



The Republic of Uganda
MINISTRY OF HEALTH

NATIONAL HEALTH LABORATORY AND DIAGNOSTIC SERVICES
NATIONAL EXTERNAL QUALITY ASSESSMENT LABORATORY

**DESIGN OF PROFICIENCY TESTING SCHEMES FOR HIV-1 QUALITATIVE ASSAYS,
HIV-1 QUANTITATIVE ASSAYS, MALARIA RDT, HEPATITIS B SEROLOGY ASSAYS,
CD4 COUNT, COMPLETE BLOOD COUNT (CBC), MALARIA MICROSCOPY, BLOOD
GROUPING, BLOOD CROSS MATCHING AND HEMOGLOBIN ESTIMATION PT
SCHEMES**

SOP PT010A Version 3.0 Effective date: 01-Oct-2025 Initials authorizer:

SOP Approval

	Name	Signature	Date
Prepared by	Ismail Kayongo	KI	27/09/2025
Reviewed by	Enock Wekia		28/09/2025
Authorized by	Patricia Akello Anok		01/10/2025

Date Retired:

Approved changes

Brief description of the change

2. Increased the scope of the sop by adding Blood Grouping, Cross matching and Hemoglobin Estimation
- 5.5.8-5.5.10. Included Blood Grouping, Cross matching and Hemoglobin Estimation PT schemes in the criteria for participation in PT
- 5.7.8-5.7.10. Included Blood Grouping, Cross matching and Hemoglobin Estimation PT schemes analytes in PT schemes
- 5.15.6-5.15.8. Included Blood Grouping, Cross matching and Hemoglobin Estimation in the description of statistical analysis. Included measurement uncertainty as a parameter to be analyzed for all quantitative assays
- 5.16. Included methods for obtaining assigned values to be used during analysis of participant results for all the schemes

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1. Design Of Proficiency Testing Schemes For HIV-1 Qualitative Assays, HIV-1 Quantitative Assays, Malaria RDT (mRDT), Hepatitis B Serology Assays, CD4 Count, Complete Blood Count (CBC), Malaria Microscopy, Blood Grouping, blood Cross matching and Hemoglobin Estimation PT schemes

2. Objectives and scope

To ensure that the Proficiency Testing process are planned and conducted in a controlled environment to ensure validity of the PT results and to have a uniform way of conducting activities of the PT schemes in order to maintain their credibility as a PT provider. These schemes include, HIV-1 Qualitative/EID PT, HIV-1 Quantitative/Viral load PT, Hepatitis B/HBV serology PT, Malaria RDT PT, CD4 Count PT, Complete blood count (CBC) PT, Blood Grouping, blood Cross matching, Hemoglobin Estimation and Malaria Microscopy (Thin smears) PT.

This Procedures Manual defines the plan and design for PT panel production for HIV-1 Qualitative/EID PT, HIV-1 Quantitative/Viral load PT, Hepatitis B/HBV serology PT, Malaria RDT PT, CD4 Count PT, Complete blood count (CBC) PT, Blood Grouping, blood Cross matching, Hemoglobin Estimation and Malaria Microscopy (Thin smears) PT. schemes

3. Abbreviations, definitions and terms

- EQA External Quality assurance
- HPV Human Papilloma Virus
- PT Proficiency Testing
- HIV-1 Human immunodeficiency Virus type 1
- EID Early Infant Diagnosis
- VL Viral load
- HBV Hepatitis B virus
- NHLDS: National Health Laboratory and Diagnostic Services
- mRDT Malaria Rapid diagnostic test
- CD4 Cluster of differentiation
- CBC Complete blood count
- MU Measurement Uncertainty
- SD Standard Deviation
- Hb Hemoglobin

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Proficiency testing: evaluation of participant performance against pre-established criteria by means of interlaboratory comparison.

assigned value: value attributed to a particular property of a proficiency test item.

participant: laboratory, organization or individual that receives proficiency test items and submits results for review by the proficiency testing provider

proficiency test item: sample, product, artefact, reference material, piece of equipment, measurement standard, data set or other information used for proficiency testing

proficiency testing provider: organization which takes responsibility for all tasks in the development and operation of a proficiency testing scheme.

robust statistical method: statistical method insensitive to small departures from underlying assumptions surrounding an underlying probabilistic model

proficiency testing scheme: proficiency testing designed and operated in one or more rounds for a specified area of testing, measurement, calibration or inspection

4. Tasks, responsibilities and accountabilities

Task	Responsible	Accountable
Enrollment of new sites	PT scheme Manager	Director
Selection of PT Analytes	PT coordinator	PT scheme Manager
PT Production	PT coordinator	PT scheme Manager
QC, storage and distribution of Panels	PT coordinator	PT scheme Manager
Submission of feedback reports	PT coordinator	PT scheme Manager
Data Analysis	PT coordinator	PT scheme Manager
Designing of a PT schedule	PT coordinator	PT scheme Manager

5.0. Planning Procedure

5.1. Name and address of the PT Provider

1. The laboratory is located in the department of National Health Laboratory and Diagnostic Services, Ministry of Health Plot 106-1062, Butabika road Luzira P.O. Box 7272 Kampala – Uganda.

