National HIV/AIDS/STD/TB Council of Zambia
Foreword

The Ministry of Health (MOH) recognizes the need for comprehensive and standardized HIV Testing Services (HTS) in Zambia.

The prevention of HIV remained a focus area for the health sector response to the HIV epidemic. HIV Testing Services is an entry point to HIV prevention, treatment, care and support. It is expected that when people know their HIV status they will make informed choice on HIV prevention or if positive, access other services. The implementation of HTS is cardinal at community level, knowledge of HIV status link the people tested to interventions and leads to a reduction in denial, stigma and discrimination and to collective responsibility.

These guidelines are meant to cater for the HIV Testing Services needs of the Zambian people. A multidisciplinary team representing public health workers, Non-Governmental Organizations (NGOs), physicians, social workers and counsellors developed these guidelines. This team solicited guidance from a wide range of experts such as support groups, people living with HIV/AIDS (PLWHA), donors, the private sector, people with disabilities and many others with varied expertise.

It is hoped that the guidelines will serve as a ‘blueprint’ for the scaling up of HIV Testing Services for adults and children in Zambia, as well as help health workers and counsellors establish and maintain high quality HIV counselling and testing services for children.

We therefore expect all public, private sector health service providers, the Zambia Defense Force Medical Services and mission hospitals to use these guidelines for provision of quality HIV Testing Services.

Hon. Dr. Chitalu Chilufya, MP
Minister of Health
Acknowledgement

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Dr. Jabbin L. Mulwanda
Permanent Secretary -Technical
Ministry of Health
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<td>Acquired Immunodeficiency Syndrome</td>
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<td>Antiretroviral Therapy</td>
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<td>ARV</td>
<td>Antiretroviral</td>
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<tr>
<td>cART</td>
<td>Combination of Antiretroviral Viral Treatment</td>
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<td>CD4</td>
<td>Cluster of Differentiation 4</td>
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<td>CLIA</td>
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<td>Counselling Testing and Care</td>
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<td>Dry Blood Spot</td>
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<td>District Health Office</td>
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<td>District Medical Officer</td>
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<td>Expanded Programme on Immunization</td>
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<td>Human immunodeficiency virus</td>
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<td>HIVST</td>
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<td>In-Patient Department</td>
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<td>LMU</td>
<td>Logistics Management Unit</td>
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<td>M &amp; E</td>
<td>Monitoring &amp; Evaluation</td>
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<td>Ministry of Health</td>
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<td>MSL</td>
<td>Medical Stores Limited</td>
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<tr>
<td>MTCT</td>
<td>Mother-to-child Transmission of HIV</td>
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<td>NAC</td>
<td>National AIDS Council</td>
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<tr>
<td>NAT</td>
<td>Nucleic Acid Testing</td>
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<tr>
<td>NGO</td>
<td>Non-Governmental Organization</td>
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<tr>
<td>OI</td>
<td>Opportunistic Infection</td>
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<tr>
<td>OPD</td>
<td>Out-Patient Department</td>
</tr>
<tr>
<td>PEP</td>
<td>Post-exposure Prophylaxis</td>
</tr>
<tr>
<td>PICT</td>
<td>Provider Initiated Counselling and Testing</td>
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<tr>
<td>PCR</td>
<td>Polymerase Chain Reaction</td>
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<tr>
<td>PLHWA</td>
<td>People living with HIV</td>
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<td>PMTCT</td>
<td>Prevention of Mother-to-Child Transmission of HIV</td>
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<td>PMO</td>
<td>Provincial Medical Office</td>
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<tr>
<td>PrEP</td>
<td>Pre-Exposure Prophylaxis</td>
</tr>
<tr>
<td>QA/QI</td>
<td>Quality assurance/Quality Improvement</td>
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<tr>
<td>RDT</td>
<td>Rapid Diagnostic Test</td>
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<tr>
<td>Acronym</td>
<td>Full Form</td>
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<td>---------</td>
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<tr>
<td>RNA</td>
<td>Ribonucleic Acid</td>
</tr>
<tr>
<td>SOPs</td>
<td>Standard Operating Procedures</td>
</tr>
<tr>
<td>STI</td>
<td>Sexually Transmitted Infection</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>UNAIDS</td>
<td>United Nations Programme on HIV/AIDS</td>
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<tr>
<td>UTH</td>
<td>University Teaching Hospital</td>
</tr>
<tr>
<td>VCT</td>
<td>Voluntary Counselling and Testing</td>
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<tr>
<td>VMMC</td>
<td>Voluntary Medical Male Circumcision</td>
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<tr>
<td>UN</td>
<td>United Nations</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>Zambia Counselling Council</td>
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<td>ZEMA</td>
<td>Zambia Environmental Management Agency</td>
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<td>ZHTSS</td>
<td>Zambia Health Technical Support Services</td>
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<td>ZVCTS</td>
<td>Zambia Voluntary Counselling and Testing</td>
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</table>
1. Background

HIV testing is the gateway to HIV prevention, treatment, care and other support services. People's knowledge of their HIV status through HIV testing services (HTS) is crucial to the success of the HIV response. Despite the remarkable increase in the knowledge of places to get an HIV test, the uptake of HIV testing remains low in both women (46%) and men (37%) who had tested in the past 12 months and received results. Voluntary counselling and testing (Client initiated counselling and testing) was the main approach to HIV prevention interventions and a number of testing centers were established nationwide. This approach did not yield positive results because the country saw very few people going for voluntary testing.

In order to increase access to HTS, the ministry of health with other stakeholders introduced more robust approaches which include provider initiated testing and counselling, home based testing and counselling, workplace HTC, diagnostic HTC and community outreach.

Zambia has adopted UNAIDS Fast Track Strategy of 90–90–90 targets calling for 90% of all people with HIV to be diagnosed, 90% of people with HIV diagnosed to receive ART and 90% of those on ART to have a suppressed viral load by 2020. The diagnosis of HIV (first 90%) is essential to the second 90% (initiation of ART) among people with HIV and the ultimate outcome of the third 90 (viral load suppression among people on ART). The achievement of 90-90-90 strategy will improve ART client outcome and prevention of HIV transmission (UNAIDS, 2016).

The guidelines aim to:

- Provide a comprehensive evidence based recommendations for HTS.
- Support HIV testing by counsellors to increase access to HTS at institutional and community levels.
- Provide guidance to apply effective HTS approaches appropriate to targeted underserved and undiagnosed populations such as infants, children, adolescents (10-19 years), pregnant women, couples and other key populations.

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1 Central Statistical Office; Zambia Demographic and Health Survey, 2013/14
2. Principles and Approaches

The Government Zambia is a signatory to the universal declaration of human rights and the United Nations (UN) Convention on the Rights of the Child, and will therefore uphold the public health guiding principles, observe the 5Cs of HTS and utilise various HTS appropriate to the Zambian situation.

2.1 Guiding Principles

- A public health approach is important for delivering HIV testing services.
- Human rights-based approach which gives priority to such concerns as universal health coverage, gender equality and health-related rights such as accessibility, availability, acceptability and quality of services.
- HIV testing for diagnosis must always be voluntary and consent must be obtained.
- HTS must be linked to prevention, treatment, care and support services to maximize both individual and public health benefits.
- HTS must be provided without discrimination.
- HTS services must ensure that the child’s rights are protected and treatment care and support are made available.
- All forms of HIV testing should adhere to the WHO five Cs which are; consent, confidentiality, counselling correct test results and connection.

2.2 The Five Cs of HTS

Consent

People receiving HTS must give informed consent, be informed of the process of HIV testing and counselling and of their right to undertake or decline testing. All clients aged 16 years and above must give full, informed consent. People younger than 16 years who are married, pregnant, or are parents, head households, or are child sex workers (mature minors) should also provide informed consent before undergoing an HIV test. For young clients under the age of 16 and those lacking full mental capacity, guardian consent is required before they are tested for HIV.

Confidentiality

HTS must be confidential, meaning that what the HTS provider and the client discuss will not be disclosed to anyone else without the expressed consent of the person being tested. Shared confidentiality with a partner or family members – trusted others – and healthcare providers are often highly beneficial.
**Counselling**

Testing services must be accompanied by appropriate quality pre-test information post-test counselling, based on the specific HIV test result and HIV status reported.

**Correct Result**

Providers of HIV testing should strive to provide high-quality testing services, and quality assurance (QA) mechanisms should ensure that people receive a correct diagnosis. All people who receive a positive HIV diagnosis should be retested to verify their diagnosis before initiation of HIV care or treatment. Results must be communicated to the person tested unless that person declines to know the test result.

**Connection**

Linkage to prevention, treatment care and support services should include effective and appropriate client referral and tracking mechanism.

