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GUIDELINES FOR MANAGING THE LABORATORY SUPPLY CHAIN (V.2)

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Abstract
The importance of quality laboratory services is indisputable. The expansion of programs for HIV and AIDS, tuberculosis, and malaria require 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 paper 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 Photo: Laboratory supplies in a laboratory in Zambia. Taken by Carmit Keddem.

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ACRONYMS

AIDS	acquired immunodeficiency syndrome
APHL	Association of Public Health Laboratories (U.S.)
ART	antiretroviral therapy
CD4/CD8	cluster of differentiation (ratio of CD4 cells to CD8 cells)
CDC	Centers for Disease Control and Prevention (U.S.)
cm	centimeter
EQAS	external quality assessment system
FEFO	first-to-expire, first-out
FPLM	Family Planning Logistics Management
g	gram
GPR	general-purpose reagent
HIV	human immunodeficiency virus
LMIS	logistics management information system
m	meter
mL	milliliter
mm	millimeter
max-min	maximum-minimum
NPHLS	National Public Health Laboratory Service
QA	quality assurance
QC	quality control
RPR	rapid plasma reagin
SOP	standard operating procedure
SDP	service delivery point
STI	sexually transmitted infection
TB	tuberculosis
VDRL	venereal disease research laboratory test
WHO	World Health Organization
WHO-AFRO	World Health Organization, Regional Office for Africa

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 require 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. 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.

In most developing countries, laboratories serve both a public health role and a clinical role.

The role of the public health laboratory is 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
- Regulate private and clinical laboratories to ensure quality laboratory practices
- 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 food for safety and water sanitation, and drug resistance and susceptibility testing

The role of the clinical laboratory is to—

- 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

The organization of laboratory services is dictated by local policy. The network usually includes a central or national-level lab, intermediate-level labs, and peripheral labs. A central or national reference laboratory provides all laboratory services possible within the health system of the country; intermediate lab facilities provide less complex services; and peripheral labs, usually located at the health centers and smaller service delivery sites, provide basic laboratory services. Typically, higher-level lab facilities provide supervision, quality control, and technical support to lower-level facilities.

Policies help set standards for laboratory practice, including the tests and techniques that will be used, which ultimately dictate the commodities that are required to support laboratory services.

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

First, laboratory commodities can be classified into three categories: reagents, consumables, and durables.

- 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.
- Consumables are items that are used once while performing a test and are not reused. Consumables can include such test-specific items as microscope slides and cover slips. 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. This classification also includes equipment and instruments used for testing.

Laboratory commodities may be classified in several other ways to help organize and rationalize decision making. For example, commodities may be organized according to whether they are slow moving or fast moving, according to the length of their shelf life, or according to whether they are in full supply or non-full supply.

Several characteristics peculiar to laboratory commodities affect the design and management of the logistics system:

- Large numbers of commodities are needed. Depending on the levels of the logistics system, 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 3 months or less.
- Some laboratory commodities have special storage requirements, such as cold-chain storage.

Given the wide range of commodities needed at the various levels of the laboratory network, a critical task is ensuring that commodities are available when and where they are needed. Recommendations for logistics system design and implementation for laboratory commodities include the following.

SERVING CUSTOMERS

- Improve the logistics system to improve customer service.
- Ensure commodity availability by securing adequate funding for laboratory commodities.

LOGISTICS MANAGEMENT INFORMATION SYSTEM (LMIS)

- At the facility level, use issues from stock as consumption data (stock issued from the stores to the bench). Use and maintain stock-keeping records.
- Use an Activity Register to track the actual consumption of only a small number of tracer commodities.
- Use the unit of issue at the facility level as the unit for stockkeeping and reporting.
- Routinely report stock levels, issues, losses and adjustments, and stockouts. If using a pull system, link reporting with resupply.

PRODUCT SELECTION

- Use standard testing protocols to develop a commodity list for each level in the laboratory supply system.
- Select products that are appropriate based on the testing protocols, cost, training of personnel, and infrastructure for storage and transportation.
- When possible, choose open systems for test instrumentation.
- Be prepared for changes in test technology.

QUANTIFICATION AND PROCUREMENT

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

INVENTORY MANAGEMENT

- Ensure that the length of the pipeline accommodates the shelf life of the products.
- If using a 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 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.

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.
- 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. Further, expanding programs for HIV and AIDS, TB, and malaria require strong and supportive laboratory services. The supply chain challenge for laboratories goes hand in hand with that of supplying commodities for HIV and AIDS prevention, care, and treatment. With the introduction of ART, recognition of the importance of laboratory services has grown because of the number of laboratory tests required to effectively monitor treatment. The need to improve laboratory services for HIV and AIDS testing and for all of these disease programs provides an opportunity to strengthen laboratories in health systems overall to accommodate the needs of the communities they serve.

The importance of quality laboratory services is indisputable. Laboratory services support clinical practice by providing information for differential diagnosis, for clinicians to choose appropriate treatment regimens, and for monitoring treatment. Monitoring tests enable clinicians to determine whether treatment is efficacious or toxicity is developing, allowing 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 of the disease.

Initiatives such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria and the President's Emergency Plan for HIV/AIDS Relief have expanded the USAID | DELIVER PROJECT's mandate to include laboratory services in support of clinical services for HIV and AIDS, TB, and malaria. Consequently, this document provides basic information to logisticians on—

- The function and organization of laboratory services
- Commodities for laboratory services—reagents, consumables, and durables
- Supply chain considerations for management of laboratory commodities

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

The material included in this document has been drawn from the literature on laboratory services, from USAID | DELIVER PROJECT documents on logistics and ART, and from our experience in the field assisting governments to assess, develop, and improve their supply chains in support of laboratory services.

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, 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, generally without regard to the community or the greater public good.

A clear-cut boundary does not always exist between public health laboratories and clinical laboratories. Some laboratories may combine the two functions for cost-effectiveness. For example, some public health laboratories perform diagnostic testing to raise revenue that can help achieve public health objectives.

