 1998 (Act 55 of 1998) protects against such workplace discrimination. In addition, potential employees cannot be tested without consent.

9.1.4 Right to refuse HIV testing

Clients have the right to refuse HIV testing, without compromising their access to standard healthcare. There shall be no mandatory HIV testing, and all testing shall remain voluntary with informed consent, even when the service provider initiates the services. The only exception is in cases of sexual assault where the survivor requests the status of the perpetrator in terms of the Criminal Law (Sexual Offences and Related Matters) Amendment Act 32 of 2007 or an order of court.

9.2 Requirements of informed consent

The information that clients require to give their informed consent may vary based on the service delivery approach and setting, but should include information about:

- benefits and implications of knowing one's status and reasons for recommending HTS,
- client's right to withdraw consent at any stage of the process,
- availability of follow-up treatment; care and support; and prevention services,
- importance of disclosure and partner/family testing and availability of couple HTS.

9.2.1 Capacity to consent

Any person aged 12 years and older, and/or with sufficient maturity and mental capacity to understand the benefits, risks, social and other implications of HIV testing, may give consent for HTS in South Africa.

Potential clients should:

- understand why they are being tested,
- understand the implication of a negative, inconclusive, or positive test result, and
- discuss how they are likely to respond to possible test results.

Consent shall be conducted in a language understood by the client, and in child-friendly versions, as applicable.

Informed consent should always be documented in the following settings and populations:

Infants and children: HTS should be offered to the parents or caregivers as applicable on behalf of the infant or child, and they should provide written informed consent. Where appropriate, pretest information should be provided in an age-appropriate manner prior to testing the child. Particularly when children consent for their own testing.

Couples: Informed consent should be given by individuals separately or willing to be tested as a couple. As part of the routine assessment, questions about the couple's relationship, including any incidents of physical, financial, or emotional abuse will be asked to make sure that everyone is safe and getting the support they need.

Research settings: Informed consent within clinical trials and other research settings should always be written and documented as stipulated by the national Department of Health's Guidelines for Good Practice in Conduct of Clinical Trials 2020

Illiteracy or inability to write: If the client cannot write or has a disability that hinders their ability to write, the right-hand thumbprint or any other fingerprint in the absence of right-hand thumb can be used instead of the signature, if the client wants to consent.

Inability to make a decision: According to the National Health Act, if a client is unable to give informed consent, for example, in the case of unconsciousness/incapacitation or cognitive disability, and if the test is clinically indicated, consent can be given by a person authorised to give such consent, in terms of any law or court order. In the case of adults, the spouse, next-of-kin (parent, grandparent, an adult child, or a sibling of the person), clinician or clinical manager, in the specific order listed, can give informed consent. In the case of children, refer to **Section 10.2** of this policy.

Any client or patient who does not consent to HTS should still be provided with the best possible care and should not be denied other health services. Client/s declining an HIV test should be offered assistance to access HTS in the future, and their decision to decline should be noted in their medical record so that a discussion of HTS can be reinitiated at subsequent visits to the health facility.

9.3 The Children's Act

The Children's Act, Section 130, stipulates when and how a child may be tested for HIV. The Act has clearly distinguished HIV testing from other forms of medical treatment and has enforced conditions for HTS among children.

Children may only be tested for HIV in two circumstances:

if testing is in their best interest and lawful consent has been given for the test
if the test is needed to establish the child's HIV status in cases where a healthcare worker, parent, caregiver, or another person may have contracted HIV from the child's body fluids (for PEP purposes or to establish the status of the person who was allegedly exposed). This provision protects children against discriminatory or arbitrary HIV testing.

Consent for HIV testing for children may be given:

by a child if he or she is older than 12 years
by a parent, caregiver, the Hospital Superintendent, or the provincial head of the Department of Social Development if the child is younger than 12 years and is not sufficiently mature.

This section of the Act ensures that a wide range of people may assist a child by consenting for HIV testing on the child's behalf. It facilitates HTS for orphans and vulnerable children.

Counselling during HIV testing among children:

HIV testing must be accompanied by a correct pre-information session and post-test counselling done by an appropriately trained person
This provision ensures that children and their caregivers make appropriate choices regarding HIV testing.

No person may disclose a child's HIV status without consent.

Consent for the disclosure of HIV status can be given by the child if he or she is older than 12 years and is sufficiently mature. If the child does not have the capacity to give consent to the disclosure, consent can be given by a parent, caregiver, and legal guardian. This provision aims to ensure that a child's right to confidentiality is protected.