### 2.3 HIV Testing Service Approaches

There are various HIV testing services approaches that are used. The approaches listed and described below are common in the Zambian context:

**Provider-Initiated Testing and Counselling (PITC)**

Provider-Initiated Testing and Counselling denotes HTS that is offered to the client by the Health worker as part of routine investigation in a health facility. It includes providing pre-test information and obtaining consent, with the option for individuals to opt out.

**Voluntary Counselling and Testing (VCT)**

Voluntary Counselling and Testing is the HIV testing that is usually client-initiated when they want to know their HIV status. This approach to HIV testing and counselling is the most common and remains one of the effective interventions to HIV prevention.

**Diagnostic Testing and Counselling (DTC)**

HIV counselling and testing in clinical settings is called HIV Diagnostic Counselling and Testing (DCT). The primary focus is on diagnosing HIV for appropriate TB and HIV management, particularly by referral for HIV care.

- Diagnostic counselling and testing should be requested by health workers as part of the diagnostic work-up for patients who present with symptoms or signs that could be attributed to HIV.
- Failure to provide such people with counselling and testing has resulted in sub-standard care for HIV infected patients.
- Health care providers must provide pre-test information, obtain informed consent and does the HIV test on site in the clinic. This is more efficient and more likely to be successful than referring patients elsewhere for HIV counselling and testing.
Facility-Based HIV Testing Services

Facility-based HIV testing services refers to HTS provided in a health facility or laboratory setting. It can be a stand-alone or integrated site.

Community Based HTS

Community-based HTS refers to HIV testing services provided within the community away from health facilities. Community-based HTS are done through various ways including the following:

- Door-to-door/home-based testing.
- Testing during mobile outreach campaigns.
- Testing in workplaces.
- Testing in hot spots.
- Testing in places of worship and educational establishments.
- Testing during various national and cultural events.

National HTS campaigns

National HTS campaigns are nationwide efforts to increase access to and uptake of HTS. These campaigns can be implemented in different ways, some focusing on testing in health facilities or using a community based approach, or combining the two approaches.

HIV Testing Services and integrated campaigns

HIV testing services and integrated campaigns offer HIV testing in addition to other health services. Depending on the context, these often include providing insecticide-treated bed nets, family planning services (FP), Expanded Programmes on Immunization (EPI) campaigns, screening for STIs, cervical cancer, breast cancer, malaria, hepatitis, as well as cardiovascular risk factors such as diabetes or hypertension.

HIV Self-Testing

HIV Self-Testing (HIVST) is a process in which a person collects his or her own specimen (oral fluid or blood) and then performs an HIV test and interprets the result, often in a private setting, either alone or with someone he or she trusts. This approach does not provide a definitive diagnosis. Regardless of approach, self-testers must be provided with clear information on how to correctly perform the test, interpret the result, as well as where and how to access stigma-free HIV testing, HIV prevention, treatment, care and support services. In particular, it is critical self-testers understand that:

- A reactive self-test result is not an HIV-positive diagnosis and requires further testing and confirmation.
- A non-reactive self-test result is assumed negative. All self-testers with a non-reactive test result should be advised to retest if at high on-going HIV risk, or if potential exposure to HIV occurred in the preceding six weeks, and referred to a relevant HIV prevention service, such as post-exposure prophylaxis, pre-exposure prophylaxis (PrEP), or voluntary male medical circumcision (VMMC).
- HIVST is not recommended for people taking anti-retroviral drugs, as this may cause a false non-reactive result.
- Any person, who is uncertain about how to correctly perform the self-test, or interpret the self-test result, should be encouraged to access facility- or community-based HIV testing.
Mandatory HIV Testing

The Ministry of Health recommends mandatory screening for HIV and other blood borne viruses of all blood that is destined for transfusion or for manufacture of blood products. Mandatory screening of donors is required prior to all procedures involving transfer of bodily fluids or body parts. Mandatory HIV Testing must be done on all perpetrators of rape cases.
3. Pre-Test and Post-Test

Pre and post-test services should be provided through counselling by trained persons. Counselling consists of pre-test, post-test as well as follow-up counseling/support. The purpose of counselling is to:

- Provide high-quality HIV prevention information to reduce one’s risk of transmitting or acquiring HIV.
- Ensure access to appropriate medical, preventive and psychosocial support services.
- Promote early diagnosis of HIV.
- Ensure that all people receive information regarding transmission, prevention, and the meaning of HIV test results.
- Help clients cope with the emotions and challenges that come with HIV testing services.

3.1 Pre-Test Counselling Guidelines

Two approaches are used in pretest counselling i.e. individual and group counselling. During a pre-test session, counselling should be centered on four main topics which include the following:

- Understanding what the HIV test is and the meaning of the test result.
- Assessing one’s risk of HIV infection (Risk assessment).
- Reducing one’s risk of HIV infection in relation to test results
- The importance of disclosing one’s HIV status and developing future plans.

In some instances, more than one pre-test counseling session may be required particularly with clients who decline to undertake an HIV test or are unprepared for the test at that time.

3.2 Post-Test Counselling Guidelines

Post-test counselling should not be offered in a group context. However, it can be provided to couples. Post-test counselling should consist of the following:

**Giving test results to the client(s)**

- Test results should be available and given to the client same day.
- Test results should be communicated to the client(s) calmly and in a private setting by trained personnel.
- Clients should be provided with ongoing support by counsellors or members of a support group if they so wish.
Discussing the window period

The window period is time between potential exposure to HIV infection and the point when the test will give an accurate result. During the window period a person can be infected with HIV and be very infectious but still test HIV negative. The window period for a 3rd generation antibody test is 6-8 weeks (usually clinics say 3 months).

The window period should be discussed with all clients who test HIV negative and encourage them to retest after three months. The counsellor should recommend retesting after three months particularly among persons who have an indeterminate HIV test results; HIV negative pregnant and breastfeeding women; HIV negative persons with an STI; HIV negative TB patients; persons with known HIV exposure as well as persons in a discordant sexual relationship.

Positive living

All HIV positive clients should be counselled and provided with information on living positively which should include the following:

- Maintaining a positive attitude.
- Disclosing one’s status to sexual partners.
- Avoiding additional exposure to the virus and other STIs by using condoms.
- Providing early referrals for medical services.
- Good diet and avoiding stress.

Risk-reduction planning

A post-test counselling session should include the development of a risk-reduction plan specific to the client’s test results and personal life situation. Ways of preventing reinfection and spreading the virus should be discussed with all HIV positive clients when developing a risk-reduction plan. Various ways of reducing one’s risks such as consistent and correct use of condoms should be discussed as part of client’s risk-reduction plan. Condoms demonstration and providing information on where condoms can be obtained should also be part of the discussion during the risk reduction planning session.

Discussing the importance of disclosure of status

During a post-test counselling session, the importance of disclosing one’s HIV status to relevant others should be discussed and clients supported to do so. Stigma associated with HIV should be discussed with the client(s) and the means by which it can be mitigated should be discussed with the clients.

Discussing sexual and reproductive health

Where appropriate, information on sexual and reproductive health including integrated family planning services should be discussed with clients, especially those who intend to have children.

Referrals

Linkages to prevention, treatment, care and support services should be discussed with the client. This should include providing the client with relevant information about existing services and where to access the services to facilitate effective and appropriate client referral and tracking mechanism. These include VMMC (Male HIV negative clients), TB corners, STI clinics, GBV and sexual abuse experts.
4. Special Circumstances

4.1 Request for testing only

In cases where clients request testing but decline counselling, the counsellor should carefully explain to the client(s) that HTS services are provided as a package which include both counselling and testing. The benefits of counselling should be explained, and the client should be encouraged to return when he/she has more time and is ready to undergo counselling and testing together. HIV test should not be undertaken without first providing pre-test counselling to the client.

4.2 Request for counselling only

In cases where a client request counselling but decline to be tested, counselling should be provided such clients without coercing them to undertake the test. Nonetheless, the benefits of testing and knowing one’s status should be communicated to the client.

4.3 Repeat testing

Clients should be encouraged to disclose if they have been to other centers for HIV testing. The reasons for seeking repeat testing should be explored with clients who have been tested elsewhere.
5. HIV Testing

5.1 Overview of HIV diagnosis

For a period of about 10 days following HIV infection, known as the **eclipse period**, no currently available serological or virological assay can detect any marker of HIV infection. The end of the eclipse period is marked by the appearance of HIV RNA or DNA detectable by nucleic acid testing (NAT).

The period prior to detection of HIV-1/2 antibodies is often referred to as **“acute infection”**. The window period is the period from the time of infection to the time of detection of antibodies.

