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LABORATORY LOGISTICS HANDBOOK

A GUIDE TO DESIGNING AND MANAGING LABORATORY LOGISTICS SYSTEMS

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USAID | DELIVER PROJECT, Task Order 1
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Abstract
The importance of quality laboratory services is indisputable. The expansion of programs for human immunodeficiency virus and acquired immunodeficiency syndrome (AIDS), tuberculosis, and malaria requires strong and supportive laboratory services. For antiretroviral therapy (ART) in particular, there has been a growing recognition of this importance, given the number of laboratory tests required to effectively diagnose and monitor AIDS treatment. The need to improve laboratory services for all of these disease programs provides an opportunity to strengthen laboratories in health systems overall so they can accommodate the needs of the communities they serve. This document describes the function and organization of laboratory services and the commodities needed for laboratory services, and it discusses supply chain considerations for management of laboratory commodities.

Cover photos: Left side—Shelves of reagents in Zambia. Photo by Farouk Umaru. 2008. Right side—Labeling drawn blood in a laboratory in Uganda. 2009. JSI.

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ACRONYMS

3TC	lamivudine
AFB	acid-fast bacillus
AIDS	acquired immunodeficiency syndrome
ALT	alanine aminotransferase
APHL	Association of Public Health Laboratories (U.S.)
ART	antiretroviral therapy
AST	aspartate aminotransferase
BD	Becton Dickinson
BMS	Bristol-Myer Squibb
CD4	cluster of differentiation 4 (cells)
CD8	cluster of differentiation 8 (cells)
CDC	Centers for Disease Control and Prevention (U.S.)
cm	centimeter
CSF	cerebrospinal fluid
CV	coefficient of variation
D4T	stavudine
EDTA	ethylene diamine tetra-acetic acid
EFV	efavirenz
EIA	enzyme immunoassay
ELISA	enzyme-linked immunosorbent assay
EQAS	external quality assurance scheme
FACS	fluorescence-activated cell sorting
FBC	full blood count
FEFO	first-to-expire, first-out
FPLM	Family Planning Logistics Management
g	gram
Hgb	hemoglobin
HIV	human immunodeficiency virus
KOH	potassium hydroxide

L	liter
LMIS	logistics management information system
m	meter
mL	milliliter
mm	millimeter
max-min	maximum and minimum
MOH	Ministry of Health
NGO	nongovernmental organization
NPHLS	National Public Health Laboratories Service
NVP	nevirapine
PCR	polymerase chain reaction
PITC	provider-initiated testing and counseling
PMTCT	prevention of mother-to-child transmission (of HIV)
QA	quality assurance
QC	quality control
RNA	ribonucleic acid
RPR	rapid plasma reagin
RT	reverse transcriptase
SGOT	serum glutamic oxaloacetic transaminase
SGPT	serum glutamic pyruvic transaminase
SOP	standard operating procedure
STI	sexually transmitted infection
TB	tuberculosis
TPHA	treponema pallidum hemagglutination assay
TPPA	treponema pallidum particle agglutination
VCNT	ancomycin, colistin, nystatin, and trimethoprim
VCT	voluntary counseling and testing
VDRL	venereal disease research laboratory (test)
WBC	white blood count
WHO	World Health Organization
ZDV	zidovudine
ZN	Ziehl-Neelsen

ACKNOWLEDGMENTS

This publication is dedicated to the many individuals from communities, nongovernmental organizations (NGOs), faith-based organizations, Ministries of Health, and other organizations that have consistently fought for access to essential public health commodities and health services. The publication is also dedicated to friends and counterparts who have worked with the USAID | DELIVER PROJECT and its predecessor projects, the John Snow, Inc./DELIVER Project and the Family Planning Logistics Management I, II, and III projects, and to the thousands of committed professionals in Ministries of Health and NGOs who work daily to supply their customers and programs with essential public health commodities.

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Sincere thanks go to the extended core team of dedicated technical staff from the field and from the project office in Arlington, Virginia, who developed and reviewed this handbook. The lessons drawn from the experience of the USAID | DELIVER PROJECT and its predecessor projects in managing laboratory supply chains in several countries would not have been possible without these valuable contributions.

EXECUTIVE SUMMARY

The importance of quality laboratory services is indisputable. The expansion of programs for human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS), tuberculosis (TB), and malaria requires strong and supportive laboratory services. For antiretroviral therapy (ART) in particular, there has been a growing recognition of this importance, given the number of laboratory tests required to effectively monitor treatment. Well-functioning supply chains will enhance the availability of the commodities required to provide necessary laboratory services.

In most developing countries, laboratories serve both a public health role and a clinical role. The organization of laboratory services usually includes a central or national-level lab, intermediate-level labs, and peripheral labs. Policies help set standards for laboratory practice, including the tests and techniques that will be used at each level in the system, which ultimately dictate the commodities that are required to support laboratory services. The unique characteristics of laboratory commodities impact the way in which the supply chain should be designed and managed to ensure the availability of these commodities. These characteristics include the following:

- Large numbers of commodities are needed. Depending on the levels of the logistics system and variety of testing services provided, laboratory services will need between 350 and 3,000 different commodities to perform testing services.
- Laboratory commodities come in a variety of preparations, including dry powders, liquids, and kits.
- Dry laboratory chemicals and consumable liquids are often packaged in bulk.
- Some laboratory commodities have extremely short shelf lives; for example, some control reagents have a shelf life of three months or less.

Classifying laboratory commodities is critical to designing, implementing, and managing supply chains for those commodities. Based on the unique characteristics of laboratory commodities, recommendations for logistics system design and implementation for laboratory commodities include the following:

STANDARDIZATION

- Follow six recommended steps for standardizing laboratory systems.
- Standardize tests, testing techniques, instrumentation, and standard operating procedures.
- Use standard testing protocols that complement existing treatment guidelines to develop a commodity list for each level in the laboratory supply system.

PRODUCT SELECTION

- Select products that are appropriate based on the testing protocols, cost, training of personnel, and infrastructure for storage and transportation.

- Consider the drawbacks and benefits of closed and open systems for test instrumentation. Though open systems allow economies of scale in the procurement of products, they require a good validation mechanism and continuous reagent quality assurance monitoring.
- Be prepared for changes in test technology.

QUANTIFICATION AND PROCUREMENT

- Use and compare multiple types of forecasting methodologies using logistics, demographic, and services data to forecast requirements for laboratory commodities.
- If using test numbers to prepare the forecast, be sure to include in the quantification all commodities required for quality assurance and quality control, loss and wastage, and training.
- As with any logistics system, make sure that procurement procedures and arrangements are flexible, for more effectiveness in ensuring commodity availability.
- Quantify and procure all items that will be needed to complete a testing protocol. Ensure that shipping schedules are coordinated to make all items available, as needed.

LOGISTICS MANAGEMENT INFORMATION SYSTEM

- Consider two ways of capturing consumption data for laboratory commodities: issues from stock as a proxy for consumption data (stock issued from the stores to the bench) or actual consumption of products (by the piece, gram, milliliter) as recorded through a daily register.
- Review each product, and how it is issued and used, to determine which is the appropriate unit for stockkeeping and reporting.
- Use and maintain stock-keeping records; consider the pros and cons of having one or multiple stock cards for each of the different packaging sizes of the same commodity.
- Routinely report stock levels, issues, losses and adjustments, and stockouts. Link reporting with resupply as data are required to make supply chain decisions at all levels of the system.
- Computerize the logistics management information system where possible.
- Develop logistics reports that are easy to complete and as concise as possible but flexible enough to accommodate program changes.

INVENTORY MANAGEMENT

- Ensure that the length of the pipeline accommodates the shelf life of the products.
- If using a maximum-minimum (max-min) inventory control system, consider the standard or forced ordering versions.
- Adjust order quantities for stockouts.
- Consider assigning different maximum and minimum stock levels for slow-moving and fast-moving commodities.
- Full-supply and non-full-supply commodities can be managed concurrently, if there is a transparent process for ordering and resupply.
- If staffing is limited, institute a push system for resupply to peripheral levels.

- Link ordering or resupply to reporting.
- Supply together commodities that need to be used concurrently to complete a testing protocol.

STORAGE AND DISTRIBUTION

- Develop guidelines for appropriate storage for each level of the system, taking into account any variations that will exist in the types of products at each level of the laboratory network.
- Maintain a cold chain for laboratory commodities that require it.
- Store flammables separately, and ensure that a fire-extinguishing mechanism is available.
- Store corrosives at normal room temperature, at ground level, and in the original manufacturer's containers.
- Keep laboratory commodities in the original packaging to protect light-sensitive commodities.
- Maintain commodities under the appropriate storage conditions during distribution.

Supply chains operate within a policy environment, with certain laboratory management practices that have supply chain implications. Recommendations for these management practices are as follows:

QUALITY ASSURANCE AND QUALITY CONTROL

- Include procedures for managing commodities in the quality assurance program.
- Define and enforce procedures and policies for internal and external retesting for quality control.
- Establish procedures for routine visual inspection of laboratory commodities.
- Establish procedures for handling of suspect, damaged, or expired commodities.

STAFFING AND MANAGEMENT

- Provide training in logistics management procedures to laboratory staff members, and establish a mechanism for communicating information on new commodities.
- Develop a schedule of routine supervision to support laboratory staff personnel.

POLICY AND REGULATORY ENVIRONMENT

- Work with national-level personnel to develop and encourage policymakers to approve testing guidelines and protocols and to clarify what personnel, by level, are qualified to provide each test.
- Work with national-level personnel and policymakers to ensure that guidelines and policies for infection prevention and universal safety precautions are put in place (including guidelines and policies for waste disposal).

FINANCING FOR LABORATORY COMMODITIES AND LOGISTICS SYSTEMS

- Establish a Laboratory Commodity Committee to coordinate donor and government inputs and to develop a commodity security strategy for laboratory services. In addition, this committee

could periodically monitor and review the standards established during the standardization exercise.

- Work with policymakers to establish a specific budget for laboratory commodities and the logistics system in which they are managed.

INTRODUCTION

Managing supply chains in support of laboratory services is a formidable challenge, especially in developing countries. Laboratory services play a significant role in a country's health system and in the delivery of quality health services. Expanding programs for human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS), tuberculosis (TB), and malaria require strong and supportive laboratory services. Laboratory capacity depends on the availability of the required commodities to perform these tests, with most tests requiring multiple commodities to be available simultaneously. Well-functioning supply chains will enhance availability of the commodities required to provide the necessary laboratory services.

Laboratory services support clinical practice by screening for different conditions and providing information for differential diagnosis, allowing clinicians to choose appropriate treatment regimens and monitor treatment. When diseases are diagnosed incorrectly, not only does the patient suffer, but valuable medicines are wasted treating a disease for which they are not effective. Correct diagnoses based on lab tests would prevent incorrect diagnoses and treatment, and the money saved could be used to purchase drugs and treat patients effectively. Monitoring tests enable clinicians to determine whether treatment is efficacious or toxicity is developing, enabling them to take action to protect the patient. In public health, laboratory tests are necessary to identify the causal agent of an epidemic (e.g., yellow fever, meningitis, severe acute respiratory syndrome); early identification of the causative agent allows rapid treatment and containment of the disease to prevent further spread.

The USAID | DELIVER PROJECT's experience has shown that to strengthen laboratory supply chains, it is necessary to look at management practices, capacity, and services. Laboratories are a service area. Product is not directly dispensed to clients, but rather utilized through the service of testing; therefore, the way laboratories function, including their human resource and equipment capacity, will impact the use of products. Consequently, this document provides basic information to logisticians on—

- the function and organization of laboratory services
- commodities for laboratory services—reagents, consumables, durables, and equipment
- supply chain considerations for management of laboratory commodities.

The appendices to this document include valuable reference materials. In addition to a glossary (appendix A), the reader will find information on laboratory tests (appendix B) and the commodities needed to perform them (appendix C), plus more detailed information about laboratory tests for diseases of public health significance, particularly HIV, sexually transmitted infections (STIs), TB, and malaria (appendix D). Sample records and reports for a logistics management information system (LMIS) for laboratory commodities are included in appendix E.

FUNCTION AND ORGANIZATION OF LABORATORY SERVICES

Public health and clinical laboratory services play a vital role in a country's health system delivery. For health laboratory services to be successful, it is essential that labs operate within a system that provides the necessary support for the entire network of labs, including support for supply chain activities, from central to intermediate to peripheral labs.

THE ROLE OF PUBLIC HEALTH AND CLINICAL LABORATORY SERVICES

In developed countries, public health laboratories and clinical laboratories exist as separate entities and operate under different managing authorities. The public health laboratories are run by national or state departments of public health and support the public health system, complementing other services provided. Clinical laboratories usually comprise private and public laboratories that focus exclusively on the provision of clinical services to the individual. The focus of this manual is on laboratories serving the public sector that come under the authority of the Ministry of Health (MOH) or similar agency.

In most developing countries, the distinction between public health and clinical laboratory service is not delineated, and most laboratories serve both a public health and a clinical role, often with an emphasis on the clinical. Laboratories serve the following roles to varying degrees, given the local needs, the available resources, and the policy environment in which they operate.

The role of the public health laboratory is to—

- provide data to assess the health of a community
- investigate, identify, report, and control infectious and emerging diseases
- inform and educate the public and community officials about risks to health
- train laboratory professionals
- participate in formulation of policies that ensure the quality of laboratory services in the country
- conduct reference and specialized testing, public health research, testing for food safety and water sanitation, and drug resistance and susceptibility testing
- provide diagnostic testing to support clinicians in the treatment and overall clinical management of health conditions in individual health facilities, such as hospitals and clinics
- serve as a reference laboratory for clinics at lower levels of the health system.

ORGANIZATIONAL STRUCTURE OF LABORATORY SERVICES

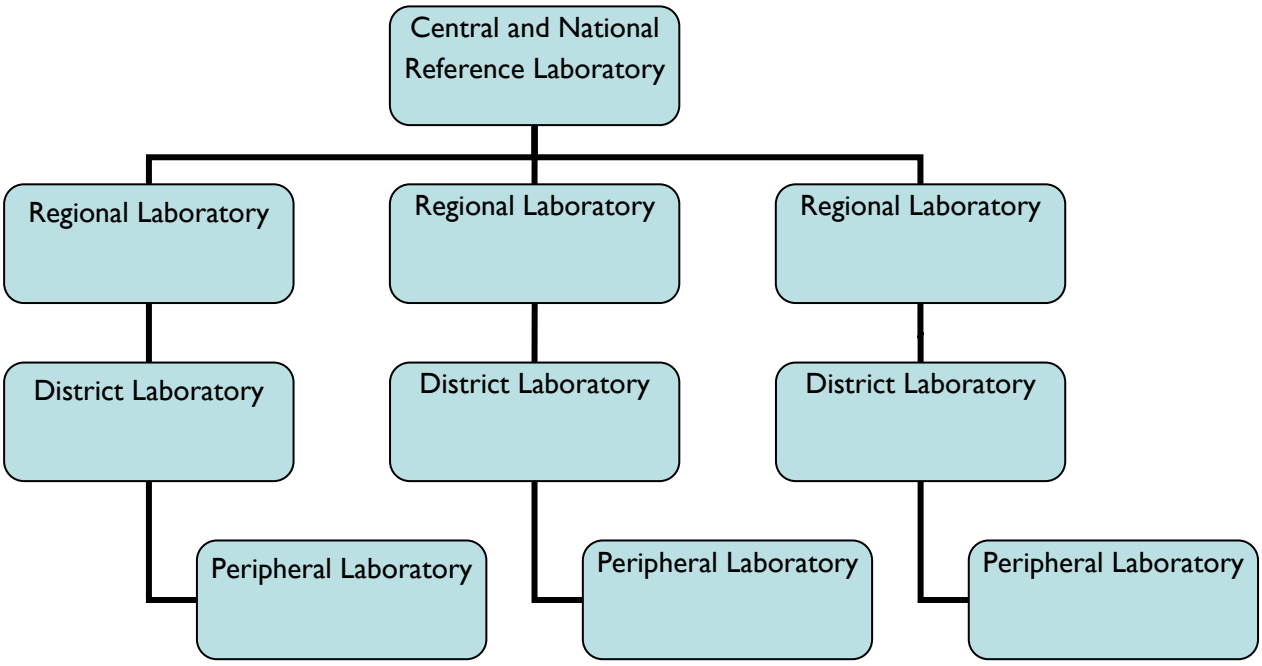
The organization of laboratories in a country will be determined by local policies, administrative structure of the health system, geography, and population considerations. Like other health services, the laboratory network is often organized by administrative levels:

- Central or national reference laboratories provide all laboratory services possible within the health system of the country.
- Intermediate lab facilities provide less complex services.
- Peripheral labs, which are usually located at the health centers and smaller service delivery sites, provide basic laboratory services.

There can be variations in this structure, and the relationships between these structures can vary between countries. For example, the expansion of HIV and AIDS and malaria programs has expanded the use of laboratory commodities out of traditional laboratory settings and by non-laboratory personnel. HIV tests may have once been administered only through laboratory scientists, but now can be administered by nurses, counselors, and health workers in voluntary counseling and testing (VCT) clinics and through mobile units.

Typically, higher-level lab facilities provide supervision, quality control, and technical support to lower-level facilities. Figure 1 illustrates a common organizational structure for lab services.

