Republic of Malawi

HIV, Syphilis and Hepatitis B Integrated Rapid Testing and Counselling Guidelines and Standard Operating Procedures

Ministry of Health

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NOTE: The mention of certain manufacturers' products does not imply they are endorsed or recommended by the Ministry of Health in preference to others of a similar nature that are not mentioned.

Foreword

Since the early eighties, when the first case was diagnosed, Malawi has made remarkable progress in the fight against the HIV epidemic. Latest epidemiological estimates suggest that by the end of 2022, **95%** of all PLHIV had been diagnosed, **97%** of whom were on ART, and **94%** of people on ART had achieved viral suppression. In order to maintain and consolidate this remarkable achievement, the HIV testing program will need to continue providing high testing coverage for all priority population groups and intensify targeted approaches for key and hard to reach populations.

As the great majority of PLHIV are already aware of their status and on ART, the proportion of clients who test positive in the testing program has declined below 5% since 2016, and positivity reached around 2.5% in 2022. In this context, and with over 3 million clients tested each year, the small possibility of any rapid test kit to produce a false positive result may lead to an unacceptable number of false positive misdiagnoses. To address this challenge, Malawi has formally adopted the World Health Organization (WHO) recommendation to replace the previous two-test algorithm with a serial three-test algorithm, selecting 3 rapid antibody tests with complementing properties. This will ensure that the risk of a misdiagnosis (false negative or false positive) is reduced to an absolute minimum.

With this new guideline edition, Malawi also formally embraces the WHO *Triple Elimination Initiative* to eliminate of mother-to-child transmission (EMTCT) of HIV, syphilis, and hepatitis B by 2030 while ensuring integration of service delivery. As Malawi moves towards triple EMTCT, with HIV ascertainment among pregnant women at 98%, the aim is to achieve more than 88% coverage in syphilis and hepatitis B testing through improved access and integration of services. In addition to prioritising testing of pregnant women, other high-risk populations will also be targeted and tested for HIV, syphilis, and hepatitis B.

Overall, Malawi will focus on maintaining high levels of routine, provider-initiated status ascertainment in all priority facility entry points, complemented by targeted testing strategies such as active index testing for partners and children of HIV-positive clients, and passive index testing for syphilis and hepatitis B clients. Testing will be offered through differentiated service delivery (DSD) models that are tailored to suit client needs. Quality assurance will be strengthened through proficiency testing and quality controls.

This document will assist programme managers to plan and implement HIV, syphilis, and hepatitis B testing in accordance with national guidance. Testing services providers will be guided by the standard operating procedures incorporated in this document to ensuring quality of services.

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Acronyms

AGYW	Adolescent girls and young women
ANC	Antenatal care
ART	Antiretroviral therapy
ARV	Antiretroviral drug
DAR	Daily activity register
DBS	Dry blood spot
DHA	Department of HIV/AIDS and Hepatitis B
DHMT	District health management team
DHO	District health office
DHSS	Director of Health and Social Services, District Health and Social Services
DIC	Drop-in centre
DSD	Differentiated service delivery
EID	Early infant diagnosis
EPI	WHO Expanded Program on Immunization
EQA	External quality assurance
FEFO	First expired, first out
FRS	Family referral slip
FSW	Female sex worker
HEI	HIV-exposed infant
HIVST	HIV self-testing
HMIS	Health management information system
HTS	HIV testing services
HTSS	Health Technical Support Services
IEC	Information, education, and communication
IPV	Intimate partner violence
M&E	Monitoring and evaluation
MoH	Ministry of Health
MOS	Months of stock
MSCE	Malawi School Certificate of Education
MSM	Men who have sex with men
NHRL	National HIV Reference Laboratory
OPD	Outpatient department
PEP	Post-exposure prophylaxis
PITC	Provider-initiated testing and counselling
PLHIV	Persons living with HIV

PMRA	Pharmacy and Medicines Regulatory Authority
PMTCT	Prevention of mother-to-child transmission
POC	Point-of-care
PrEP	Pre-exposure prophylaxis
PSHD	Presumed severe HIV disease
PT	Proficiency testing
PWID	People who inject drugs
QA	Quality assurance
QC	Quality control, quality check
RDT	Rapid diagnostic test
SOP	Standard operating procedure
SPI-RT	Stepwise Process for Improving the Quality of HIV Rapid Testing (checklist)
SRH	Sexual reproductive health
STI	Sexually transmitted infection
TB	Tuberculosis
TOT	Training of trainers
VCT	Voluntary counselling and testing
VMMC	Voluntary medical male circumcision

Definition of terms

Confirmatory HIV test: A test conducted to improve diagnostic accuracy and rule out errors before enrolling the client in the antiretroviral therapy/prevention of mother-to-child transmission programme.

Differentiated service delivery (DSD): A person-centred approach that simplifies HIV services and adapts them across the system in ways that both better serve the needs of persons living with HIV and reduce unnecessary burdens on the health system.

Discordant couple: A couple in which one partner is HIV-positive and the other is HIV-negative.

Early infant diagnosis (EID): Testing of infants to determine their HIV status. HIV can be acquired in utero (during pregnancy), intrapartum (during delivery), postpartum (through breast-feeding), or through parental exposure.

Hepatitis B surface antigen (HBsAg): A test used to check for the presence of hepatitis B virus envelope protein and excess coat particles, detectable in the blood with acute and chronic hepatitis B infection.

HIV ascertainment: The process of determining an HIV diagnosis from the results of an accurate HIV test.

HIV self-testing (HIVST): The process whereby an individual collects his or her own specimen (oral fluid or blood), performs an HIV test, and interprets the results. HIV self-tests are often done in a private setting, either alone or in the presence of someone the person trusts.

HIV status: A reference to whether a person is HIV-positive, HIV-negative, or HIV inconclusive.

HIV testing services (HTS): The full range of services provided together with HIV testing. These services include counselling (brief pre-test information and post-test counselling sessions); linkage to appropriate HIV prevention, care, and treatment, and other clinical and support services; and coordination with laboratory services to support quality assurance.

Index case: (a) An individual who is newly diagnosed as HIV-positive. (b) An individual who is HIV-positive and/or enrolled in treatment services. Index cases are empowered to notify and mobilise any sexual partners or family members (also referred to as *contacts*) to receive testing services.

Index testing (index case testing): A focused approach to HIV testing in which the household, family members (including children), and sexual partners of index cases are offered HIV testing services. This approach includes both passive systems (family referral slips) and active systems (contract, dual, and provider referrals).

Integration: The location and sharing of services and resources across different disease areas within the same facility. In the context of HIV, this may include providing HIV testing, prevention,

treatment, and care services alongside other health services, such as treatment for TB, treatment for STIs, antenatal care, family planning, and screening and care for other conditions, including non-communicable diseases.

Key populations (KPs): Specific groups who are at increased risk for HIV, regardless of the type of epidemic or local context, due to specific higher-risk behaviours. These guidelines consider the following groups to be key populations: men who have sex with men (MSM), prison inmates, transgender persons, male sex workers (MSW), female sex workers (FSW), and people who inject drugs (PWID).

Mature minor: Any child younger than 13 years of age who is married, pregnant, or sexually active.

Point-of-care (POC): *Point-of-care* refers to diagnostic tests that are performed at or near the treatment facility and have fast turnaround times, thereby enabling faster delivery of results and expedited clinical decision-making.

Pre-test information: A brief presentation of accurate information to an individual by a testing services provider prior to HIV testing. Depending on local conditions and resources, programmes may provide pre-test information through individual or group information sessions, or through such media as posters, brochures, websites, and short video clips shown in waiting rooms.

Priority populations: People who are at risk for poor health outcomes, and for whom public health interventions would have the greatest impact. Priority populations include migrants, mobile workers, adolescent girls and young women (AGYW), inmates, orphans and vulnerable children, fisher-folk, and estate workers.

Proficiency testing (PT): A type of external quality assurance that involves use of blind sample panels administered to testing services providers to evaluate their competency. The panels are distributed to all testing sites at regular intervals (twice a year); participants then test the specimens and return the results to the reference laboratory for evaluation.

Quality assurance (QA): A part of quality management focused on providing confidence that quality requirements will be fulfilled.

Quality control (QC): A process used to evaluate and monitor performance of a test. The QC process may monitor the entire test system or only one aspect of it.

Rapid diagnostic test (RDT): Immunoassays that detect antibodies or antigens.

Recency test: This is a point-of-care antibody test that can differentiate between recent infection (acquired during the past year) and long-term or established infection. This information is important to public health because it allows health care providers to target interventions, make changes to programmes, and strengthen epidemic control.

Repeat testing: Additional testing performed for an individual during the same visit, immediately following receipt of the initial test results. The same tests are used, and where possible, the same specimen is used.

Retesting: Testing individuals again after a specific period, usually a period during which the risk of transmission exists.

Seroconversion: When an individual first produces enough HIV antibodies to be detectable on a given HIV serological assay.

Status Neutral Testing Approach: This approach ensures that individuals – irrespective of one's HIV serostatus – receive the appropriate referrals, whether to initiate ART treatment, re-engage in care after a break, or to receive appropriate prevention services.

Testing algorithm: A combination and sequence of specific assays used within HIV testing strategies.

Window period: The period between when an individual becomes infected with HIV and when serological tests first detect the presence of HIV-1 or HIV-2 antibodies.

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Chapter 1: Introduction and Background

The Government of Malawi has adopted the Global AIDS, Sexually Transmitted Infections (STIs) and Hepatitis B frameworks through the Health Sector Strategic Plan III (HSSP III 2022–2030) and the National HIV & AIDS Strategic Plan (NSP 2020–2025), which aim at providing high-quality, efficient, and equitable services to all. Furthermore, Malawi has committed to the World Health Organization's initiative to eliminate mother-to-child transmission of HIV, syphilis, and hepatitis B—three diseases which remain a burden in Malawi.

Latest epidemiological estimates suggest that by the end of 2022, 95% of all PLHIV had been diagnosed, 97% of whom were on ART, and 94% of people on ART had achieved viral suppression. In order to maintain and consolidate this remarkable achievement, the HIV testing program will need to continue providing high testing coverage for all priority population groups and intensify targeted approaches for key and hard to reach populations.

As the great majority of PLHIV are already aware of their status and on ART, the proportion of clients who test positive in the testing program has declined below 5% since 2016, and positivity reached around 2.5% in 2022. In this context, and with over 3 million clients tested each year, the small possibility of any single rapid test kit to produce a false positive result may lead to an unacceptable number of false positive misdiagnoses. To address this challenge, Malawi has formally adopted the World Health Organization (WHO) recommendation to replace the previous two-test algorithm with a serial three-test algorithm, selecting 3 rapid antibody tests with complementing properties. This will ensure that the risk of a misdiagnosis (false negative or false positive) is reduced to an absolute minimum.

In 2022, Malawi has achieved 98% HIV status ascertainment of pregnant women, but syphilis testing coverage remained lower at 88%. Routine syphilis screening will therefore be expanded to match the high HIV testing rate. Hepatitis B, which is responsible for an estimated 1.4 million deaths per year globally will also be targeted. A systematic review of local studies in 2018 estimated the pooled prevalence of the hepatitis B virus (HBV) at 8.1% in the general population and 2.1% among regular blood donors. However, routine programme data from 2020–2023 showed that only around 1.2% of clients tested HBV surface antigen positive, and positivity was very low in the birth cohorts after 2002 when routine infant HBV vaccination was introduced. A population-based survey is being planned to generate representative age and sex-stratified prevalence estimates.

Globally, most people with chronic hepatitis (types B and C) are not aware of their status, and thus do not receive appropriate treatment. Ascertainment of hepatitis B status will be achieved by implementing these guidelines; however, hepatitis C testing will only be prioritised for targeted subgroups due to the low overall prevalence and high cost of treatment. Testing to ensure the safety of blood transfusions will continue to be implemented through the appropriate channels.

The emergence of COVID-19 has demonstrated the vulnerability of health services, and a considerable transient decline in testing services was seen in Malawi during COVID-19 epidemic

waves. HIV epidemic control can only be maintained by ensuring continuity of services amidst major disruptions such as COVID-19 or environmental disasters. This document provides guidance on measures to prevent and control COVID-19 while managers work to implement testing services and point-of-service delivery in both health facilities and local communities.

1.1 Rationale for the integrated testing guidelines

The document includes integrated testing standards for HIV, syphilis, and hepatitis B. Integration will accelerate elimination of mother-to-child transmission (EMTCT) of these three diseases in Malawi by improving case finding and linkage to prevention and treatment services. Furthermore, it will address inequalities in testing among high-risk populations, which include pregnant and breast-feeding women, sex workers, people who inject drugs, and other key and priority populations. Integrating services will also improve efficiency and reduce costs, since tests can be conducted by the same service providers at the same service delivery points.

These guidelines will thus be used as a technical guide and set of standard operating procedures for providers. Funders and managers will also use the document, to design services and to mobilise and implement resources for HIV, syphilis, and hepatitis B testing.

1.2 Testing strategy and target population

The **primary goal** of these guidelines is to identify people with HIV, syphilis, and viral hepatitis and link them to care and treatment as soon as possible. Malawi will therefore focus on a targeted testing strategy using index case testing for all three conditions.

Active index testing is offered for biological children and sexual partners of index cases; passive referral is offered to sexual partners of syphilis and hepatitis B infected index cases using referral slips. At each facility, trained providers will elicit information on contacts and manage the data and ensure the confidentiality of client information. This will encourage the client to voluntarily share contacts, including those in social networks, such as people who inject drugs (PWID).

The **secondary goal** of these guidelines is to identify people who are not infected with HIV, syphilis, and viral hepatitis, but at high risk of infection, and link them to effective prevention services.

Testing will be targeted according to specific age groups and populations and their geographical areas. These include female sex workers (FSW), men who have sex with men (MSM), male sex workers (MSW), transgender persons, PWID, prisoners, migrant workers, men, adolescents, and mobile populations; these groups are at greater risk of being infected with HIV, syphilis, and hepatitis due to their behaviour and probability of encounters with infected partners. Pregnant and breast-feeding women are also prioritised due to their vulnerabilities. However, testing services will be accessible for anyone in the general population who seeks testing. A status

neutral testing approach will be used to ensure that individuals – irrespective of their HIV sero-status – receive the appropriate referrals, whether to initiate ART treatment, re-engage in care, or to receive appropriate prevention services.

