Ministry of Health

National Public Health Laboratories

Kenya External Quality Assessment Scheme (KNEQAS)

# Important information to Participants on HIV Serology PT Scope

1.

## Description of HIV serology scope of the proficiency testing scheme

The PT scope is designed to be a quality improvement tool for HIV testing services. It therefore targets participation from HTS **providers working in the various service provision approaches and settings.** Performance evaluation is based on assessment of accuracy in establishing HIV sero-status of characterized HIV negative and positive samples, adherence to HIV testing algorithm an**d** proper recording & submission of the obtained test results

2.

## Charges for participation

Participation to the scheme scope does not attract payment of any fees currently. Considerations for charging fees may however be made in the future.

3.

## Eligibility criteria for participation

Participation is open to individuals who are actively providing HIV testing services at the time of an operational round.

4.

## Confidentiality arrangements

Each participant is issued with a unique identification code. Performance reports are made Available to participants on-line and are accessible to each participant through their access controlled unique accounts. KNEQAS staffs have a commitment to keep participants information, including performance confidentially. Participant's reports will only be shared to institutional quality officers for the purpose of facilitating quality interventions. If required by a regulator or legal entity the confidentiality procedure in the quality manual MUST be adhered to.

5.

## How to register & get enrolled for participation.

For a HTS provider to enroll for participation, following procedure applies:

**Registration**:

1. Go to www.rhtpt.or.ke on internet browser.
2. Click the **REGISTER** button to get started.
3. Click "NO" when the" have you been registered before" message pops up,
4. Fill in the online registration form that opens up and submit it to KNEQAS for consideration (Participants shall provide their full names, e-mail address, phone numbers, designation, facility KHMFL Code and facility in charge details (Name, phone and email).
5. Ask your sub county medical lab coordinator (SCMLC) to enable your registration VI.
6. You will be automatically be allocated a unique identification number by the system (Tester ID) to confirm registration.
7. An SMS notification is sent to the applicant with his/her Unique Identification Number (Tester ID).
8. Contact your sub county medical lab coordinator to enrol you for participation in the current round

6.

## Factors which could influence the testing of the proficiency test items

The samples used are dried plasma form and are suitable for testing for a period of at least 30 days when stored at room temperature. The sample is suitable for testing using serological tests (eg HIV RDTS) after reconstitution. The stability of the samples is gradually lost if the sample is stored and tested after a period that exceeds 24 hrs after reconstitution.

7.

## Procedure for reconstitution of the dried plasma samples

To prepare the samples for testing, eight drops of reconstitution buffer that is included to the pack are added to each of the samples using the provided Pasteur pipette. Care must be taken to prevent sample cross-contamination. The samples should then be left at room temperature for about 12 – 18 hrs to allow for complete dissolution of the samples.

8.

## Safety precautions

The samples are obtained from blood donors and some of them are known to be HIV positive. Although they have been screened and found to be free of hepatitis B and C, they should be treated as if they are potentially infectious of any blood borne diseases. All necessary precautionary bio-safety measures should therefore be taken. Remnant PT material should be disposed off in a way that takes bio-safety procedures consideration.

9.

## Conditions for testing

The PT material should be processed, maintained and tested at room temperature. There is no cold chain requirement.

10. **Testing of PT panel samples**

PT samples should be treated similarly with clients' samples. While testing, participants should use test s that are currently in use at the facility and in adherence to recommended procedure and the provided HTS national algorithm.

11. **Recording of results and other variables**

Results for each of the samples tested should be recorded by selecting the applicable reactivity against each of the samples and test by which the results are obtained eg "reactive", "non-reactive", "invalid". If a sample is not tested for some reason, "not done" should be selected and an explanation offered at the comment area of the results submission form. Other required variables should be recorded following the format outlined on the results submission form. Final results should be entered as "Positive", "Negative" or inconclusive depending on interpretation and based on pattern of results obtained upon testing. These records should be transcribed to the results entry electronic form at www.rhtpt.or.ke and submitted online (See procedure at www.rhtpt.or.ke. Help desk, User guide,"HIV PT Results Entry and Access to Feedback in 5 Easy Steps").

12. **Collusion by participants**

Participants are highly advised to work independently. Collusion amongst participants is highly discouraged. Suspected events of collusion may lead to de-enrolment from participating in future rounds among other actions.

13.

**Deadline for return of return of results**

KNEQAS will receive and evaluate results submitted within a period of 21 working days following release of the PT panels. Results received there- after may not be evaluated and performance feedback reports may not be provided to the affected.

14.

Appealing Against Evaluation of Performance

If a PT participant has reasonable grounds to believe that PT performance report does not reflect his/her performance OR notices error in the report, the below procedure is available to the affected participant to launch an appeal with KNEQAS

- Use the contacts for enquiries on page 6 to bring the complaint to the attention of KNEQAS (Alternatively, post the matter on www.rhtpt.or.ke-help desk)
- Provide participant's details to include PT enrolment ID
- Describe in details the matter of concern
- KNEQAS will institute an investigation into the matter
- An amended report will be issued if investigation reveal that an error had been made in the original report

- If no error is found, the original report will be upheld and communication regarding the decision made.

## Contacts for enquiries

Enquires, compliments, comments, assistance can be channeled through any of the below contacts:

Kenya External Quality Assessment Scheme (KNEQAS)

National Public Health Laboratories

Kenyatta National Hospital Grounds

P.O Box 20750 – 00202 Nairobi

1. KNEQAS Email – nphlpt@nphl.go.ke
2. Scheme Coordinator/Manager - 0721397766
3. Scheme data manager – 0721825737.
4. Use help desk at www.rhtpt.or.ke
   http://helpdesk.nphl.go.ke/