Figure 1. Organization of Laboratory Services



Different cadres of laboratory personnel are trained in a range of laboratory skills from in-service training, for laboratory aides and microscopists, to doctorate-level university training. These trained personnel can be found distributed across all levels of the laboratory system, depending on the policies and training requirements for each level in a particular country.

NATIONAL REFERENCE LABORATORIES: ROLE AND ORGANIZATION

A national reference laboratory is not usually managed within the national laboratory network; rather, it is considered a center of excellence. National reference laboratories are sometimes supported by external donors such as universities and research centers, which often provide necessary resources. These laboratories offer comprehensive, high-skilled testers beyond those offered at the central-level laboratories. These services at this level are highly specialized and the techniques used are often complex and automated, including specialized testing (e.g., for emerging diseases), disease surveillance, and research.

The role of the national reference laboratory is also to provide technical support and guidance to the laboratory system. The national reference laboratory generally is mandated to—

- develop standard operating procedures (SOPs) for testing services
- report and manage diagnosis and monitoring of communicable disease outbreaks
- develop a quality assurance (QA) scheme
- provide guidance to the other laboratories in management of rare diseases.

Some national reference laboratories specialize in a particular disease category and are responsible for overseeing the surveillance of that disease. In this case, this laboratory may also be the last referral site in diagnosis of certain strains of the disease; for example, a TB reference laboratory may process drug sensitivity tests for TB patients but does not perform routine TB diagnosis. This is usually the case if the test procedures are highly specialized.

CLINICAL LABORATORY SERVICES: ROLE AND ORGANIZATION

Clinical laboratories are situated in health institutions and support the delivery of health services to patients, including with diagnosis and monitoring. The organization of these laboratories differs between countries depending on how the health system is structured. These laboratories make up a network of laboratories that primarily perform diagnostic and monitoring services, though with the advent of HIV these laboratories have also become involved with screening and surveillance activities.

The management of these laboratories usually falls under a unit within the MOH that oversees the management of human resources (staff deployment, development of training curriculum for the universities and teaching centers, staff training, staffing scheme per level), support and supervision, and budgeting for national laboratory services.

Central-level Laboratory

The central-level laboratory is the highest-level laboratory within the national network of laboratory services and is usually linked to the central referral hospital or central teaching hospital. Generally,

the central laboratory provides the widest range of tests available to patients and is divided into several departments, including hematology, biochemistry, parasitology, bacteriology, histology, immunology, and virology.

The central laboratory usually serves as a laboratory to which lower-level facilities may refer samples. It is typical for laboratories within a network to refer samples to a higher-level facility when they do not have the capacity, technology, or equipment to process samples at their level. Lower-level laboratories that are linked within a laboratory network will refer samples up the chain when they are not able to process them; for example, a provincial-level lab may refer samples to the central-level laboratory.

Central-level laboratories are usually not responsible for managing laboratory commodities beyond those needed to carry out their own laboratory services. Generally, the central medical stores or its equivalent manages laboratory commodities with other commodities, such as essential medicines. Some exceptions exist. In Kenya, the central laboratory stores and distributes laboratory commodities to lower-level laboratories in the network. The central-level laboratories are usually responsible for forecasting national laboratory commodity needs for all laboratories in the network and for working with the central medical stores to ensure timely procurement of those commodities.

Intermediate Laboratory

In most developing countries, intermediate laboratories are located at district or regional hospitals and may act as clinical and public health laboratories. Intermediate laboratories help in the diagnosis and treatment of the individual patient and are also used as public health laboratories for epidemiological surveillance and control of diseases in the community. Those laboratories serve as links between peripheral laboratories and the central laboratory for the following services and functions:

- laboratory support to clinical diagnosis and public health initiatives
- support for QA at intermediate and peripheral levels
- logistics support and technical guidance
- training of staff at peripheral laboratories
- supervision and performance monitoring of peripheral laboratories
- collection, storage, and analysis of data
- distribution of reagents, consumables, and laboratory manuals
- purchase of equipment
- supervision of peripheral laboratories
- facilitation of the external quality assurance scheme (EQAS) for peripheral laboratories
- implementation of the EQAS organized by the central laboratories
- transmission of samples to higher or reference laboratories for further and more detailed examination, such as characterization of isolate and confirmation of diagnosis.

Peripheral Laboratory

Peripheral laboratories are located at the patients' first point of contact with the health system: health centers. These laboratories support preventive, curative, and health promotion services for

the individual and the community. Peripheral labs focus on common diseases and conditions and offer basic testing services. They conduct tests such as hemoglobin, malaria, HIV, TB, and pregnancy using simple testing techniques. Peripheral laboratories sometimes just collect samples and refer them to higher-level laboratories within the system, rather than processing samples on-site.

COMMODITIES FOR LABORATORY SERVICES

CHARACTERISTICS OF LABORATORY COMMODITIES

The characteristics of laboratory commodities affect the design and management of the logistics system. For example, reagents can come in a variety of preparations (solid, powder, liquid). The physical presentation of a commodity has implications for how data are collected and reported, storage and distribution, and quantification.

Large numbers of commodities are needed. Depending on the levels, laboratory services will need between 350 and 3,000 different commodities to perform testing services.

Each test performed in a laboratory requires several different commodities. For example, a simple malaria test can require nine commodities: five reagents and four consumables. More complex tests often require more commodities, including equipment. As illustrated in appendix B, the lowest-level laboratory may offer as many as 20 or more tests, whereas higher-level laboratories may offer 50 or more; appendix C demonstrates the range of commodities needed to perform a test. Although one test may require some of the same commodities as another test, typically laboratories will need to manage several hundred or, in some cases, thousands of individual commodities. The number of commodities will be determined by the number of levels of laboratory services, the size of the country, and the level to which laboratory testing is standardized. The sheer number of commodities has serious implications for most logistics functions and activities, particularly the design and management of the logistics information and inventory control systems, as well as quantification and procurement.

Laboratory commodities come in a variety of preparations, including solid and liquid reagents.

Many reagents come as solids that are measured and reconstituted with distilled water for use in tests. Solid reagents are measured using a balance or scale; the liquid used for reconstitution is measured using a graduated measuring cylinder, volumetric flask, or pipette. The solution is held and stored in a reagent bottle. Solid reagents generally have a longer shelf life than do liquid reagents; the shelf life is significantly shorter for the reconstituted reagent. Reagents that come in liquid form are often packaged in glass bottles. Amber glass is used to protect the reagent from light. Reagents packaged in glass bottles are heavier than solid powders, and the bottles break more easily during distribution.

Peripheral-level laboratories sometimes do not have scales or balances to weigh solid reagents and therefore rely on the intermediate-level laboratories to reconstitute the solutions. This practice has several supply chain implications relating to the packing and transporting of commodities, determining how to capture consumption by level, and workload issues.

Laboratory commodities can be packaged in kits.

Several tests come as kits that contain all or most of the commodities required to perform that particular test. The number of tests per kit can vary and should be specified during the procurement process. The kit always contains the reagents for the test, but it may also include consumables used for collecting and processing the sample. In some cases, those consumables need to be obtained separately. For example, the Uni-Gold™ HIV rapid test kit is packaged with 20 test devices that contain the reagents, wash reagent, and 20 disposable pipettes. To perform the test, however, the technician needs a timer and blood collection devices, which are not included in the kit package. In other cases, the quantity of consumables may not be sufficient for the number of tests that can be performed by the reagents included and additional quantities will need to be ordered. Also, the components of some kits may expire at different times.

Figure 2: Example of a Rapid HIV Test Kit

Dry laboratory chemicals and consumable liquids are often packaged in bulk.

Some laboratory commodities, particularly less expensive, often-used consumables such as disinfectant, isopropyl alcohol, and distilled water, are procured and distributed in bulk. Such items may be distributed in gallon jugs or large drums. Some dry powder reagents are also distributed in bulk. Commodities distributed in bulk generally are ordered less frequently and require more storage space. In some cases, higher-level facilities may be redistributing in smaller quantities the commodities that they receive in bulk. Those facilities need to be sure they have sufficient materials available for repackaging bulk commodities.

Some laboratory commodities have short shelf lives.

Most laboratory reagents have a shelf life of approximately 24 months. However, certain reagents have much shorter shelf lives, ranging to less than 7 months; others have longer shelf lives of up to 36 months. As a general rule, dry powder reagents, when stored properly, have a longer shelf life than do liquid reagents, and reconstituted reagents have a shorter shelf life than do liquid reagents. The length of the shelf life is an important consideration when developing the supply pipeline for laboratory commodities; a short shelf life requires a shorter pipeline. Table 1 shows the shelf life (under ideal storage conditions), storage temperature, and packaging information of an illustrative list of laboratory supplies.

Table 1. Illustrative List of Reagents and Storage Information

Reagents	Shelf Life	Storage Temperature	Packaging
CD4 antibody reagent	≥7 months	2°–8°C	50 tests per kit
Chemistry reagent kits	12 months	2°–8°C or 21°–24°C	100 tests per kit
Blood typing sera	24 months	2°–8°C	5 mL bottle (6 bottles per package)
Bacteriological media	36 months	21°–30°C	500 g bottle
Stains, dry powder	60 months	21°–30°C	25 g bottle

Some laboratory commodities have special storage requirements.

Because such a wide variety of commodities is required for laboratory services, there is a wide variety of storage requirements for their maintenance. Most laboratory commodities can be stored following general storage procedures for health commodities. However, laboratory commodities also include—

- flammables and corrosives, which should be stored separately from other commodities
- reagents, which require several levels of temperature storage, including—
  - cool storage, which requires temperature conditions up to 25°C
  - cold storage, which requires refrigeration between 2°C and 8°C
  - frozen storage, which requires frozen conditions of either –20°C or –70°C.
- commodities that deteriorate rapidly when exposed to light or moisture
- specimens (fragment of tissue) that require freezing.

CLASSIFICATION OF LABORATORY COMMODITIES

For the purpose of supply chain management, including designing and managing laboratory logistics systems, there are various ways to classify laboratory commodities. These classifications include—

- reagents, consumables, durables, and equipment
- slow-moving and fast-moving
- long shelf life and short shelf life
- non-full supply and full supply.

Because of their sheer numbers, laboratory commodities should be classified to rationalize logistics decision making. These classifications may be considered in combination when determining how commodities should be managed.

REAGENTS, CONSUMABLES, DURABLES, AND EQUIPMENT

For logistics purposes, laboratory commodities can be classified into four categories: reagents, consumables, durables, and equipment. Each category of products has different supply chain considerations. For example, reagents and consumables are generally commodities that are routinely ordered and resupplied. Durables and equipment, on the other hand, are ordered on an as-needed

basis (e.g., every year or every several years) and do not require the same level of logistics management. This document concentrates on management of reagents and consumables. However, all commodities are interdependent, and each category of product is often required to run a single test.

- **Reagents** are chemicals and biological agents that are used in laboratory testing for detecting or measuring an analyte (the substance being measured or determined). The reagents vary widely in cost, stability, cold or cool chain requirements, availability, and the hazards associated with each variant. Reagents are usually available as solids or liquids.
- **Consumables** are items that are used once while performing a test and are not reused. Consumables can include test-specific items, such as thermal paper required to run a CD4 count. Other consumables cut across all testing services and are classified as general laboratory consumables, such as bleach, alcohol, and gloves.
- **Durables** are items that can be reused for multiple tests. They include items such as glassware that can be washed, sterilized, and reused.
- **Equipment** refers to semi-automated or automated machines and instruments used in testing. Equipment ranges from complex automated equipment such as chemistry machines that require regular preventative maintenance and servicing to basic equipment such as microscopes and water baths. The servicing requirements for the equipment also vary considerably. For example, a CD4 machine is a relatively complex machine that requires servicing and maintenance, spare parts, consumables, and reagents. A spectrophotometer does not require as much servicing and maintenance as a CD4 machine does.

Figure 3 below represent all of the commodities (reagents, consumables, durables, and equipment) required to run a CD4 count using the FACSCount machine. Even though each category of products must be managed, stored, and ordered differently, proper logistics ensures all of the commodities are required simultaneously to run a CD4 count.

Figure 3. Reagents, Consumable, Durables, and Equipment Required to Run a CD4 Count

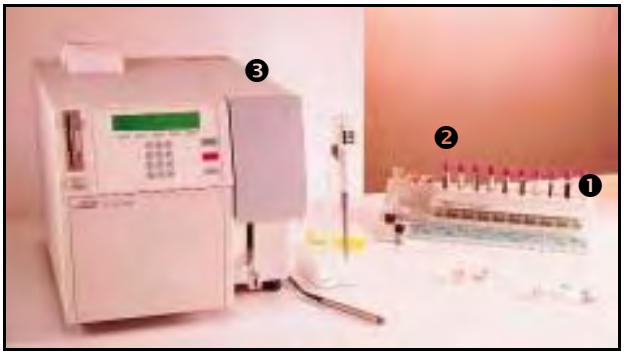


Photo courtesy of www.bdbiosciences.ca

Reagents	Consumables	Durables	Equipment
FACS flow	EDTA tubes ❶	Digital micropipette ❷	BD FACSCount instrument ❸
FACS clean	Lab request form	Micropipette charger	
FACS test kit	Thermal paper	Vortex mixer	
FACSCount controls	FACSCount Wire	Timer	
Distilled water	Laboratory register		
	Vacutainer needle holder		
	Vacutainer needle		
	Micropipette tips		
	Chlorine bleach		
	Disposable gloves		

SLOW-MOVING AND FAST-MOVING

Commodities may be classified as slow-moving or fast-moving. Slow-moving commodities are those that will take several months to be consumed once issued to the bench. In the process of identifying slow- and fast-moving commodities, it is important to include a timeframe of reference. The rate of consumption also typically depends on level. For example, a 100 g bottle of basic Fuschin used for staining may take several months to finish at a peripheral-level facility, and therefore would be considered slow-moving. In contrast, the same bottle may be used up in a matter of weeks at a regional-level facility and therefore would be considered fast-moving. Conversely, microscope slides on which the staining is performed at the peripheral-level facility would be a much faster-moving commodity because microscope slides are used for this test and many other types of testing and are disposed of after one use. This distinction is important from a supply chain perspective because it impacts how much stock a facility would want to keep and how much should be reordered and when, based on how quickly and how much product was consumed and the shelf life (see below).

Classifications should be used in combination to help determine how they should be managed. For example, a slow-moving product with a long shelf life should be managed differently than a slow-moving product with a short shelf life.

LONG SHELF LIFE AND SHORT SHELF LIFE

Furthermore, commodities may be classified according to the length of their shelf life. When logistics systems for laboratory commodities are being designed, because of the extraordinarily short shelf life of certain control agents it is important to classify these commodities differently than other products, because their management (including the ordering and

The commodities required to run a single test may have differing shelf lives. For example, the commodities required to run an automated hematology test include hematology controls that have a shelf life of up to three months; hematology reagents that have a shelf-life ranging from one to three years; and consumables, such as Vacutainer containers, that have a shelf life of three years or more.

distribution) will in most cases be different to accommodate the short shelf life. For example, controls for QA often have a three-month shelf life and may be distributed and managed through a completely separate pipeline.

FULL SUPPLY AND NON-FULL SUPPLY

The term *full supply* means that commodities are available for anyone who needs them. For example, contraceptives are often in full supply, meaning that enough contraceptives are procured and are in country to make them available to anyone who wants them. In a max-min inventory control system, full supply means that facilities will be able to reorder and receive commodities up to their maximum stock level.

For laboratory commodities, full supply and non-full supply are not generally as straightforward as with other commodities. Laboratory supply chains manage hundreds or thousands of commodities and are generally underfunded; resources supporting services often are not well coordinated and therefore are not able to meet all commodity requirements. Though everyone strives for an environment where commodities are in full supply, unlike other products (e.g., contraceptives, antiretroviral drugs), laboratory commodities as a general group are not generally in full supply. However, in some instances some laboratory commodities are in full supply (e.g., CD4 reagents or HIV tests) because they are supported by a particular donor or program. In addition, it may be true that a facility such as a teaching hospital may have sufficient funding to have all commodities in full supply, whereas a primary health center laboratory might not. Finally, full supply and non-full supply are dynamic categories for labs, meaning that commodities may be in full supply one year and not the next, and therefore systems must be dynamic enough to account for this changing environment. The full supply of some commodities and not others has significant implications where multiple commodities have to be available simultaneously in order to perform a particular test. If even one commodity is missing, it may not be possible to perform the test.

Though significantly complex, the distinction between full-supply and non-full-supply commodities is important in managing laboratory supply chains. Categorizing commodities as full supply or non-full supply makes it possible to prioritize these commodities for resource mobilization and advocacy. In addition, these distinctions are important in the design of logistics systems, specifically inventory control systems and LMIS. All of the commodities required for a particular test should simultaneously be available in full supply, because it would not be possible to conduct the test if even one is missing. This categorization can allow for the management of different products in the same system, if there is a transparent process for ordering and resupplying and staff are aware of the distinction between these products. This awareness will help them to understand why they might get everything they order of full-supply products and not get the full order of non-full-supply products.