9.4 Ethical considerations

9.4.1 Promoting equality for vulnerable groups

The vulnerable position of women, girls, children, key populations, and persons living with disabilities, concerning HIV and AIDS and its social impact is recognised. Their access to HTS services must be addressed by the policy and service implementers should ensure that services are accessible to them.

9.4.2 Promoting the best interests of children

The impact of HIV on the rights of children is considerable. Respect for the best interests of the child dictates that children's rights and needs must be at the forefront of all interventions for HIV prevention, treatment, and support. The following principles should guide any interactions with children:

provision of relevant, appropriate, and accessible information on the prevention, treatment, and care of HIV during the counselling process in the language that the child can understand,
ensuring full participation by the child in any decision-making and consent process regarding HIV testing and consideration given to the views of the child,
HIV testing only when it is in the best interest of the child,
providing post-test access to treatment, care, and support, and
ensuring confidentiality regarding HIV test results and support with disclosure of HIV status in terms of the Children's Act, 2005 (Act 38 of 2005) as amended and Criminal Law, specifically the Sexual Offences and Related Matters Amendment Act, 2007 (Act 32 of 2007).

The South African National HTS Policy is aligned with the UNAIDS and WHO Policy Statement on HIV Testing, that: 'The conditions under which people undergo HIV testing must be anchored in a human rights approach which protects their human rights and pays due respect to ethical principles.'

9.4.3 Availability of HTS services

HTS should be made available in all public health facilities, private health care facilities, non-governmental and community-based organisations (NGOs/CBOs) that have trained implementers to offer HTS.

9.4.4 Duty and responsibility of all healthcare employees

It is the duty and responsibility of all health care implementers to provide adequate pre-test information for people to make informed decisions about HIV testing and linkage to treatment and prevention services. Health care implementers should offer HIV testing to all clients so that they can access HIV care.

9.4.5 Quality of HTS

All HTS (information, counselling, testing, and testing kits) shall be subject to quality assurance according to defined national standards and should be monitored and evaluated. In addition, healthcare implementers should be trained to provide quality HTS according to the national policy framework.

9.4.6 Effective partnerships

All government departments, the private sector, implementing partners, stakeholders, and civil society should be involved in the HIV and AIDS response.

9.4.7 Using scientific evidence

The interventions outlined in the HTS policy shall, wherever possible, be evidence-based.

9.4.8 Leadership role of government

The effective implementation of the National HTS Policy and the attainment of its goals depend on government leadership in resource allocation, implementation guidance, and effective coordination of the programme. The responsibility for the provision of healthcare services, including HIV services for all people throughout the country is the responsibility of the South African government.

All government health care facilities must treat everyone and offer information, counselling, HIV testing, prevention, and treatment services free of charge. An HIV and AIDS helpline provides answers to questions and operates 24 hours on a toll-free telephone number: 0800 012 322.

PART 10 – NORMS AND STANDARDS

10.1 Operational requirements for HIV testing services

10.1.1 Requirements for HTS

HTS should be recommended for all clients attending health facilities, community and workplace testing regardless of whether they show signs or symptoms of HIV infection. Operational requirements for facility-based services include the following:

guiding documents or standard operating procedures (SOPs) that detail all elements of the HTS process must be available at every point where HTS is conducted,
health care implementers must be trained on the use of the policy and SOPs,
guiding documents must be updated as the need arises,
facilities must display signs or posters that inform clients about the availability and location of the service in compliance with the ideal clinic guidelines,
facilities must have relevant HIV and AIDS information, education, and communication (IEC) materials in languages used by the facility's catchment population, including people with a disability. Where possible, this information shall be available in braille and other relevant formats,
facilities must facilitate access to other HIV and AIDS preventative services and, where appropriate, facilitate linkage of clients to prevention, treatment, and support services,
facilities must be accessible, non-stigmatizing and convenient to all segments of the population, men, women and children, citizens, and foreign nationals alike, including people with disabilities, key populations, other marginalised and targeted populations, and
facilities should be child-friendly and ensure that children's rights are protected.
Positive identification (ID, License, Passport) will be required in cases where a client requests a copy of their HIV test results.

10.1.2 Infrastructure requirements for HTS sites

Each site or set-up where HTS is performed must have an appropriate physical space for testing. The appropriateness of the physical space includes the storage of test kits, quality control (QC) samples, and other supplies used for testing. Provision for the transportation of test kits and independent quality control/proficiency testing (IQC/PT) samples must be appropriate to meet the requirements for their storage.