Chapter 2: Guiding Principles for HIV, Syphilis, and Hepatitis B Testing

Key facts: Guiding principles

- HIV, syphilis, and hepatitis B testing must always be voluntary.
- Consent for testing must be informed by providing clients with information before testing.
- Coerced testing is never appropriate, regardless of whether that coercion comes from a health care provider, partner, or family member of the client.
- Clients have the right to decline testing without fear of negative consequences for any other services.

This chapter explains the WHO's 5Cs. These are the guiding principles for HIV testing, but they have been adapted to testing for syphilis and hepatitis B. Testing must always be beneficial to the individuals being tested, and it must aim to improve health outcomes among the population. Accordingly, all testing providers must adhere to the 5Cs.

The 5Cs are:

- **C**onsent
  Informed consent must always be obtained from clients prior to testing.

- **C**onfidentiality
  Testing services must be confidential. Test results can only be disclosed with the client's consent.

- **C**ounselling
  Pre-test information and post-test counselling must always be provided to clients accessing testing services.
- **C**orrect test results
  Providers should ensure that quality assurance mechanisms are adhered to in order to ensure that clients receive the correct test results.

- **C**onnections
  Effective linkage and referrals must be made to the appropriate services, including prevention, treatment, care, and support services.

Chapter 3: Approaches to Delivery of Integrated Testing Services

Key facts: Service delivery

- Services should continue as best as possible at all testing points during COVID-19 epidemic waves and other major disruptions such as environmental disasters.
- Infection prevention and control measures should be built into integrated testing plans.
- Targeted facility and community-based testing services are offered for high-risk populations, but are available for the general population when needed.
- All index cases must be screened for the risk of intimate partner violence (IPV) prior to providing services.
- Recency testing is currently being implemented as surveillance without returning results to clients.

3.1 Resilient integrated testing services

COVID-19 and environmental disasters have widely impacted delivery of health care services. Always adhere to the general guiding principles (the 5 C's) of service delivery.

Continuity of services is essential to the prevention and control of HIV, syphilis, and hepatitis B. It is important to provide services to all populations while observing the necessary infection prevention measures to reduce the risk of transmission among health care workers, clients, and the general population.

The following should be adhered to by all providers at all points of service during epidemic waves:

- Facilities should make sure to have the necessary staff and resources available.
- Use demand creation tools (flyers, pamphlets, community radio announcements, etc.) to make the community aware that services will continue to be provided.
- Every delivery point should observe infection prevention measures.
- Information about vaccines should be provided to clients.
- To avoid overcrowding, the time clients spend at facilities should be reduced.
- Ensure social and physical distancing between clients on queues.
- All service providers must wear protective gear when offering services.
- Commodities and supplies should be ordered on a timely basis and managed efficiently to ensure continuity of services.

3.2 Integrated testing services

A variety of service delivery approaches will be used to make integrated testing services available at facilities and in the community. These include:

- Provider-initiated testing and counselling (PITC)
- Voluntary counselling and testing (VCT)
- Index testing and partner notification services
- Social network strategy
- HIV self-testing (HIVST)
- Recency surveillance
- Integrated community outreach testing
- Mobile testing
- Status neutral testing strategy

Specific testing approaches are used for HIV, syphilis, and hepatitis B surveillance and research.

3.2.1 Provider-initiated testing and counselling (PITC)

PITC refers to testing and counselling routinely offered by providers to individuals at a health facility. Emphasis is placed on integration of testing with other services.

Entry points for PITC include:

- STI clinics
- Skin clinics
- TB clinics
- Under-5 clinics; EPI, IMCI, ARI, Nutrition Clinic
- Antenatal care (ANC)
- Postnatal care
- In-patient wards
- Outpatient departments (OPD)
- VMMC clinics
- Family planning clinics

3.2.2 Voluntary counselling and testing (VCT)

VCT refers to testing that is initiated by the client—i.e., when an individual decides they want to know their HIV, syphilis, and/or hepatitis B status and asks to be tested.

VCT must be widely promoted through community sensitisation and health education.

3.2.3 Index testing and partner notification services

Index testing is a key strategy used to identify undiagnosed children, adolescents, and adults living with HIV, syphilis, and/or hepatitis B.

The different index testing referral methods are explained in Table 1 below.

Table 1: Index testing referral methods

Type	Form	Description
Passive	Family referral slip (FRS)	Offered to HIV, syphilis, and hepatitis index clients, and to HIV-negative clients whose sexual or injection drug use partner is of unknown status. Family referral slips are issued for sexual partners and family members, including children below 13 years of age. (For more information, refer to the Family Referral Slip Standard Operating Procedures.)
Active	Contract referral (CR)	An HIV index client voluntarily makes a contract with a trained provider: • The index client will disclose their status to their contacts and refer them for testing using FRS. • If the contacts do not access testing within two weeks, the provider will directly and confidentially notify the contacts and refer them for testing.
	Dual referral (DR)	A trained provider voluntarily accompanies the HIV index client to provide support when they disclose their status to their contacts and may also provide these contacts with testing.
	Provider referral (PR)	With the consent of the HIV index client, the testing provider confidentially notifies contacts and refers them for testing.

The partner notifications and referrals that take place as part of index testing are sensitive matters. Therefore, the following accommodations must be made to protect both index clients and their contacts:

- Providers must provide a comprehensive review of all index testing methods (both passive and active) so that clients can make an informed decision.
- Index cases must not be coerced into disclosing contacts to the provider or any other cadres.
- Providers must obtain written informed consent from clients to disclose their status to others, as required by the HIV and AIDS (Prevention and Management) Act.
- Index cases must be informed that disclosure of contacts is completely voluntary, and that the client's decision will not affect the subsequent care that they receive.
- All client information, including the names and details of contacts provided, must be kept private and confidential. All records must be kept in a secured location.

All index cases must be assessed for risk of intimate partner violence (IPV) using the screening tool below:

Table 2: IPV screening questions

Intimate partner violence (IPV) screening tool
• Has [partner's name] ever hit, kicked, slapped, or otherwise physically hurt you? • Has [partner's name] ever threatened to hurt you? • Has [partner's name] ever forced you to do something sexually that made you feel uncomfortable? Do not offer active index testing if the client answers '**Yes**' to ANY of these questions.

3.2.4 Social network strategy

Social network strategy (**SNS**) is an evidence-supported approach to engage a person and motivate them to consent to HIV testing. It is an extension of index testing, based on the underlying principle that persons within the same social network who know, trust, and can influence each other share similar HIV risk behaviours. SNS is particularly useful for finding marginalised and/or hidden persons who may be at risk for HIV (such as PWID, youth, or friends).

The SNS approach includes identifying persons who are either HIV-positive or at risk for HIV and enlisting them to become 'recruiters'. They identify social network peers who may be at risk of HIV, then talk with them, encouraging them to get tested and referring and/or accompanying them to HIV testing services. Unlike peer advocates or peer educators, 'recruiters' are not engaged long term, requiring coaching rather than training and supervision.

3.2.5 HIV self-testing

HIVST refers to the process whereby a person who wants to know their HIV status collects their own sample, performs a rapid test, and interprets the test result in private.

HIVST kits can be distributed through either primary or secondary distribution strategies:

- **Primary distribution**: Health care workers and other trained personnel directly distribute HIVST kits to end users.
- **Secondary distribution**: Health care workers and other trained personnel distribute HIVST kits to third persons, who then deliver the kits to end users.

Table 3: Facility-based HIVST distribution strategies

Strategy	HIVST recipient	Targeted end user	Distributor
Primary distribution	Individuals who opt out of conventional testing delivered by a trained provider	Same as recipient	Testing services provider or layperson trained in HIVST
	Key populations	Same as recipient	Testing services provider or lay person/ peer (through SNS) trained in HIVST
Secondary distribution	Pregnant and postnatal women	Male partners	Testing services provider trained in HIVST
	Index clients	Sexual partners of PLHIV	Testing services provider trained in HIVST
	Key populations	Sexual partners of key populations Clients of sex workers	Testing services provider or lay person/ peer (through SNS) trained in HIVST
	STI Clients	Sexual partners of STI clients	Testing services provider trained in HIVST

Table 4: Targeted primary distribution for community based HIVST

Target end user	Distribution site	Distributor
Men	Workplaces (formal and informal)	Health care workers or peer educators trained in HIVST
	Targeted informal settlements	Community volunteers and testing services providers trained in HIVST
Young people (15-24)	Targeted informal settlements	Community volunteers and testing services providers trained in HIVST
	Peer-based (tertiary institutions)	Peer distributors trained in HIVST
Key population	Peer-based: hot spots and other venues	Peer distributors trained in HIVST
PrEP Clients	Community PrEP sites	Health care workers or peer educators trained in HIVST

3.2.6 HIV recency surveillance

Special rapid test for recency can give an indication if an HIV infection was acquired within the past 12 months. This type of testing makes it possible to distinguish recent from long-term infections. Recency surveillance may help identify populations (defined by behaviour or geographic area) where current transmission is occurring. Any recently infected person is linked to an index case, an infected person with an unsuppressed viral load. Therefore, targeting the

source community of the recently infected person with testing, ART linkage, and effective prevention interventions may be a promising strategy to reduce HIV incidence in the community.

The results of a recency test do not affect the treatment or care given to clients. The results are also not returned to clients.

Recency testing is being implemented for surveillance at selected facilities that account for a large proportion of new positives in Malawi.

3.2.7 Integrated community outreach testing

Integrated outreach testing is provided at designated community locations, including standalone sites, drop-in centres (DICs), and other outreach clinics.

Models of outreach testing include weekend and evening clinics that target populations who may not be reached during normal working hours, such as adolescent girls and young women (AGYW), young men, the elite, and working-class people.

3.2.8 Integrated mobile testing

After successful community mobilisation, temporary testing sites may be set up to reach high-risk communities.

Models of integrated mobile testing include:

- Mobile testing vans
- Community testing campaigns
- Testing at formal workplaces (e.g., public, and private organisations, institutions)
- Testing at informal workplaces (e.g., marketplaces, bicycle, motorcycle and taxi ranks, fisher-folk)
- Testing at bars, clubs, sporting events, and hot spots
- Testing at places of worship
- Testing at institutions of higher learning

3.2.9 Status neutral testing strategy

Status neutral testing focuses on welcoming all clients, regardless of their previous testing history and HIV status, to testing services as a gateway for appropriate referrals, whether to initiate ART, re-initiate ART, or to receive appropriate prevention services.

Case finding and linkage to treatment, care and support services:

- Target identification of PLHIV not on ART, by age, sex and geographic location
- Focus on early and effective linkage to ART (within 2 weeks of diagnosis)
- The testing register requires ART registration details for positive clients to confirm linkage.

Confirmation of diagnosis for re-initiation of ART (back to care)

- Clients who have disengaged from ART may be doubting their diagnosis. Re-testing for confirmation of status can be an important motivation to re-start and stay on treatment.
- Previously diagnosed clients are allowed to re-test for confirmation of diagnosis. Turning such clients away will drive them to seek testing at another facility, without disclosing their testing history.
- The integrated testing registers are specifically designed to capture clients with last professional positive test results. They are classified and reported as positive re-testers.
- Use the HIV diagnostic flow chart in Figure 2: HIV diagnostic algorithm for clients who have previously received a positive HIV test result from a professional testing provider. on page 62.

Linkage to prevention services

- Refer all HIV negative clients with high risk to appropriate prevention services such as PEP, PrEP, STI, TB, VMMC.

3.2.10 Other integrated testing approaches

All clients tested through these other approaches must also be linked to HIV prevention, treatment, care, and other support services.

Mandatory testing

Mandatory testing may be ordered by a court of law. In these cases, clients must be informed that their test results will be shared with court officials.

Mandatory testing services must be confidential and performed with adequate counselling.

HIV, syphilis, and hepatitis B surveillance and research testing

The following practices must be followed when conducting HIV, syphilis, and hepatitis B surveillance and research testing:

- The relevant ethics review boards must approve testing protocols for all related research prior to their implementation.
- All surveillance systems and other research studies must use the same approved national testing algorithm for diagnosis to ensure that clients are given accurate test results.
- Quality assurance measures should always be adhered to during surveillance and research.
- There should be coordination and collaboration between the Ministry of Health (MoH) and the institution conducting surveillance and research activities.

Chapter 4: Differentiated Service Delivery in Integrated Testing

Key facts: Differentiated testing service delivery

- Men are less likely to access testing services than women.
- HIV, syphilis, and hepatitis B testing is not mandatory in prisons; inmates can opt out of testing if they choose to do so.

Differentiated service delivery (DSD) is a person-centred approach that adapts testing services to better serve client needs and reduce unnecessary burdens on the health system. Employing DSD approaches to HIV, syphilis, and hepatitis B testing is essential for Malawi to reach underserved populations with prevention and treatment services.

WHO recommends DSD to address the needs of men, adolescents, young people, pregnant and breast-feeding women, infants and children, couples, key populations and their partners, and PWID. SNS is one of these strategies, whereby a trained provider asks people with HIV (and those who are HIV-negative and at ongoing risk of HIV) to encourage and invite individuals in their sexual, drug, or social networks to participate in HIV testing services (HTS). DSD should also be offered to migrant workers, people in closed settings, and displaced populations, as well as people in prisons.

When offering DSD to any of these groups, it is necessary to answer the following questions:

- When are integrated testing services provided?
- What services are being provided?
- Where are services being offered?
- Who is performing integrated testing services?

Table 5 summarizes of differentiated HIV, syphilis, and hepatitis B testing policies and scope of implementation by population and setting.

