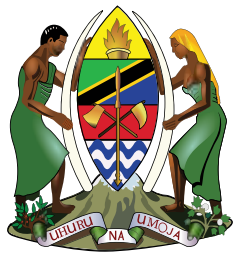
THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN.

NATIONAL GUIDELINE FOR LABORATORY SAMPLE REFERRAL SYSTEM

AUGUST 2019

THE UNITED REPUBLIC OF TANZANIA



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Contents

List of Table

List of Annex

Abbreviations and acronyms

AIDS	Acquired Immunodeficiency Syndrome
ART	Anti-Retroviral Therapy
BMC	Bugando Medical Center
CCHP	Council Comprehensive Health Plans
CHMT	Council Health Management Team
CTC	Care and Treatment Centre
CTRL	Central Tuberculosis Reference Laboratory
DACC	District AIDS Control Coordinator
DBS	Dried Blood Spot
DCS	Director of Curative Services
DHIS	District Health Information System
DHSWNS	Department of Health Services, Social and Nutrition Services
DLT	District Laboratory Technologist
DNA	Deoxyribonucleic Acid
DPS	Director of Preventive Services
DSS	Diagnostic Services Section
DST	Drug Susceptibility Testing
DTLC	District Tuberculosis and Leprosy Coordinator
DTN	Drones Transport Network
EMS	Expedited Mail Services
EQA	External Quality Assessment
ESRS	Electronic Sample referral and Results feedback System
eTL	Electronic Tuberculosis and Leprosy Register
GIS	Geographic Information Systems
HC	Health Center
HCWs	Health Care Workers
HEID	HIV Early Infant Diagnosis
HF	Health Facility
HIV	Human Immunodeficiency Virus
HIVDR	HIV Drug Resistance
HSHSPIV	Health Sector HIV Strategic Plan IV (2018-2022)
HVL	HIV Viral Load
IATA	International Air Transportation Association
IP	Implementing Partner
ISRN	Integrated Sample Referral Network

KCMC	Kilimanjaro Christian Medical Centre
Km	Kilometre
KNCV	Koninklijke Nederlandse Chemische Vereniging (Royal Dutch Chemical Association)
LPA	Line Probe Assay
M&E	Monitoring and Evaluation
MDH	Management and Development for Health
MNH	Muhimbili National Hospital
MOHCDGEC	Ministry of Health, Community Development, Gender, Elderly and Children
MTB	Mycobacterium tuberculosis
MZRH	Mbeya Zonal Referral Hospital
NACP	National AIDS Control Programme
NOPS-VL	National Operational Plan for Scaling up Viral Load Testing
NTLP	National Tuberculosis and Leprosy Programme
NTLSP	National Tuberculosis Laboratory Strategic Plan
PCR	Polymerase Chain Reaction
PLHIV	People Living with HIV
PO-RALG	President's Office Regional Administration and Local Government
POC	Point of Care
RHMT	Regional Health Management Team
RIF	Rifampicin
RIP	Rest in Peace
RLT	Regional Laboratory Technologist
RTLC	Regional Tuberculosis and Leprosy Coordinator
SOP	Standard Operating Procedure
SRS	Sample referral and Results feedback System
TAT	Turn Around Time
TB	Tuberculosis
TCAA	Tanzania Civil Aviation Authority
THIS	Tanzania HIV Impact Survey
THMIS	Tanzania HIV and Malaria Indicator Survey
UN	United Nations
UNAIDS	Joint United Nations Programme of HIV/AIDS
WHO	World Health Organization

Foreword

On behalf of the MOHCDGEC, I would like to take this opportunity to thank the Management Development for Health (MDH) for their technical and funding support towards the development of this integrated TB and HIV samples referral and results feedback guideline. Tanzania, like many low-income countries, is faced with many challenges in the deliverance of quality health care to its people. Quality health care delivery includes many aspects, among which is sample referral to higher laboratory levels for further testing, either in-country and/or referral abroad. Clearly, without quality samples submitted for testing, patient /client management is compromised, resulting to harm or death, and loss or wastage of limited resources and personnel time.

Whereas, it is in the interest of the government to bring advanced technologies in health care services close to the communities, some technologies cannot only have value for money at higher level testing laboratories at zonal or national levels, but can also significant impact in diagnostic services. In this regard, I would like to acknowledge the support the MOHCDGEC received from the US Government through Development Partners in mapping and developing national TB and HIV samples referral system. This will allow efficient laboratory sample transportation to the testing laboratory, and results back to the testing facility. This is a hub-based system, in which a number of health facilities in a particular catchment area (spokes) send samples to a sample collection facility (hub), where they are well packed and transported to testing laboratory for analysis.

The development of TB and HIV samples referral guideline is yet another endeavour by the MOHCDGEC to ensure intervention programmes are integrated for efficient utilization of available resources to improve the quality of care. By integrating TB samples referral into the existing HIV samples referral system, it will streamline service delivery, improve diagnosis through referrals, and minimize costs, while achieving the desired objectives.

This guideline has the following sections: Introduction ,which gives a brief account of HIV and TB situation in Tanzania and the rationale for developing this Guidelines; Structure, organization and management of SRS, which gives an overview necessary for proper management of sample referrals; Operation and Implementation, which describes sample collection, handling (initial processing and temporary storage), packaging and transportation in optimum conditions, suitable for the kind of testing

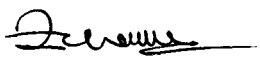
required; and Monitoring and evaluation which describes how the National Laboratory Samples Referral Systems will be monitored and evaluated to ensure compliance with available regulations and its impact in the intervention programmes, hence ultimate goal of providing quality results and appropriate patient care and management.

Having this Guideline in place will help to support other future intervention programmes that require samples to be referred and/or transported safely to a testing point; and also, guarantees timely delivery of test results for patient management or informed decision.

Although, these National Guidelines Laboratory SRS were developed to target sample referrals systems for HIV and TB testing, they are not by any means limited to only these two programmes.

Other pathological samples from disease programmes such Malaria, NCD, Research including, clinical trials, epidemic prone diseases and future health intervention programmes, planning to refer samples for testing across and to higher level testing laboratories, are encouraged to integrate and use this SRS Guideline. As and when this document is reviewed, new intervention programmes will be incorporated.

Lastly, the MOHCDGEC welcomes views and comments, which will provide valuable inputs in the updating and preparation of the subsequent edition of the TB and HIV samples referral and results feedback guideline in Tanzania.



Dr. Zainab A.S. Chaula
Permanent Secretary (Health)

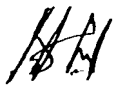
Acknowledgment

This Guideline for TB and HIV Laboratory Samples Referral System is a product of dedicated efforts and contributions of Government, Implementing Partners, Non-Government Organizations, Institutions, Health related intervention programmes and individuals. The Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGEC) is very grateful for their financial support and technical assistance towards revising and reviewing this Guideline.

The MOHCDGEC through the Department of Curative Services (DCS), and the Diagnostic Services Section (DSS) would like to acknowledge all Implementing Partners and stakeholders who in one way or another have contributed to the development of this guideline. In particular, the MOHCDGEC would like to thank Management Development for Health (MDH) for the financial and individual technical experts (**TABLE 3**) for their active participation and constructive input and comments provided in developing this guideline.

I would like to express my sincere gratitude to the task force which include the National AIDS Control Programme (NACP), National Tuberculosis and Leprosy programme (NTLP) and the Central Tuberculosis and Reference Laboratory (CTRL) for the technical support for developing this important document. Furthermore, we appreciate the technical guidance provided by WHO Tanzania experts and through referencing from their standard guidelines.

Finally, the MOHCDGEC would like to acknowledge the technical officers and support staff from the DSS for their teamwork, spirit and commitment.



Prof. Muhammad B. Kambi
Chief Medical Officer

Definition of Terms

The following definitions apply to the terms used in this Guideline

Biological Substance, Category A	An infectious substance, which is in a form that, when exposure to it occurs, it is capable of causing permanent disability, life-threatening or fatal disease in an otherwise healthy human or animal. When transporting diagnostic sample Category A, it must be assigned to UN2814.
Biological Substance, Category B	An infectious substance, which does not meet the criteria for inclusion in Category A. When transporting diagnostic sample Category B for only purpose of diagnosis or investigation, it must be assigned to UN3373.
Hub	Is a designated health facility with capacity to:- a) gather samples (HVL, TB, HEID, HIVDR) from specific sites within 30-40 km radius, for initial processing, temporally storage and transportation of the samples to the testing laboratory as per testing requirements. b) receiving and testing samples (TB and HEID) from spokes using near to Point of Care (POC) equipment such as GeneXpert. .
Spoke	Is the first level facility or TB diagnostic centre which a) collects and refers samples to the hub for initial processing, temporary storage and transportation to high level testing such HVL testing and TB culture. b) collects and refers samples (TB and HEID) to the hub for testing using near Point of Care (POC) such as GeneXpert. a) Multiple spokes are centrally connected to the “hub”.
Hub-spoke model	Hub and Spoke model for healthcare, is where the “hub” is a central health facility that is identified to serve as a central sample collection point for samples coming from multiple referring sites, termed as “spokes.”
DBS	Is blood sample collected on a special filter paper card and dried.

Diagnostic Sample	Are materials collected directly from the patient/client including, but not limited to; excreta, secretions, blood and its components, tissue and tissue fluid and body parts being collected and transported for purposes such as research, diagnosis, investigational activities, disease treatment, prevention and control
Plasma	Is the clear fluid separated from whole blood collected in a tube containing anticoagulant.
Injury	An event that results in physical harm to an employee or client.
HIV Viral Load	Is the amount of virus in a patient's blood sample measured in copies per millilitre (Copies/ml).
Sputum	Mater expectorated from the respiratory system, and especially the lungs that is composed of mucus but may contain pus, blood, fibrin, or microorganisms (such as bacteria) in diseases states.
Health Facility	Is a place that provides health care, which includes hospitals, Health care centres and dispensaries.

1. INTRODUCTION

1.1. Background

The prevalence of HIV among adults in Tanzania is 4.7% (Tanzania HIV Impact Survey-THIS, 2018), whereby current prevalence of TB is 295/100,000 population (National TB prevalence survey, 2012). The overlap between the pandemic is substantial, an estimated 36% of TB cases in Tanzania are co-infected with HIV. Additionally, WHO indicates the incidence of TB, including TB/HIV at 269/100,000 (WHO Global TB Report, 2018).

In an endeavour to accelerate HIV/AIDS control by 2020 i.e., achieving an HIV/AIDS free generation, the Joint United Nations Programme of HIV/AIDS (UNAIDS) came up with the global goal of the 90-90-90 target. The target calls upon its member states/ partners to ensure 90% of HIV infected individuals know their HIV status, provide life-saving ART to 90% of those diagnosed, and achieve viral suppression for 90% of those on treatment. Comprehensive but adequate laboratory services of sample collection, processing, transportation, storage and testing are critical/vital towards the attainment of this Global goal of 90-90-90 target, especially the ***third '90'***, which requires improved access to Viral Load testing by people living with HIV (PLHIV) and adequate utilization of test results by healthcare provides for effective VL monitoring. To increase access to VL testing, the World Health Organization (WHO) consolidated guidelines for ART, reinforced the need for a dedicated, efficient, safe and cost-effective sample referral system, (WHO ART Guideline, 2016).

Similarly, the Global End TB Strategy, approved by the World Health Organization assembly in 2014, calls for a 95% reduction in TB deaths, and 90% reduction in new TB cases by 2035 (The WHO End TB Strategy). Achieving these goals depends on early and accurate detection of TB, including drug-susceptibility testing (DST). The End TB Strategy has emphasized the important role of a quality-assured laboratory network equipped with rapid diagnostics.

In response to this global call, the Tanzanian Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGEC), through the National AIDS Control Programme (NACP), included key strategies in its Health Sector HIV Strategic Plan IV (2018-2022) to highlight on the importance of HIV Viral Load in monitoring the efficiency of ART regimen used by PLHIV. This HSHSPIII provided guidance to ensure

appropriate mitigations are implemented to institute rapid HVL scale-up country-wise, to meet the national goal of providing routine HVL monitoring to at least 50% of all PLHIV on ART by 2017.

During the early stages of implementation in 2016, strategies outlined in the National Operational Plan for Scaling up Viral load (NOPS-VL, 2015) envisaged on maximizing the resources/testing capacity at hand i.e., the pre-existing HIV DNA PCR and HVL testing at Muhimbili National Hospital (MNH), National Health Laboratory (NHLQATC), Mbeya Zonal Referral Hospital (MZRH), Kilimanjaro Christian Medical Centre (KCMC), Bugando Medical Center (BMC) as well as MDH Temeke Laboratory. In an effort to address this, the MOHCDGEC in collaboration with the Center for Diseases Control (CDC) through NACP developed and set up a national systematic sample referral network, which allows for efficient laboratory sample transportation to a referral laboratory and results feedback to the testing facility. This network is based on a hub-and-spoke model, in which a number of health facilities (10-25) **- "*spokes***" sampled within a catchment area of about 30 to 40 kilometres send samples to a collection point - "***Hub",*** where samples are aggregated before transportation to the testing laboratory. By early 2017, approximately 7,239 health facilities have been mapped to 17 HIV DNA PCR and HVL testing laboratories countrywide via 309 collection hubs. (National Laboratory Sample Referral Atlas, 2017). There are about two to three hubs per district, for 309 hubs covering the 7,239 health facilities (National Laboratory Sample Referral Atlas, 2017). These 309 hubs submit samples to 17 HVL testing laboratories across the country. Although sample referral is operational, a number of challenges have been impairing the referral network's accountability and contributes to some samples arriving in poor quality, delayed TATs and lost results.

