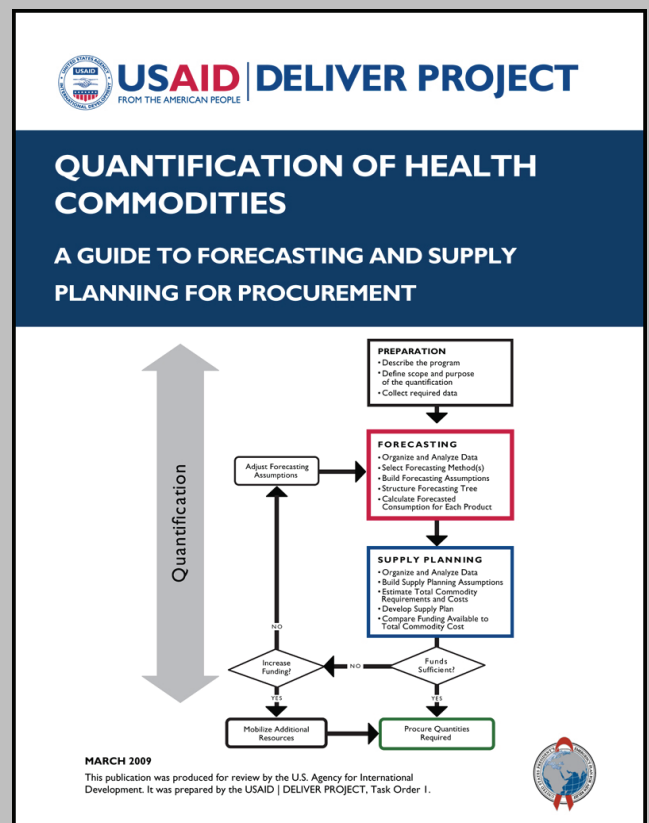# USAID | DELIVER PROJECT
FROM THE AMERICAN PEOPLE

QUANTIFICATION OF HEALTH COMMODITIES: HIV TEST KIT COMPANION GUIDE

Forecasting Consumption of HIV Test Kits

To be used in conjunction with:

USAID | DELIVER PROJECT
FROM THE AMERICAN PEOPLE

QUANTIFICATION OF HEALTH COMMODITIES

A GUIDE TO FORECASTING AND SUPPLY PLANNING FOR PROCUREMENT

Quantification

PREPARATION
- Describe the program
- Define scope and purpose of the quantification
- Collect required data

Adjust Forecasting Assumptions

FORECASTING
- Organize and Analyze Data
- Select Forecasting Method(s)
- Build Forecasting Assumptions
- Structure Forecasting Tree
- Calculate Forecasted Consumption for Each Product

SUPPLY PLANNING
- Organize and Analyze Data
- Build Supply Planning Assumptions
- Estimate Total Commodity Requirements and Costs
- Develop Supply Plan
- Compare Funding Available to Total Commodity Cost

Increase Funding? —NO— Funds Sufficient?

Mobilize Additional Resources → Procure Quantities Required

MARCH 2009
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QUANTIFICATION OF HEALTH COMMODITIES: HIV TEST KIT COMPANION GUIDE

Forecasting Consumption of HIV Test Kits

USAID | DELIVER PROJECT, Task Order 1

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Abstract

Successful implementation and expansion of HIV counseling and testing services is dependent on the continuous supply and availability of high-quality HIV test kits and the additional consumable supplies required at HIV testing sites. The variability in HIV testing procedures, the multiple purposes of testing, and the different types of HIV test kits available pose particular challenges in managing HIV test kit supply chains. The primary focus and purpose of this companion guide is to supplement the general guide on *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement* by describing in detail the specific methodology for forecasting consumption of HIV test kits as a critical step in the overall quantification process.

Cover photo: Preparing to conduct an HIV test.

CONTENTS

ACRONYMS

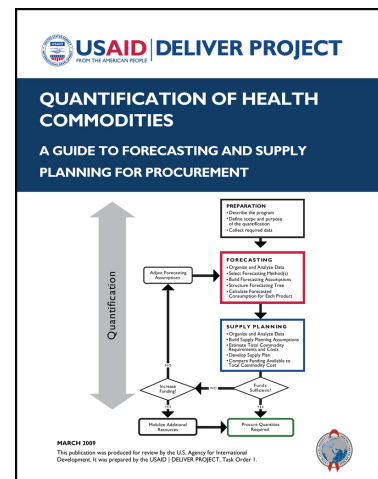|	
AIDS	acquired immunodeficiency syndrome
ANC	antenatal care
ARV(s)	antiretroviral drug(s)
CDC	U.S. Centers for Disease Control and Prevention
DBS	dried blood spot
DHS	demographic and health survey
DNA	deoxyribonucleic acid
ELISA	enzyme-linked immunosorbent assay
HCW	health care worker
HIV	human immunodeficiency virus
HMIS	health management information system
HTC	HIV testing and counseling
LMIS	logistics management information system
MOH	Ministry of Health
NBTS	National Blood Transfusion Services
NGO	nongovernmental organization
PCR	polymerase chain reaction
PITC	provider-initiated testing and counseling
PMTCT	prevention of mother-to-child transmission (of HIV)
RCC	rolling continuation channel (Global Fund)
RTD	rapid test device
STI(s)	sexually transmitted infection(s)
TB	tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	U.S. Agency for International Development
VCT	voluntary counseling and testing
WHO	World Health Organization

INTRODUCTION TO THE HIV TEST KIT COMPANION GUIDE

The purpose of this companion guide is to supplement the general guide on *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement* by describing in detail the specific methodology for forecasting consumption of human immunodeficiency virus (HIV) test kits as a critical step in the overall quantification process.

Challenges in forecasting HIV test kits include the multiple purposes of testing, the variability in HIV testing procedures, and the different types and brands of HIV test kits available. This companion guide provides instructions on how to forecast consumption of HIV test kits by purpose of testing, taking into account national HIV testing algorithms and HIV prevalence, as well as the use of HIV test kits for non-diagnostic purposes such as quality control, training, and sentinel surveillance. A country example is provided to illustrate the steps in the methodology, including the data and assumptions used and the outputs at each step.

Also included is information on the different types of HIV test kits currently available, HIV testing algorithms, and the most common purposes of testing in resource-limited settings, as well as specific guidance on the data collection and analysis required to determine which type(s) of data will be used to inform the assumptions on the demand for HIV testing services and future consumption of HIV test kits.

After following this companion guide and completing the forecasting steps, readers should refer back to the general guide on *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement* to determine the total HIV test kit requirements and costs for the program or the country. The final output of the forecasting step—the quantity of each HIV test kit needed for all purposes of testing—should be used as the starting point in the next step of the quantification, the supply planning step.

CHARACTERISTICS OF HIV TEST KITS AND THEIR USE

Before undertaking the forecasting step in a quantification of HIV test kits, it is important to have a basic knowledge of the different types of HIV test kits available and how they are used, how HIV testing services are being provided, and the different purposes for which HIV testing is being offered. This would include identifying the different program areas and locations where HIV testing is being provided. For example, facility-based testing provided through voluntary counseling and testing [VCT] and provider-initiated testing and counseling [PITC] services in VCT counseling rooms, laboratories, hospital inpatient wards and outpatient departments including antenatal care [ANC], tuberculosis [TB], and sexually transmitted infection [STI] clinics, and HIV testing provided through outreach services including mobile units, home-based testing, or HIV testing campaigns. Familiarity with national HIV testing policies and strategies and an understanding of their effect on the demand for HIV testing, and knowledge of how HIV testing commodities are managed in the country is critical for informing the forecasting assumptions and ensuring the credibility and usefulness of the final quantification results.

TYPES OF HIV TEST KITS

More than 100 brands of HIV test kits are available on the market, and HIV testing technology is evolving rapidly. In the next few years, new test kits will likely replace current ones. Table 1 shows the three different types of HIV test kits predominantly used in resource-limited settings. Readers may refer to the *Logistics Fact Sheets: HIV Test Kits* (USAID | DELIVER PROJECT, 2008) for detailed information on these HIV testing products and their estimated costs.