STANDARDIZATION

Standardization is a prerequisite to strengthening laboratory logistics systems. Standardization is the process of establishing test menus, techniques, operating procedures, and laboratory equipment for each type of test and for every level in the system. The standardization of test techniques and equipment helps to identify the specific reagents and consumables required for resupply, most often limiting the actual variety of numbers of individual items required. The development of national laboratory policies should lead to standardization of laboratory practice, which enables quality services and simplifies the supply chain. Standardizing the test menus, techniques, operating procedures, and equipment—

- facilitates affordability through economies of scale by enabling the program to buy larger quantities of fewer items
- enhances manageability by streamlining the number and range of commodities, which eases the burden of stock management
- enables rational decision making through the supply chain, particularly in product selection, forecasting, quantification, and procurement, because there are fewer items to manage
- facilitates agility in the supply chain allowing redistribution of commodities to reduce stock imbalances, because facilities using the same techniques and equipment are using the same commodities.

More information about the benefits, challenges, and steps in standardization can be found in the USAID | DELIVER PROJECT's *Laboratory Standardization: Lessons Learned and Practical Approaches*.

Standardized laboratory systems require the management of hundreds of commodities; in nonstandardized systems the number of commodities easily runs into the thousands, because different tests can be conducted using different techniques, each of which can have unique commodity requirements. The number of commodities required in a nonstandardized system presents unique challenges to supply chain management and quality, including the following:

- Managing such a large number of commodities through a single supply chain is very difficult. All of the commodities required for each test and technique add up to a large number of products that must be resupplied to facilities, stored at various levels in the system, quantified, and procured.
- If facilities at the same level are not using the same techniques and/or equipment and therefore require different products, this reduces the ability to redistribute products and the overall agility in the supply chain.
- Comparison of results from laboratories using different methods is limited. Similar laboratories are easily comparable and so performance in EQASs is comparable. The scheme is less complicated to organize and run, and results can be used to identify areas of good performance and those needing attention in the entire lab network.

CHALLENGES TO STANDARDIZATION

A number of challenges are inherent to the standardization process itself, including the following:

- Technologies for key laboratory tests are routinely changing, and programs often want to change standards as technologies both emerge and improve.
- Agreeing on equipment, at least on major equipment such as automated platforms, can be difficult because there are many options and in-country partners and stakeholders often have different preferences. Even when consensus is reached, the standardization process will almost certainly result in the obsolescence of equipment that had been in use in the nonstandard systems.
- The tests and techniques agreed on in the standardized system may not be consistent with the tests and techniques that laboratory staff have been previously trained to use or that they currently use in their laboratories.
- Procurement laws do not usually allow laboratory staff to request particular brands of equipment but instead must give specifications to the procurement unit, which then tenders based on the specifications. In implementing standardization, it is necessary to set in place a policy that allows laboratory equipment to be the exception to this practice. The procedure for reviewing the standardized equipment should be transparent and should not allow monopolies.

STEPS TO STANDARDIZATION

There are roughly six steps to standardizing laboratory systems:

- Conduct a baseline assessment to gather information from all facilities across levels in the system. The assessment should obtain the following information for each level in the system: What are the test techniques? What are the existing test menus? Which equipment is used and functioning? Is there a majority of certain test techniques, menus, and equipment concurrently in use at different levels of the system? What are staff trained on and using?
- Analyze results to facilitate decision making. In particular, the analysis should take into account whether there is a clear majority (for certain menus, techniques, SOPs, and equipment being used), if these standards are written down, and what the implications of changing existing practice might be.
- Hold a consensus-building workshop with stakeholders from all levels. Include representatives from all levels of the system in order to get perspectives from those at the central, facility, and intermediary levels and enable a productive dialogue between the stakeholders who are necessary for a final agreement. Include clinicians and program staff when selecting test menus as they are the customers of the laboratory services and it is important to consider their needs.
- Update standard equipment lists and operating procedures. Once standards have been defined, standard equipment lists and SOPs must be updated.
- Disseminate and implement standards to all facilities at all levels. Standardization outcomes must be documented and disseminated to all levels in the system in order to be fully implemented. It is important to develop the transition plan from the current standards to the new standards and recognize that it will take an investment of resources and time to change current practices.
- Review and update the SOPs regularly. In light of rapidly changing technology, the standards must be reviewed periodically to ensure that they are most appropriate for the current context.

RECOMMENDATIONS IN STANDARDIZATION

Make the process collaborative.

Conducting the standardization process through a consensus-building workshop allows appropriate and feasible SOPs to be developed. Although it is possible for national laboratory program managers to decide alone on standard testing procedures and the selection of laboratory supplies, the critical questions of infrastructure capacity and laboratory personnel skills to implement those decisions can be addressed only through a forum in which stakeholders representing the laboratory system are present. The risk of omitting wider stakeholders is that appropriate types of reagents and equipment will not be selected, thus leading to stockouts, stock imbalances, and wastage. Assembling a diverse group enables any and all questions to be answered in one forum. For example, program managers are able to provide clarification on higher-level policy considerations, clinicians can ensure that the testing services are in line with the standard treatment guidelines, and representatives from individual laboratories are able to inform participants about the feasibility of implementation at the lowest levels.

Review existing standards periodically.

The timing and review of agreed upon standards is key; if the reviews are too frequent, then countries may introduce too many different types of equipment with each review, and if standards are reviewed too infrequently, then countries may keep outdated equipment when it should be discarded. A committee composed of laboratory personnel and experts (including clinicians) from all levels of the system should be organized to undertake these reviews regularly. Though the frequency of the review should be determined on a country-by-country basis, countries might consider starting with annual reviews, at least to determine if anything significant that has taken place might warrant a closer look. This review should be done around the time of the annual quantification, given that the tests, equipment, and technique will impact commodity requirements.

Enforce new standards through the national laboratory policy.

For individuals at all levels of the system to be able to act on the standards, the standards must be incorporated into the national laboratory policy and disseminated to all relevant staff and stakeholders.

Ensure that all donations comply with new standards.

Although the standards are written in laboratory policies, their enforcement is often challenged when partners or donors donate commodities that are not in line with the standard equipment or commodities. In the majority of countries where the USAID | DELIVER PROJECT works, equipment donations are common, and many times these donations are not in compliance with the standards. Standardization is often compromised when MOHs do not have enough money to buy machines and partners and donors are not able to pledge support for machines and reagents for an extended period. In such cases, parallel supply chains may be set up to provide reagents and other consumables for different equipment.

Address potential barriers to implementation in a transition plan.

Implementing recommendations following a standardization process presents several challenges, the greatest of which may be the fate of equipment that is outside the standardized system. Logically, the equipment should be removed from the system. However, most laboratories are reluctant to discard any instrument, whether or not it works—especially high-value equipment. The decision to

remove nonstandardized equipment has financial implications. The public health laboratory system will have to secure funding and replace instruments that do not match the published standards. This will pose a challenge for the donor community by limiting its procurement options.

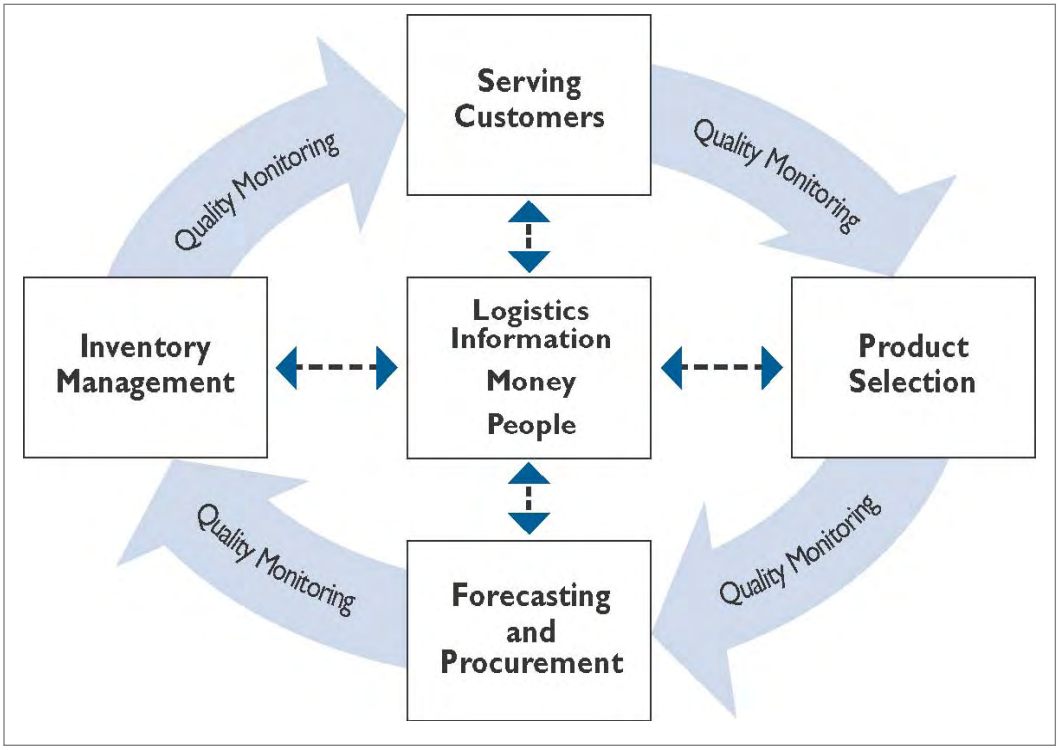
Another challenge that countries face when they standardize their laboratory system is the potential inconsistency between the standards and the training of the current laboratory staff. A change in standards may require additional training for personnel. Traditionally, personnel experience and the availability of equipment and supplies have guided testing techniques rather than standards. Consequently, during the consensus-building workshop, these issues need to be addressed and solutions need to be incorporated in the implementation strategy.

An implementation plan is as critical as the standardization process itself. Standardization is never complete until the challenges of implementation, such as training gaps and inconsistencies in the types of supplies and equipment, are addressed.

SUPPLY CHAIN CONSIDERATIONS FOR LABORATORY COMMODITIES

The logistics cycle provides a guiding framework of the functions needed to manage all health commodities, including laboratory commodities (see figure 4). Specific issues and considerations for managing each of those functions for laboratory commodities follow, along with recommendations for logistics system design and implementation for laboratory commodities.

Figure 4. The Logistics Cycle



SERVING CUSTOMERS

In laboratory logistics, there are many customers with varying expectations and needs. Customers of laboratories include the following:

- patients, who rely on laboratory results for an accurate diagnosis of their health condition
- clinicians, who rely on laboratory test results for the diagnosis and clinical management of patients

- other health care providers, including VCT providers and blood bank professionals, who rely on lab results to effectively perform their duties
- epidemiologists, who use lab results to determine the source case in an outbreak or to conduct contact studies
- policymakers, who use lab data to monitor the overall functioning of the laboratories in the health system
- laboratory staffs.

Communication between laboratory personnel and clinicians is critical. Laboratory personnel may have training to perform certain techniques and may have the product to do the technique. However, if the clinician does not know that the facility has the capacity to perform the tests and does not order them, the tests will never be performed. Products could expire and not be replaced because there has been no demand for that particular test.

Laboratory staffs are perhaps the most important customers of the laboratory logistics system. They rely on the commodities they receive to perform tests and provide results. The commodities they receive need to be in constant supply and of good quality. Laboratory personnel play a vital role in ensuring that the laboratory logistics system works.

LOGISTICS MANAGEMENT INFORMATION SYSTEMS

In all programs and for all commodity categories, personnel make routine decisions that affect commodity availability. They determine how much of each commodity to order or resupply. They forecast future demand for commodities and plan procurement and shipments. They identify potential supply problems and handle other issues related to commodity management.

An LMIS provides the mechanism through which personnel collect, manage, and report such information, which is necessary to support sound and objective logistics decision making. The goal of this decision making is to ensure an uninterrupted supply of commodities and to identify any problems in the supply pipeline. Data provided through the LMIS also help inform policy and product selection decisions.

Typically, an LMIS should collect the three essential data items needed to make logistics decisions: stock on hand, quantities dispensed to user or used in a given period (consumption), and losses and adjustments to stock for purposes other than use (expiry, damage, theft, etc.). Those data are recorded on stock-keeping records, transaction records, and consumption records. The data are then used at the facility and are reported to higher levels for resupply and management purposes. Information provided to higher levels is processed and reported back to lower-level facilities in feedback reports to encourage and improve the performance of the logistics system. For a more complete description and discussion of LMIS, refer to John Snow, Inc./DELIVER's *The Logistics Handbook* (2004b).

A laboratory logistics system, like any other supply chain, requires an LMIS. However, because of the nature of the commodities and their use, the LMIS should be adapted for use in the laboratory. A laboratory LMIS should record and report stock on hand, consumption, and losses and adjustments.

As discussed below, issues data from the storeroom to the bench should be routinely used for calculating resupply for most commodities. The collection of actual consumption data should be limited to a small number of commodities, if any.

CHALLENGES IN LMIS

- Unlike commodities such as tablets or capsules that can be easily counted, many laboratory commodities are liquids or powders that are difficult to count. Only a few drops or a weighed measure of a laboratory commodity may be used at a time. The same commodity may be used for a variety of different tests and by a number of different people in a single laboratory, thereby making actual consumption of the commodity—either as its actual use or as a function of the number of tests performed—difficult to track and measure. Add to this challenge the number of commodities used in a laboratory, and the task of tracking consumption becomes unmanageable.
- In addition to use for actual tests, a percentage of laboratory commodities are used for quality control (QC) purposes. Distinguishing the use of commodities for QC from the use of commodities for testing is difficult and time-consuming.
- Because of the short shelf life of reconstituted reagents, they may be discarded before being completely consumed, and therefore are wasted. Wastage is the quantity of a commodity that is lost during the performance of a test, and is associated with the technique and equipment used. A certain amount of wastage should be expected in laboratory services. This wastage differs from loss caused by damage, expiry, or theft. Loss should be tracked in an LMIS, while wastage is included in consumption.

RECOMMENDATIONS FOR LMIS

Consider two ways of capturing consumption: issues from stock as calculated consumption or tracking actual use through daily registers.

There are two major ways of capturing consumption for laboratory commodities. The first is to use issues from stock at the lowest level—within the laboratory itself, this means issues from the store to the bench—as a proxy for consumption. The second is to track the actual consumption of a test, that is, the amount of product used in the process of conducting a test.

Calculated consumption should be recorded by adding up the "issues" from the store to the bench as noted on the stock control card. The issues data from the store to the bench will include commodities used for QA and QC as well as wastage in issues. For example, it may be more appropriate to count issues data for Field's stain A rather than the quantity used each time it is used to prepare a slide as part of a test.

For some products, actual consumption can be recorded each time the commodity is used. The quantity used is noted on a tally sheet at each bench or location in the laboratory where the commodity is used. The quantities actually used are added up at the end of the day and recorded on the activity register for the day. For example, it is appropriate to count each use of an HIV test or other rapid diagnostic test. Both products for which issues data are used and those for which actual usage is tracked will be entered in the routine report for laboratory commodities.

Because of the difficulties in tracking actual consumption of laboratory commodities, issues from the storeroom to the bench as a proxy for consumption are the appropriate choice for the vast majority of products. In some cases, however, it may make sense to track a limited number of commodities by actual use. It may be necessary for programmatic and forecasting purposes to

capture the actual number of tests used, such as in the case of HIV tests. Examples of usage registers to record consumption for HIV tests can be found in appendix E.

Review each product, including how it is issued and used, to determine the appropriate unit for stockkeeping and reporting.

Laboratory supplies come in a wide range of preparations and packaging. Some lab supplies come in kits, others in bottles, and others in packages with pieces of 100, 1,000, or more. Though supply chains should strive to have a minimal number of pack sizes for a particular product, even in the best case multiple pack sizes may exist and can lead to confusion in ordering and managing commodities. To facilitate stockkeeping, issuing, and reporting of these commodities, review each product, how it is issued to the bench, how it is used at the bench, and the number of pack sizes to determine which unit is most appropriate to use in recording and reporting commodity information. For example, though sputum containers may be delivered to the facility in packs of a 1,000, only 100 at a time are issued to the bench; therefore, "piece" is the most appropriate unit for tracking and reporting. On the other hand, a syphilis test kit, which has 100 tests in a single kit but cannot be separated into individual tests, is issued and recorded as a kit of 100 tests. When different units are chosen for different commodities, it is important to provide a key to facility staff so that they know the units to use to complete their records and reports.

It may be more appropriate to use a smaller unit of issue used at the facility level (e.g., bottle, piece) for stockkeeping and reporting, and round up these numbers to the nearest pack size at the central level.

Use and maintain stock-keeping records; consider the advantages and disadvantages of having one or multiple stock cards for the same commodity.

Stock cards should be maintained for each commodity used by the laboratory. Stock cards should be updated each time an issue is made, and balances should be verified by physical inventory at the end of each reporting period. Stock cards should have adequate identifying information: name and description of the commodity, and a commodity code, if applicable. The description should indicate the type and packaging unit selected. For example, for the stain crystal violet, the stock card should indicate "Crystal Violet Stain, powder, 25 g bottle." Each variation in the form or packaging should be considered a separate commodity. If crystal violet were also distributed as a liquid, it would be accounted for as a different commodity because of the difference in form—"Crystal Violet Stain, liquid, 500 mL bottle."

