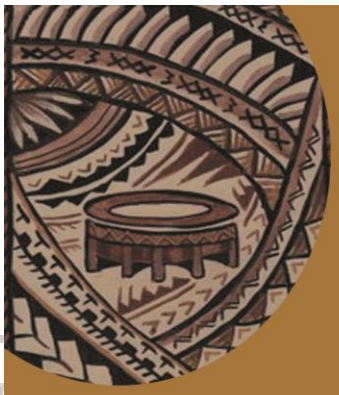

Ministry of Health
SAMOA

2018

NATIONAL GUIDELINES ON HIV TESTING SERVICES

This guideline is an adaptation of the 2015 WHO Consolidated Guidelines on HIV Testing Services

Leausa Toleafoa Dr. Take Naseri
Director General/CEO Ministry of Health

FOREWORD

The Ministry of Health is proud to present Samoa's adapted WHO Guidelines for;

1. Use of Anti-retroviral Therapy
2. Preventing Mother to Child Transmission of HIV
3. HIV testing services
4. STI Diagnosis, Treatment and Management

This document is the adaptation of the 2016 WHO guidelines that have been contextualized for Samoa's healthcare system and clinicians. The health sector, stakeholders and partners were consulted in order to tailor these guidelines to better fit Samoa's resources, service delivery systems, multilateral partnerships, and ultimately the needs of patients.

Samoa, as well as the Pacific region as a whole, has long faced high rates of STI's, which are only projected to increase within the coming 5 years. Ensuring quality clinical case management of STI's is an absolutely essential part of the national response to these diseases. Linked to STI management is HIV Testing Services (HTS), which involves clinicians, laboratories, public health, and the communities themselves in detecting infections and connecting people to the services they need. Samoa has historically adopted a treat all approach to those that test positive for HIV, giving all people ART free of cost. It is therefore essential that providers in Samoa are fluent in the latest practices for treatment.

Additionally, Preventing Mother to Child Transmission (PMTCT) encompasses all services, interventions, care, protocols and standards to support patients in maintaining their health and preventing the spread of infection from parent to infant. Samoa has always demonstrated a firm commitment on improving maternal and child health through both the Millennium and the Sustainable Development Goals.

These guidelines serve to provide clinicians a reference for the latest in global best practices, as well as the local context for implementing them. Throughout the document are clinical notes labeled below.

"  "

These notes come from numerous consultations on the guidelines and how to implement the recommendations nationally. We hope that providers will find this useful in their practice. We are grateful for all of the work from our national and international partners in health that has gone into the development of these guidelines.

Ma lo'u fa'aaloalo lava,

Leausa Toleafoa Dr. Take Naseri

ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Care
ART	Anti-Retroviral Therapy
ARV	Anti-Retroviral Drugs
CLIA	Chemiluminescence Immunoassay
DBS	Dried Blood Spot
DNA	Deoxyribonucleic Acid
ECL	Electrochemiluminescence Immunoassay
EIA	Enzyme Immunoassay
eMTCT	Elimination of Mother-To-Child Transmission
EQA	External Quality Assessment
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HIVST	HIV Self-Testing
HTS	HIV Testing Services
IVD	In Vitro Diagnostic Medical Device
NASBA	Nucleic Acid Sequence-Based Amplification
NAT	Nucleic Acid Testing
NGO	Nongovernmental Organization
OST	Opioid Substitution Therapy
PCR	Polymerase Chain Reaction
PEP	Post-Exposure Prophylaxis
PITC	Provider-Initiated Testing and Counselling
PMTCT	Prevention of Mother-To-Child Transmission
PrEP	Pre-Exposure Prophylaxis
QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement

RDT	Rapid Diagnostic Test
RNA	Ribonucleic Acid
SOP	Standard Operating Procedure
STI	Sexually Transmitted Infection
SPC	Pacific Community
TB	Tuberculosis
TNA	Total Nucleic Acid
UAT	Unlinked Anonymous Testing
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VCT	Voluntary Counselling and Testing
VMMC	Voluntary Medical Male Circumcision
WB	Western Blot
WHO	World Health Organization

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- Private clinicians
- Samoa Family Health Association
- Samoa Red Cross Society
- The Global Fund to Fight Malaria, HIV and TB
- The National Health Service
- United Nations Development Program
- World Health Organization

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DEFINITIONS

- **Acute infection:** the period in which an individual becomes HIV-infected and before HIV antibodies can be detected by a serological assay
- **Analyte:** a substance or chemical constituent that is analysed, generally referring to a component of blood or another bodily fluid. In the context of HIV, analytes include HIV p24 antigen and HIV-1/2 antibodies.
- **Assay:** a complete procedure for detecting the presence of or the concentration of an analyte, including all the components of a test kit used to identify HIV p24 antigen or HIV-1/2 antibodies.
- **Biological surveillance:** the collection and use of biological markers to inform surveillance, in this context, HIV surveillance systems. This term is replacing the term serosurveillance because biological specimens other than serum are increasingly being collected routinely.
- **Confirmed:** to issue an HIV status, initially reactive test results need to be confirmed according to the national validated testing algorithm.
- **Early infant diagnosis:** testing of infants to determine their HIV status, given that HIV can be acquired in utero (during pregnancy), peripartum (during delivery), postpartum (through breastfeeding) or via parenteral exposure.
- **Eclipse period:** the period between HIV infection and detection of virological markers, such as HIV RNA/DNA or HIV p24 antigen.
- **External quality assessment (EQA):** inter-laboratory comparison to determine if the HIV testing service can provide correct test results and diagnosis.
- **HIV status:** a collection of results from one or more assays. An HIV status is similar to HIV diagnosis. It refers to reports of HIV-positive, HIV-negative or HIV-inconclusive, whereas HIV diagnosis generally refers to HIV-positive diagnoses and in some cases HIV-negative diagnoses.
- **HIV test result:** the result from a single test on a given assay.
- **HIV testing services:** the term is used to embrace the full range of services that should be provided together with HIV testing. These include counselling (pre-test information and post-test counselling); linkage to appropriate HIV prevention, treatment and care

services and other clinical and support services; and coordination with laboratory services to support quality assurance and the delivery of correct results. The WHO 5 Cs (**C**onsent, **C**onfidentiality, **C**ounselling, **C**orrect test results and **C**onnection) are principles that apply to all models of HTS and in all circumstances

- **HIV-inconclusive status:** means in high prevalence settings, that the first reactive test result was not confirmed by additional testing using subsequent HIV assays or that, in low prevalence settings, the first two test results were reactive but the third assay was non-reactive
- **Index testing:** a focused approach to HIV testing in which the household and family members (including children) of people diagnosed with HIV are offered HIV testing services; also referred to as index case HIV testing
- **Indicator condition-guided HIV testing:** a focused approach to test people more likely to be infected with HIV who are identified through indicator conditions, such as STIs, lymphoma, cervical or anal neoplasia, herpes zoster and hepatitis B/C. These conditions occur more frequently in HIV-infected people than in uninfected people, either because they share a common mode of transmission with HIV or because their occurrence is facilitated by the characteristic immune deficiency associated with HIV infection
- **Integration:** the co-location and sharing of services and resources across different disease areas. In the context of HIV, this may include the provision of HIV testing, prevention, treatment and care services alongside other health services, such as TB, STI or viral hepatitis services, antenatal care (ANC), contraceptive and other family planning services and screening and care for other conditions, including non-communicable diseases.
- **Key populations:** Defined groups who, due to specific higher-risk behaviors, are at increased risk for HIV irrespective of the epidemic type or local context. These guidelines refer to the following groups as key populations: men who have sex with men, people who inject drugs, people in prisons and other closed settings, sex workers and transgender people.
- **Lay provider:** any person who performs functions related to health-care delivery and has been trained to deliver specific services but has not received a formal professional or paraprofessional certificate or tertiary education degree.

- **Multi-analyte testing:** similar to multiplex testing (see "Multiplex testing"), the term refers to the use of the same platform to test for different analytes with different sets of reagents, typically using more than one specimen
- **Multiplex testing:** testing a single specimen with one test device for more than one analyte, for example, a single test device that detects HIV-1/2 antibodies and antibodies to Treponema pallidum (syphilis)
- **Non-reactive test result:** a test result that does not show a reaction indicating the presence of analyte (a substance or chemical constituent that is analysed, eg. HIV 1 / 2 antibodies)
- **Nucleic acid testing (NAT):** also referred to as molecular technology, for example, polymerase chain reaction (PCR) or nucleic acid sequence-based amplification (NASBA). This type of testing can detect very small quantities of viral nucleic acid, that is, RNA, DNA or TNA, qualitatively and quantitatively
- **Pre-test information:** a dialogue and the provision of accurate information by a trained lay provider or health worker before an HIV test is performed.
- **Quality assurance (QA):** a part of quality management focused on providing confidence that quality requirements will be fulfilled.
- **Quality control (QC):** a material or mechanism which, when used with or as part of a test system (assay), monitors the analytical performance of that test system (assay). It may monitor the entire test system (assay) or only one aspect of it.
- **Quality improvement (QI):** a part of quality management focused on increasing the ability to fulfil quality requirements
- **Rapid diagnostic test (RDT):** in vitro diagnostic of immunochromatographic or immunofiltration format for, in the case of HIV diagnosis, the detection of HIV-1/2 antibodies and/or HIV p24 antigen
- **Reactive test result:** a test result that shows a reaction indicating the presence of analyte
- **Repeat testing:** refers to a situation where additional testing is performed for an individual immediately following initial test results, within the same testing visit, using the same assays and, where possible, the same specimen

- **Retesting:** refers to a situation where the individual is requested to come back after a defined period of time (14 days) to have another HIV Test. There are certain situations in which individuals should be retested after a defined period, these include: (1) HIV-negative people with recent or on-going risk of exposure, (2) people with an HIV-inconclusive status and (3) HIV-positive people before they enroll in care or initiate treatment. Reasons for retesting before initiation of care or treatment include ruling out laboratory or transcription error and either ruling in or ruling out seroconversion.

- **Self-testing (HIVST):** a process in which an individual who wants to know his or her HIV status collects a specimen, performs a test and interprets the result by him- or herself, often in private. Reactive test results must be followed by additional HIV testing services

- **Sensitivity:** denotes the probability that an HIV assay will correctly identify all specimens that contain HIV-1/2 antibodies and/or HIV p24 antigen.

- **Sentinel surveillance:** a type of surveillance that is conducted through selected sites among populations of particular interest or that may provide approximations of prevalence for a larger population, for example, in antenatal clinics.

- **Seroconversion:** when an individual first produces a quantity of HIV antibodies sufficient to be detectable on a given HIV serological assay.

- **Serodiscordant couple:** a couple in which one partner is HIV-positive and one partner is HIV-negative.

- **Serological assay:** an assay that detects the presence of antibodies in human specimens, typically serum or plasma but also capillary/venous whole blood and oral fluid. RDTs, immunoassays (including EIAs, CLIAs, ECLs) and certain supplemental HIV assays are examples of serological assays.

- **Specificity:** denotes the probability that the assay will correctly detect specimens that do not contain HIV-1/2 antibodies and/or HIV-1 p24 antigen.

- **Supplemental assay:** an assay that provides additional information for specimens that a first-line assay has found to be reactive but may not be able to definitively confirm that reactivity.

- **Task sharing:** the rational redistribution of tasks between cadres of health-care providers with longer training and other cadres with shorter training, such as trained lay providers

- **Test for triage:** a community-based HIV testing approach involving trained and supported lay providers conducting a single HIV RDT. The lay providers then promptly link individuals with reactive test results to a facility for further HIV testing and to an assessment for treatment. Individuals with non-reactive test results are informed of their results, referred and linked for appropriate HIV prevention services and recommended for retesting according to recent or on-going HIV risk and national guidelines

- **Testing algorithm:** the combination and sequence of specific assays used within HIV testing strategies (specific assay means the brand or type of the validated test kit to be used, example, Determine HIV-1/2 Ab, Unigold, INSTI, SD HIV/SypDUO, etc.)

- **Testing strategy:** generically describes a testing sequence for a specific objective, taking into consideration the presumed HIV prevalence in the population being tested.

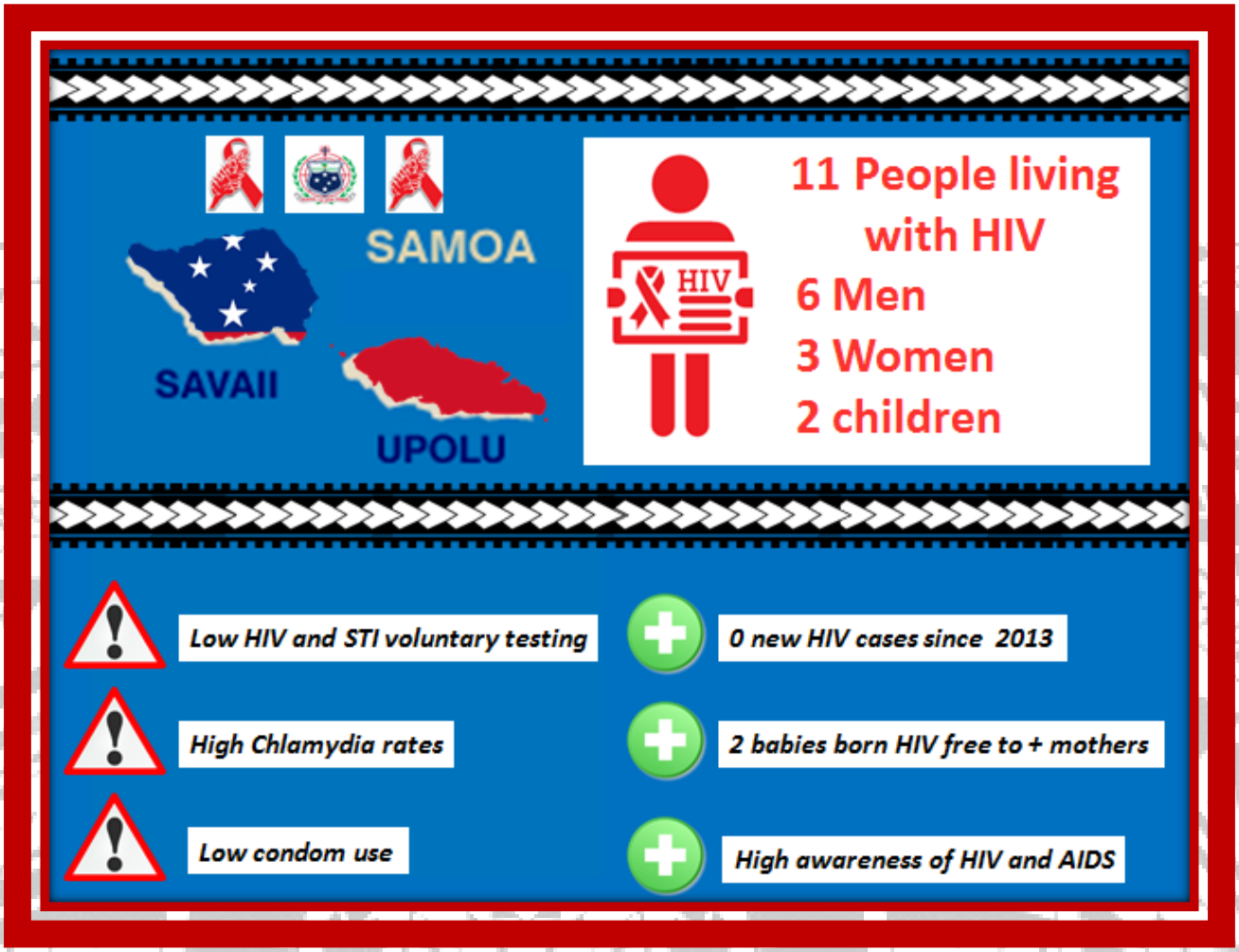
- **Verified:** people diagnosed HIV-positive are retested and their HIV diagnosis is verified before they initiate care or treatment.