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 will 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
- Regulate private and clinical laboratories to ensure quality laboratory practices
- 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

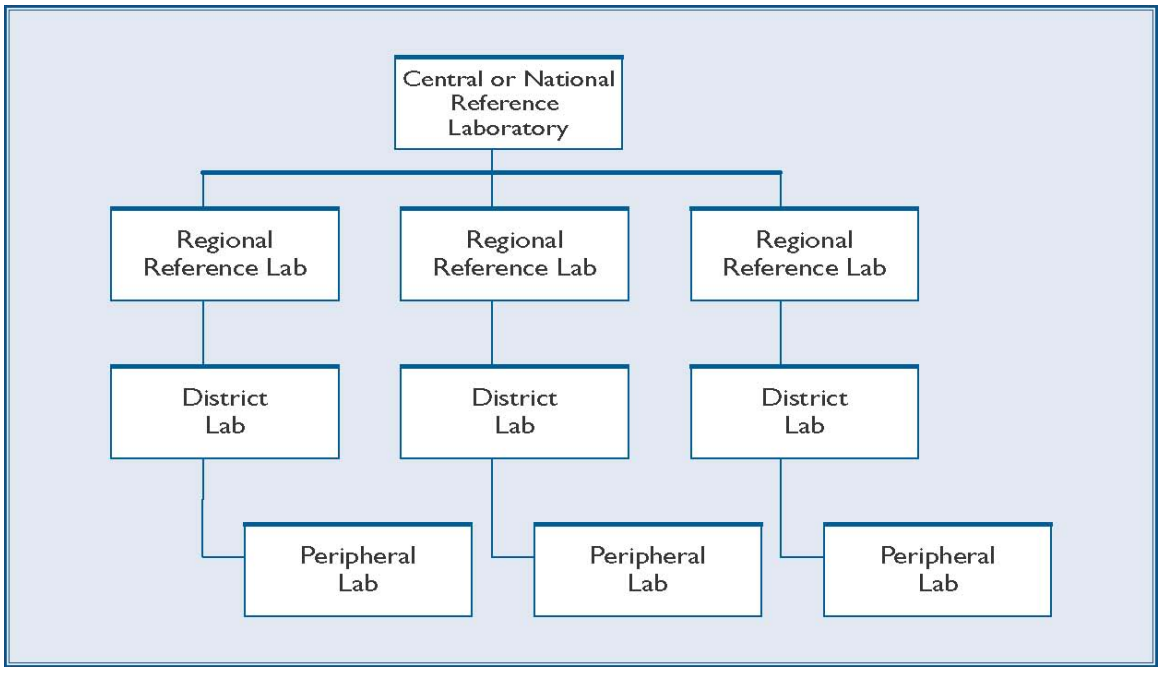
The role of the clinical laboratory is to—

- 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. A central or national reference laboratory provides all laboratory services possible within the health system of the country; intermediate lab facilities provide less complex services; and peripheral labs, which are usually located at the health centers and smaller service delivery sites, provide basic laboratory services. 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



CENTRAL-LEVEL LABORATORY ROLE AND ORGANIZATION

The central-level laboratory is the highest-level laboratory within the network of national laboratory services. It is often managed by the division of laboratory services and diagnostics within the department of curative services of a Ministry of Health and is referred to as the central or national public health laboratory services (NPHLS). Generally, the central laboratory provides the widest range of tests available to patients and is organized in several departments, including hematology, biochemistry, parasitology, bacteriology, histology, immunology, and virology.

In addition to providing direct laboratory services to patients, the primary mandate of the central level laboratory is to—

- Develop standard operating procedures (SOPs) for testing services
- Manage human resources (staff deployment, development of training curriculum for the universities and teaching centers, staff training, staffing scheme per level)
- Provide guidelines for provision of testing (test menus and equipment per level)
- Report and manage diagnosis and monitoring of communicable disease outbreaks
- Provide support and supervision to the lower-level laboratories

Multicounty regional laboratory networks have been created so laboratories from several countries can learn from each other and can share lessons.

Areas of collaboration include—

- New testing techniques
- Staff training
- Quality assurance challenges

In Africa, a laboratory network for HIV/AIDS and STI testing has been formed with support from the Regional Bureau for Africa of the World Health Organization (WHO/AFRO). A similar network has also been formed by WHO/AFRO for polio surveillance.

Additionally, the quality assurance (QA) and quality control (QC) scheme is often directed from the central-level laboratory. The central laboratory usually serves as a reference lab for lower-level facilities.

Central-level laboratories are not usually responsible for managing the 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. However, the central 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. A national referral laboratory is not usually managed within the national laboratory network; rather, it is considered a center of excellence and is sometimes used as a reference laboratory. National referral laboratories are supported by external donors such as universities and research centers, who often provide necessary resources. These laboratories offer comprehensive, high-skilled testes 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.

INTERMEDIATE LABORATORY ROLE AND ORGANIZATION

In most developing countries, intermediate laboratories are located at district or regional hospitals and may act as clinical and public health laboratories. Intermediate laboratories may be expected to provide the following services:

- 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

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 functions:

- 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 assessment 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

Although country-specific policies dictate staffing patterns and resource constraints affect space and equipment available, the following list suggests resources needed at an intermediate laboratory:

- Intermediate laboratories should be staffed with a qualified pathologist or microbiologist (Doctor of Medicine/Diplomate in Clinical Pathology), a clinical laboratory scientist, technologists, technicians with experience, laboratory assistants, laboratory attendants, a cleaner, and a clerk/storekeeper. Although hiring the services of a full-time epidemiologist may not be possible, at least part-time help of an epidemiologist should be available.
- Space should include room for a microbiology/serology laboratory (approximately 8 m × 5 m), sterilization, disinfection, and media preparation laboratory (approximately 6 m × 4 m), one storeroom (approximately 3 m × 5 m), and an office (approximately 3 m × 5 m).
- Other necessary facilities include a supply of safe water, a reliable source of energy (e.g., battery, electricity, solar, or kerosene), sterilization/disinfection facilities, and waste disposal facilities.

Equipment should include autoclaves, balances, binocular microscope, bright-field microscopes, centrifuges, pH meter, dark-field microscope, filter photometers or spectrophotometers, hot-air oven, incubators, micropipettes and venereal disease research laboratory test (VDRL) shaker, Neubauer counting chambers, refrigerator, spectrophotometers/colorimeters, water bath, and water distillation apparatus.

