Quantification of Health Commodities: Laboratory Commodities Companion Guide
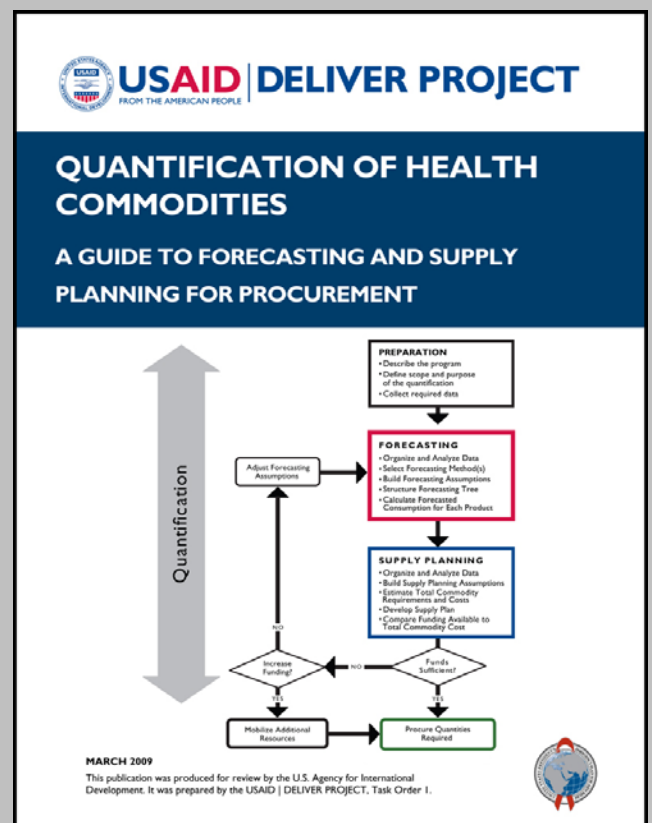
Forecasting Consumption of Laboratory Commodities

To be used with—

QUANTIFICATION OF HEALTH COMMODITIES

A GUIDE TO FORECASTING AND SUPPLY PLANNING FOR PROCUREMENT

Quantification of Health Commodities: Laboratory Commodities Companion Guide

Forecasting Consumption of Laboratory Commodities

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Abstract
The successful implementation of testing schedules and the expansion of laboratory testing services depends on the continuous supply and availability of high-quality laboratory supplies at all testing facilities. The extensive nature of testing schedules, the variety of equipment and associated reagents and consumables, and the varying characteristics of each of those products pose particular challenges in the management of laboratory commodity supply chains. The primary focus and purpose of this companion guide is to supplement the general guide, *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement,* by describing, in detail, the specific methodology for forecasting consumption of laboratory commodities as a critical step in the overall quantification process.

Cover photo: A technician uses a microscope at a laboratory in Kenya. Credit: © 2006 Johnson Ndungu/Walter Reed Project, Courtesy of Photoshare

Contents

Acronyms

AFB	acid-fast bacilli
AIDS	acquired immunodeficiency syndrome
ALT	alanine aminotransferase
ART	antiretroviral therapy
CD4/CD8	cluster of differentiation (ratio of CD4 cells to CD8 cells)
CDC	Centers for Disease Control and Prevention
CSF	cerebrospinal fluid
EDTA	ethylenediaminetetraacetic acid
ELISA	enzyme-linked immunosorbent assay
g	gram
Hb	hemoglobin
HIV	human immunodeficiency virus
HTC	HIV testing and counseling
JSI	John Snow, Inc.
KOH	potassium hydroxide
LMIS	logistics management information system
mL	milliliter
MOH	Ministry of Health
NGO	nongovernmental organization
p24	protein 24 antigen
PEPFAR	President's Emergency Plan for AIDS Relief
pH	potential hydrogen (measure of acidity)
PMTCT	preventing mother-to-child transmission
RPR	rapid plasma reagin
RTK	rapid test kit
SGOT	serum glutamic oxaloacetic transaminase (AST)
SGPT	serum glutamic pyruvic transaminase (ALT)
SOH	stock on hand
SOP	standard operating procedure

STG	standard treatment guideline
STI	sexually transmitted infection
TB	tuberculosis
TPHA	treponema pallidum hemagglutination assay
USAID	U.S. Agency for International Development
VCT	voluntary counseling and testing
VDRL	Venereal Disease Research Laboratory
ZN	Ziehl-Neelsen (stain)

Introduction to the Laboratory Commodity Companion Guide

This companion guide supplements the general guide, *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement* (USAID | DELIVER PROJECT 2009a). It describes, in detail, the specific methodology used to forecast consumption of laboratory commodities, which is a critical step in the overall quantification process.

Because of the large number of commodities that need to be forecasted, the process of forecasting the consumption of laboratory commodities requires multiple resources and time-intensive. Traditional comprehensive national forecasts often include 100 to 300 products—depending on the scope of the forecast and the level of standardization in the country doing the forecast. The extensive list of commodities means that many products have multiple purposes and uses in the laboratory. These products may have different shelf life, storage conditions, associated tests, and equipment. Some items are used concurrently, while others are used independently.

This companion guide provides instructions on how best to forecast the consumption of laboratory commodities, always considering the variety of equipment and testing protocols. To illustrate each of the steps in the methodology, the authors included an example—sample data and assumptions used and the outputs at each step. Also included is information on the various types of laboratory commodities available, testing protocols, and the most commonly used tests at various levels of the laboratory system. By using the specific guidance on the various types of data collection and analysis that are required to undertake a laboratory forecasting exercise, you will be able to select the type of data that you should use when you estimate the demand for laboratory testing services and future consumption of laboratory commodities.

After following this companion guide and completing the forecasting steps, refer back to the general guide, *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement,* to determine the total laboratory commodity requirement and associated costs for the program or country. Use the final output of the forecasting step—the quantity of each laboratory product needed for all testing purposes—as the starting point in the next step for the quantification—supply planning.
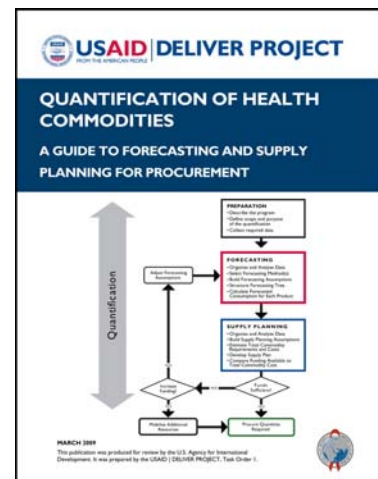
Characteristics of Laboratory Commodities and Their Use

Types of Laboratory Commodities

Before you begin quantifying laboratory commodities, it is important to have a basic knowledge of the different types of commodities found in the laboratory. Laboratory commodities are used to collect, prepare, test, analyze, store, and dispose of clinical specimens. While these activities include a wide range of items; for logistics purposes, they are broadly classified into three distinct categories of products: reagents, consumables, and durables. Each item is a necessary component in any laboratory test. Their classification depends on the commodity's characteristics and use, and also determines how you can track and forecast its usage.

As mentioned earlier, forecasting for laboratory commodities is an intensive process because of the large number of commodities involved and the multiple purposes for which these products are used in the laboratory. To avoid underestimating the quantity needed, it is critical that you document and account for all the different uses, for each commodity. Laboratory staff will use these products for all their intended purpose, whether or not you include all the purposes in the quantification. For example, you can use sputum collection jars to collect urine specimens and to collect stool specimen. If a program quantifies the number of sputum containers needed for sputum collection only, the quantity needed in the laboratory will be underestimated because these containers will be used for other purposes as well, even if they were omitted during quantification. To avoid leaving out any of the uses for particular commodities and; therefore, possibly underestimating need, we recommend that your forecast covers all the needs of the laboratory, rather than a subset of services or tests.

The quantities of laboratory products needed for the diagnostic purposes of testing are determined by the in country testing algorithm. For certain laboratory products that are used specifically for HIV testing—such as CD4 (cluster of differentiation), viral load reagents, and HIV test kits—you would need to apply a number of factors, including the HIV prevalence, attrition rates, and testing protocol to determine the quantity of laboratory reagents required. For HIV tests, you must include other considerations, including the discordance rate between the screening and the confirmatory tests because that would determine the quantity of tie-breaker tests needed. For other non-HIV specific testing areas, such as chemistry and hematology, the quantities of laboratory reagents required will not be determined solely by the afore mentioned factors. You will also need to think about additional considerations, such as the percentage of the general population that uses them routinely for non-HIV testing.

You must also pay attention to the quantity of supplies required for non-diagnostic purposes, including quality control procedures, sentinel surveillance or survey study protocols, or laboratory testing training curricula. Because you must determine supplies needed for non-diagnostic uses separately from diagnostic uses, you must forecast the consumption of laboratory commodities for each purpose separately.

Also note that laboratory commodities often include hazardous materials or ones that require special handling. These include, but are not limited to, unstable, volatile substances, such as ether; combustible or explosive substances, such as propane gas tanks; corrosive substances, such as sodium hydroxide; and radioactive substances and commodities containing biological preparations that might be biohazard risks.

This guide discusses each class of commodities below.

Reagents

Reagents are defined as compounds, such as sulphuric acid, hydrochloric acid, sodium hydroxide, etc., that are used in a chemical reaction to detect, measure, examine, or produce other substances. Reagents vary widely in cost, stability, cold chain requirements, availability, and associated hazards. Reagents can either be chemical or biological. The reagents used in a particular laboratory are determined by which tests the laboratory performs, the equipment used, and the standard operating procedures (SOH) in place.

The test protocol being used in a laboratory requires specific reagents. It is very important that you know the comprehensive set of specifications of the reagents, especially for reagents that are usually in the same category. For example, if a test protocol requires that you use an analytical grade reagent, but, instead, you use a technical grade of the same reagent, the poor quality of the testing may be significant enough to invalidate the results. In running tests, several reagents are usually required; they should not only meet the specifications, but should always be available in the right quantities.

You should also document consumption rates and shelf life for reagents, because reagents used in a test usually will not be consumed at the same rate. Some reagents are used infrequently, in very specific tests, while other reagents are used frequently and in several different tests. To forecast quantities that will ensure adequate stocks levels and minimal product expiries, carefully note all the reagents that have a shorter shelf life; in particular, the reagents that are used in small amounts or that are used infrequently.

In addition, some reagents have multiple uses that must be documented. For example, you can use methylated spirits as a disinfectant; it is also used to prepare certain stains in the laboratory. During the forecasting activity, it is critical that you document and account for the reagent's different uses.

You should also note the pack size of the reagent; if they come from suppliers, they may be available in individual packs, or as part of a kit to perform specific tests. The pack sizes will probably vary among laboratories; to avoid any inconsistencies in the forecast, you should note any differences. Kits from manufacturers are not standardized; they vary from supplier to supplier. You must establish what the kits contain and what other additional materials you will need when the kit is used. This is important to ensure that you have available all the needed materials to conduct the test; it will be useful information when you compare the prices of the reagents. Suppliers that provide reagent packs (whether as individual packs or as part of a kit) may indicate how many tests can be run with the number of packs. Note that, unless the manufacturer includes a little extra reagent in the pack, you will not be able to run the number of tests indicated on the packaging. For example, if a test requires 1 milliliter (mL) of reagent and the supplier provides 100 mLs, the kit may indicate that 100 tests can be performed; however, there is always some loss when the reagent is drawn into the pipette. This may be a small margin for an individual laboratory but, over time, it becomes significant and becomes even more so when you do a national quantification. But, if the kit contains 100 tablets, you can use all 100 tablets from the bottle without any loss.

Reagents may be available from suppliers as ready-to-use, or you may need to prepare them in the laboratory. You will need to reconstitute some of the reagents before use; the resultant reagent will have very different characteristics than the original reagent.

Reagent Preparation

To prolong the life span of reagents, which would otherwise deteriorate rapidly, reagent manufacturers sometimes use a technique called *lyophollisation* or freeze drying. These reagents can be reconstituted when needed. After reagents are reconstituted, they start deteriorating and will be depleted whether you use them to run tests or not. It is important to understand the practices of the laboratories for which quantification is being conducted to ensure that you can correctly interpret the consumption data for this type of reagent. Because reagents are usually expensive, more accurate forecasts may result in significant savings.

Wastage

Because often reagents are not precisely measured, or the reagents expire, there is an inevitable loss. In some cases, wastage occurs because most reagents cannot be completely used; a small amount of material is often left unused, which, in most cases, is not excess reagent. Whether reagents are drawn from a container by a machine or drawn manually, *dead volume* is left unused. The amount varies with the equipment and the nature of the reagent. For example, if a test requires 1 mL of reagent and the manufacturer supplies 100 mL bottles, theoretically, you will have enough reagent for 100 tests. In practice, however, you may not be able to draw out all 100 mLs of the reagent, depending on the equipment being used. The 100 mLs supplied can potentially be used to perform approximately 95 to 97 tests. Aggregating this wastage means that you need to account for the dead volume; this amount can, potentially, significantly affect the forecast for individual reagents.

In some situations, reagents are prepared from stock solutions that are used as working solutions; they should be used during a short time because they deteriorate rapidly and must be discarded after a few hours. If the volume of reconstituted reagent prepared can do more tests than the available specimens that need testing require, reagent is inevitably lost. An example is Giemsa stain for malaria parasite staining, which only lasts 8–10 hours after dilution. If it is not consumed in that time, it must be discarded. Unlike liquids or powder reagents, wastage is generally low for commodities in tablet form, because tablets can be completely used.

Consumables

You can define consumables for logistics purposes as items that are used once while performing a test and are not reused. Consumables can include test-specific items, such as microscope slides and cover slips. Other consumables cut across all testing services and are classified as general laboratory consumables, such as bleach, pipette tips, and gloves.

Some consumables are not used in the laboratory, but they are necessary to carry out testing and, therefore, you should include them in the quantification. For example, a vacutainer needle is required to draw blood; it is used once and discarded. If the needle is not available, the specimen cannot be collected and no test can be carried out, and so it should be included when forecasting for testing needs. After blood is drawn for laboratory testing, it is placed in a specific container for preservation and storage, then it is sent to the laboratory. The testing protocols in the laboratory will determine what type of container and preservative you should use. Include these commodities in the forecast.