Table 1. HIV Test Kits

Test	Location of Use	Advantages	Limitations
Simple/rapid assay (rapid test device, or RTD*)	Small labs, VCT sites, prevention of mother-to-child transmission (PMTCT) sites, STI and TB clinics, emergency care centers	• Easy to use and interpret test results • Results within 10–30 minutes • No minimum volume of tests required • Requires minimal equipment • Does not require highly skilled staff • When used in combination, results are as reliable as enzyme-linked immunosorbent assays (ELISAs) • Can be used on various types of specimens, including whole blood	• Small-scale testing • Cold chain sometimes required • May cost more per individual test • Use of rapid tests at multiple sites in resource-poor countries will pose quality assurance challenges *Continued next page*

Test	Location of Use	Advantages	Limitations
		• Include oral fluid tests developed recently that are noninvasive and do not require the use of sharps • Can be used for on-site or point-of-care testing	
ELISA	Large hospitals, blood banks, or reference laboratories	• ELISA antigen/antibody tests are more sensitive than other tests for detecting seroconverters • Batch testing • Can be automated • Easier to conduct quality assurance testing, because tests are performed in fewer, high-volume laboratories	• Requires more time to obtain results (1–3 hours) and even longer if not at point of care • Sophisticated equipment and equipment maintenance needed • Cold chain always required • Need minimum volume of tests for maximum efficiency • Skilled technicians required
Western Blot	Large teaching hospitals, reference laboratories, and the National Reference Laboratory	• The "gold standard" • Detects all antibodies present	• Requires skilled and experienced personnel • Nonroutine test (small batches only, usually <10 in a batch) used for research and for clarifying indeterminate results

* RTDs are also ELISAs, but are listed as a separate type of test because of the nearly immediate results as well as other characteristics. Traditional ELISA tests are sometimes referred to as long ELISA tests because they may take up to three hours to produce a result.

PURPOSES OF TESTING

A critical step in preparing for the forecasting step of the quantification is understanding the different purposes of testing for which the HIV test kits will be used. The most common purposes of HIV testing in resource-limited settings are discussed below, with a distinction made between diagnostic and non-diagnostic testing.

DIAGNOSTIC PURPOSES OF TESTING

Voluntary Counseling and Testing (VCT)
VCT refers to the combination of counseling and testing offered to individuals who self-refer for testing because they wish to know their serostatus; it serves as both a diagnostic tool for detecting HIV infection and as a prevention service. Until recently, VCT, also known as client-initiated counseling and testing, was the primary diagnostic testing strategy in expanding HIV and AIDS (acquired immunodeficiency syndrome) programs. Although VCT has been considered the pivotal strategy and entry point for access to HIV and AIDS prevention, care, support, and treatment services, a greater proportion of HIV testing is now being provided through the expansion of PMTCT programs that offer "opt-out" testing, and through the implementation of provider-initiated testing and counseling (PITC) recommended by the World Health Organization (WHO and

UNAIDS, May 2007) to expand universal access to testing and counseling. Individuals who test negative can take appropriate measures to avoid becoming infected. Individuals who test positive can access treatment, care, and support services, including condom distribution, PMTCT, clinical management of HIV-related illnesses including STIs and TB, antiretroviral therapy, and psychosocial and legal support. In forecasting HIV test kit needs for VCT services, it is important to take into account the expected impact of new program priorities and HIV testing strategies on the demand for VCT.

Prevention of Mother-to-Child Transmission of HIV (PMTCT)

HIV counseling and testing of pregnant women allows them to learn their own serostatus and to seek prevention, care, and treatment services for themselves, their partners, and their children. Women who test positive can take appropriate steps to reduce the probability of transmitting HIV to their child during pregnancy, childbirth, and breastfeeding. In most countries, testing is included as a core opt-out service, and the number of pregnant women tested may be close to 100 percent of antenatal care clinic attendance. In other countries, HIV testing for PMTCT is still voluntary ("opt-in"). In those countries, the percentage of pregnant women expected to seek testing must be considered in the forecasting assumptions for the quantification.

Testing of HIV-Exposed Infants

All infants born to HIV-positive mothers have acquired HIV antibodies from the mother, but may not be infected themselves. Until the mother's antibodies clear the infant's bloodstream, usually by 18 months of age (and in some cases as early as 9 months), it is not possible to test for the presence of the HIV virus using currently available HIV test kits except through use of polymerase chain reaction (PCR) testing technology to detect viral DNA. PCR testing is expensive and complicated to perform and is not routinely available at health facilities in resource-limited settings. However, access to early infant diagnosis of HIV using PCR testing has been increasing through referral networks and the submission of infant blood samples to PCR testing sites via dried blood spot (DBS) samples.

Although it may not be possible to definitively determine the HIV serostatus of newborns of HIV-positive mothers, all HIV-exposed infants can be tested using rapid HIV tests to at least identify those who are HIV antibody negative and therefore are assumed not to be infected. The benefit of testing HIV-exposed infants with rapid assay tests is that measures can be taken to prevent the infant from contracting HIV infection through the mother's breast milk.

Provider-Initiated Testing and Counseling (PITC)

With the recent development and dissemination of the WHO/UNAIDS *Guidance on Provider-Initiated HIV Testing and Counseling in Health Facilities* (May 2007), many country programs are now integrating this opt-out strategy into their HIV testing programs. In PITC, service providers routinely offer HIV testing to patients (who have the option to refuse), as opposed to the traditional paradigm of client-initiated testing and counseling. A major focus of this strategy is to expand access to hospital-based testing to patients already accessing other services, particularly symptomatic patients in ANC, TB, and STI clinics, inpatient wards, and outpatient departments.

This development has important implications for the quantification of HIV test kits. PITC, also referred to as HIV testing and counseling (HTC) in some programs, is expected to significantly increase the demand for HIV test kits. In addition, since a majority of those who are tested through this initiative are expected to be symptomatic patients referred from other departments and services

within the hospital, this group will have a higher rate of positive results than those tested through other HIV testing services (e.g., VCT, PMTCT, or blood safety), therefore greater quantities of confirmatory tests will be needed for PITC if following a serial testing algorithm.

Community- and Home-based Testing

HIV testing and counseling is also being expanded through community-based outreach services using mobile units and through home-based testing. These services are often linked to the health facilities located in the districts being served, and the same HIV testing staff from hospitals and health centers provide the testing and counseling services. It is important to forecast the quantities of HIV tests needed for this purpose because, in most cases, the supply of HIV test kits to support community- and home-based testing is provided through the stocks of district hospitals, health centers, or other testing facilities.

Blood Safety

High rates of HIV and hepatitis infection among blood donors in some countries pose a serious health risk for patients who require blood transfusions. Blood safety refers to testing blood and blood products for HIV and other infectious diseases. Testing allows for infected or suspect blood to be discarded or destroyed, thereby ensuring the safety of the blood supply.

Some blood safety programs inform blood donors of their serostatus (linked testing). In other programs, the identity of donors remains unknown and they cannot be contacted to inform them of their HIV test results (unlinked or anonymous testing). Blood donor screening is provided through regional- or central-level hospital-based blood transfusion services and through community-based services (e.g., blood donor drives).

The use of rapid assay tests for blood safety usually occurs at regional- and district-level hospital laboratories that are not able to maintain an adequate supply of screened blood bags for transfusion through other blood collection and screening efforts. The testing protocol for screening blood donors with a rapid test is typically to conduct a single screening test using the specific brand of test recommended in the national testing algorithm. Seronegative blood is not routinely retested with a confirmatory test and is considered safe for transfusion, while seropositive blood is discarded.

In some countries, recent efforts to increase the supply of safe blood through strengthened national blood transfusion services have resulted in a reduced need for rapid test kits for screening blood donors at lower-level facilities. This has become a factor to take into consideration in forecasting the quantities of HIV tests needed for blood safety.

Large-scale Institutional Testing and HIV Testing Campaigns

Other diagnostic purposes of testing that require separate forecasting of HIV tests include large-scale institutional testing of special populations such as the military (e.g., for recruitment or deployment), police, prisoners, and others who may not access HIV testing and counseling services through VCT sites or hospital-based testing and counseling services. HIV testing campaigns are another example of planned, large-scale testing events that will require an additional supply of HIV test kits that may or may not be distributed through the established system for providing HIV testing and counseling services.

Wastage

Although wastage is not a diagnostic purpose of testing, the normal handling and use of HIV tests involves a certain amount of wastage because of spillage, contamination, or damage of the test during testing. Wastage may also include quantities of defective HIV tests that are discarded, or quantities of HIV tests used for retesting because of errors in the testing procedure. While it may be difficult to collect data on actual quantities of HIV tests discarded or used for these reasons, consultation and discussion with experienced laboratory and HIV testing staff will lead to consensus on a reasonable wastage rate to apply. Because the bulk of HIV testing is conducted for the diagnostic purposes of testing mentioned above, the additional quantities of HIV test kits needed to account for wastage are calculated as a percentage of the total quantities of HIV tests needed for all diagnostic purposes of testing.

NON-DIAGNOSTIC PURPOSES OF TESTING

HIV tests used for non-diagnostic purposes will also need to be included in a quantification of HIV test kit requirements. This includes quantities of HIV tests that are used for quality control, training, epidemiological surveillance studies, surveys, and special research projects that are conducted outside of the established system for providing HIV testing and counseling services.