Facility appropriateness should include:

adequate and levelled surface for performing tests that can be cleaned and decontaminated,
measures for environmental factors such as the temperature and degree of humidity to ensure that the test kits and other testing commodities are kept in a temperature-controlled environment based on manufacturer's instructions,
a temperature controlling system where temperatures exceed the expected ranges with documented temperature monitoring, and
hand washing facilities, commodities, disinfectants, and personal protective equipment.

Testing sites should implement all safety measures to ensure the safety of all employees that may come into contact with biohazard materials including safety of the clients attending the sites. Employees should always adhere to universal safety precautions when testing.

Proposed information, counselling, and testing space should have the following:

waiting area that is well ventilated,
a room or designated area that has:

- adequate lighting, access to clean water or hand sanitizers,
- adequate privacy to ensure confidentiality, and
- adequate storage space for supplies.

10.1.3 Health care implementers requirements

Adequate safety and security measures for employees and equipment in HTS services must be ensured. All health care implementers should be trained in HIV testing services and ongoing refresher training should be provided to ensure that health implementers are kept abreast with the latest updates and developments. Trained human resources are critical to the provision of high-quality HTS.

10.1.4 Waste management

Facility-based HTS implementers must have necessary supplies where HTS is conducted to properly dispose of waste. This includes having a sharps container for sharps (e.g., lancets) and a biohazard (red) bag for other clinical waste (e.g., used gloves, cotton wool, etc.). Each HTS site must follow the infection control and prevention policy.

Procedures for handling biohazards should include:

- instructions on use of gloves, protective clothing, hand washing, handling of sharp objects, and management of blood spillages,
- visible basic safety instructions posted in the testing room,
- display of general instructions such as “no eating, drinking, or smoking,”
- availability of SOPs for safe disposal of infectious and non-infectious waste at a site,
- availability of SOPs or job aids to manage spills of blood and other body fluids, and
- availability of SOPs or job aids for accidental exposure to potential body fluids through a needle stick injury, splash, or other sharp injury.

PART 11– QUALITY ASSURANCE AND QUALITY IMPROVEMENT

Quality assurance (QA) and quality improvement (QI) encompass the entire process of HTS. Coordination with laboratory services for QA and delivery of accurate HIV test results is a priority and a core component of the 5Cs for HTS. All HIV healthcare providers providing HTS are required to complete the Rapid Test Continuous Quality Improvement (RTCQI) training and demonstrate competency in HIV rapid testing and implement the quality assurance activities.

11.1 Quality assurance for HIV testing

Quality assurance (QA) is a systematic process that provides confidence that quality requirements will be fulfilled. Continuous quality improvement (CQI) focuses on increasing the ability to fulfil quality requirements. Every effort must be made to ensure that service delivery is of the highest quality. QA for HIV testing refers to those strategies employed by HTS that ensure that the final HIV test results are correct. The availability of rapid HIV diagnostic tests with high performance characteristics alone does not guarantee accurate test results. Errors can occur at multiple points along the diagnostic continuum. The following elements are key for assuring quality of HIV testing results:

- a national HTS Policy,
- quality management system (QMS) for all HIV testing in all settings,
- regulation of selection and pre- and post-market surveillance for in-vitro diagnostics,
- validated national testing algorithms (with back-up options), action mandated by NDOH
- training and supportive supervision for HTS implementers,
- consistent adequate stock of test kits and consumables, and
- SOPs & job aids for HTS

HTS implementers must be trained in how to keep HTS records (e.g., use of standardised registers) and understand the importance of independent quality control (IQC) and proficiency testing (PT) programmes. There must be effective site supervisory visits with informed corrective actions linked to the Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) assessment.

11.2 Quality management system (QMS)

QMS is a system that consists of all the processes put in place to ensure quality. A QMS can be implemented to varying degrees, but the basic principles still apply to any service providing HIV testing results. Any site conducting HIV testing should implement a QMS that incorporates the 12 elements shown in Figure 8.