![Figure 1: HIV Infection over the Natural History of Infection](image)

**Figure 1: HIV Infection over the Natural History of Infection**

- **Days post infection**
  - 0
  - 10
  - 14
  - 21
  - 28
  - 35
  - 48

- **Eclipse period**
- **Window period**
- **Acute infection**

**Key points**

Rapid Diagnostic Tests (RDTs) are a critical tool for scaling up HIV testing services. They can be performed by trained lay providers, health-care workers and laboratory professionals in various settings, irrespective of the infrastructure, as they do not require specialized equipment or specimen collection by venipuncture.

Retesting to verify HIV diagnosis is recommended for all individuals:

- With newly established HIV-inconclusive results and
- Who have tested HIV-positive, before they enroll in care and start ART

Retesting is also recommended for certain individuals with ongoing risk who test HIV negative. Retesting is not recommended for individuals on ART, who have taken PEP, infants exposed to eMTCT regimens via their mothers or those taking PrEP.

Note: Negative status should be interpreted with caution.
5.2 Types of HIV Tests

There are two main types of HIV tests: Serological and Virological tests.

Serological Tests

These detect antibodies against HIV; they do not detect the virus itself. When HIV enters the body, the person’s immune system responds by producing antibodies to fight the new HIV infection. The presence of antibodies is used to determine HIV infection. Current practice in Zambia uses RDTs for point-of-care testing.

Virological Tests

These determine HIV infection by detecting the virus itself. Virological tests can be used to detect HIV infection from the end of the eclipse period. These assays require advanced and expensive laboratory equipment.

5.3 HIV Testing Algorithm

Ministry of Health recommends the use of two HIV tests; the First line (Screening HIV Test) and the Second line (Confirmatory Test) as shown in figure 2. These tests are based on different principles, thus when used together provide an approved testing algorithm.

The following is a summary of the testing algorithm in conformity with Figure 2:

- All samples are tested for HIV antibodies using a first line test (screening test).
- All non-reactive samples are reported as negative.
- A reactive sample will undergo a second HIV test with a second line test. If the result is reactive, it is reported as positive.
- If the result of the second line test is negative, repeat the test in parallel using both the screening and confirmatory tests.
- If the results of both the screening test and the confirmatory test are reactive, report as positive, if both the screening test and the confirmatory test are non-reactive, report as negative.
- If the results of the screening test and the confirmatory test are discrepant, request the client to be retested after 14 days.

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2 Determine™ is used as the screening test while SD Bioline™ is used as the confirmatory test in Zambia
Figure 2: Zambia National HIV Testing Algorithm

HIV Testing Algorithm without Tie Breaker

Test 1
Screening Test

Result: Reactive
Do Test 2 as confirmatory test

Test 2
Confirmatory Test

Result: Reactive
Report as Positive (+)

Result: Non-Reactive
Repeat the test using the same sample on the screening and confirmatory tests in parallel

Both Test 1 and Test 2 Result: Reactive
Report as Positive (+)

Both Test 1 and Test 2 Result: Non-Reactive
Report as Negative (-)

Test 1 and Test 2 Result: Discordant Result
Report as Indeterminate
and ask the client to come back after 14 days

Test 2 Result: Non-Reactive
Report as Negative (-)
## 5.4 Test Results

Interpretations and definitions of HIV test results are described below:

*Figure 4: Interpretation of HIV test results.*

The table below shows the definitions of HIV test results.

Table 1: Definition of HIV Test Results

<table>
<thead>
<tr>
<th>Result</th>
<th>Interpretation of Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Results</td>
<td>No HIV antibodies detected in the person’s blood because the person is either not infected or is still in the window period.</td>
</tr>
<tr>
<td>Positive Results</td>
<td>HIV antibodies were detected in the person’s blood by both the screening and confirmatory tests meaning the person is infected with HIV.</td>
</tr>
<tr>
<td>Indeterminate Results</td>
<td>HIV antibodies were detected in the person’s blood by the screening test but not detected by the confirmatory test. This could be because the person is in the process of sero-converting or the person may have a prior medical condition that is affecting the test. In this case, the person is asked to come back after 14 days for re-testing.</td>
</tr>
</tbody>
</table>

## 5.5 General recommendations for HIV Testing Services

- Rapid and simple test devices are recommended for HTS to reduce waiting time of the client.
- Only HIV test kits approved by MOH should be used.
- Facilities offering HTS must adhere to the Zambian testing protocol.
- Adequate testing spaces in stand-alone or integrated facilities are essential for HTS.
- Health care providers should have appropriate training for HTS.
- Counselors must have a minimum of psychosocial counselling certificate and HIV testing certificate.
- Facilities offering HTS must strictly adhere to maintenance of client’s confidentiality.
- Laboratories involved in HTS must set up adequate internal Quality Control and External Quality Assurance scheme as per national standards.
- Expired test kits **must** not be used.
6. Safety Procedures

Blood may contain infectious and potentially pathogenic organisms. It is important that personnel conducting tests must ensure protection and prevention of possible cross-contamination. The primary danger is parenteral exposures through accidental needle sticks, cuts with contaminated equipment, exposure of mucous membranes to aerosolized droplets, and exposure of broken skins, wounds and scratches to contaminated specimens. Universal safety precautions should be followed.

6.1 Hand Washing with Soap

Hand washing is one of the critical elements of universal safety precautions. Therefore, the HTS provider must ensure that:

- A hand basin with clean running water is available within the testing room.
- Soap is provided exclusively for hand washing.
- Paper towels or hand dryers are provided.

6.2 Personal Protective Equipment

The following protective clothing should be worn:

- Coats, gloves.
- Goggles & Mask must be used if eye splashing is a risk.

However, protective clothing must only be worn in the testing area.

6.3 Storage of Safety Materials

Safety materials must be kept in a designated and secure environment.

- Protective clothing should be stored separately from personal items (for example, outer clothing, valuables, bags), preferably in a locker or cupboard in a separate room.
- Gloves must be kept away from heat or sunlight.

6.4 Washing Protective Clothing

- Soiled protective clothing should be placed in a laundry bag, not in a locker.
- Protective clothing should be soaked overnight in one percent domestic bleach before washing.
6.5 Working area

The following safety practices should be observed in the working area:

- No eating, drinking, smoking, or chewing gum in the testing area.
- No licking of labels or placing pens and pencils in the mouth or hair while in the testing area.
- No application of cosmetics in the testing area.
- No storage of foodstuffs in testing area.
- Cuts and open wounds should be covered with waterproof adhesive dressing.

6.6 Medical waste management

Medical waste should be segregated at source of generation by:

- Use of medical waste bins.
- Use of appropriately coloured bin liners.
- Use of sharp boxes.
7. Post-Exposure Prophylaxis

In the event that a HTS provider is exposed to HIV risk, post-exposure prophylaxis (PEP) will be provided. Post-exposure prophylaxis, also known as post-exposure prevention, is preventive medical treatment started immediately after exposure to HIV in order to prevent establishment of infection by the virus. PEP (post-exposure prophylaxis) requires taking antiretroviral medicines (ART) immediately after exposure. PEP should be used only in emergency situations and must be started within 72 hours after a recent possible exposure to HIV. The exposure to HIV can be during sex, through sharing needles, needle prick and sexual assault.

It is important to note that PEP is only given to HIV negative persons. Immediately after exposure, apply the following steps:

Step 1: Wash the areas exposed to potentially infectious fluids with soap and water.
Step 2: Flush exposed mucous membranes with water. Flush your eyes with saline if available.
Step 3: Do not apply caustic agents, including antiseptics or disinfectants, to the exposed areas.
Step 4: Offer counselling to the person who has been exposed to HIV infection.
Step 5: Counsel on prevention with sexual partners until HIV infection has been ruled out.
Step 6: Perform baseline HIV test on the person who has the exposure using a rapid antibody test.
  - If the HIV test is positive refer for cART.
  - If the test is negative PEP should be started immediately.
Step 7: If the source of exposure is known, he or she should also be offered HTS.
Step 8: In Zambia, currently all exposures are treated as high risk; therefore, cART is recommended.
Step 9: Start ARV medications within 1-2 hours of exposure if possible. PEP is more effective if initiated within 24 hours. Do not administer PEP after 72 hours after exposure.
Step 10: Administer PEP for 28 days.
Step 11: Client should be re-tested after 28 days.
Step 12: Also recommended: full blood count, liver and renal function tests.
8. Priority Populations

Priority populations refer to persons who are most at risk of getting infected with HIV and for whom priority interventions are required to mitigate the impact of the problem. Priority populations include the following:

- Infants and Children
- Adolescents
- Pregnant women
- Couples
- Men
- Inmates (Prisoners)
- Sex workers
- People who use drugs and other intoxicating substances
- Mental patients
- Disabled persons
- Migrant workers
- Cross Border Traders
- Truck drivers

8.1 Infants and Children

Children can be exposed to HIV through their infected mother; when they are sexually abused by an infected person and when they come into contact with infected blood and blood products. HIV testing at the time of birth improves linkage to treatment and reduces loss to follow-up. Diagnosing HIV-exposed infants early is critical to starting ART, thus preventing morbidity and mortality.

