Guidance for Developing a Specimen Transport and Referral System for Viral Load and Infant Virologic HIV Diagnosis Testing Networks

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LIST OF ABBREVIATIONS

AMRF	African Medical Research Foundation
ANC	Antenatal care
ART	Antiretroviral therapy
ASLM	African Society for Laboratory Medicine
DBS	Dried blood spot
EID	Early infant diagnosis
EQA	External quality control
GIS	Geographical information systems
GFATM	Global Fund to Fight AIDS, TB, and Malaria
HBV	Hepatitis B virus
HRS	Hours
HTC	HIV testing and counselling
IATA	International Air Transport Association
IVHD	Infant virologic HIV diagnosis
µL	Microliter
mL	Milliliter
MCH	Maternal Child Health
M&E	Monitoring and evaluation

MoH	Ministry of Health
NGO	Non-governmental organization
PEPFAR	United States President's Emergency Plan for AIDS Relief
PITC	Provider-initiated testing and counselling
POC	Point-of-care
PMTCT	Prevention of Mother to Child Transmission
PPE	Personal protective equipment
SOP	Standard operating procedure
SMS	Short message service
TAT	Turn-around-time
TB	Tuberculosis
UAV	Unmanned aerial vehicles
WHO	World Health Organization

1.0 INTRODUCTION

1.1 Background

The 2013 World Health Organization (WHO) *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection* strongly recommends viral load as the preferred test for monitoring antiretroviral therapy (ART) failure [1]. Furthermore, WHO, in partnership with the United States President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund to Fight AIDS, tuberculosis (TB), and Malaria (GFATM), and the African Society for Laboratory Medicine (ASLM) compiled a global guidance document entitled *Technical and Operational Considerations for Scaling-Up HIV Viral Load Testing*, which provides a public health approach to implementing viral load monitoring of HIV-infected patients on ART [2].

The *Technical and Operational Considerations for Scaling-Up HIV Viral Load Testing* document is based on seven key pillars with specimen referral networks as one of the pillars and a key step in the viral load cascade (Appendix A). Specimen referral networks and strengthening of laboratories will play a key role in the scale-up of viral load (VL) testing and continued enhancement of infant virologic HIV diagnosis (IVHD). IVHD includes early infant diagnosis (EID) testing as well as testing of infants at later time points. VL and IVHD tests are still performed in specialized laboratories that require significant infrastructure development, human resources, information management and quality management systems. It is impractical to place these complex and advanced technologies in every laboratory tier due to their varying complexities. Point-of-care (POC) VL and IVHD testing could reduce the demands on specimen referral networks; however, POC testing for these tests are still in the evaluation and development phases. To immediately increase access to VL and IVHD tests, it is important to address the need to transport specimens (whole blood, plasma, and dried blood spots) and results to and from community/lower tier facilities and higher level testing facilities within the laboratory tiered system by developing an efficient and reliable specimen referral and result return network.

Increasingly, national HIV care and treatment programs are decentralizing services to primary health clinics in order to provide patients with greater access to antiretroviral therapy (ART) and meet the 90-90-90 targets [3]. HIV care that is provided closer to where patients live can improve patients' adherence to ART, as well as strengthen post-ART retention rates [4]. Access to HIV diagnosis and monitoring with VL, as well as IVHD testing is a key component of high quality HIV care. In some settings, monitoring tests like VL are conducted in laboratories that are distant from the clinic where the patient is receiving services – often in a district or provincial laboratory that operates within a national tiered laboratory network. It is critical that HIV care and treatment facilities without on-site testing capabilities, including primary health care facilities, have reliable and efficient access to essential diagnostic tests through the referral of specimens to off-site laboratories, and have similarly robust systems for results to return to the clinic. Tests performed

at peripheral sites should periodically be monitored for quality through the provision of proficiency and external quality assessment (EQA) panels (also referred to as quality control materials), administered by the national program. Proficiency and EQA panels also require a robust referral network to deliver specimen panels to testing sites and report back results. It is also important to note that transportation of proficiency and EQA panels may present unique challenges, which should be, reviewed on a case-by-case basis in consultation with the panel(s) provider(s).

1.2 Current Challenges with Specimen Referral

Specimen referral systems in resource limited settings have a unique set of challenges including absence of roads, lack of well-maintained roads in some areas, vehicles that are not well maintained and a shortage of dedicated vehicles and drivers. As such, the systems can be uncoordinated and less efficient leading to a long turnaround time (TAT) for many tests. In addition, many countries do not operate system-wide national specimen referral networks that can efficiently and reliably transport clinical specimens and quality control materials between all collection sites and testing laboratories. A fragmented, non-standardized approach can result in many complications that include but are not limited to long TATs, high rate of specimen rejections, and concerns about validity and accuracy of test results. From a patient and clinician perspective, these issues can lead to, incorrect or sub-optimal ART initiation or drug regimen switches. The scale-up of VL and expansion of IVHD services necessitate a well-coordinated specimen transportation system. More specifically, the challenges of specimen transport systems include:

- Specimens transported across long distances or under inappropriate conditions may be rejected at the laboratory if the specimen quality is compromised. As a result, clinicians will not receive results at all. If the specimen is rejected by the testing laboratory, another specimen will need to be requested leading to further delay in clinical interventions.

- There is poor specimen and result management at the point of collection. Lack of specimen collection logs, chain of custody logs, sample rejection logs and active follow-up to seek results when not returned within appropriate time, often results in delayed clinical intervention. Challenges with human resources and training often elevates this problem.

- Proficiency or EQA panels are often transported using parallel distribution systems to specimen referral systems. Under inappropriate transportation conditions, the stability of these panels may be compromised, potentially resulting in participating laboratories returning unacceptable results unnecessarily.

Existing specimen referral networks are not frequently updated or evaluated for efficiency or cost changes. Infrequent evaluation can lead to inefficient and overpriced services. Active Monitoring and Evaluation (M&E) systems are often lacking and could be utilized to identify inefficiencies

and reduce TATs. Specimen referral networks if in place often lack strong safety policies, leading to unsafe practices that put drivers and receiving laboratories at risk.

- Uncoordinated, ad hoc, specimen transport systems often result in uneven volume distributions across a laboratory testing network. This may result in high testing volumes in some laboratories, which increases the risk of equipment overload and break down. In contrast, low testing volumes at other laboratories results in testing delays as specimens need to wait longer to meet minimum batch sizes before processing. These issues delay the availability of results and potentially increases the instability of specimens.

- Staff who transport specimens may not be trained on safe handling of potentially infectious materials, and therefore put themselves at risk. They may also not be trained on proper conditions for specimen integrity and stability, increasing the likelihood that the specimens will be rejected at the referral laboratory.

- There may be inefficient utilization of scarce human resources such as the use of highly skilled nursing and laboratory staff to transport specimens.

- Specimen transport added onto other already-existing transport or distribution networks without appropriate packaging can compromise the integrity of specimens if they are kept in transit for too long while other transport activities are carried out.

The development of a robust transport network incorporating as many health facilities as possible could reduce the reliance on informal or unstructured specimen referral processes and could also improve the cost efficiency, TAT and quality of test results. Innovative methods for specimen transport (i.e., unmanned aircraft) and returning of results (i.e., short message service [SMS] and printer technologies) should be explored and used when and where possible. Further studies with samples stability should also be conducted. As the process of strengthening laboratories towards accreditation continues, building a reliable, sustainable and cost-effective specimen transportation system is of great importance. The Ministry of Health (MOH), in collaboration with partners, should establish and/or manage a national specimen transportation and referral system.

This document, *Guidance for Developing a Specimen Transport and Referral System for Viral Load and Early Infant Diagnosis Testing Networks,* can serve as a guiding principle for countries to develop a well-coordinated, standardized, well-functioning, effective, and efficient specimen transportation system. Its implementation for a particular country would require first a situational analysis of the existing system to better inform the application of this document. The guidelines in this document apply to healthcare institutions as end users and to specimen transportation service providers as suppliers. The following documents were used in the development of these guidelines:

2015 IATA Dangerous Goods Regulations Updates, *WHO Guidance on Regulations for the Transport of Infectious Substances 2013–2014* [5], and the *African Medical Research Foundation (AMREF) Guidelines on Specimen collection, Storage, and Transportation* [6].

1.3 Ownership of Specimen Referral Networks

Whenever possible and practical, specimen referral networks should be owned and coordinated by the MoH with partner support. This helps prevent parallel and uncoordinated efforts, which are often the root cause of the challenges listed above. Developing specimen referral networks under the umbrella of the MoH builds capacity and increases their sustainability as transition logistics, including long-term management and financing, can be factored in at an early stage.

1.4 Objective and Scope of this Document

The purpose of this document is to provide a systematic approach in developing a coordinated, standardized, reliable, efficient, cost-effective, and sustainable specimen transport and referral system to support IVHD and VL testing networks. This document provides technical and programmatic recommendations on the appropriate specimen storage and transportation of specimens for HIV VL and IVHD testing. Along with the national guidelines for specimen storage and transport, these standards should provide guidance on the creation or improvement of specimen referral networks and specimen transport systems. In addition, standard operating procedures (SOPs) targeting drivers and persons responsible for packing of specimens and results return are included in this document.

1.5 Target Audience

These recommendations are primarily for program managers, health facilities, laboratories, and transportation personnel. The document should be useful as well to stakeholders (including government, non-governmental organizations [NGOs] and public-private partnerships) interested in evaluating their current systems, redesigning, outsourcing, financing, operating and optimizing specimen referral networks.

2.0 STANDARD COMPONENTS OF AN EFFECTIVE SPECIMEN REFERRAL SYSTEM

An effective national specimen transportation system should be scheduled (but with the flexibility to respond to outbreaks if needed), punctual, reliable, sustainable, cost-effective, safe, scalable, robust and comprehensive. Thus, the components of effective specimen transport require careful design and management. The steps required to implement a national specimen transport system will differ from country to country based on geography, current transport networks (where available), he type of laboratory system in place (centralized or decentralized), mode(s) of transport selected, and country-specific regulations. In harmony with achieving the set goals, the

following steps should be considered in every country to ensure that systems are implemented well:

- Review of national policies, which include clear guidelines on patient confidentiality, frequent review of existing networks, responsiveness to instrument deployments, safety standards, established TAT expectations and accountability at all levels.
- Identify key partners and determine whether it is more appropriate to enhance transport service capabilities within the MOH or to outsource the service to an external organization. In the case of outsourcing, there will need to be the development of a statement of work with specific deliverables (TAT expectations, liability responsibilities, etc.).
- SOPs and a training curriculum for each specimen type and every component of the referral and transportation system should be developed, including: specimen collection, collection logs and chain-of-custody processes – storage, packaging and dispatch - at health facilities, transportation from the collection facility to the testing laboratories, specimen reception and testing at the referral laboratories, results dispatch back to the referring (collection) sites, and ongoing monitoring and evaluation at the referring sites, as well as the referral laboratories, and supportive supervision. These SOPs should include staff training requirements, proper documentation, TAT expectations, and safety [5].
- Establish a schedule and share with relevant facilities and stakeholders for regular specimen transport, and defined responsible parties at each step in the process, with appropriate specimen tracking documentation.
- Train and sensitize staff on appropriate and safe specimen handling techniques [5].

On an ongoing basis, there should be M&E of the system to ensure that adequate service is being provided, and thereby, implement corrective action as needed. Key indicators like specimen acceptance and rejection rates, TAT, and availability of results on the day the patient returns to receive results should be monitored. A combination of the transport options could be used to cover the various distances and accessibility of facilities. Ambulances should only be considered if the other options are unavailable.

3.0 TYPES OF TRANSPORT AND REQUIREMENTS FOR TRANSPORT PROVIDERS

Modes of Specimen and Results Transport

There are various options available to transport specimens and return results within a national referral network for VL and IVHD testing, some of which may build on current systems already in place, including: courier services, dedicated motorcycles, ambulances, utility vehicles and public transport and others, such as unmanned aerial vehicles (UAVs) that would likely be a new vehicle introduction. These options are not necessarily exclusive and different options may be utilized at different levels of the health system appropriately. Whichever mode(s) are chosen it should be efficient and effective within the larger sample referral network for VL and IVHD.

It is recommended that the following requirements be in place based on the transportation option in use and availability of each item in the specific country:

I. Requirements for organizations/institutions
   a. registration in Country
   b. qualified on proper handling and safe transport of infectious specimens
   c. conform to IATA standard regulations, WHO, and/or national guidelines where possible
   d. must have specimen/package tracking system

II. Requirements for mode of transport should include the following:
   a. Motorcycle/motorbike
      1. professional drivers' license with defensive driving where possible/when required
      2. protective gear (helmet, boots, etc.) where possible
      3. first aid kit, personal protective equipment (PPE), limited spill kit when possible
      4. communication device (radio, phone)
      5. comprehensive insurance coverage (both motorcycle and rider)
      6. appropriate or specially designed carrier/bag/top box to carry specimens and associated specimen documents
      7. transport log
   b. Utility vehicle (car, truck, van, bus, etc.)
      1. professional drivers' license/certificate where required (with defensive driving where possible)
      2. comprehensive insurance coverage and government certification where applicable
      3. appropriate and current vehicle registration
      4. first aid kit, PPE, portable fire extinguisher, spill kits
      5. cooler box/carrier for specimens and associated specimen documents.
      6. communication device (radio, phone)
      7. transport log
   c. Boat
      1. Professional pilots' license where applicable/required
      2. protective gear (life jackets)
      3. first aid kit, spill kit
      4. communication device (radio, phone)
      5. comprehensive insurance coverage (both the boat and pilot)
      6. specially designed carrier/bag/ top box to carry specimens and associated specimen documents
      7. transport log

Note: Unmanned aerial vehicles are a new innovation and as such, rules regarding their use will evolve. Countries must determine how their use is governed and maintain updated guidelines.

d. Unmanned aerial vehicles
    1. trained operator certificate where required
    2. permission to operate aircraft in airspace
    3. defined paths over uninhabited areas should be designated

The provision of protective safety gear for all types of transport must be stipulated to be reviewed every year and replaced/updated when deemed necessary.
More details for types of services that could be utilized for both specimen transport and results return are in the following sections.