The decision about which unit of issue to record and report regarding commodities is linked to what kind of data is needed and the type of decisions that must be made. This has implications for the number of stock cards that will need to be maintained. For example, acetone may come in 5, 10, 20, or 30 L bottles. For this reason, the system designers may choose to record and report products according to liters, especially if program managers procure in liters and do not worry about the packaging. If acetone is recorded and reported by liter, one stock card would be needed to capture stock information and one line on the routine report would be needed to report it. If acetone is recorded by packaging size, one stock card would be needed for each of the bottle sizes (e.g. 5L, 10L); multiple lines would be required on the routine report so that these separate bottle sizes can be reported separately. Each method of recording information on the stock card and reporting it up the system has trade-offs. Keeping multiple stock cards may be time-consuming, given the large number of laboratory products and therefore number of stock cards required. Nonetheless, separating out

the stock cards and reporting entries by packaging size does not require facility staff to do the calculations, requires less training, and can result in more accurate record keeping.

At a minimum, data collected on stock-keeping records should include beginning balance, quantity received, quantity issued, losses and adjustments, and ending balance. Explanations for losses should also be recorded on the stock-keeping record and should be periodically reported. An example of a stock-keeping record—an inventory control card—can be found in appendix E.

Because durables are not frequently consumed or ordered, maintaining stock-keeping records on those commodities is not generally necessary. However, a complete inventory of durables should be conducted and reported at least annually.

Routinely report stock levels, issues, losses and adjustments, and stockouts. Link reporting with resupply.

To facilitate inventory management and procurement decisions and to provide valuable consumption data for forecasting, logistics data on laboratory commodities should be routinely reported to the central level. At a minimum, the data reported should include the following:

- consumption
- losses and adjustments
- stock on hand.

Duration of stockouts should also be reported. These data can be used to inform resupply decisions for the laboratory, as well as to monitor the performance of the logistics system. One of the related pieces of information that some countries have chosen to add onto the LMIS is equipment functionality and downtime, as this may impact consumption of commodities and therefore will influence resupply decisions.

An example of a report form for laboratory commodities, "Usage Data Report for Laboratory Commodities," can be found in appendix E. Reporting on high-turnover items such as reagents and consumables should be frequent—monthly or quarterly—whereas reporting on durables may be annual. Linking reporting with ordering makes valuable information needed to confirm orders available in the combined order and report.

Computerize the LMIS where possible.

Computerization of the LMIS can occur at the site level, the central level, or both. In many countries, site-level computerization of the LMIS for laboratory supplies is only at the pilot stage, but central-level computerization may be possible and appropriate. For a more complete description and discussion of computerized LMIS, refer to *Turning the Digital Corner* (2009).

In light of the large number of commodities that need to be managed, supplied, and reported in support of laboratory services, the central-level LMIS should be computerized where possible. Intermediate levels should also be computerized where possible. Manual aggregation of logistics data for laboratory supplies can be cumbersome and time-consuming. A computerized LMIS can rapidly aggregate logistics data, accurately perform calculations, and produce reports and graphs for analysis in a timely manner. When determining the appropriateness of using a computerized LMIS, consideration should be given to the availability of computer hardware, printers, data backup mechanisms, reliable electricity, and regular support from computer technicians. The software used

to manage and analyze the data should be designed with consideration of the types of logistics decisions that will be made to support logistics activities.

Design and implement logistics reports that are easy to complete, as concise as possible, but flexible enough to accommodate program changes.

A number of characteristics of laboratory commodities, including the large number required at each level of the system as well as the continually changing technology, provide some unique challenges in designing and printing routine logistics reports. To reduce the amount of time required to complete a report for a large number of products, consider preprinting the names and unit sizes of commodities. To reduce the total number of pages for each report, consider printing separate logistics reports by level in the system. So, for example, district-level hospital laboratories would complete a report printed only with commodities used at that level in the system. Of course, this approach would require relative standardization of tests, techniques, equipment, and therefore supplies at different levels of the system. Finally, to address changing technologies, and particularly the introduction of more sophisticated machines at lower levels of the system, consider providing additional spaces on reports so that facilities can report on additional commodities not listed.

What is the difference between standardization and product selection?
Standardization is the process of defining test menus, test techniques, operating procedures, and equipment by level in the system. Once that process has been completed, specific products (and their pack sizes) that support the standards that have been set need to be selected. Standardization drives product selection in the sense that the generic product list is developed from the test technique list and included in the SOPs. This list is the equivalent of an essential medicines list for labs.

PRODUCT SELECTION

The purpose of product selection is to select the most effective and cost-efficient commodities to support the goals of the program. When commodities are selected, a number of factors need to be taken into consideration, including—

- Inclusion of the commodity in protocols and standards. In addition, the status of registration of the product with local regulatory bodies needs to be considered. Technical criteria of test sensitivity and specificity should be considered. More discussion of those criteria can be found in appendix D.
- Cost and available financing.
- Storage requirements, such as cold chain, and capacity to maintain the commodities.
- Skill level of personnel (or training requirements).
- Ease of use of the commodity.
- Packaging of the commodities to facilitate distribution.
- Shelf life.
- Compatibility with existing instrumentation (durables).

Another consideration for laboratory commodities, particularly in the selection of instruments, is whether the instrument is part of a closed or open system. Closed systems are laboratory instruments

that require specific brands of reagents, while open systems do not. Closed systems may create a dependence on a single source of supply, but they often ensure a higher level of reagent quality.

CHALLENGES IN PRODUCT SELECTION

The following challenges are often encountered in the product selection process:

- Lack of standards leads to a proliferation of the types of commodities found in laboratories.
- Rapid technology changes may improve laboratory services but may require changes in the management of the commodities.
- Closed system instruments limit the selection of reagents that can be used.
- Open systems require a robust QA system to ensure the selected commodities are of high quality; therefore, hidden costs may be associated with QA for open systems. In addition, in open systems there are often challenges in having the manufacturer of the machine provide servicing and maintenance if reagents from another manufacturer are being used.
- If generic products are used with open systems, often the manufacturer of the equipment will not provide any servicing or maintenance. Manufacturers will provide support only if their products were used.
- Uncoordinated donations of equipment, reagents, or both can result in variation of commodities.

RECOMMENDATIONS FOR PRODUCT SELECTION

Use standard testing protocols to develop a commodity list for each level in the laboratory supply system.

The standardization of test menus and techniques by level determines the personnel capacity, infrastructure, and products required. Product selection should be closely linked to the standards established for each level of the laboratory system and the tests it provides. For instance, a central or reference laboratory provides a wider range of tests than does a lower-level lab, and therefore has a larger variety of commodities than would be available at a peripheral laboratory. Developing standard lists of commodities that are based on the level of the lab and the tests performed as determined during the standardization exercise will aid in commodity selection and management.

Select products that are appropriate on the basis of the testing protocols, cost, training of personnel, and infrastructure for storage and transportation.

Standardized testing protocols and procedures will help guide selection of many of the reagents and kits used in laboratory services. For instance, HIV tests should be selected according to the purpose of use and the protocol for that use. The training of personnel should be taken into consideration when selecting products for specific facilities. The staff members must be able to work with the products selected to perform the tests. If the tests are so costly that no one can afford to have the test performed, then an alternative should be identified. Packaging of the products selected should be appropriate for the types of sites and transportation mechanisms used to get them to facilities. If commodities will be distributed to lower levels in the laboratory system, unit packaging rather than bulk packaging should be considered. Check on the registration status of the commodity before selecting it. If it is not registered, consider a comparable alternative, or the manufacturer and local authorities should work on registering the commodity.

Storage conditions and handling requirements should be considered when identifying products for procurement. For example, shelf life and storage temperature should be examined. Similar products from different manufacturers may have different shelf lives, and procurement professionals should consider choosing the commodity with the longer shelf life. In addition, corrosive, flammable, or hazardous chemicals should be considered carefully because they have unique storage requirements and may be more challenging and costly to procure and store. Less toxic options of these products might exist.

Carefully consider trade-offs between open and closed systems for test instrumentation.

Consider the drawbacks and benefits of closed and open systems for test instrumentation. Open-system instruments do not require specific brands of reagents and, therefore, can be purchased from a larger number of possible sources. This increased choice can result in more competitive pricing for the reagents and less dependency on a single manufacturer. On the other hand, because of the required adjustments with the use of each different reagent, open systems require a good validation mechanism and continuous reagent QA monitoring. The QA requirements may present additional costs for open systems despite the potentially lower cost of the reagents. Though the purchase of reagents for closed systems is more limited, they generally provide the highest quality and are typically easier to manage. Be sure to engage laboratory staff in the selection of products, and in weighing the benefits and drawbacks of closed and open systems considering the in-country context. The decisions about instrumentations should be made during the standardization process.

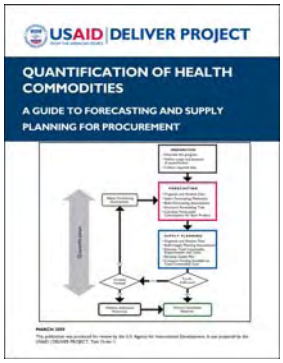
Be prepared for changes in test technology.

Technology advances can affect product selection. Testing technology will improve, and tests will have increased sensitivity or specificity and new techniques will provide results faster. As new technologies emerge or additional tests are added to testing protocols, it will be necessary for the aforementioned committee to review the standard list and determine whether new tests, techniques, and equipment should be added or others removed. Such changes will influence what commodities are selected in order to support the newly introduced test or equipment.

Selection of new testing technologies that require different commodities should be reflected in the standard testing protocols and updated standards, and commodity lists should be updated. Any change in the selection of commodities that support laboratory services will have a subsequent effect on the logistics system. Personnel should be trained in the use of the new commodity and should be informed of any special storage or inventory management procedures for the commodity. In addition, changes may need to be made to the LMIS forms or instructions for how to account for a commodity that was not previously included on the reports.

QUANTIFICATION AND PROCUREMENT

Forecasting future demand for laboratory commodities and calculating the quantities to procure—while taking into account service capacity, supply chain capacity, and resources available—are important parts of ensuring the availability of laboratory commodities. For more information on the quantification process, see the USAID | DELIVER PROJECT's *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement.*



Several challenges need to be considered when quantifying quantities of laboratory commodities to procure.

CHALLENGES IN QUANTIFICATION AND PROCUREMENT

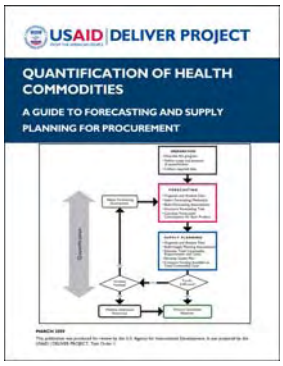
- Data on past consumption, losses, and wastage may be difficult to obtain; data on stock balances may not be available.
- Multiple commodities that are required for each type of test need to arrive in-country and must be available concurrently.
- In the absence of standardized testing procedures, it is difficult to use test numbers to prepare a forecast because there is no correlation between the number of tests performed and the types and quantities of commodities used to perform any specific test.
- Commodities used for QA and QC need to be included in quantification.
- Multiple donors (or providers of lab supplies) may use different procurement mechanisms and sources of supplies.
- Selected test kits have to match available or proposed equipment.
- Newly purchased equipment may conflict with existing equipment.
- Miscommunication between laboratory staff and procurement staff regarding specifications of laboratory products can result in the wrong products being procured, such as Vacutainer EDTA K3 versus Vacutainer EDTA K2.

RECOMMENDATIONS FOR QUANTIFICATION AND PROCUREMENT

Use and compare multiple types of forecasts using logistics, demographic, and service statistics data to forecast requirements for laboratory commodities.

The type of forecast that can be conducted will depend highly on the type of data available in-country. Triangulating two or more forecasting methodologies provides the most accurate forecast. As laboratory logistics systems are currently being designed and strengthened in many countries, logistics information for laboratory commodities will become more accurate and available for forecasting purposes. Forecasts that are based on actual consumption—or in the case of laboratory products, facility-level issues data as a proxy for consumption—provide a good reflection of demand for a commodity. Trends in past consumption can be used to project future demand for commodities. For more information on consumption-based forecasting and different data and

methods used for forecasting and quantification, see the USAID | DELIVER PROJECT's *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement.*



Service data—data on the numbers of tests performed during current and past periods—can be used to establish trends in tests provided. With standardization of tests and techniques, that information can then be translated into commodities needed to provide those tests and can be used as the forecast for those commodities. This methodology relies on a good reporting system for laboratory services provided. As with any forecast that is not based on actual commodities used, a number of intervening variables affect the reliability of the forecast. A forecast that is based on test data assumes that standardized tests and techniques will be used and that testing protocols will remain constant into the forecast period. It also assumes that each technician performing a test will strictly follow the technical SOPs (i.e., use the same quantities of commodities for each test and have the same rates of wastage).

Finally, forecasts using demographic data translate the number of patients or clients to be tested, using tests menus, into the total number of tests to be conducted, which is then translated into total product requirements. As with service data, demographic data is not based on actual consumption; therefore, a number of assumptions must be made, including the total number of patients, the menu of tests and techniques, and the number of each test conducted during the forecast period.

If using test numbers to prepare the forecast, include commodities required for QA and QC and training.

Laboratories conduct routine QA activities to ensure the accuracy of the tests they are performing. QA measures typically are defined in national laboratory policy. However, in the absence of such a policy, many laboratories generally use the same commodities that are allocated for performing the tests themselves. The labs will repeat a testing procedure or will test known positive or negative controls. In quantifying the commodity requirements for laboratory services, the commodities required for QA should be included in the quantification. Note that when consumption data is used, the commodities used in QA activities are already included.

Some laboratories will record the QC tests in the same register with the actual tests and therefore report them as part of consumption. In other situations the QC tests will be recorded separately. It is important to establish how QC tests are recorded and how this will affect consumption.

As with any logistics system, flexibility in procurement allows for more effectiveness when ensuring commodity availability.

The personnel responsible for procurement should maintain close contact with vendors and laboratory staff to discuss product improvements and changes in test technique to ensure that the most appropriate products are procured in appropriate quantities, given their specifications. Framework contracts should be established with vendors to allow flexibility in quantities and timing of orders.

Quantify and procure all items that will be needed to complete a testing protocol. Ensure that shipping schedules are coordinated to make all commodities available as needed.

Commodities to procure can be more easily identified when a standardized list of tests and test techniques by level of service is used. In addition to knowing what commodities are needed, managers should work to ensure that all commodities needed to perform each test are available concurrently. For example, if an HIV testing protocol requires two different tests to confirm a result, then both tests should be available to the provider and throughout the supply chain. When developing lists of commodities to procure by level of service, make sure those lists include a notation of the commodities that form a complete testing protocol. Although procuring all the commodities needed for a testing protocol may not be necessary because sufficient stock may remain of some commodities, procurement managers should routinely check stock balances to ensure that, in fact, all commodities needed to complete a protocol are and will be available at all times. Procurement plans should reflect this issue of concurrent availability.

As controls generally have a short shelf life, suppliers will often enter into a shipment schedule based on the shelf life. The supplier will be aware of when the previous batch of controls is to expire and supply the next batch a few days before, manufacturing the controls specifically for the country by facility. The challenges with these agreements are that even if the machine breaks down, the controls may still be on order. If countries want to enter into these arrangements, they will need to ensure that equipment is functional, or that contracts are flexible enough to accommodate some breakdowns.

Monitor your supply pipeline and update forecast on a quarterly basis.

As with other commodities, the forecast provides an estimate of the commodity requirements based on the best available assumptions at the time of the quantification exercise. After the quantification is complete, monitor the pipeline closely to ensure that the actual rate of consumption matches the forecast estimates. As necessary, adjust planned shipments to ensure continuous availability of products and avoid overstocks and expiries or stockouts at any level of your system. For laboratory supplies, changes in equipment or testing protocols may drastically impact consumption of products, and these changes should be closely monitored for their impact on the supply pipeline, so that appropriate adjustments can be made.

Define all specifications before procuring.

As for all public health commodities, specifications for laboratory reagents and consumables should be clearly defined. The grade, size, nature, and all relevant characteristics, including the packaging size, should be specified as clearly as possible (see table 2).

Table 2. Examples of Defined Specifications

Reagents	Specifications	Unit	Quantity
Field's stain A (malaria)	Azure blue powder, general purpose reagent, 25 g	25 g bottle	50
Commercial reagent kit (hepatitis B screening)	Commercial latex based non-cross-reactive; titer 1:256, sensitivity 100%, specificity at least 98%	50 test kit	15
Vacutainer	Plain red top, rubber cork, to hold 4 mL	Each piece	5,000
Microscope slide	Single frosted, precleaned, 76.2 mm x 25.4 mm x 1.2 mm, glass	Pack of 50	20

It is important to have a laboratory specialist working with the procurement unit and the medical stores to help clarify specifications and the management of laboratory supplies.

Budget appropriate freight costs during the quantification process.

Freight costs for laboratory commodities may be significant and must be considered when quantifying the total cost of commodities, in order to ensure that the appropriate resources are mobilized. Certain laboratory commodities must be shipped by airfreight because of their composition and shelf life. Laboratory commodity freight costs can range from 5 percent to 50 percent, and therefore the realistic freight costs of these commodities should be estimated during the quantification process to get a representative cost for shipping these products.