- **Window period:** the period between HIV infection and the detection of HIV-1/2 antibodies using serological assays, which signals the end of the seroconversion period.

CHAPTER 1
INTRODUCTION

CHAPTER ONE: INTRODUCTION

1.1 Background



Infographic taken from the Global AIDS Monitoring Report 2018

The first case of HIV recorded in Samoa was in 1990. Since then, 24 cumulative cases have been reported. Currently there are 11 living cases of HIV. Though this is a low prevalence, low testing rates (4-5%) indicate that there are many more cases likely undetected. The high prevalence of other STI's (Chlamydia at 20.7% in 2017), are also a concern and pose risks for increasing HIV transmission. Social stigma around sex also compounds these risks.

The primary mode of HIV transmission in Samoa is through heterosexual sex. There are currently 7 cases of mother-to-child transmission (3 adults, 4 children). Of the living cases of HIV, 9 are receiving treatment from the public health sector, while 2 receive private treatment from overseas. There have been 2 cases of successful prevention of MTC transmission through the administration of ARV regimens in pregnant women. The last

reported case of HIV was reported in 2013. In 2014, a stillbirth occurred to an HIV positive mother.

STI's (as well as HIV) generally have low voluntary testing rates (apart from ANC STI testing which is mandatory). Table 1 shows that Chlamydia, which has the highest prevalence, also has one of the lowest testing rates (23% positive, 1% of the population tested).

STI Surveillance Data at a Glance

STI	2017 Prevalence	2017 Testing Coverage (% of population)
HIV	0.00%	6.0%
Syphilis	0.68%	5.8%
Hepatitis B	2.44%	6.1%
Hepatitis C	0.10%	5.2%
Hepatitis A	14.6%	0.1%
Chlamydia	22.93%	1.1%
Gonorrhea	10.00%	1.1%

1.2 Purpose of the policy and guideline

The goal of this HTS policy is to contribute to reduction of HIV transmission and improving the quality of life by enabling persons to know their sero-status and linking them to prevention, care, treatment and support services. The specific objectives of the policy are to:

- provide a framework for implementation and regulation of quality HTS
- contribute to the strengthening of health systems for the provision of quality HTC services;
- empower the community to access HTS services and adopt positive behavior;
- identify people with HIV through the provision of quality services for individuals, couples and families;
- effectively link individuals and their families to appropriate HIV treatment, care and support, as well as HIV prevention services, based upon their status; and
- support the scale-up of high impact interventions to reduce HIV transmission and HIV-related morbidity and mortality, that is, antiretroviral therapy (ART),voluntary medical male circumcision (VMMC), prevention of mother-to-child transmission (PMTCT), pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP).

1.3 Guiding principles

A public health and human rights-based approach is important to delivering HTS. A human rights-based approach gives priority to such concerns as universal health coverage, gender equality and health-related rights such as accessibility, availability, acceptability and quality of services. For all HTS, regardless of approach, the actual public health benefits must always outweigh the potential harm or risk. Moreover, the chief reason for testing must always be both to benefit the individuals tested and to improve health outcomes at the population level. HTS should be expanded not merely to achieve high testing uptake or to meet HIV testing targets, but primarily to provide access for all people in need to appropriate, quality HTS that are linked to prevention, treatment, care and support services. Thus, HIV testing for diagnosis must always be voluntary, consent must be informed by pre-test information, and testing must be linked to prevention, treatment, care and support services to maximize both individual and public health benefits.

All forms of HIV testing should adhere to the WHO 5 Cs: **C**onsent, **C**onfidentiality, **C**ounselling, **C**orrect test results and **C**onnection (linkage to prevention, treatment and care services). Coerced testing is never appropriate, whether that coercion comes from a health-care provider, an employer, authorities (such as immigration services) or a partner or family member.

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

i. **Consent:** People receiving HTS must give informed consent to be tested and counselled (verbal consent is sufficient; written consent is not required.) They should be informed of the process for HIV testing and counselling and of their right to decline testing.

ii. **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. Confidentiality should be respected, but it should not be allowed to reinforce secrecy, stigma or shame. Counsellors should discuss, among other issues, whom the person may wish to inform and how they would like this to be done. Shared confidentiality with a partner or family members; trusted others; and healthcare providers are often highly beneficial.

iii. **Counselling:** Pre-test information can be provided in a group setting, but all people should have the opportunity to ask questions in a private setting if they request it. All HIV testing must be accompanied by appropriate and high-quality post-test counselling, based on the specific HIV test result and HIV status reported. Quality assurance (QA)

mechanisms as well as supportive supervision and mentoring systems should be in place to ensure the provision of high-quality counselling.

iv. **Correct:** 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.

v. **Connection:** Linkage to prevention, treatment and care services should include effective and appropriate follow-up, including long-term prevention and treatment support. Providing HTS where there is no access to care, or poor linkage to care, including ART, has limited benefit for those with HIV.

1.4 General policy statements

- HIV testing services shall be integrated into existing health and social welfare services and promoted in all settings: government, non-governmental, private sector, cooperatives, workplace, faith-based organizations etc.

- HIV testing services shall be strengthened through effective networking, consultation and collaboration among stakeholders.

- HIV testing services shall be standardized nationwide and shall be authorized, supervised, supported and regulated by appropriate government health authorities Informed verbal consent for testing shall be obtained in all cases, except in mandatory testing (as specified in exceptional cases). Adequate pre-test information and post-test counselling shall be offered to all clients.

- Test results, positive or negative, shall be relayed to clients *in person*, who must be provided with post-test counselling.

- No results will be provided in certificate form, however referral will be offered to access post-test services (prevention, care and support).

- Clients' confidentiality will be maintained at all times. Results can be shared with other persons only at clients' request or agreement, and with those involved in clinical management of clients. Clients can be referred on if required or upon request.

- Mandatory HIV testing is a violation of human rights, only permissible in exceptional cases by order of a court of law

- Mandatory testing will only be done on all voluntary blood, tissue and organ donors, who shall be informed about HIV testing and given opportunity to learn their test results

- Provider-initiated testing and counselling (PITC) shall be promoted as part of standard clinical management and care in all health facilities

- Non health personnel shall be promoted as counselling and testing counsellors provided they receive adequate training according to the human resource recommendations in section four of these guidelines

- Affordable HIV testing services shall be available in public health facilities, NGO and private sectors

- Provider Initiated Testing and Counselling (PITC) for HIV should be available at all health facilities offering antenatal care (ANC) including private clinics, utilising group pre-test information session and individual post-test counselling.

- Health Facilities including private health clinics, that provide ANC services must provide PITC. If RDTs are not in place, blood samples of clients should be taken to provincial hospitals or national hospital for HIV testing, other normal routine blood tests; and a followup appointment made with the clients to receive their results.

- All pregnant women should be provided HIV testing during the first ANC visit, accompanied by group pre-test information session and individual post-test counselling thereafter. This should be done with their consent (verbal consent is sufficient and written consent is not required) to be tested and counselled. They should be informed of the process for HIV testing services and their right to decline testing.

- Routine HIV testing should be offered to all patients with presumptive and diagnosed TB. Partners of known HIV-positive TB patients should be offered HTS with mutual disclosure. TB-control programmes should mainstream provision of HTS in their operations and routine services

- Pre- test information can be provided by anyone with appropriate training

- Post-test counselling should be provided by a service provider (nurse, doctor, lay counselor) who has undergone training on HIV counselling as per approved training curriculum

- Rapid testing kits for HIV should be made available and conducted on-site in all HIV testing services sites or delivery health facilities

- Testing for HIV should follow the approved and validated national HIV testing algorithm.

- Mandatory testing for employment has not been found to be beneficial for HIV prevention, care and treatment and is therefore prohibited. For the same reason, any form of HIV testing among foreigners is not mandatory. HIV Testing is therefore not mandatory for granting Visa, entry, residence, stay and employment in the country.

The current Immigration Act 2004 requires HIV testing for all residency and employment permits as part of a health screening. However this legislation is currently being redrafted and the Ministry of Health has advocated in consultations that HIV be taken out of the health screening.

- HIV testing in the context of surveillance must use a testing strategy and national validated testing algorithm that is suitable for HIV diagnosis and when possible, use programmatic data for HIV surveillance; particularly for prevention of mother-to-child transmission programmes.

CHAPTER 2

SERVICE DELIVERY

CHAPTER TWO: HTS SERVICE DELIVERY

2.1 Service delivery approaches

Use of a mix of Client and Provider Initiated HTS delivery approaches either in the clinical, community, home or and work place setting is appropriate to increase access to counseling and testing services.

Objective:

- To promote the use of various approaches to increase access to HTS

Methodology:

The following HIV Testing Services shall be delivered through provider initiated testing, community based testing and mandatory testing (as defined):

i. Provider-initiated testing and counseling (PITC) shall be promoted as part of preventive services, clinical management and care in all health care settings.
ii. Home-based, community based and work place based testing should be provided in a safe environment.
iii. Mandatory testing will be done on all donated blood, tissue and organs, and donors shall be counseled and given opportunity to learn their test results
iv. Mandatory testing shall be done on all offenders of rape and defilement or as a requirement by the courts of law
v. HIV testing services shall be provided free of charge to the client in public health facilities, public work places, and NGOs.
vi. Private health facilities should offer affordable HIV testing services.
vii. All HIV testing service providers shall adhere to the protocols for the various HTS approaches
viii. Only WHO pre-qualified HIV test kits shall be procured

2.2 HIV testing services

Promotion of HIV Testing Services is important for attaining the UN 90–90–90 targets:

- The first 90 – diagnosing 90% of people with an HIV infection. So far, it is believed that many people with HIV in Samoa have not yet been diagnosed, as evidenced by the low coverage and uptake of HIV Testing Services.
- The second 90 – that 90% of HIV-positive people who have been diagnosed are on ART, and

- The third 90 - 90% of people with HIV receiving ART have achieve viral suppression.

Receipt of an HIV diagnosis empowers individuals to make informed decisions about HIV prevention, treatment and care that will affect both HIV transmission and an individual's health and survival. Therefore, linkage to appropriate services following diagnosis should be regarded as a key component of effective and comprehensive HTS.

Objective:

- To strengthen essential services prior to HIV testing as well as post-test messages and counselling services, specifically for individuals who test HIV-negative, individuals who are diagnosed HIV-positive, individuals who receive a reactive test result but need further testing and individuals who have an inconclusive HIV status.

2.2.1 Services prior to taking an HIV test

Certain basic services should be provided prior to testing in all settings, regardless of the approach used to deliver HTS. These services apply to all adults, couples or partners, adolescents and children.

2.2.1.1 Promoting HTS

Methodology:

i. HIV programmes have vigorously promoted HTS through mass media, including radio, television, billboards and posters, the Internet and electronic social media. The expected results are that there should be widespread knowledge that HTS are provided and where they are available.
ii. Promotional activities need to focus on populations where HIV testing rates remain suboptimal, including key populations and adolescent groups, which will likely require tailored messages and approaches – for example, via social media.
iii. In clinic settings, where HIV testing is routinely offered, such as ANC, STI clinics and TB services, there should be signs, printed information and posters be displayed and group health education sessions conducted to efficiently inform pregnant women, other clients and family members that testing is offered.

2.2.1.2 Creating an enabling environment

Methodology:

i. Initiatives should be put in place to enforce privacy protection and institute policy, laws and norms that prevent discrimination and promote tolerance and acceptance of people living with HIV. This will help in creating an environment where disclosure of HIV status is easier.

ii. HIV Programme implementers, health-care providers and organizations delivering HTS should work with community-based organizations, legal authorities and advocacy organizations to ensure that the environment supports and enables people to learn their HIV status.

iii. The MoH and NHS should collaborate with other ministries, schools, NGOs and Faith-Based Organizations (FBOs) to develop necessary strategies, activities and approaches to address critical enablers. Critical enablers are conditions, to some extent outside the purview of the health sector, that facilitate the accessibility, acceptability, uptake, equitable coverage, quality, effectiveness and efficiency of HIV interventions and services. Critical enablers are key to the success of health sector HIV interventions as they support the uptake of HIV testing and linkages to prevention, treatment and care, especially for groups that are reluctant to use or have limited access to current HTS, such as men, adolescents, key populations and other vulnerable groups. This policy identifies four critical enablers which must be addressed to support the uptake of HTS. These include:

- Reviewing laws, policies and practices
- Reducing stigma and discrimination
- Empowering the community
- Preventing Sexual and Gender Based Violence

2.2.1.3 Ensuring a confidential setting and preserving confidentiality

Methodology:

i. All HTS providers must remain committed to preserving confidentiality, one of the 5 Cs of HTS

ii. Confidentiality applies not only to the test results and reports of HIV status but also to any personal information, such as information concerning sexual behaviour and the use of illegal drugs.

iii. HTS should avoid practices that can inadvertently reveal a client's test results, or HIV status, to others in the waiting room or in the health facility. Such practices might include counselling all people diagnosed HIV-positive in a special room or by a specific provider

or making it obvious to others which clients will need or is receiving additional testing or lengthy post-test counselling.