In pursuit of meeting the global target to end TB (The WHO End TB Strategy), MOHCDGEC has coordinated efforts to scale up near point of care (POC) testing for TB across Tanzania. In addition, the MOHCDGEC through the National Tuberculosis and Leprosy Programme provides a network of TB laboratory services throughout the country. TB laboratory network in Tanzania is organized into five main levels according to the type of services provided. These levels include: 1) the Central Tuberculosis Reference Laboratory (CTRL), 2) Five Zonal TB culture laboratories, 3) Thirty-one regional referral hospital laboratories, 4) 169 district hospital laboratories and 5) laboratories in peripheral health centres and dispensaries (National Tuberculosis Laboratory Strategic Plan 2013). There are 1200 TB microscopy diagnostic centres at different levels of the

health system. Health centres, hospitals, and laboratory facilities within the National Tuberculosis Leprosy Programme (NTLP) laboratory network routinely collect and test samples. Samples that require further testing (i.e., culture and/or drug susceptibility testing [DST]) are referred to appropriately designated referral laboratories by the National Postal Services through Expedited Mail Service (EMS). However, due to several limitations in the current sample referral system, laboratory diagnostic services are underutilized.

1.2. Justification

Currently, there are two parallel systems for TB and HIV sample referral (NTLSP, 2013 and NOPS-VL, 2015). However, despite being operational across the country, these systems have no standard national guideline that assures their enforcement and sustainability. Unavailability of such guidelines has led to the un-harmonized and ineffective implementation of sample referrals and result feedbacks, resulting to duplication of efforts and wastage of limited resources.

To address this challenge, MOHCDGEC has decided to formulate a guideline for nationally integrated sample referral and results feedback system that will address HIV, TB, and any other future interventions that will require the system. This national guideline envisages implementation of a well-organized sample referral and result feedback system (hub-spoke model) for HIV and TB to increase access and ensure quality, sustainability, efficiency and cost-effectiveness. It is anticipated that a quality-assured sample referral and result feedback system with national coverage will:

a. Improve the quality and integrity of transported samples and reduce the number of rejected samples by upgrading packaging and transportation conditions;

b. Advance the sample and results tracking mechanisms using tools such as sample collection and rejection logs, chain of custody and electronic sample and results referral system;

c. Build capacity for hubs to reach out spokes for sample collection instead of the other way around - to ensure samples reach the hub within the specified time;

d. Establish even distribution of sample/workload across a laboratory testing network;

e. Stop delays caused by waiting for certain sample batch size to be transported or processed.

Overall, patients and health providers will have an improved access to HIV/TB sample testing and will be able to pursue appropriate treatment in a timely manner, which results in better health outcomes and ultimately, a decrease in disease burden.

1.3. Goal

Efficient and integrated sample referral and results feedback network in Tanzania.

1.4. Objectives

a. To increase access and utilisation of laboratory services in diagnosis and management of HIV, TB and other diseases in Tanzania,

b. To harmonise standardised procedure for sample referral and results feedback,

c. To improve mechanisms for HIV and TB sample referral and results tracking,

d. To have an effective biosafety and biosecurity measures during sample referrals,

e. To establish a cost-effective sample referral system for HIV and TB samples,

f. To achieve the targeted national turn-around-times for HIV and TB,

g. To improve laboratory data management and utilization.

1.5. Users of this Guideline

The guideline targets a scope of laboratory users, consumers, and stakeholders who are involved in supporting the referral system. These users include the following:

a. Laboratory personnel and other HCWs at the facilities (spokes), Hub and Testing Laboratory, to be guided in sample referral processes,

b. Clinicians as key consumers of HIV and TB laboratory tests for collaboration and creating demand for sample referral system,

c. Couriers involved in sample transportation to be guided in sample handling and transportation,

d. RHMTs and CHMTs for ensuring proper coordination in planning, budgeting, and implementation of sample referral and result feedback system,

e. MOHCDGEC (NACP and NTLP) and PO-RALGfor planning and coordination, and ensuring funding and other support is provided to maintain and sustain an effective sample referral system,

f. Donors and Implementing Partners (IPs) for supporting sample referral system,

g. NACP and NTLP for helping in the development and reviewing of training curricula,

h.) Any health intervention that requires the use of sample referral and result feedback system.

1.6. Type of Samples

Referred samples are dried blood spots (DBS), whole blood or plasma for HIV testing parameters for staging and monitoring antiretroviral therapy (ART) and monitoring treatment of DR-TB; Sputum for TB diagnosis and serum for monitoring treatment of DR-TB patients. Any other specified pathological sample that will require referral.

2. STRUCTURE, ORGANIZATION AND MANAGEMENT OF SRS

2.1. Key System Components

Laboratory sample referral consists of the transportation of a sample from one facility to another, with laboratory diagnostic capacity for investigative purposes and send the results back. The organizational structure of the Sample Referral System (SRS) shall follow the hub and spoke model.

As shown in **Figure 1**, the SRS network shall have:

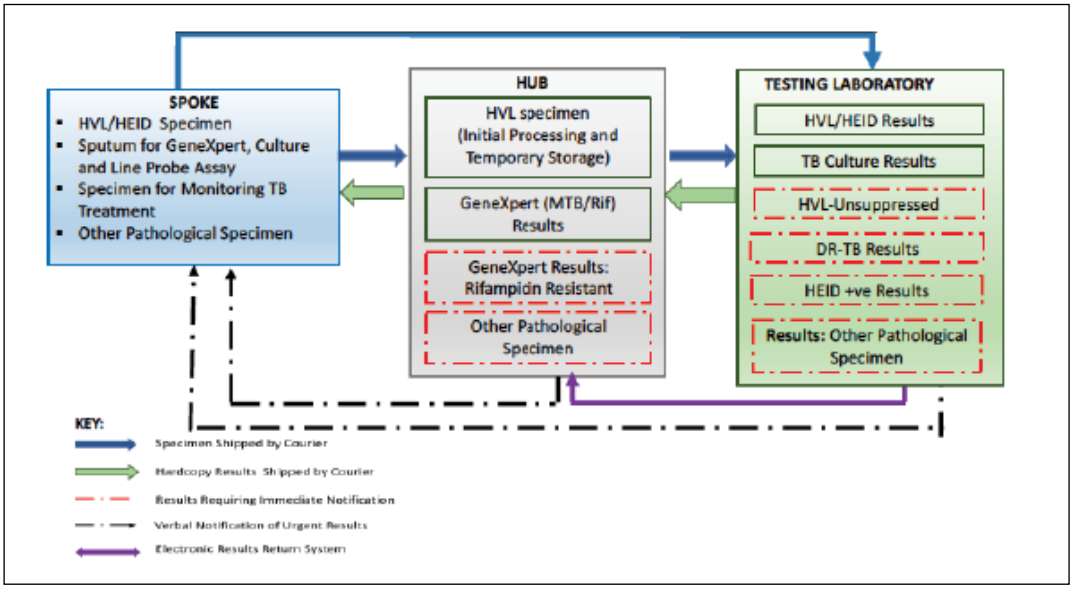
a) A spoke, is the first level health care delivery facility, which collets and refers samples to the Hub for intial processing and sotrage or for near POC testing such MTB/Rif testing .

b) A hub is a designated health care delivery facility, that receives samples from referring facilities (Spokes);

c) Testing laboratory, is the third level facility to which samples are sent for advance testing.

The three key components of the system (spoke, hub and referral testing laboratories) will be linked with the designated couriers for samples and hardcopy test results transportation.

FIGURE 1: HIV AND TB SPOKE, HUB AND MODEL



Health facilities (spokes) within the catchment area of 40-km radius has been mapped using GIS and courier routes designed to allow each spoke to be visited at least twice a week by the courier. The hub is responsible for collecting samples from each spoke in the catchment area and arranging transportation to the referral testing laboratory. The courier is responsible for shipping samples to the referral testing laboratory and returning the hardcopy of the results to the spoke. An electronic sample management system is used to transmit test results to the hub. The SRS recommended the use of local available courier service.

2.2. Roles and Responsibilities

For the referral system to function effectively and efficiently, the roles and responsibilities of each component must be clearly defined as follows:

2.2.1. Roles of Spoke

a) Collection of samples;

b) Initial preparation of samples when essential resources are available;

c) Ensuring proper sample packaging for safe transportation to the hub;

d) Ensuring timely dispatch of the collected samples and the necessary documentation as scheduled;

e) Creating demand for sample referral system and their clinical utility;

f) Laboratory personnel and/or designated HCW in health facilities (spoke) will be the main contact for sample referral system;

g) To receive and deliver test results to the clinicians and clients.

2.2.2. Roles of Hub

a) Performing initial sample processing, if required, acting as temporary/ontransit storage centre and making transportation arrangement to the referral testing laboratory;

b) Performing diagnostic test for TB and HEID using near to POC equipment (if available);

c) Ensuring proper documentation of sample, processes and providing data that can be used to monitor quality as well as the efficiency and effectiveness of the system;

d) Responsible for completeness and validity of client information and data entry in the electronic sample referral and results feedback system;

e) Ensuring registration of all sample in ESRS

f) Ensuring all available electronic results from e-SRS are printed and distributed to its spokes;

g) Expediting transportation of results received from testing laboratories to its spokes;

h) Coordination shall be done by a designated hub focal person, whose contact information should be available to all respective spokes and testing laboratories;

i) Monitoring the functionality of the sample referral network using the national sample referral indicators (**M&E Section 4, Tables 1 and 2 refers**);

j) Providing mentorship and support to spokes when necessary, to strengthen and improve sample referral system..

k) Ensuring proper waste management generated from near to POC equipment;

l) Preparing and submitting regular reports of sample referral functions to relevant authority (CHMT) on monthly basis.

2.2.3. Hub Management Team

Health Facility Management Team (HFMT) of the facility hosting a hub shall provide immediate oversight on the operations of the hub, and shall report to the council management committee. The hub focal person and the lab manager at the hubs shall implement the activities of the hub.

Below are the roles and responsibilities:

a) Providing overall supervision/oversight of the hub and related activities.

b) Supporting the laboratory staff, HEID staff, TB staff, ART clinic staff, hub coordinator and sample transporter in executing their duties.

c) Identifying potential candidates for positions of hub focal person.

d) Coordinating other stakeholders in planning for hub activities.

e) Supporting the laboratory in-charge in ensuring the hub conducts near POC tests (if available) for referred samples that can be analyzed at the hub.

f) Supporting the laboratory in-charge in ensuring the hub perfom initial processing, storage and arrangement of transport samples that cannot be analyzed at the hub level.

g) Ensuring adequate laboratory staff numbers with the right qualifications are available at official working hours.

h) Ensuring adequate Stocks of reagents and consumables for all diagnostic equipment.

i) Ensuring adequate storage space for reagents and consumables.

j) Ensuring optimal and timely utilization of electronic sample referral system (ESRS) and other paper-based laboratory information tools.

2.2.4. Roles of Referral Testing Laboratory

The testing laboratory shall have the following duties and responsibilities:

a) Receiving and evaluating sample from the Hubs as per SOP prior to testing;

b) Managing and testing samples according to the SOPs;

c) Ensuring timely delivery of results using available methods, primarily through the established courier system or via electronic sample referral and results feedback system;

d) Providing mentorship and support to hubs when necessary, to strengthen and improve sample referral system.

2.2.5. Roles of Courier Services Provider

The courier service may be operated by the MoHCDGEC/PORALG or outsourced to another government entity, implementing partner, non-governmental organization, or private company. The courier staff should be trained on bio-safety and bio-security and quality measures, including how to deal with spillages during transportation, as well as documentation requirements for the referral chain. Job aids shall be developed to reinforce the training. A spill kit with the recommended contents shall be provided to manage spillages. Any contracted courier services provider shall abide by this guideline.

Below are the roles and responsibilities:

a) Follow daily and weekly schedule of visits to the spoke, hub, and testing laboratories;

b) Transport the sample(s) properly and safely from spoke to referral laboratories via hub and return hardcopy results back to spoke in a timely manner;

c) Ensuring the quality and/or safety of the sample, environment and all parties involved in the transportation process including keeping bio-safety and bio-security;

d) Ensure that their personnel are trained on bio-safety and bio-security, spill management, confidentiality

e) and documentation requirement for sample referral;

f) Ensuring that the required documentation is available and maintained;

g) Maintaining records of samples and commodities transported;

h) Maintaining communication with spoke, hub and testing laboratories;

i) Report any incident occurred during transportation to responsible authority;

j) Preparing and submitting monthly report to CMHT, RHMT and national HVL/HEID/sample referral coordinators.

2.2.5. Roles of the Council's Health Management Team

Members of CHMT are responsible for sample transportation (DLT, DACC and DTLC) and provide oversight for the sample collection, packaging, transportation and results feedback.

2.2.5.1. Roles of DLT

a) Coordinating all sample collection, packaging and transportation according to the SRS-SOPs within the district;

b) Managing laboratory consumables and supplies required for sample transportation;

c) Making sure the entire SOP and guidelines are available to the hubs and spokes;

d) Leading the implementation of the council's laboratory sample referral networks;

e) Coordination of the council's supply of laboratory commodities in respect to sample referral system;

f) Advocating for the council's budgetary provisions to support regional sample referral system;

g) Monitoring performance of the council's sample referral networks and ensuring accurate and timely reporting of network function data to the council's health management meeting;

h) Managing the implementation of electronic sample referral system and Sample and other laboratory information tools for HVL, HEID and TB;

i) Coordination of the council's implementing partner activities in support of the sample referral system.