3.1 Professional Courier Services

Courier companies collect and deliver packages using a combination of road, air, rail and sometimes water transportation. Couriers can be distinguished from ordinary mail services by potential features such as speed, security, tracking, name and signature of receiving person, specialization and individualization of express services and collection at the desired point (instead of utilizing an already existing hub). Couriers are usually more expensive than regular mail service providers, and their use is typically restricted to instances where one or more of these features are sufficiently important to warrant the extra cost.

Most couriers typically operate within a limited geographic scope, usually within the major cities and rarely cover rural areas. Couriers that have national coverage are ideal as they are most likely to have existing national networks that can be leveraged to accommodate laboratory specimens. It is preferable to have at least two couriers operating a national specimen transportation system so that there can be a competitive tendering process at regular intervals. This will maintain a level of competition, which can improve the quality of services and reduces the risk of collapse of the transport network, should one company cease to operate.

Using couriers for specimen transportation and results return can be challenging because there may be regulations governing the transportation of biomedical specimens, and specialized biomedical couriers are rare and expensive. If a non-specialized courier for specimen transportation is utilized, regulatory hurdles may need to be overcome. Typically, this requires approval from the national authorities. Once these approvals have been obtained and couriers have been selected, they should be appropriately trained to safely transport specimens and return of results with the highest level of confidentiality.

National programs that decide to use a courier system to transport specimens and to return test results need to ensure that the responsible parties take the following steps:

1. Tender specifications for bidding should be drawn up that detail all the services that the courier must provide and requirements they must meet to effectively provide a specimen transport

service (including requirements around training of courier staff, documentation of specimen and results transportation , TAT and their rollout plan).
2. Formally announce the request for this service to be provided, either through launching a tender or through other official channels, and invite couriers to bid.
3. Carefully review all applications and select two or three couriers who can meet all of the requirements outlined at a competitive price.
4. Obtain all necessary waivers for couriers that do not meet MoH requirements for transporting bio-hazardous and/or potentially contagious specimens.
5. Enter into a contract of a specified length with the selected courier companies, and conduct necessary trainings.
6. Pilot the system in a small geographical area (e.g. district or province) before reaching national coverage to identify operational challenges and costs elements.
7. Train courier staff on good and safe specimen handling techniques and patient confidentiality.
8. Provide staff with appropriate personal protective equipment, and specimen packaging for packing specimens and/or results.
9. Provide the staff with instructions on how to handle emergency situations, including numbers to call and the name of a responsible person.
10. Monitor the courier and contract to make sure that adequate service is being provided.

3.2 Motorcycle Courier Services

Dedicated motorcycles could improve/provide vehicle reliability and mobility even in countries with limited or undeveloped road infrastructure, and at a cost lower than cars or trucks. Building a system that provides ongoing maintenance and management to ensure reliability is essential to reduce breakdowns and to increase usable time of motorcycles.

Using motorcycle couriers for specimen and results transportation can be challenging because maintaining a huge fleet of motorcycles and training many competent motorcyclists on biosafety and safe riding to minimize road accidents, and specimen loss and damage requires good coordination, management and training.

The selection of the specimen packaging also needs to be more rigorous to ensure that quality but cost effective materials are used to prevent damage due to excessive shaking - often seen on motorcycles when they go through very rough terrains, which is common in rural settings.

National programs that decide to use a dedicated motorcycle system to transport specimens and test results need to take the following steps:

1. Decide whether to build the motorcycle service capabilities (including vehicle maintenance) in-house or to outsource the motorcycle service to another organization.
    - If outsourcing: review proposals from organizations that want to provide this service for the MoH, select an organization to work with, and sign a contract.

- Otherwise: work with the relevant people and bodies within the MoH to reinforce existing sample referral systems in all necessary areas prior to rolling out the motorcycle transport system.

2. Draw up specifications for bidding in a contract that details all the services that the motorcycle service must provide and the requirements they need to meet to effectively provide a specimen transport service (including specifics around training of courier staff, documentation of specimen transportation and TATs).
3. Pilot the system in a small geographical area (e.g. district or province) before reaching national coverage to identify potential operational challenges and costs elements.
4. Train staff on appropriate and safe specimen handling techniques and patient confidentiality.
5. Provide staff with appropriate personal protective equipment and specimen packaging for transport of specimens and/or results return.
6. Monitor the system to make sure that adequate service is being provided, and take corrective action as needed.

3.3 Public Utility Vehicles

Public utility vehicles owned and operated by the government are another alternative for specimen transport and return of results. These vehicles frequently travel between health care facilities to collect and distribute essential supplies, including drugs and other health commodities.

Specimen referral systems that rely on public utility vehicles are also prone to challenges, such as breakdowns, due to poor service and maintenance, fuel shortages, lack of spare parts and diversion of the vehicle for other activities. For example, the use of ambulances is not recommended as this form of transport is unpredictable and interferes with the regular duties of these vehicles. Generally, public utility vehicles do not reach all health facilities with the frequency that is needed for reliable specimen and results transport. In some countries parastatal or private organizations provide these services to the public sector and may not be authorized to transport specimens.

National programs that decide to use public utility vehicles to support a system for transporting specimens and test results need to take the following steps:

1. Identify public utility vehicles with capabilities (scheduled deliveries, reliability, etc.) to support the specimen transportation network.
2. Get approvals from the relevant government departments.
3. Train staff on appropriate and safe specimen handling techniques and patient confidentiality.
4. Provide staff with appropriate personal protective equipment and secure bags for packing specimens and/or results.
5. Pilot the system in a small geographical area (e.g. district or province) before reaching national coverage to identify operational challenges and cost related elements.
6. Monitor the public utility vehicles to make sure that adequate service is being provided.

3.4 National Public Transport

The bus is the most commonly used form of public transport in resource-constrained countries. For the purpose of specimen transport and return of results, buses can be useful because they play a major role in both rural and urban transportation, leading to nation-wide access and coverage. Bus movements between locations are usually predictable, but they are not always mandated to keep official time schedules. Currently, buses are used to send letters, parcels and money from one location to another, especially in areas not covered by courier services. However, these transactions are generally informal and as such are not recorded or monitored, hence the specimens and test results may not be properly handled due to lack of training. However, with proper training and SOPs, health care facilities located on a bus route can potentially use buses to dispatch specimens to referral labs and return the test results to the health care facilities. The specimens can be transported within the cargo hold if it is appropriately designed with quality and effective shock absorbent materials. This approach will work best when using reputable bus companies with regular schedules, professional staff and a central depot where specimens can be collected and dispatched by health facility staff.

Using a public bus-based specimen transport system can be challenging because, programs will need to overcome regulatory hurdles around transporting biomedical specimens and confidential information along with passengers. It will be necessary for specimens to be packaged appropriately for this option to be acceptable to the relevant regulatory agencies and prevent damage due to excessive shaking as well as temperature issues. In addition, the person preparing and the person transporting the specimen should be trained on appropriate specimen handling techniques and what to do in the event of breakage/spillage. Buses will need to be equipped with spill kits to clean up spillages should the need arise.

National programs that decide to use regularly scheduled buses to support a system for transporting specimens and test results need to:

1. Draw up a document that details all the services that the bus company must provide and requirements that it must meet to effectively provide a specimen transport service (including requirements around training of company staff, documentation of specimen transportation and TATs).
2. Formally announce the request for this service to be provided, either through launching a tender or through other official channels, and invite companies to bid.
3. Carefully review all applications and select two or three bus companies who can meet the requirements outlined at a competitive price.
4. Obtain all necessary permits from all relevant government departments (e.g. biohazard handling permit from the MoH) for bus companies that do not meet MoH requirements for transporting bio-hazardous and/or potentially contagious specimens.
5. Enter into a contract of a specified length with the selected bus company.
6. Train staff on appropriate and safe specimen handling techniques and patient confidentiality.

7. Provide staff with appropriate personal protective equipment and secure bags for packing specimens and/or results.
8. Pilot the system in a small geographical area before reaching national coverage to identify operational challenges and cost related elements.
9. Monitor the bus company to make sure that adequate service is being provided.

3.5 National Postal System

National postal systems have extensive reach within a country, are typically on a predictable schedule, and may be able to be leveraged for specimen transport use – particularly for longer shelf-life specimens such as dry blood spot (DBS) specimens. National postal systems can easily be leveraged for return of test results to the health care facilities in their catchment area. While in principle, postal systems have the obligation to extend their services throughout their served regions, in resource-limited settings this cannot be guaranteed. For time and temperature sensitive specimens, this will generally mean reliance on a private courier service. If a postal service is utilized, transport should be in accordance with current postal regulations. The challenges of using postal services are similar to national public transportation especially around biosafety and getting MoH authorization. Whole blood and plasma specimens should not be shipped using a postal system unless biosafety and temperature control can be guaranteed.

3.6 Boats

Countries with populations living in areas inaccessible by road will need to explore alternative and cost effective modes of transport including boats and unmanned aerial vehicles. Both of these modes of transport have positive and negative attributes.

Boats have the advantage to expand the specimen referral network to communities cut off from the rest by large bodies of water, living in fishing villages or where bridges over rivers may be lacking. This is very common in resource limited settings in Africa and Asian and any area cut off by water. Homemade and non-motorized boats may have a role in specimen referral and results return, but motorized boats are ideal as they are faster and engineered with a higher safety standard. Specimen referral systems that rely on boats are also prone to challenges such as breakdowns due to poor service and maintenance, fuel shortages, lack of spare parts, and diversion of the vehicle for other activities.

National programs that decide to use boats to support a system for transporting specimens and test results need to take the following steps:

1. Identify boats with capabilities (scheduled deliveries, reliability, etc.) to support the specimen transportation network.
2. Get approvals from the relevant government departments.
3. Train staff on appropriate and safe specimen handling techniques and patient confidentiality.
4. Provide staff with appropriate personal protective equipment and secure bags for packing specimens and/or results.

5. Pilot the system in a small geographical area (e.g. district or province) before reaching national coverage to identify operational challenges and costs elements.
6. Monitor the boats to make sure that adequate service is being provided.

3.7 Alternative Transport

3.7.1 Unmanned Aerial Vehicles

Unmanned aerial vehicles have the potential to revolutionize specimen referral because of their wide coverage and potential to cut costs. This type of transport has been piloted in several countries and assays performed on samples that have been transported using this method [7, 8]. Their current limitation for widespread use in most countries is lack of clear regulations on their use for purposes such as specimen transportation and delivery of parcels. Biosafety standards for this type of transport have not yet been established. All aspects of biosafety need to be considered prior to piloting this time of transport. Patient confidentiality issues would also need to be considered and thoroughly vetted prior to piloting this mode of transport for either specimens and/or results return. Partners and MoHs are therefore urged to work with the relevant authority in their countries to get clear regulation and guidance on their use. Stakeholders are also urged to pilot their use and generate best practices, which can result in sustainable widespread use in resource-limited settings.

National programs that decide to pilot unmanned aerial vehicles for transporting specimens and test results needs to take the following steps:

1. Get approvals from the relevant government departments.
2. Design an appropriate pilot program to ensure that the results are credible and operationally feasible to scale up and sustain.
3. Identify specimen testing and collection sites in locations where the unmanned aerial vehicles can be flown without posing a danger to the environment and the public.
4. Train staff on appropriate and safe specimen handling techniques and patient confidentiality.
5. Provide staff with appropriate personal protective equipment (PPE) and secure methods for packing specimens and/or results.
6. Pilot the system in a small geographical area (e.g. district or province) before reaching national coverage to identify operational challenges and cost-related elements.
7. Monitor and evaluate the use of unmanned aerial vehicles.
8. Share best practices with national, regional and global stakeholders.

3.8 Mixed or Optimized Transport

Countries may find that a combination of specimen transport methods is needed to achieve full coverage. For example, a courier service may be used for transport between cities, or in the higher levels of the health system, while lower levels could be serviced by dedicated motorcycles. As long as the system is clearly documented and all healthcare workers and transport service providers are well trained in use of the system, a mixed approach may work.

The biggest challenge of this model is the increased complexity that comes with managing a multi-faceted system. More specifically, the system requires dedicated management effort, co-ordination, and a competent team within the MOH to 'own' and manage the national system.