Morbidity and mortality are high in the first year of life among infants infected with HIV who are not linked to care and support. Evidence suggests that 50% of untreated HIV infected children will die before their first birth day while 80% will die by their fifth year of life. While early testing is increasing, there are still challenges of access, such as prompt return of test results and initiation of early ART among infants who test HIV-positive.

It is important to note the following:

- HIV testing for infants should be implemented with the aim of identifying as many HIV-infected infants as possible as early as possible.
- For infants and children under 18 months, HIV infection can be diagnosed only by virological testing; maternal HIV antibodies remain in the infant’s bloodstream until 18 months of age, making test results from serological assays ambiguous.
- Virological testing using nucleic acid testing (NAT) technologies can be conducted using dried blood spot (DBS) specimens, which are collected at local sites and sent to centralised laboratories for testing.
- For children 18 months of age and older (who were not breastfed or who have stopped breastfeeding at least six weeks earlier), standard HIV serological assays such as RDTs and EIAs can reliably determine HIV status.

In this period, early HIV testing, prompt return of results and rapid initiation of treatment must be done.

**HIV Counselling for Children**

The counselling process for children depends on special circumstances, including the developmental stage of the child and needs to be adjusted according to the child's age. It is important to remember that when a child is infected with HIV, the whole family is affected. Therefore, it is recommended that:

- The family should be involved in the counselling and testing process.
- When considering HTS for the child the welfare of the child must be of primary concern, for instance, the counsellor can postpone testing if it is not in the best interest of the child.
- Additionally, counselling should be offered to the parents/guardians to enable them to come to terms with the child's status and learn how to provide ongoing support.
- Counsellors and other caregivers who provide HIV testing and counselling to children must always ensure that the child has assented and the parent/guardian has given consent before proceeding to talk to the child.
- When conducting an HIV test on a child below the age of 16, the counsellors should consider giving information using the child's age appropriate language which includes the use of media such as toys, balls, writing and coloring.
- The parent/legal guardian of the child should be consulted in order to assess the emotional maturity of the child, as well as the presenting problem. Where necessary the child may be counselled alone but with consent from the parent/guardians.

**Counselling sexually abused children**

A child may come or be brought to the counsellor when sexual abuse is suspected. If the child is brought by parent/guardian establish why they have brought the child for counselling. However, since families may not always disclose that abuse has occurred, the counsellor will have to watch for signs and symptoms, and explore the possibility with the child to ascertain the risk of HIV infection.

**Recognising signs and indicators of sexual abuse**

Sexually abused children must be thoroughly screened for HIV, other STIs, pregnancy and other indicators of abuse. Table 2 below shows signs of abuse in children:

| **Table 2: Behavioural and Physical Indicators of abuse in children** |
|--------------------|-----------------------|
| **Behavioural indicators** | **Physical indicators** |
| Excessive crying. | Unexplained pain, swelling, bleeding or irritation of the mouth, genital or anal area. |
| An increase in irritability or temper tantrums. | Sexually transmitted infections (sores, discharge, frequent itching of the genitals). |
| Fears of a particular person or object. | Pregnancy. |
| Disrespectful behaviours. | Unexplained difficulty in walking. |
| Aggression towards others. | Increase in headaches or stomach aches. |
| Sudden change in school performance. | Bruises and other physical marks. |
| Bedwetting or soiling of pants. | |
| Age-inappropriate sexual knowledge. | |
| Sexualised play (e.g., trying to have sex with other children). | |
| Unexpected change in a child's behaviour (for example, a lively, outgoing child suddenly becoming withdrawn or | |

*Members of the public have a legal responsibility to report cases of child abuse to the police/VSU/Child Protection Unit/YWCA*
Testing methods for HIV infection in children

Testing for HIV infection in children is conducted using various age-appropriate methods as shown in table 2.

Table 3: Age-appropriate HIV infection testing methods in children

<table>
<thead>
<tr>
<th>Age</th>
<th>Testing Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>For children less than 18 months</td>
<td>Collect DBS and follow EID protocols and guidelines.</td>
</tr>
<tr>
<td>For children above 18 months of age</td>
<td>Perform HIV RDTs as per national testing guidelines and protocols.</td>
</tr>
</tbody>
</table>

It is important to note that e-MTCT programme recommends children at 12 months are tested for HIV using RDTs to capture children exposed to HIV. Those who test positive DBS must be collected for EID.

Client Specific HIV testing considerations in children

Testing should only be done in the best interest of the child; there should not be any form of coercion from the counsellor. However, mandatory testing should only be considered as a means of saving the life of a child in accordance with the Law.

Table 4: Child Categories and Considerations for HIV Testing

<table>
<thead>
<tr>
<th>Child Category</th>
<th>Consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sick children</td>
<td>Testing for sick children could be indicated as provider-initiated testing and counselling (PITC). However both child and the parent/guardian must receive appropriate counselling before testing the child.</td>
</tr>
<tr>
<td>Orphans and Vulnerable Children (OVCs)</td>
<td>Children who live on the street, are in prisons, are displaced, those heading households, are refugees and those at risk of contracting HIV due to abuse should be referred to a Probation Officer, Social Welfare Officer, Medical Social Worker or any adult who has the authority to provide consent and ensure support systems are in place before testing them.</td>
</tr>
<tr>
<td>Sexually abused children</td>
<td>HTS should be done as part of standard care to determine management of the sexually abused child. Infected children should be managed as per Pediatric Antiretroviral Treatment (ART) guidelines, those testing negative and have been sexually abused must access Post-exposure Prophylaxis (PEP) as soon as possible preferable not later than 72hrs after exposure.</td>
</tr>
<tr>
<td>Children with special needs</td>
<td>Children with special needs should be given special attention using appropriate media and techniques to cater for their disability. This category includes children with hearing, speech, visual and mental disabilities. Counselling for these children should be conducted in an environment that takes into consideration their special needs. Counsellors dealing with a child under this category should be equipped with appropriate skills and work in consultation with a specialist in the area of disability.</td>
</tr>
</tbody>
</table>
Advantages of testing children for HIV Infection

If children know they are HIV positive, they can:

- Access information and services to prolong their life, for example by improving their diet and taking exercise.
- Gain the support of others in a similar situation, for example by joining a support group of peers.
- Be helped to understand how to avoid infecting others.
- Become a role model by showing that you can live well with HIV.
- Experience the relief of knowing the truth rather than being worried and stressed about the unknown.
- Be able to pursue their right to health including ART.

WHO Recommendations for HIV Testing in children

- It is recommended that all HIV-exposed infants have HIV virological testing at four to six weeks of age or at the earliest opportunity thereafter (It is recommended that all HIV-exposed infants undergo HIV serological testing at around nine months of age or at the time of the last immunization visit). Infants who have reactive serological assays at nine months should have a virological test to identify HIV-infected infants who need ART.
- It is recommended that children 18 months of age or older with suspected HIV infection or HIV exposure have HIV serological testing performed according to the validated national testing algorithm used in adults.
- It is recommended that infants with signs or symptoms suggestive of HIV infection undergo HIV serological testing and, if reactive, should be referred for virological testing Children of school age (6–12 years old) should be told their HIV-positive status and their parent’s or caregiver’s status; younger children should be told their status incrementally to accommodate their cognitive skills and emotional maturity, in preparation for full disclosure.

Disclosure of HIV status in children

Disclosure is the process of informing a child of her/his HIV status. Disclosure may also involve the sharing of caregiver’s and other family members’ HIV status. The counsellor needs to think critically about disclosure of HIV positive status to a child. This is because it may have a number of implications.

When to disclose to children

It should be noted that disclosure is a process and not an event. It is advisable to start this process as soon as the child shows readiness to understand and accept the HIV test results. Disclosure of HIV status in children should be considered when the child is mature enough to comprehend information being disclosed between the ages of 5 and 10 years. Parents/guardians must be helped by the counsellor to deal with their own fears about how they will inform their child that he or she is infected with HIV. The following are some of the situations that may warrant a child being informed of his or her HIV status. Caution must be taken to avoid overloading a child with too much information which will not be beneficial to the child.

Who should disclose to children

Parents/guardians are the best persons to disclose the child’s HIV status to the child must be encouraged to do so because they are the ones who know the child better and can provide answers when the child starts asking questions about their health or why they may be taking particular medication. However, the
counsellor should facilitate the process of disclosure. In cases where the parents/guardians are unable to disclose, the counsellor should support them to disclose to the child.

