Invitation to Suppliers/Manufacturers of Rapid HIV and Dual HIV & Syphilis Test Kits

The Ethiopian Public Health Institute (EPHI) is planning to undertake a verification study of HIV Rapid Diagnostic kits for the establishment of new quality assured national HIV Rapid Testing Algorithms. The study is aimed at assessing for the least possible shared common false HIV-reactivity among Rapid Diagnostic Tests (RDTs) to be used in the three-test serial algorithms. In addition, the planned verification study will also include rapid diagnostic kits for the dual or simultaneous detection of antibodies to HIV-1/2 and Syphilis to identify potential test kits which, at times of specific programmatic needs, will serve as the first test in conjunction with the approved national HIV Testing Algorithms. Therefore, EPHI invites interested suppliers/manufacturers to submit Rapid HIV and/or dual HIV & Syphilis Test Kits to be considered for the verification process which shall fulfill the following criteria:
(N.B. Submissions of different pack sizes of the same kit are highly encouraged).

1. **Currently in the list of World Health Organization (WHO) prequalified In Vitro Diagnostics.**
2. **Kits are complete with at least the following materials in package: Package insert/Test instruction sheet in English, lancets, alcohol swabs, sample transfer pipettes/droppers, running buffer.**
   - **Very Important Note: In the event a specific kit passes the verification study, accepted for inclusion in the potential national HIV Testing Algorithms and becomes eligible for procurement, the supplier's offer shall include all the listed items with no exception.**
3. **Shelf-life of the test kits should be for at least one year.**
4. **Submission of Letter/s of Authorization from the manufacturer/s of the kit/s submitted is mandatory for suppliers.**

Suppliers/manufacturers that have products which fulfill all of the above requirements are herewith invited to submit complete kits of two different lot numbers each sufficient to conduct 400 tests (a total of 800 tests for both lots) to EPHI at the National HIV/AIDS Laboratory Building, First Floor, Office Number 1 within 30 calendar days starting from the date of this announcement in The Ethiopian Herald or Addis Zemen Newspapers. Note should be taken that EPHI will immediately start with the verification process if at least seven different Rapid HIV and/or dual HIV & Syphilis Test Kits are received by the 30th calendar day.

Any communication or inquiry related to this announcement shall only be made in writing via e-mail at hivrdtvalidationephi@googlegroups.com or letter to:

The Director General,
Ethiopian Public Health Institute,
Gulelle Subcity, Woreda 9,
Swaziland Street, House # 625/626,
P.O.Box 1242 or 5654,
Addis Ababa

Important Notes:

- This announcement was published in The Ethiopian Herald on April 20th, 2021 (Volume I.XXVII and Number 190) and Addis Zemen Newspaper on Miazia 12th, 2013 E.C (80th Year, Number 222).
- Attached herewith please find a form that shall be filled at the time of delivery and receipt of kits.

The National Task Force for the Establishment of HIV Testing Algorithms

The Ethiopian Public Health Institute (EPHI)

Rapid HIV Diagnostic Kit Delivery & Receipt Form

1. Kit Details

Brand name: _____

Lot Number: _____

Pack Size/Number of Tests/kit _____

Manufacturing Date_____

Expiry Date_____

2. Delivery Details

Quantity delivered: _____

Date delivered: _____

Delivered by _____

3. Manufacturer Details:

Name: _____

Country:_____

E-mail address: _____

Tel:_____

4. Manufacturer's Contact person details:

Name: _____

E-mail address:_____

Tel: _____

5. Supplier Details:

Name:_____

Country: _____

E-mail address: _____

Tel: _____

6. **Supplier's Contact Person Details**:

Name:_____

E-mail address: _____

Tel: _____

7. Completeness of kits checked and received by:

Name: _____

Signature: _____

Date: _____

Time: _____

Important Notes:

- This form shall be fully completed upon receipt of kits from a supplier/manufacturer
- The completed form shall be photo-copied or scanned
- The photo or scanned copy is given to the deliverer
- The original copy is retained at the National HIV/AIDS Reference Laboratory with a photo or scanned copy of the deliverer's personal Identification Document (Passport, Employee or Kebelle Residence) attached to it.