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PT SCHEME COORDINATOR	PT SCHEME MANAGER
<p>Ismail Kayongo</p> <p>PT scheme Coordinator for HIV-1 Qualitative PT, HIV-1 Quantitative PT, HBV serology PT, mRDT PT, CD4 Count PT, Complete blood count (CBC) PT, Blood Grouping, blood Cross matching, Hemoglobin Estimation and Malaria Microscopy (Thin smears) PT Schemes.</p> <p>Contact: +256786580430/+256702343278</p> <p>Email: ismailk2014@gmail.com</p>	<p>Patricia Akello Anok</p> <p>PT scheme Manager for HIV-1 Qualitative PT, HIV-1 Quantitative PT, HBV serology PT, mRDT PT, CD4 Count PT, Complete blood count (CBC) PT, Blood Grouping, blood Cross matching, Hemoglobin Estimation and Malaria Microscopy (Thin smears) PT Schemes.</p> <p>Contact: +256772310000/+256752310000</p> <p>Email: aapatrish@gmail.com</p>

5.2. Accommodation and environment

1. The laboratory has developed specific procedures to ensure that there is appropriate accommodation for the production of the PT panels, including facilities for sample reception/retrieval, handling, storage, dispatch, and retrieval of materials, data, communications and records.
2. The laboratory environment is controlled to ensure stability of PT materials.

5.3. Facilities

1. The laboratory has facilities with controlled temperature for receiving, characterizing, storing and handling of samples before dispatch.
2. Windows in the laboratory are always closed to prevent accumulation of dust.
3. An air conditioner to control the room temperatures in the laboratory.
4. Access into the laboratory is controlled by use of an installed biometric access where only lab staffs has access into.
5. For security purposes, there are installed CCTV cameras installed in the institution.

5.4. Activities to be subcontracted

1. No activity is subcontracted, all processes are managed by the NHLDS including PT transportation

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5.5.Criteria for Participation in in the PT schemes

5.5.1. HIV-1 Qualitative/EID PT scheme

1. Any participating facility/Laboratory should meet the criteria below;
 - Should have a Platform testing for HIV-1 using Nucleic acid Testing Technology.
 - Should have a source of reagents and consumables for performing the tests
 - Should be actively participating on HIV-1 EID testing. For referral laboratories, there should be a mechanism of obtaining samples for testing
 - Should have a designated area for sample collection/reception
 - Should be Implementing a Quality management system
2. The PT panels to be provided for this PT scheme shall be tested on all platforms irrespective of the manufacturer or brand as long as the platform has a HIV-1 qualitative assay.
3. Expected participants should not exceed 1000 sites (Both point of Care sites and Referral laboratories)

5.5.2. HIV-1 Quantitative/Viral load PT scheme

1. Any participating facility/Laboratory should meet the criteria below;
 - Should have a Platform testing for HIV-1 Viral load.
 - Should have a source of reagents and consumables for performing the tests
 - Should be actively participating on HIV-1 Viral load testing. For referral laboratories, there should be a mechanism of obtaining samples for testing
 - Should have a designated area for sample collection/reception
 - Should be Implementing a Quality management system
2. The PT panels to be provided for this PT scheme shall be tested on all platforms irrespective of the manufacturer or brand as long as the platform has a HIV-1 viral load assay.
3. Expected participants should not exceed 1000 sites Both point of Care sites and Referral laboratories)

5.5.3. HBV Serology PT scheme

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1. Any participating facility/Laboratory should meet the criteria below;
 - Should be screening for Hepatitis B. At a minimum at least the HBV surface antigen
 - The Serology kits should be readily available
 - Should be screening clients for Hepatitis B serology
 - Should have a designated area for sample collection/reception
 - Should be Implementing a Quality management system
2. The PT panels to be provided for this PT scheme shall be tested on all kits irrespective of the manufacturer or brand as long as the kit is for Hepatitis B serology
3. Expected participants should not exceed 5000 sites

5.5.4. Malaria RDT PT scheme

1. Any participating facility/Laboratory should meet the criteria below;
 - Should be screening for malaria.
 - The Serology kits should be readily available
 - Should have a designated area for sample collection/reception
 - Should be Implementing a Quality management system
2. The PT panels to be provided for this PT scheme shall be tested on all kits irrespective of the manufacturer or brand as long as the kit is for malaria RDT.
3. Expected participants should not exceed 5000 sites