PERIPHERAL LABORATORY ROLE AND ORGANIZATION

Peripheral laboratories are located at the patients' first point of contact with the health system: the service delivery point. Those laboratories support preventive, curative, and health promotion

services for the individual and the community. Although country-specific policies dictate staffing patterns, and resource constraints affect space and equipment available, the following list suggests resources needed at a peripheral laboratory:

- Staff in peripheral laboratories should include one technician and one laboratory assistant/ attendant.
- Space in peripheral laboratories should include one laboratory with space for office/record room (approximately 5 m × 3 m) and one storeroom that can be used for other services (approximately 5 m × 3 m).
- Other necessary facilities include a supply of safe water, a reliable source of energy (e.g., battery, electricity, solar, or kerosene), sterilization/disinfection facilities, and waste disposal facilities.
- Transport and communication facilities must be available between the peripheral and intermediate laboratories for referral of samples and patients, procurement of supplies, and personnel discussion.

Equipment should include autoclaves, balances, centrifuges, filter photometer, incubators, pH meters, refrigerators, water bath, and working microscopes.

LABORATORY SERVICES—TESTS

The range of services provided at each level of the laboratory system is usually defined by the specific tests to be performed. Although services offered are dictated by policy and standards, the range of services will also be limited by the capacity of the staff and the availability of reagents, supplies, and equipment. For each system, logistics advisors need to understand what laboratory services are supposed to be provided at each level in the health care system so they can determine the appropriate supply needs.

To illustrate the difference in services by level, appendix B describes the range of laboratory tests offered and the techniques used at each level in the health system in many developing countries. Not only can several laboratory tests be conducted using a variety of techniques, but each technique for a test may require different commodities. The associated logistics considerations are discussed in the following sections. As would be expected, the higher levels in the system provide a more extensive range of tests than the lower levels, using more commodities and more sophisticated machinery.

POLICIES AND STANDARDIZATION OF LABORATORY SERVICES

Most developing countries are in the process of developing national laboratory policies or are in the initial stage of implementing those policies. National policies affect almost every logistics activity, particularly system assessment and design, inventory management, and quantification. Policies help set standards for laboratory practice, including the tests and techniques that will be used—standards that ultimately dictate the commodities required to support laboratory services.

National laboratory policies should include policies on—

- Laboratory administrative structure
- Test menu by level
- Staffing, responsibilities, and training by level
- Supervision roles
- QA/QC scheme
- Specimen and patient referral system, if applicable

National laboratory policies should lead to standardization of laboratory practice, which enables quality services and simplifies the supply chain. Standardization is also required if an external QC system is used and ensures internal quality when all staff members in a lab and all labs at the same level use the same procedures. Standardized laboratory systems require the management of hundreds of commodities; in nonstandardized systems the number of commodities easily runs into the thousands, since different tests can be conducted using different techniques, each of which can have unique commodity requirements.

Standardization in the context of laboratory services means—

- Test menus set by level
- Defined and standardized technical SOPs for testing services by level
- Agreed instrumentation and equipment by level

There are multiple benefits to standardization, including—

- Uniform and consistent case definition and case management, and thus improved service provision to the clients
- Manageability by streamlining the number and range of laboratory products
- Rational decision making throughout the supply chain, particularly in product selection, forecasting, quantification, and procurement
- Agility in the supply chain, allowing redistribution of supplies to reduce stock imbalances
- Affordability through economies of scale when procuring reagents and supplies.

Refer to USAID | DELIVER PROJECT's (2008) *The Supply Chain Implications of Laboratory Standardization: Lessons Learned and Practical Approaches* and to the USAID | DELIVER PROJECT's (2007) *Building a Standard Equipment List*.

COMMODITIES FOR LABORATORY SERVICES

CHARACTERISTICS OF LABORATORY COMMODITIES

For laboratory commodities, several characteristics affect the design and management of the logistics system.

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 sheer number of commodities has serious implications for the design of the logistics information and inventory control systems.

Laboratory commodities come in a variety of preparations, including dry powders, liquids, and kits.

Laboratory commodities, particularly reagents, come in a variety of preparations. The physical presentation of a commodity has implications for its storage and distribution and may present challenges in quantifying the commodity.

Many reagents come as dry powders that are measured and reconstituted with distilled water for use in tests. Dry powders are measured using a balance or scale; the liquid used for reconstitution is measured using a graduated beaker. The solution is held and stored in a reagent bottle. Dry powders generally have a longer shelf life than 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 dry powders, and the bottles break more easily during distribution.

Several tests come as kits that contain all or most of the commodities required to perform many of 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. In other cases, the quantity of consumables may not be sufficient for the number of tests that can be performed by the reagents included or does not take into consideration possible wastage. For example, the Uni-Gold™ HIV rapid test 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.

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 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 liquid reagents, and reconstituted reagents have a shorter shelf life than 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 sample categories of laboratory supplies. The list in the table is illustrative, not exhaustive.

Table 1. Illustrative List of Reagents and Their Storage Information

Reagents	Shelf Life	Storage Temperature	Packaging
Blood typing sera	24 months	2°–8°C	5 mL bottle (6 bottles in a package)
Bacteriological media	36 months	21°–30°C	500 g bottle
Chemistry reagent kits	12 months	2°–8°C or 21°–24°C	100 tests per kit
CD4 antibody reagent	≥7 months	2°–8°C	50 tests per kit
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, a wide variety of storage requirements exists 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 that require cool or cold storage
- Commodities that deteriorate rapidly when exposed to light or moisture
- Specimens (fragment of tissue) that require freezing

Only some laboratory commodities are in full supply.

The term full supply means that commodities are available for anyone who needs them. Simply put, in a maximum-minimum inventory control system, facilities will be able to reorder and receive commodities up to their maximum stock level. For example, a woman is buying groceries at the end of the month for her family. At the end of the month, supplies of vegetables and meats are running low. In a full-supply situation where there is unlimited funding and political will, she would be able to order as much meat and vegetables as required for the month. In a non-full-supply situation (maybe money is running low that month), she would not have sufficient funds or ability to order the required commodities for the following month, and therefore might be able to buy only enough to prepare lunch every other day.

