WHO recommends providing access to HIV testing in clinical and non-clinical settings for diagnosis of HIV infection. The primary objective of HIV testing for national HIV programmes is to identify people living with HIV as early as possible after acquiring HIV infection, and to link them to prevention, care and treatment services.

To diagnose HIV infection, a variety of test formats are available, including HIV rapid diagnostic tests (RDTs), or other simple assays, enzyme immunoassays (EIAs) and HIV supplemental tests. The technical characteristics of each test format make them suitable for specific levels of laboratory facilities according to physical infrastructure (availability of electricity/water), presence of phlebotomists and technical skills of staff: RDTs can be deployed in community and peripheral settings or very basic laboratory settings, while EIAs and supplemental assays require stable electrical supply, dedicated equipment and specialized laboratory staff.

The combination of HIV Diagnostic Test Kits to be used is decided according to a given testing strategy and a nationally validated testing algorithm adapted to the setting of intended use.

The testing algorithm

What is a testing algorithm? A testing algorithm describes the combination and sequence of specific HIV assays used within a given HIV testing strategy. One reactive HIV test result alone is insufficient to diagnose HIV infection, and WHO recommends the use of a combination of RDTs or a combination of RDTs and EIAs or a combination of EIAs to diagnose an HIV infection (See figures 1 and 2 in Definition sections further down see).

Depending on the testing strategy, testing algorithms must be validated to indicate which exact brands of test kits are to be used and in which sequence, this means that one brand of test kit cannot simply be replaced by just any available option. The compatibility between the different assays of a testing algorithm has to be carefully assessed as part of the validation of the testing algorithm. The first line assay must have the highest sensitivity. The second and third line assays must have the highest specificity.

The coexistence of several algorithms (with different HIV Diagnostic Tests Kits, modification of the sequence alone is not regarded as an alternative algorithm) in a given area could be considered to answer the specific needs of the various testing programmes of the country. Good practice for procurement also supports the definition and validation of a rescue algorithm facilitating the replacement of a given HIV assay should any problem occur.

Who defines a testing algorithm? The national HIV reference laboratory under the guidance of the national HIV programme is responsible for the validation of the testing algorithm.

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For how long is a testing algorithm valid?
The national HIV programme is responsible for its revision which is recommended every 4 to 5 years and should be initiated no later than during the fourth year of use of a current algorithm.

The Global Fund QA Policy

All Global Fund’s Recipients managing the procurement of HIV diagnostic test kits must comply with the Quality Assurance Policy for Diagnostic Products (QA Policy), in force since March 2011, including criteria to ensure the quality and adequate use of Diagnostic Test Kits procured with Global Fund resources.

Global Fund Quality Assurance Policy for Diagnostic Products

(a) CLINICAL CRITERIA
Product types must be selected in compliance with:
- National guidelines
- WHO guidance

(b) QUALITY STANDARDS
For all diagnostic products:
- Manufacturing site must comply with ISO 13485 + HIV-related products must be:
  - Assessed and approved according to requirements of a GHTF founder member (USA, Japan, EU, Canada, Australia),
  - or
  - Approved by WHO after technical assessment

(c) MONITORING QUALITY and ENSURING ADEQUATE USE
- Adequately trained staff
- Adequate storage and distribution
- Lot testing
- Reporting of failures

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A. Procurement principles

1. The procurement process must be organized according to the local context, in a competitive and transparent manner, according to the following recommendations.