**How to disclose HIV status to children**

The following should be considered when disclosing:

- Take time just to get to know the child (use various age-appropriate techniques/mediums).
- Create a sense of safety for the child or involve the parent(s)/caregivers.
- Address fears of loss and abandonment.
- Provide information to the child in an age-appropriate manner.
- Directly address silence/secrecy.
- Encourage openness in the disclosure/treatment process.
- Assess the possibility of negative reactions such as depression, anxiety, suicidal ideations.
- Assess current family/social/community support system
  - Assess child's/caregivers' knowledge base of HIV/AIDS.
- Move from the “known to the unknown”.

**Treatment Adherence Support for HIV positive Children**

Children testing HIV positive should be referred to the ART clinic for commencement of ART as per the Zambia Paediatric ART guidelines. Without treatment, HIV can progress rapidly in children, damaging their immune system and ultimately causing illness and death. Children, who are successfully provided with Antiretroviral Therapy (ART), can live relatively healthy lives. All HIV positive children must be assessed for ART adherence at each and every visit. Adherence assessment methods may include:

- Keeping appointments.
- Self-report – most often used in clinical settings.
- Direct observations – by caregiver or family member most often used at community level.
- Viral load level response.
- Verifying prescription refills.
- Pill counts/bottle checks.
- Pill taking diaries

**8.2 Adolescents**

WHO defines an adolescent as anyone aged between 10 and 19 years. Adolescents are generally at higher risk of contracting HIV because of many physiological, emotional and social changes that accompany their maturity process such as changing bodies, the need to feel appreciated, peer influence, curiosity and the desire to form relationships. These may also influence adherence to treatment, and play a role in the incidence of drug resistance among them. Authorities should consider supporting adolescents with strategically designed interventions such as:

- Youth friendly HTS services in health care facilities, schools, social clubs including church.
- Youth friendly reproductive health services.
- Support groups where they can feel free to share critical issues of their lives with their peers.

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5 Refer to Child counselling manual for the SOPs for disclosure
• Services need to be convenient and available, through flexible opening hours and/or walk-in or same-day appointments. Separate hours and special events exclusively for adolescents may help overcome:
  a) Links with other agencies.
  b) Referral to youth network: HTS sites should compile a register of the local youth network so that adolescents may be referred for other activities. HTS providers should work to ensure that adequate youth-friendly services are available and accessible.
  c) Condoms: for adolescents that are sexually active, male and female condom education and demonstration should be provided during counselling sessions. Condoms should be offered to the sexually active.

Only health care providers who are qualified to work with children should be allowed to provide HTS to adolescents below 16 years. To provide HTS to adolescents below the age of 16, parental/guardian consent must be sought.

Considerations for HIV Testing in Adolescents

In all settings HIV testing services, with linkages to prevention, treatment and care, are recommended for adolescents from key populations. In generalized epidemic settings such as Zambia, HIV testing services, with linkage to prevention, treatment and care, are recommended for all adolescents.

In low-level and concentrated epidemic settings, HIV testing services, with linkage to prevention, treatment and care, should be accessible to all adolescents. In all settings adolescents should be counselled about the potential benefits and risks of disclosure of their HIV status and supported to decide whether to disclose, when, how and to whom.

8.3 Pregnant Women

Initiating ART early in pregnancy reduces chances of baby being born with HIV. Therefore, early prevention, treatment and care strategies aimed at reducing the risk of HIV transmission to infants should be promoted through comprehensive HTS activities at the MCH, maternity wards, obstetrics and gynaecology clinics including female medical and surgical wards.

HIV diagnosis in pregnant women should be made following the approved National Algorithm. All HIV positive pregnant women should be initiated on ART regardless of their CD4 count. Retesting of HIV positive pregnant women is recommended in the third trimester, or during labour or shortly after delivery, because of the high risk of acquiring HIV infection during pregnancy. Lactating mothers who are HIV-negative should be retested periodically throughout the period of breastfeeding, as there is a risk of acquiring HIV at this time.

8.4 Couples and Partners

Most of the new HIV infections occur among people in a long term relationship because they do not realize that they are at risk. Current preventive interventions have not fully targeted couples as a special population group and there are few prevention programs for couples. Negotiations for safe sex among couples should to be promoted.

Therefore, targeting partners of HIV infected persons is an efficient and effective way of identifying more people who can benefit from treatment. Couples and partners should be offered HIV testing services with support for mutual disclosure. Couples and partner HTS can be conducted in various settings, including
ANC and community-based TB services, through home-based HTS, during premarital health visits and in couples’ HIVST. People attending ART services should be encouraged to bring their partners to be tested.

8.5 Men

Fewer men than women report ever testing for HIV. As a consequence, men are more likely to start ART at later stages of HIV infection and thus experience higher morbidity and mortality. There are a number of barriers to men’s access to HTS. These include, fear, stigma, the perception that health facilities are “female” spaces.

Maximising men’s uptake of HTS requires a strategic combination of the following approaches:

- Facility based HTS.
- Community-based HTS.
- Work place based HTS.
- Mobile HTS.
- HTS services in VMMC clinics

8.6 Other Vulnerable Groups

Vulnerable groups are those persons who are likely to suffer stigma, discrimination, rejection and or abandonment as a result of their social status. HIV testing services should be routinely offered to all vulnerable populations in the community while linkage to prevention, treatment and care services should also be recommended in addition to provider initiated testing and counselling. Retesting at least annually is recommended for all people from key populations. More frequent voluntary retesting may be beneficial, depending on risk behaviours.

In-mates (Prisoners)

Incarcerated persons do not only require humane treatment in prison but are entitled to comprehensive health care services including HIV testing services. Where HIV Testing Services are not available within the prison setting, prison authorities should ensure to that these are sourced from partners within their districts.

Sex workers

By nature of their work, sex workers (males and females) are constantly exposed to the risk of contracting HIV from their clients. Comprehensive community-based HIV Testing Services coupled with adequate referral services to prevention, care and treatment should be promoted in the districts.

Migrant and mobile populations

This group includes long distance truck drivers, cross border traders, fish traders and migrant workers. Just like Migrant workers, people who travel to and from different locations to do business sometimes stay long in those locations. They may fall prey to business relations which puts them at high risk of contracting HIV and infecting their partners when they return home. Border towns and fishing camps should be equipped with adequate HIV Testing, treatment and referral services to cater for the vulnerable population groups.
People who use drugs and other intoxicating substances

Ingestion of intoxicating substances is a risk factor for HIV infection. In Zambia, alcohol and marijuana are commonly used substances. Drug addicts who use needles and syringes to inject drugs are at a very high risk of contracting HIV from those whom they share needles with. Therefore, drug addiction treatment and rehabilitation facilities should include comprehensive HIV Testing, treatment and referral services to ensure that such drug addicted clients are also adequately screened for HIV.

Mental patients

Mental illness is inextricably linked with HIV/AIDS, both as a causal factor and as a consequence. The number of HIV-infected persons presenting with neuropsychiatric symptoms of HIV/AIDS increases if they are not put on ART. Comprehensive HIV Testing, prevention, treatment and referral services should therefore be promoted in all mental health facilities to ensure that mental patients are adequately screened.

Disabled persons

Disabled persons have limited access to HIV Testing Services because many buildings are not user-friendly especially to people who use wheel-chairs including the visually and hearing impaired. Efforts should be mobilized to ensure that HIV Testing Services are easily accessed by disabled persons and well-designed I.E.C. materials meant for the visually and hearing impaired are made available. Counsellors who are trained in sign language should also be made available to ensure that the HTS needs of the hearing impaired persons are well-catered for.
9. Disclosure of Results

The following should be taken into consideration when giving HIV test results to clients:

- For reactive results, reference should be made to the guide on disclosure.
- Ensure the results are for the right client to avoid error.
- Ensure the client has support from the parent/guardian/caregiver in the process of receiving results.
- Establish if they have come for the results and if not, find out when they would come (encourage them to get results as soon as possible).
- If they have come for the results give without hesitation.
- Clarify details and rationale for giving test results.
- Deliver test results in a clear, calm and professional manner. People will be anxious and may have waited for a considerable length of time for the results.
- Do not attach a judgment or value to the result, such as “I have good news…”, “I am sorry to inform you that…” and “I regret to inform you that…” but say “your results are ready and you have been found to be…” or “your blood has been tested and the results are…”
- Give time for the client to absorb the information and wait for a response before proceeding.
- Check their understanding of what the result means.
- If the result is no-reactive; inform them about the window period.
- Reinforce confidentiality.

10. Confidentiality

Confidentiality is the ethical practice of protecting clients' privacy by keeping information that they provide strictly confidential. The United Nations Convention on the Rights of the Child (UNCRC) specifically refers to the fact that every child has the right to have his/her privacy respected. In the context of HIV testing, every child has a right to have his/her HIV test result maintained confidentially. However, in situations where keeping such information may not be in the best interest of the child, the counsellor should educate and encourage the child on the importance of sharing such details with the child's parents or guardians and other healthcare providers (shared confidentiality).
11. Quality Assurance

Quality assurance system will ensure that personnel are accountable for service delivery that meets the stipulated standards, at every point in the service.