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 (if not standardized) of commodities, are generally underfunded, donors are not generally coordinated, and therefore are not able to meet all commodity requirements. While everyone strives for an environment where commodities are in full supply, unlike other products (e.g., contraceptives, ARVs), laboratory commodities as a general group are not currently 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. Additionally, it may be true that a facility, such as a teaching hospital, might have sufficient funding to have all commodities in full supply. 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 only one commodity is missing, it may not be possible to perform the test. 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.

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 and LMIS.

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. Because of their sheer numbers, it can be helpful to classify laboratory commodities to rationalize logistics decision making.

REAGENTS, CONSUMABLES, AND DURABLES

Laboratory commodities can be classified into three categories: reagents, consumables, and durables.

- 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 can be further subcategorized into liquid and solid reagents.
- Consumables are items that are used once while performing a test and are not reused. Consumables can include such test-specific items as microscope slides and cover slips. Other consumables, such as bleach, alcohol, and gloves, cut across all testing services and are classified as general laboratory consumables.
- Durables are items that can be reused for multiple tests. They include items such as glassware that can be washed, sterilized, and reused. This classification also includes equipment and instruments used for testing.

Generally, reagents and consumables are commodities that are routinely reordered and managed. Durables are ordered on an as-needed basis and do not require the same level of logistics management. This document concentrates on management of reagents and consumables.

SLOW-MOVING AND FAST-MOVING

In addition, 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. This distinction is important from a supply chain perspective because it impacts how much stock a facility would want to keep, how much should be reordered and when, based on how quickly and how much product was consumed.

SHELF LIFE

Furthermore, commodities may be classified according to the length of their shelf life. When designing logistics systems for laboratory commodities, given 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 distribution) will, in most cases be different to accommodate the short shelf life.

FULL SUPPLY OR NON-FULL SUPPLY

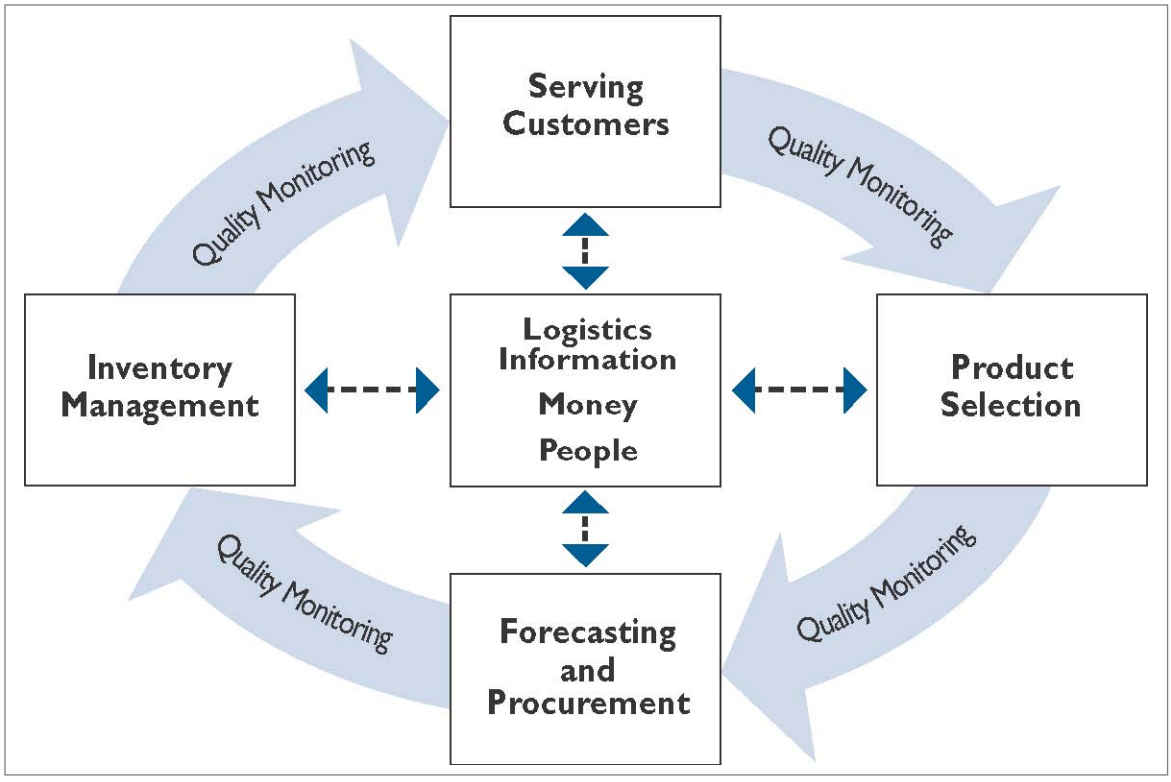
Finally, commodities can be classified according to whether they are in full supply or non-full supply. The term full supply means that commodities are available for anyone who needs them. Some, but not all, laboratory commodities are in full supply; therefore this distinction is important for supply chain purposes.

SUPPLY CHAIN CONSIDERATIONS FOR LABORATORY COMMODITIES

For laboratories to function effectively, they must have the commodities needed for the testing services offered. Given the wide range of commodities needed at the various levels of the laboratory network, the task of ensuring that commodities are available when and where they are needed can be formidable. Effective supply management practices help ensure commodity availability.

The logistics cycle provides a guiding framework of the functions needed to manage all health commodities, including laboratory commodities (see figure 2). 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 2. 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 voluntary counseling and testing 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

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.

CHALLENGES IN CUSTOMER SERVICE

- Stockouts of reagents cause delays in testing, longer hospitalization, and missed opportunities for outpatient testing.
- Many different kinds of customers with varying needs for commodities, testing, and information add complexity to the system.

RECOMMENDATIONS FOR CUSTOMER SERVICE

- Improve the logistics system to improve customer service.

Any improvement to the logistics system that improves availability of commodities at the service site results in better customer service.

- Ensure commodity availability by securing adequate funding for laboratory commodities.

