



Republic of Kenya
Ministry of Health

Kenya HIV Test Kits Logistics System

Procedures Manual

April 2005

USAID | KENYA
FROM THE AMERICAN PEOPLE

 **DELIVER**
No Product? No Program. Logistics for Health



Republic of Kenya
Ministry of Health

Kenya HIV Test Kits Logistics System

Procedures Manual

April 2005

USAID | KENYA
FROM THE AMERICAN PEOPLE

 **DELIVER**
No Product? No Program. Logistics for Health

DELIVER

DELIVER, a six-year worldwide technical assistance support contract, is funded by the U.S. Agency for International Development (USAID).

Implemented by John Snow, Inc. (JSI), (contract no. HRN-C-00-00-00010-00), and subcontractors (Manoff Group, Program for Appropriate Technology in Health [PATH], and Social Sectors Development Strategies, Inc.), DELIVER strengthens the supply chains of health and family planning programs in developing countries to ensure the availability of critical health products for customers. DELIVER also provides technical support to USAID's central contraceptive procurement and management, and analysis of USAID's central commodity management information system (NEWVERN).

This document does not necessarily represent the views or opinions of USAID. It may be reproduced if credit is given to John Snow, Inc./DELIVER.

Recommended Citation

John Snow, Inc./DELIVER. 2005. *Kenya HIV Test Kits Logistics System: Procedures Manual*. Arlington, Va.: John Snow, Inc./DELIVER, for the U.S. Agency for International Development.

Illustrated by Chimwemwe J. Chiwanda



1616 North Fort Myer Drive, 11th Floor
Arlington, VA 22209 USA
Phone: 703-528-7474
Fax: 703-528-7480
Email: deliver_project@jsi.com
Internet: deliver.jsi.com

Contents

Acronyms.....	v
Introduction	1
Who Will Use This Manual?	1
Why Was This Manual Written?	1
How Should You Use This Manual?.....	1
1. Overview of the Kenya HIV Test Kits Logistics System	3
What Is the Kenya HIV Test Kits Logistics System?	3
How Do HIV Tests Get to Service Delivery Points?.....	3
What is the Flow of Information and Commodities in the Logistics System?	4
Who Manages the HIV Test Kits Logistics System?.....	5
2. Logistics Management Responsibilities	7
Who Plays a Key Role in the HIV Test Kits Logistics System?.....	7
What Are Your Logistics Management Responsibilities?.....	8
3. Storing HIV Tests and Related Supplies	11
What Is the Purpose of Storage?.....	11
What Is Shelf Life?	11
How Do You Calculate the Expiry Date?.....	12
What Are Proper Storage Guidelines?	13
What Is FEFO and How Do You Follow It?.....	16
What Do You Do With Damaged and Expired Stock?	16
What Do You Do When You Receive HIV Tests?.....	18
4. Conducting a Physical Inventory.....	19
What Is a Physical Inventory?	19
How Do You Conduct a Physical Inventory?	19
How Do You Complete a Stock Card?.....	21
5. Recording and Reporting	25
What Is the LMIS for HIV Tests?	25
How Do You Complete the LMIS Forms?.....	26
How Do You Complete the Daily Activity Register?	27
How Do You Complete the Consumption Data Report?.....	28
What Action Is Required after Each LMIS Form Is Completed?	32
6. Reviewing Stock Status	33
What Is Your Stock Status?	33
What Is Months of Stock?.....	33
How Do You Determine Months of Stock?.....	34

How Do You Review Stock Status at the District Store?	35
How Do You Decide What Actions to Take after Stock Status Has Been Determined at the District Store?	35
How Do You Review Stock Status at Service Delivery Points?	36
How Do You Decide What Actions to Take after Stock Status Has Been Determined at a Service Delivery Point?	37
7. Calculating How Much to Order or Issue	39
Who Orders and Issues in the Logistics System?	39
How Does a Service Delivery Point Determine How Much to Order from the District?	40
How Does a Service Delivery Point or District Store Place an Emergency Order?	41
8. Logistics Monitoring and Supervision	43
Introduction	43
What Is Monitoring?	43
Why Monitor Logistics Activities?	43
What Is Supervision?	43
Why Supervise Logistics Personnel?	43
Is There a Difference between Monitoring and Supervision?	44
What Is On-the-Job Training?	44
What Are the Guidelines for Logistics Monitoring and Supervision?	45
Glossary	47
Annexes	49
A-1. Daily Activity Register for HIV Testing and Blood Safety	51
A-2. Consumption Data Report and Request for Blood Safety Commodities	53
A-3. Stock Card Form	55
A-4. Fact Sheet: Determine HIV-1/2 (Rapid Test Kit)	57
A-5. Fact Sheet: SD BIOLINE HIV-1/2 3.0 (Rapid Test Kit)	59
A-6. Fact Sheet: Uni-Gold™ HIV Test	61
A-7. Fact Sheet: OraQuick® Rapid HIV-1 Antibody Test	63
A-8. Fact Sheet: Enzygnost® Anti-HIV 1/2 Plus (ELISA Test Kit)	65
A-9. Fact Sheet: Vironostika® HIV Uni-Form II Plus O (ELISA Test Kit)	67

Acronyms

AD	auto-disable
AIDS	acquired immune deficiency syndrome
CDR	Consumption Data Report
CHAK	Christian Health Association of Kenya
DAR	Daily Activity Register
DASCO	District AIDS/STI Coordinator
DHMT	District Health Management Team
DMLT	District Medical Laboratory Technologist
DMOH	District Medical Officer of Health
DPHN	District Public Health Nurse
DPHO	District Public Health Officer
ELISA	enzyme-linked immunosorbent assay
EOP	emergency order point
FBO	faith-based organisation
FEFO	first-to-expire, first-out
FIFO	first-in, first-out
HIV	human immunodeficiency virus
JSI	John Snow, Inc.
KEMSA	Kenya Medical Supplies Agency
LMIS	logistics management information system
LMU	Logistics Management Unit
MOH	Ministry of Health
NGO	nongovernmental organisation
NPHLS	National Public Health Laboratory Service
N/RBTC	National/Regional Blood Transfusion Centre
OJT	on-the-job training
PASCO	Provincial AIDS/STI Coordinator
PGH	Provincial General Hospital
PHMT	Provincial Health Management Team

PMLT	Provincial Medical Laboratory Technologist
PMTCT	prevention of mother-to-child transmission
SC	stock card
SDP	service delivery point
SOP	standard operating procedures
STI	sexually transmitted infection
VCT	voluntary counselling and testing

Introduction

Who Will Use This Manual?

All Ministry of Health (MOH) and nongovernmental organisation (NGO) staff who manage HIV tests and related supplies will use this manual. It is their job to order, issue, distribute, store, and account for these products.

Why Was This Manual Written?

This manual provides standardised operating procedures (SOPs) and guidelines for the logistics management of HIV tests and related supplies in the MOH's supply chain. The manual will guide the MOH and NGO staff as they perform some or all of the following activities:

- Determine supply needs.
- Order, receive, and store supplies properly.
- Distribute and maintain adequate supplies.
- Record and report accurate information about supplies and their use.
- Monitor logistics activities and supervise the staff that carries them out.

By using these procedures to manage their supplies, health staff can ensure adequate supplies of quality products for clients throughout the country.

How Should You Use This Manual?

This manual will enable you to carry out your duties effectively. Become familiar with the entire manual. Refer to it frequently as you perform your job managing HIV tests.

Each chapter of the manual describes a specific logistics management activity, including—

- purpose of the logistics management activity
- when the activity should be carried out
- instructions on how to complete the activity.

A list of acronyms follow the table of contents, and a glossary of logistics terms are at the end of the manual. The annexes include copies of all recording and reporting forms you need to complete your logistics responsibilities.

The following summary explains the contents of each chapter:

- *Overview of the Kenya HIV Test Kits Logistics System*
Describes the purpose and structure of the HIV test kits distribution and information system.
- *Logistics Management Responsibilities*
Describes and lists the job responsibilities for each designation of health and medical supply staff who manage HIV tests and related supplies. Find your list of job responsibilities and refer to it regularly.

- *Storing HIV Tests and Related Supplies*
Provides guidelines for receiving and storing HIV tests and related supplies, and maintaining quality.
- *Conducting a Physical Inventory*
Describes how and when you should conduct physical inventories of your HIV test kits.
- *Recording and Reporting*
Explains how to record and report logistics information using the standard LMIS forms.
- *Reviewing Stock Status*
Describes how to calculate how many months of stock you have in your facility to determine if your facility is overstocked, understocked, or properly stocked; and what actions to take, if necessary.
- *Calculating How Much to Order or Issue*
Describes how to calculate the quantity of HIV tests and related supplies to order or issue.
- *Logistics Monitoring and Supervision*
Provides guidelines for logistics monitoring and supervision, and steps for conducting a logistics supervisory visit.

1. Overview of the Kenya HIV Test Kits Logistics System

What Is the Kenya HIV Test Kits Logistics System?

This is the Ministry of Health (MOH) medical supply system of inventory management and recording and reporting for HIV tests and related supplies. The system ensures that all Kenyans receive quality service when they visit a service delivery point (SDP), and it ensures that the logistics six rights are fulfilled.

How Do HIV Tests Get to Service Delivery Points?

HIV tests are delivered from KEMSA to the district stores where they are packed for each health facility. The tests are then delivered to or picked up by the health facility. Under this system, National/Regional Blood Transfusion Centres (N/RBTCs), Provincial General Hospitals (PGHs), and National Referral Hospitals receive HIV tests directly from the KEMSA central warehouse. While the District AIDS/STI Coordinators (DASCO) and Provincial AIDS/STI Coordinators (PASCO) do not store these commodities, they do coordinate with staff at various levels to ensure that sufficient commodities are available for HIV/AIDS activities.

Figure 1 illustrates the movement of HIV tests from the KEMSA central warehouse to district stores and SDPs, and includes the personnel who manage them.

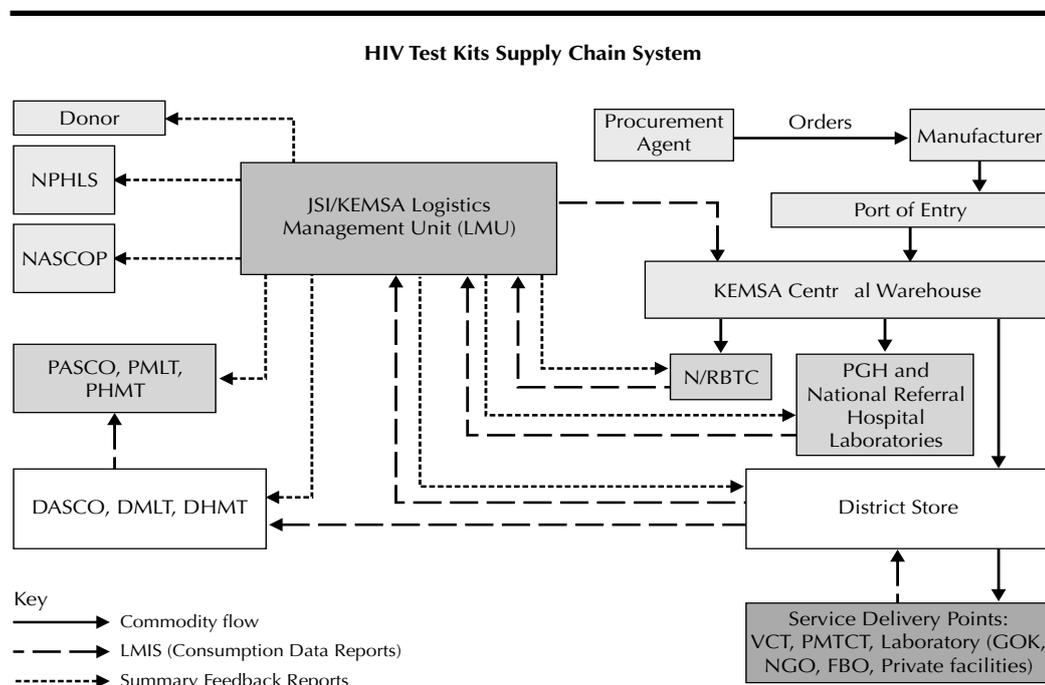
The Six Rights

Good logistics delivers—
the **RIGHT** product
in the **RIGHT** quantity
in the **RIGHT** condition
to the **RIGHT** place
at the **RIGHT** time
for the **RIGHT** cost.