4.0 CONFIDENTIALITY COMPONENTS IN TRANSPORTING SPECIMENS AND RESULTS

There are confidentiality issues for those collecting specimens and preparing them for transportation, but more so for those entrusted to transport the results regardless of mode of transport. Patients expect that all health services staff will keep personal information confidential. This includes information/results transferred through the specimen transportation system. All staff should meet the standards of practice outlined in national confidentiality policy, as well as those included within their terms of employment. Those who are registered healthcare professionals must also keep to their own regulatory organizations' standards of conduct and practice. A serious or persistent failure to follow policies and procedures, code of conduct, or practice or guidance should lead to disciplinary action.

Access to and collection of results will change from site to site based on available personnel but will include clinicians, nurses, laboratory technicians, laboratory supervisors, and data entry clerks among others. To help secure patient information the following recommendations should be considered:

1. Staff (clinical, laboratory, and transport) not bound by any confidentiality agreement should read and sign a confidentiality policy or have it included in their terms of employment.
2. Patient results should be stored in a secure area both at the point of specimen collection and testing sites. A SOP for who is permitted to have access and the security requirements should be written.
3. Only authorized and trained personnel should have access to the results. These personnel will be defined based on the staff at the site and outlined in the SOP.
4. Only authorized and trained personnel should collect results. These personnel will be defined based on the staff at the site and outlined in the SOP.
5. Paper results ready for collection should be packed into a sealed envelope before being handed over to pick-up staff. A signature can be made on the seal for inspection on delivery.
6. Broken signature seals should be reported, investigated and the appropriate disciplinary action should be taken.
7. Digital or SMS results should be securely transmitted.
8. Only authorized personnel should have access to the SMS devices and results. These personnel will be defined based on the staff at the site and outlined in the SOP.

5.0 DEFINING THE TRANSPORTATION ROUTE, FLOW OF SPECIMENS AND SCHEDULE

A transportation route and schedule must be established by determining catchment areas for each testing laboratory and the health facilities to be included within the transportation route. It is very important to map specimen collection sites to testing laboratories. During the mapping process, it is important that specimen collection sites are connected to testing laboratories that are the **closest possible distance** rather than within pre-defined geographical boundaries, (e.g., districts, counties, etc. Note, the closest testing laboratory may be in a different district). Specimen collection sites should not be mapped based on availability of reagent stocks at a particular testing laboratory, or any other preference/criteria. While planning the transportation network, attention should be paid to high burden sites as well as TAT and cost efficiency.

Specimens should be sent from collection facilities to testing laboratories at regular intervals, minimizing the time between collection and return of results, with a focus on safety at each step. If daily collection or on demand collection is not feasible, select days and times based on when most patients visit the clinic for routine visits (HTC, ANC, PITC and ART) and/or the days when, historically, the highest number of patients visit the health facilities (aka blood draw days etc.). At least twice weekly specimen collection and delivery, is strongly recommended; however, whole blood and plasma specimens require daily transport, and, storage at the correct temperature.

Timing of specimen collection also needs to be considered. A pick up time of 9:00 am isn't advantageous if specimen collection for the day is not completed until 1:00 pm. Coordinating times for several pick up locations may be required and careful consideration to each site and the distance from one to the next needs to be calculated for effective transport.

Patient accessibility for specimen collection, specimen type, sample stability, as well as machine capability at the testing laboratory, must also be considered while planning a transportation route. For Friday specimen transport, make prior arrangements to ensure that samples are either stored at the correct temperature or tested promptly. It is also possible that Fridays may not be testing days but utilized for paper work and returning of results. Keep in mind that there are limited staffing capabilities over the weekends in many testing laboratories.

Most programs find a "hub and spoke" system the most effective: many collection sites or "spokes" send specimens to one testing laboratory or "hub" which performs the required testing and then returns results back to the referring site [9]. Hubs (discussed here as referral laboratories) can also act as holding and transfer locations for surrounding health facilities/clinics (see Appendix B Figures 1 and 2). In a tiered, integrated laboratory network, there might be multiple levels of referral and specimens may be referred once, twice or multiple times, for example, when a primary health facility sends a specimen for IVHD testing to a district hospital. If, however, the primary

health facility sends a specimen to the district hospital requesting a specific test that is not available (e.g. HIV VL), the specimen will be referred to another facility for testing.

A network can have both small and large hubs. Smaller hubs are often district facilities that receive specimens from primary facilities, while the larger hubs tend to be provincial or health facilities – either hospitals or dedicated reference laboratories. Transport and storage of specimens should follow the same guidelines as above and each hub should be equipped with refrigerators, freezers and centrifuges to process the specimens when possible and ensure specimen integrity.

6.0 UNDERSTANDING THE COST(S) OF SPECIMEN TRANSPORT

Understanding the true cost of a specimen transportation system is imperative; governments and partners must know how much to budget for ongoing costs, and as a baseline to access and seek ways to seek further efficiencies when budgets are limited. The following cost categories should be fully appreciated and analyzed – preferably by costing specialists – to understand existing operation costs, and again if system changes are required to the existing specimen transport routes or modes. Sufficient funds and repair expertise must be provided to ensure that the vehicles and equipment are well maintained, in order to reduce service disruption. Implementers should also consider engaging transport and logistics specialists to develop the detailed operational plans, which should be shared with the costing specialists to ensure that all cost elements are included.

6.1 Operational Costs

- Courier fees
- Monthly vehicle running expenditures such as spare parts, maintenance, and fuel
- Replacement of vehicles and equipment
- Replacement of protective clothing (for motorcycles) and specimen carrier equipment
- Staffing salaries and benefits
- Vehicle and personal liability insurance
- Program management and oversight
- Staff re-trainings
- Phone bills / communication costs

6.2 Costs Associated with Establishing New Modes of Specimen Transport

- Consultancy fees to cover specialist skills
- Program specification development
- Feasibility study and monitoring and evaluation framework costs
- Additional human resources, including staff recruitment and training
- Vehicles (if needed)
- Additional infrastructure (if any) needed to implement the specimen transport system

- Training for individual transporting specimens, if motorcycles are used for example, training in safe riding, as well as preventative maintenance & bio-hazardous specimen handling training would be required
- Vehicle & equipment procurement
- Personal protective equipment and specimen carrier equipment

Process for monitoring existing costs should be in place to ensure visibility into the reoccurring expenses of operating the existing referral network. When proposing possible revisions to routes and modes of transport costing models should be developed for each scenario (routes or modes of transportation) as a part of the decision-making process. This information may also be helpful when making a case to reform regulations on transportation of specimens using a particular mode of transport as an option.

6.3 Ongoing Budgeting

The budgeting process pulls together the costing and financing information. When conducted regularly it can identify potential funding gaps. In the event of budget shortfalls, the cost saving strategies below may be employed.

6.4 Cost Saving Strategies

Below are a few cost saving strategies that MoHs and partners can use to reduce the cost of service without limiting service delivery.

6.4.1 Leveraging existing sample transportation systems

When already in place, IVHD sample transport systems can be used as the basis for VL transport, taking care not to impede on the existing system. When not already in place, integrating IVHD and VL sample transportation with existing sample transportation systems like CD4, TB samples, and external quality assurance (EQA) and other quality materials where possible will help increase program sustainability and cost effectiveness. This is also called layering of samples.

Economics of scale and savings are achieved when more samples are transported using the same infrastructure and resources resulting in dramatic cost reductions. Transporting paper-based results using the specimen referral network also helps increase savings.

Economics of scale in a sample transportation system can be achieved by:

- Collecting more specimens of the same or different types (e.g. adding CD4, TB sputum and disease surveillance specimens) on the same scheduled visits from the same facilities using equivalent resources.
- Collecting more specimens from supplementary sites within a neighborhood or geographical area using equivalent resources.

Layering of services needs to be well organized and managed to get a good return on investment, otherwise it can result in disruptions of specimen processing.

6.4.2 Route Network Optimization

A route network optimization effort requires a large amount of data to accurately depict the current referral network and to guide the methodology employed as part of the optimization effort. Where geographical information system (GIS) and input cost data is readily available, geospatial optimization tools can be used to generate optimization models comparing geography, distances and potential cost saving measures, relatively quickly. However, if site location data is not available, then a more involved referral site and laboratory assessment effort is required.

An example of some core data elements to conduct a route network optimization is provided below (not exhaustive):

- Referral site names, unique identifiers, and GIS coordinates (if available)
- Referral laboratory locations, unique identifiers, and GIS coordinates (if available)
- Existing referral linkages between referral site and laboratory
- Testing demand at referral site and laboratory
- Current instruments at the referral laboratory (functional status and age)
- Current instrument utilization rates
- Transport costs of referral (Fuel, per diem, vehicle maintenance)
- Variable (Staffing) costs
- TATs
- Specimen and result pick-up frequency by facility

When considering how to optimize an existing network, different scenarios should be considered. For example:

- Using the least possible number of routes possible in high population density areas.
- Using the shortest routes to reduce transport costs and TATs.
- Adding alternate or additional modes of specimen transport.
- Mixed contract or ‘in-house’ specimen transport modes.
- Reducing the number of “hub” laboratories if feasible.

Other particular optimization considerations should include:

- Current instrument utilization
- Planned programmatic scale-up
- Incoming traditional platform instruments (quantities and final destinations)
- Life expectancy and age of instruments
- Developing further redundancy/back-up capacity

- Existing referral distances

Once the current network coverage is established, the methodology and modeling approach provides the required 'what-if' analysis to understand the effects of various changes. This is an integral component of the analysis since it provides some insight into the effects of various changes to the network without having to physically make those changes. In this analysis, the easiest scenario to develop is the optimal collection site-to-laboratory testing site assignment, based on proximity.

In shifting the existing referral network, it is important to model the impact these changes would have not only on distances, but also on current instrument usage and costs. If current instrument utilization is low, then adding additional workload may not significantly affect instrument demand or costs. However, low utilization sites may actually receive less specimens and increase costs based on unit pricing. If a sub-optimal distribution of instruments exists, based on demand and existing utilization, the question about where to add additional capacity to increase access (and if that is the best way to improve access) becomes a very important question to answer. Thus, additional analysis would be recommended, possibly to include optimizing a referral network by attempting to reduce overall costs, and, by identifying candidate locations for the introduction of additional capacity based on minimizing the impact of existing instrument coverage and use.

6.4.3 Layering on Other Services

Economics of scale can also be achieved by transporting other approved commodities, like clinic and laboratory supplies, using the same infrastructure and resources as specimens. This is called 'layering'. Transporting paper based results using the specimen referral network is a great example of layering of services.

Layering transportation of external quality assurance (EQA) and other quality materials on existing specimen transportation systems where possible will help increase program sustainability and cost effectiveness. However, technical guidance on the appropriate storage and shipping methods for proficiency/EQA panels should be obtained from the providers to ensure compliance.

Layering of services needs to be well organized and managed to get a good return on investment, otherwise it can result in disruptions for specimen processing or the other layered services.

For example, programs that decide to use public utility vehicles should be aware of the existing responsibilities of these vehicles and align specimen transport as closely as possible with their ongoing activities. Synchronizing the delivery of essential medicines with specimen transportation, for example, may result in large cost savings as existing infrastructure and equipment are utilized. However, this must not compromise specimens', or essential medicines', integrity.

It is very common to increase the volume of specimens being referred through a referral system without increasing the costs. This can be achieved by:

- Collecting more specimens of the same or different types (e.g. adding CD4, TB sputum and disease surveillance specimens) on the same scheduled visits from the same facilities using equivalent resources.
- Collecting more specimens from supplementary sites within a neighborhood or geographical area using equivalent resources.

6.5 Financing Specimen Transportation Systems

Long-term financing for a specimen transportation system is challenging in resource-limited settings. Having specimen transportation itemized in the national budget is even more challenging. Some financing options are listed below:

6.5.1 Public Funding

Specimen transport systems may be funded through the MOH with funds from national and/or regional budgets. Government budgets are usually prepared on an annual basis. If specimen transportation can be included in the national budget, this process should be carefully monitored to ensure that all necessary cost centers are included. In many countries, the national budgeting process is lengthy and could leave specimen transport systems at risk of service disruptions, especially between the beginning and end of financial years or disbursements. As such, a supplementary budget may be necessary to bridge gaps. Similarly, it must be ensured that MOH re-budgeting is based upon new priorities or budget shortfalls that does not put the funding for specimen transportation systems at risk of being reduced or dropped entirely. Continual lobbying will help to prevent this from happening. As many countries have decentralized their procurement and budgeting to district or provincial-level, similar vigilance will be needed at those government departments.

6.5.2 Donor Funding

Funds from donor agencies may be utilized to finance and/or manage national specimen transport systems. Analysts and program planners will need to evaluate the risk to specimen transport systems if there are changes in donor priorities. A clear transition plan from donors to other local stakeholders is therefore key during the initial planning process.

6.5.3 Public - Private Partnerships

Opportunities may exist to engage the private sector in supporting specimen transport systems through public-private partnerships or corporate responsibility initiatives that provide concessionary pricing on specific components of logistic services or operational guidance. Private-sector businesses may be willing to support programs that benefit the communities in which they operate.