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a. When the National HIV Programme has defined and/or validated one or several testing algorithm(s) for the diagnosis of HIV infection within the last 5 years:

- A competitive procurement process is **not** required for procurement of the HIV Diagnostic Test Kits. A Request for Quotation should be launched instead.
- If the products selected by the National HIV Programme as part of the validated national testing algorithm(s), are compliant with the QA criteria defined in the Global Fund QA policy, the Principal Recipient is requested to follow the recommendations of the validated algorithm(s) and can order the products without competition, for the validity period of the algorithm.
- If one or more HIV diagnostic test kits selected by the National Programme are not compliant with the QA criteria defined in the Global Fund QA policy, the Principal Recipient should inform the National HIV Programme and request a replacement HIV assay.

b. When the National HIV Programme has NOT defined a testing algorithm for the diagnosis of HIV infection:

- The Principal Recipient is requested to procure the HIV Diagnostic Test Kits through competitive process.
- A contract of 2 years can be signed with the suppliers and may be extended to 2 more years if at the end of the first 2 years no validated testing algorithm has been defined by the National HIV Programme and if the Recipient can submit to the Secretariat evidence of:
  - the selected test(s) remain the most cost effective selection
  - continued compliance of the product with the quality criteria defined in the Global Fund QA Policy;
  - evidence of adequate performance through the inclusion in the list published by WHO;
  - absence of reports of failure in the field in the past two years.
- If no national testing **algorithm** is defined, the PR may request TA assistance and funds to accelerate the development of the testing **algorithm**.
### Selection of products when no national testing algorithm is defined:

#### B. Defining your requirements for procurement

2. To select the appropriate type of diagnostic test kits for a given area, WHO-recommended selection criteria for procurement of HIV diagnostic test kits need to be considered:

- detection target: HIV variants and sub-types;
- detection type: antibody detection only, antibody/antigen detection, discriminatory or combined detection of HIV-1 and HIV-2;
- test format e.g. immunochromatographic and immunofiltration RDTs, EIA, specimen type e.g. Serum/plasma, fingerprick (capillary)/venous whole blood, oral fluid;
- **performance** e.g. sensitivity/specificity;
- inter-reader variability, if RDTs;
- invalid rates;
- ease of use including time to result and number of steps;
- thermal stability;
- equipment and consumables required but not provided within the test kit;
- availability of test kit controls.

#### C. Short-listing HIV Diagnostic Test Kits for purchase

- In determining the compliance of HIV Diagnostic Test Kits’ with the above WHO criteria, Recipients should use the results of the [WHO Test Kit Evaluation Programme](http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/index.html) or the [WHO Prequalification of Diagnostics programme](http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/index.html). In-country studies should aim at verifying the locally chosen sequence of HIV diagnostic test kits (algorithm).

- To facilitate Recipients’ selection of HIV Diagnostic Test Kits, and based on its QA Policy, the Global Fund maintains on its website a summary *List of HIV Diagnostic Test Kits*, identified by their catalogue number/product code. The list includes:
  - products assessed by the [WHO Test Kit Evaluation programme](http://www.who.int/diagnostics_laboratory/evaluations/en/index.html) and found to comply with WHO procurement criteria and,
  - where available, products assessed by the complementary WHO Prequalification of Diagnostic programme,
  - Products approved by a GHTF founding member (EU, US, Japan, Canada, Australia).

- HIV Diagnostic Test Kits should be selected in line with national HIV testing guidelines. Selection should be guided by programmatic needs such as training requirements for health workers, level of current deployment in the country, completeness of the test kits, ease of use and cost. Assessment of ease of use in local conditions may be highly relevant in informing procurement decisions within a short list of Diagnostic Test Kits where

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validated testing algorithm does not exist.

3. Tender or Request for Quotation

A comprehensive set of information will be required from manufacturers of HIV Diagnostic Test Kits. A list of general information and technical specifications should be included in the supplier's reply to the call for tender or request for quotation such as:

- stability data for the product during transport, storage and in-use
- shelf life of product upon manufacture and guaranteed shelf-life of product upon delivery
- number of individual tests per kit
- description of individual test packaging (completeness of kits) and box sizes, and instructions for use and job-aid (package insert)
- QC lot release certificate for each production lot
- disclosure of all manufacturing sites for any critical parts of the manufacturing process
- INCOTERMS, delivery schedules and lead times (staggered delivery of products is recommended for larger orders),
- evidence of sufficient production capacity and long-term commercial viability of manufacturer,
- agreement for replacement of defective products, if appropriate, and
- agreement for a sampling-agency to take random samples for post-shipment lot testing.

