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# HIV Test Kit Selection: Operational Considerations for VCT and PMTCT Services

## Rationale for Selecting Test Kits Based on Multiple Criteria

As a result of technological advances in HIV test kit product development, cheaper and faster-acting rapid tests are frequently emerging on the international market. This new technology can greatly improve HIV testing service provision and facilitate wider expansion of voluntary counseling and testing (VCT) and prevention of mother-to-child transmission (PMTCT) services, both key interventions in the fight against HIV/AIDS.

However, without national HIV testing guidelines that standardize the types of tests used to provide these services, a *potential drawback of rapid technological advances is the proliferation of brands of test kits in countries*. Limiting the number of brands of HIV test kits used in a country for each service is key for promoting quality standards in expanding VCT, PMTCT, and other HIV testing interventions. Brand proliferation makes VCT and PMTCT expansion much more challenging, and may negatively impact the quality of services provided. It also significantly complicates the logistics management of these commodities.

In general, when countries or programs have developed national guidelines and recommended standard kits, the criteria for product selection may be limited to sensitivity and specificity and some basic requirements. Nonetheless, to facilitate expansion of quality VCT and PMTCT services at lower-level health facilities in resource constrained settings, it may be necessary to consider additional criteria pertaining to feasibility and user-friendliness of the HIV test kits.

This document provides a checklist of additional criteria that may enhance the quality of services and reduce program costs. It also presents an example from

Uganda (where a phased approach was used) of how the product selection process might work.



An example of a rapid test kit.

## Criteria for Product Selection

### Essential Characteristics

At a minimum, the test kits that are being considered for selection must have two essential characteristics:

- All test kits being considered come from prequalified suppliers, and are either registered in the country or can be registered easily with minimal delays.
- For all tests under consideration, data are available on sensitivity and specificity.

### Other Characteristics

Other product characteristics to consider during the selection process are described in the next section. The importance of each of the following characteristics depends on the design and scope of the program. In particular, some criteria may be more important for the screening test, while others might be more important for the confirmatory or tie-breaker tests. It is advisable to categorize characteristics as essential, desirable, and non-essential, which helps guide the selection process.

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## A. Type of rapid assay and complexity of use

Identifying the format of the assay provides useful information about the rapidity of test results, complexity of use, and type of sample required. Three common formats for generic assays are used: particle agglutination, membrane immunoconcentration (flow-through) devices, and immunochromatographic (lateral-flow) strips.

Particle agglutination devices, such as Capillus™, can produce results that are more difficult to interpret if the agglutination is weak. If multiple cadres of staff—with different levels of training—are interpreting results, the subjectivity of interpretation could produce inaccurate results. Another disadvantage of this format is that it must be used with serum or plasma. Testing with these types of samples requires more staff training and the use of additional equipment than testing done with whole blood or oral fluid.

Membrane immunoconcentration (flow-through) devices, such as SeroCard™ and Multispot®, and immunochromatographic strips (lateral-flow devices), such as Determine™ and OraQuick®, present the results as a dot or a line, which is easier to interpret. Both tests also have built-in control sites, which indicate to the user whether the tests are valid or not.

For tests that will be used at lower-level health facilities, it is particularly important to determine how user-friendly and practical the tests will be. Consider the following questions:

- How many steps are there between collecting the blood sample and reading the result?
- Are multiple steps required to prepare the sample (centrifugation) or the reagent?
- Is the test result easy to read and interpret? Is there a degree of subjectivity in reading the test results that might lead to false positive (or negative) results?

## B. Rapidity of test results

The total time required to conduct the test and obtain results is critical when considering program planning and expansion. For example, particle agglutination devices take 10–60 minutes to provide test results, while flow-through and lateral-flow devices can provide results within 5–15 minutes.

## C. Storage conditions for test kits

Given that many test kits require refrigeration, considering storage requirements early in the process can result in significant cost savings and enhance product quality during storage and distribution. Additionally, it is important to remember that products will expire before their stated expiration date if they are not stored in the recommended conditions. Consider the following questions:

- Do the tests or reagents require cold storage or refrigeration (2–8°C)?
- Given the conditions at most lower-level health facilities, can the tests or reagents be stored between 8–30°C?
- Would any other special storage requirements affect storage capacity at lower level health facilities, such as photosensitivity or bulk consumable and equipment requirements?