5.5.5. Complete Blood Count (CBC) PT scheme

1. Any participating facility/Laboratory should meet the criteria below;
 - Should have a functional CBC platform and performing CBC tests.
 - Reagents for CBC should be readily available
 - Should be testing internal quality controls (IQC's)
 - Should have a designated area for sample collection/reception
 - Should be Implementing a Quality management system
2. The PT panels to be provided for this PT scheme shall be tested on all CBC platforms irrespective of the manufacturer or brand
3. Expected participants should not exceed 1000 sites

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5.5.6. CD4 Count/Enumeration PT scheme

1. Any participating facility/Laboratory should meet the criteria below;
 - Should have a functional CD4 platform and performing CD4 tests.
 - Reagents for CD4 should be readily available
 - Should have a designated area for sample collection/reception
 - Should be Implementing a Quality management system
2. The PT panels to be provided for this PT scheme shall be tested on all CD4 platforms irrespective of the manufacturer or brand
3. Expected participants should not exceed 1000 sites

5.5.7. Malaria Microscopy PT scheme

1. Any participating facility/Laboratory should meet the criteria below;
 - A functional light microscope should be available
 - Should have personnel trained on interpretation of malaria microscopy slides
 - Should be Implementing a Quality management system
2. Expected participants should not exceed 2000 sites

5.5.8. Blood Grouping PT scheme

1. Any participating facility/Laboratory should meet the criteria below;
 - Should be carrying out Blood grouping as a routine test.
 - The Anti seras (Anti A, Anti B, Anti AB and Anti D) should be readily available
 - Should have a designated area for sample collection/reception
 - Should be Implementing a Quality management system
2. The PT panels to be provided for this PT scheme shall be tested on all types of anti seras or equipment used to test blood grouping irrespective of the manufacturer or brand.
3. Expected participants should not exceed 5000 sites

5.5.9. Blood Cross matching PT scheme

1. Any participating facility/Laboratory should meet the criteria below;
 - Should be carrying out Blood cross matching as a routine test.
 - Should have a designated area for sample collection/reception
 - Should be Implementing a Quality management system

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2. The PT panels to be provided for this PT scheme shall be tested on any method used for blood cross matching irrespective of the manufacturer or brand.

3. Expected participants should not exceed 5000 sites

5.5.10. Hemoglobin Estimation PT scheme

1. Any participating facility/Laboratory should meet the criteria below;

- Should have a functional Analyser for Hemoglobin estimation and test should be routinely done by the facility
- Reagents for carrying out the testing should be readily available
- Should have a designated area for sample collection/reception
- Should be Implementing a Quality management system

2. The PT panels to be provided for this PT scheme shall be tested on all equipment/platforms irrespective of the manufacturer or brand

3. Expected participants should not exceed 3000 sites

NOTE 1: For all schemes participating sites Must be served by the National Sample transport and Results Return System. (NSTRN)

5.6.Selection of Measurands or characteristic of interest

1. The programs and measurands selection for proficiency testing depends on the following

- Laboratories routine testing needs
- Cost of production
- Homogeneity and stability needs
- Commutability nature of the programs
- Analytes or measurands utility

2. Participants are expected to handle PT materials as they do patient samples

5.7.Analytes in PT materials

5.7.1. HIV-1 Qualitative/EID PT scheme

1. The Panel shall include A control sample and both negative and Positive HIV-1 Specimens.

2. The participant shall test for the presence or absence of the HIV-1 virus in the PT panel.

5.7.2. HIV-1 Quantitative/Viral PT scheme

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1. The Panel shall include specimens with viral load copies covering the analytical range of the testing platforms.
2. The specimen with the lowest viral load copy shall be determined by the platform having the highest limit of Quantification. (LoQ)
3. The participant shall measure the amount of HIV-1 virus in each specimen of the PT panel

5.7.3. HBV serology PT scheme

1. The Panel shall include A control sample and both HBV negative and HBV Positive Specimens
2. At a minimum, the participant shall screen for the presence or absence of Hepatitis B surface antigen in the specimens

5.7.4. Malaria RDT PT scheme

1. The Panel shall include both Malaria negative and malaria Positive Specimens
2. At a minimum, the participant shall screen for the presence or absence of malaria parasites in the specimens