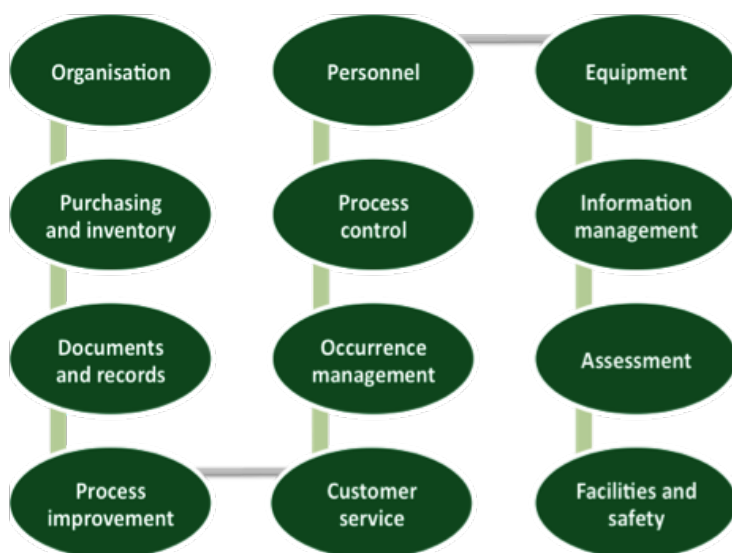


Figure 8: Twelve elements of a quality management system

There are multiple points along the diagnostic continuum that can contribute to incorrect test results, including inferior quality of HIV tests kits, improper storage of test kits, not following SOPs or poor documentation. Using routine monitoring data to support facility efforts in monitoring, improving, and evaluating quality, the six key stages of assuring and improving quality illustrated in Figure 9 should be followed. This aspect of HTS is covered in the National Guidelines on Quality Assurance for HIV Rapid Testing” 2025



Figure 9: Quality assurance cycle - A continuous quality assurance and improvement process

11.3 Regulation of HIV diagnostics

The WHO Prequalification of In Vitro Diagnostics promotes and facilitates access to safe, appropriate, and affordable diagnostics of excellent quality. The WHO systematically reviews the quality, safety and performance of HIV rapid diagnostic test that are available in the market in resource-limited settings. South Africa highly recommends the use of WHO prequalified HIV rapid test kits or products eligible for procurement through the national tender process and must have been validated and lot-verified by the national reference laboratory.

For HIVSS the government will only procure and distribute HIV self-screening kits that are WHO pre-qualified and validated by the national reference laboratory. All HIV self-screening kits must include procedures for use and safe disposal of the used test devices through the general waste system, written in English with translation into at least two local official languages. Package inserts must be simple with clear written instructions plus pictorial diagrams to make it easy for the user to accurately perform the self-screen test.

11.4 Post-marketing surveillance of diagnostics

Post-marketing surveillance for HIV rapid tests is a critical process for monitoring the quality of test kits that are procured and used within South Africa. Once a product is placed on the market, its quality, safety, and performance must be monitored to ensure that it continues to meet the set standards. All HIV rapid test kits utilized in testing sites must be subjected to both pre- and post-market surveillance.

11.5 Requirements for HIVSS instructions for use

In addition to instructions for use (IFU), it is recommended that all HIVSS kits distributed be accompanied with client education material such as frequently asked questions or pamphlets. All distribution points should display illustrations or instructions on HIV self-screening procedures with further explanation or testing support if required.

The instructions must cover:

- How to handle and store the test kits before using the test
- How to interpret test results
- What to do after reading the results, including information on available post-test services, such as counselling, confirmatory testing & care, and treatment
- How to safely dispose of the used test kit
- The ethical and legal obligations, which includes consent requirements and no coercion.

11.6 Quality control (QC)

Quality control refers to processes and activities that ensure that testing procedures are performed correctly, that environmental conditions are suitable and that the test works as expected. QC will help to detect, evaluate, and correct errors before test results are reported. It is a multi-step process with checkpoints throughout the testing process. QC should be implemented at all HTS sites and records should be kept accordingly. It is recommended that routine use be made of known positive and known negative independent quality control (IQC) samples to verify performance of the test devices prior to testing clients. The minimum frequency and conditions of the use of the IQC are described in detail in the National Guidelines on Quality Assurance for HIV Rapid Testing” 2025

11.7 External quality assessment and proficiency testing

External quality assessment, including proficiency testing (PT) refers to the external assessment of testing sites operations and inter-facility comparison to determine if the HIV testing service can provide the accurate correct test results every time a client is tested. PT involves testing of unknown HIV positive and negative samples at regular intervals by the testing sites through a PT programme approved by NDOH. The PT cycle is shown in Figure 10.