The key difference in forecasting the quantities of HIV test kits needed for diagnostic versus non-diagnostic purposes is that for each diagnostic purpose of testing, the national testing algorithm, the HIV prevalence rate, and a discordance rate are applied to the number of people expected to be tested to calculate the quantity of each of the HIV test kits needed in the testing algorithm. For non-diagnostic purposes of testing, the quantity of HIV test kits needed will depend on established quality control procedures, the number of health care workers (HCWs) to be trained, and the number of HIV tests needed per HCW; or the sample size, the frequency of sampling, and the sentinel surveillance, survey, or research testing protocols.

Quality Control

The following are the most commonly observed uses of HIV tests for quality control that have been included in national HIV test kit quantifications in resource-limited settings.

Routine use of HIV tests as positive and negative laboratory controls

This measure ensures the quality of the HIV tests being used. It entails the routine use of two HIV tests to verify the quality of the HIV tests being used against known positive and negative laboratory controls. Testing with laboratory controls is also conducted each time a new HIV test kit is opened. The need for quality control testing with laboratory controls varies among brands of tests and should be described in program testing or laboratory guidelines. Some brands of tests have an internal control feature and do not require additional use of HIV tests. In some cases, the frequency of testing with laboratory controls may be determined by the volume of testing that takes place at a facility. High-volume, medium-volume, or low-volume testing facilities may establish daily, weekly, or biweekly testing of laboratory controls, which can be used to quantify the additional HIV tests needed. Experience has shown that routine testing of HIV tests with laboratory controls may be compromised if HIV testing staff, in the face of shortages of test kits, opt to cease testing with laboratory controls in favor of maintaining the supply of HIV test kits for testing patients/clients.

Routine testing of panels of serum samples sent to HIV testing sites

An additional use of HIV tests for quality control is routine testing of panels of known serum samples by facility-based testing staff under direct observation of laboratory technicians to verify the proficiency and quality of the HIV testing being conducted by providers at HIV testing sites. The quantities of HIV test kits needed for this type of quality control testing will depend on the established frequency and procedures for the testing.

Retesting a percentage of all blood samples tested for all diagnostic purposes of testing to monitor quality of testing procedures and accuracy of test results

This refers to the use of HIV tests for routine retesting of a percentage of all the blood samples tested at the HIV testing sites. This type of quality control is conducted to monitor the quality of the HIV testing procedure and the accuracy of the test results. An example of the prescribed use of HIV tests for routine retesting of blood samples for quality control is retesting of 10 percent (1 in 10) of the negative samples and 20 percent (1 in 5) of the positive samples tested at HIV testing sites. Blood samples are typically collected from the testing sites either as venous blood or DBS samples, and submitted to higher-level hospitals or reference laboratories for retesting. This type of quality control testing is often conducted with long ELISAs rather than rapid assay tests. In this case, the number of tests required for quality control is a percentage of the total number of HIV tests conducted for all diagnostic purposes of testing.

Training

The quantities of rapid assay HIV test kits needed for training is determined by the number of HCWs expected to be trained during the period of the quantification, and the number of times each HCW is expected or required to perform each type of HIV test (screening, confirmatory, and tie-breaker test). For example, a pre-determined number of HIV tests may be provided for each HCW during a training session (e.g., five screening tests, three confirmatory tests, and three tie-breaker tests per HCW), or HIV testing curricula may require that HCWs perform each HIV test a minimum number of times. The number of times an HCW is expected to perform an HIV test to reach an accepted level of proficiency may vary by program.

Use of HIV Tests for Sentinel Surveillance, Health Surveys, and Special Research Projects

HIV testing is also conducted on select population subgroups to enable health officials to describe and monitor the HIV/AIDS epidemic in a country, to plan and advocate for responses, and to evaluate the effectiveness of the responses.

Countries with concentrated or low-level epidemics focus primarily on specific population groups that are perceived to be at high risk for infection, such as female sex workers and their clients, injecting drug users, or men who have sex with men. Countries with generalized epidemics conduct serosurveillance primarily among pregnant women at antenatal care clinics as the basis of their HIV epidemiological surveillance system. HIV sentinel surveillance testing can be linked (i.e., the source of the blood samples tested is known and the people are informed of the test results), or unlinked or anonymous (i.e., the source of the blood samples tested is unknown; therefore the people are not informed of the test results).

Because sentinel surveillance testing is restricted to a predetermined sample size of pregnant women at designated urban and rural sites for a limited period of time, estimating the HIV test kit requirements for this purpose is simpler than for other purposes. Typically, long ELISA tests are

used for sentinel surveillance testing, and, depending on the study protocols, quantities of a different type of ELISA test may also be needed for confirmatory testing of positive results and for quality control testing.

Quantities of HIV tests to be used in behavioral surveillance studies, demographic and health surveys, and other types of surveys and special studies may also need to be forecasted separately and included in the total HIV test kit requirements for the country or the program.

NATIONAL HIV TESTING ALGORITHMS

Most established HIV and AIDS programs now have a standardized, national HIV testing algorithm for VCT, PMTCT, and PITC, while HIV testing protocols for HIV-exposed infants and blood safety may vary by country. National testing protocols also vary according to the different brands of test kits selected for use by the program. The testing protocols are a guide for the individuals who are performing the HIV tests. Testing protocols are either serial or parallel.

Tables 2 and 3 illustrate the three possible variations within serial (S) and parallel (P) testing protocols.
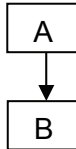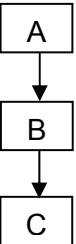
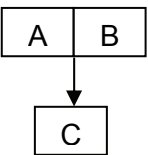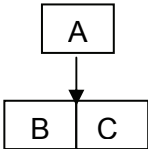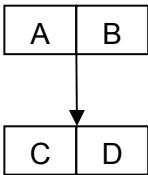**Table 2. Serial Testing Protocols**

Protocol	Tests	If, then	Examples
S1	A	If test A is positive, the result is positive. If test A is negative, the result is negative.	Unlinked blood safety program
S2	A → B	If test A is positive, run test B. If test B is positive, the result is positive. If test B is negative, refer client to higher level for third, tie-breaker test.	PMTCT or VCT program, with third test referral to the higher level
S3	A → B → C	If test A is positive, run test B. If test B is positive, the result is positive. If test B is negative, run test C. If test C is positive, the result is positive. If test C is negative, the result is negative.	PMTCT or VCT program, all testing on site

Table 3. Parallel Testing Protocols

Protocol	Tests	If, then	Examples
P1	A B → C	If tests A and B are both negative, the result is negative. If tests A and B are both positive, the result is positive. If tests A and B are discordant, run test C. If test C is positive, the result is positive. If test C is negative, the result is negative.	PMTCT or VCT program
P2	A → B C	If test A is negative, the result is negative. If test A is positive, run tests B and C in parallel. If one or both of tests B and C are positive, the result is positive. If tests B and C are both negative, the result is negative.	Mobile clinic, with referral to the health center
P3	A B → C D	If tests A and B are both negative, the result is negative. If tests A and B are both positive, the result is positive. If tests A and B are discordant, run tests C and D in parallel. If tests C and D are both negative, the result is negative. If tests C and D are both positive, the result is positive. If tests C and D are discordant, the results are inconclusive.	Referral hospital or reference laboratory

If protocol S3, protocol P1, or protocol P3 is being used in the program, the average discordance rate between all brands of test A and all brands of test B must be determined at the time of the quantification exercise. The discordance rate becomes the basis for determining the forecast quantity of tie-breaker tests required.