The consumables needed to run a test will vary depending on the test and the method the laboratory uses to carry out the test. Carefully consider the consumables needed for each test. For tests that come in kit form, it is also important to establish if and what additional consumables are required to supplement the kit. Also, other supplies may be needed, but they are not one-to-one, as described above. You may use these consumables for a single test or for a number of tests; they will not be reused. One example is reaction plates in enzyme-linked immunosorbent assay (ELISA) tests. In certain cases, some consumable items—ethylenediaminetetraacetic acid (EDTA) blood collection tube, for example—can be used to run two tests: a CD4 and a hematology test. In these cases, make sure that you do not over forecast the consumables; otherwise, you may have significant wastage.

Durables

Durables are items that can be reused for multiple tests; including glassware that can be washed, sterilized, and reused. For quantification, this category also includes the equipment and instruments used for testing. Typically, durables are not frequently replaced, so an annual quantification is a good opportunity to assess the type, quantity, and functional shelf life available for the durables in use at the facility and to plan for their eventual replacement.

Laboratory Commodities in Practice

Table 1 lists the reagents, consumables, and durables that you might use for three common laboratory tests:

- CD4 test on a FACS count

- PCR on a real time PCR machine

- FBC using an ABX-micros machine.

The specifications provided in this guide are not complete, but they are a simple illustration of the various commodities that are required. The reagents are specific to the equipment. Some consumables are specific to the machines; these, or small spares kept by the operator, will not necessarily be single-use disposables, but they are needed to run the tests. For example, the FACS wire is needed to unblock the probe if it becomes clogged. Thermal paper is needed to print CD4 test results. The coring station, micropipette, and vortex mixer are used to prepare the specimen before it is analyzed on the machine. These consumables are not true resupply items, but the quantification exercise is an opportune time to consider their state; if they are either not working properly or not working at all, you must replace them. Quantification is a good time to review these items.

Table 1. Examples of CD4, PCR, and FBC Commodities

Reagents	Consumables	Machine Specific Consumables/Spares	Durables
CD4 FACS Count 1.Test kit 50T 2.Controls 3. FACS Flow 4. FACS Rinse 5. FACS Clean	1.Pippet tips 2. Vacutainer tubes ethylenediaminetetraacetic acid (EDTA) 3. Vacutainer needles 4.Vacutainer needle holders	1.Thermal paper 2. Spares kit 3. Spare waste container 4. FACS wire	1. Coring station 2. Micropippet 3. Micropippet charger 4. Vortex mixer

Reagents	Consumables	Machine Specific Consumables/Spares	Durables
	Infection Control 5. Disposable latex gloves 6. Disinfectants 7. Swabs		
PCR 1. Primers 2. Probes 3. Positive controls 4. Ethanol absolute 5. RNAse free water 6. RNAse Away 7. RNA extraction kit	1. Centrifuge tube 0,5 mL 2. Centrifuge tube 1,5 mL 3. Centrifuge tube 15 mL 4. Centrifuge tube 50 mL 5. Aerosol barrier Tips 1000uL 6. Aerosol barrier Tips 200uL 7. Aerosol barrier Tips 100uL 8. Aerosol barrier Tips 20uL 9. Aerosol barrier Tips 10 uL 10. Cryo tube 1,8 mL 11. Parafilm 12. Plate 96-well 13. Seal plate 14. Aluminum foil 15. Autoclave tape 16. Swab, dacron polyester 17. Tongue depressor Infection Control 18. Hypochlorite solution 19. Gloves, powder free (Small 20. Gloves, powder free (medium) 21. N95a mask 22. Biohazard bag		1. Micropipettes
FBC – ABX Micros 1. ABX Miniclean 2. ABX Minilyse 3. ABX Minoton 4. Minoclair 5. Controls	1. Vacutainer EDTA tubes 2. Vacutainer needles 3. Vacutainer needle holders *Infection Control* 4. Disposable latex gloves 5. Disinfectants 6. Swabs		1. Blood mixer

Standard Operating Procedures and Commodity Usage

While laboratories usually follow standard operating procedure (SOPs) when they run tests, it is important to note that they may change some of the procedures without affecting the technical aspects of the test. This practice is common. Laboratories that follow the same protocols, but with slightly different technical modifications, may get results of comparable quality. Consider the following example:

One laboratory uses one reagent to prepare 100 specimens for testing. The specimens and reagent are pipetted into 100 tubes using a micropipette and disposable pipette tips. The laboratory technician may pipette the reagents and specimens in one of the two ways:

- *Scenario 1:* The laboratory technician uses one pipette tip, per specimen, to dispense each of the specimens into the 100 tubes. The technician will use 100 pipette tips for the 100 specimens. He pipettes the reagent into all 100 tubes using one pipette tip, for a total of 101 tips.

- *Scenario 2:* The laboratory technician uses one pipette tip, per specimen, to dispense each of the specimens into the 100 tubes, using a total of 100 pipette tips for this step. He continues to pipette the reagent into each of the tubes using one pipette tip each time. This means he uses 100 pipette tips to dispense the reagent. In this case, a total of 200 pipette tips are used.

While the procedure is the same, the way the commodities are used is significantly different. In scenario 1, 101 total tips were used; in contrast, in scenario 2, the technician used 200 tips. This means that the forecast was done under the assumptions in scenario 1; but, in practice, if the lab followed the assumptions outlined in scenario 2, the forecast will underestimate the need and could result in a stockout of pipette tips. If the forecast assumes scenario 2, and the lab practices the procedure in scenario 1, the forecast will be overstated by almost 99 percent and may result in excess inventory, making storage difficult. This example highlights the needs for SOPs to guide the use of laboratory products for each test. SOPs include standard testing protocols, standard treatment guidelines, and standard testing menus. Together, they define how specific products should be administered for treatment or used for testing, how testing should be carried out, and what equipment will be used. To avoid potential stockouts or oversupply of a given commodity, it is imperative that all laboratories follow a set of standard testing protocols when they do their testing. A breach of the SOPs may also affect the quality of results expected from a given test. Any variations to standard procedures used in the laboratory should be agreed upon and documented, because they can have an adverse effect on commodity usage.

As they come in to the laboratory, specimens can be processed as batches or individually. If you are using specimen batching, some laboratory commodities will be consumed at the same rate whether the batch has only a few or many samples. Other commodities will be consumed per batch run, rather than per test. This distinction is important when you make forecasts.

For HIV testing, the laboratory may use both the ELISA and rapid test kits. It is important to establish the ratio of usage and to investigate the possibility of changes in testing algorithms. Any changes may require new training for the health workers, and sometimes scaled-up quality assurance monitoring, until the heath workers are confident using the new algorithms. This is important to consider because it represents kits that you may need, in addition to those that are used to diagnose patients and testing clients. Sometimes testing kits may give conflicting results; in this case, use a tie breaker to resolve the result. In the past, rapid kits for tie breaking have been in excess of what is needed for tie breaking, resulting in considerable cost when the kits expire because they cannot be used for any other purpose without violating the testing algorithm. If the laboratory monitors the rapid test kits, the data for tie breaking rates will be more accurate; they can also track the data as it changes by looking at the frequency of tests found to be indeterminate in facilities outside the laboratory. Data from the laboratory on tie breakers tested is likely to be more accurate, if the laboratory does good monitoring.

Standardization

A critical prerequisite for conducting a quantification for health commodities are clear, well-defined standard treatment guidelines (STGs), standard laboratory testing menus and/or testing protocols, and a standard equipment list. Standardization, as a process, includes defining the following elements of the laboratory system:

- test menus by level

- test techniques by level

- testing protocol by test and by level

- instrumentation/equipment by level.

By using standardized protocols and commodities, laboratories can allocate and manage resources for services more efficiently. In addition, reducing the number of unique products used for the same purpose in the laboratory reduces the complexity of the laboratory system. For example, when facilities at the same level use the same techniques and equipment to conduct the same menu of tests, the commodities required for the tests are also the same.

If possible, standardization should precede quantification, because these guidelines are the basis for the assumptions in the forecasting exercise. In the case of new, rapidly expanding programs, the importance of standardized testing protocols is magnified; to allow for expansion, laboratories must procure sufficient quantities of commodities.

The standardization process should always take place during a consultative workshop that includes representatives from all programs and levels that provide testing services and donors; and all key players in laboratory services. This is a critical step toward transferring ownership of the results to in-country stakeholders. The meetings can also help mobilize resources, set expectations, and promote collaboration and coordination, especially if delays in commodity availability occur. For more information on standardizing laboratory commodities, see the USAID | DELIVER PROJECT publication, *Laboratory Standardization: Lessons Learned and Practical Approaches.*

If you do not have quality consumption data, you can conduct forecasts using demographic and morbidity data that depends on established and clearly defined STGs, laboratory testing menus, and testing protocols. A key assumption in these forecasts is that service providers follow established standard guidelines. Without STGs, testing menus, and testing protocols, program planners cannot estimate the types and quantities of products used in a given time period. Many programs and services require multiple products to be available at the same service delivery point, at the same time; adherence to STGs can help ensure that the products are used as intended.

Laboratory Testing

It is helpful to understand the steps that a laboratory uses to test a specimen from the beginning to the final result, when the result is released to the patient or clinician; this information will enable you to track and quantify the various commodities that the laboratory needs. When tests are run, the laboratory needs several commodities, including at least one reagent, one consumable, and one durable. Each commodity must meet the specifications and must be available in the required quantities. In certain settings or test types, one missing item may prevent the laboratory from running a specific test.

Considerations for Common Laboratory Tests

Special considerations associated with common clinical laboratory tests are discussed briefly in the following section.

CD4 Tests

CD4 tests are used to monitor patients on antiretroviral therapy (ART) and are also used to screen patients that will need treatment for HIV. The tests can be manual or automated; this section only explains the automated methods. For CD4 tests, the machines function in two main ways. Some machines process a blood specimen and produce a CD4 result; other machines must have a white cell count, usually from another machine, to produce a CD4 result. A machine that produces its own result, without other input, is called a single platform. When two separate machines produce a CD4 result, it is called a dual platform. When forecasting for CD4 tests, it is critical to know the number of CD4 machines available for testing and their associated reagents, because the quantity of reagents needed to perform the testing will determine the number and type of available equipment.

Chemistry Tests

While a wide range of chemistry analyzers are in use, they all have some common characteristics. Some chemistry analyzers, because of the technology they use, go into standby mode when they are not in use and are not completely turned off. In standby mode, to maintain electrode equilibrium, they continue to use reagents for calibration and rinsing; these machines may use more reagents in this state than when they are running specimens. You must consider the amount of reagents that the machine uses when it is in standby mode, in addition to the amount used for running tests. You may find this feature not only with chemistry analyzers, but also with other laboratory machines.

Some chemistry machines may require a group of tests to produce one result. In these cases, the commodities needed to perform the associated tests may not be recorded or may not be apparent. For example, to measure serum-free calcium, albumin is also measured. When requests for albumin levels are sent to the laboratory, the albumin reagent is used to measure serum albumin. In this case, it is clear that the albumin reagent is used because an albumin result is produced. In the case of serum-free calcium, the albumin reagent is also used, but it is not apparent—the albumin result is not recorded because it was used to measure the serum-free calcium. Because the reagent was used to run one test as part of another test, you could easily overlook it. In this example, the albumin reagent may *vanish*. Although the albumin is not reported or recorded, the machine uses the albumin reagent for this test. Again, to ensure the forecasted quantities are not overestimated or underestimated, you must understand and document reagent use in situations like this.

Some chemistry tests are available as panels; for example, for liver function tests. The demand for the various tests on the panel may not be the same. If a liver function panel has seven tests, but clinicians are only interested in two or three, it is important to consider that the reagents for the liver function tests may not always be needed for the full panel.

Hematology Tests

In previous years, a general lack of automated hematology machines caused clinicians to use hemoglobin (Hb) instead of a full blood count (FBC). Hemoglobin is one of the red blood cells parameters on a FBC that includes white blood cells and platelets. With the prevalence of HIV programs, the level of automation has significantly increased the requests for Hb, which can now be processed on automated machines. Automation has increased, but requests for Hb have not

decreased, in favor of a FBC, to match the increase in automation. It is important to note that the amount of reagents used to produce one Hb result on an automated machine is the same as the amount of reagent used for one FBC. On most machines, the difference in the number of parameters reported from the machine does not reflect different reagent usage. Hb from an automated machine requires the same amount of reagent as a FBC with 8–15 parameters or more. STGs may still recommend an Hb test, instead of an FBC, even with the changes in the laboratories as automated equipment has become more readily available.

HIV Test Kits

The evolution of rapid HIV test kits has made it possible to offer the test more often at the point of care, as well as in the laboratory. Test kits for HIV, like most other kits, are not standardized and may need additional items before the kits can be used. Kits from different manufactures require different additional commodities, while some may already have all the necessary commodities. It is very important to establish what comes with the kits and what additional commodities will be needed to ensure that they are included in the forecast for rapid test kits. The use of the rapid kits has made testing more accessible to clients because they do not need to go to the laboratory for the HIV test; however, a significant amount of testing still takes place in the laboratory, both for quality assurance and diagnostics. When quantifying for laboratory use, it is important to consider the other areas where test kits are used; for example, preventing mother-to-child transmission (PMTCT), outpatient departments, and campaigns. The laboratory is responsible for quality assurance for test kits used outside the laboratory; therefore, a significant amount may be used for the quality assurance program. In addition, in most cases, laboratories are responsible for training health workers to do the rapid tests; it is important to consider the kits that will be used for these purposes. You can use the data that is available in the laboratory to determine the need for kits used in the laboratory. For guidance on requirements outside the laboratory reference, use the HIV test kit companion guide, which provides more comprehensive detail on what you need to consider. See the USAID | DELIVER PROJECT publication, *Quantification of Health Commodities: HIV Test Kit Companion Guide.*

Waste Management

Medical or health care waste (HCW) refers to all waste generated by health care facilities, research facilities, and laboratories. HCW is generated in many ways—in the diagnosis, treatment, or immunization of men, women, and children; or as part of research. HCW is divided into two categories: (1) general (non-hazardous) waste and (2) hazardous (posing a risk) waste. General HCW includes paper and packaging; food; and bottles, cans, and glass for general use. Between 10–25 percent of HCW is hazardous. In the laboratory of a small health care facility, sharps and other infectious waste are the most common hazardous waste generated. Infectious waste can include used gauze/dressing, blood lines, gloves, anatomical waste, and body fluids from patients with highly infectious diseases. Sharps waste includes used needles, infusion sets, scalpels, blades, and broken glass. During the quantification exercise, it will be imperative that you include HCW items as part of the forecast. Examples of these include—

- *Waste bins.* Ideally, to ensure that waste is segregated correctly, waste bins should have color-coded liners made of plastic thick enough to prevent it from rupturing. This will help prevent possible injury or contamination to the waste handlers.