Table 5: Differentiated testing policies for HIV, HBV and syphilis by population and setting

Population	Setting	Testing for not previously diagnosed clients			Implementation
		HIV	HBV	Syphilis	
Pregnant women	ANC 1st visit	Routine PITC	Routine PITC unless previously vaccinated [1]	Routine PITC	All districts
	ANC 3rd trimester	Routine PITC	None	None	
	Maternity	Routine PITC	None	None	
Breastfeeding women	EPI / FP clinic	Routine PITC	None	None	7 high HIV incidence districts*
FSW, TG, MSW, MSM, PWID	KP prevention	12-monthly	12-monthly unless previously vaccinated [1] Offer vaccination if HBV negative [2]	12-monthly	All districts
Prisoners	Prison	On entry, at 6 months, on discharge	On entry, at 6 months, on discharge unless previously vaccinated [1] Offer vaccination if HBV negative [2]	On entry, at 6 months, on discharge	All districts
PrEP clients	PrEP clinic	At initiation and 3-monthly	12-monthly unless previously vaccinated [1] Offer vaccination if HBV negative [2]	12-monthly	All districts

[1] Clients who have previously completed a series of 3 HBV vaccinations are well protected and do not need to be tested for HBV.
[2] Offer HBV vaccination to all hepatitis B (surface antigen) negative clients at high risk of HBV infection unless they have previously completed a series of 3 HBV vaccinations.

Population	Setting	Testing for not previously diagnosed clients			Implementation
		HIV	HBV	Syphilis	
Children born to or breast-feeding from HIV infected mothers	HIV Care Clinic	PCR at 2 months, rapid test at 12 and 24 months, 6 weeks after end of BF	None	None	All districts
Children 0-14 years born to HBsAg positive women	Maternity, post-natal, EPI, OPD	None	Routine PITC as early as possible from age 9 months up to 14 years, regardless of previous vaccination status. Offer vaccination if HBV negative [2]	None	All districts
Children born to syphilis positive women	Maternity, post-natal, EPI, OPD	None	None	None	All districts
Men	VMMC	Routine for ongoing and high risk only	None	None	All districts
STI patients	STI Clinic	Routine	Routine PITC unless previously vaccinated [1] Offer vaccination if HBV negative [2]	Routine	All districts
Children	U5 clinic, OPD	On first contact when child presents with HIV compatible symptoms	Targeted if hepatitis is suspected	None	All districts
General population, low HIV risk	Any	No need unless there is high risk event	None	None	All districts
General population, ongoing HIV risk	Any	On first contact then Every 12 months	Targeted if hepatitis is suspected. Offer vaccination if HBV negative [2]	Targeted if syphilis suspected	All districts

Population	Setting	Testing for not previously diagnosed clients			Implementation
		HIV	HBV	Syphilis	
General population, HIV high-risk event	Any	Routine testing at first contact and after 4 weeks	Routine PITC unless previously vaccinated [1] Offer vaccination if HBV negative [2]	Routine at 1st contact	All districts
General, inconclusive HIV result	Any	After 2 weeks	None	None	All districts
Health worker	Routine workplace (pre-service, recruitment)	No need unless if there is a high-risk event	Routine PITC unless previously vaccinated [1] Offer vaccination if HBV negative [2]	None	All districts
Health worker	After high-risk event (e.g. needle stick)	Routine testing at first contact and after 4 weeks	Routine PITC unless previously vaccinated [1] Offer vaccination if HBV negative [2]	None	All districts
Skin disease patient	Skin clinic	Routine	Targeted if hepatitis is suspected	Targeted if secondary syphilis suspected	All districts
Sex partner of HIV index client	STI clinic, index testing	First contact then depending on risk	Targeted if hepatitis is suspected	None	All districts
Sex partner of HBV index client	STI clinic, index testing	Routine	Routine PITC unless previously vaccinated [1] Offer vaccination if HBV negative [2]	None	All districts
Sex partner of STI patient (incl. syphilis)	All service delivery points	Routine	Targeted if hepatitis is suspected. Offer vaccination if HBV negative [2]	Routine	All districts

Population	Setting	Testing for not previously diagnosed clients			Implementation
		HIV	HBV	Syphilis	
Biological child of HIV index client	Index testing	Routine	Targeted if hepatitis is suspected	None	All districts
Presumptive / confirmed TB patient	TB clinic	Routine	Targeted if hepatitis is suspected	None	All districts
Presumptive / confirmed hepatitis patient	OPD, ward	Routine PITC	Routine PITC unless previously vaccinated [1] Offer vaccination if HBV negative [2]	None	All districts
Blood donor	Laboratory	Routine screening	Routine screening	Routine screening	All districts
People in formal and informal workplaces	Formal and informal workplaces	Routine 12-monthy	None	None	7 high HIV incidence districts [3]
Adolescents	All service delivery points	12-monthly if ongoing or high risk	Targeted if hepatitis is suspected	Targeted if syphilis suspected	All districts
In-patients	Wards	Routine PITC	Targeted if hepatitis is suspected. Offer vaccination if HBV negative [2]	Targeted if syphilis suspected	All districts
Family planning clients	FP clinic	Routine 12-monthly	Targeted if hepatitis is suspected	Targeted if syphilis suspected	All districts
Clients with hypertension, diabetes, cardiovascular diseases, cancer, depression, mental health issues	All service delivery points (OPD, private clinics)	Targeted	Targeted if hepatitis is suspected	Targeted if syphilis suspected	All districts

[3] Zomba, Chiradzulu, Blantyre, Thyolo, Mulanje, Lilongwe (City), Mzimba North (Mzuzu City)

Chapter 5: Counselling Protocol

Key facts: Counselling

- Concise communication (before and after testing) that is informative, encouraging and motivating is an effective way to create demand.
- Pre-test information may be provided through individual or group sessions and through media, such as posters, brochures, and short video clips shown in waiting rooms.
- Post-test counselling messages should be tailored to specific populations as part of a deliberate strategy to support linkage.

This chapter describes the counselling protocol, which includes pre-test information, testing, and post-test counselling. However, the protocol is not complete without effective linkage to appropriate prevention, treatment, care, and support services.

5.1 Pre-test information

The pre-test information provides basic information about HIV, syphilis, and hepatitis B testing services to individuals, couples, or groups of people who will receive testing services.

The concepts of notification and disclosure should be introduced during the pre-test information session.

The following **requirements** must be observed:

- Only a trained testing services provider can conduct pre-test information sessions.
- Testing must be free of coercion; the client has the right to refuse to be tested.
- Declining testing must not affect the client's access to other health services or general medical care.
- The client must have an opportunity to ask questions.
- Pre-test information must be offered in a setting that allows for confidentiality.

The client must be capable of giving informed consent. To give informed consent for testing, a client must:

- Not be inebriated or mentally unsound;
- understand the basics about HIV, syphilis, and hepatitis B;
- understand the testing process; and
- be participating voluntarily, not under coercion.

For HIV testing:

- Ask the client if they have been tested for HIV before. If yes, ask what type of test, time since the last test and the test result.
- Ask all clients if they have taken ARVs before (PEP, PrEP, infant prophylaxis, ART). If yes, ask when ARVs were last taken.
- Clients with a previous positive professional test who are coming back to care or who were never linked, should be allowed to be re-diagnosed prior to re-engagement.
- These clients should be tested using the testing algorithm in Figure 2: HIV diagnostic algorithm for clients who have previously received a positive HIV test result from a professional testing provider on page 62.

For Hepatitis B:

- Ask the client if they have previously completed a course of 3 HBV vaccinations. Clients born after 2002 are very likely to have completed HBV vaccination in infancy (pentavalent vaccination at 6, 10 and 14 weeks). Previously vaccinated clients do not need routine HBV testing, unless there is a clinical indication.
- Explain that HBV negative clients at high risk of acquiring HBV benefit from vaccination. Vaccination also makes future HBV testing unnecessary.

For syphilis:

- Explain that syphilis rapid testing may not be able to distinguish between a current, active syphilis infection and a past, cured infection.
- Ask all clients with a positive syphilis test if they have been previously treated for syphilis. Refer such clients for additional confirmatory syphilis testing to the lab if the confirmatory tests are available.

5.2 HIV, syphilis, and hepatitis B testing

Malawi uses serial testing algorithms for HIV, syphilis, hepatitis B, and HIV recency surveillance testing. All clients must first be tested using a whole blood rapid test.

Refer to section 6.1 and the flow-charts in the Appendix.

5.3 Post-test counselling

Post-test counselling is an integral part of the testing process. All individuals undergoing HIV, hepatitis B, and syphilis testing must be counselled when their test results are given to them, regardless of the results.

Notification and disclosure should be emphasised during post-test counselling.

Receipt of a positive test result can be a distressing event for the client. Counselling services are essential when delivering test results, as this is the primary method for providers to prepare clients for their diagnosis and advise them of the next steps in linkage to treatment.

During the post-test counselling session, the provider must present clear, concise information that is based on the test result or outcome.

5.4 Post-test counselling for specific groups

Offer additional post-test information to special groups according to their needs.

Key populations

- Counsel clients about the importance of consistently using condoms and lubricants.
- Recommend PrEP and offer it as part of prevention if they are not already taking it.
- Recommend early treatment of STIs.
- Explain the dangers of sharing needles (PWID).

Adolescents and young people

- Discuss casual sexual relationships and their potential consequences.
- Discuss sexual health and advise clients on how to keep themselves safe from diseases and pregnancy.
- Give information on ways of preventing HIV and STIs with their partners.

Men

Recommend voluntary male medical circumcision (VMMC) for all uncircumcised men in target age-groups and in districts with higher incidence, and for men with high-risk behaviour.

Pregnant and breast-feeding women

Provide information on:

- The scheduled times for routine re-testing for negative clients, both during pregnancy and while breast-feeding
- Infant feeding procedures and child testing milestones for all HIV- and hepatitis B-positive mothers
- Importance of partner testing

Clients re-engaging in care

- Encourage to seek psychosocial counselling.
- Encourage to choose a convenient facility for re-staring ART.
- Welcome re-engaging clients back into care.

Chapter 6: Testing Algorithms

Key facts: Testing algorithms

- Malawi uses serial testing algorithms for HIV, syphilis, and Hepatitis B.
- Integrated testing providers must be aware that testing algorithms may change as new testing technologies are approved for use, in line with WHO guidance.
- Any reactive test for syphilis and hepatitis B should be referred to a clinician or nurse for further management.
- The three-test algorithm to determine an HIV-positive result has replaced the two-test algorithm.
- Individuals already on ART are not eligible for retesting for HIV using antibody tests, as these tests may give a false result.
- All testing providers in Malawi are required to follow the serial testing algorithm as recommended by MoH.

Integrated testing services providers are trained to provide comprehensive whole blood rapid tests in a single session. Use the rapid tests only in the sequence shown in the testing algorithms (see page 60). Testing must be done according to the nationally approved testing algorithms (see Appendix).

The selection of test kits is based on WHO and MoH-approved protocols and standards, which are available from the National HIV Reference Laboratory (NHRL).

- Integrated testing services providers must be aware that testing algorithms may change as new testing technologies are approved for use, in line with WHO guidance.
- Testing services providers must adhere to nationally approved protocols.
- All integrated testing facilities in Malawi are required to follow the serial testing algorithm as recommended by MoH.

Malawi uses serial testing algorithms for HIV, hepatitis B, syphilis, and HIV recency surveillance testing. All clients must first be tested using a whole blood rapid test.

6.1 HIV testing algorithm

6.1.1 Algorithm for adults and children 2+ years old

- If HIV test 1 is non-reactive, report the result as *HIV-negative*.
- If HIV test 1 is reactive, conduct HIV test 2 from a new finger-prick.
    - If HIV test 2 is reactive, conduct HIV test 3 from a new finger-prick.
    - If HIV test 3 is reactive, report the result as *HIV-positive*.
    - If HIV test 2 is non-reactive, repeat HIV test 1.

(For the full algorithm, see Appendix)

Note:

- All children 24 months and older should be tested using the same HIV testing algorithm used for adults.
- Using a positive parent as an index case is one of the most effective ways of identifying these children.

6.1.2 HIV testing for children under 24 months

Children of HIV-positive parents are a priority group for HIV testing. Testing for children is separated into the following age groups:

- Infants younger than 12 months
- Children 12 to 23 months

These distinctions are necessary because the testing algorithms may depend on the child's age.

Children under the age of 12 months

- All HIV-exposed infants (HEIs) must be tested for HIV at six weeks after birth (or at the earliest opportunity) using the DNA polymerase chain reaction (DNA-PCR) test. The sample must be collected at a health facility and sent to the nearest testing laboratory for testing, unless POC testing is available on site.
- If the facility has POC testing facilities, it is not necessary to send the sample to an outside lab. Diagnostic and confirmatory testing can be done on the same day while the client waits.
- If the DNA-PCR result is positive, a second dry blood spot (DBS) must be collected for retesting. This must be done before starting ART. However, ART can be started based on the first HIV-positive test result.
- If the confirmatory DNA-PCR test result is not returned within three months (for example, because the sample is lost or there is an error in the results), then another DBS sample must be collected for confirmatory testing. The client must remain on ART while that sample is processed.
- An infant under the age of 12 months with unknown HIV exposure who presents with presumed severe HIV disease (PSHD) must be tested using the approved HIV rapid test. If the result is positive, the infant must be started on ART and confirmatory testing done using DNA-PCR (DBS or POC) (see Table 6).

Children ages 12 to 23 months

- All exposed children (whether their HIV status is unknown or they previously tested negative but are but still breast-feeding) must be tested at 12 and 24 months using an HIV rapid test.
- A negative test result does not completely exclude HIV infection unless the child has stopped breast-feeding at least six weeks before the test.
- All sick children with unknown HIV status should be tested using an HIV rapid test.

Confirmatory testing for children under 24 months

- All children under 2 years of age to be started on ART require a confirmatory DNA-PCR.
- Collect the DBS sample on the day of initiation.
- Do not delay ART initiation—that is, do not wait for the confirmatory PCR result before starting ART.