- Services are implemented in a manner that meets the needs and expectations of the client and the community.
- Managers have tools that enable them to supervise and mentor staff.
- There is qualitative monitoring of HTS.

In Zambia, the relevance of quality HTS particularly in the health sector is in line with the goal to increase the number of people who know their HIV status. It is also to ensure that those testing HIV positive have access to ongoing quality care treatment and support services.

Quality Assurance is a very important consideration in providing HIV testing services. Any result, whether positive or negative, carries with it major implications in a client’s life. False positive and false negative results must be eliminated. Therefore, all components of QA i.e., pre-analytical, analytical and the post analytical phases must be adhered strictly.

11.1 Quality Assurance for HIV Counselling

A quality counselling session is one that is non-judgmental, genuine, accessible and client centered. It should help the client focus on solution and risk reduction. Only trained counsellors on counselling and testing should conduct counselling. In order to ascertain quality of counselling at all HTS sites, counsellors must adhere to the code of counselling ethics at all times and constantly refer to the ZCC code of conduct for counsellors. The following should be put in place to ensure provision of quality counselling services

Staff training

The counsellors should have undergone a comprehensive counsellors’ training by recognised institution(s) as prescribed by the Ministry of Health.

Follow up/Refresher training

To ensure quality counselling, counsellors should undergo regular refresher trainings to improve counselling skills and update HIV/AIDS knowledge annually.

Regular Supervision

Counsellors should be supervised/supported and mentored through regular technical support visits by their supervisors to prevent burnout. Burnout refers to a state of mental, physical, emotional and spiritual exhaustion caused by excessive and prolonged stress. This can be done individually or in groups.
Counsellor groups meetings should be encouraged among counsellors trained in peer supervision. This will ensure quality of the counselling services.

**Monitoring Counselling sessions**

With the consent of the client, a counsellor can be observed by an experienced counsellor supervisor while in session. The value of observed practice is that it gives the counsellor instant feedback from a supportive senior counsellor or supervisor.

Clients of HIV counselling should also demand quality in the counselling services provided to them, in both community-based and facility-based programs.

**Counsellor Supervisor Evaluation Form**

After observing a counsellor, the supervisor should complete the checklist and point out areas where the counsellor requires additional support as well as monitoring improvements in their performance over time. It is recommended that each Counsellor supervisor fills out this checklist at every supervisory visit.

**Client exit survey**

Each testing site should conduct one client exit interview weekly. These interviews should be compiled at the end of every month for analysis. Exit interviews should be kept short and be relevant. Typical questions include factors such as waiting time, cleanliness, counsellor attitude and overall satisfaction with the service.

**Mystery client survey**

A mystery client should be trained HIV counsellors a person who visits an HTS site as a regular client, while in actual fact they are there to assess the quality of services provided by counsellors. Mystery clients should be prepared to be tested on several occasions. The use of mystery clients to assess the quality of service delivery is a well-established method, this should however be used with caution.

**Stress management**

Adequate stress management prevents counsellors from burnout. Facility and community based programs should have systems in place to help counsellors avoid stress. Suggested strategies include encouraging counsellors to take some time off, reducing counsellor work load, having a support system where counsellors can report the challenges they encountering, exchange visits, and formation of a counsellor support networks.

**11.2 Quality Assurance for HIV testing**

Providers of HIV testing should strive to provide high-quality testing services, and QA mechanisms should ensure that people receive a correct diagnosis. QA may include both internal and external measures and should receive support from the national reference laboratory. All people who receive a positive HIV diagnosis should be retested to verify their diagnosis before initiation of HIV care or treatment. Linkage to prevention, treatment and care services should include effective and appropriate follow-up, including long-term prevention and treatment support.
Quality testing is a system designed to continuously improve reliability and accuracy of test results. It monitors all parts of the testing system, detects and reduces errors, improves consistency between testing sites and helps contain costs.

Accuracy and reliability of HIV test results are critical to the success of HIV/AIDS programmes. In order to ensure reliability and minimise errors, a quality system that addresses all aspects of the testing are essential.

To achieve quality results in HIV testing personnel should be adequately trained and Standard Operating Procedures (SOPs) to ensure correct interpretation of HIV test results. It should be noted that correct use of HIV test kits does not automatically guarantee accurate test results because errors can occur at any stage during the testing process such as during sample collection, testing, result interpretation and reporting.

It is the ethical responsibility of all people conducting HIV testing (including lay providers) and all programs or facilities offering HTS to conduct testing according to quality management system principles to ensure the highest level of quality and accuracy.

11.3 Quality Control

Quality control is an important means of verification by the test user that the test kit(s) and the procedures used are performing according to the manufacturer’s specifications. Two broad types of quality control should be used as quality assurance measures when performing point-of-care testing. These are (i) built-in quality controls and (ii) the use of quality control specimens.

Built-in internal quality controls are built into the testing device, forming an intrinsic part of the testing process. A control line or spot on rapid diagnostic tests, for example, is part of the device and indicate whether the proper procedure was followed. The absence of a control line or spot indicates invalid results, and the test should be repeated with a new sample. The results of quality control specimens should routinely be recorded and analysed to ensure the validity of the results. Control specimens are specimens whose HIV status is known. Known HIV positive and negative specimens can be used as controls. These can be obtained from a commercial supplier or made locally by the laboratory.

The following controls should also be run:

- Daily before starting to test patient specimens for high volume sites (sites testing 80 samples and above per week).
- Once a week, preferably at the beginning of the week, for low volume testing sites (sites testing below 80 samples per week).
- When a new tester is performing testing.
- When a new kit lot number is being used.
- When a new shipment has been received.
- When kits are exposed to the environmental conditions that fall outside the range needed for stability as designed by the manufacturer.

11.4 External Quality Assurance

EQA is designed to monitor HIV testing sites using the external party to determine the knowledge expertise and performance of personnel performing the test and the accuracy of the results. EQA enables the performance of a testing site to be regularly evaluated by an external laboratory or national quality
assurance programme. EQA is designed to identify sites and testers needing assistance. EQA can be conducted in multiple ways, namely re-testing, on site monitoring and proficiency testing.

11.5 Re-Testing

This model applies in a facility with a laboratory where every tenth sample is selected from a testing site and sent to the laboratory for retesting.

11.6 On-site Monitoring

In this model an external assessor visits the HIV testing site to review all aspects of the quality management system using a standardized supervisory tool. A team from the supporting laboratory will monitor testing sites under their jurisdiction quarterly. The supporting laboratory is monitored by a team comprising officers from the DMO and PMO during technical assistance and performance assessment.

11.7 Proficiency Testing

At regular intervals a panel of specimens with known reactivity will be send to all participating sites which will test the specimen and return results to the National Reference Laboratory. Results will be analyzed and information provided back to the participant testing site. Proficiency testing helps to ensure accurate, precise, and valid results. Community testers will undergo competence assessment once every two years.

11.8 Roles and Responsibilities Stakeholders in the National Health System

A well functional QA system requires clearly defined roles and responsibilities at various levels of the health delivery system. Table 5 below shows the some of the roles and responsibilities of stakeholders in the health system.