- *Sharps containers.* Also called safety boxes, these container provide safe temporary storage for sharp objects.

- *Needle removers.* Staff may use needle removers at the point of injection to immediately segregate and contain the sharps and mitigate the possibility of needlestick injuries.

- *Sharps barrels.* Small- to mid-size health care facilities often use sharps barrels, also called permanent disposal devices, to collect and dispose of sharps onsite or offsite.

- *Personal protective equipment (PPE).* This protects health care workers, including waste handlers, from sustaining injuries or contracting a disease.

- For more detailed information on HCW management, please refer to Logistics of Health Care Waste Management: Information and Approaches for Developing Country Settings.

Quality Assurance Programs

Quality assurance (QA) activities are an integral part of laboratory testing. The objectives of a quality assurance program, for the most part, are the same for all laboratories; but their roles in the QA program may differ, and the differences may require significant differences in commodity requirements. To validate results, laboratories are required, among other things, to run controls; this is commonly called *controls* when you refer to the materials that are used, not the process. You should consider quality control (QC) materials for logistics purposes for two main reasons; (1) the QC materials are needed in the QA program; and (2) they will require other laboratory commodities, like reagents and consumables. This usage does not produce results that go from the laboratory to the clients and patients, which is the case when a laboratory serves a hospital or a clinic. QA activities mainly take place in reference laboratories and clinical laboratories. A discussion of the role of each of these facilities, as they relate to QA, follows.

Reference Laboratories

QA activities may include running internal controls when you conduct tests and participating in an external QA program. The external program is external to the laboratory, but it may be either in or outside the country. In some instances, reference laboratories in-country prepare and distribute QC control materials to the national laboratory network. It is important to quantify the commodities needed for this program to ensure that adequate resources are available. The commodities will be the QC materials, the commodities for preparing the controls for distribution, the commodities for packaging and transportation of the QC materials, and the reagent requirements for laboratories to run the samples. The general drive toward accreditation of laboratories will likely increase the focus on the quality of testing. Commercial controls are expensive, so you must carefully consider QC materials.

Another common feature in reference laboratories is their role in national health surveys. The commodity needs for these surveys should include the additional materials needed for QA testing, which the reference laboratories will conduct when they validate the survey data. The QA protocols should be established to enable an accurate quantification. If any survey is likely to take place during

the time covered by the quantification, it is important for you to factor this in, because the survey may require significant amounts of reagents and consumables.

Clinical Laboratories

In clinical laboratories, internal and external QC materials are used. You should know the QA protocol of the laboratory so that commodities for QA activities are also identified and forecasted during the quantification. QC materials usually have a short shelf life and are expensive; therefore, take special care when quantifying them to ensure that all the commodities needed are provided in appropriate amounts. Sometimes when laboratories use in-house controls, commodities will be needed to prepare the controls. In addition, laboratories may run QC tests for external clients; for example, for rapid test kits that will be used in the field. You should also consider them when you quantify the tests. If clinical laboratories participate in surveys, it is important to quantify the survey commodity requirements to ensure they are not drawn from the commodities intended for clinical testing.

Steps in Forecasting Consumption of Laboratory Commodities

The quantification of commodities follows three basic steps (see figure 1). This section describes the first two steps, preparation and forecasting, giving specific consideration to the unique requirements of laboratory commodities. Throughout this companion guide, the outputs of these two steps are presented as country examples; see the highlighted box that follows each step.

Refer back to the general guide, *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement,* for a description and guidance on carrying out step three, supply planning.

Figure 1: Steps in Quantification
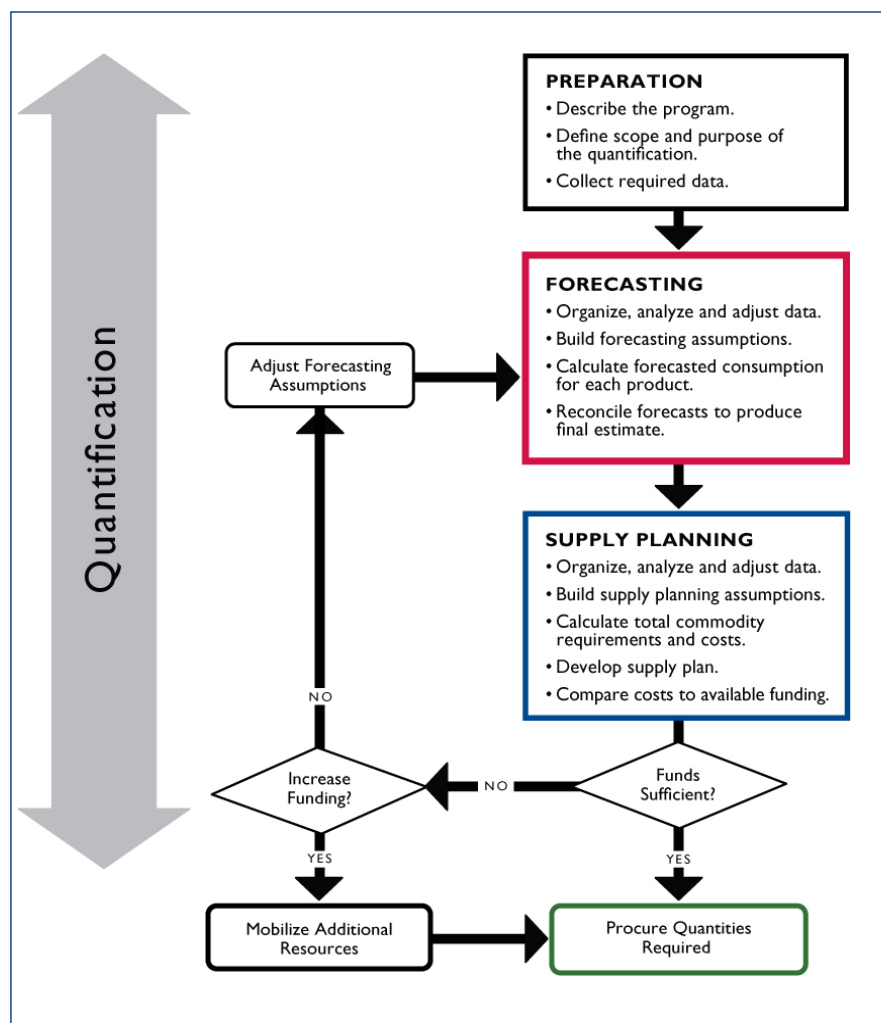
Preparation

Prior to beginning a laboratory quantification, you must complete preparatory activities—describe the laboratory system, define the scope and purpose of the quantification, and collect data.

Describe the Program (Laboratory System)

Begin the exercise by clearly describing the laboratory system where the commodities will be quantified. Laboratory systems often support multiple programs. Include in the description not only the programs but also the services for which the laboratory supplies are required. For supply chain management, a program comprises all the laboratory services that have a common distribution pipeline. The laboratory supplies can be provided from the same funding source or from different funding sources; but if they all go into the same distribution pipeline, they are considered supplies for one program and require a single quantification. Conversely, laboratory supplies that are distributed through separate distribution pipelines (e.g., the Ministry of Health [MOH] distribution system and the private sector distribution system) are considered supplies for different programs, according to its distribution pipeline. You must conduct a separate quantification for each program, because supply chain factors—lead time, buffer stock, and pipeline length—may vary by program.

Define the Scope

The scope of the quantification will depend on various political, programmatic, financial, and environmental factors. For laboratory supplies, two factors will help define the scope: (1) the laboratory services to be included and (2) the level(s) for which the quantification will be carried out. A national-level quantification is often the main objective, but separate quantifications may be required for different sectors, programs, target populations, geographic regions, funding sources, or supply chains. You should also define the number, type, and level of the facilities that the quantification should cover.

Examples of scopes for quantifications include the following:

- national-level quantification across all laboratory services to meet the needs of the whole country

- quantification by health sector (e.g., public sector, nongovernmental, or private sector) for the same laboratory services or for different laboratory services

- quantification by program (e.g., laboratory commodities for public-sector ART program, sexually transmitted infection [STI] diagnostic and treatment, tuberculosis [TB] program diagnostic and treatment)

- quantification by target population (e.g., specifically to support pediatric ART patients)

- quantification by funding source (e.g., government or donor organizations that fund procurement of commodities may require separate quantifications).

Define the Purpose

After the scope and the program(s) to be quantified are clearly defined, the next step is to determine the purpose of the quantification and how it will address the laboratory program's needs. Some examples include to—

- inform donors about funding requirements and to advocate for resource mobilization for laboratory commodity procurement

- estimate national laboratory commodity requirements and assess the stock status of the pipeline so that supply imbalances can be identified and rectified

- support an estimate of commodity procurement, storage, and distribution costs.

The quantification exercise should also answer the following key questions:

- How many tests can be conducted with the available funds? Or, conversely, how much would it cost to conduct a target number of tests within a given time period?

- How long will current stocks last if the current usage data and expected rates of growth remain the same?

- What quantities of laboratory supplies need to be procured, and when are the quantities needed to avoid stockouts or to support program expansion?

A mock country example of this background information, collected in preparation for a national laboratory quantification, is summarized in box 1.

Box 1: Country of Uniborder—Background Information for the Quantification

- The Ministry of Health (MOH) requested technical assistance to conduct a national HIV and AIDS quantification of laboratory commodities using morbidity and demographic data. Previous quantifications, based on budget allocations, resulted in underordering, frequent stockouts, and subsequent interruption of laboratory testing services.
- The national quantification was to include CD4, chemistry and hematology consumable supplies, and HIV test kits for the three MOH facilities supported by nongovernmental organizations (NGOs) and other implementing partner–supported facilities that conduct laboratory testing and are supplied through the MOH distribution system.
- The quantification was to estimate the national laboratory commodities requirements and costs for two years: 2010–2012.
- The quantification team included 10 data collectors from the MOH diagnostic services division, the National Reference Laboratory, Central Medical Stores, and both local and external logistics advisors.

Collect Required Data

Data collection is the key activity in preparing for the quantification process. Collecting the data required to complete the quantification will probably be the most time-consuming and intensive of all the steps in the process. For HIV program–specific quantifications, data on the number of people on treatment, the number of people in care (otherwise known as pre-treatment) tested for HIV, and the results of the testing can be collected through the existing health management information system (HMIS). You can use the logistics management information system (LMIS) reports to collect data on the consumption of laboratory commodities. Both types of data can also be collected directly from health facilities, if the data provided by the HMIS or LMIS are not available or are of questionable quality. You can also obtain data from key informant interviews, which can include managers from national public health laboratory services; laboratory scientists representing all levels of the health system, from both the public and the private not-for-profit sectors; and all stakeholders (nongovernmental organization [NGOs], donors, etc.) who support

laboratory services. Table 2 lists various types of data that you can use for forecasting, as well as the potential sources for data.

Table 2. Data and Information Needs and Potential Sources for Forecasting

Data	Illustrative Source
List of programs that require laboratory supplies	Ministry of Health
National or facility-level standard testing guidelines	Ministry of Health
Financing	Ministry of Health, USAID | DELIVER PROJECT
Commodity cost information	Central Medical Stores (CMS), USAID | DELIVER PROJECT
Procurement period	CMS, USAID | DELIVER PROJECT
Lead time	CMS, USAID | DELIVER PROJECT. Procurement Services Agent
Safety stock	CMS, USAID | DELIVER PROJECT
Quantity in stock and quantity on order	Ministry of Health, CMS, USAID | DELIVER PROJECT

When forecasting the consumption of laboratory commodities, you will often find constraints in the type and quality of data available. Therefore, multiple assumptions will be required about specific tests and techniques by level, by capacity and quality of service delivery, by procurement and supplier lead times, and by status of the in-country supply pipeline. A consultative process with laboratory stakeholders will help enhance the accuracy of the data used and will also ensure that the final quantities to order have been developed with input from a range of laboratory services providers. It is important to document the sources of information and input from the key informants to explain the assumptions for the quantification. You should review and update the quantification at least every three months and when any of the major assumptions change.

For laboratory quantifications, collect the minimum data items that should be used in the quantification process (see box 2):

During the data collection process, you may find the steps below useful.

For logistics data and supply chain information (when using logistics data):

- Obtain national- and facility-level logistics data on usage of laboratory commodities, losses and adjustments, and stock on hand (SOH), if available. It is important to note that for laboratory commodities, most logistics systems track usage by what was issued from a facility store to the laboratory bench, given the difficulty associated with measuring actual consumption of a reagent when it is open and on the bench.

- Calculate the wastage rate of laboratory supplies due to expiration, loss, or damage of the products that occur during storage, distribution, and usage. Currently, without data from stock cards, the wastage rate is assumed to be 3 percent to 10 percent.

- Determine whether an inventory control system (ICS) is in place to manage laboratory supplies. Determine the maximum and minimum levels of the ICS, where appropriate.

- Determine procurement lead times, supplier schedules, and lead times for delivery of supplies.

- Determine existing buffer stock levels.

- Confirm facility order intervals.

- Determine the frequency and the timing of procurement procedures.

For laboratory commodity financing and pricing information—

- Identify all sources of financing for laboratory supplies (the government, international donor agencies, foundations, and private-sector donation programs).

- Determine the amount and duration of each financial commitment for laboratory commodity procurement. Identify specifically when funds will be available for use.

- Identify the procurement mechanisms and suppliers for each product (national bulk procurement, procurement through local distributors, or direct donation of product).

- Verify local and international pricing information for each type of laboratory commodity.