5.7.5. Complete blood count (CBC) scheme

1. The Panel shall include specimens with abnormal low, normal and abnormal high parameters.
2. The parameters to be analyzed and reported include;
 - White blood cell Count (WBC)
 - Red blood cell count (RBC)
 - Haemoglobin (HGB)
 - Haematocrit (HCT)
 - Mean Cell Volume (MCV)
 - Mean Cell Haemoglobin (MCH)
 - Mean Cell Haemoglobin Concentration (MCHC)
 - Red Cell Distribution Width Standard Deviation (RDW-SD)
 - Red Cell Distribution Width Coefficient of Variation (RDW-CV)
 - Platelet Count (PLT)

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5.7.6. CD4 Count scheme

1. The Panel shall include specimens with abnormal low, normal and abnormal high CD4 counts.
2. The participant shall measure the CD4 count in each specimen from the PT panel

5.7.7. Malaria microscopy PT scheme

1. The Panel shall include malaria positive and malaria negative thin smears
2. The positive thin smears shall have different parasite densities and different malaria species
3. At a minimum, the participant shall examine the thin smears and report on;
 - Presence or absence of malaria parasites
 - Differentiation of malaria species i.e. falciparum and other species (Ovale, malariae and Vivax) for all malaria positive slides
 - Parasite density/count for all malaria positive slides

5.7.8. Blood Grouping PT scheme

1. The Panel shall include blood samples that are either carry any of the ABO and rhesus antigens or do not carry any of the antigens
2. At a minimum, the participant shall check for agglutination and determine the blood group of all the blood samples in the panel and also determine its Rhesus status

5.7.9. Blood Cross Matching PT scheme

1. The Panel shall include blood samples that are either compatible or not compatible with the plasma/serum sample that will be included in the Panel
2. At a minimum, the participant shall check for agglutination of the blood samples with the plasma/serum sample provide and determine the blood samples are compatible with the plasma/serum provided

5.7.10. Hemoglobin Estimation PT scheme

1. The Panel shall include blood samples with different hemoglobin ranges from very low to very high.
2. The participant shall estimate the hemoglobin in each sample from the PT panel

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5.8.Sources of errors in PT schemes

1. Use of expired Kits
2. Testing of Dry tube specimens that are poorly reconstituted.
3. Delay in testing of Reconstituted specimens (HIV-1 EID and HIV-1 VL)
4. Use of equipment that are not serviced or maintained
5. Testing of the PT on wrong testing kits or Assays.
6. Not following the instructions provided with the PT panels and by the Manufacturer for any assays

5.9.Requirements for production, Quality control, storage and distribution of PT materials

5.9.1. Requirements for PT Production

5.9.1.1.HIV-1 EID, HIV-1 VL, mRDT and HBV

- Trained Laboratory staff
- A laboratory with the necessary space and equipment to prepare the proficiency testing panels already in place;
- 2ml Cryo tubes
- Biosafety Cabinet
- 20ml Pipettes
- Falcon Tubes
- Cryoboxes
- Food dye
- Phosphate buffered saline (PBS 1X)
- Barcode printer

5.9.1.2. CBC, CD4, Blood grouping, Blood cross matching and Hemoglobin Estimation

- Trained Laboratory staff
- A laboratory with the necessary space and equipment to prepare the proficiency testing panels already in place;
- Whole blood Stabilizing reagents
- Biosafety Cabinet

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- Whole blood sample transportation tubes (Red tops)
- Magnetic stirrers
- Weighing balance
- Barcode printer

5.9.1.3. Malaria Microscopy

- Trained Laboratory staff
- A laboratory with the necessary space and equipment to prepare the proficiency testing panels already in place;
- SP50 (Slide preparation Unit) with all its reagents and consumables
- Slide mailers
- Slide boxes

5.9.2. Samples required

1. HIV-1 EID PT: HIV-1 negative and HIV-1 positive (High viral load titers) plasma samples from the Biorepository
2. HIV-1 VL PT: HIV-1 negative and HIV-1 positive (High viral load titers of different ranges) plasma samples from the Biorepository
3. HBV serology PT: HBV negative and HBV positive plasma samples from the Biorepository
4. mRDT PT: malaria negative and malaria positive blood samples from the Biorepository
5. CBC, CD4, Blood grouping, Blood cross matching and Hemoglobin Estimation: HIV negative, syphilis negative and Hepatitis B negative whole blood from the blood bank
6. Malaria Microscopy: malaria negative and malaria positive blood samples from the Biorepository