Table 5: Roles and Responsibilities Stakeholders

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Roles &amp; Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOH</td>
<td>• Update and maintain national HTS data.</td>
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<tr>
<td></td>
<td>• Review of the HIV testing training curriculum.</td>
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<tr>
<td></td>
<td>• Monitor the implementation of the QA strategy.</td>
</tr>
<tr>
<td></td>
<td>• Regulate quality of service delivery through HTS site registration and certification.</td>
</tr>
<tr>
<td></td>
<td>• National forecasting and quantification, procurement and distribution of HIV commodities.</td>
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<tr>
<td></td>
<td>• Coordinate partners involved in HTS.</td>
</tr>
<tr>
<td></td>
<td>• Regulate information dissemination.</td>
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<tr>
<td></td>
<td>• Regulate the use of HIV testing devices.</td>
</tr>
<tr>
<td></td>
<td>• Regularly review the HIV testing algorithms.</td>
</tr>
<tr>
<td></td>
<td>• Monitor the performance of HIV testing devices (post-market surveillance).</td>
</tr>
<tr>
<td></td>
<td>• Regulate the national QA laboratory system.</td>
</tr>
<tr>
<td></td>
<td>• Regulate the collection, management, storage and dissemination of HTS data.</td>
</tr>
<tr>
<td>NAC</td>
<td>• Facilitate review of guidelines for HTS services.</td>
</tr>
<tr>
<td></td>
<td>• Facilitating Theme Groups operations.</td>
</tr>
<tr>
<td></td>
<td>• Facilitate the review of the HIV/AIDS policy.</td>
</tr>
<tr>
<td>Stakeholder</td>
<td>Roles &amp; Responsibilities</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>National Reference Laboratory</td>
<td>• Provide technical advice and guidance on QA issues.</td>
</tr>
<tr>
<td></td>
<td>• HIV Test device evaluation and validation.</td>
</tr>
<tr>
<td></td>
<td>• Coordinate the National HIV EQA Program and other National EQA programs as mandated by MOH.</td>
</tr>
<tr>
<td></td>
<td>• Validate testing algorithms.</td>
</tr>
<tr>
<td>District level</td>
<td>• Implement HTS QA and QI activities.</td>
</tr>
<tr>
<td></td>
<td>• Ensure adherence to HTS standards.</td>
</tr>
<tr>
<td></td>
<td>• Train and supervise QA activities at the site level.</td>
</tr>
<tr>
<td></td>
<td>• Register and certify HTS sites.</td>
</tr>
<tr>
<td></td>
<td>• Coordinate all training, certification and supervision of sites and personnel.</td>
</tr>
<tr>
<td></td>
<td>• Implement quality improvement activities.</td>
</tr>
<tr>
<td></td>
<td>• Supervision of public and NGOs, private/stand-alone HTS centers.</td>
</tr>
<tr>
<td></td>
<td>• Data collection from HTS sites and reporting to the province.</td>
</tr>
<tr>
<td></td>
<td>• Provide bi-annual support supervisory visits to sites.</td>
</tr>
<tr>
<td></td>
<td>• Distribution of HIV test kits to HTS centers.</td>
</tr>
<tr>
<td></td>
<td>• Coordinating, conducting, facilitating, and monitoring training.</td>
</tr>
<tr>
<td></td>
<td>• Appoint and monitor supervisors, coordinators, and community counsellors.</td>
</tr>
<tr>
<td></td>
<td>• Ensure timely reporting and ordering of HIV test kits and supplies for HTS activities in the district.</td>
</tr>
<tr>
<td></td>
<td>• Plan and budget for resources for QA.</td>
</tr>
<tr>
<td></td>
<td>• Ensure that testers are re-certified every two years.</td>
</tr>
<tr>
<td></td>
<td>• District maintains register for testers.</td>
</tr>
<tr>
<td>Facility</td>
<td>• Report and order HIV test kits and supplies.</td>
</tr>
<tr>
<td></td>
<td>• Maintain good records.</td>
</tr>
<tr>
<td></td>
<td>• Provide monthly HTS reports.</td>
</tr>
<tr>
<td></td>
<td>• Adhere to standard operating procedure and national guidelines on HTS.</td>
</tr>
<tr>
<td></td>
<td>• Evaluate client satisfaction with HTS services.</td>
</tr>
<tr>
<td></td>
<td>• Create demand for HTS.</td>
</tr>
<tr>
<td></td>
<td>• Participate in EQA.</td>
</tr>
<tr>
<td></td>
<td>• Supervise and maintain register for testers including community testers.</td>
</tr>
</tbody>
</table>

**Site Registration and Certification**

*Registration* is mandatory for all new sites wishing to provide HTS service. Registration involves an objective quality evaluation of key structural measures that need to be in place before a site code is issued, allowing the site to provide HTS.

*Biennial certification* will be undertaken by the DMO and PMO to determine whether standards are adhered to.

**Guidance for Registration and Certification**

In order to register a new HTS site the person in charge of the facility will write to the DMO requesting for site registration using the standardized national registration and certification tools. The DMO that is
responsible for registration will then use the standardized national registration and certification tools to make an assessment of the site. MOH will then issue a site code and register the site. On a biennial basis, DMO will assess HTS sites for the purposes of certification.

11.9 Summary of Steps for HTS Site Registration and Certification

Table 6: Steps for HTS site Registration and Certification

<table>
<thead>
<tr>
<th>Steps</th>
<th>Action</th>
<th>Responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Apply for registration to DMO</td>
<td>Each HTS Center</td>
</tr>
<tr>
<td>2</td>
<td>Site Assessment</td>
<td>DMO (use registration tool)</td>
</tr>
<tr>
<td>3</td>
<td>National Registration (update database)</td>
<td>National level (MOH)</td>
</tr>
<tr>
<td>4</td>
<td>Provision of registration code to DMO (Duplicate copy sent to PMO)</td>
<td>National level (MOH)</td>
</tr>
<tr>
<td>5</td>
<td>Assessment for biennial Certification</td>
<td>DMO (Use biennial Certification tool)</td>
</tr>
<tr>
<td>6</td>
<td>Submit completed biennial certification tools and provide the result of certification to MOH (Duplicate copy sent to PMO)</td>
<td>DMO</td>
</tr>
<tr>
<td>7</td>
<td>Provision of biennial Certification</td>
<td>MOH</td>
</tr>
</tbody>
</table>

It's important to note that sites that no longer meet national criteria through modification of standard operating procedures, lack of adherence to bio-safety measures or poor quality of counselling and testing may temporarily be closed by DMO. DMO shall inform PMO on erring sites and take appropriate corrective action.

11.10 Personnel registration and certification

All personnel involved in HIV testing are required to be registered and certified by the national certification body. This is in line with the personnel certification model. The tester has to ensure that the certification status is up to date if they have to be allowed to perform HIV rapid testing.
12. Logistics Management

The quality of point-of-care testing depends strongly on reliable availability of test kits and consumables at testing facilities. With the rapid increase in the roll-out of point-of-care testing to increasingly rural, remote and community testing sites, a large burden has been placed on the logistics systems.

Proper management of HIV test kits will ensure that a consistent supply of test kits is available when and where needed to meet the needs of clients requiring HIV testing. Consistent supply of HIV test kits depends on a well-functioning logistics management system and competent personnel.

Handling Damaged or Expired HIV Test Kits

Logistics systems try to minimise the amount of damaged or expired stocks. However, if expired or damaged HIV test kits are found at a testing site, procedures illustrated in table 7 below should be followed:

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Action to be taken</th>
</tr>
</thead>
</table>
| Health Centres, NGOs and other testing sites | All damaged and expired HIV test kits must be removed from the inventory to a separate place so that they cannot be used.  
  a) Subtract the stock from the usable stock and update the stock control card.  
  b) Complete the “Report for returning products” and make arrangements to send the stock to the DMO. |
| Hospitals |  
  a) All damaged and expired HIV test kits must be removed from the inventory to a separate place so that they cannot be used.  
  b) Subtract the stock from the usable stock and update the stock control card.  
  c) Fill in the Drugs and Medical Supplies Disposal Procedures Form.  
  d) Dispose of expired or damaged HIV test kits according to the Zambia Environmental Management Authority (ZEMA) guidelines. |
| DMOs |  
  a) All damaged and expired HIV test kits must be removed from the inventory to a separate place so that they cannot be used.  
  b) Fill in the Drugs and Medical Supplies Disposal Procedures Form.  
  c) Dispose expired or damaged HIV test kits according to the Ministry of Health established disposal procedures. Refer to the stores manual for Districts and Hospitals. |
13. **Data Management**

Monitoring and evaluation of HTS sites is important to maintain required standard and should be conducted in accordance with the National Site and Personnel Certification protocols, the counselling code of ethics and the HIV counselling guidelines.

All testing sites, including private and civil society organisations must use MoH HTS registers and must submit monthly returns to the respective DMO. HTS data from testing sites should be entered into the HIMS. All copies of clients’ registers should be kept in well-secured lockable filing cabinets.

**Quality Data Management**

Quality Data Management includes accurate recording, timely reporting and appropriate entry and storage of data before it can be analysed and fed back to the appropriate service providers. The following are some of the key elements for assuring quality of data management:

1. **Data Collection**

Data at HTS sites is collected on the MOH HTS Register and Daily Activity Register for individual clients seeking the service. All persons collecting data must be trained in the use of the standardised registers.

2. **Reporting on data**

When reporting data on HTS, the following should be considered:

- All HTS sites including private and civil society organisations **must** submit monthly reports using HIA1 and HAI2 tools to the DMO by the stipulated reporting day.
- Each site produces a monthly aggregation of summarized data in line with national reporting requirements.
- The summarised electronic reports are forwarded to the DMO.
- The electronic data is then further transmitted to the PMO which in turn submits this data to the Ministry of Health.
- Timely reporting and submission is extremely important so that national and provincial databases can be kept accurate and up to date.

3. **Data Entry, Analysis and Storage of Data**

All data entry staff should be trained in using the approved software for HTS data. The staff at the district, provincial and national level should be trained on how to analyse data to produce information used for planning and policy formulation regarding quality service provision. All copies of clients’ registers should be secured to ensure confidentiality of clients’ details. Electronic data should be backed up on a regular basis.