- Identify any cost-recovery or cost-sharing mechanisms in effect. Are any costs associated with laboratory services (co-pay, free, sliding fee, partial subsidy)? What are the likely implications of the costs on client uptake of testing services?

- Identify any restrictions on financing for the types of laboratory supplies that can be procured (for example, funds from the Global Fund to Fight AIDS, Tuberculosis, and Malaria can be used only to procure laboratory supplies from World Health Organization's prequalified suppliers; while the President's Emergency Plan for AIDS Relief (PEPFAR) funds might allow only for laboratory supplies to be procured from lists approved by the U.S. Food and Drug Administration or the Centers for Disease Control and Prevention [CDC]).

- Verify flexibility in amounts and availability of funding (for example, can potential funds be reallocated to procure laboratory supplies, and how long would reallocation take?).

If key data are not available or are of very poor quality, you may need to make estimates based on information from key informants.

The sources of the different types of data that were collected for forecasting laboratory commodity needs for the national HIV and AIDS program in the country of Uniborder are summarized in box 3.

Box 3: Country of Uniborder—Data Sources for Laboratory Commodity Forecasting

The data sources include—

- the MOH, National AIDS Program provided policy and planning documents for national HIV testing policy and strategies, the five-year plan for scaling up HIV treatment and testing services, and the national HIV testing guidelines, including information on the number of antiretroviral therapy laboratories in-country
- technical reports from care and treatment partners on the number of patients in treatment that they are currently supporting the country of Uniborder and the number of patients on pre-treatment
- from the National Reference Laboratory (NRL) comprehensive, equipment map with information on all CD4, chemistry, and hematology testing equipment in-country
- from the MOH Clinical Services Division and the NRL, standardized list of approved laboratory reagents in-country, including usage rates for each reagent
- cost information from 2009 for all reagents to be procured from the Central Medical Stores
- epidemiological surveys and reports, including the UNAIDS/World Health Organization estimates and the national HIV and Syphilis Sero-Survey for 2009
- technical reports on earlier assessments and country studies, including the multipartner report on the Situational Analysis of HIV and AIDS Services, 2009
- consultative interviews and discussions with central-level stakeholders, including commodity donors, MOH, nongovernmental organizations, and other implementing partners
- data from 15 facility visits conducted at three levels of the health system, including one to the NRL, to collect data.

The specific data that you should collect for forecasting consumption of laboratory reagents are listed below, including examples of actual data collected from the country example of a national HIV and AIDS laboratory quantification.

1. **The national HIV and AIDS testing protocol that will be followed for each year of the quantification.** The testing protocol below is divided by the first year of initiation into the ART program and those that follow up. During the process of interpreting national protocols, it will

be important to have clinicians available to accurately determine the frequency of certain tests. In the case of the country of Uniborder, during the national quantification workshop, guidance was solicited from clinicians routinely treating HIV and AIDS patients who helped interpret the guidelines for HIV and AIDS patients. For ART forecasting, give special attention to patients on specific regimens. For example, in table 3 for the country of Uniborder, patients on nevirapine (NVP) and zidovudine (AZT) will need additional chemistry and hematology tests.

Table 3. Laboratory Tests for the Country of Uniborder, by Month

Test	Baseline	Month 1	Month 3	Month 6	Month 9	Month 12	Year 2 & Beyond
CD4 Tx and pre-ART	X			X		X	2
ALT/GPT Tx	X	*			*	X	2
Creatinine Tx	X						1
Glucose (fasting) Tx	X						2
Total cholesterol Tx	X						2
Hematology Ad. Tx	X	Δ		X	Δ	X	2
Hematology Peds. Tx	X	Δ	Δ	X	Δ	X	2

Key

X =   Baseline or routine monitoring test

Tx =   Treatment group and pre-ART = pre-treatment group (care)

Ad. =   Adults and Peds. = pediatric

* =   Additional test only for adult and pediatric patients on NVP treatment

Δ =   Additional test only for adult and pediatric patients on AZT

If national policies and procedures have not been developed, you should recommend that they be developed. To help maintain a quality laboratory program as laboratory technologies rapidly evolve, you need to keep guidelines current with the most appropriate and accurate tests and techniques. The development of national policies and procedures will facilitate the coordination of laboratory efforts at a national level, helping to improve efficiencies and enhance management of resources in the laboratory system.

If detailed SOPs are not available, key stakeholders should begin the process of standardizing laboratory procedures.

2. **The equipment map in the country on which all CD4, chemistry, and hematology testing will take place.** As described above, the MOH should make every effort to standardize the equipment used in laboratories across the country, prior to beginning a national quantification workshop. As part of the data collection efforts, a comprehensive list of equipment should be provided by the MOH and relevant partners. Depending on how the funding streams for the procurement of laboratory commodities are set up, only equipment on the national standardized list will be included in the scope of the quantification. In certain countries, you will have some open source chemistry equipment that is not on the standardized list. The assumption is that all the equipment will use the same reagents that the other approved chemistry equipment use. Table 4 is an example of the list of equipment in the country of Uniborder. The MOH in this country has standardized laboratory procedures and only reagents associated with equipment in **bold** in the table will be included in the quantification.

Table 4. Country of Uniborder: Laboratory Equipment and Reagents

Hematology	Chemistry	CD4
ABX Micros 60 **Sysmex KX-21N** ACT 5 Diff	**Fully Biosystems** Cobas Integra 400	FACSCalibur **FACSCount** Guava

3. **The pack size, unit, costs, and usage rates per test for each of the laboratory products approved for testing in the country.** To forecast the consumption for reagents and consumables used per test, you need to determine the commodities used for each test, their basic units, the specifications, and the quantities needed to conduct that specific test (see table 5). One or more products are often needed to conduct a single laboratory test; each testing technique may use different commodities. Therefore, there should be consensus on which commodities are needed to avoid further complicating an already complex system. After each commodity has been identified, you need to determine and specify its basic unit needs, in consultation with laboratory services managers and scientists. Similarly, each test technique uses a specific quantity of a product to conduct the test. Therefore, you should also determine the quantity of each commodity needed, per test. The amount of each commodity needed per test can be found in the SOPs, when available. If the SOPs are not available, as is the case for most automated equipment currently being used in many laboratories, the usage rates can be solicited from manufactures of the equipment or estimated in-country by consulting with experts on each piece of equipment.

Table 5. Country of Uniborder: Laboratory Products Approved for Testing

Laboratory Product	Pack Size	Unit	Price/Pack ($)	Usage Rates
BD FACS Count – CD 4/8 reagent kit	50	tests	425.00	1
BD FACS Count – FacsClean	5	L	100.00	0.012
BD FACS Count – FacsRinse	5	L	100.00	0.0005
BD FACS Count – FacsFlow	20	L	120.00	0.003003
BD FACS Count – thermal paper	1	roll	10.00	0.007
BD FACS Count – control kit	25	tests	450.00	1
Fully (biosystem) – alanine aminotransferase (ALT)/GPT	200	mL	55.00	0.5
Fully (biosystem) – creatinine	200	mL	55.00	0.5
Fully (biosystem) – glucose	200	mL	40.00	0.5
Fully (biosystem) – cholesterol	200	mL	40.00	0.5
Fully (biosystem) – Control Serum Level I	25	mL	46.00	0.5
Fully (biosystem) – Control Serum Level II	25	mL	46.00	0.5
Fully (biosystem) – calibrator	25	mL	46.00	0.1
Fully (biosystem) – cuvettes	400	cuvettes	55.00	6.5
Fully (biosystem) – sample cups with hole	1,000	cup	30.00	1
Sysmex KX-21N – cell pack	20,000	ml	71.67	30
Sysmex KX-21N – Stromatolyser WH	1,500	ml	512.73	0.8

Laboratory Product	Pack Size	Unit	Price/Pack ($)	Usage Rates
Sysmex KX-21N – Cell Clean	50	ml	108.87	1.3
Sysmex KX-21N – Control Eight Check	7.5	ml	146.82	0.05
HIV Screening – Determine HIV 1/2	100	tests	69.27	1
HIV Confirmatory – Uni-Gold HIV test	20	tests	32.00	1
HIV Tie Breaker – SD Bioline HIV 1/2 3.0	30	tests	80.00	1
Vacutainer needles	1,000	PCS	70.00	1
Gloves, latex disposable large	100	PCS	6.20	1
Pipette tips (yellow) 200 uL	500	PCS	39.60	1
Biohazard bag (610 x 760 mm)	100	PCS	54.20	1 (per week)
Blood lancet, sterile	2,000	PCS	260.00	1
Vacutainer tubes, ethylenediamine-tetraacetic acid (EDTA) purple-top, 5 mL	100	PCS	80.00	1
Vacutainer tubes, EDTA red-top, 5 mL	100	PCS	110.00	1

4. **The non-diagnostic purposes of testing included in the quantification for which consumption of laboratory reagents must be forecasted.** To calculate the quantities of each laboratory reagent needed for these purposes, it will be necessary to determine the established quality control procedures, program plans for training, and specific survey or research protocols for testing the blood samples collected (see box 4).

> **Box 4: Country of Uniborder: Non-Diagnostic Purposes of Testing Included in the Quantification**
> - Quality Control—2%
> - Training—5%

5. **Demographic and population data:** You can present the total population numbers and growth, and demographic trends data by population subgroup (e.g., adult/children, male/female, urban/rural). You can obtain this information from population-based surveys, such as the Demographic and Health Survey (DHS) or from UNAIDS/WHO estimates (see box 5).

> **Box 5: Country of Uniborder: Demographic Data**
> These data were obtained from UNAIDS/WHO estimates for 2009:
> Total population: 23,915,000
> Population ages 15–49: 14,152,000
> Population ages 0–15: 3,234,000
> Annual population growth rate: 2.2%

6. **Morbidity data: Estimates of the national HIV prevalence and the number of people living with HIV.** These data may be available, by population subgroup, from UNAIDS/WHO estimates or from national epidemiological surveillance or survey studies, and extrapolated to estimate national-level incidence and the prevalence of HIV (see box 6).

7. **Services data: The number of people tested per testing area and the percentage of HIV positive results during the previous 12-month period.** Service statistics data are also historical, program-level, or facility-level data on the number of patient visits to facilities, number of services provided, or number of people who received a specific service or treatment during a given period of time. You can find service statistics data in program monitoring reports, HMIS data, facility-level data on service utilization and attendance rates, or in patient records. In some programs, the LMIS captures a limited number of service statistics (see box 7). For laboratory supplies, service statistics are the total number of tests performed during a certain period (e.g., CD4 count tests performed in a given quarter). For HIV tests, service statistics would be the total number of clients tested during a certain period. For ARVs, service statistics data would be the total number of ART patients on treatment at a facility or the total number of patient visits to a facility at a given point in time.

8. **Consumption data: The quantities of each brand of laboratory commodity used during the previous 12 months (see box 8).**

9. **Wastage data: The quantities of laboratory reagents and HIV tests discarded, lost, or wasted through normal handling and use (due to spillage, damage, or contamination), defective product, or repeat testing due to incorrect testing procedure or expiry at the facility level or instrument down time.** You can obtain these data from LMIS records or,

specifically, from stock control cards where the quantities of laboratory reagents or HIV tests discarded, lost, or wasted should be recorded as losses/adjustments to inventory (see box 9).

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Box 9: Country of Uniborder—Wastage Data
- CD4: 3%
- Chemistry: 10% for all parameters
- Hematology: 3% for reagents and 30% for controls.

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10. **Information on current program performance, plans, strategies, and priorities, including program targets for the number of people expected to be tested in each year of the quantification (see table 6).**

Table 6. Country of Uniborder: Key Programmatic Issues Affecting the Forecast

Issue	Effect on Forecast
New testing strategies to be implemented that will expand access to comprehensive laboratory testing services	These efforts are expected to significantly increase the demand for laboratory testing services and the quantities of supplies that will be needed to support the planned scale up.
Changes in demand of tests for continuing patients, resulting from losses caused by deaths and follow up; and transfers, in and out, as new facilities open	The forecast will be affected by variable user demand for and use of laboratory testing services, in response to antiretroviral therapy (ART). Over time, as a program matures and patients start ART earlier, there will be fewer deaths but, possibly, greater drop-out rates, which would increase the overall long-term demand for new facilities. Transfers in and out, as new facilities open, sometimes with differential user fees or travel time costs, will also increase demand in newer facilities or decrease demand in the existing ones.
Improved MOH and donor coordination	Coordination is critical to supporting efforts to scale up ART programs and to ensure that procurements, including quantifications of lab commodities needs, are coordinated—this will help avoid duplication in ordering and/or incorrect assumptions in the forecast. The forecasts are, therefore, more likely to be accurate if the MOH and donor coordination is improved.
No standardized list of testing equipment; inconsistent consumption data from each testing facilities	Lack of a standardized list of equipment will make it harder for the team conducting the forecast and overall quantification to accurately determine the forecasted consumption of various laboratory reagents to be used with the equipment. The country may also have problematic downstream supply planning and procurement.
The laboratory quality assurance program includes using routine laboratory controls, supervised testing of blood serum panels, and routine collection and retesting of blood samples from ART sites	Need to forecast additional quantities of specific laboratory reagents and HIV test kits to maintain quality control testing. Using established quality control procedures, need to estimate the quantities of laboratory reagents and HIV test kits for quality control.
Upgrading or existing equipment in-country during the quantification period.	Over time, testing equipment becomes obsolete and must be upgraded, which may mean a change in the reagents

Issue	Effect on Forecast
	used on the equipment to carry out testing. As a result, the reagents that were previously quantified and procured could go to waste. Such programmatic changes will, therefore, need to consider the impact such a change will have on existing inventory of reagents.
Shift from parallel testing algorithm to serial testing algorithm	The number of confirmatory tests required in a serial testing protocol is significantly less than in a parallel testing protocol, as only those who test positive in the screening test receive confirmatory tests, whereas all people tested in a parallel testing protocol receive both tests.

Organize and Analyze Data

After all the available data on laboratory testing services, HIV prevalence, past consumption of laboratory supplies, and program targets for each diagnostic and non-diagnostic purpose of testing have been collected, the quantification team should review the data to determine their validity and usefulness for forecasting. Accuracy of the quantification will depend on the availability, completeness, and reliability of the data collected. This does not mean that the forecast cannot be performed with less-than-perfect data. It does, however, mean that a close review of the available data is critical to guaranteeing quality results (see table 7 and box 10).