2.2.5.2. Roles of DTLC, DACC and DRCH-Co

DTLC, DACC and DRCH-Co in collaboration with DLT shall coordinate all TB, HIV VL, HEID sample collection packaging and transportation within the district and manage laboratory consumables and supplies required for sample transportation. Furthermore, in collaboration with DLT shall make sure guidelines and SOP are available and used accordingly.

The roles shall include, but not limited to:

a) Coordinating implementation of the council's laboratory TB, HVL/HEID sample management through referral networks;

b) Coordination of the council's supply of TB, HVL/HEID laboratory commodities in respect to sample transfer;

c) Advocating for the council's budgetary provisions to support district TB, HVL/HEID sample referral networks;

d) Monitoring performance of TB, HVL/HEID sample referral networks and ensuring timely delivery of results to clinicians, as well as accurate and timely reporting of network function data to regional health management team (RHMT);

e) Managing the implementation of DHIS2;

f) Coordination of implementing partner activities supporting sample referral system.

2.2.6. The Roles of Regional Health Management Team

Members of RHMT are responsible for coordination of the sample referral system (RTLC, RLT, RACC and RRCH co) activities in the region. This includes reinforcement implementation of guidelines and SOPs at different levels in the region (spoke, hub and testing laboratory).

2.2.6.1. The Roles of RLT

Regional Laboratory Technologist (RLT), a member of the Regional Health Management Team (RHMT), shall oversee sample referral system within the region, including monitoring and evaluation. The RLT roles shall include:

a) Leading the implementation of regional laboratory sample referral networks;

b) Coordination of regional supply of laboratory commodities in respect to sample transfer;

c) Advocating for regional budgetary provisions to support regional sample referral networks;

d) Monitoring performance of regional sample referral networks and ensuring timely delivery of results to clinicians, as well as accurate and timely reporting of network function data to the MOHCDGEC;

e) Managing the implementation of tracking paper-based laboratory information tools and electronic sample referral system for TB and HVL/HEID sample registration and result feedback;

f) Coordination of regional implementing partner activities in support of the sample referral networks.

2.2.6.2. The Roles of RTLC, RLT, RACC and RRCHco

RTLC, RLT, RACC and RRCHco in collaboration with RLT shall oversee the sample referral system within the region, including monitoring and evaluation. The roles shall include:

a) Coordinating implementation of regional laboratory sample management through referral networks;

b) Coordination of regional supply of laboratory commodities in respect to sample transfer;

c) Advocating for regional budgetary provisions to support regional sample referral networks;

d) Monitoring performance of the regional laboratory sample referral networks and ensuring timely delivery of results to clinicians, as well as accurate and timely reporting of network function data to the MOHCDGEC;

e) Coordination of the regional implementing partner activities in support of the laboratory sample referral system.

2.2.7. Roles at the National Level

At the MOHCDGEC, guidance will be provided by the Directorate of Curative Services (DCS) as well as the Directorate of Preventive Services (DPS), through the DSS, NTLP and NACP. At PORALG it will be provided through the Department of Health Services, Social and Nutrition Services (DHSWNS). They shall, therefore, have both management and leadership roles, as described below.

2.2.7.1. Management and Leadership Roles

The DCS through the Diagnostic Services Section will be implemented through:

a) Developing policies and guidance for National laboratory sample referral and results feedback system, in support of priority diseases such as HIV and TB as part of laboratory service delivery strategy;

b) Guiding the integration of laboratory sample referral within vertical programmes;

c) Advocacy for budgetary provisions and mobilization of resources to support national sample referral system;

d) Putting in place systems to ensure allocated funds for sample referral are utilised for the intended purpose;

e) Developing the M&E framework for monitoring the performance of sample referral system;

f) Maintaining and regularly updating the National Laboratory Sample Referral Atlas (2017).

2.2.8.2. Leadership and management roles of DPS

The DPS through the NACP, NTLP and RCHS shall:

a) Coordinate national implementing partner activities in support of sample referral networks;

b) Perform quarterly monitoring and evaluation of the system;

c) Forecast and quantify the national commodity requirements for sample and results transfer;

d) Monitor the quality standards of samples in the referral system, such as establishing and overseeing TAT and conducting regular review to the sample referral system.

3. OPERATION AND IMPLEMENTATION

3.1. Sample management

Sample management is a critical process control and an essential part of quality management system (QMS) in the laboratory. The quality of work the laboratory produces is only as good as the quality of sample used for the test. Sample management starts from collection, throughout packaging, transportation and eventual testing.

3.1.1. Sample Collection

During sample collection, it is important to ensure that obtained sample meets the required quality standards by observing the following: -

a) SOPs for Sample management meeting ISO standards shall be developed and distributed to users for implementation.

b) All personnel responsible for sample collection, packaging and transportation shall receive basic training to ensure their competency.

3.1.2. Sample Packaging

Comprehensive training on proper procedures for packaging and shipping dangerous goods will be provided to HCWs by IPs supporting the region. Hub focal personnel will be certified and Job aids shall be developed and distributed to all HFs to reinforce the training.

The packaging of sample for referral must adhere to the following:

a) Blood and sputum samples shall be packaged using the triple packaging system in accordance with the International Air Transport Association (IATA). Instruction_650 on Diagnostic Samples (reference) as shown in **FIGURE 2** refers.

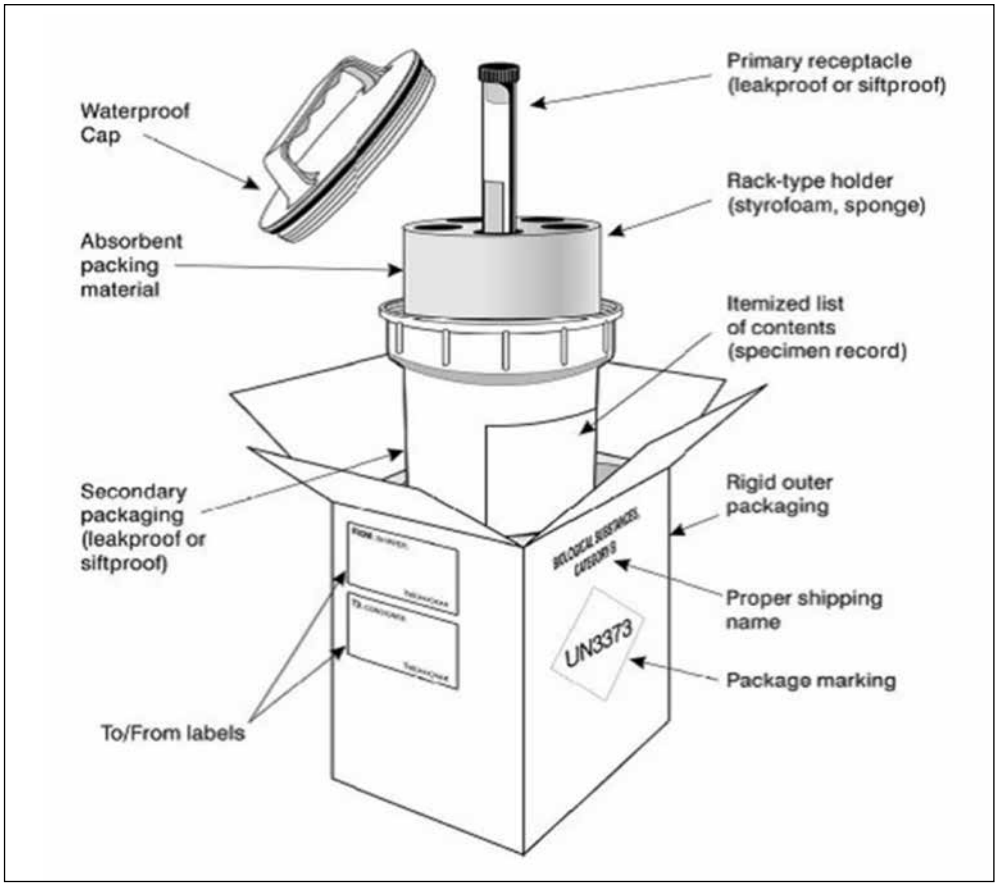
NOTE: APPROPRIATE PACKAGING MATERIALS AND BIO-HAZARD LABELS SHOULD BE PROVIDED.

b) The triple Packaging system consists of 3 layers: first layer or primary container, second layer or secondary container and the third layer or tertiary container.

c) All the required **documentations** must be incorporated into the triple package. These include laboratory request forms, sample tracking logs/sample manifest.

Accompanying documents shall be packed in accordance with the transportation SOP.

FIGURE 2: TRIPLE-PACK CONTAINER FOR LABORATORY SAMPLE TRANSPORTATION



Source: WHO Laboratory Biosafety Manual, Third Edition, page 96.

3.1.3. Maintaining Sample Quality and Integrity

The National Sample Referral and Results Feedback System aims to maintain sample quality and integrity for samples that are being transported to laboratories for testing. The sample quality and integrity shall be maintained from Spoke, Hub to the Testing Laboratory. Sample collection sites shall ensure the collected samples are of acceptable quality before dispatching to hubs. All sample transportation modalities shall maintain sample integrity throughout the transportation routes and shall comply with governing biosafety rules and regulations.

Samples from Spoke to hub shall be accepted/rejected based on the sample rejection /acceptance criteria which include:

a) Rejection at the hub level, following an approved sample rejection criterion (**ANNEX 9** refers (Sample Rejection Log);

b) Sample storage temperature monitoring, to make sure samples are stored in the required temperature. (Refer to Sample Handling, Packaging and Transport SOP);

c) Sample Packaging using triple packaging to maintain both safety and sample integrity;

d) Completeness of request forms.

3.1.4. Standard Operating Procedures

To ensure consistency, SOPs shall be developed and applied to all stages of the referral network from sample collection, processing, storage, packaging and transportation. For these to be achieved, the following should be implemented:

a) HCWs at the Hubs and Spokes shall be required to have all the necessary SOPs **(ANNEX 10)** available and in use in their respective areas;

b) All HCWs shall be required to be familiar with adapted SOPs via on-site/on-job training and orientation;

k) Competency assessment on the operation of SOPs shall be conducted to all responsible HCWs and couriers. Only competent HCWs and courier shall be responsible for sample management and transportation respectively.

3.2. Biosafety and Biosecurity regulations

Samples transported via sample referral networks potentially pose a risk of infection to both the sample handlers and the environment. Thus, safety measures should be applied in sample referral networks. These biosafety measures should include application of universal safety precautions and waste management. Therefore, every component of sample referral network shall ensure the following:

a) Staff are trained on bio-safety and bio-security regulations covering Infection Prevention Control (IPC), risk assessment and mitigation, physical security, material control and accountability, transport and transportation security, incident response and information security;

b) Bio-safety guidelines, laboratory safety handbooks, material safety data sheets (MSDS) and SOPs relevant to safety shall be developed and or adopted by MOHCDGEC and made available and utilized by all personnel or staff involved in sample transportation network;

c) Safety measures such as use of personal protective equipment (PPE), triple packaging material and SOPs shall be in place to protect the laboratory personnel, products and environment from contamination and infection;

d) Biological spill kits that incorporate universal precaution shall be accessible throughout the sample referral cascade;

e) Bio-security measures shall be in place to prevent the malicious use of biohazard materials to cause harm.

3.3. Sample transportation process

There shall be a coordination between the spokes, hub and the designated courier and the receiver (testing laboratory), to ensure that samples are transported safely and arrive on time and in good condition. Logistical support shall be provided by CHMT/RHMT in collaboration with IPs, to maintain the agreed processes for national sample referral system, whilst maintaining sample quality, biosafety and biosecurity, and client/patient confidentiality throughout.

l) Hubs should be reaching out to the spokes using designated courier services or transportation means provided by district councils or regional IP. **Note: Spokes reaching out to the hubs to bring their samples using health workers must be avoided.**

m) Once testing is complete and results have been recorded at the testing laboratory, the results shall be returned immediately to the respective health facilities. Means for results feedback shall include the following:

   i. Using a national approved and secured electronic sample referral system, which allows the Hub to access results remotely and print them out for couriers to collect as they bring in samples for referral.

   ii. If the electronic system is not available or faulty, hardcopies of results should be dispatched by the testing laboratory using the same designated courier during sample delivering at the laboratory. The courier shall return to the Hub, a hard copy of results and eventually to the spoke, via the same route the sample was referred. As with the samples, there should

be a chain of custody or transport logs that tracks the results back to the health facility. These registers should be signed by both sending and receiving parties, including transporters, along with every change of hands to create a tracking system.

NB: Spoke, hub and testing laboratory shall have a well-defined mechanism for communicating on matters including pending and received results, rejects and failures.

3.4. Laboratory information management system

The laboratory information management system (LIMS) serves to store and achieve essential laboratory data and information for immediate use and later reference, in an appropriate medium. The system shall ensure proper data management in data security, integrity, confidentiality, long term storage and archiving. The system may be in hard (paper-based) or soft (electronic sample referral system) copy.

The **requisition form** shall be the key data source that should be used to link the data between HF, Hub and Testing laboratories.

3.4.1. Electronic sample referral system

There should be an electronic sample referral system, computer-based laboratory management systems that enable hubs to log and register samples at the hub/facility level onto the Laboratory information management system (LIMS) at the testing, monitor testing progress, view results and retrieve historical results. The information captured in the request forms shall be **entered into the electronic sample referral system**. The system shall enable data entry from the hubs to reduce transcription errors hence ensuring faster delivery of data to testing laboratories and reduced turnaround times. The testing laboratories shall be responsible for ensuring integration between ESRS-LIMS is effectively utilized to ensure electronic results feedback to reduce TAT. Hub will be responsible for printing results from ESRS and distribute them to its respective facility (spokes).