 *All health professions are obligated to confidentiality and patient safety as per the requirements of the Healthcare Professions Registration and Standards Act 2007 and the Allied Health Professions Act 2014.*

2.2.1.4 Providing pre-test information

Methodology:

i. Providers and programmes may provide pre-test information through individual or group information sessions and through media such as posters, brochures, websites and short video clips shown in waiting rooms.

ii. When presenting information for children and adolescents receiving HTS, these should be presented in an age-appropriate way to ensure comprehension.

iii. Offering or recommending HIV testing to a client or a group of clients should include providing clear and concise information on:

- the benefits of HIV testing
- the meaning of an HIV-positive and an HIV-negative diagnosis
- the services available in the case of an HIV-positive diagnosis, including where ART is provided
- the potential for incorrect results if a person already on ART is tested
- a brief description of prevention options and encouragement of partner testing
- the fact that the test result and any information shared by the client is confidential
- the fact that the client has the right to refuse to be tested and that declining testing will not affect the client's access to HIV-related services or general medical care
- potential risks of testing to the client in settings where there are legal implications for those who test positive and/or for those whose sexual or other behaviour is stigmatized an opportunity to ask the provider questions.
- Situations or settings where conducting a repeat test or retest for HIV should be conducted

iv. Pre-test information or health education for women who are or may become pregnant or are postpartum should also include:

- the potential risk of transmitting HIV to the infant
- measures that can be taken to reduce mother-to-child transmission, including the provision of ART to benefit the mother and prevent HIV transmission to the infant
- counselling on infant feeding practices to reduce the risk of HIV transmission

- the benefits of early HIV diagnosis for mothers and infants
- encouragement for partner testing.

v. To support intensified TB case finding at HIV testing facilities, HTS should integrate screening for TB symptoms into the information session before HIV testing, both at health facilities and in community based testing.

vi. The pre-test information session for couples should not ask about past sexual behaviour or risks, as this is unnecessary and may create problems for the couple. The person conducting a pre-test information session should make clear that both testing and post-test counselling can be provided individually, if either partner prefers, and that disclosure of HIV status to the other person is not required.

vii. To increase access to HTS by key populations, HIV Programmes should prioritize the competency-based training of health workers so that they can provide acceptable services, better understand the needs of key populations and be familiar with local support and prevention services. Links with key population networks and/or community-based organizations to support or provide HTS, including services delivered by peers, may increase reach, uptake and acceptability.

2.2.1.5 Consent by adults

Methodology:

i. Informed consent remains one of the essential 5Cs of testing services. It should always be obtained individually and in private by an HTS provider

ii. The provider must ensure that the client has learned enough about testing to give informed consent.

iii. HTS may provide information about testing and the need for consent in a group setting, such as group health education, but clients should give consent in an individual and private manner.

iv. In settings such as ANC or TB clinics, where HIV testing is routine, health workers should carefully explain how a client can decline testing and ensure that each person has a private opportunity to opt out of testing.

v. People who are under the influence of drugs or alcohol or otherwise mentally impaired should not be tested, as they are not able to give informed consent.

vi. HTS should ensure that no one coerces clients into being tested.

2.2.1.6 Consent by adolescents

Methodology:

i. National laws, regulations and policies (on age of consent for HIV testing) should uphold adolescents' rights to make choices about their own health and well-being, with consideration for different levels of maturity and understanding.

ii. All training materials should address applicable national laws and regulations regarding age of consent for HIV testing and situations in which minors may consent for themselves.

iii. All personnel involved in HTS should be aware of their countries' laws and regulations.

2.2.2 Services for those who test HIV-negative

Methodology:

i. Individuals who test HIV-negative should receive brief health information about their test results as lengthy post-test counselling for people testing negative may divert counselling resources that are needed by those: (1) who test HIV-positive, (2) those whose results are inconclusive and; (3) those who are found to be in a sero-discordant relationship

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

- ❖ an explanation of the test result and reported HIV status;
- ❖ education on methods to prevent HIV acquisition and provision of male or female condoms, lubricant and guidance on their use;
- ❖ emphasis on the importance of knowing the status of sexual partner(s) and information about the availability of partner and couples testing services;
- ❖ referral and linkage to relevant HIV prevention services, including voluntary male medical circumcision (VMMC) for HIV-negative men, PEP, PrEP for people at substantial ongoing HIV risk;
- ❖ a recommendation on retesting based on the client's level of recent exposure and/or ongoing risk of exposure;
- ❖ an opportunity for the client to ask questions and request counselling.

iii. For most people who test HIV-negative, additional retesting to rule out being in the window period is not necessary. Retesting is needed only for HIV-negative individuals who report recent or ongoing risk of exposure.

iv. People who are diagnosed HIV-negative but remain at high risk, such as some people from key populations, may benefit from regular retesting. Retesting gives these people both the opportunity to ensure early HIV diagnosis and to receive ongoing health education on HIV prevention.

v. Adolescents who test HIV-negative need information and education about healthy behaviours, such as correct and consistent condom use, reduction of risk-associated behaviours and prevention of HIV and unwanted pregnancy and about the need for retesting if they have new sexual partners. Those testing negative also need referral to appropriate prevention services, such as VMMC, contraception and harm reduction

vi. Couples and others who test for HIV with a sexual partner and are both diagnosed HIV-negative can benefit from the standard health information and prevention education given to individuals who test negative. In addition, the counsellor or health worker may offer further counselling at the couple's or a partner's request.

vii. All clients with an HIV-inconclusive status should be encouraged to return in 14 days for additional testing to confirm their diagnosis. An HIV-inconclusive status means, in high prevalence settings, that the first reactive test result was not confirmed by additional testing using subsequent HIV assays or that, in low prevalence settings, the first two test results were reactive but the third assay was non-reactive

2.2.3 Services for those whose test results are HIV-positive

Methodology:

i. An HIV-positive diagnosis is a life-changing event. Before giving HIV-positive test results, the health worker, trained lay provider, or counsellor should keep in mind the 5 Cs of HTS, as recommended by WHO and UNAIDS, in particular correct test results.

ii. It is the professional and ethical duty of the person providing the HIV diagnosis to ensure that testing procedures follow WHO-recommended testing strategies

iii. Once health workers or lay providers are confident of adherence to all measures to ensure correct test results, they should provide post-test health education and counselling.

iv. All post-test counselling should be "client-centred", which means avoiding formulaic messages that are the same for everyone regardless of their personal needs and circumstances. Instead, counselling should always be responsive to and tailored to the unique situation of each individual or couple.

v. Health workers, professional counsellors, social workers and trained lay providers can provide counselling. People with HIV who are trained in counselling may be particularly understanding of the needs and concerns of those who receive an HIV-positive diagnosis.

vi. To ensure that clients who are misdiagnosed are not needlessly placed on lifelong ART (with potential side-effects, waste of resources and psychosocial and emotional implications), WHO recommends that all clients be retested to verify their HIV diagnosis prior to enrolling in care and/or starting ART.

vii. The information and counselling that health workers, or other providers, should provide to HIV-positive clients is listed below:

- ❖ Explain the test results and diagnosis.
- ❖ Give the client time to consider the results and help the client cope with emotions arising from the diagnosis of HIV infection.
- ❖ Discuss immediate concerns and help the client decide who in her or his social network may be available to provide immediate support.
- ❖ Provide clear information on ART and its benefits for maintaining health and reducing the risk of HIV transmission, as well as where and how to obtain ART.
- ❖ Make an active referral for a specific time and date. (An active referral is one in which the tester makes an appointment for the client or accompanies the client to an appointment, including an appointment for co-located services, and enrolment into HIV clinical care.) Discuss barriers to linkage to care, same-day enrolment and ART eligibility assessment. Arrange for follow-up of clients who are unable to enroll in HIV care on the day of diagnosis.
- ❖ Provide information on how to prevent transmission of HIV, including information of the reduced transmission risk when virally suppressed on ART; provide male or female condoms and lubricants and guidance on their use.
- ❖ Discuss possible disclosure of the result and the risks and benefits of disclosure, particularly among couples and partners. Offer couples counselling to support mutual disclosure.
- ❖ Encourage and offer HIV testing for sexual partners, children and other family members of the client. This can be done individually, through couples testing, index testing or partner notification.
- ❖ Assess the risk of intimate partner violence and discuss possible steps to ensure the physical safety of clients, particularly women, who are diagnosed HIV-positive.
- ❖ Assess the risk of suicide, depression and other mental health consequences of a diagnosis of HIV infection.
- ❖ Provide additional referrals for prevention, counselling, support and other services as appropriate (for example, TB diagnosis and treatment, prophylaxis for opportunistic infections, STI screening and treatment, contraception, ANC, opioid substitution therapy (OST), and access to sterile needles and syringes, and brief sexuality counselling.
- ❖ Encourage and provide time for the client to ask additional questions.

viii. A follow-up counselling session may be required since absorbing all of this information in one session may be very challenging. In most cases, the shock of learning of an HIV-positive diagnosis may make it difficult for a person to take in further information immediately.

2.2.4 Special considerations concerning disclosure

Methodology:

i. People who test HIV-negative often do not need assistance or support with disclosing their HIV status to others. In contrast, maintaining privacy about testing HIV-positive and deciding about disclosure are serious concerns for many who are diagnosed HIV-positive. There are three forms of disclosure relevant and appropriate to HIV testing:

(1) Disclosure by the individual to a sexual partner, family member or friend. Such disclosure can have considerable benefits, particularly for couples and sexual partners. However, many clients who learn that they are HIV-positive need time to absorb the diagnosis before they are ready to disclose and may benefit from additional counselling. Research findings on the consequences of disclosure, especially disclosure by women to their male partners, are mixed. Women who have experienced intimate partner violence prior to testing may experience violence from their partner after disclosing their HIV status. Providers and counsellors should assess the risk of intimate partner violence in the individuals they serve and make referrals as needed.

(2) Disclosure by a health worker to a sexual partner of the individual.

In some settings, laws or regulations require the disclosure of HIV-positive status to sexual and/or drug-injecting partners. Where this is the case, providers should discuss this with clients before asking for informed consent for testing. Providers need to be sensitive to clients who may be more susceptible to adverse outcomes of disclosure such as discrimination, violence, abandonment or incarceration and hence the need to adapt counselling accordingly. Such clients may need additional counselling both before and after testing.

(3) Disclosure by a health worker to other health workers involved in the client's care.

Providers need to inform people who test positive that, in order to assure appropriate medical care, the diagnosis will be shared with other medical workers as needed. Such disclosure should respect the client's basic right to privacy and confidentiality of all medical information.

ii. In the context of HTS, unless the client has consented to this, disclosure by a health worker to the police or other legal authorities is not considered ethical. In this case HTS providers should obtain written consent to disclose a client's HIV status to legal authorities.

2.2.5 Post-test counselling for special populations

Methodology:

i. **Key populations** clients who test HIV-positive may lack social networks and/or a supportive family to help them deal with their diagnosis. These people may need additional counselling as well as peer support services to cope with this diagnosis. A peer counsellor may particularly help people understand and cope with the diagnosis and support linkage to care and treatment by serving as a "peer navigator", who assists with finding, choosing and obtaining a full range of services, especially young key populations.

National consultations revealed that all those working with HIV and STI positive cases need to be trained in confidentiality practices, including peer navigators and lay-providers, due to the context of pervasive stigma. These individuals must also sign an agreement to uphold confidentiality best practices, standards, and legal requirements.

ii. **Couples** counselling requires additional training and enhanced counselling skills. Post-test counselling for serodiscordant couples may be especially challenging, as these results may be hard for the provider to explain and difficult for the couple to accept. For more guidance on post-test counselling and services for discordant couples, see Guidance on couples HIV testing and counselling including antiretroviral therapy for treatment and prevention in serodiscordant couples[1]

[1](http://apps.who.int/iris/bitstream/10665/44646/1/9789241501972_eng.pdf)

iii. **Pregnant women.** Post-test counselling for pregnant women who are diagnosed with an HIV infection should include the following, in addition to the standard messages described above for all people diagnosed with HIV infection:

- ❖ Childbirth plans: providers should encourage HIV-positive pregnant women to deliver in a health facility for their own well-being as well as to ensure access to PMTCT services;
- ❖ Use of ARVs for the client's health, when indicated and available, as well as the use of ARVs to prevent transmission to the infant;
- ❖ The importance of partner testing and information on the availability of couples testing services;
- ❖ Ensuring screening for TB and testing for other infections such as syphilis;
- ❖ Counselling on adequate maternal nutrition, including iron and folic acid;
- ❖ Advice on infant feeding options and support to carry out the mother's infant feeding choice;
- ❖ Advocate for exclusive breast feeding for mother who is living with HIV

Due to treatment adherence issues, this recommendation has been discouraged by national providers for the risk of infection is too high. Instead, providers are to support mothers in accessing breast milk products.

- ❖ HIV testing for the infant and needed follow-up for HIV-exposed infants.

iii. **Adolescents.** Along with standard messages for all those diagnosed with an HIV infection, post-test counselling for adolescents with HIV should include:

- ❖ Tailored help with linkage to HIV care and treatment;
- ❖ Counselling, referral and linkage to specific psychosocial and mental health services tailored to both the situation in which infection happened and the developmental age of the individual;
- ❖ Information on adolescents' rights and responsibilities, especially their right to confidentiality;
- ❖ An opportunity to ask questions and discuss issues related to sexuality and the challenges they may encounter in relationships, marriage and childbearing;
- ❖ Individualized planning on how, when and to whom to disclose HIV status and engage families and peers in providing support;
- ❖ Referral for small-group counselling and structured peer support groups, which may particularly benefit adolescents with HIV.

iv. **Children**. Informing children of their HIV diagnosis is complex, and the approach depends on the child's age and the counselling skills of the health-care provider. For information on disclosure to children, see Guidance on HIV disclosure counselling for children 12 years of age and younger[2]

2.2.6 Linkage to care

Methodology:

i. All people who test HIV-positive need immediate linkage to care to maximize the benefits of ART.

ii. Special efforts will be needed to link people who have a reactive test result in a community setting to facility-based services for additional testing and an HIV diagnosis. For those diagnosed HIV-positive, retesting to verify diagnosis is critical before care or treatment is initiated.

iii. People diagnosed HIV-positive and those testing HIV-negative with ongoing HIV risk need to be linked to prevention services.

iv. National policies and strategic planning are needed to improve access to and uptake of HIV testing as well as linkage from testing to prevention, treatment and care.

v. The following good practices are recommended to support linkage to prevention, treatment and care.

- ❖ Comprehensive home-based HIV testing, which includes offering home assessment and home-based ART initiation;
- ❖ Integrated services, where HIV testing, HIV prevention, treatment and care, TB and STI screening and other relevant services are provided together at a single facility or site;
- ❖ Providing on-site or immediate CD4 testing with same-day results;

CD4 testing is available annually, with regular viral load testing, as per the WHO recommendation and the low availability of test kits.