What is the Flow of Information and Commodities in the Logistics System?

District Medical Laboratory Technologists (DMLT) work with the KEMSA/Logistics Management Unit (LMU), the District Store In-Charge and the health facility staff to coordinate the management and distribution of HIV tests and related supplies. As products move through the medical supply system, information moves up the logistics management information system (LMIS) from health centres to districts and on to the LMU at KEMSA. Staff use this information to make supply decisions to order and issue HIV tests at the appropriate time and in adequate quantities.

Figure 1.
Flow of Information and Commodities



Who Manages the HIV Test Kits Logistics System?

The following table describes the personnel who manage the HIV test kits logistics system, its activities, and when the activities should take place at each level of the logistics system.

Who	Actions	When
Facility In-Charge and Laboratory In-Charge	<ul style="list-style-type: none"> Receives and stores HIV test kits and related supplies. Ensures that service providers record usage in the Daily Activity Register for HIV Testing and Blood Safety, and information about transactions on the stock card. Completes the Consumption Data Report and Request for Blood Safety Commodities and the Counter Requisition & Issue Voucher (Form S11), and submits them to the District Medical Laboratory Technologist. 	<p>During the month</p> <p>Monthly</p>
District Store In-Charge	<ul style="list-style-type: none"> Receives from KEMSA. Stores and issues HIV test kits and related supplies to service delivery points (SDPs) in the district. Records district store transaction information on the stock card. With the DMLT, completes the Consumption Data Report and Request for Blood Safety Commodities for the district, and submits to the KEMSA/LMU. 	<p>During the month</p> <p>Every two months</p>
District Medical Laboratory Technologist	<ul style="list-style-type: none"> Reviews quantities required for SDPs in the district using stock on hand and consumption data from each SDP. With the District Store In-Charge, completes the Consumption Data Report and Request for Blood Safety Commodities for the district and submits to the KEMSA/LMU. Completes the Counter Requisition & Issue Voucher (Form S11) and/or the Issue & Receipt Voucher (Form S12) and submits to the KEMSA/LMU. 	<p>Monthly</p> <p>Every two months</p> <p>Every two months</p>
KEMSA Central Warehouse Manager/ Procurement Officer Logistics Management Unit	<ul style="list-style-type: none"> Manages movement of HIV tests and related supplies to district stores, National/Regional Blood Transfusion Centres, Provincial General Hospitals and National Referral Hospitals; and records information about transactions. Coordinates health commodity needs with districts and KEMSA central warehouse to ensure the uninterrupted availability of HIV tests and related supplies. Enters data from district and SDP monthly reports into automated LMIS inventory control tool in order to manage HIV tests and related supplies. Disseminates LMIS Feedback Reports to PASCOs, DASCOS, DMLTs, and District Laboratory In-Charges. 	<p>During the month</p> <p>During the month</p> <p>Every two months</p> <p>Every two months</p>

2. Logistics Management Responsibilities

Who Plays a Key Role in the HIV Test Kits Logistics System?

Many health staff play key roles in the operation of the HIV test kits logistics system:

Central level:

Logistics Management Unit

KEMSA Central Warehouse Manager/Procurement Officer

District level:

District Medical Laboratory Technologist (DMLT)

District Store In-Charge

District AIDS/STI Coordinator (DASCO)

Service delivery points:

Laboratory In-Charge

Health Facility In-Charge

Health service providers, including mission hospitals and NGO service providers

- If no one has this designation at your level or facility, *you must assign the responsibility to someone* to ensure that the logistics system operates and adequate products are available for testing clients.
- If you manage HIV tests, find your job description below, which should help you understand your responsibilities as it relates to the logistics system.
- If you supervise staff who manage HIV tests, use the job description to ensure that the responsible staff member knows and is performing his or her job.

Contacting the Logistics Management Unit

Contact the Logistics Management Unit with any questions at—

KEMSA/LMU

c/o JSI/DELIVER

P.O. Box 322-00200

Nairobi

Tel: (020) 272-7210

Email: hahenda@cb.jsikenya.com

What Are Your Logistics Management Responsibilities?

The logistics responsibilities for each of the MOH staff are listed below. Refer to this list from time to time to ensure that you are fulfilling your logistics responsibilities.

Senior Store In-Charge/Logistics Management Unit

The Senior Store In-Charge, based at the KEMSA/LMU will—

1. Compile consumption data, issues data, losses and adjustments, and stock data for HIV test kits.
2. Use logistics data from the LMIS to produce commodity forecasts.
3. Coordinate with KEMSA and donors on what commodities should be procured.
4. Coordinate with KEMSA to ensure that HIV test kits have been received in good condition, and distributed.
5. Monitor stock status of commodities throughout the country, and advises authorities when the situation requires immediate action.
6. Orient laboratory personnel and clinicians on good storage practices for HIV test kits.
7. Give on-the-job and other training in logistics to MOH personnel with logistics responsibilities.
8. Ensure availability of forms and reports to be used in the LMIS, at all levels.

Procurement Officer—KEMSA

For HIV test kits, the Chief Stores Officer will—

1. Report the National Stock Status to the Senior Logistics Officer for discussions, and take action, as needed.
2. Receive supplies from suppliers and process for quality control testing at the National Quality Control Laboratory and then, based on previous consumption data, distribute to the district stores.
3. Monitor stock movement from suppliers and within the system. If shipments are likely to be delayed and there are not enough stocks in the system, collaborate with the Senior Store In-Charge and request an emergency shipment to bridge the gap.
4. Work with the Senior Store In-Charge Officer to ensure that storage guidelines for HIV test kits are being followed by district stores.
5. Conduct supervisory visits to district stores and provide feedback and on-the-job training, as necessary.



District Medical Laboratory Technologist

For the logistics management of HIV tests and related supplies, the District Medical Laboratory Technologist will—

1. Together with the District Store In-Charge, conduct a physical inventory of HIV tests and related supplies in the district store at least every two months.
2. Monitor storage of HIV tests and related supplies for service delivery points according to storage guidelines.
3. Assess the stock status of HIV tests and related supplies in service delivery points.
4. Monitor issuing of HIV tests and related supplies to health centres, district hospitals, and NGOs monthly; and coordinate their timely pick up or delivery.
5. Review orders for commodities from health centres, district hospitals, and NGOs monthly; and complete and submit the Consumption Data Report and Request for Blood Safety Commodities for the district every two months to the KEMSA/LMU, including copies of service delivery points' Consumption Data Reports.
6. Coordinate with District Medical Officer of Health, District AIDS/STI Coordinator, and District Store In-Charge on issues related to the management of HIV tests.
7. Supervise and monitor service delivery points on logistics issues related to HIV tests.

District Store In-Charge

For the logistics management of HIV tests and related supplies, the District Store In-Charge will—

1. Store HIV tests and related supplies for service delivery points according to storage guidelines.
2. Record all issues and receipts of HIV tests and related supplies for the district store on the stock card.
3. With the DMLT, conduct a physical inventory of HIV tests and related supplies in the district store at least every two months.
4. Issue HIV tests and related supplies to health centres, district hospitals, and NGOs monthly; and coordinate their timely pick up or delivery.
5. Coordinate with District Medical Laboratory Technologist on issues related to management of HIV tests.

Health Facility In-Charge and Laboratory In-Charge

For the logistics management of HIV tests, the Facility and/or Laboratory In-Charge will—

1. Store HIV tests and related supplies in the health facility using storage guidelines.
2. Record all issues and receipts of HIV and other related tests on the stock card.
3. Issue products to service providers and user sites using FEFO distribution.
4. Conduct a physical inventory of commodities monthly; and update the stock cards.
5. Complete the Consumption Data Report and Request for Blood Safety Commodities and submit to the District Medical Laboratory Technologist each month.

3. Storing HIV Tests and Related Supplies

What Is the Purpose of Storage?

Appropriate storage protects the quality of HIV tests and related supplies. It also preserves the integrity of the packaging while, at the same time, makes them available for use. If a product is not stored correctly, the shelf life may be shortened.

What Is Shelf Life?

The manufacturer determines the shelf life for each product. When the product reaches the end of its shelf life, it has expired and should not be distributed.

Write the expiry date of the tests directly on the product carton. Always check for the expiry dates before dispensing, and do not dispense products that have expired.

The following table shows the shelf life (under ideal storage conditions), storage temperatures and packaging information of selected HIV test kits. See annexes A4–A9 for more information on individual brands of tests.

Shelf life is the length of time a product may be stored under ideal conditions without affecting its usability, safety, purity, or potency.

Test	Shelf Life	Storage Temperature	Packaging
Determine HIV-1/2 (Rapid Test Kit)	18 months	2°–30°C	100 tests per kit & 20 tests per kit
SD BIOLINE HIV-1/2 3.0 (Rapid Test Kit)	24 months	2°–27°C	30 tests per kit & 20 tests per kit
Uni-Gold™ HIV Test	15 months	2°–27°C	20 tests per kit
OraQuick® Rapid HIV-1 Antibody Test	5–6 months	2°–27°C	500 tests per kit & 100 tests per kit
Enzygnost® Anti-HIV 1/2 Plus (ELISA Test Kit)	12 months	2°–8°C	192 tests per kit & 960 tests per kit
Vironostika® HIV Uni-Form II Plus O (ELISA Test Kit)	12 months	2°–8°C	192 tests per kit & 576 tests per kit

How Do You Calculate the Expiry Date?

Task:	Calculating expiry date	
Completed by:	All staff handling HIV tests and related supplies	
Purpose:	To determine if a product has expired or not	
When to perform:	Whenever products are received	
Actions		
If	Then	Examples
Only the manufacturing date is printed on product or its packaging.	Add the number of months of the shelf life to the manufacturing date to calculate the expiry date.	If you receive tests with a manufacturing date of 2/05, add the shelf life (18 months) to this date. The expiry date will be 8/06.
No manufacturing date is printed on the product or its packaging.	Find the printed expiry date on the carton, box, or unit.	If you receive products, and there is no manufacturing date on the carton, but there is an expiry date.
No manufacturing or expiry date is printed on the product or its packaging.	Contact KEMSA/LMU with the batch number, obtain the expiry date, and write the date on the carton.	
This task is complete when—		
<ul style="list-style-type: none"> • The expiry date of the product has been determined and is printed or written on the carton. 		



Always keep your store neat and tidy.

What Are Proper Storage Guidelines?

The following are general storage guidelines for health commodities. For specific product guidelines for HIV tests, see annexes A4–A9.

Laboratories and Testing Sites	
Task:	Storing HIV tests and related supplies
Completed by:	Facility In-Charge, District Laboratory In-Charge, etc.
Purpose:	To protect quality and package integrity while making products available for use
When to perform:	When HIV tests and related supplies are being stored
Storage Guidelines	Notes
1. Clean and disinfect storeroom regularly. Take precautions to prevent harmful insects and rodents from entering the storage area.	Rodents and some insects (for example, termites and roaches) like to eat certain health commodities. They also eat shipping cartons and inner packaging. Pest-proof your store to stop the pests from getting in. If your store becomes infested with pests, use appropriate pesticides; and keep cats on the premises—they are effective against termites, rodents, roaches, etc. After you clear pests from the store, keep it clean. A clean store keeps pests away. Food and drinks in the warehouse increases the risk of pests.
2. Store health commodities in a dry, well lit, well-ventilated storeroom—out of direct sunlight.	A hot store may cause some of the commodity supplies to spoil, which will <i>decrease shelf life</i> . For example, the shelf life of Uni-Gold rapid HIV test is 15 months. However, the shelf life will probably be much shorter if the temperature inside the warehouse rises above 27°C. Although air conditioning is ideal, it is expensive. Alternatives are ceiling fans and/or forced ventilation. Direct exposure to sunlight can also reduce the shelf life of commodities. Use roofing and windows that shade the interior of the store from sunlight. Store supplies in their shipping cartons.
3. Protect storeroom from water penetration.	Water can destroy commodity supplies or their packaging. If packaging is damaged, the product is unacceptable to the client even if the commodity is undamaged. Repair the warehouse so water cannot enter. Other measures include stacking commodity supplies off the floor on pallets (at least 10 cm off the floor and 30 cm away from walls), because moisture can seep through walls and floors and into the commodity supplies.
4. Keep fire safety equipment available, accessible, and functional. Train employees to use the equipment.	Stopping a fire before it spreads can save thousands of shillings in stored commodities and save the storage space. Keep fire extinguishers accessible and in working order. Keep one extinguisher near the door and others throughout the inside of larger warehouses. Ensure that the right equipment is available—water works on wood and paper fires but should not be used on an electrical or chemical fire. If a fire extinguisher is not available, keep sand or soil in a bucket nearby.
5. Store latex products away from electric motors and fluorescent lights.	Latex products, including gloves, can be damaged if they are directly exposed to fluorescent lamps. The lamps and electric motors create a chemical called ozone, which can rapidly deteriorate gloves. Move glove boxes away from these sources. Leave gloves in paper boxes and cartons.