Every three to six months each HTS site enrolled in PT programme should receive a panel of samples, known as a proficiency testing panel, from the National Reference Laboratory. HTS service implementers should perform HIV testing on the samples on a rotational basis, and they should record the test results on a standard form. The test results are then uploaded to the web base system and are checked for accuracy. All sites should receive and keep the results of their proficiency panel testing. Any errors or mistakes are reported back to the site, so that corrective actions can be completed. Facilities that do not meet the expected scoring for proficiency testing are required to receive technical support from national, provincial, district or implementing partner supporting that site.



Figure 10: The proficiency testing cycle

11.7.1 Supportive supervision, site assessment and observed practice

Provincial supervisors should support healthcare managers and HTS implementers at the district level. Ideally a provincial and district supervisor, quality assurance officers, trained supervisors or implementing partner supporting the site should conduct regular site visits. A standardized checklist should be used to assess compliance with QA requirements quarterly (for new sites) and annually (for existing sites) and feedback should be provided. Any recommended corrective action from a site supervisory visit should be implemented within the recommended period.

11.7.2 Quality assurance for HIV Counselling

While standard protocols for rapid testing provide the appropriate information for the testing component of HTS, the counselling skills have the greatest impact on the client's HTS experience. It is therefore important to have systems that ensure the quality of counselling. Such approaches are important for ensuring that human rights are respected, and the client's needs are met. High quality counselling is defined as non-judgmental, accessible and client centred. Counselling should increase the knowledge of HIV prevention, benefits of early treatment for HIV-positive individuals and help clients to focus on achievable steps to reduce their risk.

The following are the national requirements for QA of counselling that must be followed by all service implementers:

- all counsellors must meet the National Minimum Standards for Counselling to ensure that quality counselling is conducted,
- QA (i.e., supervision, observations of actual counselling sessions, regular training, and feedback to counsellors) of counselling must be performed at least on a quarterly basis.

These strategies are important in ensuring that quality counselling and testing is provided.

11.7.3 Mentorship and observations of counselling sessions

Given the burden of the HIV epidemic in South Africa, healthcare implementers and HTS counsellors may face increased stress and burnout that sometimes compromises the quality of HIV counselling. Counselling support supervision is important for preventing burnout of individual HTS implementers and maintaining high level communication between implementers and clients.

Quality improvement tools for counselling include:

- documented supervision and mentoring sessions and debriefing session.

PART 12 – MONITORING AND EVALUATION

12.1 Managing and documenting HIV results

Key information should be collected for each HTS encounter in all models and settings (Annexure A). This data will allow the health care provider to monitor service delivery in a standardised manner and allow for useful analysis of data. Annexure B describes the standard data collection tools that should be used when HTS is provided. Completion of these data collection tools is key to monitoring performance and identifying trends in service delivery

12.2 Documenting, monitoring, and evaluation

Monitoring and evaluation (M&E) is a necessary component of the implementation and management of the HTS programme, ensuring that resources allocated to the programme are used efficiently, services are accessed, activities occur in an effective and guided manner, and the expected results are achieved. Routinely monitoring HTS programmes ensures that quality of service is improved and the maximum health benefit for the population is obtained.

Monitoring is the routine tracking of service and programme performance using input, process and outcome information that is collected on a regular and ongoing basis. This process makes use of HTS programme tools such as the consent form, registers regular reporting systems and templates (e.g., the District Health Information System (DHIS), as well as health facility support visits, client surveys and to some extent, population-based surveys).

Evaluation is the periodic assessment of results that can be attributed to programme activities. It uses advanced data analysis and indicators that are not collected through routine information systems. It also assesses whether the programme is effective in achieving its objectives.

12.2.1 Quality assurance indicators in HTS register

QA indicators in the HTS register are used for recording the specific results of each individual HIV test kit used, and allow for easier monitoring of the lot number, kit name and expiry date, and the rate of invalid and discrepant results. They help HTS implementers to address test kit problems, such as expired test kits, invalid or inconclusive results. Every HTS provider should complete the HTS register immediately following the performance of a HIV rapid test with clients (including weekly IQC), and this register should be reviewed monthly for correctness by supervisors.

12.3 Data management

Data management is essential for the effective management and improvement of HTS. Client data should be used to monitor HTS at each site, in each sub-district, district, province and at the national level. All HTS implementers will use a standardised HTS register as a data collection tool. Data collection will take place at the site or outreach setting where clients are seen (point of service) and data entry will be done at the district level. Data will be collected at every level for analysis and reporting.

At each level, the data collected will be analysed and interpreted to help improve the service planning and decision-making. Each district and provincial health information office should have a well-defined data management protocol and data flow protocol from different peripheral service points, including those in the private sector, to a central point.