- ❖ Providing assistance with transport, such as transportation vouchers, if the ART site is far from the HTS site;
- ❖ Decentralized ART provision and community-based distribution of ART;

[2](http://www.who.int/hiv/pub/hiv_disclosure/en/)

 *Due to confidentiality concerns, clinicians should continue to coordinate ART through the Communicable Disease Clinic, using community visits to bring services to patients.*

- ❖ Support and involvement of trained lay providers who are peers and act as peer navigators, expert patients/clients and community outreach workers to provide support and to identify and reach people lost to follow-up;

 *Due to confidentiality concerns, Samoa has opted for community based healthcare providers/health workers, as opposed to lay providers, for delivering HIV and STI testing and counselling services*

- ❖ Intensified post-test counselling by community health workers;
- ❖ Using communication technologies, such as mobile phones and text messaging, which may help with disclosure, adherence and retention, particularly for adolescents and young people;
- ❖ Providing brief strengths-based case management, which emphasizes people's self-determination and strengths, is client-led and focuses on future outcomes, helps clients set and accomplish goals, establishes good working relationships among the client, the health worker and other sources of support in the community, and provides services outside of office settings;
- ❖ Promoting partner testing may increase rates of HIV testing and linkage to care, as may approaches in PMTCT settings that encourage male involvement.
- ❖ Intimate partner notification by the provider, with permission, is feasible in some settings; it identifies more HIV-positive people and promotes their early referral to care.

vi. Linkage to HIV prevention services: A range of HIV prevention services should be available for those with HIV, in addition to timely initiation of ART, and for those who are HIV-negative. It is important to support linkage to prevention services for those with the greatest ongoing risk, for example, people in settings of high HIV incidence, people from key populations and others at high risk of HIV, such as serodiscordant couples.

2.3 HIV testing strategy

For effective HIV testing services, there is need for standardized procedures. HIV rapid antibody tests as per the Samoa Algorithm are to be used for all HIV testing in Samoa except in the testing of infants under the age of 18 months for which viral tests are to be carried out.

Policy Objective:

- To ensure adherence to standardized HIV testing strategies and algorithm.

Methodology:

i. The protocol for all HTS delivery approaches shall include: Initial contact, pre-test session, HIV testing, post-test session, referral and follow up
ii. MOH shall ensure external quality assurance is conducted
iii. Service providers shall be regularly updated on the new testing algorithms.
iv. Only WHO pre-qualified products shall be procured including rapid tests, ELISA, western blot, etc.
v. HTS providers shall adhere to the nationally approved HIV testing algorithms and standard operating procedures for adults and children appended in the annex of this policy document and as described below:

1. HIV Testing Strategy for low HIV prevalence and concentrated setting (adults and children above 18 months) – refer to annex 1[3]

In settings with less than 5% HIV prevalence in the population tested, a diagnosis of HIV-positive should be issued to people with three sequential reactive tests. Recommended HIV testing algorithm using this strategy for the Pacific (including Samoa) as shown in ***annex 2.***

For individuals with A1+; A2−, the final result should be considered HIV-negative. However, if A1 is a fourth generation assay (Ab/Ag) and A2 is an Ab-only assay, when A1+; A2−, the result should be considered HIV inconclusive and the person should be retested after 14 days.

For individuals with A1+; A2+; A3−, an HIV-inconclusive status is reported, and the client should be asked to return in 14 days for retesting

2. HIV Testing Strategy for high prevalence settings (adults and children above 18 months)

In settings with greater than 5% HIV prevalence in the population tested, a diagnosis of HIV-positive should be issued to people with two sequential reactive tests.

[3] In Samoa, this is the recommended HIV testing strategy for diagnosis of HIV to be used

For individuals with A1+; A2−; A3+, an HIV-inconclusive status is reported, and the client should be asked to return in 14 days for retesting.

For individuals with discrepant test results where the A1 is reactive, the A2 is non-reactive and the A3 is non-reactive (that is, A1+, then A2−, then A3−), the final result should be considered HIV-negative.

3. HIV Testing Strategy for early infant diagnosis – refer to annex 3

HIV-exposed infants and children younger than 18 months with unknown or uncertain HIV exposure should be tested (with a virological assay) within 4–6 weeks of birth so that those presumptively diagnosed with HIV can start ART.

HIV-exposed infants with non-detectable NAT at 4–6 weeks should undergo HIV serological testing at around nine months of age (or at the time of the last immunization visit) to rule out HIV infection. Infants whose serological assays are reactive at nine months should undergo virological testing to rule in HIV infection.

2.4 HIV testing services for special populations

This section addresses priority populations that include but not limited to Key populations at higher risk (sex workers, men having sex with men, fa'afafine people LGBTQI, couples and people who inject drugs, those in prolonged confined environment), sexual minorities, health workers, people with disabilities, victims of sexual abuse and molestation, contract workers, mobile populations (tourists), couples and children. These groups may be vulnerable or at higher risk of HIV infection, and may have difficulty in accessing services.

Objective:

- To ensure that HIV Testing Services address needs and concerns of special groups.
- To ensure that all HIV Testing Services are designed to address the unique needs of the persons categorized under special groups
- To ensure that special groups have the right to information, education and communication on HTS adapted to their respective special needs, including comprehensive Sexual and Reproductive Health and Rights (SRHR) services.

2.4.1 Key Populations

Key populations are at higher risk for HIV infection. In Samoa, key populations at higher risk include sex workers and their clients, people who inject drugs Men who have Sex with men and LGBTQI, prisoners, migrants, seafarers, and other communities. These populations often suffer worse health problems and have more difficulty accessing quality health services. Strategies are needed to increase access to and uptake of HIV testing and counselling for these groups particularly through innovative client-initiated approaches such as services delivered through mobile clinics in other community settings through harm reduction programmes or through other types of outreach.

Methodology:

i. Key populations to be targeted as populations at higher risk in Samoa will include sex workers and their clients, people who inject drugs Men who have Sex with men and LGBTQI, prisoners, migrants, seafarers, taxi drivers and other communities
ii. The Samoa MoH will advocate for and ensure conducive laws enabling equitable access to HT services by key population at higher risk in the country
iii. Prisoners should be able to access client-initiated HIV testing and counselling at any time during incarceration without being subject to mandatory HIV testing.
iv. Efforts to expand access to client-initiated HIV testing and counselling for key population at higher risk should include social mobilization and education initiatives to encourage people to learn their HIV status and to access services.

2.4.2 Adolescents and young people

In promoting HTS uptake among young people, It is important to *"captivate these young people"* in their own environment and to *"make testing less scary"*. Awareness-raising events and activities can be designed specifically for adolescents in places that are comfortable for them, such as youth clinics, nightclubs, sporting venues, and churches. Adolescents consider it very important to be able to relate to the person providing the HTC service. In ideal situation this might mean engaging adolescent and ALHIV peers as health educators and HTS providers, thus bridging the gap between adolescents and health services. Above all, there is a need for respectful, accepting, friendly, understanding and supportive providers to encourage adolescents to test.

Methodology:

i. The MoH shall ensure, where possible, a youth-friendly atmosphere, flexible hours, separate waiting areas for adolescents, alternative service delivery settings (e.g. youth

friendly clinics, social centres and mobile services) and the assurance of confidentiality, which might include the option for self-testing. Refer to Section 2.4.5 for age of consent and how to deal with consent issues among minors

ii. HIV testing services and treatment should be offered free of charge

iii. Authorities will facilitate access to HIV testing services and linkage to care for orphans and vulnerable adolescents, including those living on the streets, adolescents in child-headed households, and particularly vulnerable adolescents from key populations, girls engaged in sex with older men and in multiple or concurrent sexual partnerships, and adolescent girls affected by sexual exploitation.

iv. Authorities will bear in mind their legally binding obligations in respect of children under international law. In particular, Article 3 of the 1989 Convention on the Rights of the Child (CRC) states: "In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration". Article 24 of CRC states:

   a) States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health-care services.

   b) States Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures: To ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care.

2.4.3 Women

Women are particularly vulnerable to HIV infection and face multiple challenges in making decisions concerning their reproductive lives. Counselling can empower women to make informed decisions that prevent HIV infection.

Methodology:

i) HIV Testing Services during pregnancy; labour and post-partum with the right to refuse testing shall be routinely offered for women.

2.4.4 Infants

HIV disease progression usually occurs rapidly in the first few months of an infant's life and often leads to death, particularly for those who acquired the infection around the time of delivery.

Methodology:

i. The following categories of infants must be tested for HIV within first 2 months of life as part of routine care.
   - Infant who has been exposed to HIV during pregnancy, labour or breastfeeding
   - Infant who is showing clinical signs of HIV, and/or signs of failure to thrive/grow/develop
   - Infant whose mother was not tested for HIV during pregnancy

ii. Where possible, serological antibody tests are to be used as a screening assay to determine HIV exposure in infants less than 18 months of age followed by a viral test to confirm the child's status.

iii. Given that cases of HIV are low in Samoa and that antibody tests may delay a child's diagnosis, it is recommended a DBS sample is taken and sent directly to the National Referral Laboratory for processing of the virological test.

iv. All HIV exposed infants are to have HIV viral testing at 6 weeks of age or the earliest opportunity thereafter.

v. For infants with an initial positive viral test result, ART must be initiated immediately and that a second specimen is collected to confirm the infant's status.

vi. Results of the test should be given to the child's parent or care giver within 2 to 4 weeks.

vii. HIV Positive results should be fast tracked and given as soon as possible.

viii. Infants with a presumptive diagnosis of severe HIV infection should be considered for ARV therapy.

ix. Forming a presumptive diagnosis should be followed by efforts to confirm the HIV diagnosis using the best available tests for age.

x. Infants who have been breastfed are to be re-tested at least 6 weeks after complete cessation of breastfeeding.

xi. It is unnecessary to form a presumptive diagnosis for children 18 months or older because HIV antibody tests are reliable at this age.

2.4.5 Children

Children have unique vulnerability to HIV infection, and as their ability to comprehend HIV and AIDS issues differs from that of adults, this population demands special consideration.

The welfare of the child should be the paramount guiding principle when considering testing; counsellors should determine reasons for testing with the parent or guardian.

Methodology:

i. Persons 18 years and above are considered mature enough to give informed consent for themselves.

ii. In general, HIV testing for children under 18 requires parental or guardians consent, however children under 18, who are married, pregnant, commercial sex workers, street children, heads of families, or sexually active are perceived as "mature minors" and can give consent to HIV testing

iii. Confidentiality of test results of children shall be maintained and only shared with significant persons in the best interest of the child

iv. Disclosure of HIV positive status to a child should be done by 10 years of age upon the assessment of the provider and consent of the parent/guardian.

v. Children who have been sexually abused and put at risk of HIV infection shall receive counseling and testing for HIV and be linked to appropriate services.

2.4.6 Couples and Partners

Couple counselling should be promoted to enhance safer sexual behavior and to encourage disclosure between sexual partners. Couples counselling and testing should be encouraged, and services should address couples' needs flexibly. Both partners must consent to testing and agree to learn the results together.

Methodology:

i. Couples shall be encouraged to go for counseling, testing and receive results together.

ii. The privacy and autonomy of the couple and individual must be respected.

iii. In situations where a partner has tested alone, disclosure of HIV status, partner(s) notification and testing shall be encouraged.

iv. Couples shall be encouraged to be counselled, tested and receive results together

v. Partner notification shall be encouraged in cases where one partner receives the results alone

vi. Informed decisions shall be encouraged among discordant couples to protect negatives and support positives

vii. Pre-engagement, premarital, and preconception counselling and testing will be promoted

2.4.7 Persons with Disabilities

Methodology:

i. HTS for mentally impaired persons shall be provided with the knowledge and consent of the next of kin and should be in the best interest of the client.
ii. HTS sites should be located in lower floors of buildings for easy access by PWDs in case of stairs.

2.5 Referral and linkages

HIV counseling and testing without linkage to care and treatment confers little or no benefit to the client.

Objective:

To ensure that all persons who are tested are linked and referred to prevention, care, treatment and support services in accordance with their sero status

Methodology:

i. Effective networking, consultation and collaboration among stakeholders shall be strengthened to promote linkage of clients to prevention, care, treatment and support services
ii. MoH standard referral forms shall be utilized by all service providers
iii. Community structures shall be utilized to link clients to service points.
iv. All HIV Testing service points shall have a regularly updated referral directory of community and institutional prevention, care and support services, including schools and educational institutions.
v. Please consult the WHO recommended range of services for linkage and referral.

2.6 Strategic health communication

Introduction

Strategic health communication has a critical role to play in behavior change by positively influencing knowledge, skills and attitudes, leading to increased uptake of HTC services and adoption of risk reduction positive living practices.

Objective:

- To ensure that the use of strategic health communication is effectively used in the promotion and delivery of HTS

- To ensure a clear communication content in particular to core care team on HTS

Methodology:

i. HTS programmes shall implement communication support activities based on a standard communication strategy.

ii. HTS communication interventions and development of communication materials for HTS shall follow the MoH standardized process in place, with the full involvement of the health promotion division or section.

iii. HTS programs shall employ a mix of culturally appropriate communication channels and approaches.

iv. Implementation of HTS communication interventions shall involve a participatory approach during planning, execution and evaluation processes to ensure ownership and sustainability.

v. All HTS health education material developed shall be pretested, receive feedback from the target communities before finalization and dissemination.

2.7 Quality assurance

Errors and possible misdiagnosis can come from a variety or a combination of factors related to the assays, the operator or the facility. Misdiagnosis can occur in any setting and regardless of whether laboratory technicians, health workers or trained lay providers conduct the testing. Thus, the HIV testing programmes need to adhere to a functioning quality management system to reduce the risk of errors and help to identify and correct mistakes in HTS delivery.

Objective:

- To ensure that HIV Testing Services meet the required minimum international standards.
- To ensure that there are clear process and procedure for incidence reports in relation to use of medications, reagents, etc.

Methodology:

i. Certification of all HIV Testing Services sites in government facilities, private facilities and non-governmental facilities shall be based on National Minimum Standards for HTS services as set out by the MoH

ii. All HTS service providers shall adhered to National quality standards and implementation guidelines.

iii. MoH shall ensure quality control at all HIV Testing Services –sites as defined in ***Annex 4***

iv. Quality improvement principles and approaches shall be promoted in delivery of HIV Testing Services at all levels.

v. Performance monitoring and supportive supervision shall be implemented for all HTS service providers in the country on a bi-annual basis.

vi. The MoH in collaboration with NHS primary health care services are responsible for ensuring the delivery of high quality HIV counselling.

vii. Only kits which have been pre-qualified by WHO are to be used.

viii. The MoH in collaboration with NHS laboratory services HIV are responsible for ensuring that all HTS providers have copies of and comply with National Standard Operating Procedures

ix. Serology Reference Laboratory Quality Assurance procedures and policies are to be adhered to at all times.

x. On-site evaluations are to be carried out by national and provincial laboratories to assess HIV testing practices and quality assurance and quality control practices.

xi. For External Quality Assurance (EQA), each HTS facility is required to send 5% of specimens to the National Referral Laboratory at the beginning of every quarter for re-testing and validation of results in compliance with the External Quality Assurance System / Programme.

xii. Quality Control (QC), also known as process control, refers to processes and activities to ensure that testing procedures are performed correctly, that environmental conditions are suitable and that the assay works as expected. QC intends to detect, evaluate and correct errors due to assay failure, environmental conditions or operator performance before test results are reported as the HIV status. Hence, QC is a multi-step process with certain checkpoints throughout the testing process.

a) **Before testing** (pre-analytical): Check that the temperature of the testing area is within the manufacturer's recommendations and record the temperatures; Check that stocks of test kits and required consumables are on hand.

b) **While testing** (analytical): Ensure that any QC specimens have been run (for example, test kit controls and/or external QC specimens) and that the results are within QC acceptance criteria; Ensure that a second reader will reread (double-check) all visually read assays.

c) **After testing** (post-analytical): Double-check the report of the test status to the client.

xiii. Through External Quality Assessment (EQA), the performance of a testing site can be evaluated from outside the laboratory or testing site. Methods for EQA include traditional proficiency testing, re-testing of specimens, and careful on-site monitoring using a checklist and knowledgeable assessors.