7.0 BIOSAFETY, PERSONAL PROTECTIVE EQUIPMENT (PPE), AND STANDARD PRECAUTIONS

7.1 Bloodborne Pathogen Safety

Biosafety is as important outside of the laboratory as in the laboratory. During every step of the IVHD and VL cascade, including specimen transport, bloodborne pathogen safety should be addressed to protect everyone handling the specimen (Appendix M). Standard precautions (including use of gloves and goggles or face shields) are a systematic approach to infection control to treat all human blood and certain human body fluids as if they were known to be infectious for HIV, hepatitis B virus (HBV) and other bloodborne pathogens [10]. The use of standard precautions prevents and minimizes the risk of transmission of infection that can cause harm, while conducting activities related to the handling of specimens, and should be in compliance with the guidelines stipulated by the WHO [5].

7.2 Safety Training

A safe specimen transportation system begins with the laboratory and program managers, who should ensure that safe practices and procedures are integrated into the basic training of employees. Training in safety measures should be an integral part of new employees' introduction to the program. Employees should be introduced to the code of practice and to local guidelines, including the safety manual**,** and relevant SOPs. The program supervisors play a key role in the biosafety training of their staff. The safety officer can assist in the training and development of related aids and documentation. They should also refer to the WHO biosafety manual during the development process [11]. The responsibility of the officers should also extend to other aspects of safety beyond biosafety.

Human error and poor handling during specimen transportation can compromise the quality and integrity of specimens. Safety-conscious staff, well informed about the recognition and control of biohazards, are key to the prevention of occupationally acquired infections, incidents and accidents during specimen transportation. For this reason, continuous in-service training in biosafety measures is essential to successfully develop biosafety culture amongst staff.

7.3 Biological Spills

A biological spill kit that incorporates standard precautions should also be accessible throughout the IVHD and VL cascade, including during transport. This spill kit should include the following items[5]:

- SOP for biologicals spills
- Nitrile gloves (at least 4 pairs of the appropriate size or 2 pairs of each available size)
- Safety glasses
- Disposable laboratory coats
- Sharps containers (for broken glass)

- Absorbent material and bleach or an approved viral inactivation agent known to work on HIV and other bloodborne pathogens
- Biohazard bags to contain all spill material during and after clean-up

A SOP for spill clean-up for drivers is located in Appendix N. The biological spill kits should be checked weekly and each weekly check recorded in a log. Any items used or found to be missing should be replaced immediately. Gloves deteriorate and therefore should be replaced with fresh gloves monthly or as frequently as possible.

In the event of a spill where no spill kit is available or where full spill kits are not practical (as in the use of a motorcycle), other options should be made available. These options should include a plan that allows for calling in a team that is designated for spill clean-up. This team should be able to respond in an hour or less to most areas on the designated route. At least one team for each route should be identified. Motorcycles should, however, include a reduced kit that includes at minimum PPE and absorbent material.

Dried DBS cards are considered a non-infectious material for transportation purposes. No spill procedure is required for this type of specimen. For transport and storage, dry DBS cards should be packed in zipper top bags with desiccant packs or indicator desiccant packs and humidity cards. They can be transported at ambient temperature.

Unmanned aerial vehicles need to be considered at great length prior to being utilized for specimen transport. Biosafety is of particular concern with this mode of transport as there is not a person physically there to attend to spills if they occur. Careful consideration of route and discussion with any communities that could be affected need to occur prior to employing this specimen transport system. If this mode of transport is used, a biohazard containment and spill clean-up procedure needs to be in place to handle such emergencies. A team and vehicle that can access every point along the route within two hours or less should be designated for spill clean-up.

8.0 REQUIREMENTS OF SPECIMEN LABELING AND FORMS (CHAIN OF CUSTODY, TRANSPORT LOG, ETC.) FOR TRANSPORTATION

As a national program, the specimen transportation system will handle many specimens from various sources (especially at the hubs). As a result, there is an increased chance of shared identifiers such as name, date of birth and hospital number. Where appropriate, all specimens should be accompanied by a request form specifying the tests or investigations required), as well as the signature and name of the person making the request. In order to comply fully with this standard, there should be sufficient labeling on each specimen to minimize the risk of misidentifying a patient. It is essential that the request form and specimen contain the minimum patient identification (PIN) that should include three points of identity. The following are the minimum standards acceptable for labeling specimens:

1. Surname/Family name and first name(s) in full (spelled correctly)
2. Date of Birth (not age or year of birth)
3. National Health System Number or other unique patient identifier assigned by the clinic or clinician

The specimen tube or filter paper should be labeled prior to the specimen being taken and the collection device should be initialed by the person taking the specimen. The time and date should be recorded to ensure increased accountability, which will result in most specimens meeting the requirements for the test(s) requested. Request form completion and specific national guidelines might require more stringent standards. When possible, and if funds permit, the use of barcoded labels and request forms are strongly recommended in order to decrease the rate of clerical errors associated with specimen labeling. Forms with different colors can also be used to aid testing prioritization at the testing laboratories. Forms accompanying IVHD specimens can be a different color or otherwise marked to identify them and ensure that they get tested as fast as possible.

With each specimen there should also be a chain of custody to track the specimen from collection site to delivery at the testing laboratory. The chain of custody should include a transport log that follows the specimen from collection to the lab and includes date and time of receipt/pick-up and the name of the receiving individual/person picking up (including driver) at every step of the process (an example of a Specimen Transport Log can be found in Appendix C). The Specimen Transport Log and other associated chain of custody forms can be maintained at the laboratory to be referred to as needed. When possible, carbon copies should be used to share the copies with the clinic when requested or to be maintained by the personnel responsible for transport. As stated above, where possible, this process should be performed using barcoded labels and a scanning system that **records the date, time, and name** of the individual in possession of the specimen at every step during transport. The data generated from this process should also be entered in the transport log and cross-checked for accuracy.

If a scanning system is not available and paper forms must be used, every effort should be made to ensure that the forms and transport logs are completed and copies are filed for review and M&E. The transport log should be reviewed daily by the laboratory supervisor and any discrepancies should be addressed immediately. In addition, when specimens need to be referred from a receiving to a central laboratory for testing, the extra transportation time needs to be considered. Below are additional guidelines on labeling forms and specimens.

1. The handwriting should be legible.
2. Each field must be completed in the designated area.
3. Forms should be completed using an inked pen and NOT using a graphite pen or pencil.
4. Specimens should be labeled in the designated area using an alcohol resistant marking pen.

5. Labels used for writing on or printing barcodes should have an alcohol and water resistant adhesive surface.
6. The writing area for labels should be water and alcohol resistant.

There should be a master list of all specimens being transported that day which is multi-copy (self-carbonating paper can be used to reduce the transcription load), as well as individual requisition forms. A copy of the specimen master log should remain at the clinic, and another copy be reviewed at the laboratory. As results come back from the laboratory, they should be reconciled with the master list (this is active specimen/result management).

Strong consideration should also be given to GPS devices and temperature/humidity loggers in the packaging process to track the time taken for the specimen to reach the receiving laboratory and to ensure that the specimens have been maintained at the proper temperature.

9.0 RECOMMENDATIONS FOR HANDLING, STORING AND TRANSPORTING SPECIMENS FOR VL AND IVHD

Accurate testing depends on appropriate specimen collection, storage, packaging and transport to the laboratory. After collection, specimens should be stored appropriately (see Appendix D, E and F) at the collection site and prepared for transport to ensure that they are delivered in an acceptable condition for testing [12-16]. As stated above, temperature/humidity loggers included in the packaging process can help identify specimens that were not maintained appropriately. Specimens handled inappropriately should be rejected at the laboratory and this rejection should be clearly communicated with the requesting facility. If they are not rejected, these specimens may lead to inaccurate results. The variety of storage/transport conditions required by the different sample and test types has implications for how the transport system is organized.
At the laboratory, specimens should be handled and stored appropriately before and after testing.

NOTE: Correct temperatures for storage are as follows: For whole blood, freshly drawn specimens can be held at 15-30°C for up to 6 hours and 2-8°C for 24 hours prior to centrifugation. Manufactures suggest that plasma should be separated from whole blood and transferred to new tube within 6 hours of collection. Plasma can be stored at 4°C for up to 5 days and -20°C if more than 5 days. DBS specimens can be held at ambient temperature for up to two weeks. Both DBS and plasma can be kept at -70°C for long-term storage. See Appendix D and E for more detail.

To reduce specimen rejection, redraw and re-test rates due to inconsistencies in specimen handling and transportation, it is important to standardize operating procedures. SOPs should be developed, distributed and made accessible to every facility that handles specimens. Specimen technical information from different IVHD and VL assay manufacturers has been collated in Appendix E.

10.0 RETURN OF RESULTS

Once testing is complete and results have been recorded, the results should be immediately returned to the health facilities/clinic via the transport system or other approved secure system (Section 13.0, d. Data and results management, Appendices J and K). To reduce costs and supply results in a timely manner, results should be returned when possible through secure encrypted email or emerging technologies such as specialized result printers or SMS [17]. Once results are received by the health facility/clinic, acknowledgement of receipt must occur by the receiving individual through direct communication with the sender of the result(s) either via phone call or a secure email. There should also be verification and a record indicating that the clinician providing care to the patient has received the results (Appendix K).

If specialized systems or emerging technologies fail to work for return of results, the same methods and routes used for specimen transport should be utilized. As with specimens, there should be a chain of custody or transport log that follows the results back to the health facility/clinic. The person responsible for receiving the results should communicate to the lab that the results were received in good order.

11.0 TURNAROUND TIME (TAT) FROM COLLECTION SITE TO RETURN OF RESULTS

Turnaround time is defined in this document as the time from when a specimen leaves the collection site to the receipt of results to the clinic/health center. The target TAT for IVHD and VL tests should be less than two weeks. Specimen transport and delivery of results should be done in a realistic, coherent and efficient manner, thereby, impacting service delivery positively. Program managers should always aim to have the results returned to health facilities before patients' next scheduled visits.

The target of less than two weeks is a guideline and should be modified to be a realistic representation of what is possible based on:

- Number of tests requested per day
- Frequency of clinical visits by the patient
- Number and type of platforms in use
- Human resources available to complete testing
- Specimen transportation availability and reliability
- Results return availability and reliability

As the IVHD and VL testing cascade is streamlined, every effort should be made to ensure that these targets are met.

12.0 SPECIMEN TRANSPORT SOPs

As stated in section 2.0, SOPs are required for every step of the testing and transport process at health facilities, including the entire IVHD and VL cascade and on the road between the health facilities and the testing laboratory. Failure to adhere to SOPs at any step within the cascade can significantly influence the quality and availability of results.

The SOPs should include;

a. Storage of specimens before transport (Appendix F, Recommendations for specimen handling requirements Appendix D and E)
b. Packaging of specimens (Appendix G) and transport of specimens to a testing laboratory (Example SOP Appendix H)
c. Specimen reception (including rejection criteria) and check-in (Example SOP Appendix I)
d. Transport and/or transfer of results (Guidelines for developing a SOP, Appendix J and K)
e. Reception of results at the collection site (Guidelines for developing a SOP, Appendix K)
f. Re-use and decontamination of coolers, racks and packaging (Appendix L)

13.0 TRAINING ON SOPs, SAFETY, AND TRANSPORT SYSTEM REGULATIONS

Specific training on all SOPs, safety, and transport system regulations is required for all individuals involved in the specimen transport process including:

a. Clinical health facility support, and management staff
b. Specimen transportation drivers/riders/couriers
c. Laboratory staff and management
d. Data manager/ receptionist

Training for each specific group will be given by designated staff with a standardized training tool specific to the needs of each group. At the end of the training, a test should be administered and a certificate provided for successful completion. **Refresher training must be completed yearly and updated certification of training should remain on file for review.**

The training should be tailored to the groups and depending on the roles of each group the following modules must be provided:

a. Biosafety, PPE and standard precautions

Safe handling practices and standard precautions should be used throughout the VL cascade and transportation process. Proper PPE must be available during specimen

transport (Appendix M). As stated above in section **6.0**, when possible, spill kits must accompany all specimens.

b. Packaging, storage and transportation of specimens

Specimens must be carefully packed according to SOPs for each specimen type and packaging must be designed to minimize temperature variance and movement following the "triple packing of infectious materials" (Appendix G) in compliance with WHO guidelines. Pick-up and delivery of specimens will depend on the type of specimen, their storage and their stability (Appendix D and E). When possible, a temperature/humidity recording device should be included in each package to verify that specimens were maintained at the proper temperature during transport. A GPS device to track the specimen transport should also be considered.

c. Reuse and decontamination of coolers, racks and packaging

In order to facilitate availability of clean coolers and racks for specimen transport at all health facilities/clinics, when specimens are picked up, a clean cooler with its outer box and racks should be returned. Once specimens have been removed from coolers, the coolers and specimen racks should be decontaminated according to the SOP and placed in a location that the transportation drivers can easily access for return to the health facilities/clinics (Appendix L).

d. Data and result management

Results can be communicated back to health facilities by either the same transport mode or through other available methods including email or newer innovations such as GSM printers and SMS technologies (Appendix K). To ensure that results are received at the correct facility and have reached the clinician (physician, nurse, etc.) caring for the patient as well as the patient, the receiving health facility should acknowledge receipt through signing a chain of custody form/transport log with a signature line for the person receiving the result, as well as a signature line for the clinician.

e. Road side troubleshooting and preventive maintenance of vehicles

A troubleshooting and comprehensive preventive maintenance protocol for all vehicles should be developed by the transport company or provider and put in place to ease the burden on the drivers. This will assist in preventing delays and interruption of service delivery.