INVENTORY MANAGEMENT

An inventory control system informs the storekeeper of the following:

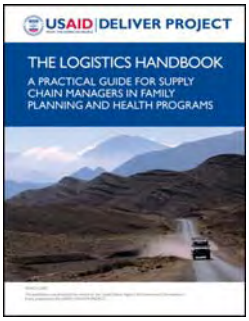
- when to order or issue
- how much to order or issue
- how to maintain an appropriate stock level of all products to avoid shortages and oversupply.

What is a rationing system?
A rationing system is utilized in situations of non-full supply, where there are not enough quantities of commodities to fill orders as necessary and serve clients. Supplies must be allocated to facilities based on an established set of criteria.

The continuous supply of laboratory commodities can be guaranteed only through the selection, design, and proper implementation of an appropriate inventory control system. A number of strategies or inventory control systems can be adopted to manage commodities of any kind. If sufficient commodity supplies are ensured, a max-min inventory control system is recommended.

A number of factors go into the choice of an inventory control system, including the number of commodities to be managed, reliability of transportation, and availability and training of staff members. In addition, several system parameters need to be determined: the number of levels in the supply chain, the order interval or review period, and the level responsible for determining the resupply quantity—pull or push—by level in the system. For more information on max-min inventory control systems and selecting inventory control systems, see the USAID | DELIVER

PROJECT's *The Logistics Handbook: A Practical Guide for Supply Chain Managers in Family Planning and Health Programs*.



The shelf life of the commodities needs to be considered when defining the levels in the pipeline, specifying the review period, and choosing the type of max-min system. A pipeline with few levels and short review periods is best for commodities with a short shelf life because less stock is held and turnover is more frequent. A max-min system with a smaller minimum stock level, such as a forced ordering or continuous review system, helps ensure product turnover, but it may be more difficult to manage with a large number of types of commodities, as is the case in laboratory services.

Because few laboratories have standard procedures for managing laboratory commodities, a number of challenges are commonplace. With the establishment of an effective inventory control system, those challenges can be minimized.

CHALLENGES IN INVENTORY MANAGEMENT

- frequent stockouts of reagents
- weak or no standard ordering process and procedures
- no established pipeline
- multiple vertical pipelines (one for HIV tests, one for TB laboratory supplies, one for STIs), often because of program involvement in the resupply process
- rationing of commodities
- associated products not ordered concurrently (buffer solution, lancets, etc.)
- existing pipeline too long.

RECOMMENDATIONS FOR INVENTORY MANAGEMENT

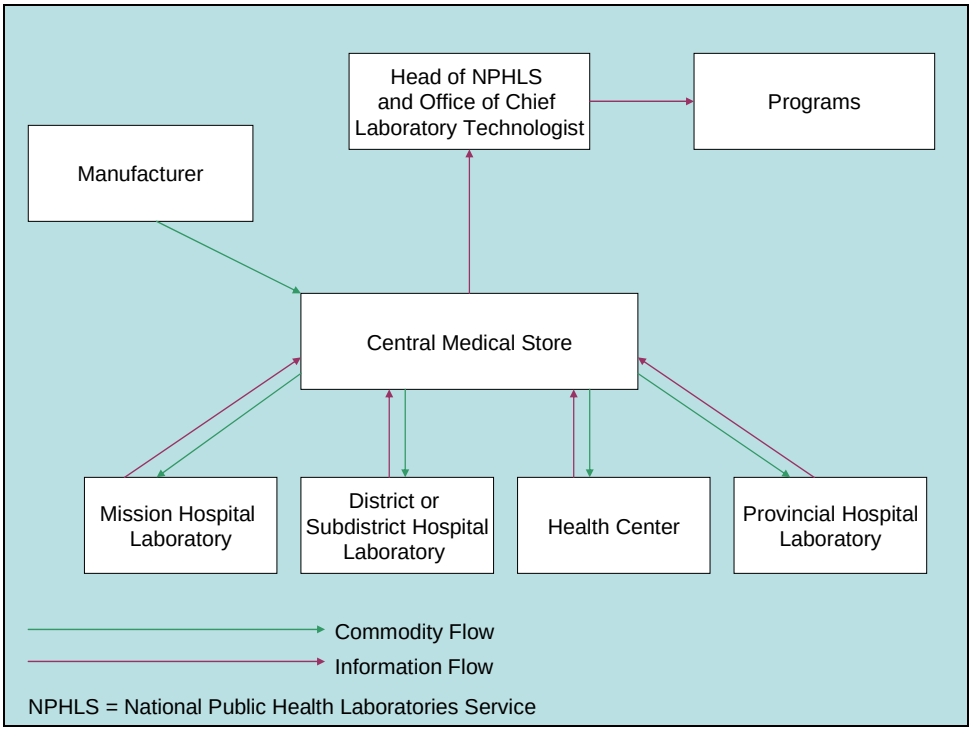
Establish as short a supply pipeline as possible.

Although many laboratory commodities have relatively long shelf lives, several key reagents have short shelf lives that make a shorter supply pipeline necessary. Rather than manage laboratory commodities through different pipelines that are based on the shelf lives of those commodities, it is preferable to establish a short, efficient pipeline that can be used to manage most laboratory commodities. To shorten the pipeline, consider limiting the number of levels. Figure 5 illustrates a typical in-country pipeline for laboratory commodities. This pipeline includes two levels: central level and service level.

In addition to limiting the number of levels in the pipeline, one can shorten the pipeline by increasing the frequency of resupply (i.e., reducing the time between orders). This strategy results in less stock being held at any time, a more frequent turnover, and a reduced chance of expiry.

However, despite all of the efforts to shorten the pipeline, it would not be possible or practical to accommodate some products, mainly control reagents whose shelf life is short (three months or less), in a typical supply chain. Instead, these should be managed independently of other products.

Figure 5. In-Country Laboratory Commodity Pipeline



If using a max-min inventory control system, consider the standard or forced-ordering versions.

Because laboratory services require a large number of commodities—from 350 to 3,000 different commodities, depending on the level of service—a standard max-min system is a good choice. In a standard max-min system, only those commodities whose stock levels have fallen below an established minimum level at the end of the review period are ordered or supplied. Therefore, the number of commodities supplied is limited in each order, as opposed to other max-min versions, such as the forced ordering version in which quantities of all commodities that have fallen below the maximum stock level are supplied at the end of the review period and some of these quantities may be quite small. This system lessens the burden of handling and recording all possible commodities used in the laboratory at any one time. However, because a standard max-min requires a higher minimum stock level than do the other versions of max-min, the pipeline should be as short as possible, as described in the preceding recommendation. Designers must ensure that there is adequate storage space to accommodate the maximum stock level, especially given the bulk of many laboratory commodities.

In light of the implications of holding more stock for the standard system, another inventory control option is the forced ordering system. Though forced ordering may require facilities to place smaller, more frequent orders because they order up to their maximum stock level for all commodities at the end of the review period, regardless of whether they have reached a minimum stock level, the relatively shorter pipeline (vis-à-vis the standard system) may be more appropriate for situations where there is limited storage space or additional levels in the system. Also, the decision rule of when to order and how much to order is simpler in the forced ordering version.

Typically a continuous review system is not appropriate for laboratory commodities because in this type of inventory control system, the facility must review the stock levels and report or order each

time a commodity is used. This can be arduous and time-consuming given the large number of commodities that must be continuously reviewed, reported, and ordered.

It may be appropriate to manage laboratory commodities through two different types of max-min inventory control systems. For example, a standard system could be appropriate for long-shelf-life items that come in bulk quantities, and a forced ordering could be used for short-shelf-life, expensive, faster-moving items. Categorizing your products is critical for making these types of design decisions.

Order quantities should be adjusted for stockouts.

When the order quantity is calculated, the number of days stocked out should be factored into the calculation. For example, if a laboratory is stocked out of a commodity for half the reporting period, then an adjustment should be made to the consumption to estimate how much of the commodity would have been consumed if the stockout had not occurred.

Consider assigning different maximum and minimum stock levels for slow-moving and fast-moving commodities.

If a facility reorders slow-moving commodities to the same stock level as fast-moving commodities, it risks being overstocked. For example, a bottle of crystal violet solid reagents is issued from the bench to the storeroom. At this particular facility, it takes four to five months at the bench to consume a full bottle of this reagent, which is therefore considered a slow-moving commodity.

If one assumes that the maximum stock level for this reagent was the same as for the other commodities, once the bottle was issued, one would order up to the maximum stock level (at least another entire bottle), even though it would take months to finish one bottle at the bench. This puts facilities at risk for overstocks and expiries of slow-moving products. One solution might be to use smaller units to generate more frequent turnovers; however, designers must consider that tracking by such a small unit for a product that would take months to finish may be too cumbersome. Instead, for slow-moving products, designers might consider using a different inventory control system.

Full-supply and non-full-supply commodities can be managed concurrently if there is a transparent process for ordering and resupply.

Max-min inventory control systems can work for commodities only in full supply, because the system is based on the fact that orders will be filled according to the intended maximum stock level. Even if not all laboratory commodities are in full supply, it is possible to manage full-supply and non-full-supply commodities concurrently if there is transparency in ordering and resupply. If a facility orders a full-supply and non-full-supply product concurrently, the central medical stores may be able to fill the facility's order up to the maximum stock level of the full-supply item, but not for the non-full-supply product. If the higher level is able to articulate the ordering and resupply decisions and be transparent in the process through feedback reports or similar mechanisms, there will be greater buy-in and confidence in the system. Including the full-supply and non-full-supply products on different sections of the reporting and ordering forms may help to highlight this distinction for those at the facility level.

Though facilities may not be resupplied up to their maximum stock levels for non-full-supply commodities, there may be value to having a maximum stock quantity in the system even for non-full-supply commodities, for a number of reasons. First, it serves as a benchmark for the total

quantity ideally wanted in the system. Further, it allows central-level decision makers to make rational decisions about the amount of products that should be available in the system, and to ward off dumping by donors or manufacturers.

If staffing is limited, consider instituting a push system for resupply to peripheral levels.

Because staffing is often limited at lower-level laboratories, it is recommended that the burden of calculating the quantities to resupply be shifted to the supplying facility or to a higher-level management unit (a push system). Higher-level facilities may have the benefit of an automated information system that can be used to calculate resupply quantities as a function of analysis of the data reported. Lower-level facilities still must complete their reports in a timely fashion because those data are essential in determining the quantities to resupply.

Link reporting to resupply.

As a corollary to the preceding recommendation, reporting should be linked to resupply so that the supplying facility has the information it needs to calculate the quantities that the lower-level laboratories need. This recommendation also emphasizes to laboratory personnel the integral relationship between information flow and resupply, and it motivates them to report regularly.

Commodities that need to be used concurrently to complete a testing protocol should be supplied together.

Because a specific set of commodities is required to complete most tests, it is crucial that all those commodities be available in the laboratory at the same time. All of the commodities required to run a test should be included in full supply in the system, because the absence of one or more will make it impossible to conduct the test. The person calculating an order should check that all the commodities required for a test are included in the order. If proper inventory control methods are being followed, then sufficient supplies of all commodities should be available at all times.

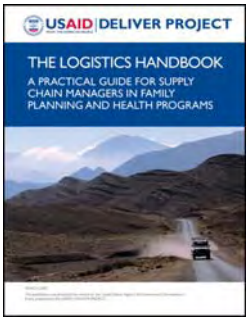
STORAGE AND DISTRIBUTION

The purpose of a storage and distribution system is to ensure the physical integrity and safety of commodities and their packaging as they move from the central storage facility to peripheral laboratories. A sound storage and distribution system will help ensure that commodities reach the laboratory in usable condition. Proper storage procedures help ensure that storage facilities issue only high-quality commodities and that little or no loss is caused by damaged or expired products.

Acceptable storage facilities (warehouses, storage rooms) must be clean and secure, and adequate distribution systems must have dependable and secure delivery vehicles. Ideally, the pipeline should be as short as possible. In the context of storage and distribution, a shorter pipeline can positively influence the security and quality of the commodities being distributed. A shorter pipeline helps get commodities to the laboratory before they expire; having fewer levels in a system means fewer storage points and fewer instances of transporting commodities—less opportunity for loss or damage.

Although the major focus in storage and distribution is on the commodities being moved, the packaging of the commodities should be considered as well. The packaging provides the primary protection to the commodity during storage and transportation, so the quality of the packaging should be specified during procurement. In addition, sufficient sturdy packaging materials should

be available for repackaging commodities for distribution to peripheral laboratories. For protection, commodities should remain within their sealed outer cartons, their inner boxes, or both during distribution. Packaging should be labeled clearly with complete information, including the expiration date. For more information on storage and distribution, see the USAID | DELIVER PROJECT's *The Logistics Handbook: A Practical Guide for Supply Chain Managers in Family Planning and Health Programs*.



Commodities generally may be distributed in one of two ways: a pickup system, in which the lower level comes to the supplying facility, or a delivery system, in which the upper-level supplying facility brings the products to the lower-level receiving facility. In many cases, storage and distribution of laboratory commodities will be integrated with that for essential medicines and other health commodities; in other cases, a vertical supply chain for laboratory commodities may be in operation.

Regardless of the type of distribution mechanism, transportation must be available whenever it is needed to fill regular or emergency orders. This requirement is particularly important in a situation where vehicles are shared for multiple purposes, such as commodity delivery and supervisory visits. To the extent possible, dedicated vehicles should be available to transport commodities.

For all products, procedures should be in place to monitor and document the movement of commodities from the upper levels to the lower levels. The following actions should be completed at each distribution or receipt:

- Verify the type and quantity of products shipped and received.
- Conduct visual inspection, including expiration dates, for QA.
- Complete and sign transaction records or vouchers.
- Store the products.
- Update stock-keeping records.

Storage and distribution are important to consider because some laboratory commodities will need to remain cold in storage and transit, and because reverse transportation may be needed when specimens must travel up the system to a higher-level laboratory for testing.

Material Safety Data Sheets can provide guidance for appropriate handling of laboratory supplies. The sheet is usually included in the packaging of hazardous materials.

SOPs on laboratory safety should be in place and clearly explain the various hazards that are associated with laboratory commodities.

CHALLENGES IN STORAGE AND DISTRIBUTION

- Cold chain is required for certain reagents.
- Flammables and corrosives require special handling considerations.
- Light-sensitive chemicals require special consideration.
- Short shelf life of some commodities may require that products be managed and distributed separately, and almost immediately upon arrival in-country, to avoid expiration.

RECOMMENDATIONS FOR STORAGE AND DISTRIBUTION

Guidelines for appropriate storage should be developed for each level of the system because the types of products at each level of the laboratory network will vary. The general storage guidelines for laboratory commodities in table 3 should serve as the basis for level-specific guidelines.

Table 3. General Storage Guidelines for Laboratory Commodities

Guideline	Notes
Clean and disinfect storeroom regularly. Take precautions to prevent harmful insects and rodents from entering the storage area.	Rodents and some insects (e.g., termites and roaches) like to eat certain health commodities. They also eat shipping cartons and inner packaging. Pest-proof your storeroom to stop the pests from getting in. If your storeroom becomes infested with pests, use appropriate pesticides. After you clear pests from the storeroom, keep it clean. A clean storeroom keeps pests away. Food and drinks in the warehouse will increase the risk of pests.
Store laboratory commodities in a dry, well-lit, well-ventilated storeroom—out of direct sunlight.	A hot storeroom may cause some of the commodity supplies to spoil, which will decrease shelf life. For example, the shelf life of most bacteriological media is three years. However, the shelf life will be much shorter if the temperature inside the warehouse rises above 30°C. Although air conditioning is ideal, it is expensive. Alternatives are ceiling fans and 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. Several laboratory commodities, such as acridine orange, iodine crystal, and phenol, deteriorate when exposed to light. These commodities are usually distributed in brown bottles that protect them from light, and they should remain in those bottles. If light-sensitive commodities are to be redistributed, distribute them in the original packaging or bottles or in packaging with the same standard of protection as the original.
Protect storeroom from water penetration.	Water can destroy commodity supplies or their packaging. If packaging is damaged, the product is unusable even if the commodity is undamaged. Repair the warehouse so water cannot enter. Other measures include stacking commodity supplies on pallets rather than off the floor (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.

Continued next page

Guideline	Notes
Keep fire safety equipment available, accessible, and functional. Train employees to use the equipment.	Stopping a fire before it spreads can save thousands of dollars in stored commodities and can 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.
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 cause gloves to deteriorate. Move glove boxes away from those sources. Store gloves in paper boxes and cartons.
Maintain cold storage, including a cold chain, as required.	Cold storage, including the cold chain, is essential for maintaining the shelf life of certain products. If those 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. Commodities requiring a cold chain include many test kits, such as rapid plasma reagin syphilis test, some HIV tests (Capillus), blood-typing sera, CD4 reagents, hematology controls, chemistry kits, coagulation reagents, and venereal disease research laboratory test reagents, which should be stored in the refrigerator between 2°C and 8°C.
Limit storage area access to authorized personnel. Lock up controlled substances.	To ensure that all stock movement is authorized, first, lock the storeroom; next, limit access by persons other than authorized staff; and finally, verify that both incoming and outgoing stock matches documentation. Periodically perform a systematic physical inventory to verify inventory records. 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 lockbox, under the control of the store manager or of the laboratory in-charge.