3.4.2. Paper-based laboratory information system

There shall be HF and Hub HVL sample registers to manage HVL sample collection and return of results to the HF, placed at the HF and Hub respectively. The HF and Hub HVL sample register should be completed using the **requisition form** from the HF and the results form received from the laboratory. The **HF and Hub sample register** is designed to allow for longitudinal follow-up of each sample and result, in particular so that turnaround time can be monitored.

3.4.3. Management of Laboratory Information system implementation

District councils' ITs and testing laboratories' ITs shall:

a) Provide support for computer hardware, software and ESRS at the hubs within their catchment area.

b) Ensure functionality and security of the computer systems.

c) Provide back-up for data.

Hub laboratory manager shall:

- Establish criteria for proper receipt and handling of information.
- Use up-to-date data collection tools.
- Ensure Good laboratory documentation practice is maintained for paper-based LIMS.
- Validate the ESRS to ensure it is appropriate for the purpose.
- Provide overall supervision of the ESRS utilization.
- Maintain confidentiality while handling client/patient information.
- Ensure sufficient and secure data storage and archiving facilities.

3.4.4. Use of LIMS for sample referral

The LIMS shall be used for the following purposes:

- Collecting and store useful and appropriate information and data on sample referral.
- Preliminary analysis and use of results at every component of sample referral.
- Periodic reporting (monthly and quarterly) on sample referral.
- Analysis and use of sample referral data at high levels.
- Achieving and retrieving sample referral information and data.

3.5. Mentorship support

There shall be a documented mentorship support framework across all hubs in the sample referral system. This framework should include an integrated tool and the plan for mentorship visits (Annex 13; 14). The hubs shall receive at least one supportive visit each quarter. Supportive mentorship visits will be a part of essential components of continual follow-up of trained personnel and on-the-job performance training of the staff. Mentorship support shall aim at ensuring that the SOPs for documentation, laboratory data management and analysis are followed in all hubs. Skill gaps shall be identified for targeted capacity building of the hub staff. Testing laboratories shall provide adequate mentorship support to staff at hubs in their catchment areas and they in turn will be supported by NHLQATC. Such mentorship and updates will enable testing laboratories to pass on new information and changes in laboratory techniques on a regular basis to the hubs.

3.6. Coordination of the Laboratory Sample Referral System

A mechanism to provide oversight to the network and monitor performance in a timely manner to ensure sustainability of the sample referral system shall be in place. This organization shall involve the national level throughout regional level to the district level and eventual HCFs.

3.6.1. National Level

There shall be a task force with members from interested programs in the DCS and DPS Directorates as well as Implementing partners. The task force shall coordinate the management of the sample referral system and make recommendations to the existing national laboratory TWGs. The task force shall carry out the following functions:

a) Provide policy guidance and related support;

b) Review and update the national laboratory sample referral mapping;

c) Coordinate training and scale-up best practices for optimizing the sample referral system;

d) Enforce optimal utilisation of the sample referral and results feedback systems;

e) Mobilize resources.

3.6.2. Regional Level

The regional health management team, including RLT, RACC and RTLC shall provide oversight management of the referral networks in their respective regions by ensuring the following:

a) Advising and making recommendations to the task force on matters related to laboratory sample referral and results feedback networks;

b) Overseeing the quality, safety standards and bio-security of sample during handling, packaging and transportation;

c) Conducting supportive supervision at specified sites to ensure that the program functions properly, in collaboration with the councils' health management teams and implementing partners.

d) Working with IPs to define uniform and the most sustainable logistics system for sample transportation;

e) Developing or revising policies and guidelines to improve the national sample referral system in the same way to ensure the stability of the system;

f) Providing training to all parties involved in the sample referral system and ensure their competency;

g) Regularly reviewing the performance of the existing laboratory sample referral system and making recommendations to the task force;

h) Ensuring the sustainability of the system.

3.6.3. District Level

The district health management team including DLTs, DACCs and DTLCs shall coordinate the referral networks in their respective Councils. They shall advise and make recommendations to the RHMT and IPs on matters related to laboratory sample referral and results feedback networks. Their support shall include, but not limited to the following:

a) Ensure that the sample transportation network operates properly;

b) Ensure that the referral linkages are integrated for all diseases to maximize use of limited resources;

c) In collaboration with the IPs to oversee the proper utilization of resources and the implementation of the programme;

d) Regularly review the performance of the existing laboratory sample referral system;

e) Ensure the sustainability of the system.

3.6.4. Hub Level

The hub management shall be responsible for organizing and coordinating the referral mechanisms and the network it serves. There shall be effective communication throughout the network to ensure prompt relay of information to spokes within the shortest possible turnaround times. Such information includes:

a) Rejected samples and corrective measures to minimize recurrences,

b) Testing service interruptions or delays (breakdowns of service) and resumption,

c) Alteration in the examination schedules for specific tests, changes in examination methods and referral mechanisms,

d) Providing monthly and quarterly reports on laboratory and referral networks performance to CHMT for decision making. (**ANNEXES 12**).

3.6.5. Testing Laboratory

Testing laboratory shall provide information on the following:

a) Provide comprehensive reports on total number of samples received, rejected and results returned to the council/district coordinators on a monthly/quarterly basis,

b) Service interruptions or delays (breakdowns of service, backlogs),

c) Changes in the examination schedules for specific tests, changes of examination methods, or changes to reference values,

d) Maintaining early notification and proper communication with referring laboratories and couriers.

3.7. Financing and Human Resources

3.7.1. Financing

There should be sustainable plan at all levels of SRS implementation to ensure funding availability and support. The plan shall be drawn and presented for budgeting annually. Establishment of SRS shall be done using dedicated resources from Councils' Comprehensive Health Plans (CCHP), with support from the medical laboratory related professionals for example laboratory technicians, laboratory technologists, laboratory advisors and laboratory scientists.

The budget to finance SRS will be under PO-RALG, which are prepared annually based on inputs from the Council levels. Therefore, finance planning for SRS activities shall start from lower levels to ensure integration into the CCHP and national budgets. Moreover, funds from implementing partners and stakeholders may be utilized to finance and manage SRS.

3.7.2. Potential Funding Sources

a) **Cost Sharing**

After sensitization of the importance of the sample referral system, the budget will be developed, approved and shared with government institutions involved in the health sector for different activities (HIV, TB, Malaria, Epidemic prone diseases, research), implementing partners, programmes and private.

b) **External Funding**

In the interim, funds shall be provided by implementing partners supporting TB and ART partners, and through the Laboratory Support Programme within the DSS and/or stakeholders interested in the SRS activity. However, in order to have a sustainable system, at the national level, the budget line for SRS activities will be determined and shared for incorporation into the CCHP budgets to implement a sustainable system at all levels.

3.7.3. Human Resources

These shall be trained and dedicated Hub (SRS) Focal persons whose roles and responsibilities include oversight in SRS activity implementation at all levels. They will ensure activities are implemented against approved plans and budgets. Hub (SRS) Focal persons supported by CHMT will ensure optimal use of the courier system at every hub and spoke for sample collection and transportation including feedback and response to challenges, whenever required. Roles and responsibilities of personnel involved in SRS should be defined to avoid duplication of efforts. At the hub level, there shall be a trained hub focal person.

4. MONITORING AND EVALUATION

There shall be a Monitoring and Evaluation system of this guideline to guide the Ministry through the respective programs and other HIV and TB stakeholders and implementing partners to track and assess the sample referral activities.

The M&E intends to facilitate performance monitoring against the set targets and provide a guide on interpretation and dissemination of the information for programs improvement at all levels. It also aims to ensure consistency of recording and reporting systems across all the partners and stakeholders involved and guide on evaluation of the sample referral system.

HSPs should strive to produce data of high quality. In order for the HFs to produce high quality data, Data Quality Assessments (DQAs) should routinely be conducted at all levels by using DQA tools that are approved by the MOHCDGEC.

4.1. Key components of Monitoring and Evaluation

4.1.1. Data recording

Collection of data on HIV, TB and other interventions shall be done by HSPs at the HF using standardized tools coordinated by R/CHMT. Reporting shall be done on quarterly basis, from HF levels to the Council level where it is posted to the DHIS2. From the DHIS2, different authorities can access data without necessarily contacting the national level. The national level, through the MoHCDGEC shall compile HF and Council data, which shall then be reported and disseminated to relevant stakeholders.

M&E tools shall be used to capture information collected throughout the sample referral systems. Recording of the data for HVL, HEID and TB services shall use the following tools:

a) HVL request form;
b) TB Laboratory request form;
c) Culture and DTS request form;
d) DBS collection form;
e) High Viral Load register;
f) TB Laboratory register (TB05);

g) TB Presumptive register;

h) MC Cohort register;

i) HVL Hub sample and results register book;

j) TB Hub sample and results register book;

k) TB Hub sample and results register book;

l) Sample manifest form;

m) Sample rejection Log

n) SRS monthly monitoring form

o) Electronic Sample Referral System (ESRS)

p) Hub quarter assessment and supervision checklist

q) Hub-LIS quarter assessment tool

r) HEID POC implementation checklist

4.1.2. Data Storage

Data from samples collected shall be stored either electronically through the CTC2, ETL, laboratory information system (LIS), electronic sample referral system, GxAlert System or at the National laboratory data repository (OpenLDR), or on hard copies of the tools used for data collecting purposes. The electronic means of data storage must be secured by passwords, while hard copies must be kept in rooms where confidentiality will be ensured in accordance with Statistical Act2015.

4.1.3. Data reporting

Reporting of data shall be done on monthly and quarterly basis. HFs reports shall be submitted to the office of the DMO by the 7thday of the following month. Data are reported from HFs to the Council, region and finally to the national level.

4.1.4. Data Dissemination and Use

Data dissemination and use shall follow approved format for presentation at national and international level. Data shall be reported and disseminated on specified period. Data shall be used at different levels by stakeholders for the purposes of planning and decision making for improvement of service delivery.

4.1.5. Document and Records Archiving

All documents and records related to sample and results management throughout all components of referral system, must be maintained and controlled in a retrievable and legible manner. It is the responsibility of the components of the referral system to archive old documents related to sample and results management within the referral network and make sure that they are stored in the old documents file within the facility and are reviewed when needed. Out-dated laboratory registers and other records of samples received by all components of referral system shall be kept for at least five years.

4.2. Monitoring of Sample Referral System

i. The operation of the sample referral system shall be monitored and evaluated to ensure the planned activities are being implemented effectively and efficiently. Indicators shall be used to track and assess sample referral system performance guided by the following questions: Is the sample referral system effective?

- Network effectiveness:
- number of samples received from spokes,
- number of samples sent to the testing laboratory,
- Average number of samples transported in a specified time,
- Number of samples with results in a specified time.

ii. Is the Network efficient?

- Reduced turnaround time,
- Reduced costs for sample referral services,
- Overall TAT (from sample collection to results available to client/requesting facility. **(Annex 15;16;17;18;19)**

iii. Is the Quality of referred samples assured?

- Proportion of sample rejection rate,
- Reduced sample failure,
- Time taken from collection point (Spoke and Hub) to testing laboratory,
- Time taken for intial sample processing,

- Time taken to return results from the testing laboratory to the hub,
- Time to return results from Hub to spokes.

Hub functionality - Capacity of the hub to serve respective spokes.
Mechanisms shall be in place to review the M&E system and use of identified gaps for performance and quality improvement of the network and its referral system. The hub staff and laboratory managers shall be trained on core referral system indicators and the methods of documentation, data retrieval, analysis and dissemination of data for interpretation and decision-making.

The MOHCDGEC through the programmes in collaboration with partners shall facilitate the M&E of sample referral system. Monitoring of data should be done in specified period, and report from HFs sent to CHMT, RHMT and relevant authorities. The MOHCDGEC through programme shall conduct annual performance evaluation and update the sample referral system, **Tables 1 and 2**: **Log frame and Indicator matrix refers**.