14.0 SPECIMEN TRANSPORT SYSTEM MANAGEMENT

Monitoring and establishing efficiencies within a specimen transport network requires a management team with expertise in logistics, biosafety, specimen handling, and storage skills at minimum. If the MOH is not directly responsible for implementing and maintaining specimen transport, the management team should still have a government representative as a co-leader. This will help to build government ownership of the program, and will also facilitate the eventual

transition of the system to the government. A core group or task force should also be formed to manage daily activities. A focal person at each facility should be available and able to provide updates on a regular basis to the task force. This task force should be responsible for addressing issues, challenges, incidents and continuity of an efficient and effective specimen transportation system. The focal person will be responsible for communicating to the task force any pertinent issues and challenges that need to be addressed, as well as facilitate supply needs and data reporting. The task force should be a core group of relevant members, manageable and responsive to the issues. The members should consider conducting meetings either in person or by conference once a month or as often as possible to discuss issues. Following the completion of the meeting, a brief report of the condition of the specimen transport and results return system should be circulated to all stakeholders along with meeting minutes.

15.0 MONITORING AND EVALUATION (M&E)

As with any program, thorough M&E are crucial to ensure the ongoing success of specimen transport systems. Collecting both quantitative and qualitative data will allow the program to measure progress over time and generate evidence on areas that need to be strengthened in order to increase efficiency.

The MOH, with assistance from partners, should facilitate the M&E of the specimen transport and referral system. This should follow the implementation science approach, which is comprised of four major components: 1) Identifying Bottlenecks and Gaps, 2) Developing and Implementing Strategies, 3) Measuring the Effectiveness and Efficiency of Strategies and 4) Utilizing Results (Figure 1) [18]. Monitoring data should be collected quarterly and a report sent to the MOH staff tasked with overseeing the system and partners so as to make evidence based decisions. Quarterly supervisory visits should also be performed. The frequency can always be scaled back as the program becomes more stable. A thorough reevaluation and update of the system should be done annually or sooner if needed.

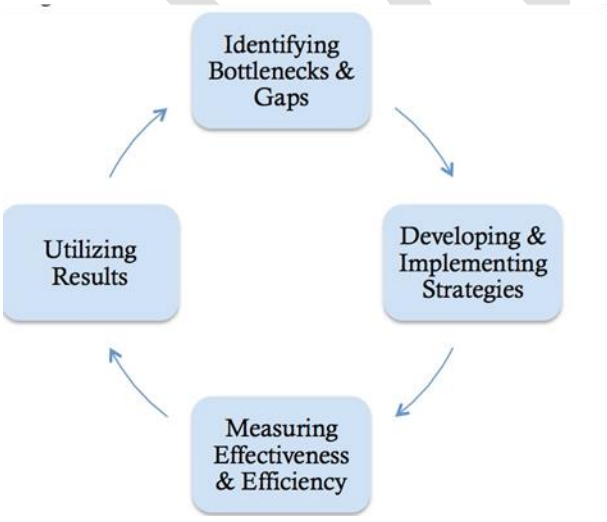

Figure 1. Monitoring and Evaluation Feedback Loop. (Fig. 1 from Lambdin et al. 2015 [18])

In order to ensure an effective, efficient and well-coordinated specimen transport system, there should be a M&E strategy in place which will track specimens and results, sample condition and temperature, specimen rejection rate, TAT for results return to the clinic/health center, TAT for results return to the patient, transportation routes and time to completion of the entire routing, and other relevant information (Appendix O and P).

Specimen transport logbooks and files (with copies of completed chain of custody forms) must be in place in all health facilities and laboratories and should include a:

a. Delivery checklist
b. Laboratory order/request form
c. Transport log and chain of custody forms including delivery time from clinic to laboratory
d. Specimen rejection log
e. Specimen temperature log (where possible)
f. Any additional log forms related to specimen transport

When possible, the MOH, with assistance from partners, should facilitate the M&E of the specimen transport and referral system. Monitoring data should be collected monthly and a report should be sent to the MOH staff tasked with overseeing the system and partners. Quarterly supervisory visits should be done. A thorough revaluation and update of the system should be done every six months. Table 2, shows the information that should be collected and analyzed at regular intervals.

Table 2: Key M&E data points that should be collected and analyzed, and responsible parties

Data Point	Responsible Party
Number of specimens sent from each collection site to the referral laboratory (daily/weekly)	Collection sites
Number of specimens transported from each collection site to the referral laboratory (daily/weekly)	Specimen transporter
Number of specimens received and tested at each referral laboratory (daily/weekly for each collection site)	Referral laboratories
Existing testing capacity at each referral laboratory	Referral laboratories

Average time taken to conduct tests after receipt of specimens at each referral laboratory by test and specimen type	Referral laboratories
Common reasons for specimen rejection	Referral laboratories
Median time to return the results to the clinic once testing is completed at the laboratory by test and specimen type	Program managers

In a well-functioning specimen transportation system, the following trends should be apparent, when reviewing the national ART program indicators:

- Increased volume of specimens collected and tested over time
- Shorter TAT for results return to the collecting facility
- Fewer specimen rejections at laboratories, as specimens are transported appropriately and in a timely manner
- More health centers offering ART services because an efficient specimen transportation system encourages decentralization of services
- Faster ART initiation for patients, as results are returned more quickly and consistently
- Reduced loss to follow up

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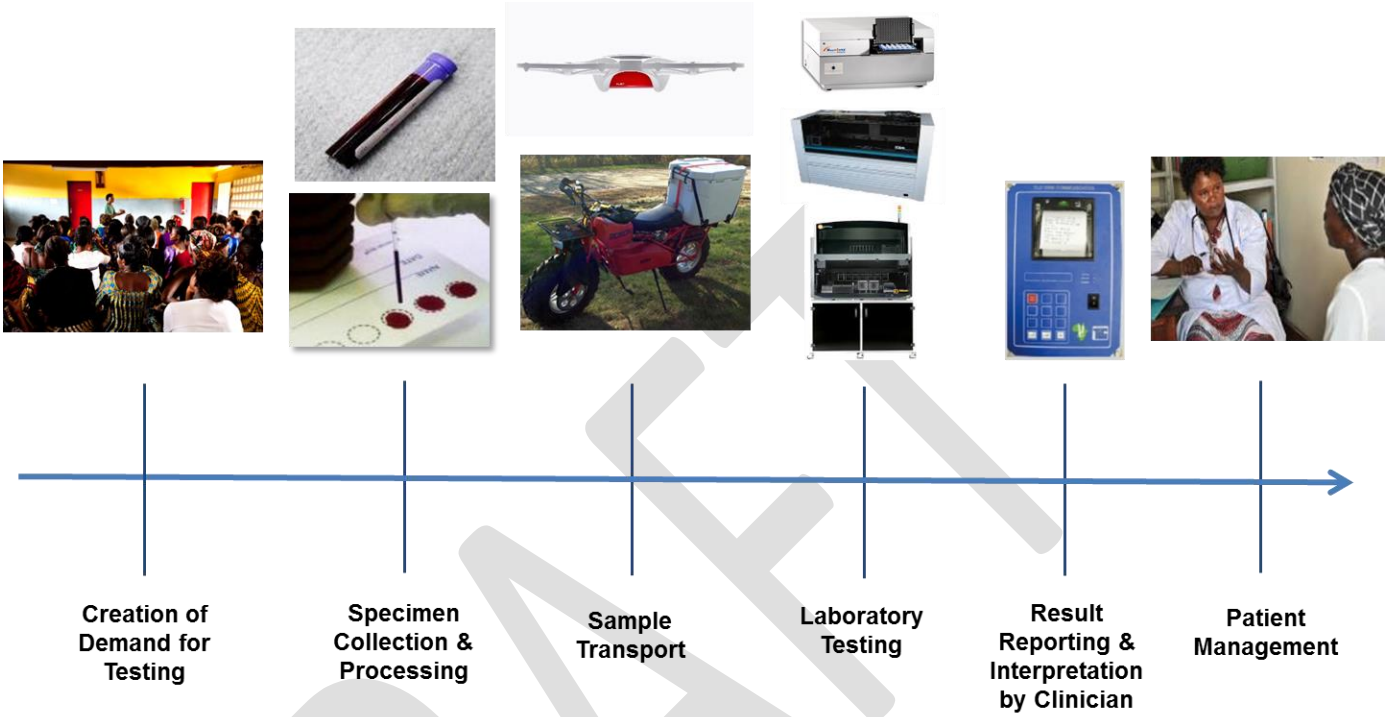
APPENDIX A. INFANT VIROLOGIC HIV DIAGNOSIS/VIRAL LOAD CASCADE



All images are open source from collaborator archives with the following exceptions:

Sample transport: Unmanned aerial vehicle, provided by Matternet.com

Laboratory Testing:

COBAS® AmpliPrep http://molecular.roche.com/assays/Pages/COBASAmpliPrepCOBASTaqManHIV-1Testv20.aspx

Abbott m2000sp https://www.abbottmolecular.com

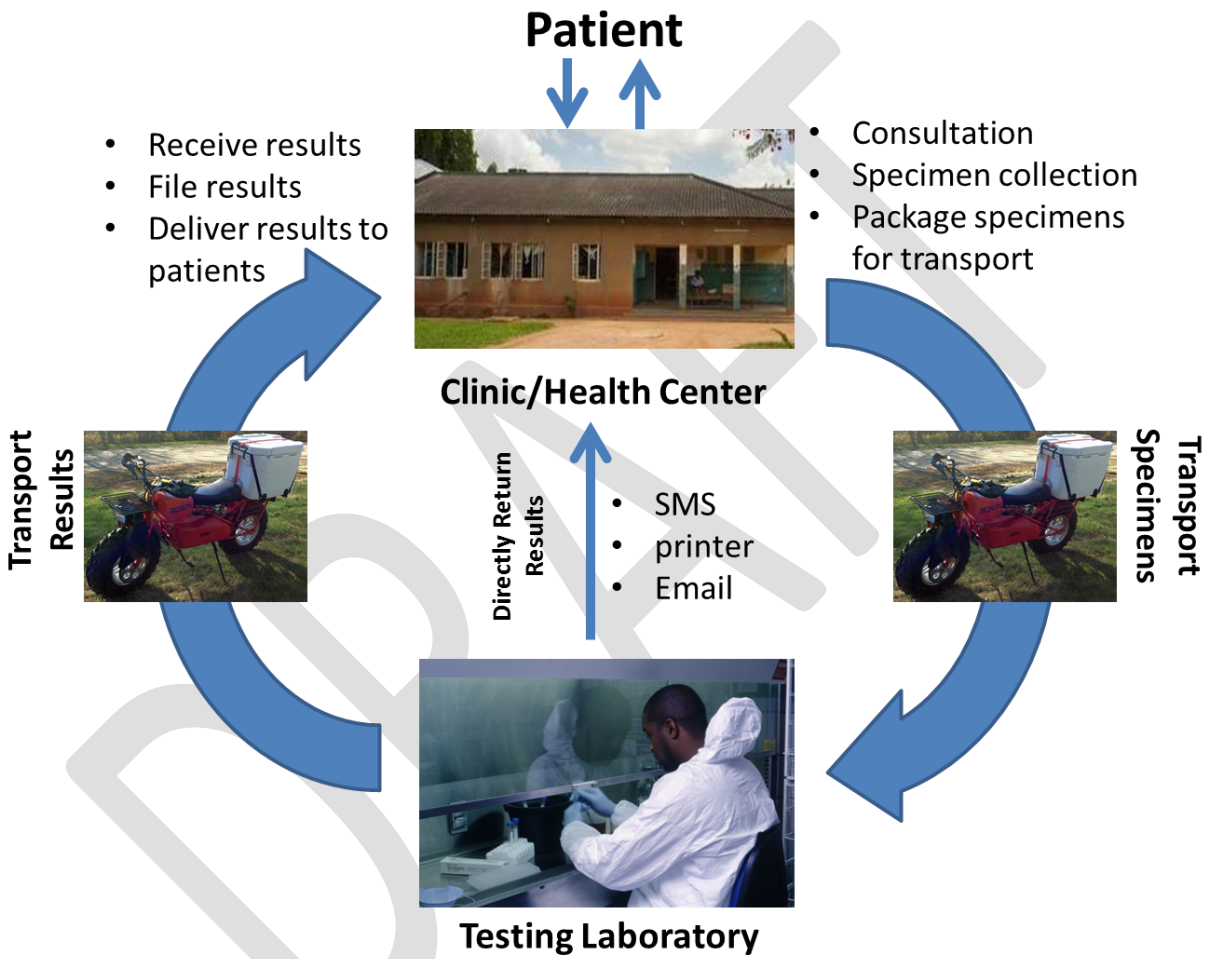
NucliSens Easy Q http://www.biomerieux-diagnostics.com/nuclisens-easyqr

Results Reporting and Interpretation by Clinician: SMS printer: citewire.com, Sandep Egis