No matter how good the supply pipeline, without adequate financing for procurement of laboratory commodities, commodity availability cannot be ensured. Adequate funds for commodities must be budgeted for the organization—or alternative resources such as donor funding must be secured—to purchase the commodities needed to provide testing services and to fill the supply pipeline (see the Financing Laboratory Commodities and Logistics Systems section).

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 and manage such information, which is necessary to support sound and objective decision making in managing the supply chain. The goal of this decision making is to ensure 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 of time (consumption), and losses and adjustments to stock for purposes other than use (expiry, damage, wastage, 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 as feedback reports to encourage and improve the performance of the logistics system.

Refer to John Snow, Inc./DELIVER's *The Logistics Handbook* (2004) for a more complete description and additional discussion of logistics management information systems.

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, losses, and wastage. In laboratory logistics, wastage is distinguished from loss and should be separately defined:

> Wastage is the quantity of a commodity that is lost during the performance of a testing technique. Wastage rates should decrease as personnel become more proficient in performing a technique. Loss occurs when commodities expire, are damaged, or are stolen.

As discussed below, the collection of actual consumption data should be limited to a small number of tracer commodities. Issues data from the storeroom to the bench should be routinely used for ordering decisions.

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 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. 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 it is difficult to separate wastage from consumption.

RECOMMENDATIONS FOR LMIS

Use issues from stock as consumption data. Use and maintain stock-keeping records.

Given the difficulties in tracking actual consumption of laboratory commodities, issues from stock at the lowest level—usually within the laboratory itself—should be used as a proxy for consumption. Include commodities used for QA and QC, as well as wastage in issues, when recording issues data from the store to the bench.

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 size of the packaging. 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 bottles.

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.

Use the smallest unit of issue as the 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, or 1,000, or more. While supply chains should strive to have a minimal number of pack sizes for a particular product, even in the best case the varied packaging can lead to confusion in ordering and managing commodities. This is because even though products are issued from the source of supply as a pack (e.g., a box of 1,000 pipette tips), they may be issued from the store to the laboratory bench as a partial pack (e.g., 50 pipette tips). To facilitate stockkeeping, issuing, and reporting these commodities, it may be more appropriate to use the smallest unit of issue used at the facility level (e.g., bottle, piece) for stockkeeping and reporting, and have the capacity to round up these numbers to the nearest pack size at the central level.

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 issues of each commodity over the reporting period, losses during the reporting period, and stock balances at the end of the reporting period. Duration of stockouts should also be reported. Those data can be used to inform resupply decisions for the laboratory, as well as to monitor the performance of the logistics system.

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 ordering with reporting makes valuable information needed to confirm orders available in the report.

Use an Activity Register to track the actual consumption of a small number of tracer commodities.

Although actual consumption data will not be collected on most laboratory commodities, a few commodities known as tracer laboratory commodities should be tracked by actual usage with an Activity Register. An example of an Activity Register can be found in appendix E. The purpose of tracking tracer commodities is to validate the rate of use of all laboratory commodities by providing a comparison of commodities issued and commodities used. In addition, tracer commodities may be those for which closer accountability is warranted on the basis of their cost or value.

Each time a tracer commodity is used, the quantity used should be noted. The example register indicates usage each day. A tally sheet or simple note of usage should be kept at each bench or location in the laboratory where the tracer commodity is used, should be added together at the end of the day, and should be recorded on the Activity Register for the day. Wastage of the commodity should also be recorded, separate from usage. Reporting on tracer commodities should be combined with the routine report of other laboratory commodities. Examples of tracer commodities include CD4 reagents and viral load reagents.

Computerize the logistics management information system where possible.

Computerization of the LMIS can occur at the site level or at the central level. In many countries, while site-level computerization of the LMIS for laboratory supplies is only at the pilot stage, central-level computerization may be possible and appropriate.

Given 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. 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 to produce reports and graphs for analysis in a timely manner. In 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.

In support of a laboratory logistics system, the LMIS should be computerized at the central level and as possible at intermediate levels in the system.

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 selecting commodities, 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).

For laboratory commodities, another consideration, 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

In selecting products, other factors need to be considered:

- 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.
- Uncoordinated donations of equipment, reagents, or both can result in lack of SOPs.

RECOMMENDATIONS FOR PRODUCT SELECTION

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

A laboratory's level in the laboratory network, the capacity of its personnel, and its infrastructure dictate the types of tests available and the testing protocols used. Product selection should be closely linked to the level of the laboratory and the tests it provides. For instance, a central or reference

laboratory provides a wider range of tests than lower-level labs, 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 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 can facilitate repackaging for distribution. Check on the registration status of the commodity before selecting it. If it is not registered, a comparable alternative should be considered, 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 less toxic options might exist.

When possible, choose 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. Nevertheless, closed systems generally provide the highest quality and are typically easier to manage.

Be prepared for changes in test technology.

Technology advances can affect product selection. Testing technology will improve, increasing the sensitivity or specificity of a test and developing techniques that provide results faster. As a result, a new test may be added to the testing protocol. Such changes will influence what commodities are selected in order to support the newly introduced test.

Selection of new testing technologies that require different commodities should be reflected in the standard testing protocols, 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

Both 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.

Refer to John Snow, Inc./DELIVER's *Guidelines for Quantification of Laboratory Commodities* (Draft March 2004) for a more complete description and instructions as to how to conduct a forecast and quantification for laboratory commodities.

Several challenges need to be considered when forecasting demand and 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.

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 could be conducted will be highly dependent 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.

Refer to John Snow, Inc./DELIVER's *The Contraceptive Forecasting Handbook* (2000) for a complete discussion and instructions for forecasting while using logistics data.

Service statistics data—data on the numbers of tests performed during current and past periods—can be used to establish trends in tests provided. 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 (that is, use the same quantities of commodities for each test and have the same rates of wastage).

Finally, demographic/morbidity data translates the number of patients or clients to be tested, using tests menus, to the total number of tests to be conducted, which is then translated into total product requirements.

If using test numbers to prepare the forecast, be sure to include in the quantification commodities required for QA and QC, loss and wastage, 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 using logistics data, the commodities used in QA activities are already included in the facility-level issues data.

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 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 for 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 readily 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 laboratory, 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 remains 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.