Table 7. Analysis of Data Quality

| Type of Data	Data	Quality of Data	Other Notes
Demographic	Total population, 2009: **23,915,000** Population aged 15–49, 2009: **14,152,000** Population aged 0–15, 2009: **3,234,000** Population growth rate, 2006: **2.2%**	Comprehensive and up-to-date.	Data used for forecasting.
Morbidity	National HIV prevalence, 2009: **12%** Current number of patients on treatment = **247,158** Current number of patients on pre-treatment (care) = **244.062** Target number of patients on treatment 2012 = **343,579** Target number of patients on pre-treatment (care) 2012 = **342,031**	Targets are clear and seem realistic given historic scale up. Targets provided by the MOH, and based on assumptions that account for the impact of new laboratory testing strategy. Data is also current.	Discussion and consensus on national targets took place during a seven-day quantification workshop and discussions with individual program managers. Data used for forecasting.
Services	The average number of monthly CD4, chemistry, and hematology tests for— **Level I facilities:** ▪ 360 CD4 tests ▪ 400 hematology tests ▪ 400 GPT tests ▪ 500 creatinine tests ▪ 550 glucose tests ▪ 500 cholesterol tests **Level II facilities:** ▪ 500 CD4 test ▪ 600 hematology tests ▪ 250 GPT tests ▪ 600 creatinine ▪ 100 cholesterol	Data from level III testing facilities was missing. Additionally, consumption data on GPT tests and cholesterol seemed questionable for level II facilities.	Not used for forecasting.

Type of Data	Data	Quality of Data	Other Notes
Services	Number of people tested for HIV testing and counseling (HTC) **= 645,116 (incomplete data, adjusted for non-reporting)** (3% positivity rate) Number of people tested for preventing mother-to-child transmission (PMTCT) **= 284,884** (9% positivity rate)	Data complete for 2007. Data on HTC for 2007 was not complete and 1.5 years old.	Data from laboratory registers are not yet being reported to central diagnostics services unit, and so are unavailable for aggregation and analysis. Not used for forecasting.
	Total number of HIV exposed infants tested and percentage of positive results, 2007	Data not available.	Not used for forecasting.
Consumption	Consumption data on quantities of laboratory reagents used in 2009	Data not available.	Facility-level consumption data reported for only 40% of facilities. Stock cards at other facilities are not used to monitor the issuing of laboratory supplies. Not used for forecasting.
	Consumption of CD4 test kit tests calculated from 2009 physical inventory data: **e.g., 168,842 BD FACSCount CD4 test kits used**	Large, unexplained discrepancies between stock on hand (SOH) at beginning of year, quantities of CD4 test kits received, and SOH at the end of the year. No data on other CD4 reagents.	Severe under-reporting from facilities. Not used for forecasting.
	Quantities of Determine tests issued from districts to health centers during the previous 12 months **e.g., 635,456 Determine (test kits)**	Attempted to use district issues data as proxy for consumption. Low reporting rates and inconsistent reporting of unit of issue (number of tests vs. number of kits) rendered data invalid for forecasting.	Not used for forecasting.
Consumption	Quantities of glucose tests issued from regional warehouses to districts over previous 12 months. **e.g., 1,447,000 glucose tests**	Attempted to use regional issues data as proxy for consumption. Frequent and prolonged stockouts at regional level during previous 12 months meant that issues data would significantly underestimate consumption.	Not used for forecasting.

Select Forecasting Method(s)

The decision on which forecasting method to use, or whether to concurrently use the morbidity, service statistics and consumption methods for the purpose of comparing or validating the forecasting results, should be based on the availability and quality of the data collected. In considering whether to use the consumption method for forecasting, it is important to analyze whether past consumption of laboratory reagents is predictive of the quantities of laboratory reagents that will be used in the future. In a scaling-up environment where new laboratory testing strategies are being implemented—for example, the activation of ART laboratories or if changes in a particular type of HIV test kit on the national testing algorithm are being considered—past consumption data will not be useful for forecasting purposes.
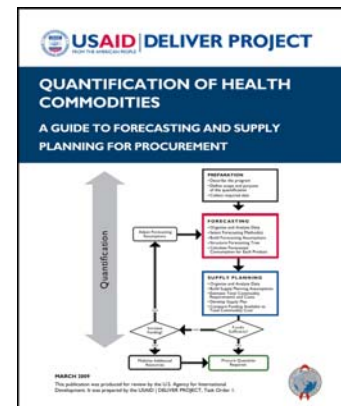
If services, morbidity, demographic data, or program targets will be used for forecasting, then use the morbidity method to convert the number of people to be tested, the expected percentage of positive results, and the discordance rates into the quantities of each of the laboratory reagents that will be needed, according to the national testing algorithm (see box 11). For a review of the consumption and morbidity methods of forecasting, refer to the section on Select Forecasting method(s) in the main quantification guide, *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement.*

Build Forecasting Assumptions

After the data collection and data analysis is complete, you will need to adjust assumptions, where necessary; and validate missing, incomplete, or poor quality usage and program data. In cases where little or no data is available, the accuracy of the forecast will depend on a set of clear and robust assumptions. It is critical that all assumptions made are clearly documented, including supporting information, where possible (see box 12).

In addition, you will also need to make assumptions when you estimate the effect of key programmatic and environmental factors expected to influence the demand for laboratory commodities for each year of the quantification. While planning for expanding ART and laboratory programs, policymakers, service providers, and quantification teams need to clearly define testing options, populations to be tested, and scaling up goals to ensure that the quantification of laboratory commodities is appropriate. Scaling up of ART programs may go faster or slower than projected; variable use and response to ART add to the complexity of decision making. These adjustments may require policy decisions regarding priority age groups, priority facilities, selection of appropriate testing equipment, standard testing guidelines to be employed at all service delivery points; in addition to demographic characteristics of the patient population groups in question.

To ensure the credibility and ownership of the forecasting results, you should obtain consensus on the forecasting assumptions through a consultative and participatory process for gathering inputs and fostering discussion making among key stakeholders.

Box 12: Country of Uniborder—Summary of Forecasting Assumptions

For all diagnostic testing purposes:

- Three approved rapid assay HIV test kits (Determine, Uni-Gold, and SD Bioline) will be used. All sites will use a serial testing algorithm with these tests in the order indicated.
- The newly adopted serial testing algorithm will be used for all HIV/AIDS testing, except for blood safety.
- Total testing targets agreed upon for all diagnostic purposes of testing were 910,896 between 2010–2012.

For all equipment:

- All the machines that were forecasted for are and will remain functional during the quantification period. Furthermore, whatever group is awarded the maintenance contract will be responsible for building the capacity at the zonal level to adequately repair and maintain the equipment.
- Only equipment on the approved MOH standardized list will be included in the quantification.
- All the sites that do not have equipment for CD4, chemistry, hematology, or viral load testing will transfer testing of samples, as indicated in the forecast period.
- All usage rates for laboratory reagents and supplies and their associated prices will remain accurate for the quantification period.

Wastage:

- The following wastage rates will remain true throughout the quantification period:
    - CD4—3%
    - chemistry—10% for all parameters
    - hematology—3% for reagents and 30% for controls
    - rapid test kit (RTKs)—10% for screening and confirmatory tests, 2% for tie-breaker tests
    - consumables—5%

For patient behavior:

- 10% of adult and pediatric patients in treatment and pre-antiretroviral therapy (ART) are lost to attrition during one year.
- 10% of adult and pediatric patients migrate from pre-ART into treatment and start ARVs during one year.
- For HIV, 5.4% of adult patients and 5% for pediatric patients test positive.

Structure the Forecasting Tree

Forecasting trees visually organize data and assumptions; they also help users identify where decisions need to be made. A forecasting tree is a diagram of patient groups (or health conditions) and the products required to treat or test one patient or one episode. When forecasting laboratory commodities, a diagram of the national testing algorithm for each diagnostic area of laboratory testing can be a useful tool in estimating future consumption of commodities.

It is important to note that in designing and building the forecast tree, include only the diagnostic purposes of testing. The forecast tree is built on patient groups and testing algorithms. Consumption of commodities resulting from non-diagnostic consumption of tests is not included in this data.

The forecasting tree shown on page 38 illustrates how you can organize available data for a CD4 laboratory forecast. It demonstrates a situation where morbidity data are available for adult and

pediatrics patients in care and treatment groups. Further data is also provided on the CD4 counts of the care and treatment percentages of patients. These sample percentages are used in the decision tree to derive final percentages of patients in each testing cohort. The example provided depicts the steps in determining the percentage of adult and pediatric patients that will receive CD4 testing for the country of Uniborder, including the data and assumptions used for each step.

Steps to constructing a forecasting tree are as follows:

1. **Identify the specific disease, health condition, or laboratory testing service for which commodities are to be forecasted.**

Country of Uniborder: HIV Laboratory Testing Services

2. **Specify the type of test and associated commodities to be forecasted (see box 13).**

Box 13: Country of Uniborder—CD4 Testing
Reagents used for CD4 tests:
- BD FACS Count – CD4 reagent kit
- BD FACS Count –nn tentrecast quantity needed oe in the quantificationipment they have at each facility to carry out the testingatric for the g FacsClean
- BD FACS Count – FacsRinse
- BD FACS Count – FacsFlow
- BD FACS Count – thermal paper
- BD FACS Count – control kit

3. **Determine the total number of patients or clients to receive treatment or services for each year of the quantification (see box 14).**

Box 14: Country of Uniborder—Total CD4 Testing
- Total CD4 testing target for patients on treatment by 2012 = 343,579
- Total CD4 testing target for patients on pre-treatment (care) by 2012 = 342,031.

4. **Separate the total targets by specific patient groups.** For CD4 testing, the patient groups are based on adults in treatment, adults in pre-treatment, pediatrics in treatment, and pediatrics in pre-treatment.

You will recall that one of the assumptions used in the case of the country of Uniborder was that, for the forecast period, 9 percent of the total population will be pediatric. With that, you can deduce that adults comprise the remainder 91 percent. For CD4 testing, patient groups are determined by the number of CD4 cell counts per patient. If any patient, whether they are adult or pediatric, has a CD4 count greater than 350, they are usually in the pre-treatment group. Any CD4 value less than 350 automatically places a patient in a treatment group. The threshold of 350 varies from country to country; it depends primarily on the treatment and testing protocols implemented by the country.

In box 15, an illustrative example is given for CD4 testing for the country of Uniborder. Similar to the CD4 count example, you can apply the same methodology when you separate patient groups for hematology and chemistry testing.

> **Box 15: Country of Uniborder—Breakdown of CD4 Testing Services by Client Groups**
> - Percentage of population that is adults = 91%
> - Percentage of population that is pediatrics = 9%
> - Adults in treatment = 52%
> - Adults in pre-treatment (care) = 48%
> - Pediatrics in treatment = 45%
> - Pediatrics in pre-treatment (care) = 55%.

5. **Document the testing protocol for each diagnostic purpose of testing (see box 16).**

> **Box 16: Country of Uniborder—CD4 Testing Protocol by Client Group and for Diagnostic Purposes of Testing**
> - For all adults and pediatrics in treatment and pre-treatment (care)
>   - one baseline test at initiation, follow-up tests in month 6 and 9 in year 1
>   - two CD4 tests every year in year 2 and beyond.

6. **Assign the number of clients to be tested for each diagnostic purpose of testing.** For CD4 testing, this number is often based on a target number of people to be tested, which determines the number of CD4 tests needed. This step is typically done automatically in most forecasting tools, including the CHAI–SCMS–USAID | DELIVER PROJECT quantification tool that you can use to forecast the consumption of CD4, chemistry, hematology, viral load, HIV test kits, and other laboratory tests (see box 17).

> **Box 17: Country of Uniborder—Number of Clients to Receive CD4 Test for Diagnostic Purposes by 2012**
> - adults in treatment = 87,743
> - adults in pre-treatment (care) = 88,172
> - pediatrics in treatment = 8,678

7. **Assign the expected percentage of tests repeated because of a clinician request and patients symptomatic characteristics for each diagnostic purpose of testing, for each client group:** Using services data, determine the percentage of clinician repeat tests requested, as well as the number of tests prescribed by clinicians because of a patient's physical presentation at the ART facility. When using demographic or morbidity data, use the percentages from soliciting information for a cohort of clinicians on the frequency with which they prescribe tests because of these two issues (see box 18). Most forecasting tools do this step automatically.

8. **Construct the forecasting tree based on the national CD4 testing algorithm and the forecasting assumptions for each diagnostic purpose of testing (see figure 2).** Assuming that the national testing algorithm and the diagnostic purposes of CD4 testing remains constant throughout the forecast period, only the testing targets and the assumptions on the size of each patient population, discordance, and wastage rates would need to be adjusted in the forecasting tree every time the quantification is reviewed.