5.9.3. Requirements for PT Quality control

1. HIV-1 EID PT: Prepared DTS, PBS, 1ml Pippete, vortexer, platform for testing (GeneXpert, mPima or Cobas.)

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2. HIV-1 VL PT: Prepared DTS, PBS, 1ml Pippete, vortexer, platform for testing (GeneXpert, mPima, Cobas or Abbott)
3. HBV serology PT: Prepared DTS, PBS, 1ml Pippete, vortexer, Hepatitis B screening kits
4. Malaria RDT PT: Prepared DTS, PBS, 1ml Pippete, vortexer, malaria RDT screening kits
5. CBC: prepared whole blood PT, shaker and CBC platforms. (Sysmex XN 330 and XN 31), CBC platforms reagents
6. CD4: Prepared whole blood PT, shaker, CD4 cartridges for either BD FACSPresto or Alere Pima
7. Malaria Microscopy: Prepared thin smear slides. (Completely stained), emulsion oil, tally counter and a light microscope.
8. Blood Grouping: Prepared whole blood PT, shaker, Antisera (Anti A, Anti B, Anti AB and Anti D), 1ml Pasture Pippetes and a white tile.
9. Blood Cross matching: Prepared whole blood PT, Prepared Plasma/Serum sample shaker, 1ml Pasture Pippetes and a white tile.
10. CBC: prepared whole blood PT, shaker and Hemoglobin Estimation platforms. (Sysmex XN 330, XN 31 HB Meters) and their Accompanying reagents

5.9.4. Requirements for PT panel storage

- Cryo boxes
- Laboratory working bench/biosafety cabinet
- Fridge
- Slide boxes for malaria slides

5.9.5. Requirements for PT panel distribution

- Sample transport drivers (HUB system)
- Prepared PT panels
- A4 envelopes
- A5 envelopes
- Markers
- List of Participants

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- Printer and printing Paper
- Participant instructions for use forms
- Result reporting form

5.10. Precautions to prevent collusions

1. Participant results must be submitted within the PT cycle.
2. A control specimen is included in the HIV-1 qualitative PT scheme and HBV serology scheme to avoid falsification of results.

5.11. Information Provided to participants

1. Results reporting template with information on submission of results
2. PT schedule highlighting the Number of specimens per PT panel sent in the Package, the date of PT panel Dispatch, results submission date and date for return of feedback

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3. The participant is provided with the following information in the instructions for use forms;
 - Type of proficiency testing materials
 - Contents of the package
 - Handling of the specimen
 - Specimen preparation and testing
 - Results reporting information
 - Contact details in cases of queries on the PT scheme

5.12. Homogeneity and stability of PT items

1. Stability studies have been done for all the analytes using Dry tube specimens to ascertain the stability of the Panels. The panels are stable at room temperatures and thus are transported at room temperature.
2. The PT provider has ensured that the PT items` homogeneity and stability is maintained.
3. This has been done through internal quality control procedures which included homogeneity and viability tests.

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5.13. Standardized reporting format for all Participants.

1. All reports bear the scheme name i.e.
 - Hepatitis B serology PT scheme report
 - HIV-1 EID PT scheme report
 - HIV-1 viral load PT scheme
 - Malaria RDT PT scheme
 - Complete Blood Count (CBC) PT scheme
 - CD4 Count PT scheme
 - Malaria Microscopy (Thin smears) PT scheme.

2. All reports have the same information as mentioned below;
 - the name and contact details for the proficiency testing provider;
 - the name and contact details for the coordinator;
 - the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the report;
 - an indication of which activities are subcontracted by the proficiency testing provider;
 - the date of issue and status (e.g., preliminary, interim, or final) of the report;
 - page numbers and a clear indication of the end of the report;
 - a statement of the extent to which results are confidential;
 - the report number and clear identification of the proficiency testing scheme;
 - a clear description of the proficiency test items used, including necessary details of the proficiency testitem's preparation and homogeneity and stability assessment;
 - the participants' results;
 - statistical data and summaries, including assigned values and range of acceptable results and graphical displays;
 - procedures used to establish any assigned value;
 - details of the metrological traceability and measurement uncertainty of any

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assigned value;

- procedures used to establish the standard deviation for proficiency assessment, or other criteria forevaluation;
- assigned values and summary statistics for test methods/procedures used by each group of participants(if different methods are used by different groups of participants);
- comments on participants' performance by the proficiency testing provider and technical advisers;
- information about the design and implementation of the proficiency testing scheme;
- procedures used to statistically analyse the data;
- advice on the interpretation of the statistical analysis; and
- comments or recommendations, based on the outcomes of the proficiency testing round.

Note 2: The stamp date on all final PT reports shall be the Approval date and the date of issue of the PT reports

5.14. Interim Reports

1. No interim reports shall be provided to participants.
2. Only Final approved reports shall be provided to participants

5.15. Description of Statistical analysis to be used

5.15.1. HIV-1 qualitative/EID and HBV serology PT schemes

1. A scoring system shall be used basing on the assigned results obtained from patient samples of known results obtained by testing on validated methods and further validated by homogeneity tests done prior to packaging and dispatch of PT panels to participants and an overall performance score generated as below

- **Scoring**

- I. A score of **C** (Certified) shall be assigned when all the panels supplied are correctly identified. I.e., when all negative panels are negative and when all positive panels are positive. There must be no false negative result, no false positive result and no indeterminate result.
- II. A score of **PC** (Provisionally certified) shall be assigned if the results include one false negative or one indeterminate outcome.