STEPS IN FORECASTING CONSUMPTION OF HIV TEST KITS

Several activities must be completed in preparation for the quantification prior to collecting the data and forecasting consumption. These include selecting the quantification team; describing the HIV testing program; and defining the scope, purpose, and timeframe of the quantification. This background information from a country example, collected in advance in preparation for a national HIV test kit quantification, is summarized in the highlighted box below.
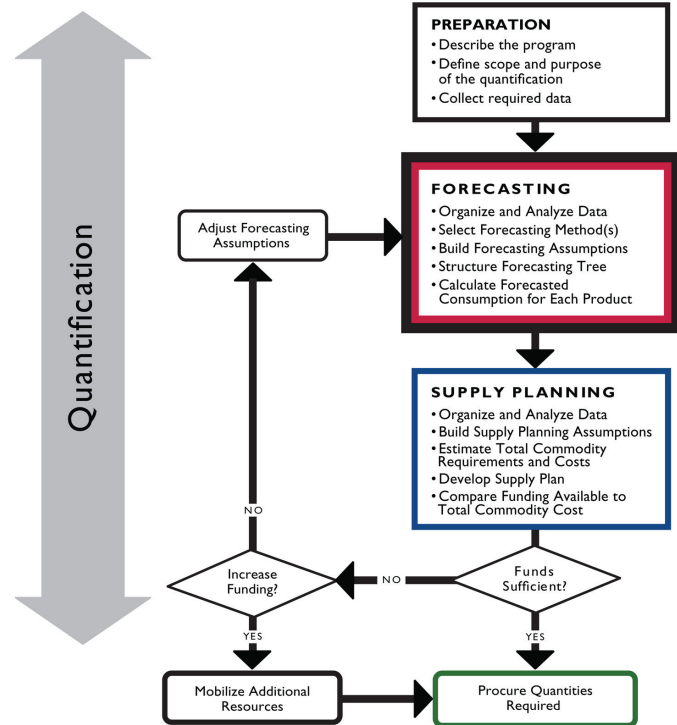
> **Country example: Background information for the quantification**
>
> - The Ministry of Health (MOH) HIV and AIDS Department requested assistance to conduct a national quantification of HIV test kits based on projected demand and utilization data on counseling and testing services. Past quantifications based on budget allocations had resulted in under-ordering, frequent stockouts, and subsequent interruption of HIV testing services.
>
> - The country recently adopted a serial testing algorithm to replace a parallel testing algorithm; the transition to the serial testing algorithm was expected to be completed at all health facilities within the next three months.
>
> - The national quantification was to include the HIV test kit requirements for all MOH facilities as well as nongovernmental organizations (NGOs), mission hospitals, and other implementing partners that conduct HIV testing and are supplied through the MOH distribution system.
>
> - The quantification was to estimate total HIV test kit requirements and costs for two years, 2008–2009.
>
> - The quantification team included seven data collectors from the MOH HIV and AIDS Department, the Central Medical Stores, and both local and external logistics advisors.

Once the data collection has been completed, the consumption of each of the HIV test kits needed should be forecasted for each year of the quantification following the steps shown in the Forecasting box in Figure 1 at right. Throughout this companion guide, the outputs of the data collection and the forecasting steps from the same country example are presented in a highlighted box at the end of each step.

Forecasting consumption of HIV test kits is complicated by the multiple purposes of testing and the different types of data that can be used. The quantities of HIV test kits needed for the diagnostic purposes of testing are determined by the HIV testing algorithm and the HIV prevalence of each population subgroup being tested. The estimated percentage of positive results for each diagnostic purpose of testing (e.g., VCT, PITC, PMTCT, blood safety), determines the quantity of confirmatory tests needed, and the discordance rate between the screening and the confirmatory tests determines the quantity of tie-breaker tests needed. For non-diagnostic purposes of testing, the quantities of HIV test kits needed are not based on the HIV testing algorithm and HIV prevalence, but rather on established testing procedures for quality control, sentinel surveillance or survey study protocols, or HIV testing training curricula. For this reason, it is necessary to forecast the consumption of HIV test kits for each purpose of testing separately to be able to estimate more accurately the quantities of each type of test kit needed. Excel spreadsheets or software programs may be used to forecast the number of HIV test kits that will be used for testing. ProQ is a software tool that was developed to collect and analyze data for forecasting HIV test kit consumption by purpose of testing; to guide users in gaining consensus on the forecasting assumptions; and to perform the calculations required at each step. ProQ is available on the USAID | DELIVER PROJECT website at deliver.jsi.com.

Figure 1: Steps in Quantification

COLLECT REQUIRED DATA

Collecting the required data is a critical activity in the Preparation step of the quantification. Program-level data on the number of people tested for HIV and the results of the testing may be collected through the existing Health Management Information System (HMIS), and data on the consumption of HIV test kits may be collected through Logistics Management Information System (LMIS) reports. Both types of data may also be collected directly from health facilities if the data provided by the HMIS or LMIS are not available or are of questionable quality. Data may also be obtained through interviews with central-level and facility-level staff, and from a review of key policy documents, technical reports, national surveillance reports, and special studies.

The sources of the different types of data that were collected for forecasting the HIV test kit needs for the national HIV testing program in the country example are summarized below.

> **Country example: Data sources**
> - The MOH HIV and AIDS Department provided policy and planning documents on national HIV testing policy and strategies, the five-year plan for scaling up HIV testing and counseling services, the national HIV counseling and testing guidelines, PMTCT guidelines, universal access indicators and targets for HIV testing, and the Global Fund RCC Proposal.
> - Epidemiological surveys and reports included UNAID/WHO estimates and the national HIV and Syphilis Sero-Survey for 2007.
> - The National Blood Transfusion Services provided data on the number of blood donors screened, HIV prevalence of blood donors, and program plans for expansion of the national blood bank services.
> - Technical reports on earlier assessments and country studies included the multipartner report on the Situational Analysis of HIV and AIDS services, 2006.
> - Consultative interviews and discussions with central-level stakeholders, including commodity donors, MOH, NGOs, and other implementing partners
> - Twenty-three facility visits conducted at different levels of the health system to collect data and interview staff

The specific data that should be collected for forecasting consumption of HIV test kits are listed below, with examples of actual data collected from the country example of a national HIV test kit quantification:

1. **The national HIV testing algorithm (including the specific brand of HIV test kit to be used at each step) that will be followed for each year of the quantification.**

> **Country example: National HIV testing algorithm for 2008–2009**
>
> The national testing algorithm was recently changed from a parallel testing protocol to a serial testing protocol with three consecutive steps (S3).
>
> - Screening Test: Determine HIV 1/2
> - Confirmatory Test: Uni-Gold HIV test
> - Tie-breaker Test: SD Bioline HIV 1/2 3.0

2. **The pack size of each of the HIV test kits approved for testing in the country.**

> **Country example: Pack size of each brand of HIV test kits**
> - Determine HIV 1/2: 100 tests per kit
> - Uni-Gold HIV test: 20 tests per kit
> - SD Bioline HIV 1/2 3.0: 30 tests per kit

3. **The diagnostic purposes of testing included in the quantification for which consumption of HIV test kits must be forecasted.**

> **Country example: Diagnostic purposes of testing included in the quantification**
> - HTC (includes VCT, PITC, and mobile and home-based testing)
> - PMTCT (antenatal care clinics, labor and delivery wards)
> - HIV-Exposed Infants
> - Blood Safety

4. **The non-diagnostic purposes of testing included in the quantification for which consumption of HIV test kits must be forecasted.** To calculate the quantities of each HIV test kit needed for these purposes, it will be necessary to ascertain established quality control procedures, program plans for training HCWs to conduct HIV testing, and the specific survey or research protocols for testing blood samples collected.

> **Country example: Non-diagnostic purposes of testing included in the quantification**
> - Quality Control
> - Training

5. **Demographic and population data:** Total population numbers and growth, and demographic trends data may be presented by population subgroup (e.g., adult/children, male/female, urban/rural) and may be obtained from population-based surveys such as the demographic and health survey (DHS), or from UNAIDS/WHO estimates.

> **Country example: Demographic data**
> These data were obtained from UNAIDS/WHO estimates for 2006.
> - Total population: 13,925,000
> - Population ages 15–49: 6,152,000
> - Annual population growth rate: 2.2%

6. **Morbidity data: Estimates of 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 prevalence of HIV.

> **Country example: Morbidity data**
>
> These data were obtained from UNAIDS/WHO estimates for 2006 and the national HIV and Syphilis Sero-Survey, 2007.
>
> - Estimated national adult HIV prevalence (ages 15–49) =   12.0%
> - Estimated number of people living with HIV =   889,833
> - Estimated number of adults living with HIV =   809,833
> - Estimated number of children living with HIV =   89,055

7. **Services data: The number of people tested and the percentage of positive results for each diagnostic purpose of testing during the previous 12-month period.**

> **Country example: Services data**
>
> These data were obtained or estimated from the national HIV and Syphilis Sero-Survey of 2007; from HTC and PMTCT program reports; from data provided by NGOs, other implementing partners, and the National Blood Transfusion Services (NBTS); and from data collected at HIV testing facilities.
>
> For January through December 2007, the reported numbers of people tested for each diagnostic purpose of testing were:
>
> - 645,116 people were tested for HTC
> - 284,884 people were tested for PMTCT
> - Data on number of HIV-exposed infants tested were not available
> - 36,000 people were tested for blood safety
>
> For January through December 2007, the percentages of positive results reported for each diagnostic purpose of testing were:
>
> - 37% for HTC (adjusted)
> - 12% for PMTCT
> - Not available for HIV-exposed infants
> - 14% for blood safety

8. **Consumption data: The quantities of each brand of HIV test kit used during the previous 12-month period.**

> **Country example: Consumption data**
>
> Program-level consumption data on the quantities of HIV tests used from January to December 2007 were not available through the LMIS. Consumption of HIV tests is not routinely collected on HIV registers nor on stock cards at HIV testing facilities; therefore, facility-level consumption data were not available.
>
> An attempt was made to calculate the annual consumption using data recorded from the 2007 national physical inventory exercise using the following formula:
>
> Calculated Consumption **=**
>
> Stock on Hand of each product at beginning of year (Jan 1, 2007)
>
> **+** Total Quantity of each product Received during the year
>
> **–** Stock on hand of each product at end of year, Dec 31, 2007
>
> Large gaps in data reporting and data quality from the physical inventory rendered these data invalid for forecasting purposes.