APPENDIX B. EXAMPLE OF SPECIMEN TRANSPORTATION FLOW

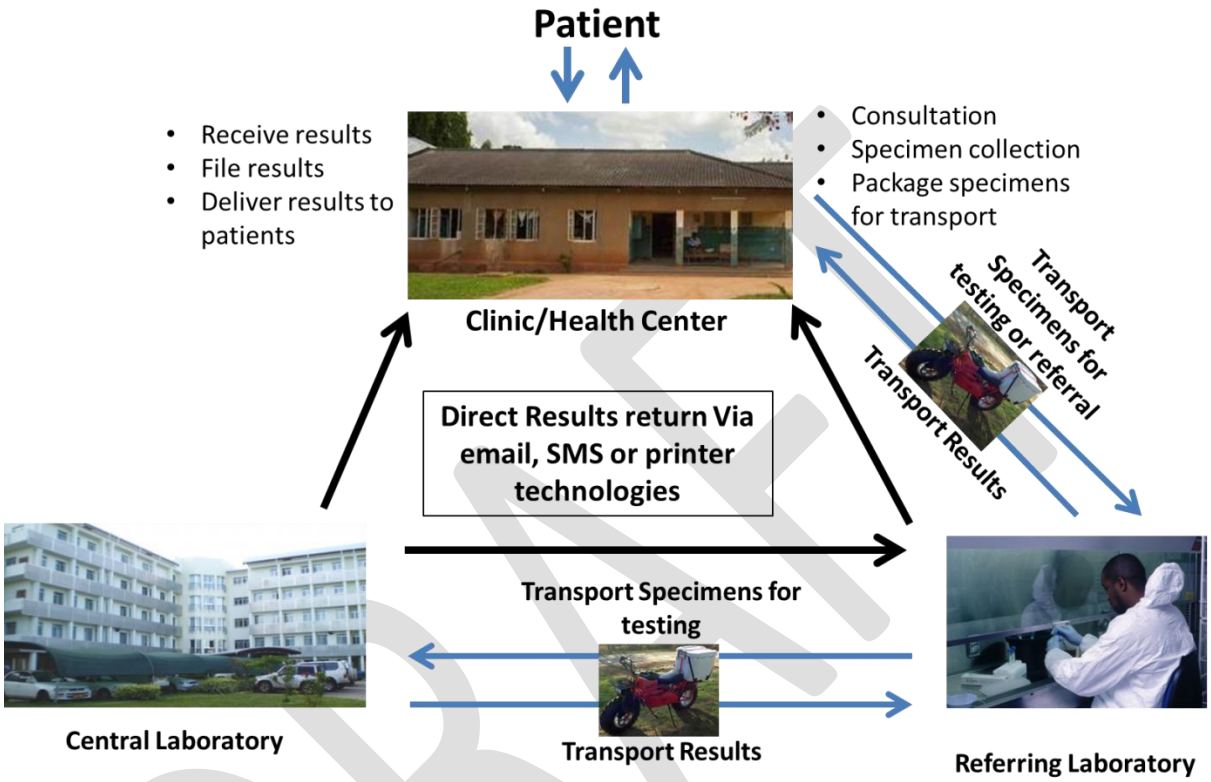
Tracing Specimens and Results

Figure 1. Single Referral System



APPENDIX B. EXAMPLE OF SPECIMEN TRANSPORTATION FLOW Continued

Figure 2. Two Way Referral System with a Central Laboratory (Hub and Spoke style model)



Key

(Black arrows) indicate digital results return options

(Blue arrows) indicate motorized specimen transport and results return options

Images for Appendix D are open source images or images from the CDC photo bank

APPENDIX C: SPECIMEN TRANSPORT LOG

COMMUNITY CLINIC SPECIMEN DELIVERY TRANSPORT LOG

Community Clinic: ________________ **Date**__ __/ __ __/ __ __

Participant ID: Name and ID # only	Specimen Type	# of Specimen Collected	Test Requested	Specimen Collection Verification	Receiving Lab: Specimen Rejected	Date Results Received at Clinic
Name: __________________ ID #: __________________	□ Whole Blood □ DBS □ Plasma □ Other Type_________		□ HIV RNA (VL) □ EID	Specimen(s) collected by: ________ Date: ________ Time:________	**Yes ☐ Reason for rejection:** □ Clotted □ Hemolyzed □ Insufficient volume □ Other____________________	
Name: __________________ ID #: __________________	□ Whole Blood □ DBS □ Plasma □ Other Type_________		□ HIV RNA (VL) □ EID	Specimen(s) collected by: ________ Date: ________ Time:________	**Yes ☐ Reason for rejection:** □ clotted □ hemolyzed □ Insufficient volume □ Other____________________	
Name: __________________ ID #: __________________	□ Whole Blood □ DBS □ Plasma □ Other Type_________		□ HIV RNA (VL) □ EID	Specimen(s) collected by: ________ Date: ________ Time:________	**Yes ☐ Reason for rejection:** □ clotted □ hemolyzed □ Insufficient volume □ Other____________________	
Name: __________________ ID #: __________________	□ Whole Blood □ DBS □ Plasma □ Other Type_________		□ HIV RNA (VL) □ EID	Specimen(s) collected by: ________ Date: ________ Time:________	**Yes ☐ Reason for rejection:** □ clotted □ hemolyzed □ Insufficient volume □ Other____________________	

To be completed by designated clinic packing staff □ Nurse □ Lab Assist. □ Phlebotomist Date: __ __/ __ __/ __ __
Requisition form complete? Yes □ or No □ If No, please explain___________
Total number of tubes confirmed? Yes □ or No □ If No, please explain___________
Specimen packed according to standard operating procedure? (See 'Specimen transport' job aid) Yes □ or No □
If No, please explain___________
Ice packs frozen? Yes □ or No □ If No, please explain___________
Data logger properly placed in the cooler box? Yes □ or No □ If No, please explain___________
Clinic packaging Staff Signature: _______

Verification to be completed by Clinical Manager Date: __ __/ __ __/ __ __ Time: __ __: __ __

Requisition form complete? **Yes □ or No □** **Verified by Manager initials**_______
Total number of tubes confirmed? **Yes □ or No □** **Verified by Manager initials** _______
Specimen packed according to standard operating procedure? **Verified by Manager initials** _______
Ice pack Frozen? **Yes □ or No □** **Verified by Manager initials** _______
Data logger properly placed in the cooler box? **Yes □ or No □** **Verified by Manager initials** _______

To be completed by designated driver for transport

Pick-up Date: __ __/ __ __/ __ __ Pick-up Time: __ __: __ __
Confirm lab request form is available? Yes □ or No □ If No, please explain___________
Confirm Transport log is available? Yes □ or No □ If No, please explain___________
Driver Signature: _______________

To be completed by the receiving Lab (LAB NEEDS TO RETAIN A COPY)
Receiving Lab _______________ Lab Receipt Date: __ __/ __ __/ __ __ Lab Receipt Time: __ __: __ __
Received lab request form with shipment? Yes □ or No □ If No, please explain___________
Received transport log with shipment? Yes □ or No □ If No, please explain___________
Confirm packaging condition:
Ice pack was received frozen? Yes □ or No □ If No, please explain___________
Data logger in cooler box? Yes □ or No □ If No, please explain___________
Receiving Staff Signature:

APPENDIX D. LABORATORY REQUIREMENTS FOR SPECIMEN COLLECTION, STORAGE, PACKAGING, AND TRANSPORT LOGS

Test	Tube Type/ Specimen Required	Minimum Amount of Specimen	Collection and Storage	Packing and Transport*	Accompanying Documents (Log Forms)
IVHD	DBS- Filter paper	70 µL	Finger/toe/heel pricked/ venous spotted blood should be air dried on drying rack for at least 4 hours. Then keep in zip lock bag with indicator desiccant until pick up; transport within 72 hrs at ambient temp (max 2 weeks)	Plastic bag with humidity indicator & desiccants or indicating silica gel packs at ambient temp	Laboratory requisition form Chain of custody form(s)
Viral load	DBS filter paper/	70 µL per spot/5 spots per card	Finger/toe/heel pricked/ venous spotted blood should be air dried on drying rack for at least 4 hours. Then keep in zip lock bag with indicator desiccant until pick up; transport within 72 hrs at ambient temp (max 2 weeks)	Plastic bag with humidity indicator & desiccants or indicating silica gel packs at ambient temp	Laboratory requisition form Chain of custody form(s)
	EDTA Whole Blood	5 mL-7 mL	Freshly drawn blood can be maintained at 2-8^{o}C. for up to 24 hrs	Cool box at at 2-8^{o}C ideally within 6hrs	Laboratory requisition form Chain of custody form(s)
	Plasma	1-2 mL	Plasma can be stored at 4 ^{o}C for up to 5 days and -20 ^{o}C if more than 5 days	Cool box at 2-8^{o}C unless frozen. If frozen, place in cool box and maintain at -20 ^{o}C	Laboratory requisition form Chain of custody form(s)

* Refer to Triple packing system & mark "handle w/ care" and biohazardous materials

APPENDIX E. RECOMMENDATIONS FOR SPECIMEN HANDLING, STORAGE AND TIME TO PROCESSING BY MANUFACTUROR

Seimens Versant HIV-1 kPCR Viral Load Assay [16]

Recommended specimen handling conditions at the collection site		
Specimen type	***Specimen processing at collection site***	***Onsite storage and transportation conditions***
Whole blood in EDTA and ACD tube	Collection only	15 to 25ºC
		2 to 8ºC
Plasma in PPT	Collection and centrifugation within 6 hours after collection	2 to 8ºC
Whole Blood on DBS	Collection only	15 to 25ºC
Recommended time from collection to specimen processing		
Specimen type	***Transportation conditions***	***Acceptable time period***
Whole blood in EDTA and ACD tube	15 to 25ºC	6 hours
	2 to 8ºC	24 hours
Plasma in PPT	2 to 8ºC	24 hours
Whole Blood on DBS	15 to 25ºC	7 days
Specimen handling at the testing laboratory		
Specimen type	***Storage at the laboratory***	***Time from delivery to testing in the laboratory***
Plasma from whole blood in EDTA and ACD tube	15 to 25ºC	24 hours / 1 day
	2 to 8ºC	120 hours / 5 days
	Minus 70ºC	1 year
Plasma in PPT	15 to 25ºC	24 hours / 1 day
	2 to 8ºC	120 hours / 5 days
	Minus 70ºC	1 year
Whole Blood on DBS	15 to 25ºC	30 days
	Minus 70ºC	1 year

Roche Cobas AmpliPrep-Cobas TaqMan HIV-1 Viral Load Assay [14, 19, 20]

Recommended specimen handling conditions at the collection site		
Specimen type	***Specimen processing at collection site***	***Onsite storage and transportation conditions***
Whole blood in EDTA and ACD tube	Collection only	15 to 25ºC
		2 to 8ºC
Plasma in PPT	Collection and centrifugation within 6 hours after collection	24h at RT
		2-8 ºC
Whole Blood on DBS	Collection only	15 to 25ºC
Recommended time from collection to specimen processing		
Specimen type	***Transportation conditions***	***Acceptable time period***
Whole blood in EDTA and ACD tube	15 to 25ºC	6 hours
	2 to 8ºC	24 hours
Plasma in PPT	2 to 8ºC	24 hours
Whole Blood on DBS	15 to 25ºC	7 days
Specimen handling at the testing laboratory		

	Specimen type	*Storage at the laboratory*	*Time from delivery to testing in the laboratory*
	Plasma from whole blood in EDTA and ACD tube	15 to 25ºC	24 hours / 1 day
		2 to 8ºC	120 hours / 5 days
		Minus 70ºC	1 year
	Plasma in PPT	15 to 25 ºC	24 hours / 1 day
		2 to 8ºC	120 hours / 5 days
		Minus 70ºC	1 year
	Whole Blood on DBS	15 to 25ºC	30 days
		Minus 70ºC	1 year

BioMerieux NucliSENS Easy Q HIV-1 Viral Load Assay [13, 21]			
	Recommended specimen handling conditions at the collection site		
	Specimen type	***Specimen processing at collection site***	***Onsite storage and transportation conditions***
	Whole blood in EDTA and ACD tube	Collection only	
			2 to 8ºC
	Plasma in PPT	Collection and centrifugation within 6 hours after collection	2 to 8ºC
	Whole Blood on DBS	Collection only	15 to 25ºC
	Recommended time from collection to specimen processing		
	Specimen type	***Transportation conditions***	***Acceptable time period***
	Whole blood in EDTA and ACD tube	15 to 25ºC	6 hours
		2 to 8ºC	24 hours
	Plasma in PPT	2 to 8ºC	7 days
	Whole Blood on DBS	15 to 25ºC	7 days
	Specimen handling at the testing laboratory		
	Specimen type	***Storage at the laboratory***	***Time from delivery to testing in the laboratory***
	Plasma from whole blood in EDTA and ACD tube		
		2 to 8ºC	120 hours / 5 days
		Minus 20 ºC	1 month
		Minus 70ºC	1 year
	Plasma in PPT	15 to 25ºC	24 hours / 1 day
		4 to 8ºC	120 hours / 5 days
		Minus 70ºC	1 year
	Whole Blood on DBS	15 to 25ºC	30 days
		Minus 70ºC	1 year

Abbott m2000sp/m2000rt HIV-1 Viral Load Assay [12, 22, 23]