Continued next page

Guideline	Notes
If possible, stack cartons at least 10 cm off the floor, 30 cm away from the walls and other stacks, and no more than 2.5 m high. Note: This arrangement may not be possible in all facilities.	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 arrangement promotes air circulation and facilitates movement of stock, cleaning, and inspection. Most facilities are more likely to have shelving than pallets. Pallets are usually more efficient than shelving, particularly for bulk items, because they— • 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. Correct stacking of supplies will avoid crushing cartons at the bottom of a stack. Stacking cartons no more than 2.5 m high will also reduce the potential for injury to warehouse personnel. Keep commodities away from walls to promote air circulation and to prevent moisture damage, which may occur if water condenses or penetrates walls.
Arrange cartons with arrows pointing up (⬆), with identification labels, expiration dates, and manufacturing dates clearly visible.	The commodity should be stored with the arrows pointing up. Identification labels make it easier to follow first-to-expire, first-out (FEFO) warehouse management systems and to make it easier to select the right product. If shipping cartons do not show either a date of manufacture or an expiration date, contact the supplier for that information. If the original markings are small or difficult to read, rewrite the manufacturing or expiration dates in large numbers.
Store laboratory commodities to facilitate FEFO procedures and stock management.	Ensure that FEFO is followed. Recently received commodities may sometimes be older than the store's existing stock. On receipt of new stock, always review existing stock expiration dates to ensure FEFO.
Store lab commodities according to their properties: chemicals, flammable products, hazardous materials, office supplies, and equipment; always take appropriate safety precautions.	It is important that laboratory commodities be stored away from other materials; they pose serious hazards because of their chemical or biological nature. Storing old junk may slow access to products and may take up needed storage space.

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Guideline	Notes
Store flammables separately from other commodities.	Large supplies of flammables should never be stored in the same areas as other commodities. A small stock of flammables may be kept in a steel cabinet in a well-ventilated area, away from open flames and electrical appliances. Mark the cabinets to indicate that they contain highly flammable liquids, and display the international hazard symbol. In addition, cabinet shelves should be designed to contain and isolate spillage. Always store flammables in their original containers. Flammable liquids each have a flash point, which is the minimum temperature at which the liquid gives off vapor in sufficient concentration to form an ignitable mixture with air near the surface of the liquid. The flash point indicates the susceptibility to ignition. • Acetone has a flash point of –18°C. • Undiluted alcohols have a flash point of 18°C to 23°C. • The flash point for kerosene is 23°C to 61°C. It is not necessary to store flammables below their flash point, but it is very important to store them in the coolest location possible and never in direct sunlight. It is important to control the evaporation rate and to avoid the buildup of pressure.
Store corrosives at normal room temperature, at ground level, and in the original manufacturer's containers.	Corrosive substances should be stored away from flammables, ideally in a separate steel cabinet to prevent leakage. Use appropriate industrial-type protective gloves and eyeglasses when handling those items. Common corrosives found in the laboratory include sulfuric acid, sodium hydroxide, formalin, phenol, potassium hydroxide, iodine crystal/Lysol, and sodium hypochlorite.
Certain laboratory supplies should not be stored together because they may cause a heated or explosive chemical reaction.	Concentrated mineral acids can be very reactive, even with each other. Concentrated acids can even react vigorously with dilute solutions of the same acid, if mixed together rapidly. For example, concentrated sulfuric acid mixed quickly with 1 molar of sulfuric acid will generate a lot of heat. Different acids should be stored apart. If they are stored within the same cabinet, then plastic trays, tubs, or buckets work well to keep different acids apart within the cabinet. Ammonium hydroxide is a base, or corrosive, chemical that should be kept separate from all acids. All acids are generally incompatible with bases. Ammonium hydroxide does not substantially attack steel, painted steel, or wood, so no special cabinet is needed for it. Acetic acid and picric acid are organic acids and should be kept separate from the inorganic or mineral acids, such as phosphoric acid, hydrochloric acid, nitric acid, sulfuric acid, and (especially) perchloric acid. Acetic acid is also flammable and should be more appropriately stored in a flameproof storage cabinet.

Continued next page

Guideline	Notes
Separate damaged and expired laboratory commodities from usable commodities, remove them from inventory immediately, and dispose of them using established procedures.	Separating such products makes FEFO easier to implement. Destroying damaged products immediately will make more space available for usable commodities.

The conditions under which laboratory commodities are stored should be maintained during distribution. Protect light-sensitive commodities from direct sunlight and maintain a cold chain for commodities that require it. Pack glass bottles in well-cushioned cartons. Pack corrosives and flammables separately, handle with care, and transport according to manufacturer's instructions. Stains should be tightly stoppered to avoid spillage and transported separately in well-cushioned containers.

LABORATORY MANAGEMENT AND POLICIES WITH SUPPLY CHAIN IMPLICATIONS

Supply chains for laboratory supplies do not operate in a vacuum but rather within a larger context of laboratory management and policies of the larger health system. The approach to strengthening supply chains must expand beyond forecasting and quantification, inventory control systems, and storage and distribution. Building capacity for staff, rationalizing policies and protocols, and strengthening management practices are also essential components to improving commodity availability and strengthening laboratory systems. Laboratory management, practices, and policies will have supply chain implications.

QUALITY ASSURANCE AND QUALITY CONTROL

A well-managed laboratory should have a good QA system that checks and eliminates errors. These errors can be either system errors or random errors. A QA program allows one to identify whether the quality of the products is good and if the testing procedures are being done properly, to achieve good quality results.

Checks for system errors include pre-analytic, analytic, and post-analytic processes, such as training, interlaboratory comparison, preventive maintenance, and result reporting. These checks ensure the following:

- The right test is being carried out on the right specimen from the right patient.
- The right result and the right interpretation are obtained.
- The right result is given to the right person at the right time.

In light of the high level of importance ascribed to quality in laboratory services, a laboratory QA program is typically designed and implemented to monitor and evaluate laboratory functions and services. There are often written procedures for each element of the QA process to provide accountability and clarity on how to carry out the procedures. The national reference laboratory typically manages the laboratory QA program that applies to all levels of the laboratory system. In managing the supply chain, it is important to understand how the QA program functions and the commodities that are required to run the QA program effectively to ensure a reliable flow of commodities.

In addition to the QA program for lab testing, QA measures

Quality control refers to measures that are included during each assay run to verify that the test is running properly. QC is an important component of a QA program. Random errors that can occur during testing are checked using QC materials. When QC falls outside of an acceptable range, the test results should not be released. QC ensures the following:

- The test is working properly.
- Technical aspects of the test—temperature, checks, controls—are valid.
- Results are correct, acceptable, and valid.

should be incorporated in the management of commodities. From a supply chain perspective, a QA program can help to identify issues in the quality of the products. QA for laboratory commodities should include the following components:

- Quality should be considered in developing the specifications for the procurement of laboratory supplies. Is the reagent of the appropriate grade—that is, is it analytical grade where required or technical grade? For example, the use of methanol widely ranges from cleaning to very complex tests, and it has the same name but requires very different concentrations and levels of purity for each application.
- Quality of products should also be checked after product is procured and received in-country, using the national procedures governing this process.
- Quality must be monitored in the storage and distribution of laboratory commodities. Product must be stored and transported in the appropriate conditions and must still be viable for use upon issuing to the bench. The product must be within its shelf life, not have exceeded the recommended excursions from the specified storage temperature, have intact packaging, and be protected from environmental factors such as dust and humidity.
- The final check in the quality of products happens through routine monitoring through QC (see text box on page 45). Running regular controls helps verify that the product is still of the highest quality, given the other supply chain interventions, and can produce quality results.

CHALLENGES IN QUALITY ASSURANCE AND QUALITY CONTROL

- Lack of standardization of laboratory tests, techniques, and procedures
- Lack of internal QC materials
- Lack of procedures and knowledge for visual inspection of laboratory commodities and for disposal of expired or damaged commodities
- Failure to participate in external quality assurance programs
- Lack of continuous supply of high-quality laboratory commodities

RECOMMENDATIONS FOR QUALITY ASSURANCE AND QUALITY CONTROL FOR COMMODITIES

Include procedures for managing commodities in the QA program.

Adherence to logistics management procedures for laboratory commodities should be monitored with as much vigilance as are procedures for other aspects of laboratory management and services. By following logistics management procedures such as inventory control, recording and reporting, and storage, laboratory personnel help ensure that they always have the commodities they need to perform tests and that those commodities are of good quality.

Define and enforce QC procedures and policies for internal and external retesting.

Because visual inspection is not always adequate to tell the quality of reagents or other commodities used in a test, internal and external retesting can offer another mechanism by which to determine quality. Although a number of factors, including laboratory practice, contribute to the result of a test, the quality of the commodities also influences the quality of the test. QA procedures can help identify possible commodity quality problems.

Establish procedures for routine visual inspection of laboratory commodities.

Routine visual inspection of laboratory commodities should be conducted to help determine the quality of the commodity. Inspection does not have to be cumbersome or time-consuming. It should take place when commodities are first received in storage, when they are issued to the bench, when they are close to expiration, or whenever a quality problem is suspected. During routine visual inspection, any mechanical and chemical changes or damage should be noted.

Mechanical damage can compromise the integrity of commodities. Mechanical damage could include the following:

- damage to packaging, such as tearing or water damage
- missing or illegible labeling, including expiration dates
- missing components, such as a chase buffer missing from a test kit.

Chemical damage can make commodities unreliable and therefore unusable. Chemical damage could be indicated by—

- changes in color of reagents or chemicals
- unusual odors for reagents or chemicals
- caking of powders.

Establish procedures for handling suspect, damaged, or expired commodities.

Damaged, expired, or suspect commodities take up valuable storage space. They may be mistaken for usable commodities and inadvertently used, and they are likely to affect the accuracy of test results. Unusable commodities should be disposed of promptly and removed from stock-keeping records. Laboratories should have clear procedures for handling suspect commodities and disposing of unusable commodities.

MANAGEMENT AND STAFFING

For a laboratory logistics system to work, adequate staff must be in place at all levels to manage it. All personnel need to be trained in system procedures and supported in their jobs by effective and knowledgeable supervisors. As new commodities enter the system, staff members need to be made aware of the products' particular logistics considerations (e.g., storage requirements). When new procedures are put in place, personnel need to be trained to perform those procedures.

Because it is important to maintain the highest quality standards, procedures and policies for laboratory practices should be regularly reviewed with staff members. Performance should be routinely monitored and supported with supervision. A schedule for supervisory visits helps make supervision more routine, participatory, and supportive.

CHALLENGES IN MANAGEMENT AND STAFFING

- staff members not trained in logistics management or evaluating considerations for new products (storage, supply chain, resupply procedures, or issues)
- limited number of personnel
- lack of supervision

- unclear or weak laboratory administrative structures.

RECOMMENDATIONS FOR MANAGEMENT AND STAFFING

Provide training in logistics management procedures to laboratory staff members, and establish a mechanism for communicating information on new commodities.

In addition to specific training in the management of laboratory commodities, which should include recording, reporting, ordering, inventory management, and storage, laboratory staff members should have documented logistics SOPs for those functions to support their work. Regular updates on new commodities and procedures should be provided through meetings, refresher training, supervisory visits, or written communication.

Develop a schedule of routine supervision to support the laboratory staff.

Routine supervision of laboratory personnel should support and improve their ability to follow laboratory logistics procedures, encourage accurate recording and reporting, and reinforce the importance of maintaining proper storage for laboratory commodities.

POLICY AND REGULATORY ENVIRONMENT

Policy and regulatory matters related to laboratory services must also be considered when supporting laboratory logistics. Four broad categories of issues are of key concern:

- guidelines, policies, testing protocols, and operating procedures for laboratory services
- infection prevention and control guidelines and policies, including use and disposal of sharp devices, and the use and availability of protective clothing and equipment for staff members
- licensure and certification requirements for individuals owning or operating laboratory facilities
- product registration requirements and tax considerations, such as exempt status.

Those policies and regulations affect commodity availability and the functioning of the logistics system. Product selection will be further influenced by which products have been registered in the country. If specific requirements exist for infection prevention and control, then laboratory personnel must obtain and use the commodities needed to implement those requirements in order to safely undertake laboratory procedures. As discussed in the section on standardization, standardization of testing and techniques by level in the system will help reduce and standardize the list of commodities managed in the laboratory logistics system.

Policies, guidelines, and other national-level guidance can provide a framework for understanding the position of laboratory services in the health system, the amount of attention this category of services is given, and the degree to which requirements for health personnel are articulated. In countries where those documents do not provide clear specifications, the logistician will likely have to seek additional input from key informants, because the lack of these policies makes quantification and other supply chain activities difficult. In countries where requirements and expectations are clearly laid out, decisions regarding the logistics systems for the laboratories must be made in compliance with the national standards.

CHALLENGES IN THE POLICY AND REGULATORY ENVIRONMENT

- lack of guidelines on testing and testing protocols
- unclear policies on staffing and staff responsibilities and authority
- burdensome policies and procedures for product registration
- lack of guidelines or commodities for infection prevention and universal safety precaution.s

RECOMMENDATIONS FOR THE POLICY AND REGULATORY ENVIRONMENT

Work with national-level personnel to develop—and encourage policymakers to approve—testing guidelines and protocols and to clarify what personnel, by level, are qualified to provide each test.

As mentioned in the section on standardization, to ensure standardization of testing and, therefore, identification of the commodities needed, testing guidelines and protocols must be established that define the test menus and techniques by level in the system.

Work with national-level personnel and policymakers to ensure that guidelines and policies for infection prevention and universal safety precautions are in place (including a guideline and policy for waste disposal).

Both infection prevention and waste disposal are important activities that take place in a laboratory and that require commodities to be available to carry them out adequately. Guidelines should specify the procedures for those activities and the commodities needed to carry them out. Such commodities should, in turn, be included in the routine inventory management of laboratory commodities.

FINANCING LABORATORY COMMODITIES AND LOGISTICS SYSTEMS

In many countries, the budget for laboratory services is usually included in the budget for essential health services. In some countries, national public health laboratory services have separate budgets for performance improvement, supervision, and supplies. As health systems become more decentralized, the local health administration (state, province, or district) is responsible for funding laboratory services, including commodities. Most of the time such funding covers only lower-level facilities. National and teaching hospitals are often funded through one of the following ministries: health, education, finance, or any combination of those. External donors (universities and research institutions) also support the national and teaching hospital labs.

In some settings, fees are required for laboratory tests at hospitals. Often the revenue from those fees goes back to the hospital and is then allocated to all activities in the hospital, not just for procuring supplies for lab services. From there, money allocated to laboratory commodities is used for local procurement of reagents and supplies that are stocked out at the national-level store.

CHALLENGES IN FINANCING OF LABORATORY COMMODITIES AND LOGISTICS SYSTEMS

- Funding for full supply for all laboratory tests at all levels is unlikely because of the magnitude of required resources.
- Long-term commitment from donors to fund laboratory commodities is limited or nonexistent.
- Funding for overall laboratory services is limited, with different sources of funding, some focusing specifically on one piece or part (e.g., CD4 testing, HIV test kits, malaria rapid diagnostic tests).
- Donors do not coordinate efforts: Some provide just equipment without reagents and consumables; others face the challenge of either providing matching supplies or duplicating efforts.
- The current tendency is to support disease programs, such as HIV- and AIDS-related tests, diagnostics, baseline investigations, and monitoring of ART patients.
- Often, no specific budget or funding exists for logistics functions beyond procurement and storage at the central level.

RECOMMENDATIONS FOR FINANCING LABORATORY COMMODITIES AND LOGISTICS SYSTEMS

Establish a Laboratory Commodity Committee to coordinate donor and government inputs and to develop a commodity security strategy for laboratory services.

As with other commodities—particularly HIV-related commodities—a strong central coordinating committee or body is important. Without that body, no control over the commodities that are brought into the country is possible. The body also holds an important position as a finance coordinator and should coordinate with all donors and stakeholders to make sure that all aspects of the laboratory logistics system are supported. The same committee should develop a strategy for meeting critical needs and for providing a full supply of priority commodities and a plan for achieving laboratory commodity security.

Work with policymakers to establish a specific budget for laboratory commodities and the logistics system to manage them.

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APPENDIX A

TECHNICAL TERMS AND DEFINITIONS FOR LABORATORY LOGISTICS

TECHNICAL TERMS

analyte

An analyte is the substance that is being identified or measured in a lab test.

CD4

Also known as T4 cells, CD4 cells are one of several types of T cells that are important to the immune response. They protect against viral, fungal, and protozoal infections and are the cells most susceptible to HIV. A CD4 count is an indicator of the health of patients' immune systems and thus their risk of developing opportunistic infection. Test results from a CD4 count can also be used to judge when antiretroviral therapy should begin (see *T cell count*).

closed systems

Closed systems are laboratory instruments that require a specific brand of reagents. Closed systems usually (but not always) cost more; they can be of higher quality because of the manufacturing practices. However, the instruments must come from a single source. Closed systems can create more medical waste than can open systems.

coefficient of variation

The coefficient of variation (CV) is a measurement of the precision (or reproducibility) of a laboratory test or process. Modern instruments have a CV of 3 percent to 5 percent. When all other parameters are equal, the lower the CV, the better the test.

consumables

Consumables are items that are used once in performing a test and are not reused, such as microscope slides and cover slips.

durables

Durables are items that can be reused for multiple tests, such as some types of glassware that can be sterilized and reused.