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TABLE 1: LOG FRAME FOR SAMPLE REFERRAL SYSTEM

Goal	Indicator	Source	Means of Verification	Frequency	Assumption
Efficient and integrated sample referral and results feedback network in Tanzania.	Proportion of TB presumptive cases tested using GeneXpert	Annual assessment, NTLP DHIS2-ETL	DHIS2-ETL, Central Database Repository	Annually	Natural calamities and availability of resource
	Proportion of clients who have been tested for HVL and HEID	CTC2 Database	CTC3 Marco Database, CTC3 Dashboard	Annually	Natural calamities and availability of resource
	Proportion of sample collected, transported, tested and resulted for other diseases	NBS	NBS, Central Database Repository	Annually	Natural calamities and availability of resource
Objective 1					
To increase access and utilisation of laboratory services in diagnosis and management of HIV, TB, and other diseases in Tanzania.	Number of samples collected	HVL register/CTC 2 database/MC cohort register/TB Laboratory register (TB05)/DHIS2-ETL	CTC2 Database, CTC3 Macro database, Central Database Repository, DHIS2-ETL, DHIS2	Quarterly	Natural calamities and availability of resource
	Percentage of samples transported	HVL Sample manifest, HEID sample manifest, TB Laboratory register (TB05), DHIS2-ETL	Electronic Sample Referral System, Central Database Repository, DHIS2-ETL, DHIS3	Quarterly	Natural calamities and availability of resource

Goal	Indicator	Source	Means of Verification	Frequency	Assumption
	Percentage of results returned within targeted national TAT	HVL register/CTC 2 database/MC cohort register/ TB presumptive register/DHIS2-ETL	Electronic Sample Referral System, Central Database Repository, DHIS2-ETL, DHIS2	Quarterly	Natural calamities and availability of resource
	Percentage of referred samples of which results were returned	Hub HVL Sample manifest, HEID sample manifest, TB presumptive register, DHIS2-ETL	Electronic Sample Referral System, DHIS2-ETL, Laboratory LIS	Quarterly	Natural calamities and availability of resource
Objective 2					
To harmonise standardised procedure for sample referral and results feedback	Sample referral guidelines in place	Workshop reports, Distribution reports	Workshop reports	Once	Natural calamities and availability of resource
	Number of HFs with Sample referral SOP in place	Workshop reports, Supervision reports	Workshop reports	Once	Natural calamities and availability of resource
Objective 3					
To improve mechanisms for TB and HIV sample referral and results tracking	Percentage of hubs with functional electronic sample referral and result tracking system	DHIS2-ETL, e-SRS	Electronic Sample Referral System, DHIS2-ETL, Laboratory LIS	Quarterly	Natural calamities and availability of resource

Goal	Indicator	Source	Means of Verification	Frequency	Assumption
Objective 4					
To ensure an effective biosafety and biosecurity measures during sample referrals.	Number of health care workers trained on biosafety and biosecurity measures at the hubs	Training reports	Training reports	Once	Natural calamities and availability of resource
	Number of non-health care workers involved in SRS trained in biosafety and biosecurity measures.	Training reports	Training reports	Once	Natural calamities and availability of resource
	Integrated biosafety and biosecurity guideline in place	Workshop reports	Workshop reports	Once	Natural calamities and availability of resource
	Number of HFs with biosafety and biosecurity SOPs.	Supervision report	Site Visit reports	Once	
Objective 5					
To establish a cost-effective sample referral system for HIV and TB samples	Cost- effective sample transportation model identified and implemented	Assessment report	Assessment report	Once	Natural calamities and availability of resource

Goal	Indicator	Source	Means of Verification	Frequency	Assumption
Objective 6					
To ensure quality of referral samples	Percentage of TB samples for culture referred to the testing laboratories within required/ targeted time	TB Laboratory registers, Hub Sample and Results register	DHIS2-ETL, Central Database Repository, Electronic Sample Referral System	Quarterly	Natural calamities and availability of resource
	Percentage of HVL samples referred to the testing laboratories within required/ targeted time	Hub Sample manifest, Hub Sample and Results register	Electronic Sample Referral System, DHIS2-ETL, Laboratory LIS	Quarterly	Natural calamities and availability of resource
	Percentage of HEID samples referred to the testing laboratories within required/ targeted time	Hub sample manifest, Hub Sample and Results register	Electronic Sample Referral System, DHIS2-ETL, Laboratory LIS	Quarterly	Natural calamities and availability of resource
	Proportion of samples rejected	Rejection log	Electronic Sample Referral System,	Quarterly	Natural calamities and availability of resource
	Percentage of referred TB samples tested within national TAT	TB Laboratory registers, Hub Sample and Results register TB hub sample and results registers,	DHIS2-ETL, Central Database Repository, Electronic Sample Referral System	Quarterly	Natural calamities and availability of resource

Goal	Indicator	Source	Means of Verification	Frequency	Assumption
Objective 7					
To improve integrated sample referral data management and utilization	Recording and reporting integrated transport referral data collection tool in place	Workshop reports	Workshop reports	Once	Natural disaster and availability of resource
	Number of sample requests entered in the sample referral system and accepted at testing Laboratory	electronic Sample referral system	Monthly Reports	Monthly	Natural disaster and availability of resource
Objective 8					
To utilize TB/HIV sample referral system for other pathological samples	Number of other pathological samples transported using TB/HIV sample referral system	Laboratory information system, manifest form, laboratory sample log/book	Central repository system	Quarterly	Natural calamities and availability of resource
	Percentage of results of other pathological samples returned through TB/HIV sample referral system	Laboratory information system/result tracking form	Central repository system, laboratory result dispatch book	Quarterly	Natural calamities and availability of resource

TABLE 2: M&E MATRIX FOR SAMPLE REFERRAL INDICATORS

S/N	Indicator	Level of priority	Reporting level	Indicator description	Numerator	Denominator	Disaggregation	Frequency	Source of data
SPOKES LEVEL INDICATORS									
1	Number of samples collected at the spoke	Medium	Facility & District	To monitor the number of samples collected at the spoke	Number of sample collected at the spoke	N/A	Testing category (TB/ HEID/HVL)	Monthly	HVL register/CTC 2 data base/MC cohort register/ TB Laboratory register (TB 05)
2	Percentage of samples transported to the hub	High	Facility, District	To monitor total number of samples transported to the hub and total number of samples collected	Number of samples transported to the hub	Total number of samples collected at the spoke	Testing category (TB/ HEID/HVL)	Monthly	HVL Sample manifest, HEID sample manifest, TB Sample manifest
3	Turnaround time for results at the spoke	High	Facility, District & National	To monitor time from date of sample collection to date results received at the spoke	Average/ Median time taken between sample collection to result receipt at the spoke	N/A	Testing category (TB/ HEID/HVL)	Monthly	HVL register/CTC 2 data base/MC cohort register/ TB Laboratory register

S/N	Indicator	Level of priority	Reporting level	Indicator description	Numerator	Denominator	Disaggregation	Frequency	Source of data
4	Percentage of results returned within targeted national TAT	High	Facility, District	To monitor results returned within targeted time to the total number of results returned	Total number of test results returned at the facility within specified turnaround time	Total number of results returned at the spoke	Testing category (TB/ HEID/HVL)	Monthly	HVL register/CTC 2 database/MC cohort register/ TB Laboratory Register and Spoke Level Sample referral integrated register
HUB LEVEL INDICATORS									
5	Number of samples collected from spokes	High	Hub, District & National	· To monitor total number of sample collected from the spokes · To monitor hub performance	total number of sample collected from designated spokes	N/A	Testing category (TB/ HEID/HVL)	Monthly	HVL/HEID/ TB Laboratory Register, Hub sample and result register
6	Percentage of samples referred to the testing laboratories within required/ targeted time	High	Hub, District	Monitor performance of Hub and sample referral mechanism	Total number of samples transported from the Hub to the testing Laboratory	Total number of samples received at the Hub from the spokes	Testing category (TB/ HEID/HVL)/ result system (Hardcopy/ electronic	Monthly	Hub HVL Sample manifest, HEID sample manifest,

S/N	Indicator	Level of priority	Reporting level	Indicator description	Numerator	Denominator	Disaggregation	Frequency	Source of data
7	Percentage of referred samples for which results were returned	High	Hub, District	To monitor the performance of Hub and result feedback mechanism	Total number of results returned to the Hub from testing Laboratory in particular reporting period	Total number of samples transported from the Hub to the testing Laboratory	Testing category (TB/ HEID/HVL)/ result system (Hardcopy/ electronic	Monthly	Hub HVL Sample manifest, HEID sample manifest,
8	Percentage of results returned within specified hub TAT	Medium	Hub, District	To monitor the overall sample referral system between sample dispatch and result receipt at Hub	Total number of test results returned within specified hub TAT	Total number of results received from the testing Laboratory	Testing category (TB/ HEID/HVL)/ result system (Hardcopy/ electronic	Monthly	Hub HVL Sample manifest, HEID sample manifest,
9	Percentage of spokes submitting samples at the hub.	Medium	Hub/ District	To monitor coverage of sample referral system	Total number of active spokes submitting samples to the Hub	Total number of spokes mapped to the designated Hub	Facility testing category (CTC/PMTCT/ TB)	Semi-Annually	Hub HVL/TB Sample manifest, HEID sample manifest,
10	Percentage of sample rejected	High	Hub/ District/ National	To monitor the quality of sample received from the spokes	Total number of samples rejected at the Hub	Total number of sample receipt and registered at the Hub	Testing category (TB/ HEID/HVL)/ Rejections reasons	Monthly	Hub sample register/Hub rejection log register

S/N	Indicator	Level of priority	Reporting level	Indicator description	Numerator	Denominator	Disaggregation	Frequency	Source of data
LABORATORY INDICATORS									
11	Number of samples received from the hubs	High	Laboratory/ Regional/ National	To monitor the performance and workload of the Laboratory	Total number of samples received at the Laboratory from Hub and few spokes submitting samples directly to the Laboratory	N/A	Testing category (TB/ HEID/HVL)	Monthly	TB and HIV Laboratory sample reception register/ Laboratory information systems(TB LIS, DHIS2-ETL)
12	Percentage of samples received within required time.	Medium	Laboratory	To monitor the overall sample referral system between sample collection(hub) and sample receipt at the testing Laboratory	Number of samples received within required time.	Total Number of samples received at the testing Laboratory.	Testing category (TB/ HEID/HVL)	Quarterly	Laboratory sample reception register/ Laboratory information system (TB LIS, DHIS2-ETL)
13	Percentage of samples rejected	High	Laboratory/ National	To monitor the quality of sample received from the hub	Number of samples rejected at the Laboratory	Total number of sample receipt and registered at the Laboratory	Testing category (TB/ HEID/HVL)/ Rejections reasons	Monthly	Laboratory sample reception/ rejection register/ Laboratory information system;(TB LIS, DHIS2-ETL)

S/N	Indicator	Level of priority	Reporting level	Indicator description	Numerator	Denominator	Disaggregation	Frequency	Source of data
14	Percentage of samples tested.	High	Laboratory/ National	To monitor the performance and workload at the Laboratory	Number of samples tested at the Laboratory	Total number of sample receipt and registered at the Laboratory	Testing category (TB/ HEID/HVL)	Monthly	Laboratory sample reception register/ Laboratory information system
15	Percentage of results dispatched	High	Laboratory/ National	· To monitor number of result from tested samples returned to the specific hub/spoke · To monitor the performance and workload of the Laboratory	Number of valid results dispatched to the Hub/ spokes from the Laboratory	Total Number of samples tested at the Laboratory	Testing category (TB/ HEID/HVL)	Monthly	Laboratory result dispatch register/ Laboratory information system (TB LIS, DHIS2-ETL)
16	Percentage of results dispatched within required Laboratory TAT	High	Laboratory/ National	Monitor the performance and workload of the Laboratory	Number of results dispatched within required time form the testing Laboratory	Total Number of results dispatched to the Hub/ spokes from the Laboratory	Testing category (TB/ HEID/HVL)	Monthly	Laboratory result dispatch register/ Laboratory information system

S/N	Indicator	Level of priority	Reporting level	Indicator description	Numerator	Denominator	Disaggregation	Frequency	Source of data
COUNCIL LEVEL INDICATORS									
17	Percentage of functional hubs	High	District/ National	Monitor the Hub functionality and coverage of sample referral system	Number of functional Hubs.	Total number of mapped Hubs.	N/A	Semi-Annually	sample referral atlas/ supervision report
18	Percentage of active spokes	Medium	District/ National	Monitor the coverage of sample referral system	Number of active spokes.	Total number of mapped spokes.	Testing category (HEID/HVL/TB)	Semi-Annually	sample referral atlas/ supervision report/ Hub sample register
19	Percentage of hubs with functional electronic sample referral and result tracking system	Medium	District/ National	To monitor the utilization of electronic sample referral system at the hub(s)	Number of functional Hub with functional electronic sample referral system	Total number of Functional Hubs.	Type of electronic sample referral system	Semi-Annually	Supervision reports/ electronic sample referral system

S/N	Indicator	Level of priority	Reporting level	Indicator description	Numerator	Denominator	Disaggregation	Frequency	Source of data
NATIONAL LEVEL INDICATORS									
20	Percentage of functional hubs	High	National	To monitor coverage of hubs nationally	Number of functional Hubs in country	Total number of mapped Hubs in country	Region/Zonal	Semi-Annually	National laboratory sample referral atlas/ supervision report
21	Percentage of active spokes	Medium	National	To monitor coverage of spokes nationally	Number of active spokes in country	Total number of mapped spokes in country	Region/Zonal	Semi-Annually	National laboratory sample referral atlas / supervision report/ Hub sample register
22	Percentage of hubs with functional electronic sample referral and result tracking system.	Medium	National	To monitor the utilization of electronic sample referral system at the hub(s) nationally	Number of functional Hub with functional electronic sample referral system in country	Total number of Functional Hubs in country	Region/Zonal	Semi-Annually	Supervision reports/ electronic sample referral system
23	Average TAT	High	National	To monitor the overall turnaround time for the sample referral system.	Average/ Median time taken between sample collection to result receipt.	N/A	Testing category (TB/ HEID/HVL)	Quarterly	District & Regional reports/LIS: TBLIS, DHIS2-ETL

S/N	Indicator	Level of priority	Reporting level	Indicator description	Numerator	Denominator	Disaggregation	Frequency	Source of data
GENERAL INDICATORS									
24	Number of other pathological samples transported to Hub /testing Laboratory using TB/HIV sample referral system	High	Spoke / hub	To monitor the number of other pathological samples transported using TB/ HIV sample referral system to hub/testing laboratory	Number of other pathological sample transported to Hub/ testing laboratory	N/A	Testing category (other pathological samples)	Quarterly	Laboratory information system, manifest form, laboratory sample log/book
25	Percentage of results of other pathological samples returned through TB/HIV sample referral system	High	Spoke / hub	To monitor percentage of results of other pathological samples returned to the facility through TB/HIV sample referral system	Number of results of other pathological samples returned to the facility through TB/ HIV sample referral	Total number of other pathological samples transported to Hub/testing laboratory using TB/HIV sample referral system	Testing category (other pathological samples)	Quarterly	ESRS, result tracking form, laboratory result dispatch book

S/N	Indicator	Level of priority	Reporting level	Indicator description	Numerator	Denominator	Disaggregation	Frequency	Source of data
26	Number of health care workers trained on biosafety and biosecurity measures	Medium	National/R/ CHMT	To increase number of HCW involvement in biosafety and biosecurity measures for sample handling in laboratories	Number of HCW trained	N/A		Annually	Training reports
27	Number of non-health care workers involved in SRS trained in biosafety and biosecurity measures.	Medium	National/R/ CHMT	To increase number of non HCW involvement in biosafety and biosecurity measures for sample handling in laboratories	Number of non HCW trained	N/A		Annually	Training reports

ANNEX 1: HIV VIRAL LOAD SAMPLE AND RESULTS REGISTER

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN.