(continued)

Storage Guidelines	Notes
6. Maintain cold storage, including a cold chain, as required.	<p>Cold storage, including the cold chain, is essential for maintaining the shelf life of certain products. After these items are removed from cold storage and not used immediately, they become irrevocably damaged. If electricity is unreliable, it may be necessary to use bottled gas or kerosene-powered refrigeration. Cold boxes or insulated coolers may be sufficient for rapid transport. Ensure that all cold storage has a thermometer to monitor temperatures.</p> <p>Most rapid tests require storage temperatures of 2°–27°C, while most ELISA tests require cold storage of 2°–8°C.</p>
7. Limit storage area access to authorised personnel. Lock up controlled substances.	<p>To ensure that all stock movement is authorised, lock the storeroom; limit access to persons other than authorised staff; and verify that both incoming and outgoing stock matches documentation. Periodically perform a systematic physical inventory to verify inventory records.</p> <p>More than one key to the storeroom should be available to ensure that the storeroom can always be accessed. However, the second key should not be available for everyone. Keep the key in a centrally located lock box, under the control of the Store In-Charge.</p>
<p>8. Stack cartons at least 10 cm off the floor, 30 cm away from the walls and other stacks, and no more than 2.5m high.</p> <p><i>Note: This may not be possible in all facilities.</i></p>	<p>Use pallets to keep products off floors to make them less susceptible to pest, water, and dirt damage. Stack pallets away from walls and far enough apart so an employee can walk completely around each pallet. This promotes air circulation and facilitates movement of stock, cleaning, and inspection.</p> <p>Pallets are usually more efficient than shelving, particularly for bulk items because they—</p> <ul style="list-style-type: none"> • Reduce the amount of unpacking for storage and repacking for delivery. • Facilitate shipment in lot sizes. • Are cheaper to construct. • Hold more stock for the space they occupy. <p>Most facilities are more likely to have shelving than pallets.</p> <p>Correct stacking of supplies will <i>avoid crushing cartons</i> at the bottom of a stack. Stack cartons no more than 2.5 meters high. This will also reduce potential injury to warehouse personnel.</p> <p>Keep commodities <i>away from walls to promote air circulation</i> and prevent cartons from moisture damage, which may occur if water condenses or penetrates walls.</p>
9. Arrange cartons with arrows pointing up (↑), with identification labels, expiry dates, and manufacturing dates clearly visible.	<p>Arrows indicate that the commodity should be stored with the arrows pointing up. Identification labels make it easier to <i>follow FEFO</i>, and make it easier to select the right product.</p> <p>If shipping cartons do not show either a date of manufacture or an expiry date, contact KEMSA/LMU for this information. If the original markings are small or difficult to read, rewrite the manufacturing or expiry dates in large numbers.</p>

(continued)

Storage Guidelines	Notes
10. Store health commodities to facilitate FEFO procedures and stock management.	Ensure FEFO is followed. Recently received commodity supplies may sometimes be <i>older</i> than the store's existing stock. On receipt of new stock, always review existing stock expiry dates to ensure FEFO.
11. Store health commodities away from insecticides, chemicals, flammable products, hazardous materials, old files, office supplies, and equipment; always take appropriate safety precautions.	Insecticides and other chemicals may affect the shelf life for many products. To make health commodities easy to access, keep other supplies away from health commodities. Some health commodities have a relatively short shelf life overall, and they must be moved quickly to the end user. Storing old junk may slow down access to products and take up needed storage space. Some medical procedures require the use of flammable products. Bottled gas or kerosene is used to power refrigerators, alcohol is used in sterilisation, and mineral spirits is used to power Bunsen burners. These products should be stored away from other products, near a fire extinguisher.
12. Separate damaged and expired health commodities from usable commodities, remove them from inventory immediately, and dispose of them using established procedures.	By separating these products, FEFO is more easily implemented. By destroying damaged products immediately, more space will be available.

This task is complete after—

- All health commodities are stored according to these guidelines.



Never store health commodities near insecticides or electric motors.

What Is FEFO and How Do You Follow It?

FEFO means first-to-expire, first-out. Always issue those products that will expire first. Do not follow first-in, first-out (FIFO).

Task:	Distributing HIV tests according to FEFO
Completed by:	Facility In-Charge, Laboratory In-Charge, District Store In-Charge
Purpose:	To ensure that products are distributed before they expire
When to perform:	Whenever HIV tests are issued
Step	Action
1.	Mark expiry dates on outside of cartons or boxes.
2.	Place cartons or boxes so that stocks first to expire are stacked in front or on top of stocks that will expire later.
3.	Issue stocks from front to back or top to bottom so stocks that expire sooner will be issued first.
This task is complete when—	
<ul style="list-style-type: none"> All HIV tests are issued according to FEFO. 	

What Do You Do With Damaged and Expired Stock?

Task:	Handling of damaged or expired HIV tests	
Completed by:	Facility In-Charge, Laboratory In-Charge, District Store In-Charge	
Purpose:	To remove unusable products from storage so they are not distributed to clients	
When to perform:	Whenever damaged or expired HIV tests are known or discovered	
Step	Action	
1.	Stack damaged or expired products separately from usable stocks; keep them in an unused box or on an unused shelf.	
2.	Write <i>Damaged or Expired Stock</i> on the box or shelf.	
3.	Note the quantity of expired or damaged stock as a loss on the appropriate <i>stock card</i> and subtract the quantity from the <i>Quantity On Hand</i> column.	
4.	If you are	Then
	At a health facility or laboratory	Inform the District Medical Laboratory Technologist of the quantity of expired or damaged stock, and send the stock to the district store.
	At a district store	Inform KEMSA/LMU and the DMLT of the quantity of expired or damaged stock and await orders. The DMLT will inform the District Public Health Officer (DPHO) for collection of the damaged/expired product for proper disposal.

This task is complete when—

- Damaged or expired stock has been separated from usable stock.
- Stock card has been updated.
- Appropriate authorities have been notified.



Separate damaged or expired HIV tests.

What Do You Do When You Receive HIV Tests?

Task:	Receiving HIV tests
Completed by:	Facility In-Charge, Laboratory In-Charge, District Store In-Charge
Purpose:	To ensure that only the right brand, quantity, and quality of products are received and recorded
When to Perform:	Each time HIV tests are received

Step	Action	
1.	Ensure that there is sufficient storage space, including cold storage, if required.	
2.	Prepare and clean space to receive and store the supplies.	
3.	Conduct a visual inspection to see if any products are damaged or expired and look for—	
	<ul style="list-style-type: none"> • Package and product integrity: Check for damage to packaging (tears, perforations, water, or oil) and products. • Manufacturing defects: Incomplete supply, and missing or illegible identification information. • Labelling: Make sure that products are labelled with date of manufacture or expiry, lot number, and manufacturer's name. 	
	If	Then
	Not damaged or expired	<ol style="list-style-type: none"> 1. Count the number of cartons, boxes, or units received, including any additional test kit contents, and compare with quantity on delivery document. 2. Enter the date and quantity (number of units) received on the stock card. 3. Mark boxes with expiry dates. 4. Arrange product in storage area to facilitate FEFO distribution.
	Damaged or expired	<ol style="list-style-type: none"> 1. Separate damaged or expired stock from usable stock. 2. If damage or expiry is discovered before the delivery truck leaves, refuse delivery and note problem on requisition or transfer voucher book. 3. If damage or expiry is discovered after delivery truck has left, follow procedures listed above for handling damaged or expired stock.
4.	Ensure that products requiring cold storage are separated and stored appropriately.	

Note: If you are a district store, arrange for products to be delivered to (or picked up by) the health facility as soon as possible.

This task is complete when—

- Received stock has been given a visual inspection.
- Stock card has been updated.

4. Conducting a Physical Inventory

What Is a Physical Inventory?

When you count and record HIV test kits, always count and record them by individual brands and tests.

A physical inventory is the process of counting by hand the total number of each health commodity in your store or health facility, at any given time.

How Do You Conduct a Physical Inventory?

Task:	Conducting a physical inventory
Completed by:	Facility In-Charge, Laboratory In-Charge, District Store In-Charge
Purpose:	<ol style="list-style-type: none"> 1. To verify the quantity of usable stock available for distribution. 2. To identify discrepancies between actual supplies and the stock balance on the stock card. 3. To detect damaged or expired items. 4. To provide an opportunity for store reorganisation.
When to perform:	<ol style="list-style-type: none"> 1. Every two months at the district store and monthly at service delivery points (on the last day of the month). 2. Any time you think there may be discrepancies in the amounts of usable stocks available.

Step	Action	Notes
1.	Separate and count any expired or damaged HIV tests.	<p>Record the amount of damaged or expired product in <i>Losses/Adjustments</i>, column (F) of the stock card.</p> <p>In <i>Remarks</i>, column (H), provide a brief explanation for the expiry or damage.</p>
2.	<p>Count every brand of usable HIV test <i>by hand</i>.</p> <p>Count unopened/complete cartons first. Multiply the number of cartons by the number of units in the carton to determine the total number of commodity units in the carton.</p> <p>Count open cartons. If an open carton contains unopened boxes, count the boxes and multiply the number by the number of units in a box, to determine the total number of the commodity units in unopened boxes.</p> <p>Count all the units that are in open boxes, shelves, drawers, etc., and add them together.</p> <p>Add the total units from unopened boxes, open boxes, shelves, drawers, etc. This will give you the total number of units of the commodity available in your store (quantity on hand).</p>	<p>Include stock held in storerooms, cabinets, or racks. Do not count stock already issued to user sites.</p> <p>Always count the smallest countable unit of the commodity. Example: HIV tests = individual test.</p> <p><i>Example:</i> You have an open carton with 4 unopened test kits, each one containing 100 tests.</p> <p>$4 \times 100 = 400$ total tests in the unopened boxes.</p> <p><i>Example:</i> You have counted 15 tests in an open box on a shelf. You have counted 4 tests in a drawer.</p> <p>$15 + 4 = 19$ total tests from an open box and a drawer</p> <p>400 tests from unopened boxes</p> <p><u>19 tests</u> from open boxes, etc.</p> <p>419 total tests = quantity on hand</p>

(continued)

Step	Action	Notes
3.	On the stock card, record any losses or adjustments.	On a separate line, record any losses or adjustments in column (F) of the <i>stock card</i> .
4.	On the next line of the stock card, write the date of the physical inventory; the words <i>Physical Inventory</i> ; and, in red ink, the quantities counted.	Record the quantity counted in the <i>Quantity on Hand</i> , column (G). In the <i>Remarks</i> , column (H), provide a brief explanation for the loss or adjustment. Always enter each transaction on a separate line. After recording a physical inventory on the stock card, draw a line in red underneath the physical inventory row and continue recording transactions on the next row.
5.	Mark the expiry date clearly with large, dark numbers on each box or carton.	These steps may have been taken during routine receipt and management of HIV tests. However, if unmarked stocks are found during a physical inventory, proceed with these steps.
6.	Reorganise products according to expiry dates to comply with FEFO distribution.	