ELISA test

The enzyme-linked immunosorbent assay (ELISA) is used to detect the presence of antibodies in serum. ELISA is used for first-line screening for HIV antibodies; a positive result indicates that antibodies have been detected. The test is sensitive but not specific; thus a positive ELISA is typically confirmed with a Western Blot assay. In resource-constrained settings, first-line screening can be done with either a rapid assay and confirmatory ELISA or a combination of rapid assays.

equipment

Instruments used in a laboratory to conduct a test are considered equipment. These items often are automated and require regularly scheduled maintenance; examples include microscopes and hematology machines. (See below for descriptions of the different systems commonly found in laboratories.)

external quality assurance

External quality assurance is a program that allows testing sites to assess the quality of their performance by comparing their results with those of other laboratories. This comparison is done by analyzing proficiency panels or blind rechecking. External quality assurance often includes on-site evaluation of the laboratory to review the quality of test performance and operations.

feasibility

The feasibility of providing a specific test depends on the availability of all the elements needed to conduct the test: proper equipment; standard operating procedures; adequate quality of water and reagents; and a clean, constant power supply. The human resources, which are equally necessary, include adequate staffing, training, and supervision.

good laboratory practice

Good laboratory practice includes the practices, processes, and conditions required for high-quality laboratory studies to be planned, performed, monitored, and reported.

maintenance spares

Maintenance spares are often overlooked but are necessary for a functioning laboratory. Without adequate spare parts, the laboratory cannot provide reliable service. Most manufacturers can provide an accurate prediction of the type and number of parts required for a given instrument for one year.

medical technician

A medical technician typically has a two-year specialized education and is supervised by a medical technologist.

medical technologist

A medical technologist—or clinical laboratory scientist—typically has a baccalaureate degree and a specialized internship. Many nations require certification examinations and continuing education. Some states also require licensure.

open systems

Open systems are laboratory instruments that do not require a specific brand of reagents. Open systems do not rely on a single source but can use reagents from any manufacturer that develops the specifications needed for the test.

pathologist

A pathologist is a medical doctor specializing in disease or pathology.

preventive maintenance

Preventive maintenance is the sum of the tasks performed on equipment, based on the manufacturer's schedule, to prevent failure of an instrument. It is a proactive process designed to prevent testing errors from instrument failure; it is part of the QA process.

quality assurance

Quality assurance manages the quality of all aspects of the testing process. QA considers pre-analytic, analytic, and post-analytic processes, such as training, interlaboratory comparison, preventive maintenance, and result reporting.

quality control

Quality control (QC) is a statistical control for precision and accuracy of laboratory results. Daily QC provides a benchmark to measure the quality of the testing process. When QC falls outside an acceptable range, the laboratory results may not be released.

reagents

Reagents are the chemical or biological substances used in laboratory testing to detect or measure an analyte (see *analyte*). They vary widely in cost, stability, cold/cool chain requirements, availability, and associated hazards.

reference ranges

In any given population, the reference range describes the range of normal test results. For example, for adult males, the normal glucose range (for a particular technique) will vary from 85 mg percent to 110 mg percent. This variance is considered the normal range for that population.

reliability (or precision)

The reliability of a test is measured in precision. Reliability is not directly related to the sensitivity of the technique but rather to its reproducibility. For example, automated instruments provide more reliability than do manual techniques. As shown by the *coefficient of variation* (CV)—the measurement of precision reported in percentage—automated instruments typically have a CV of less than 8 percent while manual procedures may have a CV of 15 percent or more.

sensitivity

Sensitivity is the probability that a test is positive if the person being tested has the disease or condition. That is, high-sensitivity assays detect a high percentage of true positives. Screening tests, such as rapid HIV tests, must be highly sensitive. Screening tests may require confirmation with a highly specific test, such as the Western Blot test.

sharps

Used needles and lancets, which are biohazardous and medical waste, are called sharps and must be discarded in sharps containers.

specifications

Operational parameters from the manufacturer of a reagent, test, or instrument are defined in the specifications. Specifications may be found in package inserts and instrument manuals. National and international approval of reagents, tests, or instruments is based on meeting those specifications.

specificity

Specificity is the probability that if a test is negative, then the person being tested does not have the disease or condition. That is, high-specificity assays detect a high percentage of true negatives. A highly specific test should be used when a need exists to minimize the number of false negatives, such as when diagnosing an infection in an individual.

standard operating procedures

Standard operating procedures (SOPs) explain step-by-step how to do a particular test, including specimen requirements, environmental conditions, reference ranges, and reporting units. SOPs should be defined or standardized across each level of the laboratory system. For example, every district lab should have the same set of SOPs for the test techniques carried out at the district level.

standardization

Standardization (in the laboratory context) is the process of ensuring that the—

- same menu of laboratory tests, defined by level of the laboratory system (central, regional, district), is offered
- same techniques, defined by level, are used to carry out those tests
- same technical SOPs are followed for those techniques
- laboratory instrumentation, defined by level, is agreed upon.

standards

Standards are the concepts, procedures, and designs needed to achieve and maintain the required levels of compatibility, interchangeability, or commonality in the operational, procedural, material, technical, and administrative fields.

T cell (T lymphocyte)

T cells are white blood cells that stimulate the immune system to fight disease, and they are the primary target of HIV. Called T cells because they mature in the thymus gland, they include T4 and T8 cells, also known as CD4 and CD8 cells.

T cell count (CD4 count)

The T cell count is the number of T4 cells per cubic millimeter (mm^3) of blood—1 mm^3 is the size of a pinhead. As HIV disease progresses, the T4 cells fall from a normal count of 500 to 1,500 to as low as zero. When the T cell (CD4) count goes below 200, the risk of opportunistic infections increases; when the T cell count drops below 50, the risk rises dramatically.

test menus

Test menus describe the defined list of tests that should be offered at a specific laboratory or level (central, regional, district, etc.) of the laboratory system.

usage

Usage refers to the amount of laboratory commodities consumed during a set period. the USAID | DELIVER PROJECT uses the terms *consumption* and *dispensed to user* to describe amounts of health commodities, such as drugs. In the laboratory, *usage* is more appropriate because the supplies are not being consumed by or dispensed to a patient but are being used to conduct a laboratory test.

viral load

Viral load is the measurement of the number of viral particles in circulating blood. HIV and hepatitis C are often quantified with the viral load test. Viral load and CD4 counts are both predictors of the risk of HIV disease progression. Viral load testing is also used to determine when to initiate or change antiretroviral therapy.

Western Blot test

The Western Blot (WB) is a confirmatory test for the presence of HIV antibodies; it is performed only if the ELISA is positive. The WB can be positive, negative, or indeterminate, which is neither positive nor negative. An indeterminate result usually means that a person has just begun to seroconvert at the time of his or her test. In the rare cases in which this result occurs, the person will need to be retested, usually about one month later. False positive results are extremely rare with the WB; the WB confirms that HIV antibodies are present.

SYSTEMS IN THE LABORATORY

chemistry

Chemical information assesses the body's chemical balance. Liver function, kidney function, glucose levels, and enzyme levels are typical chemistry tests. Usually, a specific chemical reaction produces a colored product proportional to its concentration. The instrumentation can range from a very simple filter photometer to an automated testing system. Chemistry tests provide an excellent opportunity to use open systems. Reagent test kits provide high-quality reagents and standards but may be expensive. Consolidated purchasing could provide high-quality reagent kits with competitively priced bulk reagents. Many of these reagents require a cold chain.

hematology

Hematological information assesses the body's ability to carry oxygen, provide immunological surveillance, and prevent hemorrhage. Typical tests include complete blood counts, which measure the number of red blood cells, white blood cells, and platelets. Originally, these tests were done by diluting blood and counting cells, and measuring hemoglobin by comparing the color of the blood. Typically, in resource-poor settings, semi-automated instruments are used, with manual backup in the event of stockouts or instrument failure. The instruments used are almost always closed systems, requiring the manufacturers' reagents. When generic reagents have been used in the past, quality has suffered, and most manufacturers would not support the instruments.

immunology

Classic immunological procedures could also be classified as hematological or microbiological tests. However, many new tests are based on detection of antibodies or antigens. Thus, immunology is a growing field with many new tests introduced each year. Tests for classifying white blood cells into CD type as well as viral load procedures can be included.

Classic serological tests, such as the Weil-Felix and Widal tests, are labor-intensive and have some cold chain reagents. The enumeration of CD4 cells and measurement of viral load require sophisticated instrumentation, expensive labile reagents, and a high degree of training. Emerging low-cost, low-tech systems are being introduced into this dynamic field. This area requires very careful analysis of the appropriateness of any technology proposed.

microbiology

Microbiological procedures can be either observation of stained specimens by microscope, immunological detection of antibodies to a microbe, or growth and isolation of a microorganism on agar-based media. Typical tests include malaria preps, Widal tests for typhoid antibodies, and stool cultures. The required instruments are often open systems and can be labor-intensive and relatively low cost. Many microbiological media are very sensitive to absorption of water from the air and require good laboratory practice for storage and reconstitution. In a resource-limited environment, automation is usually not an option.

urinalysis

The testing of urine is a low-technology, labor-intensive part of the laboratory. Test strip technology is used in many resource-poor settings. The test strips require good laboratory practice to prevent premature expiration.

APPENDIX B

COUNTRY EXAMPLE OF TEST MENU AND TECHNIQUE BY LEVEL

Tests Performed at the Health Center Laboratory

Laboratory Test	Standard Technique
• Hemoglobin estimation	• Oxyhemoglobin, Lovibond comparator
	• Cyanmethemoglobin, Sahli
• Blood slide for hemoparasites	• Field stain
• Stool microscopy for parasites	• Direct saline, iodine
• Sputum for AFBs (acid-fast bacilli)	• Ziehl-Neelsen (ZN) stain
• Skin slit for AFBs	• ZN stain
• Urine sediment microscopy	• Direct microscopy
• Urine protein, sugar	• Uristix
• Syphilis screening	• RPR/VDRL carbon antigen
• Sickle cell screen	• Sodium metabisulphite
• Genito-urinary tract specimens	• Wet preparation/Gram stain/KOH
• Pus swabs	• Gram stain
• Bubo aspirate (plague)	• Wayson staining
• HIV screening	• Rapid screening kits
• Blood grouping (ABO)	• Slide method
• Rhesus typing (Rh)	• Manual, hemocytometer with appropriate dilution fluids
• Total white cell count	• Manual, using stained thin film
• Total red cell count	
• Differential white cell count	• Gram/Leishman/Turks fluid
• Cerebrospinal fluid microscopy	
• Cerebrospinal fluid chemistry	• Turbidimetric
• Serum bilirubin	

Additional Tests Performed at District Hospital Laboratory

• Concentration technique	• Collection and fixation of histological specimens
— Blood	• Buffy coat (Knott's)
— Stool	• Formal ether
• Urine qualitative chemistry (protein, sugar, ketones, blood bilirubin, urobilinogen)	• Multistix or equivalent
• Skin snip for microfilaria	• Saline direct
• Hemoglobin	• Photometric cyanmethemoglobin
• Collection and fixation of cytological smears	• Formalin

Tests Performed at the Regional Hospital Laboratory

• Hemoglobin estimation	• Hematology analyzer
• Total white cell count	
• Total red cell count	
• Differential blood counts	
• Platelet count	
• Reticulocyte count	
• Blood indices	
• CD4/CD8 count	• Flow cytometer
	• Noncytofluorimetric
	• Manual
• Viral load	• HIV RNA
	• Real-time polymerase chain reaction (PCR)
	• Heat-dissociated p24 antigen
	• Cavidi Reverse Transcriptase (RT)
• Sickle cell screening test	• Sodium metabisulfite
• Blood slide examination for parasites	• Manual microscopy (field)
	• Concentration
• Film comment	• Manual microscopy—Romansky
• Stool microscopy	• Direct saline/iodine concentration
• HIV screening	• Rapid screening kits

Additional Tests Performed at District Hospital Laboratory, *continued*

• Hemoglobin types	• Examination for fungi
• Serum proteins	• Confirmatory test for syphilis
• Hepatitis B screening	• Electrophoresis
• Syphilis screening	• Rapid ELISA
• Serum bilirubin	• RPR/VDRL carbon antigen
• SGOT/AST (serum)	• Chemistry auto-analyzer (or manual photometer)
• SGPT/ALT (serum)	• Chemistry auto-analyzer (or manual photometer)
• Alkaline phosphatase (serum)	• Negative staining—India ink
• Renal function tests	• Gram stain
• Blood glucose	• Aerobic
• Serum electrolytes	• Anaerobic
• Total protein	• Microaerophilic
• Examination of CSF for yeast	• Disc diffusion
• Examination of CSF, pus, deposit, etc., micro-organisms	• Wayson staining
• Culture	• Hematoxylin and eosin
• Drug sensitivity	• Microscopy
• Microscopy for plague	• Pap smear
• Processing biopsy	• ZN stain
• Semen analysis	• Direct microscopy
• Cytology	• Multistix or equivalent
• Sputum for TB	• Wet prep
• Urine sediment microscopy	• Gram
• Urine chemistry	• KOH
• Genito-urinary tract specimens	• Tube method
• Blood group, type, and cross-matching	• Saline direct
• Skin snip for microfilaria	• TPHA

APPENDIX C

COMMON LABORATORY TESTS AND COMMODITIES

Note: The supplies identified in this annex are for one standard operating procedure. There may be different SOPs for the technique that require different supplies. Therefore, this list is exemplary, not exhaustive.

Manual Hemoglobin Tests and Laboratory Supplies Needed

Test Technique	Reagents	Consumables	Durables/Equipment
Filter paper comparison		• filter/blotting paper • sterile lancet • 70% alcohol • cotton wool	• color comparison chart
Copper sulfate method	• copper sulfate	• graduated transfer pipette • capillary tube • sterile lancet • 70% alcohol • cotton wool	• flasks • weighing scale • amber-tinted bottles
Hematocrit by centrifuge		• capillary tube • graph paper • sterile lancet • 70% alcohol • cotton wool	• microhematocrit centrifuge

Continued next page

Test Technique	Reagents	Consumables	Durables/Equipment
Lovibond comparator	• ammonia OR • potassium • ferricyanide • potassium • cyanide • dihydrogen • phosphate • surfactant	• blood pipette • sterile lancet • 70% alcohol • cotton wool • parafilm or foil	• glass tubes • Lovibond comparator • colored glass standards
Grey Wedge (BMS) photometer	• saponin powder • EDTA powder	• toothpicks • sterile lancet • 70% alcohol • cotton wool	• BMS Grey Wedge photometer • glass chamber for blood sample • calibrating glass standard • batteries (1.5 volt)
Sahli method	• hydrochloric acid	• sterile lancet • 70% alcohol • cotton wool	• Sahli hemoglobinometer • Sahli blood pipette • dropper
HemoCue		• cuvettes • standard cuvettes • sterile lancet • 70% alcohol • cotton wool	• HemoCue instrument • batteries
Colorimetry-hemiglobincyanide method	• potassium ferricyanide • potassium cyanide • potassium dihydrogen phosphate • surfactant	• standard solution of hemoglobin • graph paper • tube labels	• photoelectric colorimeter • cuvettes • test tubes • watch or timer • calibrated pipettes

Malaria Smear Tests and Laboratory Supplies Needed

Test Technique	Reagents	Consumables	Durables/Equipment
Giemsa stain	• absolute methanol • Giemsa stain powder • glycerol • methyl alcohol • disodium hydrogen phosphate, 1-hydrate • disodium hydrogen phosphate, anhydrous • distilled water	• sterile lancet • 70% alcohol • cotton wool • small plastic bulb pipette • microscope slide • smooth-edged slide spreader • graduated plastic bulb pipette • cover slide • immersion oil	• weighing scale • brown bottle • measuring cylinder • thermometer • volumetric flask • staining rack or Coplin jar • staining trough • draining rack • microscope
Field's stain	• absolute methanol or ethanol • Field's stain A powder • Field's stain B powder • absolute methanol • sodium azide • buffer tablets	• sterile lancet • 70% alcohol • cotton wool • small plastic bulb pipette • microscope slide • smooth-edged slide spreader • graduated plastic bulb pipette • cover slide • immersion oil	• weighing scale • Pyrex beaker • heating source to boil water • storage bottles • measuring cylinder • staining rack • draining rack • microscope

TB Tests and Laboratory Supplies Needed

Test Technique	Reagents	Consumables	Durables/Equipment
Ziehl-Neelsen stain	• basic (carbol) fuchsin • methanol, absolute • hydrochloric acid, concentrated • phenol crystals • malachite green • distilled water	• microscope slides • swab • 70% alcohol • plastic sputum containers • screw-cap container • glass Pasteur pipette or plastic bulb pipette • bleach • immersion oil	• weighing scale • storage bottles • beaker • centrifuge • spirit flame or Bunsen burner • measuring cylinder • draining rack • microscope
Auramine-phenol stain	• phenol crystals • auramine O • methanol, absolute • hydrochloric acid, conc. • potassium permanganate • distilled water	• microscope slides • swab • 70% alcohol • plastic sputum containers • screw-cap container • glass Pasteur pipette or plastic bulb pipette • bleach	• weighing scale • screw-cap bottle • measuring cylinder • beaker • thermometer • storage bottle • brown bottle • spirit flame or Bunsen burner • staining jar • draining rack • fluorescence microscope
Sputum culture	• physiological saline • Columbia agar • horse (or sheep, rabbit) blood • MacConkey agar	• plastic sputum containers • autoclave tape • sterile petri dish • aseptic transfer pipettes	• autoclave • incubator

Chlamydia

Test Technique	Reagents	Consumables	Durables/Equipment
Direct immunofluorescence (at referral lab level only)	• specific reagent kit for chlamydia, syphilis, or Legionella	• depends on kit • microscope slides • swab • dry sterile tube for transport of swabs	• fluorescence microscope
EIA (enzyme immunoassay)	• specific reagent kits	• depends on kits • microtiter plates • swab • dry sterile tube for transport of swabs	• ELISA washer/reader
Rapid assay	• rapid chlamydia test kit—two common test kits[1]: • chlamydia STAT-PAK, manufactured by Chembio Diagnostic Systems • Clearview Chlamydia, manufactured by Unipath	• all consumables are supplied with the kits	• heat block (if using Clearview Chlamydia test kit)

[1] From Monica Cheesbrough, *District Laboratory Practice in Tropical Countries,* Part 2 (Cambridge, U.K.: Cambridge University Press, 2000), 234.