Recommended specimen handling conditions at the collection site		
Specimen type	***Specimen processing at collection site***	***Onsite storage and transportation conditions***
Whole blood in EDTA and ACD tube	Collection only	15 to 30ºC
		2 to 8ºC
Plasma in PPT	Collection and centrifugation within 6 hours after collection	2 to 8ºC
Whole blood on DBS	Collection only	15 to 30ºC
Recommended time from collection to specimen processing		
Specimen type	***Transportation conditions***	***Acceptable time period***
Whole blood in EDTA and ACD tube	15 to 30ºC	6 hours
	2 to 8ºC	24 hours
Plasma in PPT	2 to 8ºC	24 hours
Whole blood on DBS	15 to 30ºC	7 days
Specimen handling at the testing laboratory		
Specimen type	***Storage at the laboratory***	***Time from delivery to testing in the laboratory***
Plasma from whole blood in EDTA and ACD tube	15 to 30ºC	24 hours / 1 day
	2 to 8ºC	120 hours / 5 days
	Minus 20 ºC	1 month
	Minus 70ºC	1 year
Plasma in PPT	15 to 30ºC	24 hours / 1 day
	2 to 8ºC	120 hours / 5 days
Whole blood on DBS	15 to 30ºC	30 days
	Minus 70ºC	1 year

Cavidi ExaVir Load HIV-1 viral load assay [15]

Recommended specimen handling conditions at the collection site		
Specimen type	***Specimen processing at collection site***	***Onsite storage and transportation conditions***
Whole blood in EDTA and ACD tube	Collection only	15 to 25ºC
Recommended time from collection to specimen processing		
Specimen type	***Transportation conditions***	***Acceptable time period***
Whole blood in EDTA and ACD tube	15 to 25ºC	6 hours
Specimen handling at the testing laboratory		
Specimen type	***Storage at the laboratory***	***Time from delivery to testing in the laboratory***
Plasma from whole blood in EDTA and ACD tube	Minus 20ºC	Freeze and thaw when needed for testing
	Minus 20ºC	6 months
	Minus 60ºC	1 year

APPENDIX F. STORAGE OF SPECIMENS BEFORE TRANSPORT

Note: Refer to the manufacturers' guidance for specimen handling for the specific assay that will be utilized (Appendix E).

The below steps are strongly recommended as a minimum for the appropriate storage of specimens before transport:

1. After specimens are appropriately labeled, place them at the correct temperature until packing and transport.

2. Dried blood spots (DBS) may be kept at ambient temperature before and during transport. DBS can be held at ambient temperature for up to 2 weeks. After 2 weeks, DBS should be frozen at -70^{o}C for long term storage.

3. Keep whole blood EDTA specimens at 15-30^{o}C for up to 6 hours or at 2-8^{o}C for up to 24 hours prior to centrifugation. Use a designated refrigerator with temperature tracking.
   Note: Different manufacturers suggest plasma separation from whole blood between 4 and 6 hours after specimen collection and it is strongly suggested that whole blood be transported at 2-8^{o}C.

4. Keep plasma separated from whole blood at 2-8^{o}C for up to 5 days. After 5 days, store plasma at -20^{o}C for up to 60 days. For more than 60 days, store plasma at -70^{o}C. Use a designated refrigerator or freezer with temperature tracking.

5. Do not remove specimens from the designated storage refrigerator or freezer until packing occurs.

APPENDIX G. PACKAGING SPECIMENS FOR TRANSPORT

Figure 1: Triple Packing System Using a Cooler for many specimens

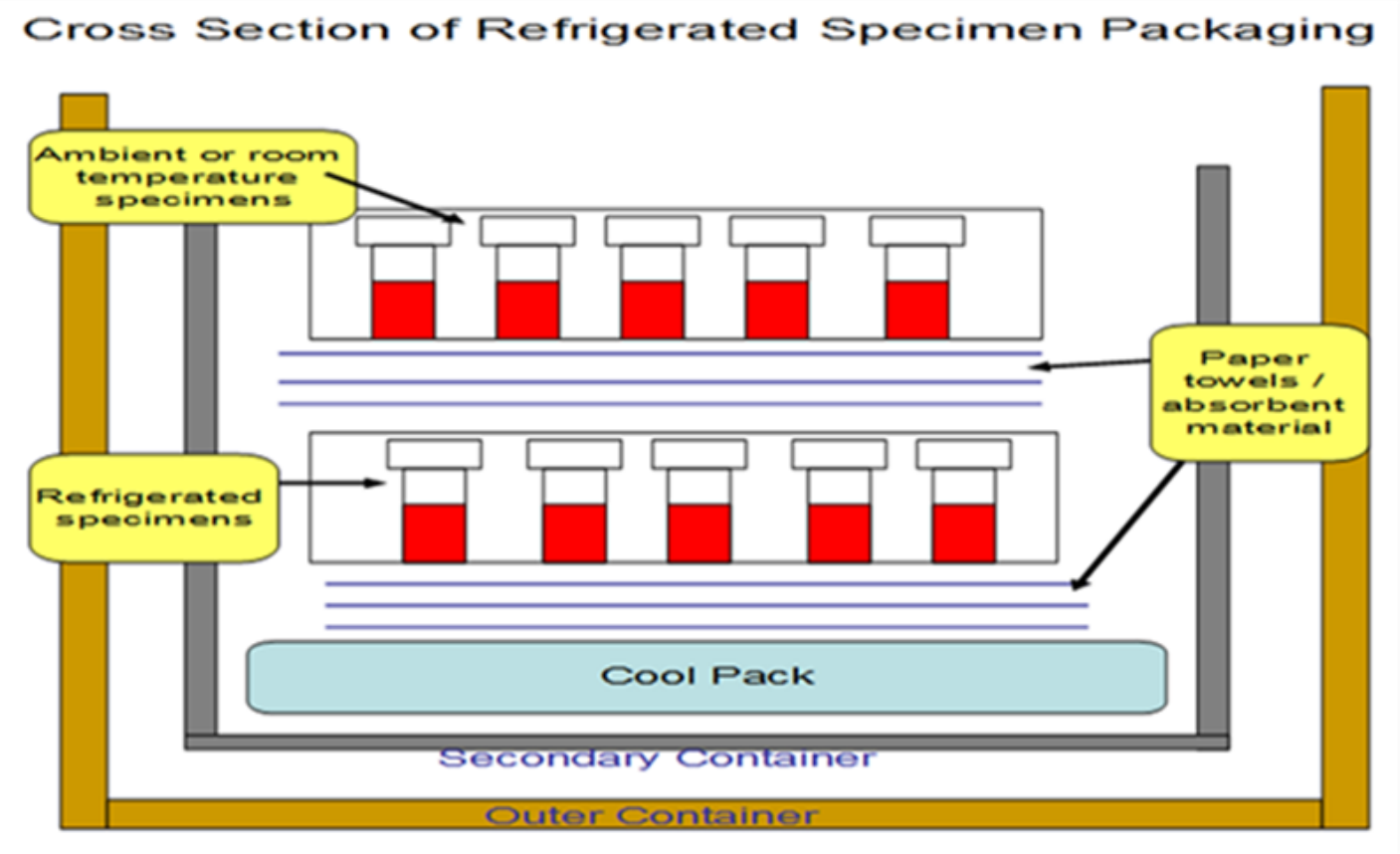
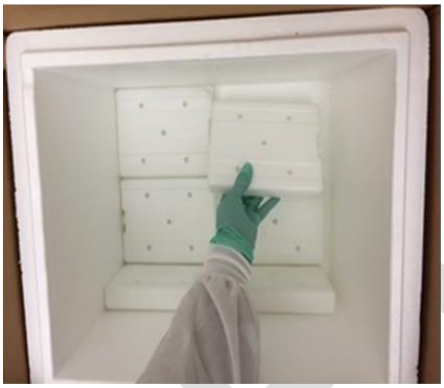


Figure 2. Example of an improvised triple packaging system for specimen transport with step-by-step packaging instructions.

Steps to properly pack a cooler for transport for viral load and other specimens that need to be kept between 2-8ºC.

Step 1: Place cooler in box for transport

Step 2: Add **frozen** ice packs to cooler. Temp for whole blood should be 2-8 ºC.



Step 3: Cover frozen ice packs with absorbent material (paper towels, kimwipes, etc.)

Step 4: Add specimen racks, place in zip-top bag, close and add to cooler.

Step 5: Add racks and more frozen ice packs to minimize movement.

Step 6: Close cooler with lid and keep closed unless more specimens are added.

*All images were produced by CDC staff

Figure 3. Improvised Triple Packaging

Image provided by the Zambia MoH

APPENDIX H. TRANSPORT OF SPECIMENS TO A TESTING LABORATORY

Example of a SOP for Transport of Specimens to a Testing Laboratory

- Transport **all** blood specimens collected from the clinics/health centers in racks, in a cooler box to the testing laboratory.
- Each cooler box must have frozen ice packs and a thermometer/data logger.
- The cooler box must be accompanied by specimen transport log.
- When the driver receives the cooler box and all accompanying paper work, he/she will sign and fill in the time and date on the transport log.
- The driver will only make approved stops (to pick up specimens at clinics along the route, etc.).
- Upon arrival at the testing laboratory, the driver will deliver the cooler box and all accompanying paper work to the designated receiver and ensure that the person receiving the cooler box signs and fills in the time and date of receipt.
- The driver will then pick up any cleaned (decontaminated) cooler boxes and racks for return to the clinics/health centers.
- The spill kit in/with the vehicle should be inspected weekly and any required items replaced.
- If there is any biohazardous waste produced in the transport vehicle due to a spill, collect the waste from the driver and dispose in bins designated for biohazardous waste.

APPENDIX I. SPECIMEN RECEIPT, REJECTION CRITERIA, CHECK-IN, AND STORAGE UNTIL TESTING

Example SOP for Specimen Receipt, Rejection Criteria, Check-in and Storage until Testing.

1. Specimen Receipt at Testing Laboratories

- When specimens are delivered to the laboratory, the laboratory scientist who receives the cooler box must check it to ensure there are no issues with the container.
- The person receiving the specimens must record time of arrival on the *Chain of Custody Form*/*Specimen Transport Log*. Record delays in specimen transportation in the comments section of the *Chain of Custody Form/Specimen Transport Log*. Transport delays should be documented on the *Occurrence Management Form*.
- Open the cooler box and check for spillage. Document the spill on an *Occurrence Management Form*. Inform laboratory manager and/or safety officer.
- Record temperature on arrival on all *Chain of Custody Form*/*Specimen Transport Log* and any other specimen tracking forms.
- Count the number of EDTA tubes, plasma tubes and dried blood spots (DBS) then cross reference with the total on the *Chain of Custody Form*/*Specimen Transport Log*.
- If there is a discrepancy in sample totals, match each unique identifier on the tube or DBS with the unique identifier on the *Chain of Custody Form*/*Sample Transport Log*. Check all samples received with the corresponding unique identifier until the missing/discrepant sample has been identified. Fill out an *Occurrence Management Form* and comment on the *Chain of Custody Form*/*Specimen Transport Log*. Immediately contact the laboratory supervisor or QA officer who will follow-up with the clinics/health centers to locate the specimen.

2. Specimen Rejection Criteria (all rejections should be noted o the specimen transport log)

DISCARD ALL SAMPLES WHICH ARRIVE AT THE LABORATORY WITHOUT ANY LABELLING AND NOTE ON THE SAMPLE TRANSPORT LOG.

- Whole Blood EDTA specimens should be rejected for the following:
  - EDTA tube with specimen identification that cannot be read.
  - EDTA tubes that arrive with less than 3.5 mLs of whole blood should be rejected and a note made on the specimen transport log.
  - EDTA tube specimens that arrive hemolyzed.
  - EDTA tube that arrives more than 24 hours after specimen collection.
- Plasma specimens should be rejected for the following:
  - Plasma tube with specimen identification that cannot be read.
  - Plasma that arrives at a temperature above 8^{o}C.
  - Plasma tubes that contain less than 1.2 mL.
- DBS specimens should be rejected for the following:
  - DBS cards with specimen identification that cannot be read.
  - DBS cards with insufficient blood spots (less than 2 filled spots).
  - DBS cards with clotting present in spots.
  - DBS cards that have serum rings indicating contamination around the spots.
  - DBS cards where all of the spots have run together due to too much blood per spot.

3. Specimen Check-In

- Until specimen check-in is initiated, whole blood and plasma should be kept refrigerated between 2 and 8^{o}C. Whole blood should ideally be centrifuged within 6 hrs of collection for viral load testing. Whole blood should not be spun down until check-in has been completed. If this is not possible, maintain the whole blood EDTA tube refrigerated between 2 and 8^{o}C for no more than 24 hrs. DBS cards can be held at ambient temperature until check-in is complete.
- All specimens received at the laboratory should have a unique identifier affixed to them during the check-in procedure. When possible, use barcodes as the unique identifier so that barcode readers can be utilized to reduce human error at input.
- Specimens received should be logged into a database or on a receiving log with their original specimen ID and the unique identifier assigned.
- Whole blood for DBS should be spotted as soon as possible or within 24 hrs of collection.
- As stated above, whole blood for plasma must be centrifuged and the plasma removed and placed into fresh tubes as soon as possible.