Table 6: HIV testing of children: Choice of test, interpretation of results, and follow-up management

Age (months)	Test	Schedule	Result	Interpretation	Action
Under 12	DNA-PCR (if available)	First opportunity after 6 weeks	Negative	Not infected, but at risk of infection if breast-feeding	• Continue HCC. • Do a rapid test at 12 months.
			Positive	HIV infected	• Start ART. • Do confirmatory DNA-PCR test at ART initiation.
	Rapid antibody	Immediately, if signs of PSHD are identified OR If mother's HIV status cannot be ascertained	Negative	Not infected, but at risk of infection if breast-feeding from HIV+ mother	• Treat condition. • Continue HCC. • Repeat rapid test at 12 and 24 months.
			Positive	Possibly HIV infected if no PSHD symptoms	• Enrol in HCC. • Do DNA-PCR test at first opportunity.
				Likely AIDS if symptoms for PSHD	• Start ART. • Do confirmatory DNA-PCR test at ART initiation.
12 to under 24	Rapid antibody	From 12 months OR If mother's HIV status cannot be ascertained	Negative	Not infected, but at risk of infection if breast-feeding from HIV+ mother	• Continue HCC. • Repeat rapid test at 24 months.
			Positive	HIV Infected	• Start ART. • Do confirmatory DNA-PCR test at ART initiation.
24 and above	Rapid antibody	From 24 months (but confirm that breast-feeding stopped at least 6 weeks prior to testing)	Negative	Not infected	• Discharge child from HCC.
			Positive	HIV Infected	• Start ART. • Do confirmatory (parallel) rapid test at ART initiation.

6.1.3 HIV recency surveillance

At facilities implementing recency surveillance:

- Inform the client about recency surveillance, obtain consent for rapid recency testing and potentially an additional finger prick for DBS blood sample for viral load.
- Inform the client that recency results are preliminary and will not be reported back to the client.
- Conduct the rapid recency test in parallel with HIV test 2 from the same finger-prick if possible.
- If recency test is negative: ignore for summary HIV test result given to client.

See the flow charts in the Appendix for integration of recency test and separate recency guidelines for details.

6.2 Hepatitis B algorithm

Key facts: Hepatitis B virus (HBV)

- HBV is much more infectious than HIV. It is most commonly transmitted from mother to child during birth and delivery, but also through blood or body fluids during sex, unsafe injections, and sharp instruments.
- Most people who get infected with HBV have only mild symptoms and fully recover without treatment. Only few develop chronic infection which can gradually destroy the liver (cirrhosis), and also lead to liver cancer.
    - Young children and older people newly infected with HBV have a higher risk of developing chronic infection, cirrhosis, and cancer.
    - Further tests and investigations are needed to look for chronic liver damage to determine ARV treatment need.
- Hepatitis B virus (HBV) rapid tests detect virus particles (surface antigen) in blood.
- A single reactive HBV test confirms hepatitis B infection, but it cannot tell the difference between acute and chronic infection.
- There are 2 aims for HBV rapid testing:
    - Refer all high-risk HBV negative clients for a course of 3 HBV vaccinations (unless already fully vaccinated in the past). Vaccination is very effective.
    - Refer all infected clients for investigations to decide who needs treatment.
- Chronic infection is also confirmed if the HBV rapid test remains positive after 6+ months.
- People with HIV and HBV infection have a much higher risk of developing chronic liver damage. They always need HBV treatment.
    - Two of the most commonly used ARVs for HIV are also effective for HBV, so most people on ART for HIV are also fully treated for HBV.
- Pregnant women with acute or chronic HBV infection are routinely treated with ARVs until 6 weeks after delivery to prevent transmission to the baby.
    - The risk of HBV transmission during breastfeeding is very low, so treatment may be stopped after that depending on additional tests.

- Report the hepatitis B result as *negative* if HBV test is non-reactive.
- Report the result as *positive* if HBV is reactive.
    - Offer HIV testing unless the client is already known HIV positive.
    - Refer to the clinician or nurse for a baseline liver function test and further management.

For the full algorithm, see Figure 4 on page 64.

6.3 Syphilis Testing Algorithm

Key facts: Syphilis

- Syphilis is a bacterial, sexually transmitted infection (STI).
  - In the early stage, most people have a painless sore on the genitals that heals after some weeks, even without treatment. Syphilis is easily transmitted by skin contact with syphilis sores.
  - In the second phase, people may have skin rash, sores, headache, fever, body pain, hair loss.
  - Without treatment, it then enters a hidden stage with few or no symptoms. This can last for years, and the bacteria remain active in the body.
  - Without treatment, some people then enter a third stage with severe damage to skin, bones, cartilage, heart, eyes, nerves, and brain.
  - In pregnancy, untreated syphilis of any stage severely damages the baby, often leading to stillbirth or permanent disability.
- Some people never notice any symptoms from syphilis infection. This is why routine syphilis testing is needed for all high-risk groups, even if they have never noticed any STI symptoms.
- Syphilis rapid tests detect antibodies against syphilis bacteria.
  - Most people have syphilis antibodies for life, even if the infection was treated and cured.
  - Therefore, a positive syphilis rapid test cannot tell the difference between a previously cured infection and an active current infection.
- Additional lab tests (RPR or VDRL) are needed to confirm active syphilis infection.
  - Lab tests for confirmation of active syphilis infection may not be available at all sites. In this case, refer all positive clients for presumptive syphilis treatment to ensure that any potentially new syphilis infection is treated.

- If the syphilis rapid test is non-reactive, report the result as syphilis *negative.*
- If the syphilis rapid test is reactive, report as syphilis *positive.*
  - Refer to the lab for additional tests to confirm active infection.
  - If additional lab tests are not available, refer for presumptive syphilis treatment

For the full algorithm, refer to Figure 5 on page 65.

Chapter 7: Standards and Procedures

Key facts: Testing standards

- Integrated testing services must follow MoH standards and procedures.
- Rapid testing is conducted by both trained laypersons and laboratory personnel; other professional testing is done only by laboratory personnel.
- All testing sites must provide IEC materials that include key messages regarding HIV, syphilis, and hepatitis B.

All facilities and providers must be officially approved in writing and registered with the Director of Health and Social Services (DHSS) in order to perform testing services. Only medical and non-medical staff who have been adequately trained and certified can perform whole blood rapid tests for HIV, syphilis, and hepatitis B.

Organisations and facilities offering testing services must ensure that all standards and procedures for rapid testing are implemented according to MoH guidance. These standards and procedures apply to human resources, maintenance of test kit standards, infrastructure, equipment and supplies, IEC materials, and quality assurance.

7.1 Staffing of testing services

Only medical and non-medical staff who have been adequately trained and certified by the national testing services programme can perform whole blood rapid tests for HIV, syphilis, and hepatitis B.

Other tests (i.e., non-rapid tests) must be sent to the appropriate district or central laboratories. Laboratory technicians at these sites must ensure quality of testing.

Each testing site must have a minimum of two staff members who have been trained and certified to perform testing services.

For full descriptions of the responsibilities of each testing services cadre, refer to **page 48** Roles and Responsibilities in Implementing Integrated Testing.

7.1.1 Training and professional advancement

Appropriate training and certification of staff is critical to the provision of quality testing services. The Department of HIV/AIDS, STI and Viral Hepatitis (DHA) approves training curricula, coordinates and monitors the quality of trainings, and acts as the certifying authority in the training of testing services providers. The following training courses are currently approved:

- *Integrated Testing Services Providers Training.* This is the standard certified training required for all testing services providers and is the minimum training requirement. At present, this is a four-week course, consisting of three weeks of classroom sessions

and one week of supervised practice at an officially recognised site. Certification is dependent on full-time attendance and passing all assessments and examinations.

- *Integrated Testing Services Supervision Training Course.* This is an MoH-approved five-day training course in supervising testing services. The prerequisite for this course is one year of experience in testing services.
- *Integrated Testing Services Training of Trainers Course.* This is an MoH-approved two-week training of trainers (TOT) course. Trainees are certified upon successful completion of the course, followed by co-facilitating at least one four-week general training course in testing services with an experienced trainer. The prerequisite for this course is two years of experience in testing services.

Refresher training

Refresher training must be provided for all practising testing providers (including trainers and supervisors) every two years (or more often, based on need and changes to guidelines). The DHSS must schedule mentoring and supportive supervision activities for all testing providers within their districts.

7.1.2 Training organization: eligibility, requirements, and responsibilities

- Only organizations and individuals directly involved in testing service provision after successful completion are eligible to register for integrated testing certification trainings.
- Integrated testing training sessions must be booked and confirmed by the responsible office at least four weeks before the planned start date.
- Training request must be submitted in writing to the Director of the Department of HIV, STI and Viral Hepatitis.
- The training organiser is responsible to source and provide all necessary training materials.

7.2 Test kit standards

Testing services must follow WHO and MoH standards and requirements. These include the following:

- Only rapid test kits evaluated and approved by MoH can be used for testing. This includes both new batches and donated kits. All new batches of rapid test kits must be validated by NHRL before distribution for use.
- Test kits and supplies must be stored securely.
- Consumption of test kits must be closely monitored and documented.
- Storage area temperatures must be within the ranges recommended by kit manufacturers and regularly monitored and documented.

- The first expiry, first out (FEFO) policy for test kits must be enforced—i.e., use kits with the nearest expiry dates before using kits with later expiry dates.
- Adhere to both internal and external quality control practices.

7.3 Infrastructure requirements

Organisations and facilities must ensure adequate infrastructure for testing services. Testing locations must guarantee privacy, confidentiality, and reasonable comfort.

Minimum requirements for static testing sites:

- Adequate reception or waiting area
- Minimum of one designated testing room that ensures privacy, is well lit, and has at least three chairs, a surface area for testing, and a desk for documentation
- Hand washing facility with running water and soap
- Lockable file system or lockable drawers
- Secure storage facilities for reagents and consumables
- Appropriate waste disposal system for both infectious and non-infectious materials, including sharps containers.

7.4 Equipment and supply requirements

- Laboratory supplies and other consumables
- Printed testing protocols, standard operating procedures, and job aids that are well displayed or bound in booklet form
- Male and female condoms, including vagina and penis models for condom demonstration
- Standardised testing services registers and reporting tools
- First-aid kits
- Soap for hand washing
- Inventory and ordering system to manage supplies, including a testing services daily activity register (DAR).

7.5 Information, education, and communication materials

All testing sites must provide information, education, and communication (IEC) materials that include key messages and important information about services available for HIV/AIDS, hepatitis B, and syphilis. These can be sourced from Health Education Services (HES) through their district health offices (DHOs). MoH regularly develops and print IEC materials and job aids with support from its partners.

7.6 Quality assurance

NHRL mandates Quality Assurance Reference Laboratory technicians to provide on-site quality control (QC) and quality assurance (QA) for staff performing HIV testing. The emphasis is on supervision, proficiency testing (PT), and QC testing using known samples from reference laboratories. PT feedback must be provided to the testing services sites in written form and must be kept on file.

7.6.1 Post-marketing evaluation

The NHRL takes a sample of tests from every batch of kits imported into the country for testing with a known panel to ensure the tests perform as expected. Once a consignment of kits is distributed to testing sites, testing services providers are required to perform quality control testing as described below, and to record the results in the QC testing pages of the integrated testing registers.

7.6.2 Quality control requirements for rapid tests at the facility

HIV (professional blood-based), syphilis, HBV, HIV recency

At a minimum, QC must be done **every 2 weeks** in each testing room where test kits are stored for use, plus in the following situations:

- When rapid test kits have been exposed to conditions outside the recommended temperature range
- When a new test kit lot is opened
- When a new provider starts to work at the site (including trained staff who have not conducted testing for some time)

QC results must be documented in the appropriate section of the testing services register. The testing services supervisor must countersign to verify the results.

HIV self-tests

Note that the QC requirements for HIV self-testing (HIVST) are different.

- Every two weeks: send two HIVST kits to either their district or to designated laboratories.
- Include QC forms for both negative and positive outcomes with the kits.
- The lab keeps one copy of the QC results; the other is sent to the facility.

7.6.3 Proficiency testing

Proficiency testing (PT) is a type of external quality assurance that involves “blind” testing of a panel of samples as if they were clients, and comparing the obtained results with the expected results. PT serves to evaluate provider competency. PT panels are administered by NHRL every six months to all practising providers through their district laboratories.

- The performance of each provider is recorded in their individual proficiency testing logbook. Each provider must receive timely written feedback from NHRL.
- District testing services supervisors and zone lab supervisors are required to take corrective action with service providers who score less than 100%.
- Laboratory assessments are required at least once every quarter; providers scoring less than 100% on two consecutive proficiency tests must immediately stop testing until they have been retrained.

Note: Only NHRL is mandated to provide QC and PT samples.

7.6.4 Certification

Certification refers to the issue of an official document (a certificate) by an independent body which indicates that the product, service, system, or person in question meets specific requirements. National certification procedures for site and provider certification are detailed below.

Site certification

Testing services site certification provides formal authorization to offer testing services. Certification is performed annually by the Medical Council of Malawi (MCM) after Level 4 achievement based on the SPI-RT checklist. Site certification must be requested from the district commissioner (though DHSS) to the Malawi Testing Services Certification Committee. Site certificates are valid for 1 year.

All testing sites must fulfil all certification criteria (see Table 8: Minimum standards for integrated testing services on page 66).

Provider certification

Testing services provider certification ensures that the provider conducting tests is competent and authorised. Provider certification is administered every two years by the Malawi Testing Services Certification Committee.

Recertification requirements:

- Passing refresher training (required scores: at least 80% on theory and 100% on the practical test)
- Passing four proficiency tests in the two-year period
- Contributing at least 10% of the total number of clients tested at the designated testing point in the 2-year period.

Provider certification may be withdrawn under any of the following circumstances:

- **If a provider fails a certification training, he/she is allowed to repeat (once) using his/her own resources. If the provider fails the second time he/she is no longer allowed to practice.**

- A provider does not participate in the national recertification process without valid reason, which shall be assessed and determined by the Malawi Testing Services Certification Committee
- A provider does not successfully complete the national recertification process.

7.6.5 Supervision

Using nationally approved supervision tools, district supervisors will conduct site supervision visits at least once every quarter at all facilities.

In addition, the national supervision team will make supervisory visits to testing sites every quarter and provide written reports to district health management teams (DHMTs) and stakeholders.