FACILITY HIV VIRAL LOAD REGISTER

S/N	Clients' CTC ID (RR-DD-FFFF-PPPPPP)	Age	Sex (M/F)	Pregnant/ Breast feeding Woman (YES/NO) (tick below)		Date of Sample collected	Time sample collected	Sample type	Quality of the sample collected (tick below)		Name of the Person who collected the sample	Date Sample transported to Hub	Time Sample transported to Hub	Date results received	TAT (Days)	Name of the Person who received the results	Results		Signature	Remarks
				YES	NO				ACCEPTABLE	NOT ACCEPTABLE							Copies/ml	Log 10		

ANNEX 2 HVL HIGH VIRAL LOAD REGISTER

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN.

HIGH HIV VIRAL LOAD REGISTER

S/N	Clients' CTC ID (RR-DD-FFFF-PPPPPP)	Age	Sex (M/F)	Current Regimen	Pregnant women (YES/NO) (tick below)		Breest-feeding (YES/NO) (tick below)		Date First HVL sample taken	HVL results (Copies/ml)	Results (Log 10)	Date HVL results received	Date of First EAC session	Date of Second EAC session	Date of Third EAC session	Additional EAC session	Date HVL sample taken after completing EAC	HVL results after EAC (Copies/ml)	HVL Results after EAC (Log 10)	Remarks
					YES	NO	YES	NO												

ANNEX 3: FACILITY HEID REGISTER

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN.

FACILITY EID REGISTER

SN	Facility Name	HEI Number (_ _-_ _-_ _ _ _ _-_ _ _ _ _ _ _.C_ _)	Date of Birth (DD-MM-YYYY)	Age*	Sex (M/F)	Mother's/ Caregiver's Address	Sample Collection Date (DD-MM-YYYY)	Sample Collection Time (_ _:_ _)	Collected By (Name)	Date of Sample Sent To Hub/Laboratory (DD-MM-YYYY)	Sent by (Name)	Date Results Received (DD-MM-YYYY)	Results Received By(Name)	Results (P/N/Indeterminant)	Date Results Given to Mother/Caregiver(DD-MM-YYYY)	TAT (Days)	Initials	Remarks

ANNEX 4: TB LABORATORY REGISTER

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN.

TB LABORATORY REGISTER

Patient Name	Lab No.	Age	Sex	Contacts *(Mob #)*	Date sample Collected	Quality of the sample collected *(tick be low)*		Date Sample transported to the Hub/Testing laboratory	Date Results Received	TAT (Days)	TB Results	Comments
						ACCEPTABLE	NOT ACCEPTABLE					

ANNEX 5: HVL HUB SAMPLE AND RESULT REGISTER

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN.

HIV VIRAL LOAD-HUB SAMPLE REGISTER

S/N	CTC ID. (RR-DD-FFFF-PPPPPP)	Age	Sex (M/F)	Name of the Referring Health Facility (Spoke)	Date of Sample collection	Time Sample collected at the facility (Spoke)	Date Sample received	Time Sample received	Type of Sample (Whole Blood, Plasma, DBS)	Quality of the sample collected (tick below)		Date Results received	TAT (Days)	Viral load Results		Date Results dispatched to Health Facility	Comments
										ACCEPTABLE	NOT ACCEPTABLE			Copies/ml	Log10		

ANNEX 6: TB HUB SAMPLE AND RESULT REGISTER

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN.

TB HUB SAMPLE REGISTER

S/N	Patient name	Lab No.	Age	Sex (M/F)	Name of the Referring Health Facility (Spoke)	Date of Sample collection	Time Sample collected at the Referring Health (Spoke)	Date Sample received at the hub	Type of Sample received *(tick below)*			Quality of the sample collected (tick below)		Date sample tested/ transported to zonal Lab	Date Results out/ received	TAT (Days)	TB test results			Date Results dispatched to the referring Health Facility (Spoke)	Comments
									Sputum for Xpert MTB/RIF testing	Sputum to be referred for Culture	Fixed smear	ACCEPTABLE	NOT ACCEPTABLE				Xpert MTB/RIF testing	Culture	Fixed smear		

ANNEX 7: HEID HUB SAMPLE AND RESULTS REGISTER

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN.

EARLY INFANT DIAGNOSIS-HUB SAMPLE REGISTER

S/N	Name of the client	HEI No. (RR-DD-FFFF-PPPPPP-CC)	Age	Sex (M/F)	Name of the Referring Health Facility (Spoke)	Date of Sample collection	Time Sample collected at the facility (Spoke)	Date Sample received	Quality of the sample collected *(tick below)*		Name of the person who received the sample	Date sample tested using near POC or transported to EID testing laboratory	Date Results out/ received	TAT (Days)	DBS Results (Positive/ Negative/ Indeterminant)	Date Results dispatched to Health Facility	Name of the person dispatching results	Comments
									ACCEPTABLE	NOT ACCEPTABLE								

ANNEX 8: SAMPLE MANIFEST

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN.

SAMPLE MANIFEST										
Facility Name				District				Region		
Facility Contact										
S/N	CTC ID./HEID No. *(/for HIV samples)*	Pateint name *(for TB and other pathological samples)*	Date of Sample Collection	Sputum *(tick below)*				Sample Quality *(tick below)*		
				Whole Blood	HVL	Sputum	HEID/DBS	Good	Satifactory	
Time	pick up time	After 2 Hrs	After 4 Hrs	After 6 Hrs	After 8 Hrs		After 10	On Arrival		
Temperature										
Samples sent by				Signature			Date		Time	
Samples delivered by				Signature			Date		Time	
Samples received by				Signature			Date		Time	

ANNEX 9: SAMPLES REJECTION LOG

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN.

Viral Load/EID & TB Hub Rejection form

SECTION A

Name of facility (Spoke):	
Name of Requester:	
Phone number:	

SECTION B

The sample(s) below have not met the criteria of a good sample for the HVL, EID and MTB/RIF test requested. Processing this/these sample(s) will yield unreliable results. Therefore, we cannot accept the samplen(s) for further analysis.

CTC ID/HEI No. or Client name(for TB or other pathological samples)	Date of sample collection	Type of test (EID , TB or HVL)	Sample type (Plasma, DBS,Sputum, Whole blood)	Reason for Rejection (Choose code below)	Name of person rejecting	Comments

You are advised to collect another sample(s) from the patient and resend it/them as soon as possible.

SECTION C:

Report submitted by		Date of rejection	
Hub Name		Tel Contact	

HVL/EID REJECTION CRITERIA

Haemolyzed, 1.3-Short draw, 1.4- Lipemic)	6=Serum rings		11= Improper drying/shipment	
2=Incorrect container	7=Expired filter paper/tubes		12=Missing sample	
3=Missing patient ID	8=Specimen processing delay		13=Insufficient volume	
4=Sample request & sample mismatch	9=No requisition form		14=Poorly collected DBS samples (scratched, scattered, 2 layer spots)	
5=Delayed delivery	10=Improper packaging		15= Other (Specify)_____	

MAKE 2 SIGNED COPIES: one for Hub, one for referring facility (Spoke),

ANNEX 10:SPOKE AND HUB STANDARD OPERATING PROCEDURES - MASTER LIST

1. Instructions for filling out HIV Viral Load request form
2. SOP for whole blood sample collection
3. SOP for separating whole blood into plasma
4. SOP for sputum collection for AFB staining, GeneXpert , Hain assay and Culture
5. SOP for DBS collection for HEID
6. SOP for DBS collection for HVL
7. SOP for sample collection for POC-EID GeneXpert
8. SOP for sample storage, packaging and transportation
9. SOP for decontamination of cooler boxes
10. SOP for accurate requisition form completion
11. SOP for chain of custody
12. SOP for sample reception
13. SOP for POC-MTB/RIF GeneXpert testing
14. SOP for POC-HEID GeneXpert testing
15. SOP for result pick up at laboratory
16. SOP for barcoding samples
17. SOP for rejecting poor sample(s)
18. SOP for rejected sample(s) notification
19. SOP for test result return from the Hub to facilities(Spokes)
20. SOP for handling results after return from the laboratory (recording results into the logbook, separating results, patient chart logging, filling out of register)
21. SOP for handling outstanding results identified from the sample(s) daily log
22. SOP for remote login into ESRS and general ESRS utilisation
23. SOP for communication between Hub and the testing Laboratory
24. SOP for e-SRS validation and quality check
25. SOP for POC waste management
26. SOP for Hub Mentorship
27. Sop for Hub supportive supervision

ANNEX 11: INDICATORS PERFORMANCE FOR SAMPLE REFERRAL SYSTEM

1. Key performance indicators for a sample referral system at spoke level:
   - 1.1. Total number of samples collected at the spoke;
   - 1.2. Total number of samples transported to the hub;
   - 1.3. Turnaround time from sample taken/collected to return of result at the spoke;
   - 1.4. Percentage of results returned within national TAT.

2. Key performance indicators for a sample referral system at hub level:
   - 2.1. Total number of samples collected (delivered) from spokes;
   - 2.2. Percentage of samples referred to the testing laboratories with specified time;
   - 2.3. Percentage of referred samples for which results were returned;
   - 2.4. Percentage of results returned electronically through ESRS;
   - 2.5. Number of samples referred for testing/ Number of samples transported;
   - 2.6. Percentage of results returned within specified hub TAT;
   - 2.7. Percentage of spokes submitting samples at the hub;
   - 2.8. Percentage of samples rejected.

3. Key performance indicators for a sample referral system at the testing laboratory:
   - 3.1. Total number of samples received;
   - 3.2. Percentage of samples recived within specified time;
   - 3.3. Percentage of samples rejected;
   - 3.4. Percentage of samples tested;
   - 3.5. Percentage of results dispatched;
   - 3.6. Percentage of results dispatched within required laboratory TAT.

4. Key performance indicators for a sample referral system at Council level:
   - 4.1. Percentage of functional hubs;
   - 4.2. Percentage of active spokes;
   - 4.3. Percentage of hubs with functional electronic sample referral and result tracking system (eSRS).

5. Key performance indicators for a sample referral system at National level:
   - 5.1. Percentage of functional hubs;
   - 5.2. Percentage of active spokes;
   - 5.3. Avarage overall TAT;
   - 5.4. Percentage of hubs with functional electronic sample referral and result tracking system (eSRS).

ANNEX 12: SRS MONTHLY MONITORING FORM

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN.

EARLY INFANT DIAGNOSIS-HUB SAMPLES AND RESULTS MONTHLY REPORT						
SECTION A						
1	**Month**					
2	**Name of the Hub**					
3	**Distrct**					
4	**Region**					
5	**Name of the Hub Focal Person**					
SECTION B: GENERAL HUB REPORT						
		HVL	**TB**		**EID**	
1	Total number of facilities (Spokes) that suppose to submit samples at the hub					
2	Total number of facilities(Spokes) that have submit samples in that month					
3	Total number of samples received					
4	Total number of samples rejected					
5	Total number of samples entered in electronic sample referral system(e-SRS)					
6	Total number of samples transported to the testing lab *(for TB sample for culture only)*					
7	Total number of results received fro testing laboratory (hardcopy+electronic results)					
a	Hardcopy results					
b	Electronic results					
8	Average Turn Around Time					
a	Hardcopy results					
b	Electronic results					
9	Total number of results (hardcopy+electronic) received within the national TAT(14 days)					
	SECTION C: HUB TESTING CENTRE					
10	Total number of samples tested at the hub		**MTB/RIF testing**	**AFB Examination**	**EID-Near Point of care (POC) testing**	
11	Total number of results dispatched/sent to the spokes/TB diagnostic centres					
12	Average Turn Around Time within the hub					

ANNEX 13: HUB QUARTERLY ASSESSMENT AND SUPERVISION CHECKLIST

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN.