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 should be specified as clearly as possible, including the packaging size (see table 2).

Table 2. Examples of Defined Specifications

Reagents	**Specifications**
Field stain A (malaria)	Azure blue powder, GPR (general purpose reagent), 25 g
Commercial reagent kit (hepatitis B screening)	Commercial latex based non-cross reactive; Titer 1:256, sensitivity 100%, specificity at least 98%, kit of 50
Consumables	**Specifications**
Vacutainer	Plain red top, rubber cork, 4 mL, pack of 100 pieces
Microscope slide	Single frosted, precleaned, 76.2 mm x 25.4 mm x 1.2 mm, glass; pack of 72 slides

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 due to their composition and shelf life. Laboratory commodity freight costs can range from 5% to 50%, and therefore an estimation of the realistic freight costs of these commodities should be completed during the quantification process in order 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

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. Some of those strategies, such as a rationing system, are more appropriate in situations where the commodity supply being managed—or even the financial resources available to purchase the commodities being managed—is unsure. In a traditional rationing system, supplies are allocated on the basis of some set of criteria. For instance, one criterion may be to serve a certain proportion of the poorest clients, to treat a certain proportion of the priority disease burden in the region, or to ensure that a commodity accounts for no more than a certain proportion of the available budget. If sufficient commodity supplies are ensured, a maximum-minimum inventory control system (also known as a max-min system) is recommended.

A number of factors go into the choice of an inventory control system. They include 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 order—pull or push—by level in the system.

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.

Refer to John Snow, Inc./DELIVER 's *The Logistics Handbook* (2004) for a complete description of maximum-minimum inventory control systems and factors to consider in the selection of an inventory control system.

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
- Rationing of commodities

- Associated products not ordered concurrently (buffer solution, lancets, etc.)
- Existing pipeline too long

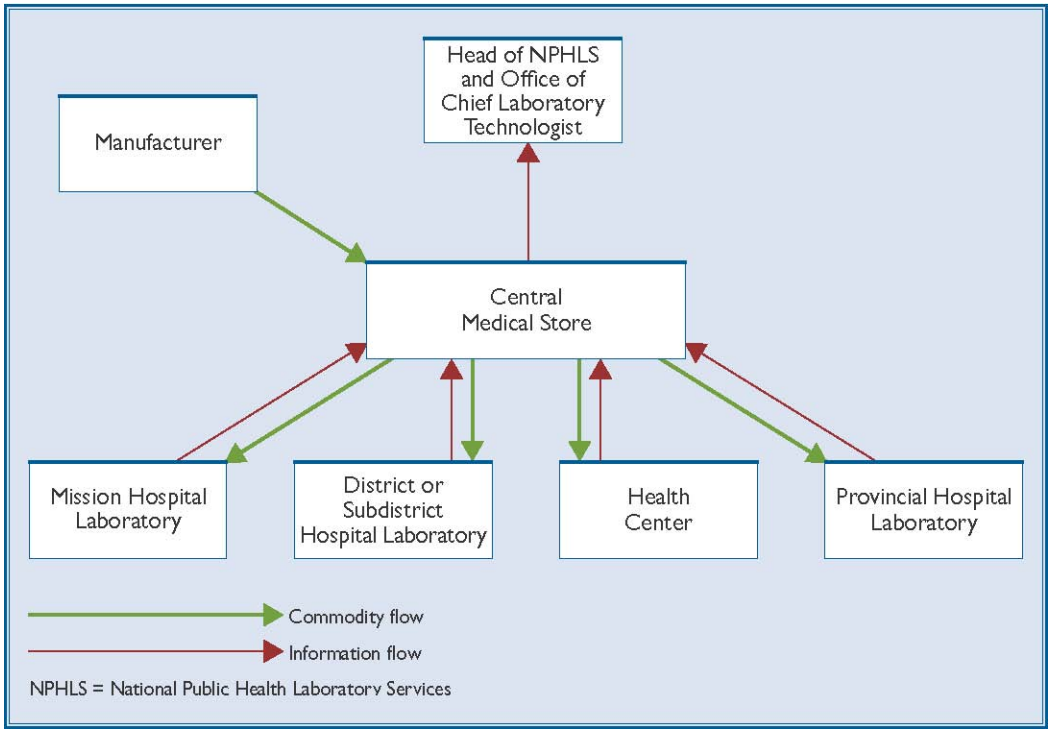
RECOMMENDATIONS FOR INVENTORY MANAGEMENT

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 one pipeline that can be used to manage all laboratory commodities: a pipeline that is short and efficient. To shorten the pipeline, consider limiting the number of levels. Figure 3 illustrates a typical in-country pipeline for laboratory commodities. This pipeline includes two levels: national-level storage and service-level laboratories.

In addition to limiting the number of levels in the pipeline, the pipeline can be shortened by increasing the frequency of resupply (that is, 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. Monthly or bimonthly resupply would be ideal, but it requires dedicated transportation.

Figure 3. In-Country Laboratory Commodity Pipeline



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

Based on the characteristics of laboratory supplies and the in-country context, there are several options for inventory control systems. 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, where smaller quantities of all commodities are supplied. 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 the other versions of max-min, the pipeline should be as short as possible, as described in the preceding recommendation. In addition, designers must ensure that there is adequate storage space to accommodate the higher minimum stock level, especially given the bulk of many laboratory commodities.

Given the implications of holding a higher minimum stock level for the standard system, another inventory control option is the forced ordering system. While forced ordering may require facilities to place smaller, more frequent orders, since they order up to their maximum stock level for all commodities a 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.

Order quantities should be adjusted for stockouts.

When calculating the order quantity, the number of days stocked out should be factored into the consumption. 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, because the length of time it takes to consume a slow-moving products. For example, a bottle of Crystal Violet Solid reagents is issued from the bench to the storeroom. In a typical facility, it takes 4 to 5 months at the bench to consume a full bottle of this reagent. If you assume that the maximum stock level for this reagent was the same as for the other commodities, once your bottle was issued, you would order up to your 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 to this problem is to assign different, lower, minimum and maximum stock levels to slow-moving commodities to take into consideration the time it takes to use up these commodities.