Each facility appoints a senior testing provider as Internal Supervisor to be in charge of day-to-day QA. External supervisors from the DHO or national testing programme staff visit the facility every 6–12 months for QA purposes. It is the responsibility of supervisors to communicate any changes in protocols and related new developments to providers. They must also make sure that all necessary supplies and commodities are available to ensure the quality of results.

Chapter 8: Roles and Responsibilities in Implementing Integrated Testing

Key facts: Roles and responsibilities

- Appropriate training and certification of staff is critical to providing quality integrated testing services.
- Different stakeholders play different roles in implementing HIV, syphilis, and hepatitis B testing.

To implement integrated testing services requires several stakeholders at both national and district levels. This chapter outlines their roles and responsibilities in implementing HIV, syphilis, and hepatitis B testing at all levels of the system.

8.1 Ministry of Health

8.1.1 Department of HIV, STI and Viral Hepatitis

- Policy formulation, dissemination, and periodic review
- Mobilisation of resources
- HIV programme monitoring
- HIV commodity management
- Capacity building
- Serve as primary point of contact for all national testing service matters.
- Coordinate M&E activities, including data collection and analysis as well as writing and dissemination of reports.
- Ensure adequate, up-to-date information systems and adherence to standardised reporting, including maintenance of a reliable research and development database for testing service matters.

8.1.2 Diagnostic & Biomedical Engineering Division

- Provide overall national leadership for all diagnostic testing services in the Ministry.
- Develop diagnostics policies and standards.
- Provide national guidance on implementing new technologies as they come to market.
- Support inventory control of testing commodities.
- Strengthening delivery of quality diagnostics at each level of the health care system
- Provide guidance on implementing integrated laboratory quality assurance for both conventional and point-of-care testing across the continuum of care.

8.1.3 Reproductive Health Department

- Collaborate with the HIV/AIDS and Viral Hepatitis Directorate to integrate and coordinate policies and guidelines for sexual reproductive health (SRH), HIV, and gender-based violence.

8.1.4 Public Health Institute of Malawi: National HIV Reference Laboratory

The National HIV Reference Laboratory (NHRL) oversees all matters relating to quality assurance and assessment of HIV, syphilis, hepatitis B, and HIV recency testing:

- Implementing the external quality assurance (EQA) programme
- Evaluating new rapid test kits
- Making recommendations to MoH before test kits can be used in-country
- Conducting post-market surveillance of rapid test kits

8.2 Ministry of Local Government and Rural Development

8.2.1 Director of Health and Social Services (DHSS)

- Authorise the establishment of new testing sites.
- Evaluate and supervise both facility and community-based testing services, including decertification of testing sites when standards are not met.
- Develop and implement an overall district testing services strategy within the context of the District Implementation Plan.
- Appoint district testing services coordinators from within district councils to coordinate all testing services in their districts.

8.2.2 Coordinators

The Testing Services Coordinator reports to the DHSS and is responsible for coordinating testing services in their district.

Prerequisites

- Certificate in HIV, syphilis, and hepatitis B testing provided by MoH
- A minimum of two years as a practising testing provider
- Demonstrated management and interpersonal skills
- Conversant with M&E, supply chain, and quality assurance issues

Responsibilities

- Ensure that adequate commodities, supplies, and personnel are available to provide testing services in the district.
- In consultation with DHMT and MoH, set up district capacity-building programmes.

- Develop and coordinate networks of providers; hold quarterly meetings with integrated testing services stakeholders at the district level.
- In consultation with DHMT, identify and recommend integrated testing services supervisors for training.
- Compile and submit quarterly reports to DHSS.
- Manage district integrated testing services administrative issues in consultation with DHMT, the integrated testing services supervisors, and testing site staff.

8.2.3 District supervisors

Prerequisites

- Certificate in HIV, syphilis, and hepatitis B testing provided by MoH
- A minimum of two years as a practising testing provider
- Demonstrated management and interpersonal skills
- Conversant with M&E, supply chain, and quality assurance issues

Responsibilities

- Supervise integrated testing sites.
- Conduct counselling and supportive supervision visits.
- Ensure proper completion of M&E tools.
- Compile monthly and quarterly reports and submit them to the testing services coordinator.

8.2.4 Laboratory supervisors

Prerequisites

- Quality assurance supervisory knowledge and skills
- Completion of whole blood integrated rapid test training
- MoH certification

Responsibilities

- Prepare and provide QC testing samples.
- Monitor site performance in whole blood rapid testing and QC testing; give feedback and provide corrective action in the event of an identified non-conformity.
- Provide samples for PT or panel testing, give feedback to providers and provide corrective action in the event of an identified non-conformity.
- Coordinate DBS sample collection and transmission to the testing laboratory; give feedback on validation testing to sites.
- Identify capacity gaps for testing services providers; generate training recommendations.

8.2.5 Site supervisors

Prerequisites

- Integrated testing services supervisor training
- A minimum of one year as an integrated testing services provider
- Demonstrated management and interpersonal skills

Responsibilities

- Conduct supportive counselling supervision.
- Coordinate all testing services for all counselling and testing activities at both facility and community levels.
- Write and submit reports to the health facility in-charge (or to the manager at standalone sites).
- Ensure proper completion of M&E tools.
- Ensure that each service delivery point has sufficient supplies and equipment.
- Ensure that providers are participating in quality assurance activities.
- Provide general site management.

8.2.6 Trainers

Prerequisites

- A practising integrated testing services provider
- Two years of experience in counselling
- Two years of experience performing whole blood rapid tests
- Available to conduct training when required
- Minimum certification: Malawi School Certificate of Education (MSCE)
- Successful completion of MoH-certified TOT course for testing services

Responsibilities

- Advise districts on the requirements for testing services training sessions.
- Screen participants in testing services training using the approved criteria in the testing services training manuals.
- Conduct testing services training using the nationally approved training curriculum.
- Write training reports, including the full names of participants and their institutional affiliations, and share with DHA through the district testing services coordinator.
- Using the MoH-approved curriculum, plan and conduct refresher courses.

8.2.7 Providers

Prerequisites

- Age 18 or older

- At least one year of experience working in Malawi
- No criminal record
- Have adequate vision or wear corrective lenses
- Reasonably good health and a clear state of mind
- Ability to read and write English
- Successful completion of the official testing services training course
- MoH certification before practising
- Ability to provide services consistent with these guidelines

Additional qualifications for medically trained providers

- Certificate in any medical discipline (e.g., nursing, clinical officer, medical assistant, dental therapist, or environmental health officer/assistant)
- Motivated to provide testing services in a clinical setting, with an intention to practise after training
- Fluency in the local language

Additional qualifications for non-medically trained providers

- Minimum certification: MSCE
- Motivated, enthusiastic, sensitive and have a genuine desire to help others
- Familiar with the language, culture, and religious beliefs of the community with which he or she is to work
- Be recruited by MoH or an HIV implementing organisation, or affiliated with an HIV organisation-affiliated social or support group, with the objective of providing testing services at the end of training

Responsibilities

- Provide pre-test information to clients.
- Conduct post-test counselling using the protocols outlined in these guidelines.
- Ensure effective client referral and linkage to other services.
- Data collection, recordkeeping, and report writing.
- Collect samples for viral load monitoring.
- Distribute HIV self-test kits.
- Provide active index testing services to all eligible clients.
- Participate in quality assurance activities.

NOTE: Access to testing certification trainings is strictly limited to participants with a formal commitment by their employer that they will provide testing services regularly upon certification.

8.3 Implementing partners

The roles and responsibilities of implementing partners are as follows:

- Complement the government's efforts to implement HIV, syphilis and hepatitis B services.
- Collaborate with the District Health and Social Services team to deliver testing services.
- Adhere to policy guidance when providing testing services.
- Ensure quality of testing services.
- Support health systems strengthening for HIV, syphilis, and hepatitis B testing.
- Use MoH monitoring tools; ensure that they remain at facilities after community testing.
- Submit reports to the appropriate district health offices on a monthly basis, focusing on clients tested (including commodity consumption and stock on hand).

8.4 Recipients of care and persons living with HIV

Recipients of care and persons living with HIV are expected to be involved in all areas of the comprehensive HIV/AIDS response, including prevention, treatment, care, support, impact mitigation, and policy development.

Chapter 9: Test Kit Supply Chain Management

Key facts: Supply management

- Uninterrupted availability of rapid diagnostic test kits is critical to the success of the testing services program.
- MoH is responsible for procurement and distribution of test kits to ensure optimal utilisation of resources.
- All RDTs delivered to district and health facilities must be accounted for using MoH-approved registers and logistics forms.
- Test kits are delivered every two months from a central warehouse directly to sites.
- Distribution volumes for all facilities are calculated based on reported test use.

Test kits are critical to the success of the testing services programme. A regular, reliable supply of rapid diagnostic tests is critical to providing effective testing services. Management of test kits is integrated with that of other commodities. Testing commodities are delivered to all health facilities every two months. Refer to Figure 6 on page 75 for an illustration of the testing commodity stock management cycle.

9.1 Quantification and procurement planning

MoH coordinates the calculation of inventory, planning, and procurement of test kits.

DHA works with Health Technical Support Services (HTSS) to determine how many test kits are needed based on the assumptions generated using programmatic strategies. The results of these calculations are documented in the annual quantification report. All NGOs must check with DHA before procuring test kits, to minimise the waste that may arise from parallel (duplicate) procurement systems.

MoH will be responsible for coordinating procurement planning activities to ensure optimal utilisation of national resources allocated for test kits.

9.2 Warehousing and inventory management

Central warehousing is managed according to the Malawi National Drug Policy. Because of central warehouse storage capacity constraints, storage services are currently outsourced.

Between six and nine months of stock are maintained at central warehousing facilities. Between two and four months are maintained at health care facilities (see Table 6 below). Deliveries are staggered to maintain stock levels within these ranges.

Table 7: Minimum and maximum stock levels of test kits

Pipeline level	Maximum months of stock	Minimum months of stock
Health Facilities	4	2
Central	9	6

9.3 Distribution of test kits

Test kits are delivered every two months from central warehousing directly to ART/PMTCT sites on a top-up basis. Supplies destined for standalone testing sites are delivered to their respective district hospital pharmacies.

Distribution volumes for all facilities are calculated based on:

- Test use data reported in daily activity registers
- Planned special testing events
- Stock reports collected during quarterly testing programme supervision visits

The distribution list is shared with the DHSS and relevant stakeholders every two months.

To be added to the distribution mailing list, send a request to one of the toll-free numbers below or email hivdeptlogistics@gmail.com:

- Airtel: **59191**
- TNM: **6882**

All implementing partners are required to seek prior approval from the director of the DHA before implementing testing services at the district level.

The testing services coordinator supervises all testing sites within the district, reviews the distribution list, and monitors use of rapid diagnostic tests at the health facilities.

9.4 Receiving testing supplies at the health facility

Inspect the entire consignment in the presence of a witness designated by the DHMT or facility in-charge:

- Physically count all tests kits delivered and check expiry dates.
- Indicate the verified quantity received into the respective box on the delivery invoice.
- Write 0 (zero) for any items not received—do not leave any boxes empty.

The facility in-charge must sign, date, and stamp the delivery invoice to confirm receipt of the items as indicated.

9.5 Storage at the health facility

All items received must be properly stored (i.e., in a clean, dry, cool location, and off the floor) in a secured storage area. Enter the quantities and dates of receipt on stock cards. Arrange items by expiry date to make it easy for staff to follow the FEFO principle.

9.6 Documentation for test kit transactions

Follow the procedures below when handling test kits.

- Stock cards must be updated when moving stock from the pharmacy or drug store to the dispensing area.
- Requisitions and issue vouchers must be used when making requisitions from the pharmacy or drug store.
- DARs are used to track data for consumption and stock on hand at each testing point.
- Keep separate DARs at all places where testing is done.
- Use separate DARs for different types of rapid tests. (For example, there is a separate DAR for each test in the algorithm: A1, A2, and A3.)
- Test kits used for clients must match the entries in the testing services register.
- DARs include sets of three carbonated sheets:
    - White sheet: keep at the facility.
    - Blue sheet: send to the DHO.
    - Pink or yellow sheet: retain for collection by the MoH HIV logistics team.
- Fill out the monthly summary on the testing services report by adding the numbers from all DARs used at the facility. Submit this report to the DHO and DHA.

9.7 Stock management at the testing site and commodity tracking

Follow the procedures below for managing stocks at testing sites and tracking commodities.

- Conduct monthly physical stock counts for all test kits (in store and at all testing points), and update stock cards.
- Calculate the average monthly consumption (AMC) and months of stock (MOS) on hand for all HIV test kits after doing the monthly physical count:

$$\textbf{MC} = \frac{\text{units used in last 3 months}}{3} \qquad \textbf{MOS} = \frac{\text{stock on hand}}{\text{AMC}}$$

- Call the DHA logistics team as soon as possible if a shortage, excess, or expiry is noted.

- The DHA logistics team will send a unique authorisation code (or disposal code, where applicable) by SMS (text message) or phone.
- For each adjustment, fill out a Registration Form for Relocation or Disposal of Commodities.

9.8 QC of test kits

Comply with all quality assurance policies to ensure that test kits are properly validated before they are distributed to user points.

The Pharmacy Medicines Regulatory Authority (PMRA) and MoH Community Health Science Unit must be notified upon receipt of HIV test kits to enable them to conduct QC testing on the kits before they are distributed to user points.

Chapter 10:Monitoring and Evaluation

Key facts: Documentation and reporting

- All clients tested for HIV, syphilis, and/or hepatitis B must be recorded in the standard MOH testing registers.
- All testing sites must follow standard MOH reporting requirements and use standard MOH reporting tools.
- All practising testing providers must be certified, registered with the DHA, and have a unique provider ID and professional logbook.

HIV, syphilis, and hepatitis B testing services will be monitored as part of the Essential Health Package. Routine data collection and reporting at each side should be done using the standard MoH M&E tools to measure and report indicators specified in health management information system (HMIS) guidelines.