Only health care implementers, HTS counsellors and data capturers/information officers permanently designated to work with health information, at all levels (facility, sub-district, district, provincial, and national), should have access to data for verification and quality checks (completeness, correctness, and accuracy). The confidentiality of clients' records should always be maintained.

12.4 Roles and responsibilities for information flow

All required data should flow from the HTS service points to and from the district, provincial and national health offices. Compliance with the data flow policy and the data user agreement must be maintained at each level. All HTS sites, including government and health centres, NGOs, CBO's, private and commercial sites offering HTS must follow these procedures.

Data is collected routinely at the following levels:

Service points: All HTS record-keeping forms and registers will be completed at the service points by the health care implementers and HTS counsellors, consolidated by the facility data capturers and signed off by the facility or programme manager. Periodic reports will be completed at the service points and transmitted to the appropriate health districts.

Sub-district office: Data collected from the service points and NGOs or private facilities within sub-districts will be collated, captured on the District Health Information System (DHIS), and reported to the respective district office. This will be done monthly by the sub-district health information officers and the respective supervisors.

District office: Data collected from the service points and NGOs or private facilities within districts will be collated, captured on the District Health Information System (DHIS), and reported to the respective provincial office. This will be done monthly by the district health information officers and the district HTS coordinator.

Provincial office: The provincial health information officer and HTS coordinator will compile all district data and report to the national Department of Health.



National Department of Health: Final compilation of national HTS data will occur at the national office. The flow of information will ensure that feedback is provided at each level.

Figure 11: HTS data flow chart

12.5 Monitoring and evaluation framework and objectives

The “input-output-outcome-impact” framework is used in most monitoring and evaluation environments. These stages represent the flow of interventions over time and are intended to capture the relationship starting with input and ending with impact. For an HTS programme to achieve its goals, input (policies, budget, employees, HIV test kits), must result in outputs (number of people tested, new or improved HTS services and appropriate ratios of trained employees).

These outputs are often the result of specific processes, such as training sessions for employees and campaigns aimed at promoting the uptake of HIV testing. If these outputs are well designed and reach the prioritized populations, the programme is likely to have positive short-term effects or outcomes, such as an increased number of people from the prioritized population testing for HIV. These positive short-term outcomes should lead to changes in the longer-term impact of HTS programmes, possibly reflected in fewer new cases of HIV infection in a prioritized population.

12.6 HTS programmes: Essential and strategic indicators

HTS programmes should continually monitor the minimum set of indicators established by the national HTS Programme. These indicators, which include antenatal care (ANC), TB, STI, post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) in primary healthcare clinics and community HTS programmes should be monitored at every service delivery point offering HTS. Indicators measuring referral to appropriate services (e.g., TB screening, STI treatment, ART, VMMC) should be collected. Table 4 shows the set of indicators that are recommended for the purpose of reporting on the implementation of the HTS programme and policy.

Table 4: Recommended HTS indicators

No	Indicator	Data Source	Frequency of collection
1.	Number of active lay counsellors on stipend	Programme monitoring	Quarterly
2.	Number of clients tested excluding ANC	DHIS	Monthly
3.	Number of clients tested HIV negative	DHIS	Monthly
4.	Number of clients tested HIV positive	Programme monitoring	Monthly
5.	Number of clients screened with an HIVSS RDT	Programme monitoring	Quarterly

A data collection tool should be available with a minimum set of data elements, which reflect policy goals and objectives. Indicators should be dynamic and should be revised periodically depending on the availability of information and changing circumstances or technologies.

Indicator relatedness: Programme monitoring activities (in-year monitoring) and periodic outcome and impact activities should be closely linked. Indicators that are logically connected (i.e., inputs, outputs, and outcomes) should be used.

Reporting requirements: For reporting, all facilities and community programmes providing HTS will be required to comply with agreed reporting standards and schedules as well as to comply with the data flow policy outlined in figure 12.