2.8 Facilities and safety

It is critical that testing facilities are well designed and maintained. The testing site, including where counselling takes place; where specimens are taken and where the test is performed, should be clean and comfortable, with adequate lighting (for reading visually read assays) and free of any potential hazards.

Methodology:

i. Facilities should be organized to protect the confidentiality of clients, including a separate waiting room for those requiring additional testing, as how long a person stays in the same waiting room or how often a person leaves and returns may imply the result of their first assay (A1).
ii. For HIV testing that takes place outside of a facility, programmes must ensure that the providers can conduct the testing without hazard to themselves or to the clients. Providers must observe universal precautions and appropriate waste disposal procedures. In addition, providers must make all efforts to protect clients' confidentiality and privacy.
iii. Hospitals must ensure that 'youth-friendly' services are also linked to care and support services.

CHAPTER 3

ETHICS AND HUMAN RIGHTS

CHAPTER THREE: HTS ETHICS AND HUMAN RIGHTS

3.1 HIV testing ethics

A code of ethics in HIV testing and counselling ensures competent professional behaviour, responsibility to the service users, and supports providers in monitoring their own and their colleagues' behaviour.

Methodology:

i. All service providers shall abide by the rules, regulations and protocols contained in this policy document and other related guidelines
ii. All service providers shall observe the ethical requirements of confidentiality, informed consent, proper counselling, anonymity and privacy
iii. Clients shall be encouraged to disclose their HIV status to their partners at the earliest opportune time.
iv. Where necessary, and at the discretion of the person being tested, shared confidentiality with counselors and health workers, or in some cases family members; loved ones; caregivers; and trusted friends shall be promoted in order to provide appropriate care.

3.2 Human rights

All aspects of HIV programming should ensure the protection of human rights of the people living with HIV and of marginalized populations who are vulnerable to acquiring infection. In line with this, HTS programs and services in Samoa shall further enhance the realization of human rights as laid down in the Universal Declaration of Human Rights and other international conventions and national human rights instruments to uphold the rights of all persons. This section of the guideline therefore provides framework for HTS provision in realization of the stated rights and promotes reduction of stigma and discrimination.

Objectives:

- Ensure all forms of HIV mandatory testing are prohibited with exceptions of blood; tissue and organ donation; court orders,  *and special cases covered under the Health Ordinance 1959.*
- Ensure that all testing is voluntary;
- Ensure that informed consent of patients is obtained before testing;
- Ensure the confidentiality of test results and establishing mechanisms to minimize harms or

- ❖ Provide redress for wrongful disclosure of results; minimizing stigma and discrimination or other forms of harassment/abuse against those who test and those who test positive;

Methodology:

i. All persons shall have the right to access quality HIV Testing services
ii. Clear and accurate information, education and communication on HTS shall be provided to all persons
iii. All service providers shall observe the ethical requirements of confidentiality, informed consent, quality counseling and privacy
iv. All persons accessing HIV counseling and testing shall have the right to health services based on their HIV status
v. Persons who test HIV positive shall not be discriminated against directly or indirectly on the basis of their HIV status.
vi. HIV testing for post exposure prophylaxis (PEP) shall be done using the PEP protocol for the exposed person.
vii. For circumstances where testing shall be done to inform medical and other decisions the persons shall be informed and given opportunity to know their results and such circumstances shall include;
    a) Blood and organ/tissue donation
    b) Occupational and non-occupational exposure
viii. In Samoa, clients are not encouraged to perform their own HIV tests
ix. HIV testing should not be required for employment whether at the time of recruitment, or as a condition for continued employment or for insurance purposes
x. HIV Testing shall not be required for visa, entry, residence, stay and employment in the country.

3.3 HIV confidentiality and information security

The procedures that yield HIV data must conform to international ethical and legal standards. Fundamental ethical and legal standards for protecting privacy and confidentiality exist in relevant human rights instruments. The *Right to Privacy* is cited in Article 12 of the Universal Declaration on Human Rights; Article 17 of the International Covenant on Civil and Political Rights; and Article 37 of the Convention on the Rights of the Child. The HIV-related action is to ensure that HIV test results are confidential and to guarantee the right of non-disclosure to third parties. The Declaration of Commitment on HIV and AIDS (UNGASS 2001) states that "the full realization of human rights for all is an essential

element in a global response to HIV and AIDS" (paragraph 16). In particular, governments committed themselves to enforce legislation, regulations and other measures to ensure all the rights of people living with HIV, including privacy and confidentiality (paragraph. 58).

Another source of international standards is the UNESCO *Universal Declaration on Bioethics and Human Rights.* Article 9 of the Declaration, entitled Privacy and Confidentiality, states: "The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law."

Objective:

- The purpose is to ensure that HIV data and information are used to serve the improvement of health as well as the reduction of harm for all people.

Methodology:

i. Organizations; institutions; and individuals have a duty to respect the rights of those whose identifiable data that may be collected or stored of certain individuals. These rights include but are not limited to:
   a) The right to refuse to answer questions posed by those collecting the data;
   b) The right to have free a copy of their health record;
   c) The right to access, review, and correct identified data that can be verified to be erroneous;
   d) The right to voluntary informed consent when appropriate;
   e) The right to seek redress for a perceived breach of confidentiality without negative consequences.

ii. Organizations; institutions; and individuals having access to the data have an obligation to ensure that that confidentiality and security protections for identifiable information are in place.
   a) Confidentiality and security protections are required to ensure the quality of prevention, treatment, and care programs.
   b) Local ownership and proper steps to ensure confidentiality and security help to provide good data for reporting upstream.
   c) Measures for confidentiality and security protection should go hand in hand with community and advocacy efforts to reduce HIV-related stigma, including stigma

experienced by populations most at risk.

iii. HIV-related information and data collected for patient management and monitoring should be stored in a technically and physically secure environment.

iv. Individuals authorized to access HIV-related information should receive appropriate training / briefing and should be responsible for protecting confidentiality.

v. Security breaches and loss of confidentiality should be investigated thoroughly and appropriate sanctions imposed.

vi. Security laws; related regulations and policies should be continuously reviewed, independently assessed, and changed when required.

v. Data may be shared between or among organizations or institutions provided that:

   a) The recipient will be using the data for a legitimate health purpose;

   b) The nature and amount of data shared is contingent on the reason for the data transfer, but should always be the minimum amount of data required to successfully complete the task. For example, personal identifiers should never be transmitted when a pseudo-anonymized record can complete the task;

   c) The confidentiality and security measures of the receiving organization are equivalent to those of the organization, which collected the data as agreed to at the time when the data is collected.

vi. Organizations and institutions should collect only information that fulfills the clearly stated purpose(s) of the activity.

vii. Organizations, institutions, and individuals have an obligation to ensure that all policies and procedures related to confidentiality and security of identifiable information should be transparent and available. This includes potential future use of routinely collected patient information, including on deceased individuals.

viii. Organizations, institutions, and individuals who fail to adequately protect the confidentiality and security of identifiable information should be held accountable and appropriate remedies should be imposed.

ix. Individual level information should not be shared with those charged with law enforcement, immigration control, management of the public welfare system, or other non-health functions without consent from the individual to whom the information relates, except in circumstances involving the threat of imminent danger of grave physical harm to individuals or populations.

x. All authorized persons involved when dealing with the data, should be responsible for ensuring data confidentiality and security and for reporting suspected security breaches.

xi. All authorized staff members should be provided with the policy document and must receive training in maintaining the appropriate confidentiality and security measures.

xii. Personal identifiable data should be collected only by people who have already signed a confidentiality agreement

xiii. Confidentiality and security guidelines must protect against the disclosure of data during the data collection process, in addition to protecting data during the storage, analyses and feedback phases. For instance, the conversation between patients and the personnel in charge of the collection must be done in a way that unauthorized people cannot hear the personal data shared.

xiv. The collection of personal data should be kept at a minimum.

xv. Staff access to information, whether for data collection, use, dissemination, or disposal, must be based on the role assigned to the staff member. For example, clinical staff would need full access to individual records within their facilities, but not, usually, across facilities; district supervisors need access to data from across their districts, but not necessarily to personally identifying data, except under special circumstances such as focused evaluations or investigation of breaches; data analysts will typically not need access to personally identifiable data.

xvi. Staff access to equipment and hardware used for collecting, storing, or disposing of HIV related information must be based on the role assigned to the staff member.

xvii. Systems used for the authentication of staff accessing HIV related data must be robust and secure and must include procedures for withdrawing access rights when staff is no longer employed at the site.

xviii. Rooms containing individual medical records or HIV program data, whether stored as paper documents or electronically, must be properly secured to limit unauthorized access.

xix. Data being moved within sites or from site to site, whether on paper or on removable data storage equipment, need to be properly secured.

xx. All removable or portable equipment should be properly secured within facilities (rooms or cabinets) which are locked and appropriately monitored.

xxi. Fixed computers and other hardware need to be properly secured using locks and passwords.

CHAPTER 4

SYSTEMS & INFRASTRUCTURE

CHAPTER FOUR: SYSTEMS AND INFRASTRUCTURE

4.1 Coordination

Coordination with reference to HIV Testing Service delivery leads to a harmonized response of HTS programs in the country. The essence is to set a vision, minimize overlaps and ensure a unified response amongst diverse and numerous providers and funders.

Objective:

- To harmonize and strengthen the implementation of HIV Testing Services by different stakeholders and sectors

Methodology:

i. HTS services shall be standardized nationwide and shall be authorized, supervised, supported and regulated by MoH
ii. HTS services shall be strengthened through effective networking, consultation and collaboration among stakeholders
iii. The MoH shall provide guidance on effective utilization of resources for HTS by all implementers, in both public and private sectors.

4.2 Human resources for HIV testing services

Health personnel, laboratory personnel, policy makers, nongovernment organizations, youth groups and many others play a crucial role in the delivery of HIV testing Services. To ensure a high quality service is provided it is crucial that personnel involved in HIV testing and counselling receive standardized training, supervision and ongoing professional support.

Objective

- To ensure quality HTS provision through qualified and appropriately trained personnel

Methodology:

i. HIV testing services will be carried out by health care workers who have completed and passed the required training or an equivalent training recognized by the Samoa Ministry of Health. Health care workers include doctors, nurses, midwives, and ancillary and laboratory personnel.
ii. HTS providers must at all times adhere to the latest national HIV Testing services policy and guidelines.

4.3 HTS by lay providers

The New (2015) WHO Consolidated guidelines on HIV testing services recommend that Lay providers who are trained can, using rapid diagnostic tests, independently conduct safe and effective HIV testing services. Services delivered by trained lay providers, including peer-led interventions, can be both welcome and important, providing information and teaching skills that facilitate safer behaviours. Trained lay providers based in the community or a facility can conduct HTS and also can link people to treatment and prevention services and provide ongoing care and support. Beyond this, trained lay providers who are their clients' peers can act as role models and offer non-judgmental and respectful support. Their role can help to reduce stigma, expand the coverage of HTS and improve the uptake of services.

A **Lay provider** is any person who performs functions related to health-care delivery and has been trained to deliver specific services but has received no formal professional or paraprofessional certificate or tertiary education degree.

 *Due to confidentiality concerns, Samoa has opted for community based healthcare providers/health workers, as opposed to lay providers, for delivering HIV and STI testing and counselling services. These are defined as individuals with some form of clinical or health-based training and are registered as per the requirements of the Healthcare Professions Registration and Standards Act 2007 and the Allied Health Professions Act 2014. These professionals can include community health workers, medical assistants, and midwives. These registered practitioners will be utilized with their practiced regulated under this guideline, in place of lay-providers.*

Objective:

- Expanding HIV testing services to trained lay providers working in the community may help to increase access to these services and their acceptability to people from key populations and other priority groups. These groups may be reluctant or unable to use HTS in health facilities.

Methodology:

i. Lay counsellors are permitted to carry out HIV counselling as long as they have undertaken appropriate training approved by the Samoa Ministry of Health.

ii. Persons who have completed at least minimum level of education as defined by Samoa Education Authority, shall be qualified to be trained as Lay Providers, and shall be

accepted to conduct HIV Counseling and Testing using RDTs, with the supervision of a health worker

iii. HIV Programmes should select and train lay providers who are well-matched to the people they serve. They may be their clients' peers, people with HIV and people from key populations.

iv. This policy permits trained lay providers to provide all HIV testing services, including collecting specimens, performing HIV rapid diagnostic test, interpreting tests results and issuing an HIV status, giving pre-test information and post-test counselling, and supporting linkages to prevention, care and treatment services.

v. Trained lay providers should have the trust of their clients and demonstrate professional conduct, knowledge, skill in dealing with sensitive issues, respect for confidentiality and an ability to listen.

vi. Ongoing supportive supervision of lay providers must be done regularly and it should cover both the testing and counselling aspects of their work, provide up-to-date job aides and standard operating procedures, and involve regular external quality assessment.

vii. A system for quality assurance, including external quality assessment should be in place for HTS provided by trained lay providers.

viii. National competency standards can help to ensure that lay providers offer high-quality HTS and are adequately trained in medical ethics and how to conduct full HTS procedures.

ix. Trained lay providers should receive adequate wages and/or other appropriate compensation. Otherwise, turnover may be high. The main reason for involving lay providers is to increase access to HTS, not to cut costs.

x. National policies and regulatory frameworks, such as human resource for health and HIV testing policies, should address the roles of trained lay providers.

4.4 Training and capacity building

Delivery of effective HTS depends largely on the knowledge, skills, motivation, equitable and appropriate deployment of personnel responsible for organizing and delivering health services. A training package on HTS, ART and STI case management needs to be adopted by MoH in Samoa to be used for training of services providers.

Objective:

- To ensure that competent HTS providers are available at all service delivery levels according to the establishment.