4. Specimen storage until testing

- DBS can be maintained at ambient temperature for up to two weeks. If testing is not possible within two weeks, DBS must be placed at -70^{o}C for long term storage.
- Whole blood cannot be used more than 24 hrs post collection.
- Plasma aliquots can be kept at -70°C until tested.

APPENDIX J. RELEASE OF RESULTS

Guidelines for Release of Results

1. Once testing is complete and results have been recorded, the results should be immediately returned to the clinic/health facilities.
2. Final results are distributed to submitters by e-mail whenever possible. In the event a submitting laboratory does not have internet access reports can be sent via SMS, specialized results printers, scanned and faxed, mailed, sent via courier service or returned with the specimen transport service drivers.
3. In the event that results reports are sent by courier or specimen transport drivers, documents must be placed in a sealed envelope and the transport log must accompany the envelope. The transport log must be signed, and the time and date must be filled out by the driver when they take custody of the report.
4. Employees who send final reports must verify they are received by appropriate authorized individuals.
    - Copies of reports must be retained at the testing laboratory for at least one year. Hard copies are kept in the reports binder in a locked cabinet. Electronic copies should be kept in a restricted access drive. Result folder access is limited to the laboratory manager, their designee(s), quality assurance officer, and laboratory

APPENDIX K. TRANSPORT AND/OR TRANSFER OF RESULTS BACK TO CLINIC/HEALTH CENTER AND RECEIPT OF RESULTS AT COLLECTION SITE

Below are guidelines for the transport and/or transfer of results and receipt of results at the collection site.

1. Once results reports are generated, they should be immediately returned to the clinic/health facility.

2. Distribute final results to submitters by secure e-mail whenever possible. If a submitting laboratory does not have internet access, reports can be sent via SMS, specialized results printers, scanned and faxed, mailed, sent via courier service, or returned with the specimen transport service drivers.

3. If results reports are sent by courier or specimen transport drivers, documents must be placed in a sealed envelope and the transport log must accompany the envelope.
    a. The transport log must be signed, and the time and date must be filled out by the driver when they take custody of the report.
    b. Upon arriving at the clinic/health center, the driver must deliver the results to the appropriate designated personnel and only those personnel.
    c. Once the designated person has received the results report, he/she must sign for accepting the results and fill in the date and time of receipt on the transport log.
    d. If the receiving individual is not the clinical staff in charge of the patient(s) care, then the results must be given directly to the clinical staff responsible for the patient(s) care.
    e. The clinician in charge of the patient(s) care must also sign and fill in date and time on the transport log. If there are multiple patients' results with different responsible clinicians, each staff responsible for direct care must sign for their patient's results.

4. The receiving staff and the clinical staff responsible for care must confirm receipt with the laboratory via email, SMS or phone call whenever possible.

5. When results are transported via courier or specimen transport driver, the transport log must be completely filled out and a copy returned to the testing laboratory.

6. If no response (via email, SMS, phone or transport log) from the receiving clinic/health center is received by the testing laboratory within **5 days** of the original report, the sender must contact the submitter and resend report if necessary.

APPENDIX L. DECONTAMINATION AND REUSE OF COOLERS, RACKS AND PACKAGING

Steps for Decontamination of Coolers, Racks, Cold Packs, and Packaging for Re-Use.

- Once specimens have been removed from the cooler box, all items should be decontaminated.
- Put on the appropriate personal protective equipment (PPE) prior to decontaminating the items.
- The cooler box, along with the racks, the cold packs/ice blocks and packaging (such as reusable zipper top bags) should be sprayed down and **saturated on all sides with a 1:10 bleach solution .**1:10 dilution of bleach solution (final concentration of the active ingredient, sodium hypochlorite is no less than 0.5%).
- The bleach solution should be left on these items for a minimum of 15 minutes or alternately, the items should be allowed to completely dry.
- After at least 15 minutes, the items can then be wiped down to eliminate any residual liquid.
- All racks, cold packs/ice blocks and reusable packaging material should be placed back into the cooler box.
- When the next set of specimens is dropped off for testing by the specimen transport personnel, the clean cooler box and all contents should be given to the driver for return to the specimen collection site.

APPENDIX M. BLOODBORNE PATHOGEN SAFETY AND POST EXPOSURE FOR TRANSPORT DRIVERS

Bloodborne Pathogen Safety and Post-Exposure

Note: Transport drivers, in general, should not come into direct contact with specimens. In the event of a spill, the following safety precautions and post-exposure steps should be followed.

- All specimens should be treated as if they were contaminated with potentially infectious bloodborne pathogens and universal precautions should be used.
    - Standard Precautions incorporate the appropriate use of PPE (gloves, eye protection, and gowns) and hand hygiene to help eliminate exposure to bloodborne pathogens.

- Hands and other exposed skin surfaces must be decontaminated immediately after accidental exposure using either soap and water or another skin disinfectant.

- An exposure to bloodborne pathogens is defined as broken skin or mucus membrane (eyes, nose or mouth) exposure to blood or body fluids, direct contact with blood or body fluids over a large skin area.

- Should an exposure incident occur:
    - First, perform the initial first aid (clean wound, flush eyes or other mucus membrane, etc.).
    - Notify supervisor of transport company and laboratory director of receiving laboratory.
    - Immediately report to the closest MOH designated clinic.
    - Ensure incident report form is filed and followed-up.
    - The supervisor or safety officer will review the circumstances of all exposure incidents to determine what issues if any contributed to the incident. Remedial training should be completed if needed.

APPENDIX N. SPILL CLEAN-UP PROEDURE FOR INFECTIOUS MATERIAL FOR DRIVERS

Cleaning an Infectious Material Spill

1. Notify people in surrounding area that a biohazardous material spill has occurred.
2. If available, open Biological Spill Kit.
3. Put on gloves, eye protection, and laboratory coat PPE.
4. Hang spill notification signs if available.
5. Define/isolate contaminated area (establish parameter) around the spill if outside of transportation vehicle.
6. Soak paper towels or other absorbent material with appropriate disinfectant (hospital grade triclosan or a 1:10 dilution of bleach solution (final concentration of the active ingredient, sodium hypochlorite is no less than 0.5%).
7. Cover the outside of the spill first with soaked paper towels and end with the inside.
8. Remove PPE and put on new PPE.
9. Leave absorbent material with disinfectant on contaminated surfaces for at least 15 minutes.
10. Working from outside to inside, pick up towels and dispose into biohazardous waste bag. If there is broken glass, use forceps or other mechanical device to pick up glass and dispose in a sharps container.
11. Re-wipe area of spill with disinfectant and dispose of material into biohazardous waste bag.
12. Remove PPE and dispose of into biohazardous waste bag. Biohazardous waste bags should be taken to the laboratory receiving the specimens for disposal.
13. Wash hands thoroughly. If soap and water are not available, use an alcohol based hand sanitizer.
14. Remove spill signs and restock spill kit.
15. Report incident to transportation supervisor, laboratory director at receiving laboratory, and relevant staff at clinic/health center.

APPENDIX O. EXAMPLE OF INDICATORS BY TYPE OF TEST

This should be completed at least every month and ideally weekly.

Date:	Completed by:		
	Indicator Name	Type of Test	
		Viral Load	IVHD
1.	Number of specimens collected		
2.	Number of specimens transported to the testing laboratory		
3.	Number of specimens tested		
4.	Number of specimens rejected		
5.	Reasons for rejection		
6.	Average time period specimens spend at the collection facility		
7.	Average time from specimen collection at Health Centre to specimen arrival at district hospital laboratory		
8.	Average time specimens take to get from the collection at the clinic/healthcare facility to testing laboratory		
9.	Average time between specimen arrival at testing laboratory to result departing testing laboratory		
10.	Average time between result dispatch from testing laboratory to result return to clinic		
11.	Average time between result return to clinic/healthcare facility and result received by clinician		
12.	Average time from receipt of results by clinician to return of results to patient for management of care		
13.	Total time from specimen taken to return of result		

APPENDIX P. EXAMPLE OF M&E FRAMEWORK FOR THE SPECIMEN TRANSPORTATION SYSTEM

The purpose of collecting these indicators is to provide direction in the establishment of a well-coordinated, standardized, reliable, efficient, cost – effective and sustainable specimen transport system in the country that is acceptable to MoH, DHOs, health workers and stakeholders"

Indicator Name	Data Source	Frequency	Responsibility
Number of specimens collected at the clinic/healthcare facility	Register/ Logbook, Delivery Checklist	Monthly	Nurse/Healthcare Worker in Charge of Specimen Logbook
	Register /Logbook, Delivery Checklist, Monthly Reports	Quarterly	Clinic/Healthcare Facility Supervisor
	Quarterly Reports	Bi-annually	Chair STS Committee
Number of specimens transported to the testing laboratory	Register/ Logbook, Delivery Checklist	Monthly	Testing Laboratory Manager
	Register/ Logbook, Delivery Checklist, Monthly Reports	Quarterly	Zone Laboratory Supervisor
	Quarterly Reports	Bi-annually	Chair STS Committee
Number of specimens tested	Register/ Logbook, Delivery Checklist	Monthly	Testing Laboratory Manager
	Register/ Logbook, Delivery Checklist, Monthly Reports	Quarterly	Zone Laboratory Supervisor
	Quarterly Reports	Bi-annually	Chair STS Committee
Number of specimens rejected	Register/ Logbook, Rejection Logbook, Delivery Checklist	Monthly	Testing Laboratory Manager
	Register/ Logbook, Delivery Checklist, Monthly Reports	Quarterly	Zone Laboratory Supervisor
	Quarterly Reports	Bi-annually	Chair STS Committee
Reasons for rejection	Register /Logbook, Rejection Logbook, Delivery Checklist	Monthly	Testing Laboratory Manager

Indicator Name	Data Source	Frequency	Responsibility
	Register/ Logbook, Delivery Checklist, Monthly Reports	Quarterly	Zone Laboratory Supervisor
	Quarterly Reports	Bi-annually	Chair STS Committee
Average time period specimens spend at the collection facility	Register/ Logbook, Transport Log, Delivery Checklist	Monthly	Testing Laboratory Manager
	Register/ Logbook, Transport Log, Delivery Checklist, Monthly Reports	Quarterly	Zone Laboratory Supervisor
	Quarterly Reports	Bi-annually	Chair STS Committee
Average time from specimen collection at Health Centre to district hospital lab (if using two way referral system with central laboratory)	Register/ Logbook, Transport Log, Delivery Checklist	Monthly	Testing Laboratory Manager
	Register/ Logbook, Transport Log, Delivery Checklist, Monthly Reports	Quarterly	Zone Laboratory Supervisor
	Quarterly Reports	Bi-annually	Chair STS Committee
Average time specimens spend from collection at referring facility to testing lab	Register/ Logbook, Transport Log, Delivery Checklist	Monthly	Testing Laboratory Manager
	Register Logbook, Transport Log, Delivery Checklist, Monthly Reports	Quarterly	Zone Laboratory Supervisor
	Quarterly Reports	Bi-annually	Chair STS Committee
Average time specimens spend from collection district hospital to testing lab	Register/ Logbook, Transport Log, Delivery Checklist	Monthly	Testing Laboratory Manager
	Register/ Logbook, Transport Log, Delivery Checklist, Monthly Reports	Quarterly	Zone Laboratory Supervisor
	Quarterly Reports	Bi-annually	Chair STS Committee

Indicator Name	Data Source	Frequency	Responsibility
Average time results spend in the testing lab back to the collection facility	Register/ Logbook, Transport Log, Delivery Checklist	Monthly	Testing Laboratory Manager
	Register/ Logbook, Transport Log, Delivery Checklist, Monthly Reports	Quarterly	Zone Laboratory Supervisor
	Quarterly Reports	Bi-annually	Chair STS Committee
Average time taken from specimen being taken from the patient to when results are returned to clinic/healthcare facility	Register/ Logbook, Transport Log, Delivery Checklist	Monthly	Testing Laboratory Manager
	Register/ Logbook, Transport Log, Delivery Checklist, Monthly Reports	Quarterly	Zone Laboratory Supervisor
	Quarterly Reports	Bi-annually	Chair STS Committee
Average time from receipt of results by clinic/healthcare facility to return of results to clinician	Register/ Logbook, Transport Log, Delivery Checklist	Monthly	Nurse/Healthcare Worker in Charge of Specimen Logbook
	Register/ Logbook, Transport Log, Delivery Checklist, Monthly Reports	Quarterly	Clinic/Healthcare Facility Supervisor
	Quarterly Reports	Bi-annually	Chair STS Committee
Average time from receipt of results by clinician to return of results to patient for management of care	Register/ Logbook, Transport Log, Delivery Checklist	Monthly	Nurse/Healthcare Worker in Charge of Specimen Logbook
	Register/ Logbook, Transport Log, Delivery Checklist, Monthly Reports	Quarterly	Clinic/Healthcare Facility Supervisor
	Quarterly Reports	Bi-annually	Chair STS Committee
Total turnaround time	Register/ Logbook, Transport Log, Delivery Checklist	Monthly	Testing Laboratory Manager
	Register/ Logbook, Transport Log,	Quarterly	Zone Laboratory Supervisor

Indicator Name	Data Source	Frequency	Responsibility
	Delivery Checklist, Monthly Reports		
	Quarterly Reports	Bi-annually	Chair STS Committee