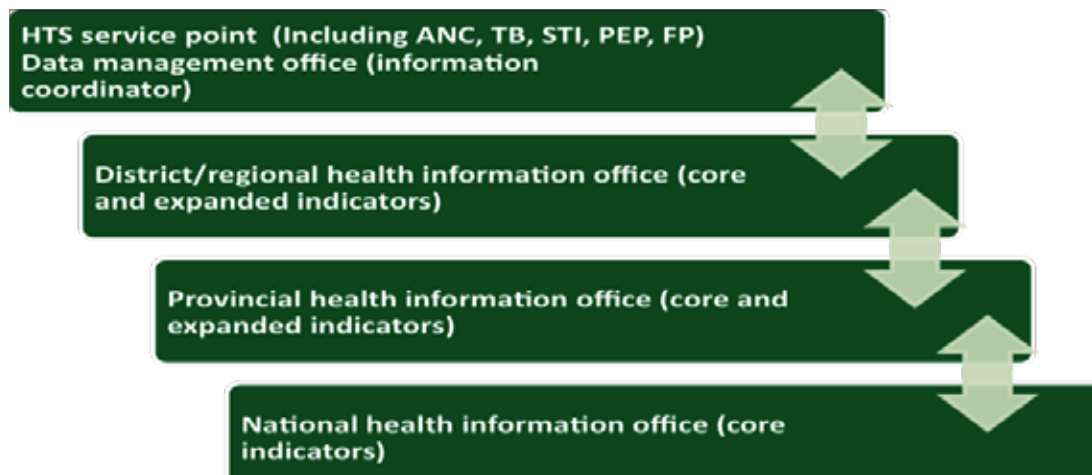


Figure 12: Information flow within the HTS Programme

12.7 Data quality assurance

To assure the quality of the data that is reported, the district, regional and national level DHIS officers should select sites to be visited for data verification every quarter. A data verification tool should be developed to assist in this process.

PART 13 – SUPPLY CHAIN MANAGEMENT

Procurement processes and procedures should be rigorous enough to minimise stockouts of rapid test kits and other testing commodities. This is essential for ensuring the quality of HTS.

13.1 Forecasting

Accurate forecasting is necessary to ensure an adequate and ongoing supply of HIV test kits and other consumables. Forecasting for HIV rapid test kits should be based on the programme's capacity to provide HIV testing. The province and district authorities should ensure proper adherence to inventory management protocols, including maintenance of quality records, timely reporting, accurate forecasting and adequate supply of tests and other essential commodities, to prevent the disruption of HTS service provision.

13.2 Procurement of rapid test kits

Only Rapid HIV test kits procured through the national tender shall be used in the public health sector and in other sectors where testing is undertaken.

13.3 Storage of HIV test supplies

Rapid test kit quality assurance standards must be followed. Storage of rapid test kits must adhere to the manufacturer's storage instructions. Refer to the Guidelines for Assuring the Accuracy and Reliability of HIV Rapid Testing: Applying a Quality System Approach, National Department of Health, 2023.

13.4 Stockouts

To avoid stockouts, proper forecasting shall be done. Shortage of test kits must be reported through the district, province, and national department.

13.5 Human resources

HTS sites should have adequate human resources including trained professional health workers, counsellors or community health workers and other support employees to provide the required services. Service implementers should ensure a safe working environment for all healthcare employees.

HTS must be carried out by trained healthcare implementers, community health workers, or counsellors, working under the supervision of a suitably trained health care worker. Counsellor training should be conducted according to the National HTS curriculum. HTS counsellors should have appropriate training in counselling children.

Counsellors working in facilities and/ or community outreach should counsel and test a minimum of twelve (12) clients a day inclusive of children.

13.6 HTS training requirements

All HTS implementers should be trained using the national HTS training curricula for standardized messaging and the HTS online training which is available on NDoH knowledge Hub platform.

There are three (3) components to HIV testing –

- 1) **National HIV Testers/Counsellors Training** – 10-day initial training (every 36 months for existing employees and every new employee should be trained within 3 months of employment). In addition, employees should be offered a 3 – 5-day refresher every 36 months
- 2) **Rapid Test Continuous Quality Improvement** – Nationally approved curriculum – 10 modules – online/self-paced or face-to-face with a practical component. Two to three days if face-to-face training is provided. Training should be completed in six months if the tester is doing the self-paced training. Refreshers are required every 24 months. Certificates need to be available at the testing site.
- 3) **National Tester Certification** - Testers need to be deemed competent on successful completion of a written exam (80%), Direct observation (90%), and sample testing (100%). Once competent, the tester will form part of the National Tester database. They will require continuous supervision and monitoring and recertification after 36 months.

13.6.1 Qualifications of HTS implementers

HTS implementers should at a very minimum have the following qualifications:

Matric

National Department of Health-aligned HTS training (HIV Testers/Counselling Training and RTCQI). HTS training provides skills development on counselling, rapid testing, and quality assurance. The rapid test training must include a competency component to ensure implementers are proficient.

Continuous evaluation of competence must be implemented at the testing site level to ensure compliance with the HIV testing standards.