Syphilis

Test Technique	Reagents	Consumables	Durables/Equipment
RPR	• specific reagent kit	• depends on kit • evacuated collection tube • needle • 70% alcohol • cotton wool	• card rotators
VDRL	• specific reagent kit	• depends on kit • evacuated collection tube • needle • 70% alcohol • cotton wool	• microscope
TPHA/TPPA	• specific reagent kit	• depends on kit • evacuated collection tube • needle • 70% alcohol • cotton wool	

Gonorrhea

Test Technique	Reagents	Consumables	Durables/Equipment
Culture	• Gonococcus (Thayer-Martin) agar • hemoglobin powder • Factor X/V supplement • VCNT antibiotic supplement	• sterile petri dish • swab	• autoclave • round bottom flasks
Gram stain	• crystal violet stain • potassium iodide • iodine • acetone • neutral red	• microscope slide • swab	• microscope

APPENDIX D

CRITERIA FOR LABORATORY TEST SELECTION

Lab tests are selected for each level of the health system on the basis of their efficiency in identifying positive tests when the results are truly positive (i.e., true positive) and in identifying negative tests when the results are truly negative (i.e., true negatives). A test is considered highly efficient when it is both sensitive and specific. These measures can be considered a determinant of the quality of the test.

- **Sensitivity or validity:** A test that is highly sensitive will correctly detect all or most of those people who have the disease or condition. It will detect a high number of true positives.
- **Specificity:** A highly specific test is one that reliably identifies those people who do not have the disease. It will detect a high number of true negatives.

There are also two other important determinants of the quality of a test:

- **Reliability or repeatability:** The reliability of a test is the ability for the same biological sample to produce similar results. Reliability is closely related to the sensitivity of the technique. For example, devices that automate measurement offer more reliability than when a technician interprets the results.
- **Feasibility:** The feasibility of a test depends on the availability and quality of all the elements needed to conduct a test, such as having the necessary equipment, having appropriate storage facilities for the reagents to ensure their potency, and having adequate quality water and a constant power supply. Equally important is having equipment in good working condition with available spare parts to repair them when needed.

In addition to the preceding qualities, various criteria are used in the selection of laboratory tests, including the following:

- **Clinician preference within policy boundaries.** In standard medical practice, laboratory tests are prescribed by clinicians. Ideally, they choose tests that are clinically useful in making diagnoses and in treating disease. The tests available are typically limited to those permitted by the policies established in the country.
- **Convenience.** Tests should be easy to obtain and perform, and the results should be clear for interpretation.
- **Economic feasibility.** Supplies needed, such as reagents, should be reasonably priced to ensure their availability. In resource-poor settings, the tests should be affordable to patients if they will be responsible for some or all of the cost.

- **Service feasibility.** Not all tests are available at every level of the health system. Only tests that are part of the package at the health center level can be offered there; tests requiring more complicated techniques and equipment are typically done at higher levels in the health system.
- **Public health significance.** Tests that require specific technology for rare diseases or public health significance (e.g., Ebola, multidrug-resistant tuberculosis, Lassa fever, yellow fever) are typically performed by a public health reference laboratory.
- **Purpose of the test.** Laboratory tests are conducted to diagnose an illness or condition, fine-tune treatment, and monitor effectiveness of the treatment and possible side effects and toxicity. Pretreatment tests provide clinicians with baseline data that can be used for comparison later.

APPENDIX E

SAMPLE LABORATORY LMIS RECORDS AND REPORTS

Card No. _____

MINISTRY OF HEALTH
INVENTORY CONTROL CARD

District:

Facility/Store Name:

Name of Officer In-Charge:

Commodity Code:		**Name of Commodity:**		
Unit of Issue	**Unit Cost**	**Minimum Stock Level (Months)**	**Maximum Stock Level (Months)**	**Location**

Date	**Transaction Reference**		**Quantity Received**	**Quantity Issued**		**Losses –/+ Adjustment**	**Quantity on Hand**	**Remarks**
	No.	**Name of Facility**		**Amount**	**Batch No.**			
					Balance to Carry Forward			

Daily Log for Consumption of HIV Tests

Date	Client Name/ Number	Purpose of testing						Determine	Uni-Gold	Bionor	
		PMTCT	VCT	PITC	Blood Safety	Sentinel Surveillance					
Page total											
Running monthly total											

LMIS Report and Request for HIV Tests

Reporting Period: From _____ to _____
mm/dd/yy mm/dd/yy

Maximum Stock Level: 4 months

Minimum Stock Level: 2 months

Facility:_____ District: _____

HIV Test	Basic Unit	Opening Balance	Quantity Received	Losses/ Adjustments	Quantity Consumed	Physical Count/ Closing Balance	Maximum Stock Quantity	Quantity Needed
		A	B	C	D	E	F = D x 4	G = F – E
Determine	Test							
Uni-Gold	Test							
Bionor	Test							
	Test							
	Test							

Summary of clients by purpose of testing

	VCT	PMTCT	PITC	BLOOD SAFETY		
Total clients						

Prepared by: _____

Date prepared: _____

MINISTRY OF HEALTH
USAGE DATA REPORT FOR LABORATORY COMMODITIES
SAMPLE FORM

Facility Name:

AGENCY

District:

Province:

Ministry of Health:

Local Authority:

Private:

Faith-Based Organization:

OTHER (Specify)

Report of Period Beginning

Report of Period Ending

Part I. Full-supply commodities

		A	B	C	D	E	F
Laboratory Supply	**Unit**	**Beginning Balance**	**Quantity Received**	**Quantity Issued**	**Losses**	**Adjustments**	**Balance**

Part II. Non-full-supply commodities

		A	B	C	D	E	F
Laboratory Supply	**Unit**	**Beginning Balance**	**Quantity Received**	**Quantity Issued**	**Losses**	**Adjustments**	**Balance**

Name: Signature: Designation: Date:

Explain:

APPENDIX F

LABORATORY TESTS FOR SELECTED DISEASES OF PUBLIC HEALTH SIGNIFICANCE

This section summarizes key clinical features for HIV/AIDS, gonorrhea, syphilis, chlamydia, tuberculosis, and malaria. It also reviews the most pertinent tests for those diseases. The diseases are significant because of their high rates of morbidity and high rates of mortality for AIDS, malaria, and tuberculosis.

HIV/AIDS

With the advent of antiretroviral therapy, HIV-infected individuals are living longer and with a higher quality of life. To initiate therapy and to effectively monitor the patient on antiretroviral therapy (ART), several laboratory examinations are required. According to the *2003 Revised Guidelines for ART in Developing Countries* (WHO, n.d.), the following tests should be available for patients on ART:

MINIMUM TESTS REQUIRED

HIV antibody test is required before treatment to confirm the seropositive status of the patient. Hemoglobin or hematocrit is also required to monitor treatment because of the risk of anemia.

BASIC RECOMMENDED TESTS

The World Health Organization (WHO) does not consider these tests as essential for starting ART in resource-poor countries because of the sense of urgency to provide treatment, coupled with the fact that laboratory services needed to administer the tests might not be available. However, these tests are recommended where the resources exist.

The tests are as follows:

- white blood cell count and differential to assess for neutropenia and total lymphocyte count
- serum alanine or aspartate aminotransferase levels to assess for hepatitis co-infection and to monitor for hepatotoxicity (liver damage)
- serum creatinine and/or blood urea nitrogen levels to assess baseline renal (kidney) function

- serum glucose level to assess for insulin resistance given the tendency of protease inhibitors to induce this condition
- pregnancy (When efavirenz is used, pregnancy testing is mandatory because of teratogenicity.)

The following tests allow the health care provider to obtain baseline data regarding the functioning of the immune system as well as the patient's viral load.

DESIRABLE TESTS

Bilirubin, amylase, serum lipids, and CD4 cell counts are important for monitoring efficacy as well as toxicity of treatment. CD4 counts are relatively expensive in resource-poor settings and, therefore, are available in few locations.

OPTIONAL TESTS

The viral load test for HIV is an expensive test that is typically available at only higher-level laboratories, if it is available at all.

Medical management requires comparing baseline laboratory data to measure progress made in controlling the disease or to assess whether treatment is inducing toxicity. Tests may be requested on a regular basis according to the treatment protocol or in response to symptoms reported by the patient.

WHO proposes the following tests for monitoring first-line ART regimens at primary health care centers and district hospitals.

Regimen	Laboratory Assessment at Baseline (pretherapy)	Laboratory Assessment on Therapy
D4T/3TC/NVP	Desirable but not required: CD4	Symptom-directed determination of alanine aminotransferase (ALT) indicating toxicity and possible liver cell damage CD4 every 6–12 months, if available, to monitor efficacy of treatment
ZDV/3TC/NVP	Recommended: Hemoglobin (Hgb) Desirable but not required: Full blood count (FBC), CD4	Symptom-directed determination of Hgb, white blood cell (WBC) count, ALT for toxicity CD4 every 6–12 months, if available, to monitor efficacy of treatment
D4T/3TC/EFV	Pregnancy test mandatory when efavirenz is used due to teratogenicity Desirable but not required: CD4	Symptom-directed testing, but none routinely required for toxicity CD4 every 6–12 months, if available, to monitor efficacy of treatment
ZDV/3TC/EFV	Pregnancy test mandatory when efavirenz is used due to teratogenicity Recommended: Hgb Desirable but not required: FBC, CD4	Symptom-directed determination of Hgb, WBC count for toxicity CD4 every 6–12 months, if available, to monitor efficacy of treatment

SEXUALLY TRANSMITTED INFECTIONS

Although the list of sexually transmitted infections (STIs) is long, the list below includes information on only three that have high prevalence worldwide. In 1995, WHO estimated that worldwide prevalence of STIs was 333 million cases. STI prevalence is particularly important because several studies have shown that some STIs facilitate the transmission of HIV, such as in the case of patients with genital ulcer. In this light, STI treatment and prevention are included as strategies to prevent HIV.

GONORRHEA

Gonorrhea is caused by a microorganism called *Neisseria gonorrhoeae*. Because gonorrhea symptoms appear differently in males and females, laboratory examination is often required to confirm diagnosis.

A swab is used to collect secretions from either the urethra for the male or the cervix for the female.

Lab tests

- **Direct microscopy.** The Gram stain of a urethral discharge is the preferred lab test to diagnose gonorrhea in men. Staining the urethral specimen with methylene blue is another method that can give a quick and reliable diagnosis in men.
- **Culture identification.** The specimen is grown on culture media in an incubator with a rich carbon dioxide (CO_2) environment. Colonies of the bacteria (*N. gonorrhoeae*) appear after 24 to 48 hours of incubation. In the laboratory, identification is made by colony morphology, microscopic morphology, and positive oxidase reaction. In women, repeated culturing may be necessary to successfully grow the organism.

SYPHILIS

Syphilis is a widespread infectious disease caused by the infectious agent *Treponema pallidum*. The most common clinical feature in the primary stage of the disease is the presence of a chancre (painless ulcer) in the genital area. Other clinical features typify secondary and tertiary stages of the disease. Because a genital discharge is not a feature of this disease, blood specimens are used for laboratory examination.

Lab tests

- **Direct microscopy.** Use of a dark-field microscope provides the quickest diagnosis of syphilis in the primary and secondary stages, but staff members must be well trained and appropriate equipment is required.
- **Venereal disease research laboratory.** VDRL is a blood test using a slide flocculation method employing treponemal antigens such as cardiolipin, lecithin, and cholesterol as antigen. The results of the test should be read with a microscope at 100× magnification.
- **Rapid plasma reagin.** RPR is another blood test using flocculation methodology that has a reaction visible with the naked eye. The method uses plastic-coated cards in lieu of slides and a stabilized antigen to which charcoal particles are added.

CHLAMYDIA

Chlamydia is caused by a bacterium called *Chlamydia trachomatis* and can affect men and women. Although many women are asymptomatic, some patients have a clear or white urethral or vaginal discharge. Chlamydia and gonorrhea may coexist in 30 percent of cases of acute gonococcal urethritis, so testing for both conditions may be warranted based on clinical presentation and patient history.

Lab tests

The lab tests can involve culture and nonculture methods of detection. Laboratory specimens include urine and swabbings from the urethra and cervix.

- Giemsa staining (low sensitivity) not recommended
- culture not recommended
- recommended tests:
  - urethral swab for enzyme immunoassay (EIA) or polymerase chain reaction (PCR)
  - urine EIA or PCR

Specimens submitted for EIA or PCR can also be tested for gonorrhea.

TUBERCULOSIS

Tuberculosis (TB) is an infectious disease caused by *Mycobacterium tuberculosis.* Although TB can affect any organ, it primarily involves the lungs, which facilitates airborne transmission. TB is one of the most common opportunistic infections in HIV-positive persons. For example, Kenya reported a sevenfold increase in TB cases, from 12,320 in 1991 to 82,114 in 2002, an increase that was closely linked to the HIV pandemic there. Note that although several mycobacteria can cause illness in humans, TB is the only one of public health significance.

Lab tests

- **Sputum smear.** This test is performed on a sputum sample that is obtained through deep expectoration (not just spitting) to identify pulmonary tuberculosis. It is common to examine three smears collected on separate days for each patient because it can be difficult to get a good specimen, particularly from children. Sputum samples continue to be collected and tested during treatment until the tests indicate that the person is no longer infective (i.e., sputum-smear results are negative).
- **Sputum culture.** Culturing sputum for TB can be performed to diagnose pulmonary tuberculosis in patients who produce too few bacilli to be detected on a smear. In addition, cultures are used to test for drug sensitivity and resistance.

MALARIA

Four types of human malaria exist worldwide, but only *Plasmodium falciparum* tends to be life threatening. The others—*Plasmodium vivax, Plasmodium malariae,* and *Plasmodium ovale*—have significant effect on human populations by causing incapacitating illness, loss of time at work and school, and strain on the health care system. Infection with falciparum can be dramatic and can affect many organs. Although clinical management of a patient might require many laboratory examinations, the most important is the test to identify whether a parasite is present and, if so,

which parasite is present, because treatment can vary depending on the type of malaria parasite the patient has.

Lab tests

- **Microscopic blood film examination.** This test is the gold standard for laboratory confirmation of malaria and is sometimes repeated during treatment to monitor whether the parasite has been eliminated from the blood. Because of the endemic nature of malaria in many locations, repeat films are often not performed if the patient is responding well to treatment. The test is performed by collecting two drops of blood from the patient, one for a thick smear and one for a thin smear. After the specimens are treated with a stain (typically Giemsa stain), parasites can be identified by examining the specimen using a microscope. The reliability of this test depends on the quality of the stain and the microscope and the experience level of the lab technician.

Because patients with malaria may have severe anemia, additional tests may be required, such as full blood count and hematocrit. However, those tests are not available at all levels, and clinical indications of anemia are used when laboratory examination is not possible.

Additional postdiagnosis tests

The following are additional tests that can be performed after malaria has been confirmed. Note that most are not available in resource-limited settings.

- **Antigen detection.** Still under evaluation are test kits using rapid (dipstick-style) diagnostic methods yielding results in 2 to 10 minutes. Unfortunately, those methods are costly and may be too expensive for general use in malaria-endemic countries.
- **Molecular diagnosis.** A test that may eventually be more widely available is one that identifies parasite nucleic acids through PCR. Although PCR is more accurate than microscopy, it is expensive and requires a specialized laboratory. In time, it is envisioned that field-operated PCR machines will be available.
- **Serology.** A serological blood test detects antibodies formed by the body to fight the malaria parasites. Either indirect immunofluorescence assay or enzyme-linked immunosorbent assay methods are used. Serology does not detect current infection but rather measures past experience describing a person's relative immunity to the disease.
- **Drug resistance test.** Drug resistance tests are performed in specialized laboratories to assess the susceptibility of the parasite to antimalarials. Two methods are available: in vitro tests and molecular characterization. Those tests are not commonly used in clinical practice but are used in research settings to examine resistance patterns.

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