Figure 2. Country of Uniborder—Forecasting Tree

Total Number of Adults and Pediatrics Expected to Receive a CD4 Test by Testing Group
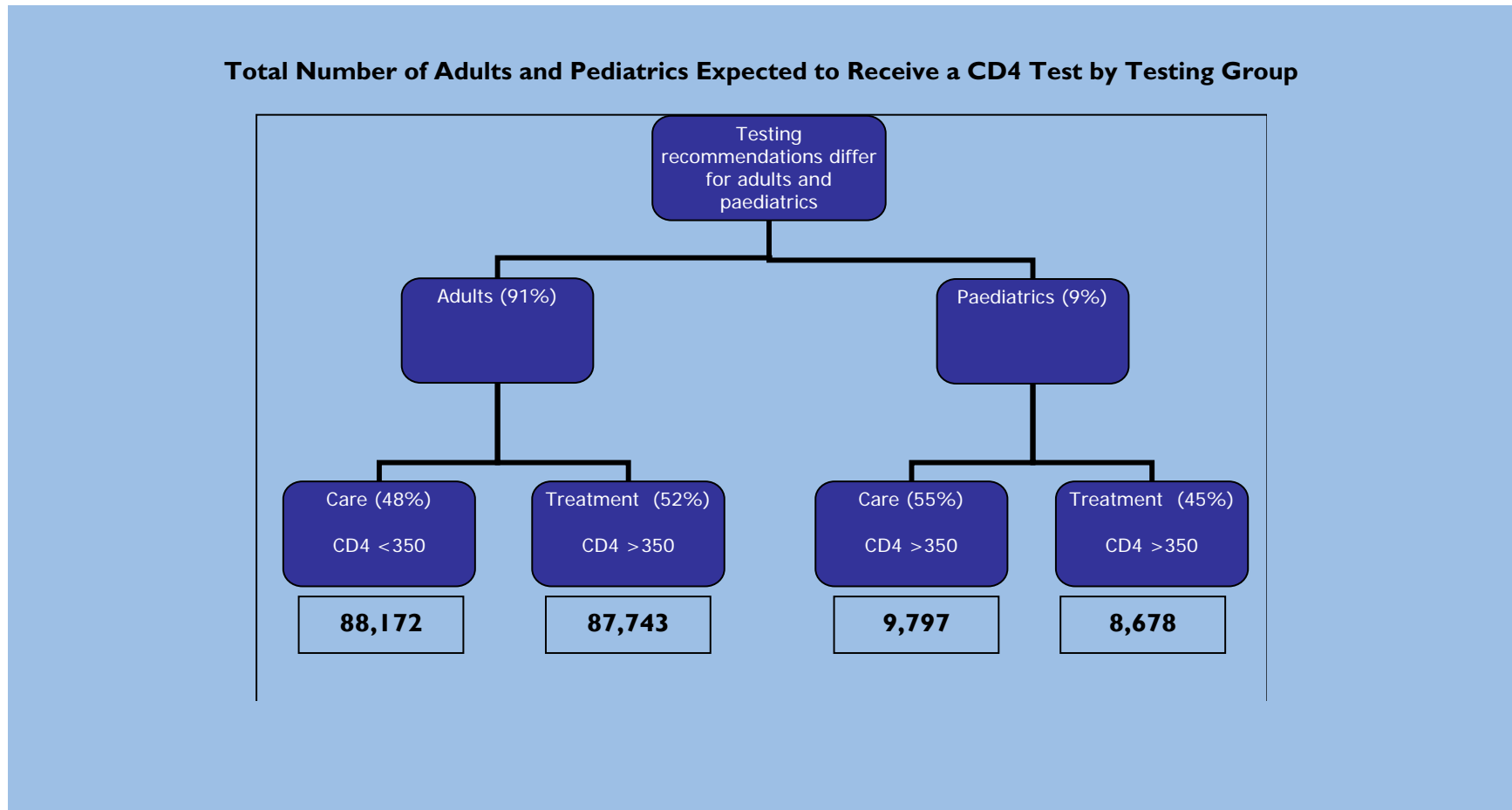
Calculate Forecasted Consumption for Each Product

After completing the forecasting tree and agreeing on the target (total) number of people to be tested, you must convert these numbers into the quantity of each type of laboratory commodity that will be needed. Forecasting the consumption for reagents and consumables used per test is complicated because of the requirements for some of the laboratory supplies being used. You should consider the nature of these products when you determine the quantities needed per test. For example, some laboratory reagents require reconstitution, while others need to be used concurrently.

You can use Excel spreadsheets or other software programs to forecast the number of laboratory commodities that will be used for diagnostic testing. The CHAI–SCMS–USAID | DELIVER PROJECT quantification tool is an Excel-based program that was developed to forecast CD4, chemistry, hematology, viral load, HIV test kits, and other HIV-related laboratory tests. Users input a series of data elements, per testing area; the built-in calculator determines the appropriate quantities of laboratory reagents required. To access this tool, please contact the Clinton Health Access Initiative (CHAI), the Supply Chain Management System (SCMS) Project, or the USAID | DELIVER PROJECT.

Complete the steps below to calculate the total forecast quantity of each laboratory product required for all diagnostic and non-diagnostic testing purposes, for each year of the quantification. You can complete these calculations in Excel, or use other quantification tools, as noted above.

1. **Calculate the forecast quantity needed for each laboratory reagent, consumable, and durable for all diagnostic testing purposes.**

Reagents

- Determine the list of health facilities to be included in the quantification.

- Agree on the list of tests that will be forecasted for each facility, as well as the equipment available at each facility to carry out the testing.

- Agree on the target number of people to be tested at each facility, in each patient group (*adults in treatment, adults in pre-treatment, pediatrics in treatment, and pediatrics in pre-treatment*).

- Determine the testing schedule to be used at the testing facility. Determine the frequency of laboratory testing schedule by patient group and testing area.

- For control materials, determine the frequency with which control materials will be run on all the equipment available at the testing facility and the number of days per month a specific laboratory facility will be open for testing.

Multiply the target number of patients per group (adults and pediatrics), per facility, by the usage rate of each reagent or machine-associated consumable, by the frequency of test. Ensure that the usage rate corresponds to the smallest basic unit of the reagent. For example, the BD FACSCount - CD 4/8 Reagent kit comes in a pack of 50 tests, but the usage rate is 0.2 per test. Where possible, differ to the manufacturer recommended usage rate per reagent (see table 8).

Table 8. Country of Uniborder: Calculating the Forecast Quantity of CD4, Chemistry, and Hematology Reagents

The forecasted consumption calculated below is per facility and only for adult patients in treatment during their first year of treatment.

Reagent	Units	Usage Rate	Equipment	Target Number of Adults	Frequency of Test per Year	Quantity per Year
BD FACS Count – CD 4/8 reagent kit	50 tests	0.2	1 Facscount	300	3	18
BD FACS Count – FacsClean	5 L	0.012	1 Facscount	300	3	2.16
BD FACS Count – FacsRinse	5 L	0.0005	1 Facscount	300	3	0.09
BD FACS Count – FacsFlow	20 L	0.003003	1 Facscount	300	3	0.14
BD FACS Count – thermal paper	1 roll	0.007	1 Facscount	300	3	6.3
BD FACS Count – control kit	25 tests	1	1 Facscount	run daily	264 days*	10.56
Fully (biosystem) – alanine aminotransferase (ALT)/ GPT	200 mL	0.5	1 fully	500	2	2.5
Fully (biosystem) – creatinine	200 mL	0.5	1 fully	500	1	1.25
Fully (biosystem) – glucose	200 mL	0.5	1 fully	500	1	1.25
Fully (biosystem) – cholesterol	200 mL	0.5	1 fully	500	1	1.25
Fully (biosystem) – control serum level I	25 mL	0.5	1 fully	run daily	264 days*	5.28
Fully (biosystem) – control serum level II	25 mL	0.5	1 fully	run daily	264 days*	5.28
Fully (biosystem) – calibrator	25 mL	0.1	1 fully	run quarterly	4 days	0.02
Fully (biosystem) – cuvettes	400 cuv	6.5	1 fully	500	1	8.1
Fully (biosystem) – sample cups with hole	1,000 cup	1	1 fully	2500 tests1	1	2.5
Sysmex KX-21N – cell pack	20,000 mL	30	1 Sysmex	450	3	2.03
Sysmex KX-21N – Stromatolyser WH	1,500 mL	0.8	1 Sysmex	450	3	0.72
Sysmex KX-21N – Cell Clean	50 mL	1.3	1 Sysmex	run daily	264 days*	20.59
Sysmex KX-21N – Control Eight Check	7.5 mL	0.05	1 Sysmex	run daily	264 days*	1.76

*Assuming 22 testing days per month for a period of 12 months

[1] This is an estimate of the total number of chemistry diagnostic tests that will be done including 1000 ALT, 500 Creatinine, 500 Glucose and 500 Cholesterol over the course of 12 months

Consumables

Although quantifiable per test, general laboratory consumables are commodities used across many tests, and can often be found outside the laboratory (e.g., alcohol, gloves, disinfectant). Without question, the commodities are necessary to run a laboratory and must also be included in the forecast. Ideally, historical usage data would guide forecasting demand of general consumables. However, in the absence of logistics data, it may be necessary to make assumptions on the usage of those commodities, in consultation with laboratory personnel. It is critical to document the assumptions, as well as all assumptions made throughout the quantification process.

Unlike the forecasting of the reagents discussed thus far, the steps for determining quantities required by type of test and technique are not applicable to general laboratory consumables (see table 9). Therefore, the steps for forecasting the consumption of general consumables are—

- for each consumable, identify its basic unit and the specifications

- to determine the quantities of consumables usually required to run a test in the laboratory, for each facility, multiply the estimated usage by the pack size.

Table 9. Country of Uniborder: Calculating the Forecast Quantity of General Consumables

The forecasted consumption calculated below is per facility.

Consumable	Pack Size (pcs)	Basic Unit	Usage Rate Parameter	Estimated Usage	Quantity per Year
Vacutainer needles	1,000	1	Total adult blood draws	4.323	4,323
Gloves, latex disposable large	100	1	Per week per site	52	5,200
Pipette tips (yellow) 200 μL	500	1	Total blood draws	9.5	4,750*
Biohazard bag (610 x 760 mm)	100	1	Per week per site	52	5,200
Blood lancet, sterile	2,000	1	Total pediatric blood draws	0.214	0.214428
Vacutainer tubes, EDTA purple-top, 5 mL	100	1	CD4 & hematology tests	22.5	2,2501
Vacutainer tubes, EDTA red-top, 5 mL	100	1	Total chemistry tests	25	2,500

*This is based on the assumption that a unique blood draw will occur for 900 CD4; 1,350 hematology; and 2,500 chemistry tests. The estimated number of tests is drawn from the target number of patients and testing protocol, as indicated in the previous section of forecasting reagent quantities. Per the earlier assumption, adult blood draws represent 91 percent of all blood draws and pediatrics represent the remaining 9 percent.

[1] This assumes that each CD4 and hematology test will be run on a unique day, therefore necessitating the use of an EDTA vacutainer tube for each test.

HIV Test Kits

Forecasting the consumption of HIV test kits is usually done nationally, instead of site-by-site. For this reason, after the forecasted consumption has been calculated for diagnostic purposes, you do not need to aggregate the total value site-by-site (see box 19).

The steps to consider for HIV test kits include, for each diagnostic purpose of testing—

- Agree on the target number of people to be tested, the percentage of positive results, and the discordance rate.

- Convert the number of people to be tested into the total number of screening tests.

- Based on the expected percentage of positive results and the discordance rate, calculate the estimated number of confirmatory and tie-breaker tests that will be needed.

Box 19: Country of Uniborder—Quantities of HIV Tests Needed for the Forecast Period

- Testing target for 2010–2012 was 910,896, a 40% increase over the number of clients tested between 2008 and 2010. Each client will be tested with one screening test (Determine). Therefore, the number of Determine HIV tests needed for year 1 is 910,896.

  910,896 x 1 = 910,896 Determine tests needed in year 1

- Each client with a positive result on the screening test will be retested with a confirmatory test (Uni-Gold). Based on the estimated percentage of positive results of 37%, 337,032 Uni-Gold tests will be needed for year 1.

  910,896 x 37% = 337,032 Uni-Gold tests needed in year 1

- Each client who has a discordant result (positive result from screening test and negative result from confirmatory test) will be tested with a third, tie-breaker test. The discordance rate was estimated to be 2% of all patients who had an initially positive result.

  337,032 x 2% = 6,741 SD Bioline tests needed in year 1.

Challenges in forecasting HIV test kits include the multiple purposes of testing, including quality control, training, and sentinel surveillance; the variability in HIV testing procedures; and the different types and brands of HIV test kits available. For more guidance on the best practices for completing a comprehensive HIV test kit quantification, please refer to *Quantification of Health Commodities: HIV Test Kit Companion Guide* (USAID | DELIVER PROJECT 2009b).
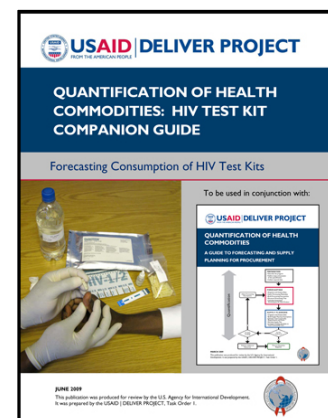
Durables

The forecasting of durables is divided into two parts: durable supplies and durable equipment. Forecasting the consumption of durables will require the same steps as estimating the quantity required for general consumables. However, equipment and durable supplies are typically not included in the forecast, unless specifically requested. That said, the forecast should always include spare parts that are likely to be needed during the forecast period (see table 10). For example, chemistry machines typically require bulbs and needles as replacement parts.

Table 10. Country of Uniborder: Examples of Durable Supplies and Equipment

Supplies	Equipment
Anaerobic jar	Hematology auto-analyzer
Bijou bottle	Binocular-powered microscope
Serological pipette	Enzyme-linked immunosorbent assay (ELISA) reader and washer

The main considerations for forecasting durable supplies and equipment will include—

- inclusion of spare parts in the equipment contract

- availability of spare parts in the local market

- availability of funds to procure equipment and spare parts

- length of time an equipment or supply has been in service and its reliability.

2. **Calculate the additional quantities of laboratory supplies that will be needed to account for wastage and training.**

   It is important to account for product wastage, including product loss through spillage, incorrect measurement, or damage during use. Initially, product wastage rates can be assumed to be between 3 percent and 10 percent of the total quantity required; this will depend on the test and a number of external factors, such as the quality of storage and distribution systems or historical wastage in the system. However, product wastage rates can drop if staff improve their testing skills, have appropriate equipment, and have infrastructure of approximately 3% of the total quantity required. The percentage of the product that should be allocated for training will be determined by national training protocols; this value will vary from country to country. As a standard, 5 percent is usually allocated for training purposes (see table 11).

   The wastage rate will also vary distinctly between each testing category. For example, in an ART program, the general population will be given certain chemistry and hematology tests, as will the patients enrolled in the HIV program. Conversely, CD4 testing does not have this issue because the tests are specifically used for patients enrolled in the HIV program. Hematology reagents tend to have short expiry dates of three months or less after production; they also require cold chain storage. If they are being managed by a supply chain that is not able to get the products to facilities before they expire, then their associated wastage will be higher than products with a longer shelf life. To account for this additional usage in countries where funding streams only

provide chemistry tests for the HIV program patients, or where product expiries are prevalent, the quantification team may consider using a higher wastage rate for certain product categories.