This task is complete when—

- The *Quantity on Hand* units of the commodity have been counted and recorded on the stock card.
- *Losses and Adjustments* have been calculated and recorded on the stock card.

How Do You Complete a Stock Card?

When conducting a physical inventory (and whenever issuing or receiving HIV tests), the stock card must be updated. Complete the instructions in the following box:

-
- Task:** Filling in the stock card
- Completed by:** Facility In-Charge, Laboratory In-Charge, District Store In-Charge
- Purpose:**
1. To maintain a continuous record of all HIV test transactions
 2. To record results of a physical inventory
- When to perform:** Each time you—
1. Receive or issue HIV tests
 2. Record a loss or adjustment
 3. Conduct a physical inventory

Note: Complete one stock card for each brand of HIV and other tests.

After recording a physical inventory on the stock card, draw a line in red underneath the physical inventory row and continue recording transactions on the next row.

There should be one stock card for each brand of test you store. When you have completed both sides of a stock card for a product, attach a new stock card to the top of the old card and write the words Balance Forward or B/F on the first line. Write the quantity brought forward from the old card in the first Quantity on Hand space on the new card.

Step	Action	Notes	Example
1.	<i>Product:</i> Enter the name of the health commodity.	Use one stock card for each health commodity.	Product: Determine rapid HIV test
2.	<i>Date:</i> Enter the date of the transaction.		12/4/2005
3.	<i>Voucher To/From:</i> Enter the delivery note number of the item received or issued.	Get this number from the requisition or issue voucher that accompanies the item.	Voucher #: 0039
4.	<i>Batch Number:</i> Enter the batch number of the item received or issued.	Get this number from the requisition or issue voucher that accompanies the item.	Batch #017-309
5.	<i>Quantity Received:</i> Enter the exact amount of the product received on this date in red ink.	Stock received at service delivery points from the district store, and stock received at the district store from KEMSA.	Tests received: 40
6.	<i>Quantity Issued:</i> Enter the exact amount of the product issued on this date.	Stock that has physically left the storage area.	Tests issued: 60
7.	<i>Losses/Adjustments:</i> Enter the exact amount of losses or adjustments (additions) to inventory on this date.	Always use a (-) sign to indicate losses and a (+) or (-) sign to indicate adjustments. Losses include theft, expiry, damage, or items used for either training or counselling. Adjustments include usable stock returned from lower level facilities or transferred from one facility to another, and products returned to the district store.	Tests losses/ adjustments: (-) 2

(continued)

Step	Action	Notes	Example
8.	<p><i>Quantity on Hand:</i> Add any receipts or adjustments and subtract any issues or losses from the existing <i>Quantity on Hand</i> to determine the new <i>Quantity on Hand</i>.</p> <p>Write this figure in the <i>Quantity on Hand</i> column for this date.</p>	<p>This column should always represent the amount of this item presently in your store.</p> <p>When conducting a physical inventory, always record the exact amount counted. If the physical count does not match the amount recorded in this column, review the issues and receipts against the delivery vouchers, check the math, note the adjustment in the <i>Losses/Adjustment</i> column and update the figure in this column.</p> <p>Record losses or adjustments discovered during a physical inventory before and on a separate line from the physical inventory entry. Record the physical inventory on the stock card in red ink.</p>	<p>Tests quantity on hand = 88</p> <p>Physical Inventory = 88</p>
9.	<p>Remarks:</p> <ol style="list-style-type: none"> When an item is received, enter the origin. When an item is issued, enter the destination. When there is a loss or adjustment for an item, provide a brief explanation. When conducting a physical inventory, write "physical inventory." 		<ol style="list-style-type: none"> Received (Origin): KEMSA Issued (Destination): Namwera Loss/ adjustment: Damaged by water Physical Inventory
10.	<p><i>Initials:</i> Write your initials here when you have finished filling in the stock card.</p>		J.M.

This task is complete when—

- The *Product Name, Date, Voucher To/From, Batch Number, Quantity Received, Quantity Issued, Losses/Adjustments, Quantity on Hand,* and *Remarks* columns are correctly completed.

Ministry of Health

Stock Card

CODE: Product: Determine HIV Rapid Test								
Date (A)	Voucher To/From (B)	Batch Number (C)	Quantity Received (D)	Quantity Issued (D)	- Losses/ +Adjustments (E)	Quantity on Hand (F)	Remarks (G)	Initials (I)
10/4/05	B/F	017-309				110		J.M.
12/4/05	0039	017-309	40			150	KEMSA	J.M.
20/4/05	121			60		90	Namwera	J.M.
30/4/05		009-412			(-) 2	88	Damaged by water	J.M.
30/4/05	Physical Inventory					88		J.M.



During a physical inventory, count every item by hand and record the quantities on the stock card.

5. Recording and Reporting

What Is the LMIS for HIV Tests?

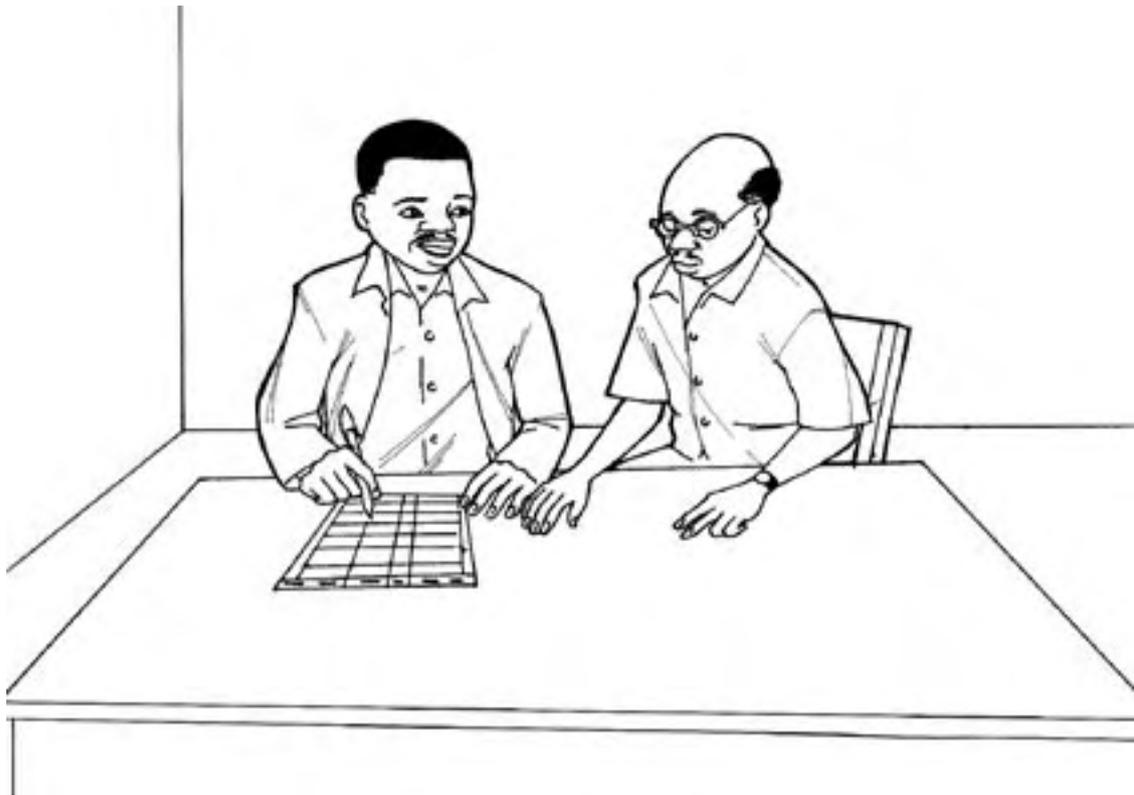
One component of the HIV test kits logistics system is a logistics management information system (LMIS) of records and reports that are used to collect and transmit information about HIV tests and related supplies issued/used and in storage.

The following table lists all the records and reports that are part of the LMIS and also lists the people responsible for completing them, by level. Some reports may be generated by computers.

Level	Designation	Records and Reports	Form No.
Service Delivery Point	Facility In-Charge and Laboratory In-Charge	Daily Activity Register for HIV Testing and Blood Safety	
		Consumption Data Report and Request for Blood Safety Commodities	
		Counter Requisition and Issue Voucher	S11
		Stock Card	
District	District Medical Laboratory Technologist	Consumption Data Report and Request for Blood Safety Commodities (for the district store)	
	District Store In-Charge	Counter Requisition and Issue Voucher	S11
		Issue and Receipt Voucher	S12
		Stock Card	
Central Warehouse	Central Warehouse Manager/ Procurement Officer	Stores Ledger Card	S3
		Bin Card	S5
		Stock Adjustment Card	S16
		Counter Requisition and Issue Voucher	S11
		Issue and Receipt Voucher	S12
		Counter Receipt Voucher	S13
	Logistics Management Unit	Summary Feedback Reports	

How Do You Complete the LMIS Forms?

This section includes detailed instructions for completing the Daily Activity Register for HIV Testing and Blood Safety and the Consumption Data Report and Request for Blood Safety Commodities. Refer to these instructions when you complete the forms at your level or when you provide supervision and on-the-job training.



A. Daily Activity Register for HIV Testing and Blood Safety

How Do You Complete the Daily Activity Register?

The following instructions are for completing the Daily Activity Register for HIV Testing and Blood Safety. The service provider completes this form at the service delivery point.

Task:	Completing the Daily Activity Register for HIV Testing and Blood Safety
Completed by:	Health Facility Service Providers and/or In-Charge, Laboratory In-Charge
Purpose:	To record the usage of HIV tests used for VCT, PMTCT, clinical diagnosis, and blood screening within the facility
When to perform:	Daily or whenever an HIV test is used
Materials needed:	Forms booklet with the Daily Activity Register for HIV Testing and Blood Safety

Step	Action	Notes
1.	<i>Facility Name:</i> Write the name of the facility where the HIV testing is being provided.	
2.	<i>Facility Type:</i> Write the type of facility.	Enter health centre, hospital, etc.
3.	<i>SDP/VCT No.:</i> Write the MOH number assigned to this facility.	Contact KEMSA/LMU if you do not know your SDP/VCT number.
4.	<i>Type of Service provided:</i> Tick the boxes next to the services provided by this facility.	
5.	<i>BALANCE BROUGHT FORWARD:</i> Write the <i>Ending Balance</i> from the bottom of the previous DAR for each type and brand of test.	The <i>Ending Balance</i> from the previous DAR is always the <i>Balance Brought Forward</i> on the current DAR.
6.	<i>QUANTITY RECEIVED:</i> Write the total number of tests, by type and brand, received during the period covered by the DAR.	Get this number from the <i>Quantity Received</i> column of the product stock card. Only enter the number of tests received from the district store or KEMSA central warehouse. Any tests received from other sources should be recorded as a positive adjustment (see step 9).
7.	<i>BALANCE ON HAND:</i> Write the number of tests, by type and brand, that were available for use during the period.	Add the <i>Quantity Received</i> to the <i>Balance Brought Forward</i> to obtain this number.
8.	<i>DATE:</i> Write the date that the test was given.	Enter as day/month/year.
9.	<i>OP/IP No.:</i> Write the <i>Out Patient</i> or <i>In Patient</i> number.	Get this number from the patient card.
10.	<i>RAPIDS, LONG ELISAS, HEPATITIS, SYPHILIS, OTHER TESTS:</i> For each patient, put an X in the appropriate box for each type and brand of test performed. If the test is inconclusive, put a O in the box.	Write the names of tests not listed in the blank spaces provided on the form.
11.	<i>QUANTITY USED:</i> Write the total number of tests used during the period by type and brand.	Add all the boxes marked X and O for each type and brand of test, and enter the total here.

(continued)

Step	Action	Notes
12.	<i>ENDING BALANCE</i> : Write the total number of tests remaining in the facility at the end of the period.	Subtract the <i>Quantity Used</i> from the <i>Balance on Hand</i> , and enter the result here.