Policy Statements:

i. Institutions, MoH certified trainers and implementing partners conducting HIV testing services training shall follow the MoH approved curricula
ii. All persons that receive training according to the MoH approved curriculum shall qualify to offer HTS
iii. Medical laboratory personnel shall perform all HIV tests, however other health service providers and community service providers trained in HIV rapid testing can carry out rapid HIV tests
iv. MoH shall coordinate, guide and where necessary supervise HTS in-service trainings to all service providers intending to offer HTS; HTS trainings to service providers shall not in any circumstances be encouraged without the knowledge or approval of the MoH
v. HTS logistics management training shall be provided to all health care service managers
vi. HTS trainings shall be conducted by MoH accredited institutions and certified trainers
vii. The MoH in collaboration with Ministry of Education and Sports shall ensure integration of HTS training modules in pre-service training curricula of health workers and other relevant professions.
viii. HTS providers shall regularly update their knowledge and skills through appropriate means such as attending refresher trainings and workshops, use of updated guidelines, job aides and standard operating procedures in place, participating in supportive supervision.

4.5 Logistics management

HTS test kits, supplies and commodities approved by the MoH are essential to delivery of quality HTS. Effective supply chain management system is critical for maintenance of adequate levels of stock for sustained service delivery. Given the Samoa context , in consideration of factors such as cost and availability of the test kits, reagents pre-qualified by WHO and equipment; available staff, resources and infrastructure; the number of samples to be tested; sample collection and transportation and the ability of clients to return for HIV test results; the Rapid Diagnostic Testing of HIV is recommended. The advantages of using rapid HIV test particularly for health facilities where laboratory services are weak/unavailable include; visibility of the test and quick turn-around, increasing confidence in results and avoidance of clerical errors. Rapid HIV testing can occur outside laboratory settings, does not require specialized equipment and can be carried out in primary health facilities and community settings.

Objectives:

- To ensure availability of quality, adequate and essential HTS supplies and commodities at all levels.
- To regulate the inflow and usage of HIV diagnostic tests.

Methodology:

i. MOH will ensure availability of adequate essential HTC supplies and commodities at all levels.
ii. Functional Logistics management systems shall be utilized at all levels
iii. MOH shall define specifications for HIV diagnostic tests.
iv. The checklist for HTS supplies (See ***Annex 5)*** shall act as guidance for procurement by HTS programmes in the country.
v. All HTS service providers, to enable accurate quantification of demand and consumption levels, and mitigate stock-out and expiry of kits, shall adhere to regular stock taking and updating of stock records.
vi. The MOH shall develop and distribute HTS stock cards to all service providers, and compile a monthly update on consumption of HTS test kits and supplies across the country
vii. Consumption of HTS test kits and supplies shall be on a First-to-Expire First Out (FEFO) basis

4.6 Infrastructure

HTS may be conducted in a variety of settings that ensure privacy, confidentiality, and convenience for the client. Adequate space and safety of the provider and client are essential for quality service delivery.

Objective:

- To ensure that HTS are provided under appropriate infrastructure that meet the minimum standards

Policy Statements

i) All HTS shall be provided in an environment that ensures safety of the provider, client and the community.

ii) HTS programs shall minimize infrastructural barriers to HTS through innovation and improvisation whilst meeting quality standards, especially during mobile HTS outreach programmes.

iii) HTS programs shall ensure safe storage of HTS supplies and commodities

iv) HTS sites shall be certified if they meet the minimum standards for HTS points (See ***Annex 6).*** In case of Home Based HIV testing services, it shall be done by a trained HIV counselor, and observe the standard operating procedures for counseling and testing as well as universal precautions.

v) There shall be coordination mechanisms for HTS implementation at National, Provincial and Health Zonal levels, integrated with other RH coordination platforms.

vi) HTS Implementing partners shall be required to participate in the National, technical, management and planning meetings when called upon by the MOH or representatives.

4.7.Monitoring & evaluation

4.7.1 Management Information System

A functional monitoring system is essential in delivery of quality HTS. This requires appropriate tools for data collection and reporting. Confidentiality, storage, analysis and utilization of data are critical elements of Management Information System.

Objective:

- To utilize strategic information for HTS programming

Policy Statements:

i. MoH shall develop and ensure that standard HTS data collection and reporting tools are available and utilized at all HTS delivery points in the country.

ii. MoH standard mechanisms for HTS data storage and reporting shall be adhered to by all implementers

iii. Monitoring and Evaluation of HTS shall be in line with the National Monitoring and Evaluation Framework for NSP in the health sector.

iv. All HTS providers in the public, private and not-for-profit sectors shall report to the MoH on a monthly basis, data on HTS provided, for harmonization into the HMIS or HIS

v. The MoH shall map all HTS providers in the country, including private sector, NGOs and Government Health Facilities, and update this list bi-annually.

vi. HTS programs shall document referrals to prevention, care and support services.

4.7.2 Research

The surveillance of HIV is essential for monitoring epidemic trends and evaluating the effectiveness of a country's response. HIV sentinel surveillance and population-based and community surveys that include HIV testing are important components of HIV surveillance. They are used to estimate the prevalence and geographical distribution of HIV infection, identify and characterize key populations at risk for HIV infection and track trends over time.

Objective:

- To guide HTS research for programming in the country, as Samoa MOH needs these data to inform effective policies, strategic plans and programmes and to set evidence-based programme targets.

Policy Statements:

i. HIV surveillance should prioritize key populations as well as other vulnerable groups.

ii. Biological surveillance should be conducted among people with presumed or diagnosed TB or at high risk for other STIs, including HBV and HCV infections.

iii. This policy recommends a collaborative approach to surveillance of HIV and closely linked infections to expand epidemic monitoring and response and enhance efficiency. Any of these infections that are diagnosed as part of HIV surveillance activities should be managed according to WHO guidelines.

iv. HIV surveillance projects should ensure that all participants in biological surveillance receive their HIV status to further facilitate appropriate linkage to care. However, all efforts must be made to prevent any adverse consequences of informing participants of their HIV status, especially in surveys among marginalized and criminalized populations.

v. Linked testing is the HIV testing approach recommended to be used in surveillance as it enables participants to receive their HIV status.

vi. Linked testing can be confidential (using personally identifiable information) or anonymous (using only a code or number as a unique identifier).

vii. This approach contrasts with unlinked anonymous surveillance, which is **no longer** recommended.

 *There is current no mechanism in Samoa to facilitate linked identifiers between healthcare services, as the system is paper and facility based.*

viii. With linked HIV testing, the participants should receive pre-test information and post-test counselling as well as their test results and their HIV status.

ix. In linked confidential testing:

a) The participants agree to be tested for HIV with the assurance that their HIV status will remain confidential and will be available only to the participant and, on a need-to-know basis, to health-care staff.

b) As with all HIV testing, the staff member must obtain the participant's consent before collecting the specimen and conducting HIV testing.

c) The consent process must inform the person how the data are to be used, including security details of any registry where the data are maintained.

d) The staff member / researcher collects the demographic details of the participant (for example, age, sex, marital status, geographical area of residence, parity, education and medical history) at the time the specimen is obtained and records this information on a surveillance form (either paper or electronic).

e) The surveillance form should be indexed with an identifying code or other details (for example, the participant's name or the clinic's client/patient identification number) that can be used to match the form to the specimen.

f) On completion of HIV testing, the demographic details collected on the surveillance form are linked to the result.

x. HTS related studies in Samoa shall be done with knowledge or ethical approval of the MoH Research and Ethics Committee.

xi. There shall be regular dissemination of HTS research findings to all stakeholders.

xii. Research results shall be utilized to inform HTS policy and implementation; and shall be presented based on the data needs for reporting of the MoH of Samoa

xiii. MoH shall provide guidance on HTS priority research areas.

xiv. All HTS research shall conform to the relevant legislation and ethical standards of practice set by appropriate research ethical committees and bodies of government at various levels

xv. Documentation and sharing of lessons learned and good practices shall be promoted

4.7.3 HTS Indicators, Data Collection & Reporting Algorithm

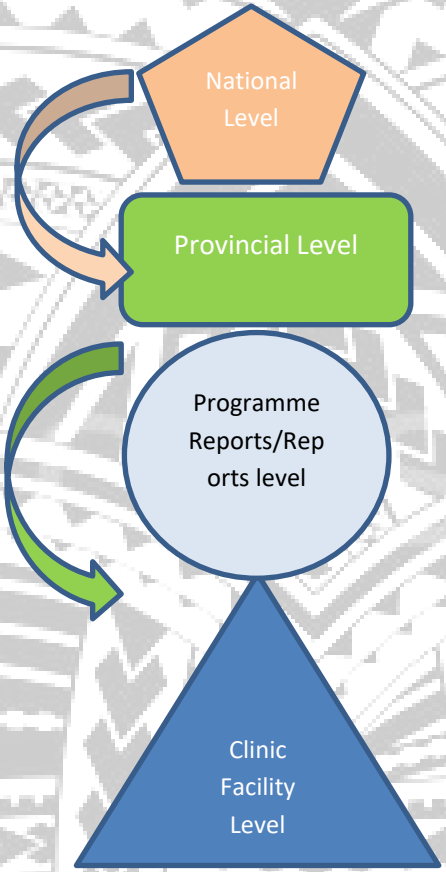
WHO 2015 Recommended HTS Indicators				
Indicator	**Numerator/ Denominator**	**Disaggregation**	**Measurement Method**	**Programme relevance & interpretation**
HTS.1 % of People with HIV who have been diagnosed and tested HIV-positive	**Numerator:** Number of people with HIV who have been diagnosed and received their results **Denominator:** Number of people with HIV	Sex, age (<1, 1–4, 5–9, 10–19, 15–19, 20–24, 25–49, 50+ years), key population, other target populations	Best estimate based on available data sources, for example; **1.** Based on facility data: **Numerator:** Cumulative number of reported new HIV diagnoses minus deaths; **Denominator:** national estimate of people with HIV based on internationally consistent modelled estimates, for example, Spectrum AIM. **2.** Based on population-based surveys collecting HIV status and with a question to assess whether respondents know their positive status. The indicator will be calculated as people with HIV who report knowing their status. **3.** Based on population-based surveys collecting HIV status without a question to assess whether respondents know their positive status. Construct a plausible range and midpoint based on: the higher value of (the percentage of survey respondents with HIV who have been tested in the past 12 months and received the results) and (the percentage of all people with HIV on care) as the lower end of the range, and the percentage of people with	Critical to determine the proportion of people living with HIV who know their HIV status, as this knowledge is the entry point to the continuum of care. Disaggregated estimates can reveal gaps in diagnosing people with HIV. The proportion of people with HIV who know their HIV positive status should also be globally reported for target populations where these are collected as national indicators, including: 1. % of key populations 2. % of pregnant women who have been tested in the past 12 months and know their status.

			HIV ever tested as the upper end of the range. 4. Other surveys, related programme data and modelled estimates can be used as additional data sources for developing and triangulating estimates.	

These indicators are aligned with the Monitoring and Evaluation Manual for HIV, STI's, and TB 2017

National HIV diagnosis outcome indicators
1. Percentage of adults (men and women of 15-49 years) who received an HIV test in the last 12 months and who know the result 2. Percentage of identified vulnerable population who received an HIV test in the last 12 months and who know the result. 3. Percentage of laboratories that are accredited according to national/international standards.

4.7.4 HTS Data Collection and Reporting Channel



TIPS:

- *Types (name) of reporting forms used at each level*
- *Agree on Frequency of Reporting at all levels*
- *Identify responsible staff at each level*
- *Clarity on where to send reports*
- *Establish a feedback mechanism*

REFERENCES

1. WHO (July 2015) Consolidated Guidelines on HIV testing services, (http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/)

2. WHO (2014) WHO reminds national programmes to retest all newly diagnosed peoplewith HIV (http://www.who.int/hiv/pub/vct/retest-newly-diagnosedplhiv-full/en/)

3. WHO (2014) Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations (http://www.who.int/hiv/pub/ guidelines/keypopulations/en/)

4. WHO (2013) Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (http://www.who.int/hiv/pub/guidelines/arv2013/download/en/index.html).

5. WHO (2013) Guidelines on HIV testing and counselling for adolescents and care for adolescents with HIV (http://www.who.int/hiv/pub/guidelines/adolescents/en/).

6. WHO (2012) Guidance on couples HIV testing and counselling, including antiretroviral therapy for treatment and prevention in serodiscordant couples (http://www.who.int/hiv/pub/guidelines/9789241501972/en/index.html).

7. WHO (2011) Guideline on HIV disclosure counselling for children up to 12 years of age (http://www.who.int/hiv/pub/hiv_disclosure/en/)

8. WHO (2010) WHO recommendations on the diagnosis of HIV infection in infants and children (http://www.who.int/hiv/pub/paediatric/diagnosis/e/)

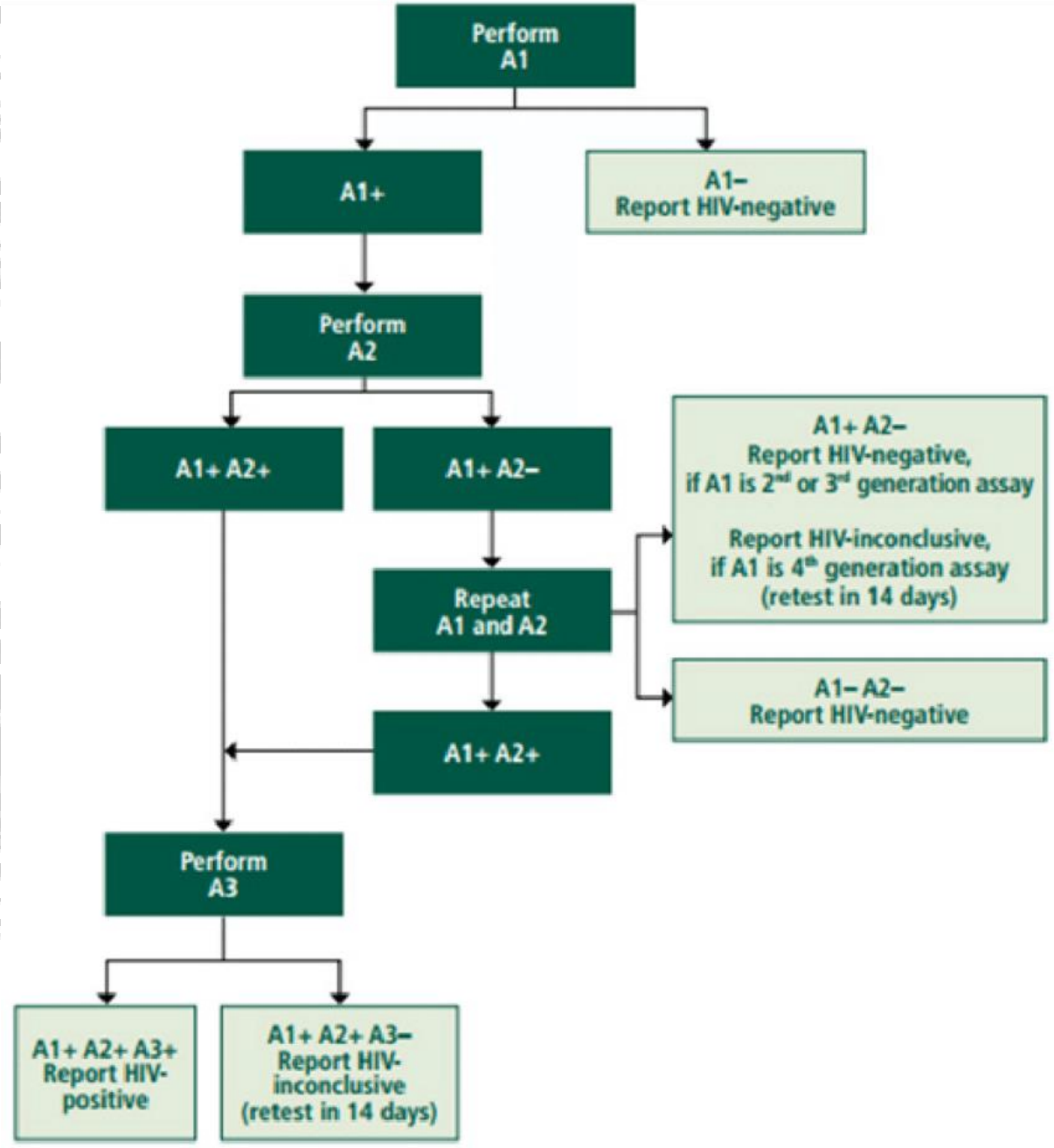
9. WHO (2010) Delivering HIV test results and messages for re-testing and counselling inAdults (http://www.who.int/hiv/pub/vct/hiv_re_testing/en/index.htm)

10. WHO (2007) Guidance on provider-initiated HIV testing and counselling in health Facilities, (http://www.who.int/hiv/pub/vct/pitc/en/index.html).