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

Maximum-minimum inventory control systems work best for commodities in full supply, because they work under the assumption that orders will be filled according to the intended maximum stock level. Even if not all laboratory commodities are currently in full supply, it is possible to manage full-supply and non-full-supply commodities concurrently if there is transparency in ordering and resupply. So, while a facility may order 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. However, 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.

While 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 that you would ideally want in the system. Further, it allows central-level decisionmakers 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, institute 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. 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 ordering or resupply to reporting.

As a corollary to the preceding recommendation, reporting and ordering should be linked 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. The person calculating an order should check that all the commodities required for a test are included in the order. This information may be difficult to determine because many commodities can be used in more than one type of test, but an effort should be made to obtain it. If proper inventory control is 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. It is desirable for the pipeline to 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.

Refer to John Snow, Inc./DELIVER 's *The Logistics Handbook* (2004) for a more complete description and for an additional discussion of standard storage guidelines for health commodities.

Commodities generally may be distributed in one of two ways: a pickup system, where the lower level comes to the supplying facility, or a delivery system, where the upper-level supplying facility brings the products to the lower-level receiving facility. In most 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. In a shared system, supervisory visits might take precedence over commodity delivery, which could delay the movement of commodities and could result in stockouts at the receiving facility. 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 products shipped and received: type and quantity.
- 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. The standard storage guidelines for health products can form the basis of the guidelines, with additional points to address the special storage requirements for laboratory products. For example, a separate refrigerator should be maintained for laboratory reagents that require cold storage, while flammables, corrosives, and hazardous chemicals need secure storage that is isolated from other 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. Keep cats on the premises—they are effective against termites, rodents, and roaches. 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 health 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 3 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.
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 off the floor on pallets (at least 10 cm off the floor and 30 cm away from walls), because moisture can seep through walls and floors and into the commodity supplies.
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. Most blood-typing sera, CD4 reagents, and some chemistry reagents require cold storage temperatures of 2°–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 then, 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.
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— o Reduce the amount of unpacking for storage and repacking for delivery o Facilitate shipment in lot sizes o Are cheaper to construct o 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.	Arrows indicate the way commodities should be stored. 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 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 health 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 health commodities away from insecticides, chemicals, flammable products, hazardous materials, old files, office supplies, and equipment; always take appropriate safety precautions.	Insecticides and other chemicals may affect the shelf life of many products. To make health commodities easy to access, keep other supplies away from health commodities. Some health commodities have a relatively short shelf life, and they must be moved quickly to the end user. Storing old junk may slow access to products and may take up needed storage space. Some medical procedures require the use of flammable products. Bottled gas or kerosene is used to power refrigerators, alcohol is used in sterilization, and mineral spirits are used to power Bunsen burners. Such products should be stored away from other products and near a fire extinguisher.
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.
Separate damaged and expired health 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.

When available, Material Safety Data Sheets, which are required in developed countries for all hazardous substances to protect workers, can provide guidance for appropriate handling of laboratory supplies. The sheet is usually included in the packaging of hazardous materials.

Maintain a cold chain for laboratory commodities that require it.

Commodities requiring a cold chain include many test kits, such as rapid plasma reagin (RPR) syphilis test, some HIV tests (Capillus), hematology controls, chemistry kits, coagulation reagents, and VDRL test reagents, which should be stored in the refrigerator between 2° and 8°C.

Store flammables separately, and ensure that a fire-extinguishing mechanism is available.

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, the shelves of the cabinet 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° to 23°C.
- The flash point for kerosene is 23° 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 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.

Keep laboratory commodities in their original packaging to protect light-sensitive commodities.

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, at any time, light-sensitive commodities will be redistributed, be sure to distribute them in their original packaging or bottles, or in packaging with the same standard of protection as the original.

Maintain commodities under the same storage conditions during distribution.

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.

QUALITY ASSURANCE AND QUALITY CONTROL

Ensuring quality in laboratory services is vital, given that results from tests significantly influence diagnosis and treatment of patients. A well-managed laboratory should have a good quality system that ensures provision of accurate and reliable test results and should adhere to that system. Quality in the laboratory is ensured through two mechanisms: quality assurance and quality control.

QA is the management of the quality of all aspects of the testing process. It includes pre-analytic, analytic, and postanalytic processes, such as training, interlaboratory comparison, preventive maintenance, and result reporting. QA ensures 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.

QC is the statistical control for precision and accuracy of laboratory test results. Daily QC provides a benchmark to measure the quality of the testing process. 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.

Given 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 must be 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. A QA program includes the following elements:

- Quality control means the measures taken to monitor the quality of the test itself. For example, specimens with known results can be retested to verify that the test itself—or the procedure by which it is applied—is functioning properly. This service is often coordinated with internationally accredited laboratories.
- External quality assurance identifies laboratories or testing sites and technicians that do not perform according to standards. Three methods are used to evaluate laboratory performance: on-site evaluation, proficiency testing, and blinded rechecking.
- Safety precautions enforce use of universal precautions in laboratories and testing sites to prevent transmission of HIV and other blood-borne diseases. Such precautions protect not only the patient, but also the laboratory personnel and other members of the health facility's staff.

- Supervision improves staff performance and quality of testing procedures. Insofar as supervisory visits for logistics are concerned, some of the aims of the visits include checking supply levels, completing stock cards, removing expired products, observing staff work, and helping to address performance problems, as well as providing on-the-job training.

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

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 procedures for other aspects of laboratory management and services. By following logistics management procedures—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 procedures and policies for internal and external retesting for QC.

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 managers. 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 trained to perform those procedures (e.g., resupply procedures, issues, receipts).

In addition to managing commodities, laboratory personnel are required to maintain the specialized equipment on which they rely. Regularly needed spare parts should be available on site, and procedures should be in place for ordering them.

Given the importance of maintaining 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 regarding considerations for new products (storage, supply chain, resupply procedures or issues)
- Limited number of personnel
- Lack of supervision

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 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 Policies and Standardization of Laboratory Services, 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.

In summary, 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. 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
- Lack of guidelines and policy about waste disposal
- Burdensome policies and procedures for product registration
- Lack of guidelines or commodities for infection prevention and universal safety precautions

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.