This task is complete when—

- The *Date*, *OP/IP No.*, and type and brand of test are filled in for every test used.
- The *Quantity Used* and *Ending Balance* are filled in for each type and brand of test.

B. Consumption Data Report and Request for Blood Safety Commodities

How Do You Complete the Consumption Data Report?

Use the following instructions to complete the Consumption Data Report and Request for Blood Safety Commodities. This form is completed by the Health Facility In-Charge, Laboratory In-Charge, and District Medical Laboratory Technologist (for the district store). Prior to completing the Consumption Data Report, the In-Charge or DMLT should conduct a physical inventory. See chapter 4 for instructions on conducting a physical inventory.

Task:	Completing the Consumption Data Report and Request for Blood Safety Commodities
Completed by:	Health Facility In-Charge Laboratory In-Charge District Medical Laboratory Technologist
Purpose:	To report information on stock balances and quantities used by service delivery points, on stock balances and quantities issued by the district store; and to order the quantity of HIV tests and related supplies required at the health facilities.
When to perform:	No later than the fifth day of every month (service delivery points), or the fifteenth day of the month every two months (district stores).
Materials needed:	To complete this form at a service delivery point, including district laboratories, use the Daily Activity Register for HIV Testing and Blood Safety and the health facility stock cards. To complete this form at the district level, use the district store stock cards.

Step	Action	Notes
1.	<i>FACILITY NAME</i> : Write the name of the facility you are completing the Consumption Data Report for.	
2.	<i>SDP/VCT No.</i> : Write the MOH number assigned to this facility.	Contact KEMSA/LMU if you do not know your SDP/VCT number.
3.	<i>DISTRICT</i> : Write the name of the district where the facility is located.	
4.	<i>PROVINCE</i> : Write the name of the province where the facility is located.	
5.	<i>TYPE OF SERVICE(S) PROVIDED</i> : Tick the appropriate boxes according to the type of services provided at the facility.	
6.	<i>AGENCY</i> : Tick the appropriate box according to the facility's affiliation.	

(continued)

Step	Action	Notes
7.	<i>Report of PERIOD BEGINNING:</i> Write the date of the first day covered by this report.	Enter as day-month-year.
8.	<i>Report of PERIOD ENDING:</i> Write the date of the last day covered by this report.	Enter as day-month-year.
Write the REAGENT NAME and UNIT OF ISSUE of each product in the first two columns. Complete columns A–G. Write the names of any tests not listed in the blank space.		
9.	Column A, BEGINNING BALANCE: Write the total number of tests, by type and brand, available for use on the first day of the reporting period.	The <i>Ending Balance/Physical Count</i> from the previous report is always the <i>Beginning Balance</i> for the current report.
10.	Column B, QUANTITY RECEIVED: Write the number of tests, by type and brand, received from official suppliers during the period covered by the report.	Get this number from the <i>Quantity Received</i> column of the product stock card. Enter only the number of tests received from the district store or KEMSA central warehouse. Any tests received from other sources should be recorded as a positive adjustment (see step 13).
11.	Column C, TESTS USED (SDPs & Labs) or TESTS ISSUED (Stores): If you are a service delivery point, write the number of each type and brand of test used during the month, by purpose of use. Write the total number of tests used for all purposes in the <i>Total</i> column. If you are a storage facility, write the total number of each type and brand of test issued to other facilities during the two-month period in the <i>Total</i> column. Leave the purpose of use (VCT, PMTCT, etc.) columns blank.	If you are reporting for a service delivery point, including laboratories, get these numbers from the <i>Quantity Used</i> boxes of the Daily Activity Register for HIV Testing and Blood Safety. If you are reporting for a district store, get these numbers from the <i>Quantity Issued</i> column on the store's product stock cards.
12.	Column D, LOSSES: Write the number of tests, by type and brand, that were removed from the store's or facility's inventory for reasons other than usage.	Include tests that were damaged, expired, lost, etc., during this period. Also use this column to record any negative discrepancies between stock records and physical counts discovered during a physical inventory.
13.	Column E, ADJUSTMENTS: Write the number of tests, by type and brand, that were added or subtracted to the store's or facility's inventory for reasons other than receipts from official suppliers.	Include tests received from suppliers other than the district store or KEMSA central warehouse during the period, for example, donations. Also use this column to record any positive or negative discrepancies between stock records and physical counts discovered during a physical inventory.

(continued)

Step	Action	Notes
14.	<p>Column F, ENDING BALANCE/PHYSICAL COUNT:</p> <p>Write the total number of tests remaining in the facility at the end of the period. Use this formula to calculate the number:</p> <p style="text-align: center;">Column A + Column B – Column C (Total) – Column D + Column E = Column F</p>	<p>This number should always be the same because of the physical inventory you conducted prior to completing this report.</p> <p>If the number is different, there is an error. Recheck the math calculations and losses and adjustments. If necessary, repeat the physical count.</p> <p>If the number is still different, use the number obtained from the physical count, and add or subtract the amount of the discrepancy in column D, <i>Losses</i> or column E, <i>Adjustments</i>.</p>
15.	<p>Column G, QUANTITY REQUESTED:</p> <p>Write the number of tests by type and brand, that you are ordering for your facility. Leave this column blank if you are reporting for a district store.</p>	<p>If you are a service delivery point, including laboratories, use this formula to calculate the number:</p> <p style="text-align: center;">Column C (Total) from previous month's report + Column C (Total) from current month's report – Column F = Column G</p> <p>If you are a district store, leave this column blank—KEMSA will use the same formula to calculate the amount to issue to your store.</p>
16.	<p><i>NAME:</i> Write the name of the person preparing this report.</p>	
17.	<p><i>SIGNATURE:</i> The person preparing this report signs here.</p>	
18.	<p><i>DESIGNATION:</i> Write the job position of the person preparing this report.</p>	<p>Write Facility In-Charge, Laboratory In-Charge, or District Medical Laboratory Technologist here.</p>
19.	<p><i>DATE:</i> Write the date you are preparing this report.</p>	
20.	<p><i>Explain Losses & Adjustments:</i></p> <p>Write the type of any losses or adjustments included in columns D and/or E.</p>	<p>Include any additional information that could help interpret data from your facility/district.</p>

This task is complete when—

- All identifying information for the facility and the report period has been completed.
- All columns of the report have been completed for each HIV and other tests managed at the facility.
- The *Quantity Requested* is calculated for each type and brand of test.
- The person that prepared the report has written their name, signature, designation, and date.
- The completed and signed report has been submitted to the District Medical Laboratory Technologist (if the report is prepared for a service delivery point or laboratory), or when the report has been submitted to the KEMSA/LMU (if the report is prepared for a district store).
- A copy of the report has been filed at the facility.

(continued)

If you are a service delivery point or laboratory, send the top two copies of the form to the District Medical Laboratory Technologist, and keep a copy in the booklet in the health facility.

If you are a District Medical Laboratory Technologist, the Consumption Data Report reports information on the district store as a storage facility. Send the first copy of this report to the KEMSA/LMU with the copies of the Consumption Data Reports from service delivery points attached, and send the second copy to the PMO. Keep the last copy in the booklet in the district store.

If you are a National/Regional Blood Transfusion Centre, Provincial General Hospital, National Referral Hospital, or other facility that is supplied directly by KEMSA, send the original copy of the report to KEMSA/LMU. Send one copy of the report to the DMLT of the district where your facility is located, and keep the last copy in the booklet in the facility.

When the District Medical Laboratory Technologist receives a Consumption Data Report from a service delivery point, he/she reviews it carefully and confirms column G, *Quantity Requested*, using the following formula:

$$\text{(Column C Total from previous month + Column C Total from current month) – Column F = Column G}$$

What Action Is Required after Each LMIS Form Is Completed?

The following table will tell you what action is required after you complete each of the forms in the LMIS:

Form	When to Submit	Where to Submit
Daily Activity Register for HIV Testing and Blood Safety	Completed daily	Remains at the health facility—do not send this form anywhere.
Consumption Data Report and Request for Blood Safety Commodities (Service Delivery Points & Laboratories)	By the 5th day of every month	<ol style="list-style-type: none"> 1. Submit top two copies to District Medical Laboratory Technologist (district will forward one copy to KEMSA/LMU). 2. Keep last copy in the booklet at the health facility.
Consumption Data Report and Request for Blood Safety Commodities (District Stores)	Every two months, by the 15th day of the month	<ol style="list-style-type: none"> 1. Submit first copy to KEMSA/LMU 2. Submit second copy to PMO. 3. Keep last copy in the booklet at the district store.
Stock Card	Keep this form, with the HIV tests, at the service delivery points and district stores.	Remains at the health facility—do not send this form anywhere.

6. Reviewing Stock Status

What Is Your Stock Status?

When you review your stock status, you determine how much of each HIV test and related supplies you have available at your facility. You can review your stock status by counting the stock available, as you do during a physical inventory. (See chapter 4 for how to conduct a physical inventory.) When you finish, you will have an absolute quantity of stock available. But, when managing HIV tests, it is much more important to know *how long the stocks will last* and if you have enough stock available until you receive your next order. We refer to this as *months of stock*. This chapter covers procedures that you can use to determine how much of each product you have in relation to the rate at which these commodities are used at service delivery points.

What Is Months of Stock?

Months of stock is the number of months HIV tests and related supplies will last based on the present consumption rate. When you review your stock status, you need to determine how many months of stock you have in your facility. Three months of stock means that your stock will last three months, as long as consumption remains at the current rate.

By reviewing your stock status you will be able to determine if your facility is understocked, overstocked, or adequately stocked. If you are understocked, you may need to place an emergency order. (See chapter 7 for placing an emergency order.) If you are overstocked, you may need to redistribute the stock.

To help you maintain adequate stocks, a *maximum months of stock*, *minimum months of stock*, and an *emergency order point* have been established. The maximum months of stock is the largest amount of each HIV test or related supplies a facility should hold at any one time. If a facility has more than the maximum, it is overstocked and risks having stocks expire before they are used. The minimum months of stock is the least amount of each HIV test or related supplies a facility should hold at any one time. If a facility has less than the minimum, it is understocked and risks having to place an emergency order. The emergency order point is the level where the risk of stocking out is likely, and an emergency order should be placed immediately.

The maximum months of stock, minimum months of stock, and emergency order points for the different levels of the logistics management system are shown in the following table:

Level	Maximum Months of Stock	Minimum Months of Stock	Emergency Order Point
KEMSA Central Warehouse	6 months	3 months	2 months
District Stores	4 months	2 months	1 month
Service Delivery Points	2 months	1 month	0.5 month

How Do You Determine Months of Stock?

To determine how many months each product will last, add the latest three months' usage of a particular product, then divide by three to determine your Average Monthly Consumption (AMC). Use the following formula to determine AMC:

$$\frac{\text{Current month's usage} + \text{previous two months' usage}}{3} = \text{Average Monthly Consumption}$$

Next, divide the stock on hand by the AMC to obtain the Months of Stock on Hand. Use the following formula to determine how many months the current quantity available for each product will last:

$$\frac{\text{Stock on Hand}}{\text{Average Monthly Consumption}} = \text{Months of Stock}$$

You must remember one rule when you determine months of stock—use only *one* number after the decimal point—round up or down all numbers after that number.



Because you issue monthly, you should check your stock status monthly.

How Do You Review Stock Status at Service Delivery Points?

Each month when you prepare (service delivery points) or receive (District Medical Laboratory Technologist) the Consumption Data Report and Request for Blood Safety Commodities, you should review the stock status of the reporting service delivery point. This is an important monitoring activity to ensure that there are always adequate stocks available at all the service delivery points in the district. To review the stock status of a service delivery point using information on the Consumption Data Report, follow the procedures outlined below.