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- III. A score of **P** (Poor/Failed) shall be assigned for;
- One false positive,
 - At least two false negatives,
 - At least two indeterminate outcomes or a combination of at least one false negative, at least one false positive and one indeterminate result.
 - if the control has not passed irrespective of the outcome of the other panel members.
- IV. Panel results are considered invalid and a final score of **P** is given if the control in the panel round has not passed.
3. Overall performance scoring of each Participant
1. An overall performance score of “**satisfactory**” is assigned when the participant scores a “**C**” or “**PC**”
 2. An overall performance score of “**Unsatisfactory**” is assigned when the participant scores
 3. A grading of “**Ungraded**” is assigned when the participant has not submitted PT results.
 4. This is detailed in SOPs PT014(I) for HIV-1 EID PT and PT014(K) and for HBV PT
- 5.15.2. Malaria RDT PT scheme
1. A scoring system shall be used basing on the assigned results obtained from patient samples of known results obtained by testing on validated methods and further validated by homogeneity tests done prior to packaging and dispatch of PT panels to participants and an overall performance score generated as below
 2. A grading system shall be used as below;
 - I. A score of **20** is awarded for any result reported correctly
 - II. A score of **0** is awarded for any result that is incorrectly reported
 - III. An overall score is generated by addition of all the individual participant scores for every result submitted
 3. Overall performance scoring of each Participant
 - A grading of “**satisfactory**” is assigned when the participant overall score is $\geq 80\%$

DESIGN OF PROFICIENCY TESTING SCHEMES FOR HIV-1 QUALITATIVE ASSAYS, HIV-1 QUANTITATIVE ASSAYS, MALARIA RDT, HEPATITIS B SEROLOGY ASSAYS, CD4 COUNT, COMPLETE BLOOD COUNT (CBC), MALARIA MICROSCOPY, BLOOD GROUPING, BLOOD CROSS MATCHING AND HEMOGLOBIN ESTIMATION PT SCHEMES

- A grading of “**Unsatisfactory**” is assigned when the participant overall score is < **80%**
- A grading of “**Ungraded**” is assigned when the participant has not submitted PT results.

4. This is detailed in SOP PT014(L)

5.15.3. Complete blood count (CBC) , CD4, HIV-1 Quantitative/Viral load and HB Estimation PT schemes

1. A robust analysis of Participant results basing on the Hampel’s method is used to obtain the participant consensus Robust mean and Robust Standard deviation and to remove outliers.
2. These shall be used to compute for Z scores and obtaining overall participant performance as below

$$Z \text{ score} = (\text{participant result} - \text{robust mean}) / \text{Robust SD}$$
3. Measurement Uncertainty of the Robust consensus mean shall be computed.
4. Interpretation of results for each panel ID
 - A grade of Acceptable is assigned when $|z| \leq 2$
 - A grade of Warning is assigned when the $2 < |z| < 3$
 - A grade of Unacceptable is assigned when $|z| \geq 3$
5. An overall score of “**satisfactory**” is assigned if;
 - The participant was graded with “Acceptable” in all specimen IDs in the PT round
 - The participant was graded at most one “unacceptable” or “warning” result in the PT round
6. An overall score of “**unsatisfactory**” is assigned if;
 - The participant has at least two “Unacceptable” or “warning” results in the PT round
 - The participant has a combination of Unacceptable” and “warning” results in the PT round.
7. A grading of “**Ungraded**” is assigned when the participant has not submitted PT results.
8. This is detailed in SOP PT014(J) for HIV-1 Quantitative/Viral load, SOP PT014(S) for CBC PT, PT014(T) for CD4 Count PT and PT014(W) for HB estimation

DESIGN OF PROFICIENCY TESTING SCHEMES FOR HIV-1 QUALITATIVE ASSAYS, HIV-1 QUANTITATIVE ASSAYS, MALARIA RDT, HEPATITIS B SEROLOGY ASSAYS, CD4 COUNT, COMPLETE BLOOD COUNT (CBC), MALARIA MICROSCOPY, BLOOD GROUPING, BLOOD CROSS MATCHING AND HEMOGLOBIN ESTIMATION PT SCHEMES