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 most countries where the USAID | DELIVER PROJECT has worked, 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.
- Current tendency is to support disease programs, for example 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 is possible over the commodities that are brought into the country. 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 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, for example, microscope slides and cover slips.

durables

Durables are items that can be reused for multiple tests, for example, 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 (EQA) 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. EQA 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 are equally necessary and include adequate staffing, training, and supervision.

good laboratory practice

Good laboratory practice (GLP) 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 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.

medical technician

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

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 postanalytic processes, such as training, interlaboratory comparison, preventive maintenance, and result reporting.

quality control

Quality control 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 definition). 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 manual techniques. As shown by the coefficient of variation—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.

sharps

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

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.

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, for example, 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.

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.

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.

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—an mm^3 is the size of a pinhead. As HIV disease progresses, the T4 cells fall from a normal count of 500–1,500 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 of time. JSI/DELIVER uses the terms consumption or dispensed to user to describe amounts of health commodities, for example, 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 the 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 test (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

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.

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.

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.

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 can be included as well as viral load procedures.

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.

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 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 AFB (acid fast bacilli)	• Ziehl-Neelsen (ZN) stain
• Skin slit for AFB	• 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)	• Slide method
• Total white cell count	• Manual, hemocytometer with appropriate dilution fluids
• Total red cell count	
• Differential white cell count	• Manual, using stained thin film
• Cerebrospinal fluid microscopy	• Gram/Leishman/Turks fluid
• Cerebrospinal fluid chemistry	• Turbidimetric
• Serum bilirubin	

Additional Tests Performed at District Hospital Laboratory

• Concentration technique	
• Blood	• Buffy coat (Knotts)
• 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
• Collection and fixation of histological specimens	• 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 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

• Hb types	• Electrophoresis
• Serum proteins	• Electrophoresis
• Hepatitis B screening	• Rapid ELISA
• Syphilis screening	• RPR/VDRL carbon antigen
• Serum bilirubin	• Chemistry auto-analyzer (or manual photometer)
• SGOT/AST (serum)	
• SGPT/ALT (serum)	
• Alkaline phosphatase (serum)	
• Renal function tests	
• Blood glucose	• Chemistry auto-analyzer (or manual photometer)
• Serum electrolytes	
• Total protein	
• Examination of CSF for yeast	• Negative staining-India ink
• Examination of CSF, pus, deposit, etc., micro-organisms	• Gram stain
• Culture	• Aerobic
	• Anaerobic
	• Microaerophilic
• Drug sensitivity	• Disc diffusion
• Microscopy for plague	• Wayson staining
• Processing biopsy	• Hematoxylin and eosin
• Semen analysis	• Microscopy
• Cytology	• Microscopy
	• Pulp smear
• Sputum for TB	• ZN stain
• Urine sediment microscopy	• Direct microscopy
• Urine chemistry	• Multistix or equivalent
• Genito-urinary track specimens	• Wet prep
	• Gram
	• KOH
• Blood group, type, and cross matching	• Tube method
• Skin snip for microfilaria	• Saline direct
• Examination for fungi	• KOH
• Confirmatory test for syphilis	• 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
Lovibond comparator	• ammonia OR • potassium • ferricyanide	• blood pipette • sterile lancet • 70% alcohol • cotton wool	• glass tubes • Lovibond comparator • colored glass standards

Test Technique	Reagents	Consumables	Durables/Equipment
	• potassium • cyanide • potassium • dihydrogen • phosphate • surfactant	• parafilm or foil	
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, I □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 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 • terile 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 upon kit • microscope slides • swab • dry sterile tube for transport of swabs	• fluorescence microscope
EIA (enzyme - immunoassay)	• specific reagent kits	• depends upon 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, UK: Cambridge University Press, 2000), 234.

Syphilis

Test Technique	Reagents	Consumables	Durables/Equipment
RPR	• specific reagent kit	• depends upon kit • evacuated collection tube • needle • 70% alcohol • cotton wool	• card rotators
VDRL	• specific reagent kit	• depends upon kit • evacuated collection tube • needle • 70% alcohol • cotton wool	• microscope
TPHA/TPPA	• specific reagent kit	• depends upon 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 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, when using devices that automate measurement, there is 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 REPORT: LABORATORY LOGISTICS SYSTEM INVENTORY CONTROL CARD, ACTIVITY REGISTER, AND USAGE DATA REPORT

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								

MINISTRY OF HEALTH
USAGE RECORD FOR TRACER LABORATORY COMMODITIES

ACTIVITY REGISTER

Facility Name:																																
Month:																																
Date:		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**
Supply	**Unit**																															
FACS Count CD4 Reagents	Tests Used																															
	Wastage																															
	Tests Used																															
	Wastage																															
	Tests Used																															
	Wastage																															
	Tests Used																															
	Wastage																															

MINISTRY OF HEALTH
USAGE DATA REPORT FOR LABORATORY COMMODITIES
SAMPLE FORM

Facility Name:

District:

Province:

AGENCY

Ministry of Health:

Local Authority:

Private:

FBO:

OTHER (Specify)

Report of Period Beginning

Report of Period Ending

		A	B	C	D	E	F
Laboratory Supply	**Unit of Issue**	**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 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—

- white blood cell count and differential to assess for neutropenia and total lymphocyte count
- serum alamine or aspartate aminotransferase levels to assess for hepatitis co-infection and to monitor for hepatotoxicity (liver damage)
- serum creatinine and/or blood urea nitrogen (BUN) 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 (pre-therapy)	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 STIs is long, this reference 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.* Given that 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 in order 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 EIA or PCR
  - Urine EIA or PCR

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

TUBERCULOSIS

Tuberculosis 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., their sputum-smear results are negative).
- **Sputum culture.** Culturing sputum for TB can be used to diagnose pulmonary tuberculosis in patients who produce too few bacilli to be detected on a smear. Additionally, 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 have significant effect on human populations by causing incapacitating illness, loss of time at work and school, and strain on the health care system. They are *Plasmodium vivax, Plasmodium malariae,* and *Plasmodium ovale.* 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. Given 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 2–10 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 polymerase chain reaction. 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 rather in research settings to examine resistance patterns.

For more information, please visit deliver.jsi.com.

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