10.1 Overview of M&E tools

All sites should at a minimum use approved MoH data collection and reporting tools. In addition to these tools, an approved electronic medical records system (EMRS) with an HTS module will be deployed at some high-volume sites. Standard M&E tools should not be altered without approval from the Central Monitoring and Evaluation Division (CMED) and the DHA. Any individual or institution requiring additional HIV, syphilis, and hepatitis B testing data should seek authorisation from the DHA. Any additional data collected should be shared with DHO to ensure effective management of testing services.

Given the sensitivity of testing data, it is important that there is a clear rationale for any additional data collected; the protection of client privacy and confidentiality is of paramount importance. Additional testing data collected for research purposes should receive ethical clearance from the Ethical Review Board and the DHA.

Table 9 in the Appendix summarises the key registers and reports used for providing testing services in Malawi. In addition to the M&E tools highlighted in the table, the following tools must be available to facilitate smooth testing services at each site:

Daily activity register

All testing service points within health facilities are required to track the use of test kits. A daily activity register (DAR) for maintaining up-to-date records of test kit stocks, receipts, losses, and use is to be kept at every testing point.

Testing services provider logbook

The DHA issues registers all new testing providers at the time of certification and issues a unique Provider ID and a professional logbook to document and track individual performance

and compliance with quality assurance policies. The logbook is filled by the provider and supervisors to document duty stations, training sessions attended, sit-in observations, proficiency testing results, and the total number of tests done each month.

10.2 Data analysis, use, and feedback mechanisms

Data should be used from the point of collection to improve the coverage and quality of testing services. At the district and national levels, these data will be used to produce quarterly and annual reports that track key indicators.

The staff involved in data entry, analysis, and publication should be trained in the specific requirements of their roles. They should understand the connection between their work at the various levels of the system and its effect on the implementation of quality data, information, policy, and strategy.

The HMIS office should ensure proper development of human resources in case of any changes to the system, software packages, or staff.

Testing services are regularly evaluated as specified by the national M&E framework.

10.3 Data quality

All testing locations are required to produce high-quality data by following the instructions in the registers.

District teams will check data quality through such initiatives as quality improvement and district review meetings. Central support for data quality is provided through site supervision visits, external data quality assessments (or DQAs), mentorship visits, and other initiatives.

Each site is given regular feedback on any gaps in data quality that need to be improved. Sites must:

- Use only the standard national reporting forms
- Keep copies of all monthly reports submitted to the DHO
- Properly file all registers and make sure they are securely stored

10.4 Record keeping and filing

All registers are the property of MoH and should be kept either at the facility or in the National Archives. Registers must be stored in a locked room, with only the clinic staff responsible for providing services and the national supervision team allowed to access them.

Appendix

Figure 1: HIV diagnostic algorithm for clients who have not previously received a positive HIV test result from a professional testing provider

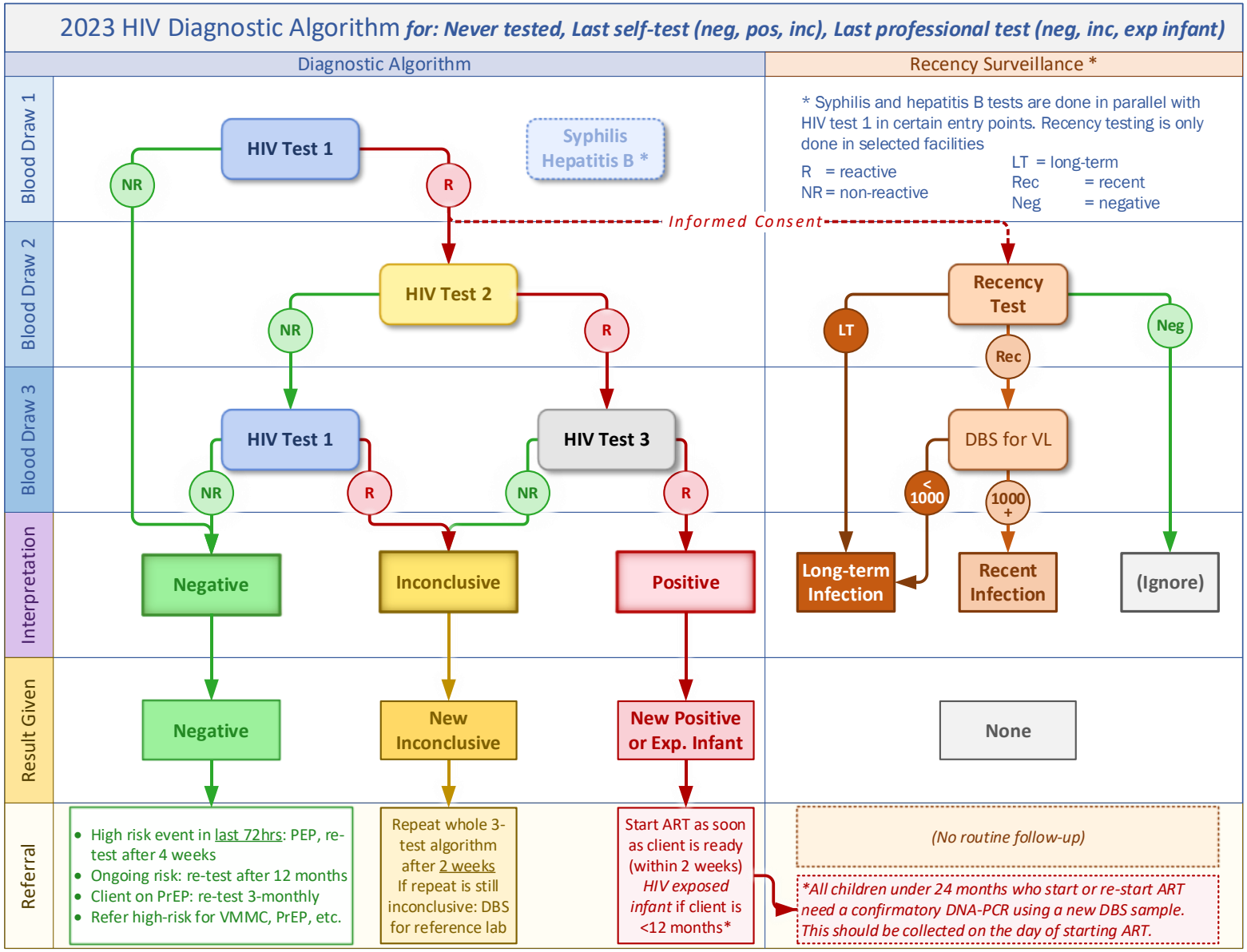


Figure 2: HIV diagnostic algorithm for clients who have previously received a positive HIV test result from a professional testing provider

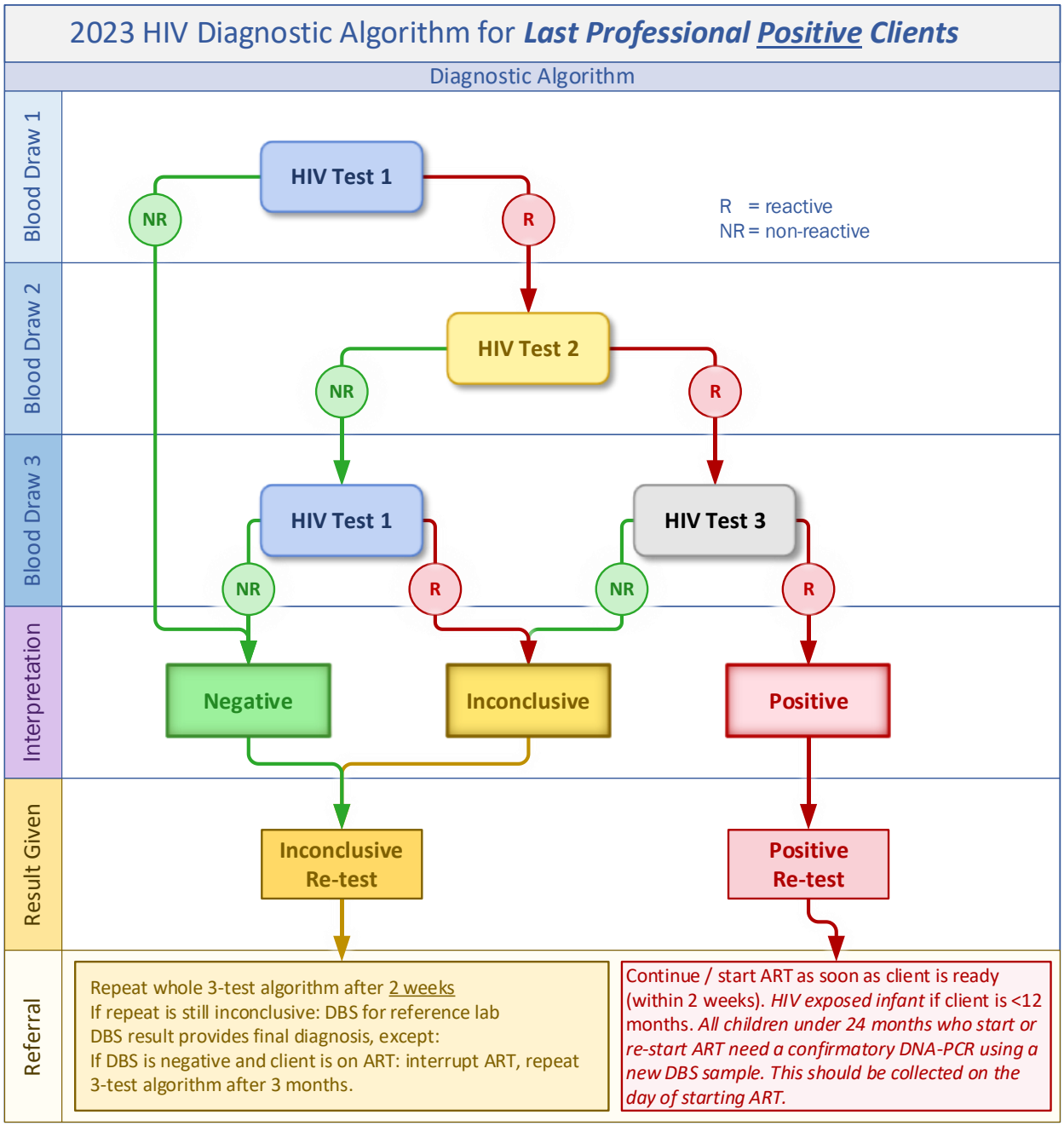
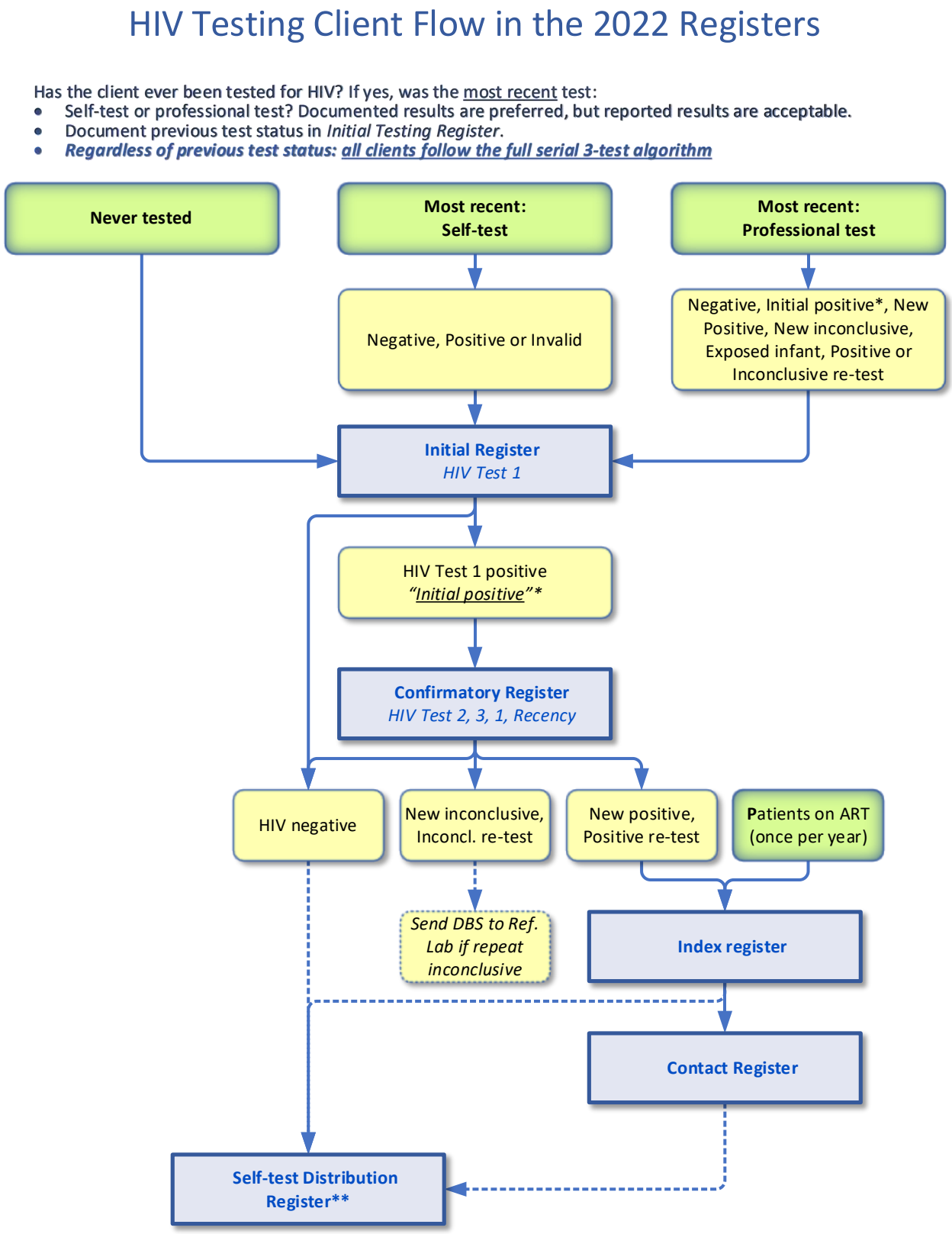
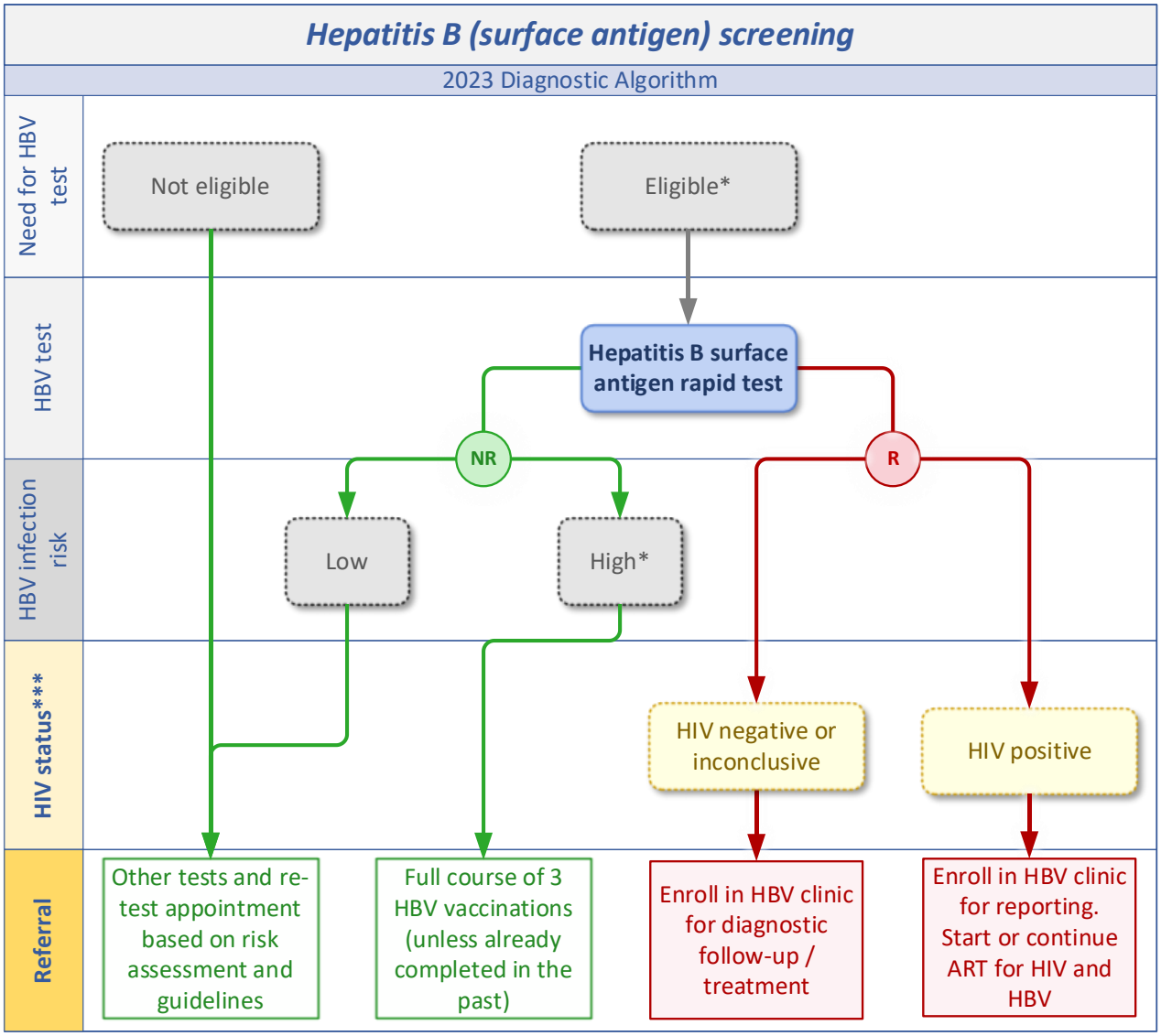