4. **Feedback**

Feedback mechanisms have to be in place to ensure that each level of services and management and staff is informed on the findings. Therefore, HTS sites, DMOs, PMOs should follow the appropriate feedback mechanism in place.
List of References

15. World Health Organization, Adolescent Health: www.who.int/topics/adolescent_health/en/
Annex 1: Daily Activity Register for HIV Tests

Date: _________________________________

Day/month/year

<table>
<thead>
<tr>
<th>Type of Test</th>
<th>Screening</th>
<th>Confirmatory</th>
<th>Tiebreaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beginning Balance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quantity Received</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Client No.</td>
<td>Purpose*</td>
<td>Result</td>
<td>Result</td>
</tr>
<tr>
<td>Quantity Used</td>
<td>Page Total</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Losses/Adjustments</th>
<th>Page Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Count</td>
<td>Daily Total</td>
</tr>
<tr>
<td>Remarks:</td>
<td></td>
</tr>
</tbody>
</table>

* Purpose of the Test: VCT, PMTCT, Clinical Diagnosis (CD), Quality Control (QC), Other (explain)

<table>
<thead>
<tr>
<th>Type of Test</th>
<th>Product</th>
<th>Summary of HIV Tests Used by Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>VCT</td>
<td>PMTCT</td>
</tr>
<tr>
<td>Screening</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confirmatory</td>
<td></td>
<td></td>
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<tr>
<td>Tiebreaker</td>
<td></td>
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<tr>
<td>TOTAL</td>
<td></td>
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</tbody>
</table>
I. Facility

The physical facility should display a level of professionalism and client orientation relevant to the population served.

__________________________________________
The site must be geographically accessible to the population it serves. The site must operate during appropriate hours and minimize any delay in providing services.

Counseling rooms must be private to ensure confidentiality of the counseling session.

II. Staff

Counselors must meet locally established qualification standards, i.e., Must have a HIV Psycho-social Counselling Certificate and an HIV Rapid Testing Certificate. Are there counsellors’ certificates filed in the Health centre in-charges Office? Is there a written job description should be provided for all counselors.

Any evidence of performance tasks and standards established and reviewed with each counselor?

All counselor and supervisory staff should be familiar with all services connected with the counseling program.

New counselors should be observed (with client consent) daily until proficiency is assured and periodically thereafter to ensure that proficiency is maintained.

The supervisor should routinely provide constructive feedback to the counselor based on observations.

The supervisor must ensure adequate on-site supervision for staff. Any evidence of written site supervision?

Case presentations should be conducted routinely, using techniques such as team problem solving sessions with medical, supervisory, and counseling staffs.

Each counselor and supervisor should be provided additional information through training and/or in-service about HIV, STIS, TB, immunization, family planning, substance abuse, and early interventions such as antiviral treatments, etc.

III. Educational and Risk Reduction Materials

Are condoms available to the client-directly from providers and easily accessible without the client having to ask? If no, state the reason why not available.

Are current written materials prominently displayed in public areas and made available to clients? (Posters, leaflets & pamphlets)

Are there current written and audiovisual materials culturally and linguistically appropriate for the client population? Materials sensitive to the reading levels, gender, and ethnicity of the client population.

IV. OBSERVATION OF COUNSELING SESSION

WHO has defined five key components—the “5 Cs”—that must be respected and adhered to by all HTS services. These components are:

Consent
Confidentiality
Counselling
Correct test results
Connection/linkage to prevention, care and treatment.

**Necessary Elements to assessment of HIV Testing Services**

**Confidentiality**

Strict protection of client confidentiality
Must be maintained for all persons offered and receiving HIV testing services

**Risk Assessment**

Risk assessment is the portion of a client-centered discussion that encourages the client to identify, understand, and acknowledge his or her personal risk for acquiring HIV.

**Prevention Counseling**

Counseling provides a critical opportunity to assist the client in identifying his or her risk of acquiring or transmitting HIV. It also provides an opportunity to negotiate and reinforce a plan to reduce or eliminate behavioral risk. Counseling prior to HIV testing (pretest) should prepare the client for receiving, understanding, and managing his or her test result.

**Providing Test Results**

Providing HIV antibody test results to a client involves interpretation that is based upon the test result and the client's specific risk for HIV infection. Knowledge of HIV status is important information that a client can use to plan behavior change. Skillful, client-centered counseling is required to reassess behavioral risks which may influence the interpretation of test results. The client will most often focus on the actual result itself rather than behavioral and prevention messages.

**Provision of Referrals**

Clients may require referral for physical and psychological evaluations, appropriate therapies (i.e., drug treatment), and support services to enhance or sustain risk reduction behaviors. Each program should maintain complete knowledge of referral resources, including the availability, accessibility, and eligibility criteria for services.

**V. Fundamentals of Rapid HIV Testing**

The Mentor must observe the Rapid HIV Testing service offered by the providers:
Does the Counselor/Tester have a certificate in HIV Rapid Testing?
Yes---------No-----If no explain reason allowed to test-------------------------
Demonstrate safe work practices. ---------------------------------------------
Identify the quality assurance (QA) steps required before, during, and after rapid HIV testing to assure accurate and reliable results. ---------------------------------------------
Perform a finger stick and collect a blood sample. ---------------------------
Perform a rapid HIV test correctly, following the national protocol---------------------
Demonstrate the integration of HIV prevention counseling into the rapid testing process.
VI. Referral Service Development

A thorough client assessment often indicates a need for services that cannot be provided by the counselor (e.g. drug treatment, peer support groups, etc.). To ensure that clients receive appropriate care, the program must establish a procedure for referring persons to sites that provide services in a timely, efficient, and professional manner. A collaborative relationship should have already been established with the appropriate representative of the referral site.

HIV prevention program managers must develop a process for routine referral which include the following:

A written referral process for identifying, evaluating, and updating referral sources

A mechanism to provide clients with immediate access to emergency psychological or medical service;

Appropriate referral resources for;

Any client at-risk for HIV infection who may be in need of support to maintain safer behaviors, HIV positive or high risk HIV negative clients who need STIS diagnosis and/or treatment, and HIV positive persons who need a medical assessment.

Written standards for the follow-up of confidentially tested HIV positive clients who do not return for results and counseling.

VII. Risk Assessment Development

Health center In-Charges, from sites that provide HIV counseling services, should review available data to identify site-specific HIV prevention needs. (This review and evaluation should include AIDS case surveillance data, HIV seroprevalence data, STIS morbidity, prevention counseling data), demographic and risk behavior profiles of the population and the catchment community served by each site. Based on analysis of these data, the program should develop policies for each site that address the appropriate provision of primary and secondary HIV prevention services e.g. HTS Campaign.

Is there an establishment of site-specific demographic and risk profiles, based on analysis of HIV test data;

Is there ongoing collection and review of available site-specific data, including AIDS case surveillance data, HIV seroprevalence data, STIs morbidity, prevention counseling data, demographic, and risk behavior profiles for targeting of resources and quality assurance of service delivery;

Determination of appropriate site-specific strategies for risk assessment of clients, based on demographic and risk profiles;

Analyze, by site, the extent of HIV prevention counseling coverage (number of clients seen, blinded and number of HIV infected persons identified through prevention counseling).

VIII. Records/Forms

Client records (confidential and anonymous) must contain a copy of the informed consent document (if appropriate), laboratory slip with test results, documentation of prevention counseling, result, and formulation of risk-reduction plans.

Records with patient identifiers must be secured.

All personal identifying information in connection with the delivery of services provided to any person must not be disclosed unless required by law or unless the person provides written, voluntary informed consent.
IX. Health Centre In-Charge/Data Analysis

Availability of HTS Register ..............................................................
Are outreach/mobile HTS data entered into the register and later into HIA1 ..........
Do the In-Charge plan, refine and target HTS program intervention strategies.
If no, explain why..............................................................................
If yes -What are the intervention strategies? ...........................................
Analyze resource allocation,
How much resource has been allocated to HTS Program? ........................
Provide site specific feedback to clinic staff, and to counselors. ........................
.................................................................................................

X. Logistics and Supply Chain for HIV Test Kits

Annual returns for HTS: 20…-------------------20…------------------20…. (first six months)-------------------
What is the district population?  ------------------------------------------What is the district annual target for HTS ----
Are the test kit available ........................................................................
Has the Facility experienced a stock out?  No ---- Yes ---- If yes when give reasons why
......................................................................................................
Does the district have a Trained Laboratory Focal Person for HIV supply chain management?
Yes ---- No ------------ If no explain why ....................................................
What challenges does the facility have in offering HTS Services?
...................................................................................................

Feed Back to the Facility/District:-------------------------------------------