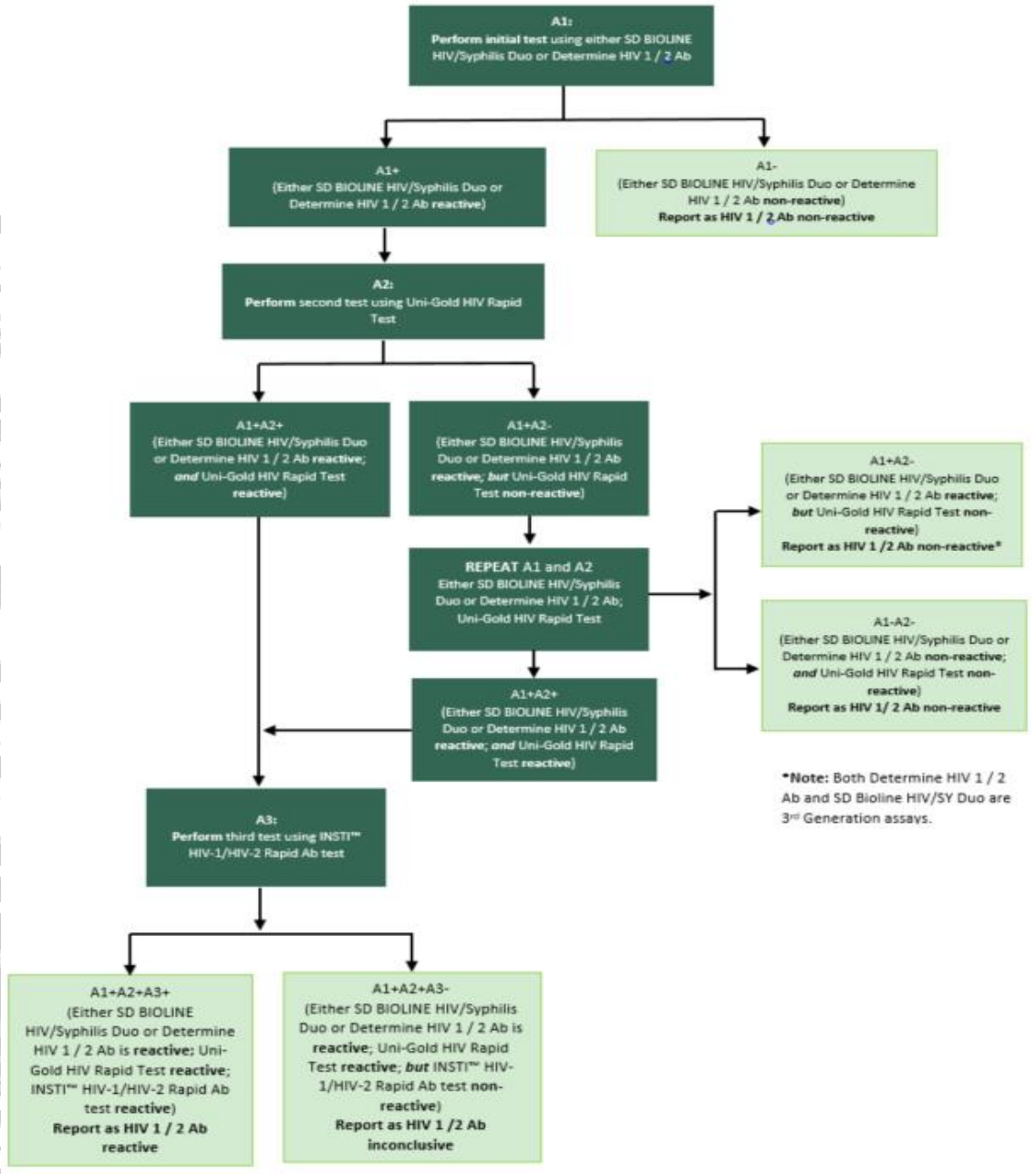
ANNEX SECTION

ANNEXES

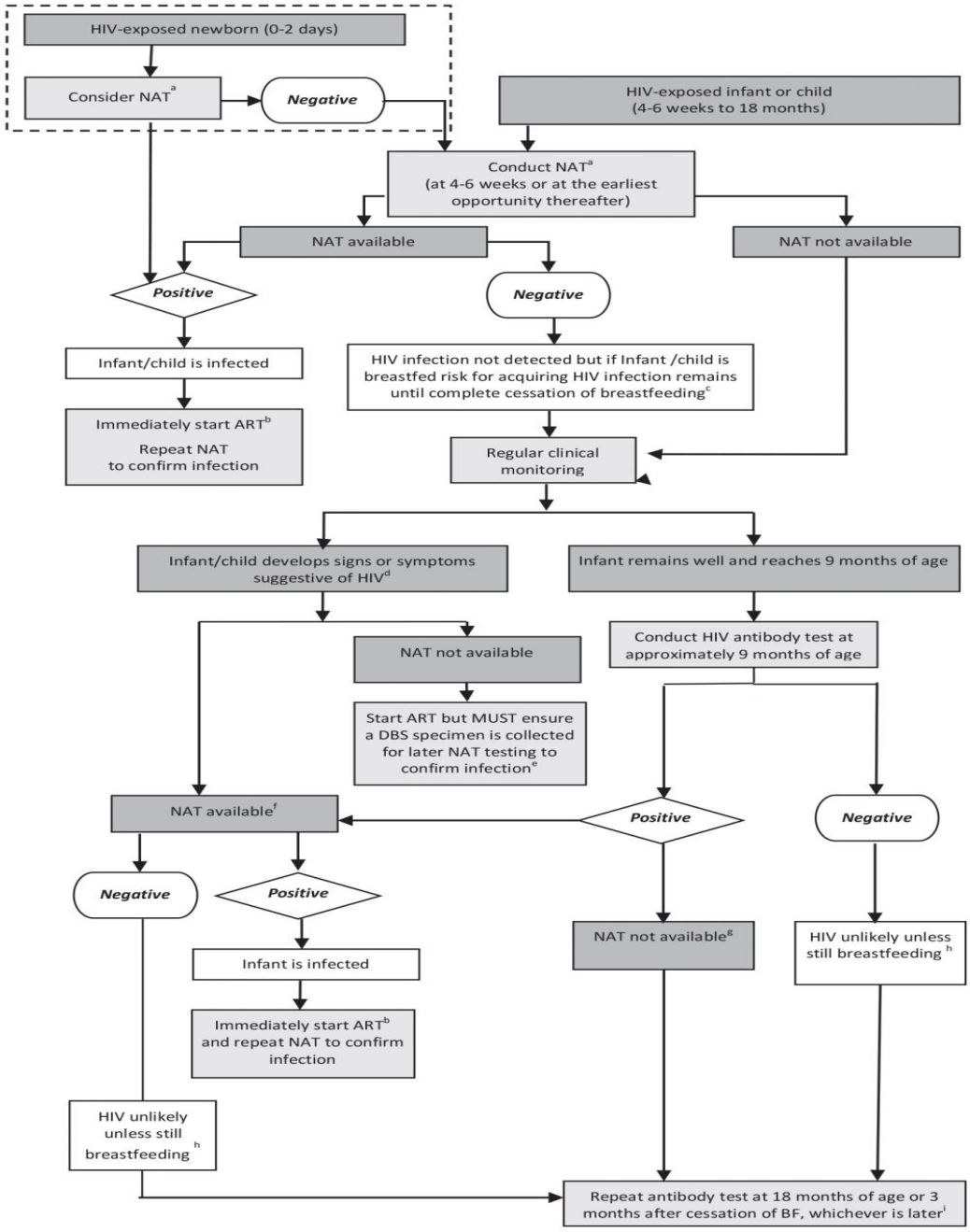
Annex 1: HIV testing strategy for HIV diagnosis in low prevalence setting



Annex 2: Recommended HIV Testing Algorithm for HIV diagnosis in Pacific Island Countries (PICs) using either Determine HIV 1 / 2 Ab or SD BIOLINE HIV/Syphilis Duo as first assay



Annex 3: Testing Strategy in Early Infants and Children



Annex 4: HIV Testing Sites in Samoa

List of active HIV Testing Services Sites in Samoa - 2017

Basic Information				Location			Operational		
Facility ID	Name of Facility	Alternate Name (Village Name)	Designation	Province	Island	Health Zone	Ownership	Setting	Current Status (2017)

Annex 5: HTS Rapid Test Supplies Checklist

(a) Checklist of supplies to carry out HIV rapid tests in hospital laboratory setting

____	HIV Rapid Test Kit(s)	____	Surgical Gloves
____	Alcohol or alcohol prep pads	____	Cotton gauze / wool
____	Laboratory Coats or Aprons	____	Timer, clock, or watch
____	Sterile Lancets	____	Lancet bin or Disinfectant jar
____	Transfer pipettes, pipette tips	____	Pens for labelling
____	Paper towels	____	Hand washing soap
____	Leak-proof bag	____	Disinfectant
____	Band-Aids or plasters	____	Thermometer
____	Positive and Negative Controls	____	Log book or register
____	Spray/Wash bottle	____	Standard Operating Procedures
____	Waste Container	____	Safety box for sharps disposal
____	Specimen bottle for referral of reactive specimens		

Checklist of supplies to carry out HIV rapid tests in community setting

_____	HIV Rapid Test Kit(s)	_____	Surgical Gloves
_____	Alcohol or alcohol prep pads	_____	Cotton gauze / wool
_____	Paper towels	_____	Timer, clock, or watch
_____	Band-Aids or plasters	_____	Lancet bin or Disinfectant jar
_____	Positive and Negative Controls	_____	Pens for labelling
_____	Waste disposal container/ Safety box	_____	Log book or register
_____	Standard Operating Procedures	_____	Client Consent forms

Annex 6: HTS Site Assessment Tool

SAMOA HIV TESTING SERVICES (HTS)
HEALTH FACILITY CERTIFICATION CHECKLIST

Facility: …….. Zone: ……
Province: …….. Date: ……

Ref #	Assessment Criterion / Benchmark	Comment	Rating (Fully Met / Met in Part / Not Met)
1	A room available for pre-test information session; group / family counselling; and post test counseling		
2	The counselling room(s) is(are) private and adequately sound proof		
3	A confidential filing system is in place for client medical records / HTS records		
4	Appropriate communication materials are available for clients health education		
5	Occupational safety charts are available & displayed in blood taking rooms		
6	A procedure is in place for transport of medical records / HTS records		
7	HTS staff meet the minimum training standards		

RECOMMENDATIONS:*(Certified / Not Certified; give reasons & next steps)*

……
……
……..

ASSESSMENT DONE BY:

Name:…… Title:……
Signature:……..

ENDORSED BY:

Name: …… Title: Program Manager, HIV and STI Unit – MOH/DOH
Signature:……

Annex 7: HTS Support Supervision Tool

HIV TESTING SERVICES (HTS) SUPPORT SUPERVISION CHECKLIST

Health worker Supervised: …… Support Supervisor: ……
Health Facility:…… Date of Visit: ……

(a) HTS SUPPLIES & COMMODITIES

	HTC Service benchmark	Observation		Comment
		Yes	No	
1	RDT HIV test kits are available on site.			
2	Test kits are stored appropriately, as per manufacturer's recommendations			
3	RDT stock cards are in place			
4	RDT stock cards are filled daily and are up to date			
5	A sharps container is available for disposal of sharps and other wastes			
6	The RDT kits SOP is available on site and visibly displayed for reference by HW			
7	Condoms are recommended for distribution at the site			

(b) PRE-TEST / GROUP information session guide to counsellor

	HTS benchmark	Observation		Comment
		Yes	No	
1	**Step 1:** Counselor greets participants, introduces self and the (HTS) service and facilitates group introductions			
2	**Step 2:** Counselor gives information on; - Basic facts about HIV - Basic information about HIV transmission and risk reduction - Talks about the window period - Demystifies common myths and misconceptions - Demonstration and discussion of condom use - Benefits of HIV testing and			

	counseling - HIV Testing and results giving procedures - Confidentiality and privacy - Refers to appropriate job aides			
3	**Step 3:** Counselor gives the following extra information for pregnant women; - The risk of transmitting HIV to the infant - Measures that can be taken to reduce mother-to-child transmission, including antiretroviral prophylaxis and infant feeding counselling - The benefits to infants of an early diagnosis of HIV - Refers to appropriate IEC materials			
4	**Step 4:** Summarizes key points			
5	**Step 5:** Allows time for questions and comments			

(c) HIV TESTING

	HTS benchmark	Observation		Comment
		Yes	No	
1	Clients are called in one at a time or as couples, to a private counseling room for HIV testing.			
2	Patient information form is in place, and is duly completed before the test			
3	Counselor explains why the form has to be completed, reassuring on confidentiality			
4	The counselor / lab personnel maintains a clean work station for conducting the test			
5	Specimen is appropriately labelled with a client number during the test			
6	Health worker observes minimum infection control and occupational safety standards (use of gloves, new sharps)			
7	Health worker strictly follows the SOP steps for the HIV test kit being used.			