9. **Wastage data: Data on the quantities of 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.** These data can be obtained from LMIS records, specifically stock control cards where the quantities of HIV tests discarded, lost, or wasted should be recorded as losses/adjustments to inventory.

> **Country example: Wastage data**
>
> In the absence of these data, an estimated wastage rate had to be agreed upon with HIV testing staff (see Build Forecasting Assumptions, page 21).

10. **Information on current program performance, plans, strategies, and priorities, including program targets for the number of people expected to be tested for HIV for each year of the quantification.**

Table 4. Country Example: Key Programmatic Issues Affecting the Forecast

Issue	Effect on forecast
New HIV testing strategies to expand access to HIV testing through facility-based and non-facility-based testing. • Expansion of HTC through integration of "opt-out" testing and PITC • Rapid scale-up of HIV testing at ANC clinics and labor and delivery wards, and partner testing through the PMTCT program • Expansion of community-based testing through deployment of mobile units and an annual HIV testing campaign • Introduction of door-to-door, home-based testing	These efforts are expected to significantly increase the demand for HIV testing services and the quantities of HIV test kits that will be needed to support the planned scale-up.
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 screening and confirmatory tests.
Expansion of provider-initiated testing and counseling to STI and TB clinics, outpatient departments, and inpatient wards at health facilities.	Many of these patients are expected to be symptomatic and will therefore have a higher rate of positive results. As the proportion of positive results will be higher than for other diagnostic purposes of testing, a larger quantity of the confirmatory test will be required for PITC.
The laboratory quality assurance program includes the routine use of laboratory controls, supervised testing of blood serum panels, and routine collection and retesting of blood samples from HIV testing sites.	Additional quantities of HIV test kits will need to be forecasted to maintain quality control testing. The quantities of HIV test kits for quality control will need to be estimated according to established quality control procedures.
The MOH plans to conduct decentralized, district-level training of HTC staff over the next several years. In addition, the MOH will train laboratory technicians in HIV testing, and NGOs and other implementing partners already have training activities funded for the next two years.	Additional quantities of HIV test kits will also be needed to support training of health facility staff to conduct HIV testing and counseling. The quantities of HIV test kits needed for training will need to be estimated according to the national HIV testing curriculum.
The MOH plans for rapid scale-up of HIV testing and counseling services over the next two years has led to ambitious program targets: 1,300,000 people in 2008 (almost 40% increase over 2007) and 1,500,000 in 2009 (a 15.4% increase over expected targets for 2008).	Interruptions and shortages in the supply of HIV test kits and limitations in the number and capacity of staff available to perform testing have been reported as constraints to scaling up HIV testing and counseling services. HIV testing targets for 2008 and 2009 will need to be reviewed in light of current human resource constraints and ability to ensure a continuous supply of HIV test kits.

ORGANIZE AND ANALYZE DATA

Once all available data on HIV testing services, HIV prevalence, past consumption of HIV tests, 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.

Table 5. Analysis of Data Quality

Type of Data	Data	Quality of Data	Other Notes
Demographic	Total population, 2006: **13,925,000** Population ages 15–49, 2006: **6,152,000** Population growth rate, 2006: **2.2%**	1 ½ years old.	Not used for forecasting.
Morbidity	National HIV prevalence, 2006: **12%** Number of people living with HIV, 2006: **889,833**	1 ½ years old.	Not used for forecasting.
Services	Total number of people tested by diagnostic purpose of testing, 2007: **e.g., 645,116 tested for HTC** Percentage of positive results for each diagnostic purpose of testing, 2007: **e.g., 37% for HTC (adjusted figure)**	Data on HTC for 2007 was not complete.	Facility-level data on the number of people tested and the number of positive results is aggregated at the central level. HTC includes all testing for VCT, PITC, and testing provided through mobile units and door-to-door testing. Data used for forecasting.
	Total number of blood donors screened, 2007: **36,000 donors screened**	Data complete for 2007.	Data on blood donors screened and test results are recorded on HIV blood donor laboratory registers. Data from laboratory registers are reported to central diagnostics services unit, where they are aggregated and available. Data used for forecasting.
	Total number of HIV exposed infants tested and percentage of positive results, 2007:	Data not available.	

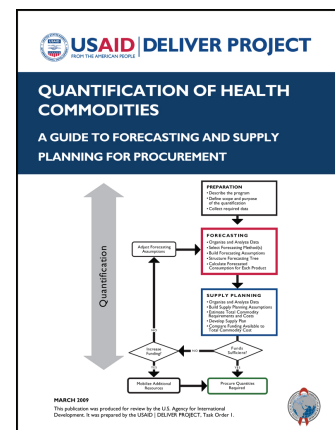| Type of Data	Data	Quality of Data	Other Notes
Consumption	Consumption data on quantities of HIV tests used, 2007:	Data not available.	Facility-level consumption data not recorded on HIV registers at health facilities. Stock cards not used for HIV test kits at testing facilities.
	Consumption of HIV tests calculated from 2007 physical inventory data: **e.g., 168,842 Determine tests used**	Large, unexplained discrepancies between stock on hand at beginning of year, quantities of HIV test kits received, and stock on hand at end of year. Severe under-reporting from facilities.	Not used for forecasting.
	Quantities of HIV test kits issued from districts to health centers over previous 12-month period **e.g., 635,456 Determine (tests or 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 test kits) rendered data invalid for forecasting purposes.	Not used for forecasting.
	Quantities of HIV test kits issued from regional warehouses to districts over previous 12-month period. **e.g., 14,470 Determine kits = 1,447,000 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.
Target	National testing targets for all diagnostic purposes of testing for 2008: **1,300,000 people to be tested in 2008** National testing targets for each diagnostic purpose of testing, 2008: **e.g., 910,896 people to be tested for HTC in 2008**	Provided by the MOH and based on assumptions about impact of new testing strategies.	Discussion and consensus on national testing targets took place during five-day quantification workshop and through discussion with individual program managers.

SELECT FORECASTING METHOD(S)

The decision on which forecasting method to use, or whether to use both the morbidity and the 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 HIV test kits is predictive of the quantities of HIV test kits that will be used in the future. In a scaling-up environment where new HIV testing strategies (e.g., implementation of Provider-Initiated Testing and Counseling) or changes in the selection of HIV test kits or 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 the morbidity method should be used to convert the number of people to be tested, the expected percentage of positive results, and the discordance rates into the quantities of each HIV test kit that will be needed according to the national testing algorithm. For a review of the consumption and morbidity methods of forecasting, readers should 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.*

> **Country example: Morbidity method selected for forecasting consumption of HIV test kits**
>
> Based on the availability and quality of the different types of data available, the morbidity method was selected using a combination of services data and program targets.
>
> The consumption method was not selected, not only because of the scarcity and quality of the data available on consumption of HIV test kits, but because of the recent shift from a parallel to a serial testing protocol and the effect that integration of PITC and expansion of community- and home-based testing was expected to have on the demand for testing over the next two years.
>
> The quantities of HIV tests needed for quality control and training are not calculated according to past consumption or the national testing algorithm, but rather according to established quality control procedures and requirements of the national HIV testing training curriculum.

BUILD FORECASTING ASSUMPTIONS

Assumptions will need to be made to account for missing or incomplete data and to estimate the effect of key programmatic and environmental factors expected to influence the demand for HIV testing and the supply of HIV test kits for each year of the quantification (see Table 4, page 44). Consensus on the forecasting assumptions should be obtained through a consultative and participatory process for gathering inputs and fostering discussion among key stakeholders to ensure the credibility and ownership of the forecasting results. The forecasting assumptions should be documented to guide the steps for calculating the forecast quantities of each HIV test kit needed for each year of the quantification.