Table 11. Country of Uniborder: Adjusting Forecasted Quantities to Account for Wastage and Training

Laboratory Product	Estimated Quantity Required for One Year	Estimated Wastage Rate (%)	Estimated Training Rate (%)	Total Quantity Required for One Year
BD FACS Count – CD 4/8 reagent kit	18	3	5	19.4
BD FACS Count – FacsClean	2.16	3	5	2.3
BD FACS Count – FacsRinse	0.09	3	5	0.1
BD FACS Count – FacsFlow	0.14	3	5	0.2
BD FACS Count – thermal paper	6.3	3	5	6.8
BD FACS Count – control kit	10.56	3	5	11.4
Fully (biosystem) – ALT/GPT	2.5	10	5	2.9
Fully (biosystem) – creatinine	1.25	10	5	1.4
Fully (biosystem) – glucose	1.25	10	5	1.4
Fully (biosystem) – cholesterol	1.25	10	5	1.4
Fully (biosystem) – Control Serum Level I	5.28	10	5	6.1
Fully (biosystem) – Control Serum Level II	5.28	10	5	6.1
Fully (biosystem) – calibrator	0.02	10	5	0.02
Fully (biosystem) – cuvettes	8.1	10	5	9.3
Fully (biosystem) – sample cups with hole	2.5	10	5	2.9
Sysmex KX-21N – cell pack	2.03	3	5	2.2
Sysmex KX-21N – Stromatolyser WH	0.72	3	5	0.8
Sysmex KX-21N – Cell Clean	20.59	3	5	22.2
Sysmex KX-21N – Control Eight Check	1.76	30	5	2.4
HIV screening – Determine HIV 1/2	910,896	10	5	1,047,530.4
HIV confirmatory – Uni-Gold HIV test	337,032	10	5	387,586.8
HIV tie breaker – SD Bioline HIV 1/2 3.0	6,741	2	5	7,212.9
Vacutainer needles	4.323	5	5	4.8
Gloves, latex disposable large	0.52	5	5	57.2
Pipette tips (yellow) 200 uL	9.5	5	5	10.5
Biohazard bag (610 x 760 mm)	0.52	5	5	57.2
Blood lancet, sterile	0.214	5	5	0.2
Vacutainer tubes, EDTA purple-top, 5 mL	22.5	5	5	24.8
Vacutainer tubes, EDTA red-top, 5 mL	25	5	5	27.5

3. **Round up the quantities of laboratory commodities required for all diagnostic purposes of testing and the additional quantities needed to cover wastage and training.**

Up to this point, the forecasted quantities of each commodity have been expressed in partial units of each particular reagent, test kit, or consumable item required per facility. However, most laboratory commodities are not available in partial quantities; therefore, you should round them up to reflect the packaging size available for that specific commodity. For example, if a facility requires 19.4 kits of the BD FACS Count – CD 4/8 Reagent annually, when considering the actual quantities of each of the commodities required, the forecasted consumption should be adjusted up to 20 kits. In certain cases, the quantities of control materials with a short shelf life should also be adjusted to ensure there are adequate quantities of usable control material available throughout the forecast period. For example, if the annual forecasted consumption for a facility is 0.9 for the Sysmex KX-21N – Eight Check Control, the quantity of control required should be rounded up to one and then adjusted up to four, with planned receipts of one unit each quarter. The latter adjustment would ensure that a sufficient amount of the control is available in each quarter because its shelf life after delivery to country is three months.

Take extra care when estimating the quantities of reagents that are produced in kits, such as the BD FACS Count – CD 4/8 Reagent. Because the product is procured and distributed as a kit, rather than by individual items, extra resources would be required to break down and repackage the product in order to distribute smaller quantities to facilities.

Note that this forecasting step is not applicable to durables.

In the country of Uniborder, all the reagents forecasted were rounded up to the highest whole number to ensure the country does not stock out of these reagents (see table 12).

Table 12. Country of Uniborder: Rounding Up Forecasted Quantities of Laboratory Products

Laboratory Product	Estimated Quantity Required for One Year	Total Quantity Required for One Year
BD FACS Count – CD 4/8 reagent kit	19.4	20
BD FACS Count – FacsClean	2.3	3
BD FACS Count – FacsRinse	0.1	1
BD FACS Count – FacsFlow	0.2	1
BD FACS Count – thermal paper	6.8	7
BD FACS Count – control kit	11.4	12
Fully (biosystem) – ALT/ GPT	2.9	3
Fully (biosystem) – creatinine	1.4	2
Fully (biosystem) – glucose	1.4	2
Fully (biosystem) – cholesterol	1.4	2
Fully (biosystem) – Control Serum Level I	6.1	7
Fully (biosystem) – Control Serum Level II	6.1	7
Fully (biosystem) – calibrator	0.02	1
Fully (biosystem) – cuvettes	9.3	10

Laboratory Product	Estimated Quantity Required for One Year	Total Quantity Required for One Year
Fully (biosystem) – Sample cups with hole	2.9	3
Sysmex KX-21N – cell pack	2.2	3
Sysmex KX-21N – Stromatolyser WH	0.8	1
Sysmex KX-21N – Cell Clean	22.2	23
Sysmex KX-21N – Control Eight Check	2.4 (4)	3
HIV Screening – Determine HIV 1/2	1,047,530.4	1,047,531
HIV Confirmatory – Uni-Gold HIV test	387,586.8	387,587
HIV Tie Breaker – SD Bioline HIV 1/2 3.0	7,212.9	7,213
Vacutainer needles	4.8	5
Gloves, latex disposable large	57.2	60
Pipette tips (yellow) 200 uL	10.5	11
Biohazard bag (610 x 760 mm)	57.2	60
Blood Lancet, sterile	0.2	1
Vacutainer tubes, EDTA purple-top, 5 mL	24.8	25
Vacutainer tubes, EDTA red-top, 5 mL	27.5	28

* Multiply by 4 to adjust for a short shelf life of three months and to ensure that one per quarter is available.

4. **Aggregate the rounded-up quantities of laboratory commodities required for all diagnostic and non-diagnostic tests for all facilities in the country.**

After determining the laboratory commodity needs for individual facilities, aggregating quantities across facilities is the next and final step in calculating the forecasted consumption of each product to be included in the national quantification. Doing this will provide a comprehensive overview of the total quantity of laboratory commodities forecasted. The country of Uniborder depicts this step (see table 13). In this case, the country only has a total of three facilities. Remember that for HIV test kits, annual quantities have already been calculated and representative quantities of that total figure have been allocated to each facility in this example.

Table 13. Country of Uniborder: Aggregating the Forecasted Quantities of Laboratory Products

Laboratory Product	Lab 1	Lab 2	Lab 3	National Forecasted Consumption
BD FACS Count – CD 4/8 reagent kit	20	60	300	380
BD FACS Count – FacsClean	3	9	45	57
BD FACS Count – FacsRinse	1	3	15	19
BD FACS Count – FacsFlow	1	3	15	19
BD FACS Count – thermal paper	7	21	105	133
BD FACS Count – control kit	12	36	180	228
Fully (biosystem) – ALT/ GPT	3	9	45	57

Laboratory Product	Lab 1	Lab 2	Lab 3	National Forecasted Consumption
Fully (biosystem) – creatinine	2	6	30	38
Fully (biosystem) – glucose	2	6	30	38
Fully (biosystem) – cholesterol	2	6	30	38
Fully (biosystem) – Control Serum Level I	7	21	105	133
Fully (biosystem) – Control Serum Level II	7	21	105	133
Fully (biosystem) – calibrator	1	3	15	19
Fully (biosystem) – cuvettes	10	30	150	190
Fully (biosystem) – sample cups with hole	3	9	45	57
Sysmex KX-21N – cell pack	3	9	45	57
Sysmex KX-21N – Stromatolyser WH	1	3	15	19
Sysmex KX-21N – Cell Clean	23	69	345	437
Sysmex KX-21N – Control Eight Check	3	9	45	57
HIV screening – Determine HIV 1/2	349,177	349,177	349,177	1,047,531
HIV confirmatory – Uni-Gold HIV test	129,196	129,195	129,196	387,587
HIV tie breaker – SD Bioline HIV 1/2 3.0*	2,405	2,404	2,404	7,213
Vacutainer needles	5	15	75	95
Gloves, latex disposable large	60	180	900	1140
Pipette tips (yellow) 200 uL	11	33	165	209
Biohazard bag (610 x 760 mm)	60	180	900	1,140
Blood lancet, sterile	1	3	15	19
Vacutainer tubes, EDTA purple-top, 5 mL	25	75	375	475
Vacutainer tubes, EDTA red-top, 5 mL	28	84	420	532

* Divide the total forecasted consumption by three for the three facilities.

Challenges and Lessons Learned in the Quantification of Laboratory Commodities

Common Challenges

After conducting the national laboratory commodity quantifications in a number of countries, the USAID | DELIVER PROJECT and its predecessors identified several common challenges across countries. Those challenges, summarized below, have become guiding principles in developing the approach to quantification reflected in this laboratory quantification companion guide.

- Data on consumption (usage) of laboratory supplies are limited and, where available, often are unreliable or insufficient for use in quantifying requirements for laboratory supplies. Therefore, a number of countries have started implementing logistics systems from which they can collect reliable consumption data to use for forecasting. Before these data are used for forecasting, they should be verified for completeness and quality.

- Standard operating procedures (SOPs) for testing services are often not available. Laboratories tend to develop their own SOPs, based on the experiences of personnel, which results in inconsistent techniques and procedures across laboratories at the same level.

- In certain cases, standard testing protocols are not regularly adhered to; forecasts carried out using morbidity data tend to overestimate the quantities of reagents, consumables, and test kits required for the quantification period.

- Implementation of a standard system can pose challenges in training laboratory personnel in the recommended testing techniques.

- Program targets may not consider the testing capacity at each facility or level of the system to provide services; nor of the supply chain capacity to finance, procure, and manage greater volumes of laboratory supplies.

- Multiple sources of funding, procurement mechanisms, and distribution channels are used for laboratory supplies.

- Often lacking is the communication and coordination between policymakers, service providers, funding sources, and procurement agents on issues related to the selection, quantification, and procurement of laboratory supplies. As a result, incompatibility of reagents and equipment procured from different sources is a frequent issue.

- The multiple purposes of use in testing for most consumables is challenging for staff to collect, aggregate, and report data that will be useful during quantification.

- Program targets for increasing HIV testing may not be linked to program targets for increasing antiretroviral therapy patient enrollment. As a result, the quantities of HIV test kits required might be underforecasted.

- Programs may not expand as rapidly as expected. In the case where a target-based forecast is carried out, there is a danger of overstocking and a large quantity of supplies could expire.

- Quantification capacity at the country and program levels is often limited; although, with the number of trainings that have been completed, this has started to improve over time.

- Manufacturers of controls are often not given an adequate lead time for the time when the forecasted supplies should be available in-country. As a result, some countries may experience stockouts of key control materials.

- To identify alternate sources of supply for the required quantities of product, global shortages of HIV test kits caused by limitations in supplier production capacity after spikes in demand may need to be addressed during quantification.

- Similarly, while manufacturers of new HIV test kits may offer promising alternatives; short term, they may not be able to respond to exponential increases in demand for their product.

- Additional consumable items required to perform HIV diagnostic tests (e.g., lancets, capillary tubes, pipettes) may not be included in the test kits; you may need to find or procure them separately.

- Many countries do not have standardized instruments lists and testing protocols.

- Changes in regimen or changes in technology cause frequent changes in testing protocols or instruments.

- Frequent changes in HIV testing algorithm may cause problems.

- Frequent instrument breakdowns and the lack of maintenance contract make usage reports unreliable.

- Some commodities are stocked out at the central level.

Useful Lessons

This companion guide also includes the following lessons learned from the USAID | DELIVER PROJECT when the project conducted national-level HIV test kit quantifications.

- The quantification exercise is time and resource intensive. Therefore, you should plan and budget for adequate time and funding, including human resources with appropriate skills to conduct the quantification exercise. A quantification may require four to six weeks to complete all the steps.

- Currently, quantifications are based on informed assumptions, but they will become more evidence-based over time as the availability and quality of data improve. Therefore, the project encourages simultaneous efforts to strengthen the LMIS.

- If you do not have logistics data or morbidity data, the best methodology for quantifying laboratory supplies is service statistics—use the number of each test performed over a given period, but do not include general laboratory consumables and durables. The latter commodities

require assumptions based on usage data, in consultation with laboratory personnel. However, you should have comprehensive and quality service statistics data available for this step.

- For programs that are rapidly scaling up, using morbidity data is the most appropriate way to ensure that a sufficient amount of supplies are available for the forecast period.

- Quantification requires a consultative process; multiple stakeholders can inform the assumptions about the selection, quantification, and procurement of laboratory supplies.

- Before quantifying laboratory supplies, if you can, conduct a standardization exercise to either develop or update test menus, techniques, testing procedures, and equipment for each level of the health system.

- Ensure that the standardization process is always a consultative workshop; include representatives from all programs and levels that provide testing services; also include donors, and all key players in laboratory services. This is a critical step toward transferring ownership of the results to in-country stakeholders. The meetings can also help mobilize resources, set expectations, and promote collaboration and coordination, especially if there are delays in commodity availability.

- Base the quantification on realistic program plans and available financing.

- Use the results of the quantification to determine specific order quantities and shipment schedules for short-term procurement planning, based on available funding.

- Also, use the results of the quantification for medium- and long-term program planning and resource mobilization for laboratory testing services.

- Review and update the quantification at least every six months; update more frequently if major changes in the forecasting assumptions, funding commitments, or timing of procurements might significantly impact the selection of the test kits, quantities of HIV test kits required, or shipment delivery schedule to the country.

Additional Considerations

As mentioned earlier, to determine the consumption of laboratory commodities, the morbidity method used as an illustrative example in this guide includes standard treatment guidelines (STGs), test menus, or other testing protocols to estimate the number of patients expected to receive treatment or services within the forecast period. One of the advantages of using this model is that it does not require any historical data and, therefore, is suitable for new treatment policies; it is often cited as the best approach when justifying a budget request.