When comparing the price of equivalent HIV Diagnostic Test Kits in a competitive process, the additional costs linked to the introduction of a new HIV Diagnostic Test Kit not previously used in the country should be taken into account (re-training, re-design of job aids,). The consideration of all associated cost, as defined in the **Total Cost of Ownership** (TCO) are recommended.

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D. **Lot Testing**

4. Routine lot testing

- Pre-shipment lot testing should be evidenced and checked by a QC lot release certificate issued by the manufacturer or an independent regulatory body according to the regulatory requirements,
- Where national capacity exists, post-shipment lot-testing can be performed on any lot within a randomly selected consignment by laboratories delegated to perform this task (complying with ISO 15189 or 17025 as per recommendation[10]). Testing using a panel of a biological reference specimen at the national or international reference laboratory is the recommended approach[11]. As most countries do not yet possess this capacity for lot testing, this will not be a mandatory requirement for procurement of HIV Diagnostic Test Kits with Global Fund resources.

5. In case of suspected quality problem for a given HIV Diagnostic Test Kit being use in a

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country, lots testing may be requested in accordance with the following steps:

a. Quarantine suspected faulty Diagnostic Test Kits,
b. Inform the national reference laboratory who may conduct a preliminary investigation to ensure that the quality issue is not related to the end user or the local use of the Diagnostic Test Kit rather than the product itself,
c. Concurrently inform the Global Fund and WHO Prequalification Programme. The programme will in turn inform the manufacturer and provide guidance to the country.

### E. Transport and storage requirements

HIV Diagnostic Test Kits can be affected by exposure to high temperatures, freezing and moisture. Always check product-specific instructions on temperature restrictions for storage. Transport, storage and in-country distribution of HIV Diagnostic Test Kits should be performed in temperature-controlled environment to ensure that the temperatures remain within the manufacturer’s specified limits at any time.

### F. Ensuring adequate use

6. Training and supervision of the end-users of the HIV Diagnostic Test Kits are indispensable tasks to be considered. Training materials and user-friendly instructions (job-aids) should be developed. They should be appropriate to the language and literacy of users. Generic templates should be used as much as possible. Adequate supervision of technicians is paramount to monitor the correct specimen collection, preparation and use of HIV Diagnostic Test Kits and the correct interpretation of testing results, and ensuring universal precautions at all times.

7. Participation in an External Quality Assessment (EQA) scheme (also known as proficiency testing) is an essential component of quality management systems. Recipients should facilitate the identification of an existing national or international EQA scheme and the participation of the testing sites.

8. A specific training for end users is required whenever a new HIV Diagnostic Test Kit is introduced in the country at any level of the testing algorithm. The use of a standardized logbook for the reporting of the test results is instrumental for quality testing activities. It will also facilitate the choice of the HIV Diagnostic Test Kits for the local testing algorithm.

### G. Further guidance

9. This briefing note lists some key points to be considered for the procurement of Diagnostic Test Kits with Global Fund grants. It is strongly recommended that Recipients refer to WHO guidance on Components of HIV testing and counselling services, specifically the section dedicated to supply and management of commodities.

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External Quality Assessment: means a programme that assesses the performance of laboratories and/or testing sites by demonstrating the reliability and accuracy of testing results. EQA may include proficiency testing (otherwise known as an EQA scheme), or on-site visits to assess and supervise the laboratory practices and procedures, or a combination of the above.

HIV Immunoassays: means a serological technique that relies on the interaction between antigen and antibody for detection of HIV-1/2 antibodies and/or HIV-1 p24 antigen, i.e. rapid diagnostic tests (RDTs), solid phase (comb or dipstick) assay, agglutination assays, enzyme immunoassays (EIA) (including microtiter plate EIA), line immunoassays, and Western blotting.