SAMPLE REFERRAL QUARTER ASSESSMENT TOOL

	Name of the Health Facility							
	Level of health Facility	**Dispesary**		**Health Centre**	**Hospital**	**District Hospital**	**Regional Hospital**	
	Facility Affiliation	**Govement**		**Faith Based Organization**		**Private**		
	District							
	Region							
	Facility In-charge/Manager/Director		Name			**Signature**	**Date**	
	Laboratory In-charge/Manager		Name			**Signaure**	**Date**	
	1. Available Sample Referral System							
		TB		**HVL**		**EID**		
1a	Does the hub receive samples from its surrounding spokes? (Functional hub)? *(Check VL/TB/EID register Book)*	**YES**	**NO**	**YES**	**NO**	**YES**	**NO**	
1b	If (1a) is NO, is the hub collecting samples from its CTC, RCH or TB Clinic ? i.e. **(acting as spoke)**	**YES**	**NO**	**YES**	**NO**	**YES**	**NO**	
1c	Which laboratory does the hub refer its samples. (Name of the laboratory)	**HVL Lab**		**EID Lab**		**TB Lab**		
1d	If the hub is acting as a spoke*(either the equipment not functioning or it doesn't have therequired capacity/equipment)* , to which hub does it submitting its samples?	**Name of Hub**		**Name of Testing lab** (If the hub is submitting samples direct to the lab)				
1e	Indicate what type(s) of transport is/are used for sample transportation from spokes to the hub?	**Health Care Provider**	**Courier Services (eg.**	**Implementing partner(IP)**		**Other(specify)**		
1f	What is the average **monthly cost** (if known) for sample transportation from spoke to the hub?							
1g	Indicate type(s) of transport is/are used for sample transportation from Hub to the Testing lab(VL and EID) or to Culture/Hain Probe assay laboratory?	**Health Care Provider**	**Courier Services(eg(**	**Implementing partner(IP)**		**Other (Specify)**		
1h	What is the average **monthly cost** for sample transportation from Hub to the Testing lab/Culture/Hain probe laboratory?							
1i	Are test results for all spokes pass through the hub?	**HVL**		**TB**		**EID**		
		YES	**NO**	**YES**	**NO**	**YES**	**NO**	
1j	Indicate how results of HVL, EID and Culture/Hain probe tests delivered at the hub.	**Hardcopy (paper) picked by Health Care Provider at the testing lab**	**Delivered through courier services/EMS)**	**Delivered by Implementing Partner (IP)**		**Delivered through elctronic system**	**Other Specify**	
1k	If (1i) is YES. What type(s) of transport is/are used for results transportation from Hub to the Spokes?	**Health Care Provider**	**Courier Services/EMS picking**	**Public transport (such as boda boda) Picking**		**Delivered through elctronic system**	**Other (Specify)**	

	2. Hub and Facilities(Spokes) level linkage for Viral Load (VL), TB and EID						
2a	What is a total number of primary health facilities(spokes) that supposed to refer specimens to the hub?	HVL		TB		EID	
2b	What is a total number of primary health facilities (Spokes) that currently referring specimens to the hub?	HVL		TB		EID	
2c	What is the average number of samples received at the hub from the facilities (spokes) ? (monthly average for the past six months). /*sample register book*/	HVL		TB		EID	
2d	What is theaverage number of specimens sent from the hub to the HVL or EIDtesting lab or TB culture and DST? (monthly average for the past six months)	HVL		TB		EID	
2e	What is the total number of results received from the testing lab for the past three months?	HVL		TB		EID	
2f	What is the proportion of referred specimens for which results were returned? (quarterly) Total no of result received for sample collected in a quarter/total number sample sent for testing in a	HVL		TB		EID	
2g	How many times in a week does the hub refer samples to the HVL/EID Lab or TB culture lab	HVL		TB		EID	
	3. Documentation and Chain of Communication						
3a	Are standardized register books being used at the hub? (If YES, ask for a copy)	HVL hub egister Books		TB Hub registers		EID hub registers	
		YES	NO	YES	NO	YES	NO
3b	Are standardized tracking tools/checklist being used at the hub? (If YES, ask for a copy)	YES	NO	YES	NO	YES	NO
3c	Are there specific records and tools for monitoring viral load cascade? (If YES, ask for a copy).E.g. Sample and Results Monthly progress monitoring tool.	YES	NO	YES	NO	YES	NO
	4. Equipment						
4a	Are there functional equipment for initial processing, storage and transportation of samples at the hub?	Centrifuge		Fridge		Freezer	
		YES	NO	YES	NO	YES	NO
4b	Centrifuge	Model	No of cubes that can be	Speed Used		Triple packaging material	
						YES	NO
4c	At what temperature are HVL samples stored?	2-8 °C		-20			
		(Fridge)		(Freezer)			
4d	How frequently do samples transported from the hub to the testing laboratories (HVL, EID and TB) ? Once-1, Twice-2, three times -3 four-4 and daily basis-5)	TB		HVL		EID	
	5. Near Point of Care Testing Capacity for TB (MTB/RIF), EID and HVL						
5a	Is there a near POC device for HVL, MTB/RIF and EID?	HVL		TB		EID	
		YES	NO	YES	NO	YES	NO
5b	If (5a) YES, which type of device?	Name of the Device		Name of the Device		Name of the Device	
5c	If the hub uses POC device for testing, how many personnel have been trained?	Total No.		Total No.		Total No.	
5d	Is a standardized register for samples tested using POC device? (If YES, ask for a copy)	HVL		TB		EID	
		YES	NO	YES	NO	YES	NO
5e	Is there a LIMS used to manage data of HVL samples tested and results from POC device?	HVL		TB		EID	
		YES	NO	YES	NO	YES	NO
5g	Total number of sample tested using near-POC device quarterly.	Total No.		Total No.		Total No.	
5h	If the hub uses POC device for testing, how many personnel have received a centralized training?	Total No.		Total No.		Total No.	
	6. Human Resources and Training						
	Cadre	Number					
6a	Number Laboratory scientist						
6b	Laboratory technologist						
6c	Laboratory technician						
6d	Laboratory attendant						
6e	Volunteer/ Intern/ Trainee						
6f	Health records information officer (Data officers)						
6g	Technical staff affiliation (employer)	GOT	IP				
6h		HVL		TB		EID	
6i	Number of staff (hub levels) dedicated to handling and processing referred samples						
6j	How many have been trained on the MoH training package?	Total number		Total number		Total number	

ANNEX 14: HUB LABORATORY INFORMATION SYSTEM –QUARTER ASSEMENT TOOL

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN.

LABORATORY INFORMATION MANAGEMENT SYSTEM- HUB QUARTER ASSESSMENT TOOL

Name of the Health Facility					
Level of health Faclity	**Dispesary**	**Health Centre**	**Hospital**	**District Hospital**	**Regional Hospital**
Facility Affiliation	**Govement**	**Faith Based Organization**		**Private**	
District					
Region					
Facility In-charge/Manager/Director		Name		**Signature**	**Date**
Laboratory in-charge/Manager		Name		**Signaure**	**Date**

S/N	Tool	HVL			TB			EID		
		Available	Complete	Correctly filled	Available	Complete	Correctly filled	Available	Complete	Correctly filled
1	Lab request and report forms									
2	Hub register									
3	Sample Manifest/Tracking tool									
4	Rejection log									
5	Referral register data monthly summary report form									

		HVL		TB		EID	
		YES	NO	YES	NO	YES	NO
6	Does the hub record your specimen/clients information in the authorized laboratory register upon receipt? (Check the reception						
7	Are the specimens received accompanied by the recommended laboratory request forms?						
8	Do the requests contain relevant data?						
9	Does the hub cross check request forms complete and accurately filled?						
10	Are unique laboratory numbers assigned for every specimen received?						
11	Does record results received from HVL/EID/ TB Culture and Line probe testing laboratories?						
12	Does the lab have an officer assigned to compile the Hub reports?						
13	Does the lab send reports to higher levels according to the recommended reporting period?						
14	Are the specimens received accompanied by the recommended lab request forms?						
15	Do the requests contain relevant data?						
16	Are the request forms complete and accurately filled?						
17	Are unique laboratory numbers/barcode label assigned for every specimen received?						
18	Does the Hub retain and file duplicate copies of the original results?						
19	Does the Hub send reports to higher levels according to the recommended reporting period?						
20	Are there copies of recent Hub Monthly data reports sent to relevant authorities?(Verify)						
21	Does the hub receive feedback after sending reports?						
22	Does the hub have a designated mode of sending reports?						
23	Does the hub have a computer where you log in the lab information?						
24	Are there functional equipment for Laboratory Information System/electronic sample tracking and results return system (i.e eTL						
26	Is Laboratory information /electronic Sample Referral and Result system(LIMS/ESRS) functional?						

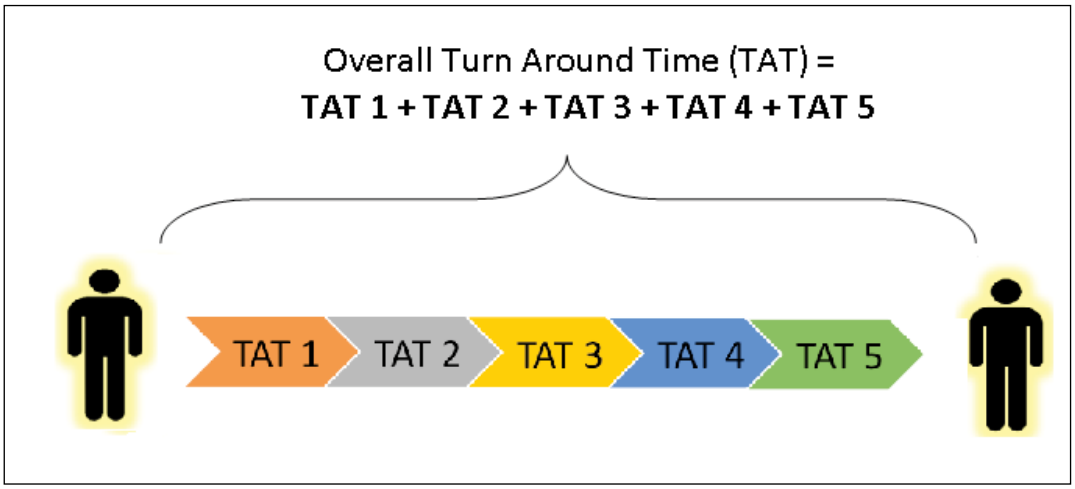
		No Internet	No Printer/ Printer not functional	Staff Not well	LIMS/ESRS
27	**If LIMS/ESR NOT functional, tick what is the reason ?**				

If LIMS/ESRS is functional,		HVL		TB		EID	
		YES	NO	YES	NO	YES	NO
28	Does th hub uses the LIMS/ESRS to register/remote log in samples ?						
29	Does th hub uses the LIMS/ESRS to register/remote log in rejected samples ?						
30	Does th hub receive results electonically through LIMS/ESRS ?						
31	Does the hub uses theLIMS/ESRS to produce monthly report?						

		HVL	TB	EID
32	Total Number of sample entered/remote logged at the hubs in a quarter			
33	Total Number of results received electronically in a quarter			
34	Total number of rejected samples registered at the hubs in a quarter			
35	Average TAT for results received electonically			

		YES	NO	YES	NO	YES	NO
36	Does the lab have measures to ensure data security?						

ANNEX 15: HIV VIRAL LOAD TURN AROUND TIME

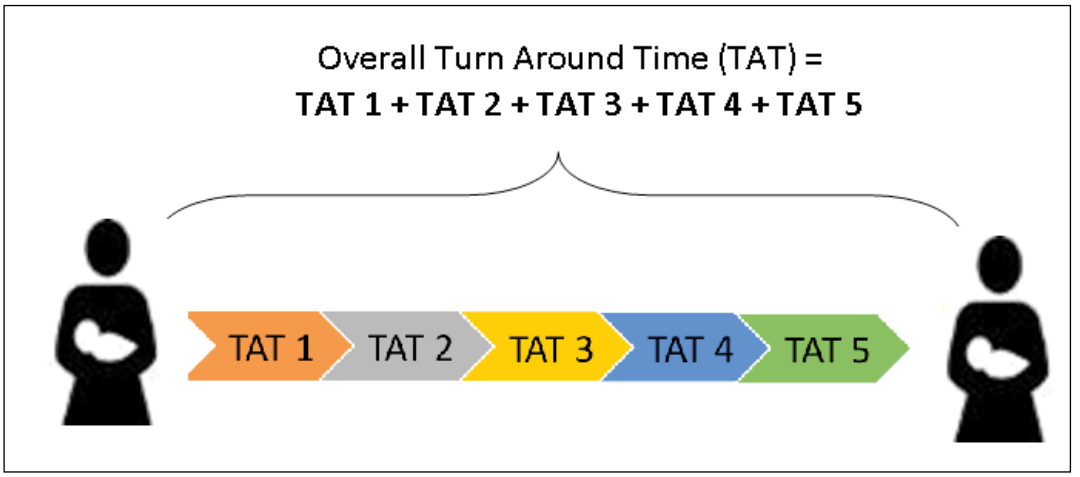


TAT between steps:

1. **TAT1:** Whole blood should reach a hub and be processed for plasma separation within **six hours** of sample collection.
2. **TAT 2:** Plasma should be transported from the hub and reach the testing laboratory within **96 (4 days)** hours of sample collection.
3. **TAT3:** Time taken from sample received at laboratory to result released for pick up shall be **72 hours (3 days).**
4. **TAT4:** The signed hard copy of the results should reach the hub within **72 hours (3 days)** of testing of the sample
5. **TAT5:** The signed hard or approved soft copy of the results should reach Spokes/ CTCs from the hub within **48 hours (2 days)** of testing of the sample.

Overall TAT: The Turnaround Time (TAT) for reporting of results to the Spoke/CTC is **14 days** from the time of sample collection.