8	A sharps are disposed off in sharps container			
9	Results are timed, and read in accordance with test specifications			
10	Results are carefully recorded as per the client code on the specimen and form			

(d) POST-TEST COUNSELING

	HTS benchmark	Observation		Comment
		Yes	No	
1	**Step 1:** Counselor reviews results - Reviews the client's pre-test counselling notes. - Checks laboratory results against the client's code to ensure results are given to the right client - Calls clients one at a time, or as couples, into the private counseling room to receive results			
2	**Step 2:** Assesses the client's readiness to receive the HIV test result - Begins the post test counselling session by asking the service user how he/she has been feeling since having the blood drawn for the test. - If the client has a history of drug and alcohol abuse assess whether he or she is sufficiently alert and coherent to receive the results.			
3	**Step 3:** Gives the HIV test result - Tells the client what a positive result means, and what a negative result means - Asks the client what they will do next if their result was negative (and then counsel on prevention) - Asks the client what they would do next if their result was positive (and the counsel on positive living) - When the client is ready, give test result in a neutral tone of voice and wait for the client to respond. - Give the client time to absorb the information.			
4	**Step 4: If client is negative;** - Counsels client on prevention, gives a condom			

	demonstration and gives the client condoms			
5	**Step 5:** If client is positive, provides brief information on follow up and support - Provides brief information on HIV treatment, care and advice on healthy living. - Assesses service user's capacity to cope with results within the next 48 hours - Discuss strategies for partner disclosure			
6	**Step 6:** Gives follow up appointments and referrals to other services as required - Refers client for TB screening - Refers client to ART clinic - Assesses if the client will reach home safely - Assesses if the client will reach referral point, and make arrangements to accompany client			
7	**Step 7:** Completes the post HIV test counselling form ensuring all relevant steps have been followed			

(e) REFERRAL

	HTS benchmark	Observation		Comment
		Yes	No	
1	Referral forms are in place, for referral of clients for care or confirmatory testing			
2	Referral cases are referred immediately they are identified			
3	Clients are supported to reach the referral point			
4	There is a procedure in place for follow-up of referred clients			
5	Referral forms are properly filed and kept for follow-up			

(f) HTS RECORD KEEPING / M&E / REPORTING

	HTS benchmark	Observation		Comment
		Yes	No	
1	HTS data collection and reporting tools are in place			
2	HTS data collection tools are completed daily and are up-to-date			
3	There is a procedure in place for sending monthly reports to the National			

	HIV and STI Unit			
4	Client medical records including HIV Testing & Counselling records are stored securely			

(g) ACTION PLAN:

	Key actions to address gaps identified and improve quality of service delivery	By Whom	By When
1	▪ ▪		
2	▪ ▪		
3	▪ ▪		

Annex 8: Standard Operating Procedures for HIV Test Kits

1. Determine HIV 1 / 2 Ab Rapid Test
2. Uni-Gold HIV Rapid Test
3. Insti HIV Rapid Test
4. SD BIOLINE HIV/Syphilis Duo (recently validated and currently being piloted in 5 PICs)

Determine HIV Rapid Test

(For use with whole blood, serum, or plasma)
Store kit: 2 - 30° C

- Check kit before use. Use only items that have not expired or been damaged.
- Bring kit and previously stored specimens to room temperature prior to use.
- Always use universal safety precautions when handling specimens. Keep work areas clean and organized.

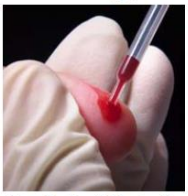
This outline is not intended to replace the product insert or your standard operating procedure (SOP).

1. Collect test items and other necessary lab supplies.

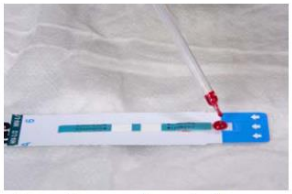
2. Use 1 strip per test and be sure to preserve the lot number on the remaining packet of strips.

3. Label the test strip with client identification number.

4. Pull off the protective foil cover.



5. Collect 50 µl of specimen using either a pasteur or precision pipette.



6. Apply the specimen to the absorbent pad on the strip.

7. For whole blood only add 1 drop of chase buffer to the specimen pad.

8. Wait 15 minutes (no longer than 60 minutes) before reading the results.

9. Read and record the results and other pertinent info on the worksheet.

Determine HIV Rapid Test Results

Reactive
2 lines of any intensity appear in both the control and patient areas.

Non-reactive
1 line appears in the control area and no line in the patient area.

Invalid
No line appears in the control area. Do not report invalid results. Repeat test with a new test device even if a line appears in the patient area.

Use of trade names and commercial sources is for identification only and does not imply endorsement by WHO, the Public Health Service, or by the U.S. Department of Health and Human Services (2005).

Uni-Gold HIV Rapid Test

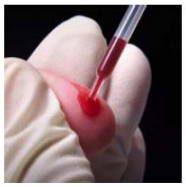
For use with whole blood, serum, or plasma
Store Kits: 2 - 30° C

- Check kit before use. Use only items that have not expired or been damaged.
- Bring kit and previously stored specimens to room temperature prior to use.
- Always use universal safety precautions when handling specimens. Keep work areas clean and organized.

This outline is not intended to replace the product insert or your standard operating procedure (SOP).

1. Collect test items and other necessary lab supplies.

2. Remove device from package and label device with client identification number.



3. Collect specimen using the disposable pipette.

4. Add 2 drops (approx. 60µl) of specimen to the sample port in the device.

5. Add 2 drops (approx. 60µl) of the appropriate wash reagent to sample port.

6. Wait for 10 minutes (no longer than 20 min.) before reading the results.

7. Read and record the results and other pertinent info on the worksheet.

Uni-Gold HIV Rapid Test Results

Reactive

2 lines of any intensity appear in both the control and test areas.

Non-reactive

1 line appears in the control area and no line in the test area.

Invalid

No line appears in the control area. Do not report invalid results. Repeat test with a new test device even if a line appears in the test area.

WHO

Use of trade names and commercial sources is for identification only and does not imply endorsement by WHO, the Public Health Service, or by the U.S. Department of Health and Human Services (2005).

CDC

ILLUSTRATED USE OF A SINGLE INSTI™ TEST KIT

The INSTI™ HIV-1/HIV-2 Rapid Antibody Test is a rapid *in vitro* qualitative test for the detection of antibodies to Human Immunodeficiency Virus Type 1 and Type 2 in human whole blood, fingerstick blood, serum or plasma. The test is intended for use by trained personnel in medical facilities, clinical laboratories, emergency care situations, and physicians' offices as a screening assay capable of providing test results in as little as 60 seconds. The assay is packaged as a kit containing INSTI™ Membrane Units, Sample Diluent, Color Developer and Clarifying Solution, and is available in point-of-care use packaging, or packaging suitable for laboratory use.

Collect 50µl of fingerstick blood, venous whole blood, serum or plasma and add bottle number 1, Sample Diluent, re-cap and invert 3-4 times.

2) Pour the entire contents of bottle number 1 into the center of the Membrane Unit well. HIV antibodies, if present, are captured at the test spot by proteins on the membrane.

3) Add the entire contents of bottle number 2, Colour Developer, into the center of the Membrane Unit well to generate a blue control spot and a second spot if HIV-1/HIV-2 antibodies are present.

4)Add the entire contents of bottle number 3, Clarifying Solution into center of the Membrane Unit well to reduce background colour and produce more distinct test and control spots. The control spot will appear only if human blood or blood component is present.

Method of collection

1. **Wash your hands**

2. **Put on gloves**

3. **Select the site:**
   - Young infants – heel or big toe
   - Infants older than 9 months – finger

4. **Clean the selected area of skin (heel, toe or finger) with the skin disinfectant swab and allow to dry for 30 seconds.**
   Take care to keep away from bony prominences.

Remember:
Show the mother how to warm the baby's foot to increase circulation.

5. **Position the foot or hand with the puncture site downwards.**
   Read the instructions on the protective tab and check whether to twist or pull off the tab. Press the loaded lancing device firmly against the skin and push the white plunger.

6. **While holding the foot correctly, apply and release pressure to allow a drop of blood to form.** Do not squeeze or "milk" the puncture site as this may dilute the blood with tissue fluid.
   - Allow a large drop of blood to collect. Lightly touch the drop to the pre-printed circle on the DBS card allowing it to soak onto the circle.
   - Allow the next drop of blood to form and soak it onto the next marked circle.
   - Repeat until at least three marked circles are filled with blood.
   - The pre-printed circles hold ±75µl blood each when completely filled.
   - Samples with insufficient blood cannot be processed since the PCR result may be unreliable.
   - If insufficient blood flow occurs, a second puncture may be required.
   - Do not excessively saturate the card with blood or attempt to smear the blood spots.

7. **Apply pressure to the puncture site using gauze (or cotton wool) to stop further bleeding.**

8. **Dispose of the lancet into a sharps container.**

Heel prick method

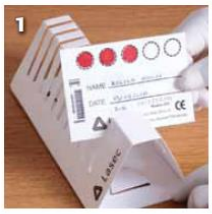
Toe prick method

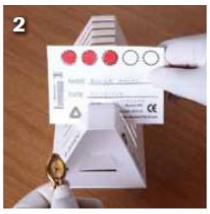
Method for drying

1. **DBS card drying rack.**
   - Place one DBS card into each slot of the drying rack without allowing the cards to touch each other.

2. **Dry for at least three hours at room temperature.**
   - Do not dry artificially with heat or expose to direct sunlight.

3. **Dry completely before packing.**
   - Properly dried blood spots are dark red or brown in colour.

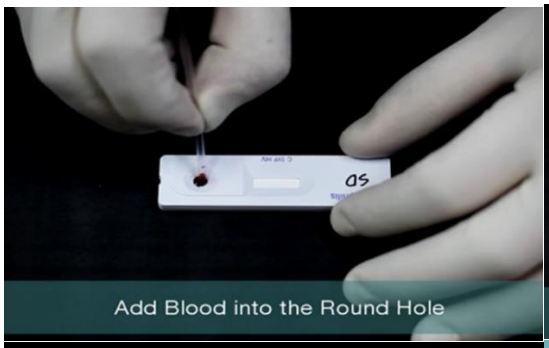


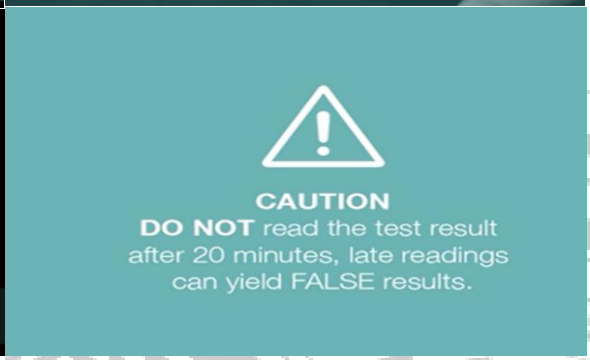


Features of acceptable and unacceptable DBS samples

SD BIOLINE HIV/Syphilis Duo

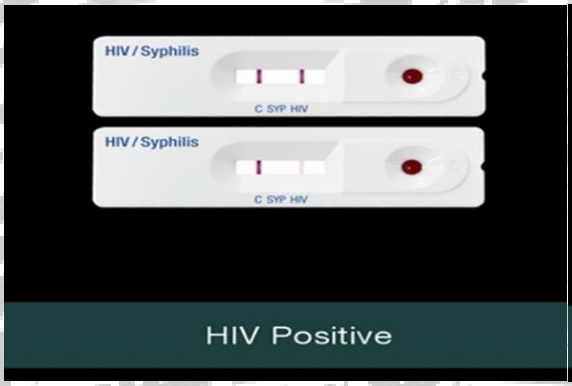
(Further SOP detail: http://www.standardia.com/en/home/support/training/Syphilis1.html**)**

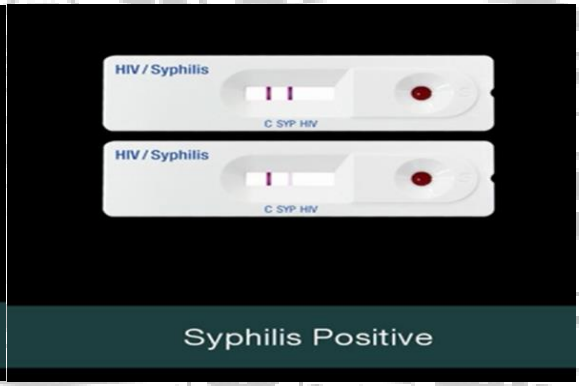


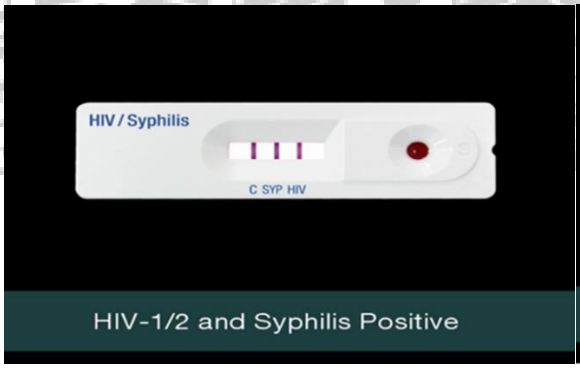


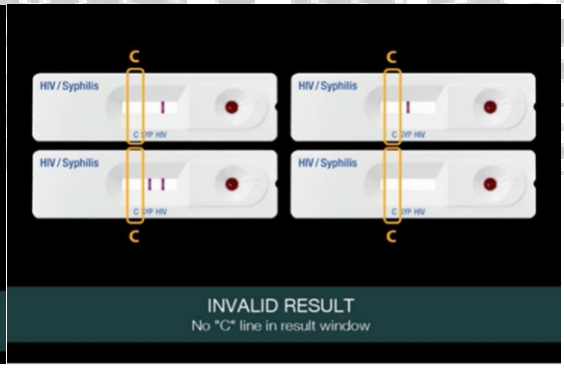
HOW TO READ THE TEST RESULTS

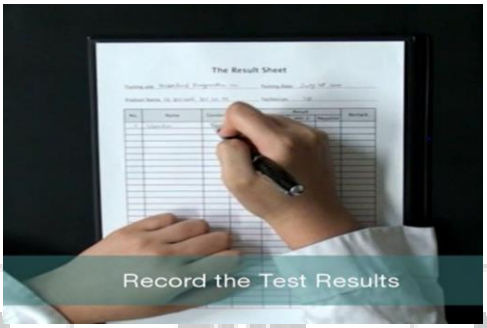
INTERPRETATION










The Result Sheet
Record the Test Results