Task:	Determining the number of months of stock on hand for HIV tests and related supplies at each service delivery point
Completed by:	Health Facility In-Charge, Laboratory In-Charge, District Medical Laboratory Technologist
Purpose:	To determine if the service delivery points are maintaining adequate stocks
When to perform:	Each time a Consumption Data Report and Request for Blood Safety Commodities is received or prepared

Step	Action	Notes	Example
1.	Add the Total Tests Used for each product for the current month and previous two months, then divide by 3 to determine Average Monthly Consumption (AMC).	Determine the Total Tests Used from column C on the Consumption Data Report.	Total Tests Used for current month is 32 tests. Last month 28 tests were used, and the month before 27 tests were used. $32 + 28 + 27 = 87$ $87/3 = 29$ (AMC = 29)
2.	Divide the facility's Ending Balance/Physical Count (stock on hand) by the Average Monthly Consumption for each product.	Obtain the physical count from column F on the Consumption Data Report.	Physical count is 54 tests. $54/29 = 1.9$ months of stock
3.	Enter the number of months of stock next to the name of the product on the facility's Consumption Data Report.		

This task is complete when—

- The months of stock on hand for each product is entered for each facility.
-

How Do You Decide What Actions to Take after Stock Status Has Been Determined at a Service Delivery Point?

Task:	Decide what action to take after stock status has been determined for HIV tests and related supplies at a service delivery point
Completed by:	District Medical Laboratory Technologist
Purpose:	To monitor the stock status in the service delivery points, and to correct any overstocking or understocking discovered after determining stock status
When to perform:	Each time a Consumption Data Report and Request for Blood Safety Commodities is received and/or completed

Situation	Interpretation	Decisions
Months of stock is between 2 months and 1 month.	Stock status is adequate.	No action required.
Months of stock is greater than 2 months.	The service delivery point is overstocked with this product.	Contact the service delivery point and discuss the stock status of the product. If some or all of the stock will expire in the near future, you can transfer some stock to another facility that may be able to use it more quickly.
Months of stock is less than 1 month but greater than 0.5 months.	The facility is understocked with that commodity, but stock levels have not yet reached the emergency order point.	Continue to monitor stock levels until the next delivery arrives, or until they reach the emergency order point.
The number of months is less than 0.5 month.	The service delivery point is understocked with this product. The stock level is below the emergency order point of 0.5 month.	Contact the service delivery point and discuss the stock status of the product. <i>An emergency order may be needed.</i>

How Do You Review Stock Status at the District Store?

Every two months when you conduct a physical inventory, aggregate the latest three months' usage of a particular product, divide by three, then divide the stock on hand in the district store by the result. The usage for each item should be the total quantity used in all service delivery points in your district for the past three months. Calculate this figure by adding the totals for each product and each facility from the Consumption Data Report and Request for Blood Safety Commodities for the most recent three months.

How Do You Decide What Actions to Take after Stock Status Has Been Determined at the District Store?

Task: Deciding what actions to take after stock status has been determined for HIV tests and related supplies at the district store.

Completed by: District Medical Laboratory Technologist

Purpose: To correct any overstocking or understocking discovered after determining stock status

When to perform: Each time you do a physical inventory (at least every two months)

Situation	Interpretation	Decisions
Months of stock is between 2 and 4 months.	Stock status is adequate.	No action required.
Months of stock is greater than 4 months.	The district store is overstocked with that commodity.	Contact the KEMSA/LMU and tell them that your district is overstocked. They may want to transfer stock from your district to another district that may be understocked.
Months of stock is less than 2 months but greater than 1 month.	The district store is understocked with that commodity, but stock levels have not yet reached the emergency order point.	Continue to monitor stock levels until the next delivery arrives, or until they reach the emergency order point.
Months of stock is at or less than 1 month.	The district store is understocked with that item. The stock level is at or below the emergency order point of 1 month.	Contact the KEMSA/LMU for an emergency order.

7. Calculating How Much to Order or Issue

Who Orders and Issues in the Logistics System?

In the HIV test kits logistics system, HIV tests and related supplies move down the system from the KEMSA central warehouse directly to the district stores, to Provincial General Hospitals (PGH), to the National & Regional Blood Transfusion Centres (N/RBTC), and to the National Referral Hospitals. The district stores issue the tests to service delivery points. These facilities use the tests, and provide them to other user sites, for example, VCT and PMTCT centres. Determining how much of each product to order and issue is a critical element in managing these supplies.

In this system—

- By the fifth of each month, the service delivery point submits a Consumption Data Report to the district store.
- Every two months, by the 15th of the month, the District Medical Laboratory Technologist reviews the Consumption Data Report for each service delivery point, and prepares a Consumption Data Report for the district store. He/she then forwards copies of the service delivery point reports, with the district store's Consumption Data Report, to the KEMSA/Logistics Management Unit.
- The KEMSA/LMU determines how much of each commodity to issue to each district store, PGH, N/RBTC, and National Referral Hospital. Procedures for this are *not* included in this manual.

The ordering and issuing of products in the logistics system is directly linked to the reporting system. If the District Medical Laboratory Technologist does not receive a Consumption Data Report from a service delivery point, he or she cannot determine how much of each product the facility needs. It is very important that reports be submitted on time to ensure a consistent supply of products. *If you are a district medical laboratory technologist and do not receive the report you need from a service delivery point in time to complete the district's Consumption Data Report, do not issue any HIV tests to that service delivery point.* Submit the district's report, along with copies of other service delivery points' reports, on schedule. Follow up with the facility and make every effort to get the report.

In addition, when ordering and issuing HIV test kits, be sure to order and issue the related supplies needed to administer them. These may include extra chase buffer, gloves, record books, etc.

How Does a Service Delivery Point Determine How Much to Order from the District?

Task: Calculating the quantities for each HIV test and related supplies to order for a service delivery point

Completed by: Health Facility In-Charge, Laboratory In-Charge

Purpose: To determine the quantity of each product to order for each service delivery point

When to perform: Every month, while completing the Consumption Data Report and Request for Blood Safety Commodities

Note: Calculating the quantity required is the last activity in completing the Consumption Data Report, which is submitted by each service delivery point. Do these steps for each product reported.

Step	Action	Notes	Example
1.	Add the Total Tests Used for the current month to the Total Tests Used in the previous month.	This information can be found in column C on the current month's and previous month's Consumption Data Report.	The total used for Determine rapid tests in April was 42. The total used in March was 37. $42 + 37 = 79$
2.	Subtract the Physical Count (stock on hand) from the result of step 1. The result of this computation is the Quantity Requested.	The Ending Balance/Physical Count (stock on hand) is the result of a physical inventory.	Stock on hand is 31. $79 - 31 = 48$ tests required.
3.	Enter this amount under Quantity Requested, column G on the Consumption Data Report.	If the result is a negative number, enter 0.	

How Does a Service Delivery Point or District Store Place an Emergency Order?

In-Charges at the service delivery points and district stores should know how to place an emergency order. See chapter 6, Reviewing Stock Status, in this manual for emergency order points for each level. When the stock status at the service delivery point or district store is at or below the emergency order point, the In-Charge should use the following procedures to place an emergency order:

Task:	Placing an emergency order
Completed by:	Health Facility In-Charge, Laboratory In-Charge, District Medical Laboratory Technologist
Purpose:	To order supplies when stock levels are at or below the emergency order point
When to perform:	Any time the stock levels of HIV tests and related supplies are at or below the emergency order point
Step	Action
1.	Complete a Consumption Data Report and Request for Blood Safety Commodities.
2.	Write the words EMERGENCY ORDER in red ink at the top of the form.
3.	Take the completed Consumption Data Report to the District Medical Laboratory Technologist. If you are the District Medical Laboratory Technologist receiving an emergency order from a service delivery point, issue stock to fill the emergency order and forward a copy of the Consumption Data Report to the KEMSA/LMU.

Note: You can avoid emergency orders if you follow the steps for calculating order/issue quantities.

8. Logistics Monitoring and Supervision

Introduction

In addition to ensuring the availability of commodities, two of the most important responsibilities logistics personnel have are monitoring and supervision. They are the backbone of an effective logistics system. Without continuous monitoring of logistics activities and supervision of the personnel who carry out these responsibilities, overall quality of the logistics system may weaken, which, in turn, may jeopardise the quality of service provided to clients.

What Is Monitoring?

Monitoring is checking on a regular basis to ensure that assigned activities are being carried out.

Why Monitor Logistics Activities?

Logistics activities should be monitored on a regular basis to ensure that the *six rights* are being met. Specifically, to—

- Ensure that clients are getting the services they want when they need them.
- Ensure that planned logistics activities are being carried out according to schedule.
- Ensure that all records are correctly maintained and reports are submitted on time.
- Determine the quantity of supplies to order or issue.

What Is Supervision?

Supervision is the process of ensuring that personnel have the knowledge and skills required to carry out their responsibilities effectively, and to provide immediate on-the-job training, as needed.

Why Supervise Logistics Personnel?

There are several reasons why logistics personnel should be supervised:

- To ensure they have the knowledge and skills they need to effectively manage the logistics system.
- To identify weaknesses in performance, and to improve performance by providing immediate on-the-job training, as needed.
- To ensure that established logistics guidelines and procedures are being followed.

Most supervisors agree that if they are to be truly effective supervisors, they must have the same knowledge and skills as the people they supervise. In the logistics system, this means that supervisors must be able to effectively carry out all the responsibilities of the personnel at the level below them. See “Overview of the Kenya HIV Test Kits Logistics System” for a detailed list of the responsibilities of the personnel you supervise.

Is There a Difference between Monitoring and Supervision?

Yes, there is a difference. An easy way to think about the difference between monitoring and supervision is—

Monitor logistics activities.
Supervise the people who carry out these activities.

It is usually safe to say that most logistics activities can be monitored by reviewing records and reports, which you can do frequently from your office. For example, by checking reports you can determine if a health facility is maintaining adequate stock balances or if there are unusual quantities of commodities expiring or being lost. Effective supervision, on the other hand, can only take place in the presence of logistics personnel. You should plan to spend time supervising and providing on-the-job training every time you visit the personnel you supervise, whether they are in the same office, at a district store, or at a service delivery point.

What Is On-the-Job Training?

On-the-job training is helping someone improve his or her performance by demonstrating the correct way to do a task. It is training that takes place on the job, working closely with the worker, often during supervision visits. Effective on-the-job training should take place as soon as a performance problem is identified.

What Are the Guidelines for Logistics Monitoring and Supervision?

The following guidelines should help you monitor logistics activities and provide the necessary supervision.

#	Action	Yes/No
1. Prepare for the visit.		
	Develop objectives for your visit.	
	Liase with DMOH for transport and allowances at least 1 week prior to visit.	
	Notify health facility of your visit after you have confirmed transport.	
	Review the report from your previous visit and the recommendations you made.	
	Review the previous reports for the health facilities to be visited.	
	Collect your tools for supervision: stationary, procedures manual, and calculator.	
	Review this checklist.	
2. Establish rapport.		
	Meet with the Facility In-Charge, introduce yourself and others, explain your objectives, and ask to visit with the service providers.	
	Assemble the team (service providers and In-Charge) when business permits.	
	Make any necessary introductions.	
	Explain the objectives of your visit.	
	*Ask, "How are the STI and HIV/AIDS programmes doing?"	
	*Ask, "Do you believe you are able to serve the clients using the guidelines?"	
	*Ask, "Do you have any problems related to HIV tests?"	
	<i>*Note responses to these questions under "Additional comments."</i>	
3. Check the storage area.		
	Verify that HIV tests and related supplies are kept according to the storage guidelines in chapter 3 of this manual.	
	Verify that commodities are dispensed according to FEFO. See chapter 3 of this manual.	
	Verify that commodities are held securely but accessible, when needed.	
	Conduct a physical inventory. See chapter 4 of this manual.	
	Compare the results of the physical inventory with the stock card.	
	Write the physical inventory results on the stock card; make any necessary adjustments.	
4. Review the stock cards.		
	Are stock cards available with the commodities?	
	Verify that stock cards are correctly/completely filled out (in units, dates, and batch #).	
	Verify that physical inventories were recorded monthly.	
	Check the math.	
	Check to see if there are any stockouts reported on the stock card.	
	Compare the receipt date of commodities with the dates you thought supplies were shipped.	
	Check to see if issues match the delivery notes.	
	Ask the In-Charge, "Do you have any difficulty completing the stock card?"	