However, in addition to relying on clinicians to prescribe tests according to standard protocols, one limitation of this method is that it is the most complex and time-consuming forecast method. In the country of Uniborder, numerous data points—for example, the number of blood draws for an existing adult patient and the number of blood draws for a new adult patient on treatment—were not considered because of the complexity of doing those calculations by hand. Additionally, to calculate the forecasted consumption for an entire country where every laboratory, on average, manages more than 50 products, the forecasting process can quickly become a lengthy, cumbersome process.

For these reasons, the project strongly recommends using the existing forecasting tools that were co-developed by CHAI, SCMS, and the USAID | DELIVER PROJECT as a way to carry out these forecasts. These tools allow for improved accuracy in forecasts because of the number and variety of data inputs they can handle. They also provide the added benefit of automatically calculating and aggregating laboratory commodity needs across facilities, programs, and regions. While this companion guide provides adequate guidance on how to conduct a laboratory forecast, it is important to ensure that the forecasting process itself is carried out using validated tools that will guarantee accurate results.

This companion guide does not cover the selection, procurement, storage, distribution, and end use of laboratory commodities. However, several points related to these activities are worth mentioning.

If all other technical factors are equal, preference in selection should be given to laboratory commodities, in particular HIV kits, that do not require cold storage, have the longest shelf life, and are as self-contained as possible. The emphasis in procurement should be on developing supplier relationships that allow for frequent shipments of smaller quantities of freshly manufactured laboratory reagents and test kits. When possible, the purchasing contract should allow for accelerating or delaying the delivery of test kits to the program, in response to actual consumption and stock levels of the test kits in-country.

The shipment schedule for laboratory reagents and test kits must reflect the lead time and shelf life of each product, as well as the logistics system's current storage and distribution capacity. For example, tests with a short shelf life and cold chain storage requirements may have to be manufactured and shipped to a country at more frequent intervals than tests with a longer shelf life that can be stored at room temperature. In addition, the in-country supply pipeline for short-shelf-life items may need to be shorter than for drugs and supplies. For reagents, in particular, the controls may need to be delivered to service delivery points more frequently.

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Appendix A

Types of Data Used for Forecasting Consumption of Health Commodities

The ultimate goal of the forecasting step in the quantification process is to determine the quantities of each product that will be consumed, or used for a particular service or treatment, during a specified period. Countries and programs will vary in the type of data that are available for forecasting and the quality of those data. Generally, more than one type of data should be produced and compared for different forecasts. In practice, multiple challenges in the availability and quality of the data may result in forecasts that are based on only one source of data, including the estimates of demand from qualified experts in the field of practice for which the commodities are needed.

Four basic types of data can be used to forecast consumption of health commodities: (1) consumption data, (2) service statistics data, (3) demographic/morbidity data, and (4) target data. The goal is to use these different data types to determine the quantities of each product that will be consumed during a given period. With consumption data, the starting point is the quantities of products dispensed. With service statistics data, demographic/morbidity data, and target data; the starting point is not quantities of products but the number of people, number of cases of a disease or episodes of a health condition, or number of visits. The number of people expected to be served, number of episodes expected, or the number of visits expected must then be converted into the estimated quantities of products that will be consumed.

Consumption Data
Consumption data are historical data on the actual quantities of a product that have been dispensed to patients or used at a service delivery point within a given time period; the data are typically reported by month or by quarter. Daily consumption data can be found in pharmacy dispensing registers, laboratory registers, or other point of service registers. If a well-functioning LMIS captures and aggregates these data from service delivery points, aggregated consumption data can be found in monthly and annual facility-level and program-level reports. For antiretroviral drugs (ARVs), consumption data would be the actual quantity of each ARV dispensed to ART patients. For HIV tests, consumption data or *usage data* are the actual number of HIV tests used during a given period. For laboratory supplies, consumption data are the actual number of laboratory commodities used.

When using consumption data, the forecast is based on the quantities of HIV tests used in the past. Consumption data are most useful in mature, stable testing programs that have a full supply of test kits and where reliable data are available. One caution on using consumption data is that data on past consumption of HIV tests will not be predictive of future use in a scaling-up environment. Also, if the program has had stockouts of test kits, past consumption data will underestimate what

the consumption would have been if HIV test kits had been continuously available at all HIV testing facilities.

Service Statistics Data

Service statistics data are also historical, program-level, or facility-level data on the number of patient visits to facilities, the number of services provided, or the number of people who received a specific service or treatment within a given time period. You can find service statistics data in program monitoring reports, health management information system (HMIS) data, facility-level data on service utilization and attendance rates, or in patient records. In some programs, the logistics management information system (LMIS) captures a limited number of service statistics. For ARVs, service statistics data would be the total number of ART patients on treatment at a facility, or possibly, the total number of patient visits to a facility at a given point in time. For HIV tests, service statistics would be the total number of clients tested during a certain period. For laboratory supplies, service statistics are the total number of tests performed during a certain period (e.g., CD4 count tests performed in a given quarter).

Demographic/Morbidity Data

Demographic/morbidity data are data on the proportion of a specific population estimated to be affected by a given health condition that requires a specific treatment, or estimates of the number of episodes of a given health condition that will occur in a common denominator of the population (e.g., number of episodes per 1,000 or per 100,000 population). The quantities of drugs needed to treat the estimated population, or an estimated number of episodes of the disease or health condition per year, are then calculated based on standard treatment guidelines. In some cases, these population-based figures are further refined to estimate a more segmented population that may have access to a health facility where the services are provided. Demographic/morbidity–based estimates are often used to estimate the total unmet need for a service or treatment in a program or country; and, therefore, would represent what the uppermost boundary of the potential drug requirements might be for a program.

For ARVs, demographic/morbidity data would represent estimates of the total population that would be HIV positive, eligible to receive ART, and have access to care and treatment services. For HIV tests, demographic/morbidity data would estimate the total population and the number of people who are expected to receive an HIV test, and then apply the HIV prevalence rate. For laboratory supplies, demographic/morbidity data would estimate the total population that is affected by a particular disease or illness, and how many of those would access services.

Because demographic/morbidity estimates are not based on actual service delivery or use of commodities at health facilities, but on broader population estimates of potential need, forecasts based on such data tend to overestimate forecast consumption and, generally, are not appropriate for estimating the quantities of drugs to be procured. Sources of demographic and morbidity data include census surveys, specialized health surveys, epidemiological surveillance data, or research studies. Typically, when data are limited, nonexistent, or of poor quality, you can use demographic/morbidity data to estimate drug requirements.

Program Target Data

Typically, political or programmatic targets are not related to the actual numbers of patients being served or who can be served by a program, the volume of commodities being used at health facilities, or the capacity of the supply chain to manage the volume of commodities required. Broad

program targets of this type are best used for advocacy and resource mobilization; therefore, generally, you should not use them as estimates for procuring commodities. Sources of program target data include program planning documents, national policy and strategy documents, and materials published for dissemination and advocacy.

Conversely, you can also base program targets on current levels of service delivery that is adjusted to reflect program expansion plans over a specified period. They are usually a combination of service statistics data and estimates or projections of increased program coverage; and you should, ideally, consider the funding available, service delivery capacity, and supply chain capacity to manage increased volumes of commodities. For procurement purposes, these types of program target data are recommended for quantifying program commodity requirements.

Appendix B

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 acid acid-fast bacilli (AFB)	❒ Ziehl-Neelsen (ZN) stain
❒ Skin slit for AFB	❒ ZN stain
❒ Urine sediment microscopy	❒ Direct microscopy
❒ Urine protein, sugar	❒ Uristix
❒ Syphilis screening	❒ Rapid plasma reagin (RPR)
❒ Sickle cell screen	❒ Sodium metabisulphite
❒ Genitourinary tract specimens	❒ Wet prep/Gram stain/potassium hydroxide (KOH)
❒ Pus swabs	❒ Gram stain
❒ Bubo aspirate (plague)	❒ Wayson staining
❒ HIV screening	❒ Rapid screening kits
❒ Blood grouping	❒ Tube method
❒ Rhesus typing	❒ Tube
❒ Total white cell count	❒ Manual, hemocytometer using Turks fluid
❒ Differential white cell count	❒ Manual, using stained thin film
❒ Cerebrospinal fluid microscopy	❒ Gram/Leishman/Turks fluid
❒ Cerebrospinal fluid chemistry	❒ Turbidimetric

Additional Tests Performed at District Hospital Laboratory

❒ Concentration technique	❒ Buffy coat (Knotts)	
❒ Blood	❒ Formal ether	
❒ Stool		
❒ Urine qualitative chemistry (protein, sugar, ketones, blood bilirubin, urobilinogen)	❒ Uristix	
❒ Skin snip for microfilaria	❒ Saline direct	
❒ Collection and fixation of cytological smears	❒ Formalin	

Tests Performed at Regional Hospital Laboratory

Laboratory Test	Standard Technique
❐ Hemoglobin estimation	❐ Hematology analyzer
❐ Total white cell count	
❐ Differential blood counts	
❐ Platelet count	
❐ Reticulocyte count	
❐ Blood indices	
❐ CD4/CD8 count	❐ Flow cytometer
	❐ Non-cytofluorometric
	❐ Manual
❐ Viral load	❐ HIV RNA
	❐ Real Time PCR
	❐ Heat Dissociated p24 antigen
	❐ Cavidi RT
❐ Sickle cell screening test	❐ Sodium metabisulphite
❐ Blood slide examination for parasites	❐ Manual microscopy (field)
	❐ Concentration
❐ Film comment	❐ Manual microscopy- Romanosky
❐ Stool microscopy	❐ Direct saline/iodine concentration
❐ HIV screening	❐ Rapid screening kits
❐ Hb types	❐ Electrophoresis
❐ Serum proteins	❐ Electrophoresis
❐ Hepatitis B screening	❐ Rapid ELISA
❐ Syphilis screening	❐ RPR/Venereal Disease Research Laboratory (VDRL) carbon antigen
❐ Serum bilirubin	❐ Chemistry auto-analyzer (or manual photometer)
❐ Serum glutamic oxaloacetic transaminase (SGOT) (serum)	
❐ Serum glutamic pyruvic transaminase SGPT (serum)	
❐ Alkaline phosphatase (serum)	
❐ Renal function tests	

Tests Performed at Regional Hospital Laboratory, continued

Laboratory Test	Standard Technique
❏ Blood glucose	
❏ Serum electrolytes	
❏ Total protein	
❏ Examination of cerebrospinal fluid (CSF) for yeast	❏ Negative staining-India ink
❏ Examination of CSF, pus, deposit, etc., micro-organisms	❏ Gram stain
❏ Culture	❏ Aerobic
	❏ Anaerobic
	❏ CO2
❏ Drug sensitivity	❏ Disc diffusion
❏ Microscopy for plague	❏ Wayson staining
❏ Processing biopsy	❏ Hematoxylin and eosin
❏ Semen analysis	❏ Microscopy
❏ Cytology	❏ Microscopy
	❏ Pulp smear
❏ Sputum for tuberculosis (TB)	❏ ZN stain
❏ Urine sediment microscopy	❏ Direct microscopy
❏ Urine chemistry	❏ Uristix
❏ Genitourinary 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	❏ Treponema pallidum hemagglutination assay (TPHA)

Appendix C

List of Consumables

Consumables Used for a Specific Test	General Consumables
Anaerobic sachets	Alcohol
Bijou bottles	Applicator stick
Blood culture bottles	Autoclave tape
Blood lancets	Cotton wool
Blotting paper	Face masks
Capillary tubes	Filter paper
Centrifuge tubes	Gloves
Cotton swabs	Immersion oil
Cover slips	Lens tissue
Gauze mesh	Lysol
Heparinized capillary tubes	Methylated spirit
Immersion oil	Petri dish (if disposable)
Khan tubes	Potential hydrogen (pH) paper
Lancet	Printed labels
Microaerophilic sachets	Soap
Microscope slide	Sodium hypochlorite
Microtainer	Xylene
Microtitre plates	
Pipette tips	
Pipette tips (filtered)	
Prepacked iodine swabs	
Printer paper for CBD machine	
Printer paper for CD4/CD8 machine	
Sputum container	
Stool container	
Test tubes	
Universal containers	
Vacutainer, red top	
Vacutainer, grey top	
Vacutainer, ethylenediaminetetraacetic acid (EDTA)	
Vacutainer needles	
Vacutainer needle holder	

Appendix D

Sample Data Collection Questions

Sample Data Collection Questions for Forecasting Consumption of HIV Test Kits for Voluntary Counseling and Testing (VCT)

Consumption Data	Demographic/ Morbidity Data	Services Data	Program Targets Data
1. How many of each brand of HIV test kits were used for VCT in the past year? 2. What is the lowest level of the logistics system that has relatively complete consumption data? 3. At each facility/level of the logistics system, what was the beginning inventory for each brand of test kit at the start of the year? 4. At each facility/level of the logistics system, what is the total quantity of each brand of test kit received during the past year? 5. At each facility/level of the logistics system, what were the expiries, losses, and adjustments for each brand of test kit during the past year? 6. At each facility/level of the logistics system, what was the ending inventory for	1. What is the total population of the catchment areas served by VCT sites? 2. What percentage of the population in the catchment areas served by VCT sites is likely to come for counseling? 3. What percentage of counseled clients is likely to request an HIV test? 4. What is the HIV prevalence rate of VCT clients requesting an HIV test? 5. What is the average discordance rate between the screening and confirmatory tests? 6. What is the testing protocol for VCT?	1. How many VCT clients were tested for HIV during the past year? 2. How many VCT clients tested positive for HIV during the past year? 3. What is the expected rate of change in the number of clients to be tested for VCT for each year of the quantification? 4. What is the average discordance rate between the screening and confirmatory tests for VCT? 5. What is the testing protocol for VCT?	1. What is the target number of VCT clients to be tested for HIV for each year of the quantification? 2. What is the expected percentage of positive results among VCT clients who will be tested for HIV? 3. What is the estimated discordance rate between the screening and confirmatory tests for VCT? 4. What is the testing protocol for VCT?

Consumption Data	Demographic/ Morbidity Data	Services Data	Program Targets Data
each brand of test kit at the end of the year? 7. What is the expected rate of change in consumption of HIV test kits for VCT for each year of the quantification?			

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