5.15.4. Malaria Microscopy PT scheme

9. Analysis of participant results is as per the table below

PARAMETER	Expected Result	Lab results	SCORE
DETECTION	Present	Present	10
	Absent	Absent	20
	Blank/Invalid	BLANK/INVALID	0
IDENTIFICATION	P.Falciparum and others present	P.Falciparum and others present	5
		Only. P.falciparum present	2.5
		Other species present	2.5
		No species Identified	0
	Only.P.falciparum present	Only. P.falciparum present	5
		Other species present	0
		P.Falciparum and others present	0
		No species Identified	0
QUANTIFICATION	Density range	Within range	5
		Outside the range	0
Total Score Per ID		20	
Overall Score		100	
Satisfactory Performance		≥ 80%	
Unsatisfactory Performance		≤80%	
Ungraded		No Results submitted	

10. This is described in SOP PT014(U)

5.15.5. Blood Grouping PT scheme

1. Analysis of participant results is as per the table below

Variable	Lab results	Score
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DESIGN OF PROFICIENCY TESTING SCHEMES FOR HIV-1 QUALITATIVE ASSAYS, HIV-1 QUANTITATIVE ASSAYS, MALARIA RDT, HEPATITIS B SEROLOGY ASSAYS, CD4 COUNT, COMPLETE BLOOD COUNT (CBC), MALARIA MICROSCOPY, BLOOD GROUPING, BLOOD CROSS MATCHING AND HEMOGLOBIN ESTIMATION PT SCHEMES

Blood grouping	Correct Agglutination Result	4
	Incorrect Agglutination Result	0
	No Result	0
	Total Agglutination results per ID	16
Blood Type	Correct Blood type	4
	Incorrect Blood type	0
	No result	0
Total Results per Sample ID		20
Overall Score		100
Satisfactory Performance		≥ 80%
Unatisfactory Performance		≤80%
Ungraded		No Results submitted

2.This is described in SOP PT014(X)

5.15.6. Blood Cross Matching PT scheme

1.Analysis of participant results is as per the table below

Variable	Lab results	Score
Cross Matching	Correct Agglutination Result	10
	Incorrect Agglutination Result	0
	No Result	0
Compatibility result	Correct Compatibility Result	10
	Incorrect Compatibility Result	0
	No result	0
Total Results per Sample ID		20
Blood Group of Plasma distributed for Cross Matching		
Overall Score		100
Satisfactory Performance		≥ 80%
Unatisfactory Performance		≤80%

DESIGN OF PROFICIENCY TESTING SCHEMES FOR HIV-1 QUALITATIVE ASSAYS, HIV-1 QUANTITATIVE ASSAYS, MALARIA RDT, HEPATITIS B SEROLOGY ASSAYS, CD4 COUNT, COMPLETE BLOOD COUNT (CBC), MALARIA MICROSCOPY, BLOOD GROUPING, BLOOD CROSS MATCHING AND HEMOGLOBIN ESTIMATION PT SCHEMES

Ungraded	No Results submitted
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2. This is described in SOP PT014(Y)

5.16. Assigned Values used for grading of Participants

1.HIV-1 qualitative/EID, HBV serology, Malaria RDT, Blood Grouping and Blood Cross Matching PT schemes

- Assigned/expected results from patient samples of known results used are used. These shall be obtained by testing on validated/verified methods and further validated by homogeneity tests done prior to packaging and dispatch of PT panels to participants

2.HIV-1 Quantitative/Viral load PT scheme

- Assigned values are obtained using the Robust Consensus mean and Standard deviation obtained from participants that have submitted results for a particular PT sample in a PT round.
- These are computed from all participant results irrespective of platform used.

3. CBC, CD4 and Hemoglobin Estimation PT schemes

- Assigned values are obtained using the Robust Consensus mean and Standard deviation obtained from participants that have submitted results for a particular PT sample in a PT round.
- These are computed from all participant results irrespective of platform used.

4.Malaria microscopy PT scheme

- Assigned/expected results from patient samples are used for parasite detection and species differentiation parameters. These are obtained by analysis of slides by at least 3 competent staff and validated by homogeneity tests done prior to packaging and dispatch of PT panels to participants.
- Assigned values for Parasite density are obtained using the Parasite density range computed from the Homogeneity parasite density counts. The range are obtained by using the mean density obtained during homogeneity

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- Parasite density range are computed by mean \pm (25% of the mean).

Note: In case the robust mean and SD is to computed platform used for quantitative assays, The PT coordinator shall communicate to the scheme manager for approval with reasons why.

5.17. Minimum number of participants for Data analysis

- For all quantitative PT (CBC, CD4, Hemoglobin Estimation and Viral load) schemes, a minimum of 10 participants shall be required for data analysis.
- For all qualitative PT schemes (EID, mRDT, HBV, Blood Grouping, Blood Cross matching and microscopy), a minimum of 5 participants shall be required for data analysis.

5.18. Evaluation of Participant Performance

For all schemes, the following are evaluated.