(continued)

#	Action	Yes/No
5. Review record keeping.		
	Verify that all records are filed and organised. Are they accessible?	
	Does the In-Charge have the job aids available to assist in filling out forms?	
Daily Activity Register for HIV Testing and Blood Safety and Consumption Data Report		
	Are the forms filled out correctly?	
	Is the stock on hand at the clinic correctly reported from the stock cards?	
	Do the number of months of stock suggest an understock or overstock?	
	Does the In-Charge know the day the report is due? (Does the date the form was completed suggest that it was completed on time? Did you receive it on time?)	
	If there are losses/adjustments, are these explained?	
	Is the In-Charge completing the forms?	
	Ask the In-Charge, "Do you have any difficulty in completing the forms?"	
6. Take actions during the visit.		
	Offer words of encouragement, pointing out a few tasks that the person has been doing well.	
	Use the procedures manual to provide on-the-job training for any areas that need improvement.	
	Make an agreement with staff on future performance.	
	Ask the In-Charge, "Do you have any additional comments or questions about LMIS?"	
	Give the In-Charge any materials they need to do their jobs.	
	Sign the visitors' book.	
7. Take actions after the visit.		
	Did you document any problems, actions to be taken, and plans for follow-up?	
	Did you send the report to the In-Charge and DMOH?	
	Keep a copy of the report for follow-up during your next visit.	
	Address any concerns you found during the visit.	

*Additional comments: _____

Glossary

average monthly consumption rate. The average number of HIV tests and related supplies that are used each month.

brand. A specific product identified by a distinctive name and packaging given to it by the manufacturer. For example, Determine HIV is a brand of HIV rapid tests.

co-ordination. The process of working together on specific activities to achieve a common goal.

dispensed to user. The provision of an item of supply to its ultimate user by a provider. The same as *dispensed to client*.

emergency order. Non-routine order that is placed when stock levels fall below the emergency order point before the routine order period (see chapter 7).

emergency order point. The stock level that triggers an emergency order, regardless of the timing within the review period.

feedback. Information provided from one level of the system to another, or from one individual to another, with the purpose of improving the performance of the overall system or individual.

first-to-expire, first-out (FEFO). A method of managing HIV test kits in a storage facility to ensure that the oldest stock is issued before newer stock (see chapter 3).

issue. The provision of an item of supply from one storage facility to another.

level. The specific location in the health system hierarchy: central, region, district, or service delivery point level (see chapter 1).

logistics. The science of procuring, maintaining, and transporting supplies.

logistics system. The structure through which a quantity of supplies is moved to different levels according to a schedule. Information about the quantities issued or dispensed to clients at each level is gathered to determine the quantity and schedule of future deliveries.

maximum months of stock. The number of months of stock above which stock levels should not rise in a given facility (see chapter 6).

minimum months of stock. The number of months of stock below which stock levels should not normally fall in a given facility (see chapter 6).

monitoring. Checking on a regular basis to ensure that assigned logistics activities are carried out (see chapter 8).

months of stock. A measurement of stock quantity that indicates the number of months HIV tests and related supplies will be available based on the present consumption rate.

overstock. A situation in which a storage facility has more stock than is recommended.

physical inventory. The process of counting by hand the total number of each HIV test and related supplies in your store or health facility at any given time (see chapter 4).

recording. The process of entering information or data on a form or record (see chapter 5).

reporting. The process of transmitting information, usually by submitting a document, form, or report on regular basis—monthly, quarterly, or annual (see chapter 5).

service delivery point. Any health facility in the logistics system that provides services directly to clients.

shelf life. The length of time a product can be stored under ideal conditions without affecting the usability, safety, purity, or potency of the item (see chapter 3).

stock on hand. Stored quantities of usable stock.

stockout. Refers to a situation in which a storage facility has no stock on hand.

stock status. The number of months of stock available for distribution at a facility at a given time (see chapter 6).

supervision. The process of ensuring that logistics personnel have the knowledge and skills required to carry out their responsibilities effectively, and to provide immediate on-the-job training, as needed (see chapter 8).

user site. A unit of a service delivery point where a specific service, such as VCT, PMTCT, etc., is offered.

Annexes

- A-1 Daily Activity Register for HIV Testing and Blood Safety
- A-2 Consumption Data Report and Request for Blood Safety Commodities
- A-3 Stock Card
- A-4 Fact Sheet: Determine HIV-1/2 (Rapid Test Kit)
- A-5 Fact Sheet: SD BIOLINE HIV-1/2 3.0 (Rapid Test Kit)
- A-6 Fact Sheet: Uni-Gold™ HIV Test
- A-7 Fact Sheet: OraQuick® Rapid HIV-1 Antibody Test
- A-8 Fact Sheet: Enzygnost® Anti-HIV 1/2 Plus (ELISA Test Kit)
- A-9 Vironostika® HIV Uni-Form II Plus O (ELISA Test Kit)

MINISTRY OF HEALTH

CONSUMPTION DATA REPORT AND REQUEST FOR BLOOD SAFETY COMMODITIES

FACILITY NAME:		SDP/VCT No:			DISTRICT:			PROVINCE:											
FACILITY TYPE:		TYPE OF SERVICE(S) PROVIDED:			PMTCT			CLINICAL DIAGNOSIS											
AGENCY:		LOCAL AUTHORITY			PRIVATE			OTHER											
REPORT OF PERIOD BEGINNING:		REPORT OF PERIOD ENDING:			BLOOD SCREENING			BLOOD SCREENING											
MOH		NGO			VCT			PMTCT											
A		B			C			D			E			F			G		
REAGENT NAME	UNIT OF ISSUE	BEGINNING BALANCE	QUANTITY RECEIVED	TESTS USED (SDPs & Labs) or TESTS ISSUED (District Stores)				LOSSES	ADJUSTMENTS	ENDING BALANCE/ PHYSICAL COUNT (A+B-C-D+E=F)	QUANTITY REQUESTED								
RAPIDS					VCT	PMTCT	CLINICAL DIAGNOSIS	BLOOD SCREENING	TOTAL										
<i>Determine</i>	test																		
<i>SD BIOLINE</i>	test																		
<i>Uni-Gold™</i>	test																		
ELISAs																			
<i>Enzygnost®</i>	test																		
<i>Vironostika®</i>	test																		
HEPATITIS																			
<i>Hep B SAH</i>	test																		
<i>Hep C</i>	test																		
SYPHILIS																			
<i>RPR</i>	test																		
OTHER																			
NAME:											SIGNATURE:								
DESIGNATION:											DATE:								
<i>Explain Losses & Adjustments:</i>																			

DETERMINE HIV-1/2 (RAPID TEST KIT)

Manufacturer

Abbott Japan Co., Ltd.
Diagnostics Division
Roppongi First Building, 4th Floor
9-9, Roppongi 1-Chome
Minato-ku, Tokyo 106-8535
Japan
Tel: 81 3 3589 9441
Fax: 81 3 3589 9591
www.abbott.com

Kit Contents

- ◆ 10 tests per card
- ◆ 10 cards
- ◆ Whole blood assay requires 1 additional bottle of chase buffer (2.5 ml)

Percent Accuracy

- ◆ Sensitivity: 100%
- ◆ Specificity: 99.75%

Types of Samples

- ◆ Serum, plasma, or whole blood

Run Time of Test

- ◆ 15 minutes

Packaging Information

- ◆ 100 tests per kit
- ◆ Kits of 20 tests are available in some countries.

Test Kit Package

- ◆ Dimensions: 27 x 16 x 1 cm
- ◆ Volume: 432 cm³
- ◆ Weight: 500 g

Shipping Carton

No standard shipping carton. Quantity is tailored to customer's needs.

- ◆ Volume: 432 cm³ x number of kits
- ◆ Weight: 500 g x number of kits

Storage Conditions

- ◆ Storage temperature: 2-30°C
- ◆ Can withstand short periods (up to 4 weeks) at up to 25°C.
- ◆ Store away from extreme heat.
- ◆ Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- ◆ Do not freeze the test kits or reagents.
- ◆ Expiration date is based on ideal storage conditions.
- ◆ Kit components are stable until expiration date.
- ◆ DO NOT use any component after expiry date.

Shelf Life and Disposal

- ◆ Shelf life: 18 months
- ◆ Disposal methods:
 - Autoclave @121°C for 60 minutes
 - Incinerate
- ◆ Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

Quality Control

- ◆ A procedural control is incorporated in the device. If the control bar does not turn red by assay completion, the test result is invalid, and the sample should be retested.

Indicators of Potential Quality Problems

- ◆ Physical damage to shipping carton, inner box, or test kits
- ◆ Presence of foreign matter inside unit package
- ◆ Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- ◆ Missing contents
- ◆ Leakage or stains
- ◆ Improper storage conditions

Materials Required but Not Provided

- ◆ Serum/plasma and whole blood (venipuncture preferred) assay
 - Pipette
 - Pipette tips
- ◆ Whole blood (fingerstick) assay
 - Lancets
 - EDTA capillary tubes

Estimated Price

- ◆ Approximately U.S.\$1.00-1.30 per test
- ◆ Price varies depending on the quantity being procured.

SD BIOLINE HIV-1/2 3.0 (RAPID TEST KIT)

Manufacturer

Standard Diagnostics, Inc.
156-68, Hagal-ri, Giheung-eup,
Yongin-si, Kyonggi-do, Korea
Tel: 82-31-899-9700
Fax: 82-31-899-9740
e-mail: taylor@standardia.com
www.standardia.com

Kit Contents

- ◆ 30 test kit contains 30 test devices, assay diluent (5 ml) and 1 package insert
Optional: pipettes or capillary tubes and lancets, and alcohol swabs.
- ◆ 20 test kit contains 20 test devices, assay diluent (5 ml), capillary tubes, lancets and alcohol swabs, and 1 package insert.

Percent Accuracy

- ◆ Sensitivity: 100%
- ◆ Specificity: 99.9%

Types of Samples

- ◆ Serum, plasma, or whole blood

Run Time of Test

- ◆ 20 minutes
– Serum and plasma can be interpreted at 5–20 minutes.
– Whole blood should be interpreted within 10 minutes; do not interpret after 10 minutes.

Packaging Information

- ◆ 30 tests per kit, 40 kits per carton
- ◆ 20 tests per kit, 54 kits per carton
- ◆ Other test packages available, such as a multi-cassette type, upon request.

Test Kit Package

- ◆ Dimensions:
22.2 x 12.4 x 7 cm (30 tests)
18.5 x 13.8 x 7.3 cm (20 tests)
- ◆ Volume:
1,927 cm³ (30 tests)
1,864 cm³ (20 tests)
- ◆ Weight:
300 g (30 tests)
.24 kg (20 tests)

Shipping Carton

- ◆ Dimensions:
53 x 48 x 40 cm (30 tests)
56.5 x 42 x 45 cm (20 tests)
- ◆ Volume:
101,760 cm³ (30 tests)
106,785 cm³ (20 tests)
- ◆ Weight:
300 g (30 tests)
.24 kg (20 tests)

Storage Conditions

- ◆ Storage temperature: 2–30°C, room temperature.
- ◆ Can withstand short periods (up to 4 weeks) at up to 30°C.
- ◆ Store away from extreme heat and humidity.
- ◆ Do not freeze the test kits or reagents.
- ◆ Expiration date is based on ideal storage conditions.
- ◆ Kit components are stable until expiration date.
- ◆ DO NOT use any component after expiry date.

Shelf Life and Disposal

- ◆ Shelf life: 24 months
- ◆ Disposal methods:
– Autoclave @121°C for 60 minutes or incinerate
- ◆ Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

Quality Control

- ◆ A procedural control is incorporated in the device. If the control bar does not turn purple by assay completion, the test result is invalid, and the sample should be retested.

Indicators of Potential Quality Problems

- ◆ Physical damage to shipping carton, inner box, or test kits
- ◆ Presence of foreign matter inside unit package
- ◆ Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- ◆ Missing contents
- ◆ Leakage or stains
- ◆ Improper storage conditions

Materials Required but Not Provided

- ◆ Disposable tips
- ◆ Latex gloves
- ◆ Timer

Estimated Price

- ◆ Approximately U.S.\$.85–1.10 per test
- ◆ Price varies depending on the quantity being procured and can be negotiated on a case by case basis.