Country example: Summary of forecasting assumptions by diagnostic purpose of testing

For all diagnostic purposes of testing:

- Three approved rapid assay HIV test kits (Determine, Uni-Gold, and SD Bioline) will be used
- Newly adopted serial testing algorithm will be used, except for blood safety
- Total testing targets agreed upon for all diagnostic purposes of testing were 1,300,000 for 2008 and 1,500,000 for 2009

For HTC (VCT, PITC, outreach testing via mobile units and home-based testing):

- Estimated 40% increase in testing in 2008 (910,896 clients) and a 7% increase in 2009 (975,000 clients)
- Estimated percentage of positive results was 37.0%, and the agreed-upon discordance rate was 2.0%

For PMTCT:

- Estimated 22.9% increase in testing in 2008 (350,000 clients) and a 37.1% increase in 2009 (480,000 clients)
- Estimated percentage of positive results for 2008 and 2009 was 12%, and the agreed-upon discordance rate was 2.0%

For Testing of HIV-Exposed Infants:

- Testing targets provided by the PMTCT program were 13,104 for 2008 and 28,800 for 2009
- It was not possible to determine the estimated percentage of positive results for HIV-exposed infants at 18 months. However, it was determined that the quantities of confirmatory tests needed would represent less than 1% of the total quantities of confirmatory tests needed for the program; therefore it was assumed that this need would be covered within the general HIV test kit supply.

For Blood Safety:

- Screening of blood donors with rapid assay HIV tests will continue at central, district, rural, and mission hospitals where the need for screened blood for transfusion is still not completely covered by NBTS services.
- Testing targets provided by the NBTS were 26,000 for 2008 and 16,000 for 2009. It was assumed that facility-level screening of blood donors would be reduced by 10,000 per year based on increased capacity and coverage of NBTS.
- The testing algorithm for screening blood donors requires the use of a single rapid assay test. HIV-positive blood is discarded and the blood donor is referred to VCT. Therefore, it is not necessary to estimate the number of confirmatory tests needed to retest positive results.

For Wastage:

- A 2% wastage rate to be applied to the quantities of HIV test kits needed for all diagnostic purposes of testing was agreed upon by quantification workshop participants.

Country example: Summary of forecasting assumptions for non-diagnostic purposes of testing

Quality Control

For routine laboratory controls, it was assumed based on established protocols, that:

- At the 127 high-volume testing sites, laboratory controls will be conducted every day that testing is performed.

- At the 30 medium-volume sites, weekly laboratory controls will be conducted.

- At the 556 low-volume testing sites, laboratory controls will be conducted every two weeks.

For routine testing of panels of known blood samples, it was assumed that:

- All 2,500 staff trained in HTC are currently active and will be tested quarterly using a panel of five known blood samples.

- With each panel, a positive and a negative control will be run for each brand of HIV test.

- A screening test (Determine) will be performed on each of the five samples in the panel.

- Three of the five known blood samples will be positive, and a confirmatory test (Uni-Gold) will be performed.

Training

- The total number of HCWs estimated to be trained was 2,152 in 2008 and 2,172 in 2009.

- The national-HIV testing training curriculum states that each HCW should perform at least five Determine tests, three Uni-Gold tests, and three SD Bioline tests to achieve an acceptable level of proficiency.

STRUCTURE THE FORECASTING TREE

It is helpful to create a diagram of the national testing algorithm for each of the diagnostic purposes of testing to organize and utilize the data and the assumptions for estimating future consumption of the HIV test kits. The data and assumptions that will determine the forecast quantities of each brand of HIV test kit that will be needed for each year of the quantification are identified at each step of the algorithm. The forecasting tree at the end of this section depicts the steps in the national testing algorithm and the data and assumptions for each diagnostic purpose of testing in the country example.

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 example: HIV diagnostic testing services**

2. **Specify the type of commodities to be forecasted.**

> **Country example: Rapid assay HIV test kits**

3. **Determine the total number of patients or clients to receive treatment or services for each year of the quantification.**

> **Country example: Total HIV testing target for 2008 is 1,300,000**

4. **Separate the total targets by specific patient or client groups.** For HIV testing, the client groups are based on the different diagnostic purposes of testing (e.g., VCT, PMTCT, blood safety). Only the diagnostic purposes of testing are included in the forecasting tree, because the use of HIV test kits for non-diagnostic purposes is not determined by the national HIV testing algorithm nor by the HIV prevalence of the population being tested.

> **Country example: Breakdown of HIV testing services by diagnostic purpose of testing**
> - HIV Testing and Counseling
> - PMTCT
> - HIV-Exposed Infants
> - Blood Safety

5. **Document the testing protocol for each diagnostic purpose of testing.**

> **Country example: HIV testing protocols by diagnostic purpose of testing**
>
> HIV Testing and Counseling, PMTCT, and testing of HIV-Exposed Infants follow the national serial testing algorithm (S3):
>
> - Screening Test: Determine HIV 1/2
> - Confirmatory Test: Uni-Gold HIV test
> - Tie-breaker Test: SD Bioline HIV 1/2 3.0
>
> Testing for Blood Safety requires the use of a single screening test (S1):
>
> - Screening Test: Determine HIV 1/2

6. **Assign the number of clients to be tested for each diagnostic purpose of testing.** For HIV diagnostic testing, this number is often based on a target number of people to be tested, which determines the number of screening tests needed.

> **Country example: Number of clients to be tested for each diagnostic purpose of testing in 2008**
>
> - HTC: 910,896
> - PMTCT: 350,000
> - HIV-Exposed Infants: 13,104
> - Blood Safety: 26,000

7. **Assign the expected percentage of positive results and discordance rate for each diagnostic purpose of testing. The percentage of positive results determines the quantity of confirmatory tests needed, and the discordance rate determines the quantity of tie-breaker tests needed.** When using services data, the percentage of positive results is based on the number of positive results recorded over the previous year. When using demographic or morbidity data, the percentage of positive results will be assumed to be the HIV prevalence for each population subgroup.

> **Country example: Expected percentage of positive results and discordance rate for each diagnostic purpose of testing**
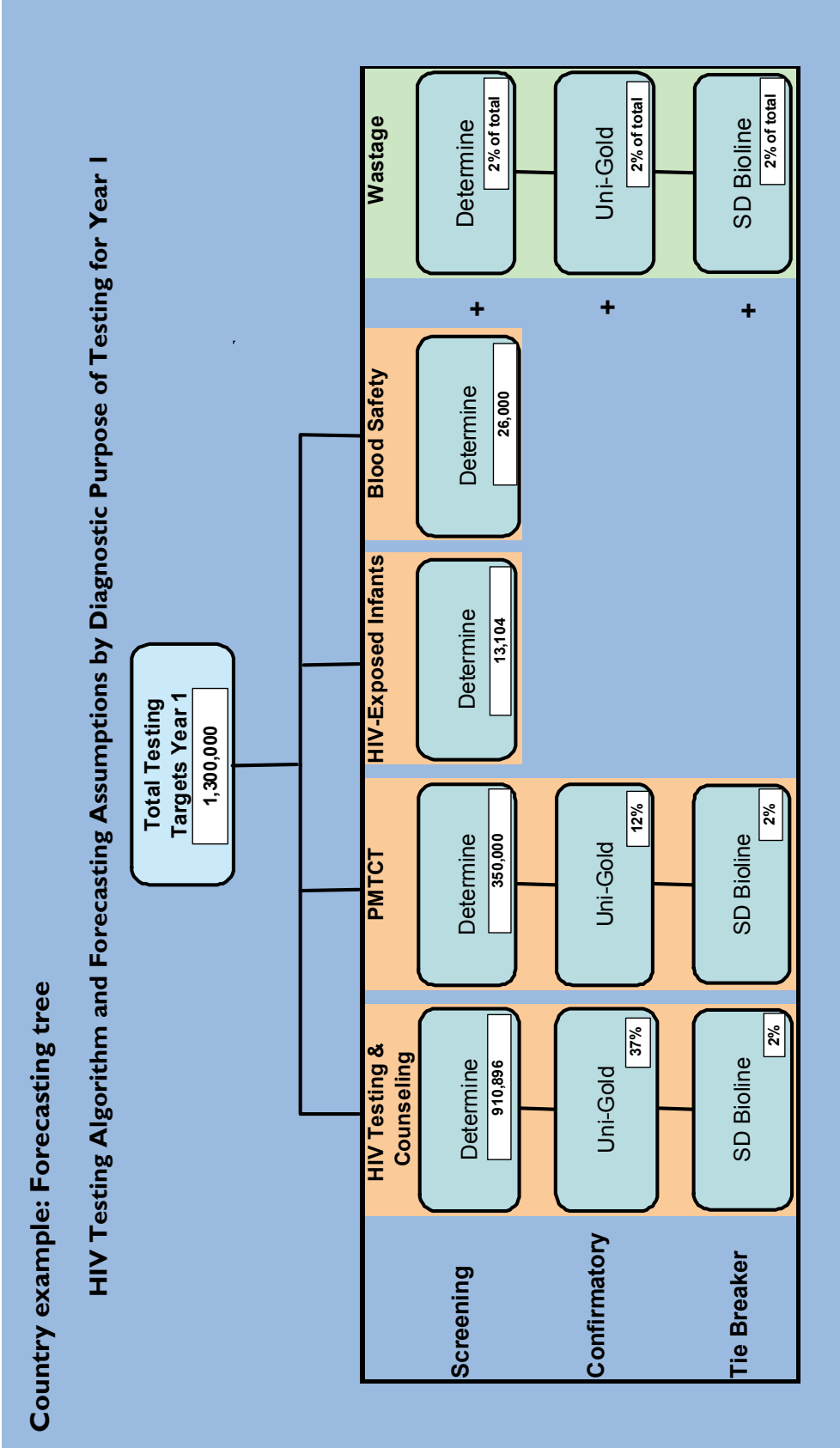>
> Example: HIV Testing and Counseling following the national serial testing algorithm.
>
> Screening Test: 910,896 people to be tested for HTC
>
> Confirmatory Test: 37% of target number
>   (expected percent of people tested through HTC that will have positive result)
>
> Tie-breaker Test: 2% discordance rate
>   (percent of confirmatory test results that will be negative)