13.6.2 Certification and re-certification

Certification: Persons completing nationally approved HTS curricula will receive a certificate of completion. Upon submission of a portfolio of evidence which includes the direct observation of testing by a supervisor, a certificate of competency will be issued by a recognised training institution/department. This includes the Rapid Test Continuous Quality Improvement training programme and Tester Certification process as described in the National Guidelines on Quality Assurance for HIV Rapid Testing” 2025

Refresher training: Periodic refresher training is necessary to ensure that HTS implementers have the most accurate up- to-date information and that they can deliver high-quality HTS. RTCQI training and Tester re-certification is required every 36 months. Certificates must be up to date when site assessments are conducted for the site to comply with the standards linked to personnel training and certification. National Guidelines on Quality Assurance for HIV Rapid Testing” 2025.

14. CONCLUSION

The aim of the National Testing Services: Policy and Guideline, 2025 is to provide a national framework to direct the provision of HTS to children, youth, and adults in the public and private sectors in South Africa. The main purpose of the policy guidelines is to ensure better quality and greater consistency in the delivery of the many elements within the programme.

For these policy guidelines to take root and have meaning in the lives of the communities who access and ultimately use HTS, all service implementers, programme planners and policy makers must commit and adhere to the spirit and intention underlying in the policy. Collective commitment and consistent implementation of the policy will achieve greater quality and improve standardization of HTS across the country.

ANNEXURE A: HIV TESTING CONSENT



**NATIONAL DEPARTMENT OF HEALTH
HIV TESTING CONSENT FORM – ADULTS AND CHILDREN**

CONSENT

I, _____ (*name of client/parent/guardian or caregiver*) have been counselled about the HIV test and HIVSS and agree to have myself/child tested for HIV. I understand that the results of this test will be strictly confidential and may only be shared with relevant healthcare workers when necessary. Depending on the results of this test I will be linked to the appropriate prevention and treatment services timely.

CLIENT DETAILS						
Client name & Surname						
Date of Birth	Age		Gender	M	F	Specify (LGBTQIA+)
ID/Passport/Refugee/Asylum number	Client/Caregiver contact number			Key Population		
Client Address				SW/ MSM/ PWUID/ TG		
First ever HIV Test	Yes	No	Most recent HIV status?	Date of last HIV test?	Positive	Negative
Facility/Site/Community			Folder Number			

TB SCREENING (for adults and children)				STI SCREENING (All clients should be screened for STIs regardless of clinical presentation)			
Close contact with a person with confirmed TB infection?	Yes	No		Do you have any genital discharge or ulcers (sores)?	Yes	No	Do not know
Do you have a cough of any duration?	Yes	No		Has/have your partner(s) been treated for an STI in the last 8 weeks? (Not applicable to children)	Yes	No	Do not know
Do you have a fever or high temperature more than 38 degrees Celsius?	Yes	No					
Are you or the child experiencing weight loss? (Or is the child not growing well?)	Yes	No		If the client answered "YES" to any of the above questions refer to the clinician for further management.			
Do you have drenching night sweats?	Yes	No		MENTAL HEALTH SCREENING			
If HIV negative and answered "YES" to one (1) or more of these questions, please refer to a clinician. All HIV positive clients to be referred for TB testing. (Regardless of answers above).				Are you sleeping poorly or has your sleeping pattern changed?	Yes	No	
				Have you ever intentionally hurt yourself or thought of hurting yourself?	Yes	No	
				Referred to clinician/ psychologist or social worker	Yes	No	

RESULTS				REFERRALS (mark with x)			
PCR	Reactive	Non-reactive		ART (for HIV +ve)			
HIVSS (Assisted)	Reactive	Non-reactive		Condoms			
HIV screening (initial test)	Reactive	Non-reactive		PrEP (for HIV -ve)			
HIV confirmatory test 1	Reactive	Non-reactive		PEP (for HIV -ve)			
HIV confirmatory test 2	Reactive	Non-reactive		VMMC			
Final HIV Result	HIV +ve	HIV -ve	Discrepant	SRH			
Syphilis result (if dual test used)				Other Services (specify):			

All clients should be counselled and referred/linked to appropriate services regardless of HIV status.

Name of person consenting			Signature of person consenting			
Relationship to client (if applicable)			I confirm that I have received my/child's HIV test result	Yes	No	
If not parent/legal guardian/caregiver. State the reason for consenting?						
Date			Signature			
Name & Surname of healthcare provider			Designation of healthcare provider			



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