## D. Shelf life of test kits

Test kits have some of the shortest shelf lives of all commodities used in the public sector, and many public sector programs have pipelines that are longer than the shelf lives of HIV test kits. Remember, the pipeline includes the entire chain of storage facilities and transportation links that products must go through, from the point of manufacture until they are put into the hands of the customer. Thus, if shelf lives of HIV tests are not considered during product selection and program planning, there is a great risk of wasted financial resources when these items expire. Consider the following questions:

- What is the shelf life at the recommended storage conditions? Is it 12 months or more? Or six months or less?
- Keep in mind that, in general, the majority of test kits (unless they are locally manufactured) will arrive in a country with at least three months less than their total shelf life remaining. For example, a product with a 12-month shelf life will have 8–9 months left on arrival in any given country.
- When considering shelf life, match the remaining shelf life (total shelf life minus three months) with the length of the in-country pipeline.



- If the test requires chase buffer or other reagents, do these have different shelf lives than the testing device?

#### E. Equipment and consumable requirements

Equipment and consumable requirements can add significantly to the total cost of a selected product and potentially affect storage and distribution capacity. Consider the following questions:

- What additional equipment is required to perform the assay?
- Is use of the equipment limited to certain cadres of staff, e.g., lab technicians?
- How many consumable items are not provided in or with the kit but are necessary to perform the test?
- What is the average cost of these items and will they add significantly to the cost of the test kit?
- Are the items bulky to store and transport?

#### F. Packaging of tests per kit

Programs have the option of customizing certain components of packaging when developing specifications for procurement. In some cases, customized packaging will add to the cost of the product. Consider the following questions:

- Is the kit designed for high-volume or low-volume testing sites?
- Is there flexibility in specifying the number of tests per kit and the volume of chase buffer or other reagents?
- Are the tests individually packaged within the kit? For example, if the kit is being considered as a tie-breaker, for which demand is relatively low, can the tests from one kit be distributed to several sites?

#### G. Cost of tests

Because of how rapidly new test kits are emerging, prices can vary significantly from one year to another. Additionally, product quality and production capacity by small manufacturers have been problematic in some countries. Thus, although cost is an important consideration, it should not be the sole criteria used in making product selection decisions. Consider the following questions:

- What is the price range for the test kit?
- What is included in the price, i.e., how many tests, what consumables, etc.?
- Are there any “hidden” or associated costs, such as for equipment or reagents; complex training requirements for staff; or storage and distribution costs?
- Is the quoted price competitive regionally and internationally?

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# Example of a Phased Approach to Product Selection<sup>1</sup>

**Step 1** Establish or work within an existing working group of key stakeholders involved in HIV testing, including VCT and PMTCT.

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**Step 2** Ensure key decisions that affect product selection are taken or in place, including—

- Program or purpose for selecting the tests (for example, VCT or PMTCT).
  - Levels of the system at which tests will be used.
  - The cadre of staff that will be authorized to use the tests.
  - Testing protocols for each purpose, e.g., whether there will be a parallel or serial testing algorithm for VCT.
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**Step 3** Identify the total list of products to be assessed and the list of criteria to use in the various phases of the selection process. At this stage, the group may want to identify characteristics that are essential, desirable, and non-essential.

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**Step 4** Conduct Phase I. Use a small number of criteria to rapidly eliminate a significant number of products on the list. An example of preliminary elimination criteria includes the following:

**Products:**

- Not currently registered in the country, not from prequalified suppliers, or not likely to be registered within 3–6 months.
  - Requiring refrigeration at 2–8°C.
  - That are relatively complex to use (for example, products requiring centrifuging of the sample).
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**Step 5** Conduct Phase II. Ideally, there should be a much shorter list (10–15) of product candidates to choose from. Identify criteria for this stage of the assessment and assign a score for each characteristic. Criteria might be sensitivity/specificity, storage, type of sample used, complexity of use, shelf life, cost, etc. Consider weighing essential or desirable characteristics. For example, if storage is a crucial factor, then room temperature storage can be assigned a score of 2, while refrigeration receives no score (0 points). Another example of non-weighted scoring is with shelf life:

- 12 months+ = 3 points
- 9–11 months = 2 points
- 6–8 months = 1 point

Criteria may need to be different for screening, confirmatory, and tie-breaker tests, depending on the program and testing protocols.

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**Step 6** Finalize the selection. Create a matrix of all the products assessed under Phase II and their scores within each category, as well as their total score. As a committee, determine what the final products are and develop a timeline for reevaluating the choices.

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<sup>1</sup> The example is based on a similar process used by the Ministry of Health in Uganda in product selection for HIV test kits for VCT and PMTCT in 2002.