8. **Construct the forecasting tree based on the national HIV testing algorithm, the selection of HIV test kits, and the forecasting assumptions for each diagnostic purpose of testing.** Assuming that the national testing algorithm, the HIV test kits, and the diagnostic purposes of testing remain the same from one year to the next, only the testing targets and the assumptions on percentage of positive results, discordance, and wastage rates would need to be adjusted in the forecasting tree for the second year of the quantification.

Country example: Forecasting tree

HIV Testing Algorithm and Forecasting Assumptions by Diagnostic Purpose of Testing for Year I

CALCULATE FORECASTED CONSUMPTION FOR EACH PRODUCT

On completing the forecasting tree and agreeing on the target number of people to be tested, these numbers need to be converted into the quantity of each brand of HIV test kit that will be needed. The following steps should be completed to calculate the total forecast quantity of each HIV test kit needed for all diagnostic and non-diagnostic purposes of testing for each year of the quantification. These calculations may be completed in Excel spreadsheets or other software program designed for this purpose.

1. **Calculate the forecast quantity needed of each HIV test kit for all diagnostic purposes of testing.**

   - Agree on the target number of people to be tested, the percentage of positive results, and the discordance rate for each diagnostic purpose of testing.

   - Convert the number of people to be tested into the total number of screening tests for each diagnostic purpose of testing.

   - 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 for each diagnostic purpose of testing.

Country example: Quantities of HIV tests needed for HTC in 2008

- Testing target for HTC for 2008 was 910,896, a 40% increase over the number of clients tested in 2007. Each client will be tested with one screening test using Determine. Therefore, the number of Determine HIV tests needed for Year 1 is 910,896.

  910,896   x   1   =   910,896 Determine tests needed for HTC in Year 1

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

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

---

2. **Calculate the additional quantities of HIV tests that will be needed to account for wastage.**

> **Country example: A wastage rate of 2% was applied to the total quantities of HIV tests needed for all diagnostic purposes of testing in 2008**
>
> 1,300,000   x   2%   =   26,000 additional Determine tests needed in Year 1

3. **Add the quantities of HIV tests needed for all diagnostic purposes of testing and the additional quantities needed to cover wastage.**

Country example: Quantities of HIV tests needed for all diagnostic purposes of testing, including wastage, for each year of the quantification

Purpose of Testing	Jan - Dec 2008				Jan - Dec 2009			
	Testing Target	% Positive	No. Positive	Discordance Rate (2.0%)	Testing Target	% Positive	No. Positive	Discordance Rate (2.0%)
HTC[1]	910,896	37.0%	337,032	6,741	975,200	37.0%	360,824	7,216
PMTCT[2]	350,000	12.0%	42,000	840	480,000	12.0%	57,600	1,152
HIV-Exposed Infants[3]	13,104	-	-	-	28,800	-	-	-
Blood Safety[4]	26,000				16,000			
Subtotal	1,300,000		379,032	7,581	1,500,000		418,424	8,368
Wastage Rate (2.0%)	26,000		7,581	152	30,000		8,368	167
TOTAL	1,326,000		386,612	7,732	1,530,000		426,792	8,536

[1] HTC = all Provider Initiated Testing and Counseling; Client Initiated Counseling and Testing (VCT); and all testing provided through Mobile Units, Outreach Sites, and Home Based Door-to-Door testing

[2] PMTCT = Estimated no. of pregnant women tested for HIV in ANC clinics, labor wards; no. of partners tested

[3] HIV-exposed infants = No. of exposed infants tested for HIV at 18 months. (It has not been possible to determine what the percentage of positive results would be for HIV-exposed infants at 18 months. Since the quantities of Uni-Gold needed for testing positive HIV- exposed infants at 18 months would represent less than 1% of the total quantities of Uni-Gold needed for the program, it was assumed that this need for Uni-Gold HIV tests will be covered within the general HIV test kit supply).

[4] Blood Safety = Estimated no. of blood donors screened for HIV at central, district, mission, and rural hospitals not covered by NBTS

4. **Calculate the forecast quantity needed of each HIV test kit for all non-diagnostic purposes of testing:**

- Calculate the number of HIV tests required for routine quality control in the laboratory.
- Calculate the number of HIV tests required for supervised testing of known serum panels.
- Calculate the number of HIV tests required for training.

Country example: Quantities of HIV tests needed for quality control in 2008

- *For routine use of laboratory controls:* The frequency of testing is multiplied by the number of sites. For example, high-volume sites perform positive and negative controls (two tests) for the screening (Determine) and confirmatory (Uni-Gold) tests every day that testing is provided (on average, 260 days per year). There are 127 high-volume sites, 30 medium-volume sites, and 556 low-volume sites in this country. The quantities of Determine and Uni-Gold tests required for laboratory controls are:

  127   x   260   x   2   =   66,040 for high-volume sites

    30   x   52   x   2   =   3,120 for medium-volume sites

  556   x   26   x   2   =   28,912 for low-volume sites

- *For routine testing of panels of known blood samples:* Each staff member who performs HIV testing is required to test panels of known blood samples every quarter. There are currently 2,500 staff trained and conducting HIV testing who will be tested four times a year.

  2,500   x   4   =   10,000 panels tested for Year 1

  – For each panel, a screening test is performed on each sample and a positive and negative control is conducted; therefore, seven screening tests must be performed.

  10,000   x   7   =   70,000 Determine tests needed for Year 1

  – For each positive result on the panel, a confirmatory test is performed and positive and negative controls are also conducted. It was assumed that, on average, three of the five known blood samples would be positive; therefore, five confirmatory tests were needed on average.

  10,000   x   5   =   50,000 Uni-Gold tests needed for Year 1

	Jan - Dec 2008		Jan - Dec 2009	
	Determine	Unigold	Determine	Unigold
High-volume testing sites	66,040	66,040	66,040	66,040
Medium-volume testing sites	3,120	3,120	3,120	3,120
Low-volume testing sites	28,912	28,912	28,912	28,912
External quality assurance	70,000	50,000	70,000	50,000
Total	**168,072**	**148,072**	**168,072**	**148,072**

5. Calculate the total forecast quantity of each HIV test kit needed for each year of the quantification.

SUMMARY OF CHALLENGES AND LESSONS LEARNED IN QUANTIFICATION OF HIV TEST KITS

COMMON CHALLENGES

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

- Data on HIV testing services and consumption of HIV tests are limited and, when available, are often outdated, unreliable, or insufficient for use in forecasting consumption of HIV test kits.

- The multiple purposes of testing and multiple testing sites within a facility make it challenging for staff to collect, aggregate, and report data on HIV testing services and commodities.

- Program targets may not take into account service delivery capacity to increase HIV testing or supply chain capacity to finance, procure, and manage greater volumes of HIV test kits.

- Program targets for increasing HIV testing may not be linked to program targets for increasing antiretroviral therapy patient enrollment.

- Programs may not expand as rapidly as expected.

- Multiple sources of funding, procurement mechanisms, and distribution channels for HIV test kits may exist.

- Quantification capacity at the country and program levels is limited.

- Communication and coordination among key stakeholders and implementers (i.e., policymakers, program managers, service providers, funding sources, procurement agents, and suppliers) on issues related to the selection, quantification, and procurement of HIV test kits are often lacking.

- Quantification and procurement often occur when funding becomes available, rather than as a program planning activity that identifies commodity needs and then mobilizes resources for timely procurement. The lack of procurement planning has led to stockouts and expensive emergency procurements.