UNI-GOLD™ HIV TEST

Manufacturer

Trinity Biotech
IDA Business Park
Bray
Co. Wicklow, Ireland
Tel: +353-1-276-9800
Fax: +353-1-276-9888
www.trinitybiotech.com
Free phone: +1-800-603-8076

Kit Contents

- ◆ 20 test devices
- ◆ Wash reagent (2 ml)
- ◆ 20 disposable pipettes
- ◆ 1 package insert

Percent Accuracy

- ◆ Sensitivity: 99.6–100%
- ◆ Specificity: 98.7–100%

Types of Samples

- ◆ Serum, plasma, or whole blood

Run Time of Test

- ◆ 10 minutes

Packaging Information

- ◆ 20 tests per kit
- ◆ Up to 150 kits per carton



Test Kit Package

- ◆ Dimensions: 24 x 14 x 10 cm
- ◆ Volume: 3,360 cm³
- ◆ Weight: 200 g

Shipping Carton

Size of the carton is tailored to the number of kits ordered. The maximum carton size (Eurocarton), holding 150 kits is:

- ◆ Dimensions: 120 x 80 x 80 cm
- ◆ Volume: 768,000 cm³
- ◆ Weight: 52.5 kg

Storage Conditions

- ◆ Storage temperature: 2–27°C
- ◆ Do not freeze test kits/reagents.
- ◆ Store away from extreme heat.
- ◆ Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- ◆ Expiration date is based on ideal storage conditions.
- ◆ DO NOT use any component after expiry date.

Shelf Life and Disposal

- ◆ Shelf life: 15 months
- ◆ Disposal methods:
 - Autoclave @ 121°C for 60 minutes
 - Incinerate
- ◆ Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

Quality Control

- ◆ A built-in procedural control on the test device indicates that the test is functioning correctly. A pink/red band should always appear in the control window.

Indicators of Potential Quality Problems

- ◆ Physical damage to shipping carton, inner box, or test kits
- ◆ Presence of foreign matter inside unit package
- ◆ Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- ◆ Missing contents
- ◆ Leakage or stains
- ◆ Improper storage conditions
- ◆ Quality control criteria not achieved (Pos/Neg control result, control band presence, etc.)

Materials Required but Not Provided

- ◆ Timer or stopwatch
- ◆ Blood collection devices (i.e., lancets, capillary tubes/test tubes)

Estimated Price

- ◆ Approximately U.S.\$1.15–2.25 per test
- ◆ Price varies depending on the quantity being procured.

ORAQUICK® RAPID HIV-1 ANTIBODY TEST

Manufacturer

OraSure Technologies, Inc.
150 Webster Street
Bethlehem, PA 18015 USA
USA Sales
Tel: +1-800-869-3538
Fax: +1-610-882-2275
International Sales
Tel: +84-90-33-65-712
Fax: +84-8-845-7251
www.orasure.com

Kit Contents

- ◆ The 100 test kit contains 100 test devices, 105 loops, 10 test stands, 1 product insert, 100 information pamphlets, and 1 customer letter.
- ◆ The 500 test kit contains 500 test devices, 30 loops, 6 test stands, 1 product insert, 25 information pamphlets, and 1 customer letter.
- ◆ Test kit controls are required to conduct the test and need to be ordered separately. The positive and negative controls are packaged in 0.2 ml vials.

Percent Accuracy

- ◆ Sensitivity: 99.5%
- ◆ Specificity: 99.87%

Types of Samples

- ◆ Fingertick whole blood

Note: The FDA approved OraQuick in November 2002. This fact sheet contains the current specifications of the FDA-approved product. Prior to FDA approval, OraQuick was sold with different specifications for shelf life and types of samples. It is expected that specifications of the FDA-approved product will be expanded when the results of ongoing tests are confirmed.



Run Time of Test

- ◆ 20 minutes

Packaging Information

- ◆ Tests are packaged in individual pouches. Each pouch contains one test and one chase buffer.

Test Kit Package

- ◆ Dimensions:
35 x 39 x 21 cm (100 tests)
44 x 59 x 44 cm (500 tests)
- ◆ Volume:
28, 665 cm³ (100 tests)
114,224 cm³ (500 tests)
- ◆ Weight:
5 kg (100 tests)
20 kg (500 tests)

Storage Conditions

- ◆ Storage temperature: 2–27°C
- ◆ If the test is refrigerated, bring the pouch to ambient temperature (15–27°C) before opening.
- ◆ Do not open the pouch until you are ready to perform a test.
- ◆ Store away from extreme heat. Do not store close to radiator, motor, or other source of heat.
- ◆ Expiration date is based on ideal storage conditions.
- ◆ DO NOT use any component after expiry date.

Shelf Life and Disposal

- ◆ Shelf life: 5–6 months
- ◆ Dispose of in a biohazardous waste container.
- ◆ Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

Quality Control

- ◆ A control line in the 'C' area of the result window indicates a valid result. The control line will appear on all valid tests, whether or not the result is reactive.
- ◆ Kit controls should be run once per shift, and whenever changing to a different lot of tests.

Indicators of Potential Quality Problems

- ◆ Physical damage to shipping carton, inner box, or test kits
- ◆ Presence of foreign matter inside unit package
- ◆ Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- ◆ Missing contents
- ◆ Leakage or stains
- ◆ Improper storage conditions

Materials Required but Not Provided

- ◆ Timer or watch
- ◆ Antiseptic wipes
- ◆ Sterile lancets
- ◆ Sterile gauze pads
- ◆ Disposable gloves
- ◆ Biohazard disposal container

Estimated Price

- ◆ Approximately U.S.\$3.30/test for bulk purchases outside the U.S.
- ◆ Price varies depending on the quantity being procured.

The information provided on this sheet pertains to non-U.S. manufactured tests.

DELIVER John Snow, Inc.

1616 N. Ft. Myer Drive, 11th floor • Arlington, VA 22209 USA

tel.: 703-528-7474 • email: deliver_pubs@jsi.com

February 2005

www.deliver.jsi.com

ENZYGNOST® ANTI-HIV 1/2 PLUS (ELISA TEST KIT)

Manufacturer

Dade Behring Inc.
1717 Deerfield Rd.
Deerfield, Illinois 60015 USA
Tel: +1-847-267-5300
Fax: +1-847-267-1066
www.dadebehring.com

Kit Contents

- ◆ The 192 test kit contains 2 plates of 96 tests.
- ◆ The 960 test kit contains 10 plates of 96 tests.
- ◆ Kits of 960 tests contain:
 - Test plates
 - HIV Ag/POD conjugate
 - Sample buffer
 - Control serum, positive
 - Control serum, negative
 - Washing solution
 - Buffer substrate
 - Chromogen
 - Stopping solution
 - Adhesive foils
 - Polyethylene bag
- ◆ Enzygnost TMB reagent supplies are not included with the 192 test kit, and need to be ordered separately. The reagent kit includes washing solution, buffer/substrate, chromogen, and stopping solution. One reagent kit is sufficient for 4 kits of 192 tests.

Percent Accuracy

- ◆ Sensitivity: 99.6–100%
- ◆ Specificity: 98.7–100%

Types of Samples

- ◆ Serum and plasma (must separate from whole blood)

Run Time of Test

- ◆ 30 minutes

Packaging Information

- ◆ Kits of 192 or 960 tests
- ◆ 25 kits per carton

Test Kit Package

- ◆ Dimensions: 18 x 17.5 x 11.5 cm (192 tests)
- ◆ Volume: 3,622.5 cm³ (192 tests); 18,112.5 cm³ (960 tests)

Storage Conditions

- ◆ Storage temperature: 2–8°C
- ◆ Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- ◆ Expiration date is based on ideal storage conditions.
- ◆ Kit components are stable until expiration date.
- ◆ DO NOT use any component after expiry date.

Shelf Life and Disposal

- ◆ Shelf life: 12 months
- ◆ Disposal methods:
 - Autoclave @ 121°C for 60 minutes
 - Incinerate
- ◆ Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

Quality Control

- ◆ 6 per test run

Indicators of Potential Quality Problems

- ◆ Physical damage to shipping carton, inner box, or test kits
- ◆ Presence of foreign matter inside unit package
- ◆ Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- ◆ Missing contents
- ◆ Leakage or stains
- ◆ Improper storage conditions

Materials Required but Not Provided

- ◆ Piston-type pipettes (25, 100, and 1,000 µL)

Estimated Price

- ◆ Approximately U.S.\$0.75–0.99 per test
- ◆ Price varies depending on the quantity being procured.

VIRONOSTIKA® HIV UNI-FORM II PLUS O (ELISA TEST KIT)

Manufacturer

BioMérieux
F-69280 Marcy l'Etoile
France
Tel: (+33) (04) 78 87 20 00
Fax: (+33) (04) 78 87 20 90
www.biomerieux.com

Kit Contents

- ◆ 192 test kit contains 2 plates of 96 tests
- ◆ 576 test kit contains 6 plates of 96 tests
- ◆ 12 strips per plate, each with 8 wells
- ◆ Can break strips in half and use as 4-well-strips
- ◆ Each kit contains sufficient control serum, specimen diluent, phosphate buffer concentrate, TMB solution, peroxide solution, and plate sealers

Percent Accuracy

- ◆ Sensitivity: 99.6–100%
- ◆ Specificity: 97.6–100%

Types of Samples

- ◆ Serum and plasma

Run Time of Test

- ◆ 2 hours and 4 minutes

Packaging Information

- ◆ Kits must be identified by the catalogue number
- ◆ 192 tests per kit—No. 284017
- ◆ 576 tests per kit—No. 284018

The information provided on this sheet pertains to non-U.S. manufactured tests.



Test Kit Package

- ◆ Dimensions:
27 x 23.5 x 6.6 cm (192 tests);
27 x 23.5 x 9.6 cm (576 tests)
- ◆ Volume: 4,188 cm³ (192 tests);
6,091.2 cm³ (576 tests)
- ◆ Weight: .975 kg (192 tests);
1.550 kg (576 tests)

Shipping Carton

- The shipping carton will hold maximum of:
- 192 tests—8 kits;
 - 576 tests—6 kits
 - ◆ Dimensions: 50 x 29 x 32 cm
 - ◆ Volume: 46,400 cm³
 - ◆ Weight:
192 tests—7.8 kg
576 tests—9.3 kg

Storage Conditions

- ◆ Storage temperature: 2–8°C
- ◆ Allow the reagents, samples, and foil test pack to come to room temperature (15–30°C) before testing.
- ◆ Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- ◆ Expiration date is based on ideal storage conditions.
- ◆ DO NOT use any component after expiry date.

Shelf Life and Disposal

- ◆ Shelf life: 12 months
- ◆ Disposal methods:
 - Autoclave @ 121°C for 60 minutes
 - Incinerate
- ◆ Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

Quality Control

- ◆ 4–5 per test run

Indicators of Potential Quality Problems

- ◆ Physical damage to shipping carton, inner box, or test kits
- ◆ Presence of foreign matter inside unit package
- ◆ Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- ◆ Missing contents
- ◆ Leakage or stains
- ◆ Improper storage conditions
- ◆ Quality control criteria not achieved

Materials Required but Not Provided

- ◆ Microplate washer
- ◆ Microplate reader
- ◆ Incubator
- ◆ Vortex mixer
- ◆ Microshaker
- ◆ Spectrophotometric reader
- ◆ Dispensing system and/or disposable tip pipettes
- ◆ Distilled/deionized water
- ◆ Sulfuric acid
- ◆ Disinfectant
- ◆ Absorbent tissue
- ◆ Disposable gloves
- ◆ Timer
- ◆ Reagent trough
- ◆ Disposable vial
- ◆ Biohazard waste containers

Estimated Price

- ◆ Approximately U.S.\$0.75–1.56 per test
- ◆ Price varies depending on the quantity being procured.

DELIVER John Snow, Inc.

1616 N. Ft. Myer Drive, 11th floor • Arlington, VA 22209 USA
tel.: 703-528-7474 • email: deliver_pubs@jsi.com

February 2005

www.deliver.jsi.com