Figure 3: HIV testing client flow in the initial, confirmatory, and self-test distribution registers



* ***Initial Positive***: Clients with a positive HIV test 1 result (entered in the Initial Testing Register) who did not complete the full 3-test algorithm (confirmatory testing). This may happen with community-based testing.
** ***Self- tests*** *may be distributed for use by partners or others, regardless of the recipients own HIV status. However, never give self-tests for self-use by clients with a previous positive or inconclusive test result.*

Figure 4: Hepatitis B screening algorithm

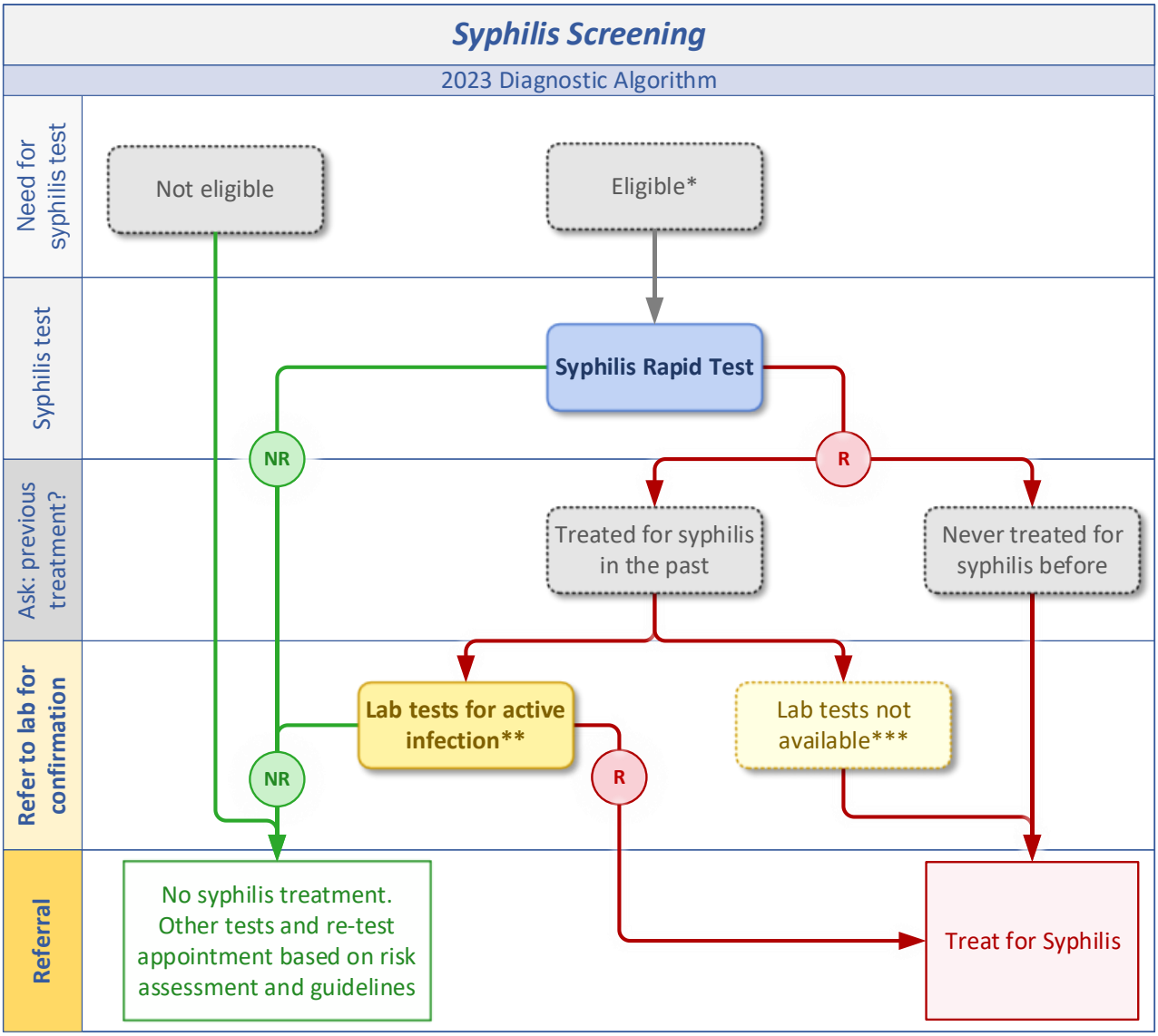


** **Eligibility for HBV testing***: see **Table 5** in Integrated Testing Guidelines for who and when to test for Hepatitis B.

**** Table 5** shows high risk groups who should be referred for a course of 3 HBV vaccinations unless they have previously completed 3 HBV vaccinations: FSW, TG, MSW, MSM, PWID, prisoners, PrEP clients, children 0-14 years born to HBV positive women, STI patients, general population at ongoing HIV risk or after high-risk event, health workers, sex partners of HBV index clients, sex partners of STI patients, presumed hepatitis patients, in-patients.

**** **HIV status must be ascertained** for all HBV positive clients. Perform a new HIV test using the full 3-test algorithm unless the client is already known to be HIV positive.*

Figure 5: Syphilis screening algorithm



*** Eligibility for syphilis testing***: see **Table 5** in Integrated Testing Guidelines for who and when to test for syphilis.

**** Lab test for active infection***: Clients with a previous syphilis infection usually have a positive rapid test for life, even if the infection was cured. Additional lab tests (RPR or VDRL) are needed to confirm a new, active syphilis infection.

***** Lab tests not available:*** Lab tests for confirmation of active syphilis infection may not be available at all sites. In this case, refer for presumptive syphilis treatment to ensure that any potentially new syphilis infection is treated.

Table 8: Minimum standards for integrated testing services

Testing services minimum standards checklist		
Human resources		
1.	At least two certified counsellors at the site	
2.	Site focal person identified who will be in charge of the testing site	
Policy, standards, and guidelines		
1.	National testing services guidelines available and in use at the site	
2.	Testing protocol booklet available	
3.	Standard operating procedures and job aids on display	
4.	Safety protocol on display (infection prevention, waste management, and post-exposure prophylaxis, including hand washing)	
5.	An updated logbook for each provider at the site	
6.	Incident report booklet. See Form 3: Integrated testing services incident report form, page 71	
Main counselling unit infrastructure		
1.	Waiting area	Clean and adequate sitting area
		Information, education, and communication materials available
2.	Counselling room	Clean, tidy, spacious, well lit, and ventilated
		Working timer
		Calendar
		Wall thermometer with a recording chart
		At least three chairs and one table, separate testing surface
		Lockable cabinet for records (provider access only)
		Door tags (*Counselling in Progress*/*Please Enter*)
		Penis model available
		Male condoms freely available
		Vagina model available
		Female condoms freely available
		Information, education, and communication materials available
Safety		
1.	Running water and soap available	
2.	Sharps container available	
3.	Two separate waste bins available (contaminated waste and non-contaminated waste)	
4.	Functional pit or incinerator for safe disposal	
5.	Disposable gloves available	
6.	Cotton wool available	
7.	Methylated spirit available	
8.	Antiseptic or decontamination solution available	
9.	Antiseptic solution made according to standard operating procedures	
Quality assurance for testing services		
Internal quality assurance		
1.	Quality control materials available (dry tube specimen with known positive and negative samples)	
2.	Performance of quality control and proper recording of results	
3.	Monthly review of internal quality assurance by the supervisor	
External Quality Assurance		

Testing services minimum standards checklist	
4.	Proficiency testing conducted every six months
5.	Timely receipt of feedback from the reference laboratory on proficiency testing results
6.	Filter papers for dried blood spots available on site
7.	Zip-lock bags, desiccant packs, and glycine papers available on site
8.	Dried blood spot specimens collected on site
Quality assurance for counselling	
1.	Blank Ministry of Health session observation checklist available
2.	Number of counsellors who have participated in sit-in session observations in the last quarter
3.	Number of counsellor meetings conducted during the last quarter
4.	Minutes of quarterly meetings
Monitoring and evaluation tools	
1.	National HIV, hepatitis B, and syphilis testing registers available and properly filled out
2.	Daily activity registers available and properly filled out
3.	Monthly report forms available and properly filled out
4.	Family referral slips available and regularly used
Test kit management	
1.	Test kits kept in pharmacy or drug store
2.	Proper storage (safe, off the floor, dry, cool, arranged by expiry date and lot number, appropriate temperature)
3.	Standard stock card used for test kits
4.	Adherence to issuing procedures (first expiry, first out)

Form 1: Standard operating procedures for outreach and mobile testing services

Models

Outreach testing services involve regular, non-full-time services provided at designated health centres or community sites using staff from another static or mother site. These sites often do not have adequate staff or other resources to implement regular, full-time services throughout the week. A plan is then arranged with a mother site that has adequate resources to provide regular part-time testing—for example, one or two days a week, or one or two days in a fortnight.

Mobile testing is commonly implemented through a 'mobile unit' van or other suitable vehicle, with tents and moveable furniture that can easily be set up as counselling rooms. The mobile unit and testing providers move into the designated space in the community and provide services in accordance with a predetermined plan.

Approval

The decision to implement mobile or outreach testing must be approved through the District Health Management Team (DHMT). Reports should be submitted—in cases of non-compliance, approval can be withdrawn.

Proposal

Institutions or agencies planning to provide mobile or outreach testing must submit a proposal to the district commissioner, indicating which model of testing is to be implemented, and where, how, and when services will be provided.

In cases involving outreach, include a memorandum of understanding with the head of the facility where the services will be provided. In cases involving mobile testing, the proposal should include permission obtained from technical advisers and other traditional leaders of the community in which mobile services will be provided.

Mandatory preparations

1. Involve the community in the planning and obtain permission from Traditional Authorities.
2. Inform key stakeholders, community-based organisations, nongovernmental organisations, faith-based organisations, and post-test health and social support services.
3. Ensure that referral networks will be operational.
4. Ensure that the community is mobilised and sensitised.
5. Provide dates and times when testing services will be provided. Use flyers, pamphlets, community radio announcements, etc. to inform the community.
6. Visit the location or premises to ensure suitability for providing testing services.
7. Ensure that there will be adequate supplies of test kits and other medical and nonmedical consumables available.