ANNEX 16: HEID TURN AROUND TIME (CONVENTIONAL)

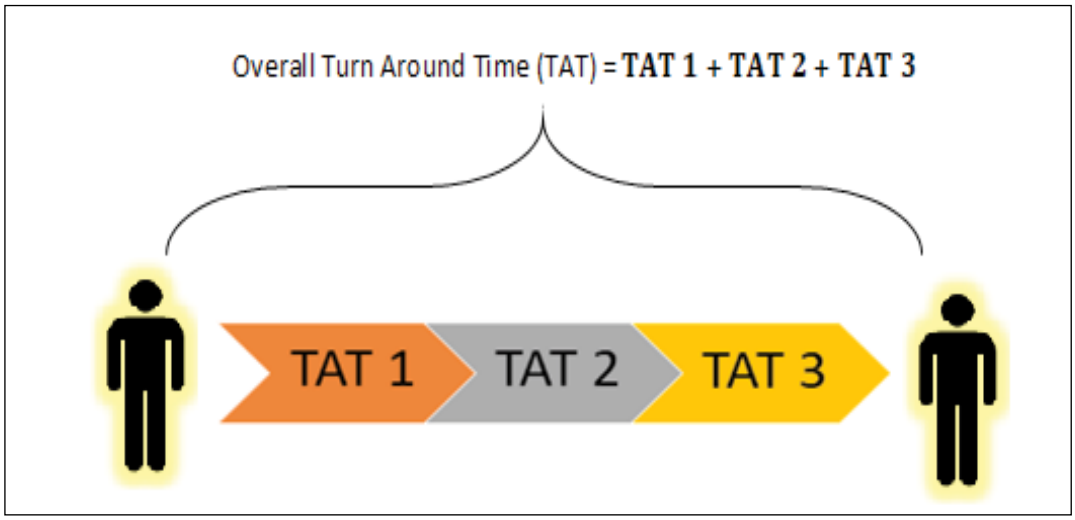


TAT between steps:

1. TAT1: DBS should reach a hub within 24 hours of sample collection.
2. TAT 2: DBS should be transported from the hub and reach the testing laboratory within **72 (3 days)** hours of sample collection.
3. TAT3: Time taken from sample received at laboratory to result released for pick up shall be **72 hours (3 days)**.
4. TAT4: The signed hard copy of the results should reach the hub within **72 hours (3 days)** of testing of the sample.
5. TAT5: The signed hard or approved soft copy of the results should reach Spokes/RCHs from the hub within **48 hours (2 days)** of testing of the sample.

Overall TAT: The Turnaround Time (TAT) for reporting of results to the Spoke/RCHs is 14 days from the time of sample collection

ANNEX 17: XPERT MTB/RIF TESTING TURN AROUND TIME

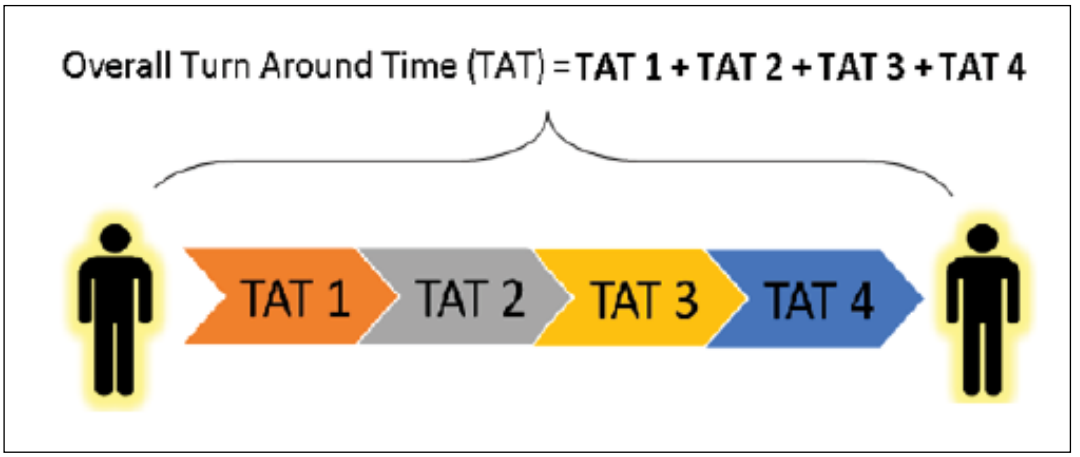


TAT between steps:

1. **TAT1:** Sputum collection should reach the hub testing Centre within 24 hours of sample collection.
2. TAT2: Time taken from sample received at the hub testing centre to result released for pick up shall be 48 hours (2 days)
3. TAT3: The signed hard or approved soft copy of the results should reach the hub within 24 hours (1 day) of testing of the sample.

n) **Overall TAT**: The Turnaround Time (TAT) for reporting of results to the spoke/TB diagnostic centre is 96 hours (4 days) from the time of sample collection

ANNEX 18: LINE PROBE ASSSAY TURN AROUND TIME

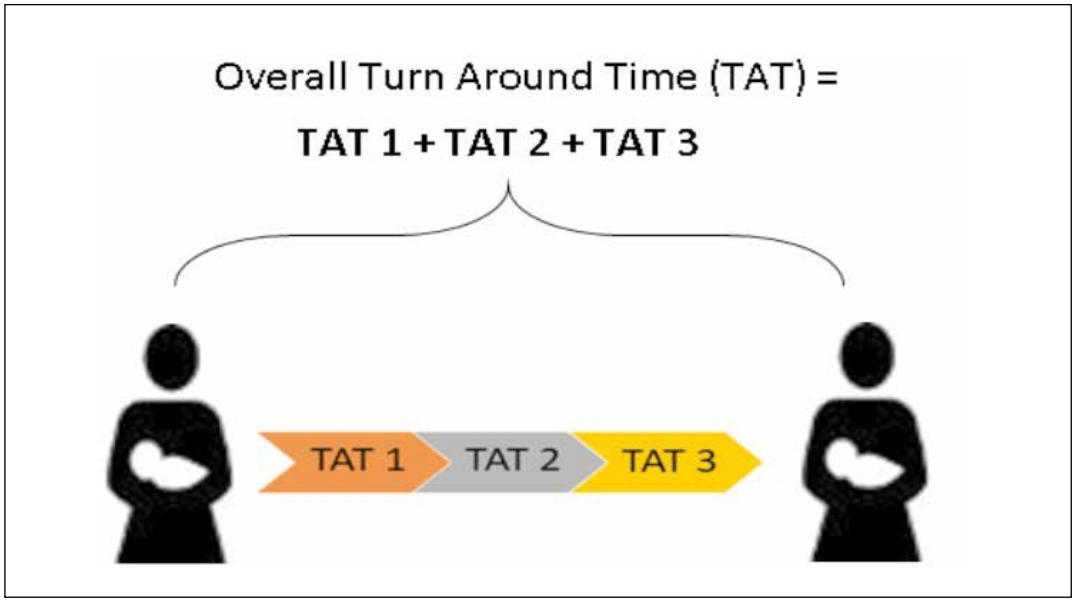


TAT between steps:

1. **TAT1:** Sputum should reach the hub within 24 hours of sample collection.
2. **TAT 2:** Sputum should be transported from the hub and reach the testing laboratory within 48 (2 days) hours of sample collection.
3. **TAT3:** Time taken from the sample received at laboratory to result released for pick up shall be 5 days
4. **TAT4:** The signed hard copy of the results should reach the hub within 48 hours (2 days) of testing of the sample.
5. **TAT5:** The signed hard or approved soft copy of the results should reach Spokes/ TB diagnostics from the hub within 24 hours (1 day) of testing of the sample.

Overall TAT: The Turnaround Time (TAT) for reporting of results to the Spoke/TB diagnostic centre is 10 days from the time of sample collection.

ANNEX 19: HEID POC TURN AROUND TIME



TAT between steps:

1. **TAT1:** DBS collection should reach the hub testing Centre within 24 hours of sample collection.
2. TAT2: Time taken from sample received at the hub testing centre to result released for pick up shall be 24 hours (1 day)
3. TAT3: The signed hard or approved soft copy of the results should reach the hub within 24 hours (1 day) of testing of the sample.

o) **Overall TAT**: The Turnaround Time (TAT) for reporting of results to the spoke/TB diagnostic centre is 72 hours (3 days) from the time of sample collection

ANNEX 20: HEID POC IMPLEMENTATION CHECKLIST

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN.

	POC HEID Implementation Site Monitoring Checklist: Hub Testing Site				
1	Facility name:				
2	Name(s) of trained instrument operators/end users:				
3	Date of monitoring visit:				
4	Name(s) of monitors or supervisors:				
	Observe and ask about the activities in the table below. For each activity, check the appropriate box to indicate if the activity is being done (Yes), partially done (Partial) or not being done (No). If an activity is partially or not done, write a brief explanation and describe the assistance or mentoring provided. If possible, observe at least one instrument operator performing a test. Provide assistance and mentoring as needed or requested. Enter additional information as required, such as the number of POC EID/DBS Testing Forms collected.				
	SECTION A-SOPs, Job Aids and Documentation				
	SOPs, job aids, registers, tracking logs, electronic sample referral system and testing forms: (NOTE: Observe the facility, discuss with staff, and review error logs and	**Yes (100%)**	**Partial(%)**	**No**	**COMMENTS**
1.1	SOPs and job aids are available in the appropriate language.				
1.2	SOPs and job aids are available and visible to staff (e.g. job aids are hung on the wall, training manuals are near the testing platform).				
1.2	SOPs and job aids are used and adhered to by all staff.				
1.4	ANC, PMTCT and ART Initiation registers from the previous three months are properly and completely filled out.				
1.5	An Error and Specimen Rejection Log and sections from the training manual describing the meaning of error codes are placed next to the instrument.				
1.6	The Error and Specimen Rejection Log is up to date and properly filled in.				
1.7	HEID requesting Forms from the previous three months are properly and completely filled out.				
1.8	HEID request forms were collected during the monitoring visit for data entry.				
	SECTION B-Operator Training and Performance				
	Training and competency of instrument operators/end-users: (NOTE: Discuss with facility staff and platform end users)	**Yes (100%)**	**Partial (%)**	**No**	**COMMENTS**
2.1	All staff performing POC testing received initial instrument training from a certified trainer.				
2.2	All staff performing POC testing have passed a competency assessment.				
	Observation of operator(s)/end user(s): (NOTE: If possible observe at least one instrument operator/end user	**Yes (100%)**	**Partial (%)**	**No**	**COMMENTS**
3.1	Before the sample is drawn, the POC instrument is switched on and ready.				
3.2	The operator correctly: (a) handles and fills the cartridge; (b) checks the sample; and (c) closes the cartridge.				
3.3	Before running the test in the POC instrument, the infant's name is verified.				
3.4	The operator correctly inserts the cartridge into the instrument.				
3.5	The operator correctly enters the User ID and Sample ID into the device.				
3.6	The operator adheres to universal safety precautions for the handling of human blood (e.g. wears gloves and protective clothing, washes hands, disposes of lancets in puncture resistant containers, changes gloves after each specimen).				
	SECTION C-Inventory and Waste Management				
	Reagents and Supplies: (NOTE: Observe and discuss with facility staff)	**Yes (100%)**	**Partial (%)**	**No**	**COMMENTS**
4.1	All supplies needed to perform POC testing are available at the facility (e.g. cartridges, gloves, lancets, alcohol wipes, gauze, and thermal paper).				
4.2	The area where POC testing supplies are stored is clean and well organized.				
4.3	There is a thermometer in the area where testing cartridges (i.e. reagents) are stored.				
4.4	Testing cartridges (i.e. reagents) are stored at the required temperature of 2 to 30° degrees Celsius.				
4.5	Stock cards for POC supplies are used and kept up to date. (NOTE: For each individual product, stock cards should indicate the quantity of stock received, on hand, and lost/expired as well as adjustments, such as transfers of stock to another facility).				
4.6	In the last 90 days, there have been stock outs of supplies needed to perform POC testing. (NOTE: If yes, the reason for stock outs in the comments box.)				
a	If yes, which products were not available?				
b	Approximately how long did the stock out last (in days)?				

4.7	A physical count of POC HEID cartridges was completed within the last four (4) weeks.				
a	If yes: what was the date of last physical count: DD MM YY				
b	How many cartridges were reported on that date:				
4.8	If there is any concern about inventory management, and time permits, conduct a physical inventory of POC supplies and cross check the quantities available against those written in the stock cards. Do the quantities match those indicated in the stock cards?				
	Waste management: (NOTE: Observe and discuss with facility staff)				
5.1	Cepheid cartridges are used at this location.				
5.2	If yes, Cepheid HEID and Viral Load cartridges are disposed of using a high-temperature incinerator (>1000 °C)				

	SECTION D-Receiving samples from spoke sites (for hub sites only)				
		Yes (100%)	**Partial(%)**	**No**	**COMMENTS**
6.1	There is a log book for sample reception from spoke sites.				
a.	If yes, the log book is properly filled out.				
6.2	Samples are received from spokes sites within 24 hours of sample collection (if kept at room temperature) or within 72 hours of collection (if kept at 4 degrees C).				
6.3	Samples are transported in appropriate conditions (e.g. in cool boxif kept at 4 degrees C)				
6.4	All samples arrive with HEID request forms appropriately filled out and with linked sample.				
6.5	Samples from spokes sites are tested as soon as they arrive and withing 48 hours.				
a.	If samples are not tested immediately, how many hours ypically elapse between the time when samples are delivered to the hub site and when they are tested?				

	SECTION E-Linkage to Care				
		Yes (100%)	**Partial (%)**	**No**	**COMMENTS**
7.1	All HEID test results are conveyed to caregivers on the same day as the sample tested				
7.2	All infants who have a positive initial result have a second POC sample run for confirmation within 48 hours.				
7.3	All infants who have a positive initial POC result are initiated on ART with 24 hours.				
7.4	For all infants who have a positive initial POC test result, but a negative second POC test result (i.e. discordant result), a DBS sample is sent to a conventional lab, and contact information is collected from the patient for follow up.				
7.5	In the previous three (3) months, all infants diagnosed as HIVpositive were successfully linked to ART services (NOTE: If possible, cross check positive cases in POC HEID/DBS Request Forms/HEID Hub register or logbooks against the facility's ART register)				

	SECTION F-Mentoring, Training, and Information Sharing				
		Yes (100%)	**Partial (%)**	**No**	**COMMENTS**
8.1	**List the topics covered and the recipients of mentoring, training and information sharing.**				
8.2	**List recommendations or plans for future training, mentoring or information sharing.**				

TABLE 3: LIST OF PARTICIPANTS WHO DEVELOPED THE GUIDELINE

Name of participants	Title	Organisation	Contact
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