Lot testing: as the performance of a given Diagnostic Test Kit may vary between lots over time, production lots should be checked through specific activities aiming at gaining evidence of the continued quality of each production lot of the tested product. Lot testing can be conducted prior the shipment of the Diagnostic Test Kits to the recipient country or at arrival in the country prior initiation of use.

Performance evaluation: investigation of data of an in vitro diagnostic device (IVD) intended to establish or verify the performance of an IVD under the anticipated conditions of use.

The performance of an IVD consists of an analytical and clinical performance supporting the intended use of an IVD. Therefore, the data should originate from a clinical or other appropriate environment (EN13616:2002, GHTF/SG5/N6:2012).

Quality Monitoring means all activities undertaken to ensure that the Diagnostic Products continue to conform with the Manufacturer’s established quality specifications during the storage, distribution and use of such product, including but not limited to Lot Testing, reporting of deficient Diagnostic Product and surveillance, as part of a quality assurance system.

RDTs (Rapid Diagnostic Tests): are a type of in vitro diagnostic device (IVD) that can be utilized with a range of biological specimens, including those collected through less invasive methods, that are intended to give an immediate test result, i.e. in less than 30 minutes. Here restricted to refer to immunochromatographic (lateral flow) or immunofiltration (flow through) RDTs that operate by the principle of immunoassay i.e. antibody binding to antigen and vice versa.

Test format: technology used to achieve the detection of the target analyte, i.e. RDT or EIA.

Testing strategy: generically describes a testing approach for a specific need (e.g., transfusion and transplantation safety, surveillance, diagnosis of HIV infection)

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15 Refer to WHO Evaluation report for comprehensive explanations.  
http://www.who.int/diagnostics_laboratory/evaluations/hiv/131107_hiv_assays17_final.pdf
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**WHO recommended testing strategies for diagnosis of HIV infection**

**Figure 1:** HIV testing strategy for diagnosis in **high prevalence** settings

**Figure 2:** HIV testing strategy for diagnosis in **low prevalence** settings

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**Notes:**


**A1 test should be highly sensitive. A2 should be highly sensitive and highly specific. A3 should be highly specific.**

“Report” – result may be reported.

For newly diagnosed individuals, a positive result should be confirmed on a second specimen to rule out laboratory error.

Re-testing should be performed on a second specimen taken after 14 days to rule out seroconversion.

If A1 is an antigen/antibody detection assay and A2 or A3 is an antibody detection-only assay, re-testing should be performed with a second specimen taken after 14 days.

**Testing algorithm:** A testing algorithm describes the combination and sequence of specific HIV assays used within a given HIV testing strategy. One reactive HIV test result alone is insufficient to diagnose HIV infection, and WHO recommends the use of a combination of RDTs or a combination of RTDs and EIAs or a combination of EIAs to establish an HIV infection (See Figures 1 and 2).

**Validation (of HIV testing algorithms)**: A scientifically led process to select and validate a series of pre-approved/qualified assays with minimum performance characteristics (e.g. sensitivity, specificity) for use within a given testing algorithm. A combination of both performance and operational characteristics must be considered, and most importantly the degree of cross-reactivity shared between each of the assays. Validation should be carried out in the setting of intended use and should demonstrate that user requirements have been met.

**Total Cost of Ownership (TCO)** means the total amount of all direct and indirect monetary costs related to the procurement, storage and distribution of a Diagnostic Product by a Recipient, including the price of the product itself, any reagents and other consumables, transportation, customs clearance, insurance, in-country distribution and storage, Quality Assurance and Quality Monitoring, training, and validation of new diagnostic algorithms, and, as applicable, operating costs including cost of installing, servicing, commissioning and maintaining equipment.

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16 Source: WHO document to be published in 2014.