Implementation requirements

1. Ensure that the services provided comply with testing services guidelines:
    a. Counselling space that guarantees privacy
    b. Equipped with everything needed to operate a laboratory, including running water
    c. Waste disposal system in place

    d. All requirements for implementing partners available
    e. Reliable transport available for counsellors serving at outreach sites
    f. Standard data collection tools available
    g. Standard testing protocols available
    h. Post-exposure prophylaxis starter packs available
    i. Quality assurance programme that follows national guidance
2. Ensure enough counsellors are available to meet unexpected high demand.
3. Arrange for suitable overnight accommodation and meals for all mobile service staff.
4. Ensure regular administration of quality assurance procedures in compliance with standard protocols.
5. Ensure that standard approved methodologies are used for monitoring and evaluation.
6. Provide necessary feedback to DHSS regarding provision of testing services.

Form 2: Standard client referral form

From TESTING Site to Other Services

Date: _____

Client name: _____

Client phone number: _____

Age: _____ Sex: _____

Current residence: _____

Referred from (health facility/section): _____

Referred to (health facility/section): _____

Test result: _____

(Tick all that apply)	List of services
	ART/PMTCT Clinic
	STI
	TB
	Family Planning
	PLHIV Support Groups
	Home-based Care
	VMMC
	PrEP
	Social Welfare
	Post-test Clubs
	Other, Specify:

Testing provider ID and Signature: _____

Receiving Facility: _____

Client enrolled on (Date) _____

Client enrolled by _____ Signature _____

Remarks_____

_____

Form 3: Integrated testing services incident report form

<table>
<tr><td colspan="2">Date of Incident:</td><td>Time of incident:</td></tr>
<tr><td colspan="3">Location of incident:</td></tr>
<tr><td colspan="3">Reporting person details
Name:
Provider ID:
Contact information:
Signature:</td></tr>
<tr><td colspan="3">Type of incident (explain in detail):</td></tr>
<tr><td colspan="3">How did the incident occur?</td></tr>
<tr><td colspan="3">Action taken to resolve the incident:</td></tr>
<tr><td colspan="2">Supervisor informed about the incident</td><td>Yes</td><td>No</td></tr>
<tr><td colspan="2">If supervisor informed, what action has been taken?</td><td colspan="2">Signature of supervisor</td></tr>
<tr><td colspan="3">Follow-up plan:</td></tr>
</table>

Form 4: Code of ethics and conduct for testing services providers

General Principles

Testing providers must understand the fundamental values involved in providing testing services and maintain a professional relationship with their clients. The ethical standards serve to safeguard integrity, impartiality, and respect for both parties.

Testing providers must be competent:

- Responsible for their own physical safety, effectiveness, competence, and conduct, thereby avoiding any compromise of the profession
- Ensure that they have received the required skills and techniques in testing and counselling
- Regularly monitor their competence through supervision or consultative support, and by seeking the views of their clients and other providers
- Recognise the boundaries and limitations of their competence, and provide services, skills, and techniques for which they are qualified through training and practice
- Refrain from making any claims that they possess qualifications or expertise that they do not
- Make appropriate referrals to others who have the expertise that they themselves do not possess
- Refrain from making exaggerated claims about the effectiveness of the HIV, hepatitis B, and syphilis prevention and care services they offer.

Consent

- Obtain their clients' consent to engage in the counselling and/or testing process. Unless otherwise sanctioned by legal authorities on criminal or mental health grounds, testing is to be voluntarily undertaken by clients, and should take place in a private and confidential setting.
- It is the provider's responsibility to inform clients about the nature and duration of the counselling and testing process.
- All clients taking a test must give informed consent prior to being tested. This consent must be obtained or provided in the context of the counselling relationship.
- Testing providers are expected to ensure that clients have adequately understood all the issues involved in testing and counselling before they give informed consent for testing.
- Testing providers must recognise the rights of those whose ability to give valid consent to testing may be diminished because of age, learning disabilities, or mental illness.
- Testing providers must recognise the right of clients to withdraw their consent at any time, even after their blood has been taken for testing.

Confidentiality

- Testing providers must maintain adequate records of their work with clients or patients and take all reasonable steps to preserve the confidentiality of information obtained through client contact. They should take steps to protect the identities of individuals, groups, and others revealed through counselling.

- Confidentiality should be upheld, and no information concerning the client or patient given to others without the permission of the client. The results of a test must be kept confidential. However, shared confidentiality is encouraged. *Shared confidentiality* refers to sharing confidential information with family members, loved ones, care givers, and trusted friends. Shared confidentiality is provided only upon request of the person undergoing testing. Although results of a test should be kept confidential, other professionals (such as health care workers) may also need to be aware of a person's test result to provide appropriate care.
- Testing providers must take all reasonable steps to clearly communicate the extent of confidentiality they are offering to clients. Normally this should be made clear in the pre-counselling information session or the initial contract.
- Testing providers must not disclose any information about a client or patient to colleagues not directly involved in their care or with their patients without first seeking the consent of the client.
- Testing providers must make provisions for maintaining confidentiality in the storage and disposal of client or patient records.
- Testing providers may break the confidentiality agreement only if there are sound reasons for doing so, such as:
    - Believing that a client will cause serious physical harm to himself or herself, or to other persons, or that the client will be harmed by someone else.
    - Believing that a client is no longer able to take responsibility for his or her decisions and actions.
- The decision to break confidentiality that has been agreed upon between a provider and client should be made only after consultation with a supervisor or an experienced provider.

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Culture, Religion, Gender, and Racial Differences

Testing providers must recognise the fundamental human rights, dignity and worth of all people. Like any other health care professionals, providers are expected to provide services to people irrespective of their race, culture, religion, values, or belief systems.

Testing providers must:

- Be aware of the cultural and role differences of the client's gender, race, ethnicity, religion, sexual orientation, disability, and socioeconomic status.

- Be aware of personal prejudices and biases based on the above-mentioned human differences, and not allow these to interfere with the counselling process.
- Refer clients to another provider if cultural and role differences of gender, race, ethnicity, religion, sexual orientation, disability, and socioeconomic status interfere in any way with the ability to provide services.
- Refrain from participating in or condoning any discriminatory practices based on the above-mentioned human differences.

Personal Conduct

- Testing providers must provide services in a way that does not damage the interests of their clients or undermine public confidence in their service or their colleagues.
- Testing providers must maintain respect for clients in the counselling relationship by not engaging in activities that seek to meet the provider's personal needs at the expense of clients, and must not attempt to secure financial or other benefits other than those contractually provided for or awarded by salary.
- Testing providers should not exploit any counselling relationship for the gratification of personal desires. Sexual harassment, unfairness, discrimination, stigmatisation, and derogatory remarks must be avoided.
- Testing providers should refrain from performing their counselling duties when their physical or psychological condition is impaired by alcohol or drugs use, or when their professional judgement and abilities are impaired for any other reason.
- Testing providers should appear professional and presentable in dress and manner.

Integrity

- Testing providers must seek to promote integrity through honesty, fairness, and respect for others, and avoid improper and potentially harmful dual relationships with clients.
- Providers should not engage in personal or sexual relationships with current clients.
- Providers should not agree to counsel clients with whom they have engaged in a former sexual relationship or with whom they have a current personal relationship.

Figure 6: Commodity supply chain management cycle

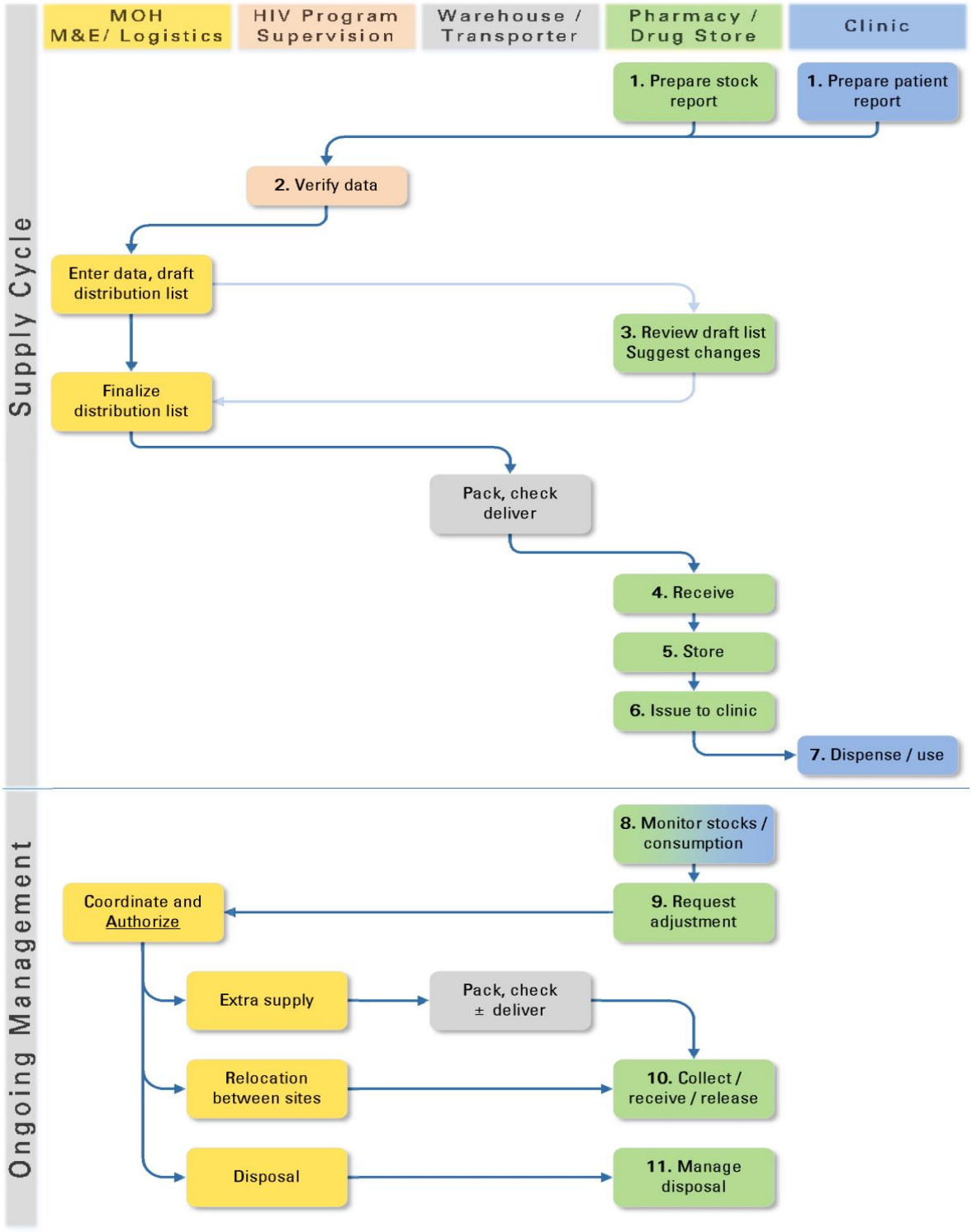

Table 9: Overview of M&E registers for professional testing and self-testing

Service	M&E register	Contents
Blood-based testing	Initial testing register	• HIV testing details for all clients for all testing modalities and locations • Outcome of HIV test 1, hepatitis B and syphilis results
	Confirmatory testing register	• Continuation from the initial register for all clients with a reactive HIV test 1: HIV test 2, 3 and potentially repeat test 1 results • Final HIV test outcome • ART linkage outcomes • Recency testing, DBS sample details
Oral fluid-based self-testing	HIVST distribution register	• Distribution of HIV self-test kits for recipients and/or other end users
Active index testing	HIV index testing register A: Index	• Details of the index client and summary of contacts to be traced
	HIV index testing register B: Contacts	• Details about contacts for tracing and their outcomes

Table 10: Standard reporting requirements

	Report	Description	Frequency
1	HTS Summary	HIV test summaries from initial and confirmatory registers	Biweekly Monthly
2	Initial testing register: clients tested for HIV	Complete data elements from the initial register	Monthly
3	Initial testing register: clients tested for hepatitis B	Summaries of hepatitis B testing	Monthly
4	Initial testing register: clients tested for syphilis	Summaries of syphilis testing	Monthly
5	HIV confirmatory testing summary	Confirmatory register summaries	Monthly
6	HIV self-test distribution summary	HIVST summaries	Monthly
7	PEPFAR disaggregated HTS report	HTS age /sex summaries PEPFAR	Monthly
8	PEPFAR disaggregated HIV self-testing report	HIVST age /sex summaries PEPFAR	Monthly

Table 11: Summary of differentiated testing services

Target Population	When	Where	Who	What
Key populations: MSM, FSW, PWID, MSW, transgender persons, etc.	Offer services according to the specific group, where they meet, and when they gather	• Drop-in centres (DICs) • Hotspots, bars, clubs • Mobile vans • Health facilities • Other meeting places	Trained and certified providers	• HTS • Condom and lubricant distribution • Family planning • STI screening and treatment • Prevention services (PEP or PrEP)
Adolescents and young people, in or out of school	• Weekdays • Weekends	• College clinics at institutions of higher learning • Health facilities • Youth-friendly health clinics • Youth CBOs for out-of-school adolescents	Trained and certified providers	• HIVST • Syphilis • Condom distribution • Hepatitis B testing • Family planning • PrEP, PEP • VMMC
Men in formal and informal work sectors	• Weekdays • Weekends • Nights	• Workplace (formal or informal) • Mobile testing at bars, clubs, and sporting events • Mobile testing vans • PITC at in-patient male wards, OPD, STI, TB, and VMMC clinics	Trained and certified providers	• HIVST • Syphilis • Condom distribution • Hepatitis B testing • VMMC
People in prisons	• On entry • At 6 months • On discharge	• Prison clinics • Health facilities	Trained and certified providers	• HIV, syphilis and hepatitis B testing

Pregnant and breast-feeding women	• Pregnant women
	  ○ First contact
	  ○ Third trimester
	  ○ Labour and delivery
	• Breast-feeding women with negative HIV test at delivery
	  ○ At 6 to 9 months
		• ANC
		• Labour
		• Family planning
		• EPI
			Trained and certified providers	• HIV, syphilis, and hepatitis B testing
				• Family planning