1. Response rate: The acceptable response rate shall be $\geq 80\%$
2. Pass rate: The acceptable pass rate shall be $\geq 80\%$

5.19. Confidentiality of PT schemes Information

- All participant information including results, performance among others will be treated as confidential unless otherwise stated.
- All Final reports shall bear only the identity and name of laboratories participating in the PT scheme for purposes of improving performance and implementation of the schemes by the Implementing partners.
- Participant information shall be disclosed to the public only if a waiver is signed by the participant.

5.20. Use of Reports by participants and Customers

PT reports are issued solely to the participating laboratory and are intended for internal quality assurance purposes. Participants may share their reports with accreditation bodies or regulatory

Initials authorizer:

DESIGN OF PROFICIENCY TESTING SCHEMES FOR HIV-1 QUALITATIVE ASSAYS, HIV-1 QUANTITATIVE ASSAYS, MALARIA RDT, HEPATITIS B SEROLOGY ASSAYS, CD4 COUNT, COMPLETE BLOOD COUNT (CBC), MALARIA MICROSCOPY, BLOOD GROUPING, BLOOD CROSS MATCHING AND HEMOGLOBIN ESTIMATION PT SCHEMES

authorities as evidence of participation and performance. PT reports or results shall not be used for marketing, advertising or public comparison without written consent from the provider

5.21. Dispatch of PT panels, PT reports and Extension of the PT round

- PT panels shall be dispatched to participants as per the PT schedule PT008F1. The dispatch of Panels shall not exceed 7 days (1 week) from the expected date of dispatch
- Participant PT feedback reports shall be sent to participants as per the PT schedule PT008F1. The distribution of feedback reports shall not go beyond 7 days (1 week) from the expected date of the report distribution
- The PT coordinator in consultation with the PT scheme manager may extend the PT round due to unforeseen factors such as delay in delivery of PT panels, facilities requesting for replacements panels, participants requests for extension among others but the extension shall not exceed 2 weeks from the date the participants are expected to submit their results

5.22. Actions taken for damaged or Lost PT items

In case of damage, missing items in the package or specimens lacking labels, reject the package and request for a replacement package using the contact details provided in the instructions for used documents.

5.23. Access to technical Expertise

The laboratory shall have access to the necessary technical expertise and experience in the relevant fields of the PT schemes including PT preparation, homogeneity and stability testing as well data analysis when required.

The technical expertise shall not be limited to;

1. PT scheme planning.
2. Identification and resolution of issues due to stability, homogeneity and obtaining of assigned/consensus values
3. Preparation of participant information
4. Solving of technical difficulties raised by participants.
5. Advise on evaluation of participants performance and data analysis

6.0. Related documents

DESIGN OF PROFICIENCY TESTING SCHEMES FOR HIV-1 QUALITATIVE ASSAYS, HIV-1 QUANTITATIVE ASSAYS, MALARIA RDT, HEPATITIS B SEROLOGY ASSAYS, CD4 COUNT, COMPLETE BLOOD COUNT (CBC), MALARIA MICROSCOPY, BLOOD GROUPING, BLOOD CROSS MATCHING AND HEMOGLOBIN ESTIMATION PT SCHEMES

PT014(I): Data management for HIV-1 qualitative/EID PT scheme.

PT014(J): Data management for HIV-1 quantitative/viral load PT scheme.

PT014(K): Data management for Hepatitis B serology PT scheme.

PT014(L): Data management for malaria RDT (mRDT) PT scheme.

PT014(S): Data management for Complete Blood Count (CBC) PT scheme.

PT014(T): Data management for CD4 Count PT scheme.

PT014(U): Data management for malaria microscopy PT scheme using thin smears.

PT014(W): Data management for Hemoglobin Estimation PT scheme.

PT014(X): Data management for Blood Grouping PT scheme.

PT014(Y): Data management for Blood Cross Matching PT scheme.

9. Related forms

PT008F1: PT schedule for participating laboratories

PT010AF1: Participant Enrolment form

10. References

ISO 17043:2023 standard

ISO 13528:2022 standard

CLSI Guidelines GP2A3

GCLP guidelines

WHO manual for Preparation of EQA materials (2016)

11. Attachments / Annexes

N/A

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DESIGN OF PROFICIENCY TESTING SCHEMES FOR HIV-1 QUALITATIVE ASSAYS, HIV-1 QUANTITATIVE ASSAYS, MALARIA RDT, HEPATITIS B SEROLOGY ASSAYS, CD4 COUNT, COMPLETE BLOOD COUNT (CBC), MALARIA MICROSCOPY, BLOOD GROUPING, BLOOD CROSS MATCHING AND HEMOGLOBIN ESTIMATION PT SCHEMES
