



**Division of National Laboratories Services
National Public Health Laboratories,
Kenya External Quality Assessment Scheme (KNEQAS)**

KNEQAS Participation Charter

1. Purpose of the Scheme

The HIV Serology Proficiency Testing (PT) scheme is a quality improvement tool designed to strengthen HIV testing services across Kenya. Participation is intended for HIV Testing Services (HTS) providers in diverse service delivery settings.

2. Eligibility to Participate

Participation is open to individuals actively providing HIV testing services during an operational PT round. Institutions must ensure participants are competent and authorized to perform HIV testing.

3. Charges for Participation

Currently, participation is free of charge. Future considerations for cost recovery may be introduced, with prior notification to participants.

4. Scheme's Impartiality Commitment

KNEQAS scheme is committed to ensuring impartiality in the design, operation, and implementation of the rapid HIV Serology proficiency testing scheme in line with ISO 17043:2023 requirements and has put in place the following among others to ensure the same.

- Independence of Operations:** All proficiency testing activities are carried out independently, free from undue influence by external parties, sponsors, or participants, in strict accordance with the scheme's governance structures.
- Conflict of Interest Management:** Staff and evaluators must declare and document any potential conflicts of interest. This is in place to prevent any potential or actual bias in the operations of the scheme (such as sample preparation, distribution, evaluation, and reporting.)
- Fair Treatment of Participants:** All participants are treated equally, with no preferential access to information, materials, or evaluation criteria.
- Transparent Procedures:** Enrollment, testing, evaluation, and reporting processes are standardized, documented and shared through our resource module of the system which is accessible to all participants to ensure consistency and fairness.
- Oversight and Accountability:** The impartiality of the scheme is monitored by the scheme's Technical Advisory Committee, with corrective actions taken if impartiality risks are identified.
- Routine internal audits and systematic risk assessments** are carried out to identify and address potential issues, ensuring the scheme's operations remain



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National Public Health Laboratories,
Kenya External Quality Assessment Scheme (KNEQAS)**

compliant and effective. Report findings are presented in the Management review meeting.

5. Confidentiality and Information Management

- **Your information is protected:** KNEQAS manages all data collected during proficiency testing (PT) activities under strict legal agreements. You will be told in advance if any of your information is planned to be shared publicly.
- **Your identity stays private:** Your name and participation details are kept confidential. Only staff directly involved in running the PT scheme will know who you are, unless you give permission, the law requires it, or a contract allows it. If information must be shared, you will be notified unless the law prevents it.
- **External staff follow the same rules:** Committee members, contractors, and anyone working on behalf of the scheme must also keep all PT information confidential.
- **Information from others:** If a complaint or regulator provides information about you, that information will be kept confidential. The identity of the source will not be shared with you unless the source agrees.
- **Public information:** If you choose to make your own information public, the scheme shall not be responsible for how it is used. All other information is treated as private and proprietary unless you and the PT provider agree otherwise.

6. Homogeneity and Assigned Values

- All PT samples are subjected to homogeneity testing prior to distribution to ensure that observed differences in participant results reflect testing performance rather than sample variability. Only batches that meet homogeneity criteria are released.
- Assigned values for PT items are determined using results from ISO accredited national reference laboratories using standardized and validated testing methods. The process follows the requirements of ISO 17043:2023 and ISO 13528 to ensure technical validity, transparency, and comparability. Where applicable, the uncertainty associated with the assigned values is estimated and documented. This ensures that participant performance is evaluated against values that are scientifically sound, traceable, and impartial.

7. Enrollment Procedure

Participants must register online via www.rhtpt.nphl.go.ke and provide:

- Full name, designation, contact details (email, phone).



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- Facility details (KHMFL Code, facility in-charge contact).
- Approval by the Sub-County Medical Laboratory Coordinator (SCMLC).
- Upon approval, participants receive a **Tester ID** via SMS and wait to be enrolled in an upcoming cycle. Kindly contact your SCMLC if you suspect not to have been enrolled in a proficiency test cycle.

8. Handling of PT Samples

- PT samples are provided in dried plasma form, stable for at least 90 days at room temperature.
- After reconstitution, samples must be tested within 12 hours.
- Reconstitution requires eight drops of buffer using the provided pipette per sample, followed by 8–12 hours at room temperature for complete dilution.
- Samples must be handled as potentially infectious and disposed of according to biosafety protocols.

9. Testing Conditions

- PT materials should be tested under routine laboratory conditions at room temperature.
- Participants must use the same HIV rapid diagnostic tests (RDTs) and algorithms applied in client testing.
- PT samples must be treated with the same rigor as patient samples.

10. Recording and Submission of Results

- Results must be recorded as **Reactive, Non-Reactive, Invalid, or Not Done**.
- Final interpretation should be entered as **Positive, Negative, or Inconclusive**.
- Results must be submitted electronically via www.rhtpt.or.ke within **21 days** of receiving your panel.
- Timely reporting is essential for comparability and integrity of the scheme. Extensions may be granted only under exceptional circumstances (e.g., technical difficulties, unforeseen operational disruptions), and must be formally requested before the submission deadline.

11. Collusion and Integrity

- Participants must work independently when testing the proficiency test items.
- Collusion or falsification of results is strictly prohibited and may result in de-enrollment or other disciplinary actions.
- KNEQAS reserves the right to investigate suspected breaches of integrity.

12. Appeals Process

Participants may appeal performance evaluations if errors are suspected:

- Submit a complaint via www.rhtpt.nphl.go.ke help Desk or official contacts.



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- Provide your **name** and **Tester ID** and detailed description of the concern.
- KNEQAS will document, investigate and issue an amended report if errors are confirmed.
- If no error is found, the original report will stand and the participant shall be notified of the same.

13. Performance evaluation is based on:

- Accuracy in establishing HIV sero-status of characterized HIV-negative and HIV-positive samples.
- Adherence to the national HIV testing algorithm.
- Compliance with documentation and reporting practices.

14. Safety and Compliance

- All participants must adhere to biosafety and ethical standards when handling PT materials.

Commitment to Scheme Principles and Policies

By registering to participate in the scheme, participants are deemed to have accepted and committed to the principles and policies outlined herein. Registration constitutes:

- *Agreement to comply fully with scheme rules, procedures, and confidentiality provisions.*
- *Recognition of the scheme's impartiality and commitment to independence from undue influence.*
- *Acceptance of responsibilities regarding confidentiality, transparency, and accountability as defined by contractual and legal obligations.*
- *Acknowledgment that participation reflects a collective responsibility to uphold the integrity, credibility, and international compliance of the scheme.*

<i>Contacts for Enquiries</i>	
<i>Address</i>	<i>Contact info</i>
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