- Global shortages of HIV test kits related to limitations in supplier production capacity as a result of spikes in demand may need to be addressed in the quantification to identify alternate sources of supply for the required quantities of product.

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

- Additional consumable items required to perform the tests (e.g., lancets, capillary tubes, pipettes) may not be included in the test kits and must be obtained or procured separately.

USEFUL LESSONS

The following lessons learned from the USAID | DELIVER PROJECT experience in conducting national-level HIV test kit quantifications have also been incorporated into the approach to quantification presented in this companion guide.

- The quantification exercise itself is time and resource intensive. Therefore, adequate time, funding, and human resources with appropriate skills to conduct the quantification exercise should be planned and budgeted for. Four to six weeks may be needed to complete all steps in a quantification.

- Quantifications that are currently based on informed assumptions will become more evidence-based over time as the availability and quality of data improve through strengthening of the LMIS.

- Quantification requires a consultative process with multiple stakeholders and implementers to reach consensus on decisions about the selection, quantification, and procurement of HIV test kits.

- Conducting a quantification workshop or a series of consultative meetings with stakeholders and implementers throughout the quantification process is recommended to review and analyze the available data and to reach consensus on the forecasting assumptions.

- Collaboration and participation of key stakeholders and in-country counterparts in the quantification exercise is an effective way of building capacity in quantification and transferring ownership of the results.

- The quantification should be based on realistic program plans and on available financing.

- The results of the quantification should be used for developing a two-year supply plan with specific order quantities and shipment schedules and to guide short-term procurement based on available funding.

- The results of the quantification should also be used for medium- and long-term program planning and budgeting and to advocate for mobilization of resources to address funding gaps identified.

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

ADDITIONAL CONSIDERATIONS

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

All other technical factors being equal, preference in selection should be given to HIV test kits that do not require cold storage, have the longest shelf lives, 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 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 the country.

The shipment schedule for HIV test kits must reflect the lead time and shelf life of each product, as well as the current storage and distribution capacity of the logistics system. 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 that have a longer shelf life and 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, and the test kits may need to be delivered to service delivery points more frequently.

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APPENDICES

APPENDIX A

SAMPLE DATA COLLECTION QUESTIONS

Table 1: Sample Data Collection Questions for Forecasting Consumption of HIV Test Kits for Voluntary Counseling and Testing (VCT)

TYPE OF DATA

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

Table 2: Sample Data Collection Questions for Forecasting Consumption of HIV Test Kits for Provider-Initiated Testing and Counseling (PITC)

TYPE OF DATA

Consumption	*Demographic/ Morbidity*	*Services*	*Program Targets*
1. How many of each brand of HIV test kits were used for PITC 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 were the total quantities received of each brand of test kit during the 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 year? 6. At each facility/level of the logistics system, what was the ending inventory for 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 PITC for each year of the quantification?	1. What is the total population of the catchment area served by health facilities offering PITC? 2. What percentage of the population in the catchment area will access health facilities that offer PITC? 3. What is the AIDS prevalence of the population in the catchment area (i.e., will be symptomatic for STIs, TB, or other HIV-related illnesses)? 4. What percentage of symptomatic people accessing health facilities will be offered/referred for HIV testing and counseling? 5. What percentage of symptomatic people will receive an HIV test? 6. What is the average discordance rate between the screening and confirmatory tests? 6. What is the testing protocol for PITC?	1. How many people were tested for HIV through PITC during the past year? 2. How many people tested through PITC tested positive for HIV during the past year? 3. What is the expected rate of change in the number of people to be tested for HIV through PITC for each year of the quantification? 4. What is the average discordance rate between the screening and confirmatory tests for PITC? 5. What is the testing protocol for PITC?	1. What is the target number of people to be tested for HIV through PITC for each year of the quantification? 2. What is the expected percentage of positive results among people that will be tested for HIV through PITC? 3. What is the estimated discordance rate between the screening and confirmatory tests for PITC? 4. What is the testing protocol for PITC?

Table 3: Sample Data Collection Questions for Forecasting Consumption of HIV Test Kits for Prevention of Mother-to-Child Transmission of HIV (PMTCT)

TYPE OF DATA

Consumption	*Demographic/ Morbidity*	*Services*	*Program Targets*
1. How many of each brand of HIV test kits were used for PMTCT in the past year?	1. How many women of reproductive age live in the catchment area of ANC sites offering PMTCT?	1. How many pregnant women were tested for HIV through PMTCT services during the past year?	1. What is the target number of pregnant women to be tested for HIV through PMTCT for each year of the quantification?
2. What is the lowest level of the logistics system that has relatively complete consumption data?	2. What is the pregnancy rate in the catchment area?	2. How many pregnant women tested positive for HIV through PMTCT services during the past year?	2. What is the expected percentage of positive results among pregnant women that will be tested for HIV through PMTCT?
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?	3. What percentage of pregnant women in the catchment area will make at least one ANC visit (or deliver in health facility)?	3. What is the average discordance rate between the screening and confirmatory tests for PMTCT?	3. What is the estimated discordance rate between the screening and confirmatory tests for PMTCT?
4. At each facility/level of the logistics system, what were the total quantities received of each brand of test kit during the year?	4. What percentage of these ANC clients will be offered "opt out" HIV counseling and testing?	4. What is the expected rate of change in the number of pregnant women to be tested for HIV through PMTCT for each year of the quantification?	4. What is the testing protocol for PMTCT?
5. At each facility/level of the logistics system, what were the expiries, losses, and adjustments for each brand of test kit during the year?	5. What percentage of these ANC clients will receive an HIV test?	5. What is the testing protocol for PMTCT?	
6. At each facility/level of the logistics system, what was the ending inventory for each brand of test kit at the end of the year?	6. What is the HIV prevalence rate among ANC clients?		
7. What is the expected rate of change in consumption of HIV test kits for PMTCT for each year of the quantification?	7. What is the average discordance rate between the screening and confirmatory tests?		
	8. What is the testing protocol for PMTCT?		

Table 4: Sample Data Collection Questions for Forecasting Consumption of HIV Test Kits for Testing HIV-Exposed Infants

TYPE OF DATA

Consumption	*Demographic/ Morbidity*	*Services*	*Program Targets*
1. How many of each brand of HIV test kits were used for testing HIV-exposed infants in the past year?	1. What percentage of infants of HIV-positive PMTCT clients will be brought for HIV testing at age 9 months?	1. How many HIV-exposed infants were tested for HIV in ANC clinics offering PMTCT during the past year?	1. What is the target number of HIV-exposed infants to be tested for HIV at ANC clinics offering PMTCT for each year of the quantification?
2. What is the lowest level of the logistics system that has relatively complete consumption data?	2. What percentage of HIV-exposed infants test HIV-negative at age 9 months?	2. How many HIV-exposed infants tested positive for HIV at ANC clinics offering PMTCT during the past year?	2. What is the expected percentage of positive results among HIV-exposed infants that will be tested for HIV at ANC clinics?
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?	3. What percentage of HIV-negative infants at age 9 months will still be breastfeeding?	3. What is the average discordance rate between the screening and confirmatory tests of HIV-exposed infants tested for HIV?	3. What is the estimated discordance rate between the screening and confirmatory tests for HIV-exposed infants that will be tested for HIV at ANC clinics?
4. At each facility/level of the logistics system, what were the total quantities received of each brand of test kit during the year?	4. What percentage of HIV-negative infants still breastfeeding at 9 months will be brought for retesting three months after being weaned from breast milk?	4. What is the expected rate of change in the number of HIV-exposed infants to be tested for HIV at ANC clinics offering PMTCT for each year of the quantification?	4. What is the testing protocol for testing HIV-exposed infants?
5. At each facility/level of the logistics system, what were the expiries, losses, and adjustments for each brand of test kit during the year?	5. What percentage of HIV-exposed infants test HIV-positive at age 9 months?	5. What is the testing protocol for testing HIV-exposed infants?	
6. At each facility/level of the logistics system, what was the ending inventory for each brand of test kit at the end of the year?	6. What percentage of HIV-positive infants at age 9 months will be brought for retesting at age 18 months?		
7. What is the expected rate of change in consumption of HIV test kits for testing HIV-exposed infants for each year of the quantification?	7. What percentage of HIV-negative infants at age 18 months will still be breastfeeding?		
	8. What percentage of HIV-negative infants still breastfeeding at 18 months will be brought for retesting three months after being weaned from breast milk?		
	9. What is the average discordance rate between the screening and confirmatory tests of HIV-exposed infants tested for HIV?		
	10. What is the testing protocol for testing HIV-exposed infants?		

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