Guidelines for External Quality Assessment (EQA) of HIV Serology Testing Using Dried Tube Specimen (DTS) Proficiency Panels

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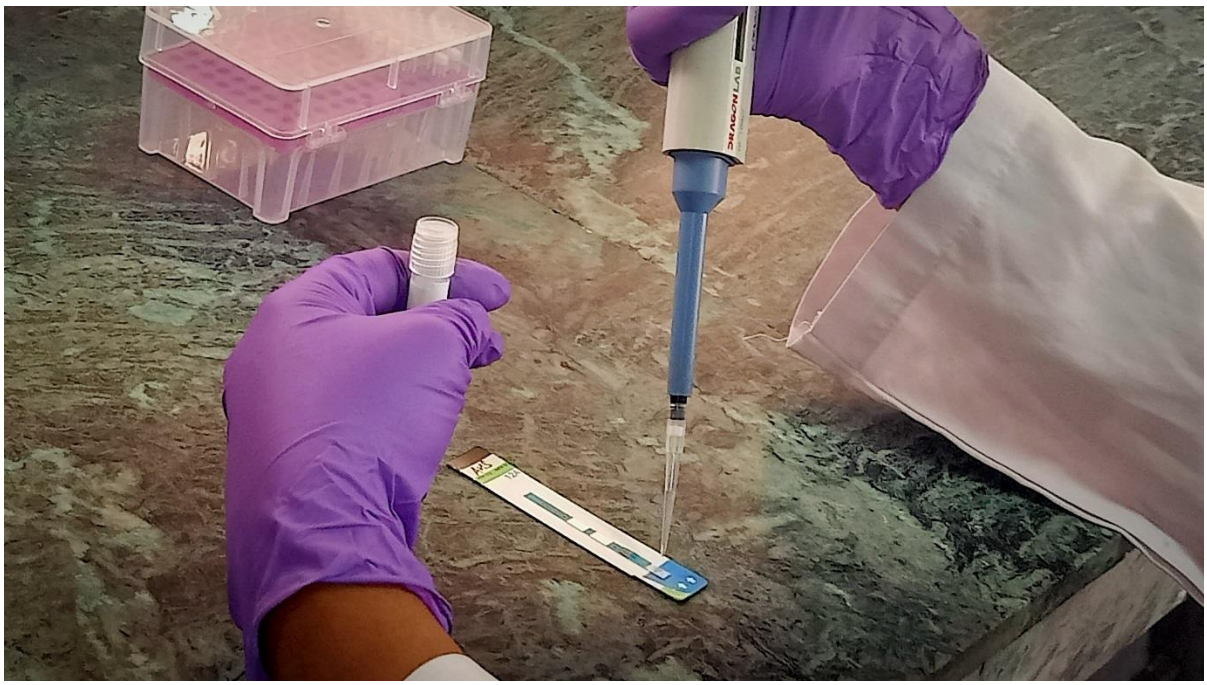

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Ministry of Health & Population
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FOREWORD

According to National HIV Estimates (NCASC, 2019), there are 29,503 people living with HIV in Nepal with an adult HIV prevalence (15-49 years) of 0.13%. Nepal is considered as a country with concentrated HIV epidemic with low prevalence of HIV in general population but higher HIV prevalence in key populations such as Female Sex Workers (FSW), Men having sex with Men and Transgender (MSM/TG), People who Inject Drugs (Male and Female), Male Labor Migrants (MLM) and their spouses, and Clients of Sex Workers (CSW).

The national HIV program has accepted the challenges of fast-tracking towards ending the AIDS epidemic as a public health threat by 2030. Laboratory services have central role in achieving all the targets set by the National HIV Strategic Plan. Quality assured HIV diagnostic services are key to HIV diagnosis and treatment according to the National HIV Testing and Treatment Guidelines and to achieve the targets set by the strategic plan.

HIV cases in Nepal are diagnosed following the National HIV Testing algorithm which utilizes combination of rapid diagnostic test (RDTs) prequalified by World Health Organization (WHO). Though all laboratory quality system essentials need to be in place to ensure quality of HIV diagnosis, external quality assessment (EQA) provides an objective evidence for quality of HIV testing under the national HIV program. EQA also helps identifying errors, improvement areas and training needs for HIV testing sites. National Public Health Laboratory (NPHL) jointly with National Center for AIDS and STD Control (NCASC) and Provincial Public Health Laboratories (PPHLs) has decided to implement proficiency panel (PT) testing using dried tube specimens (DTS) for EQA of HIV testing under the national HIV program. This document provides guidance for National HIV Reference Laboratory, PPHLs and HIV testing centers for successfully organizing and implementing HIV EQAS program. We expect that this guideline will help national HIV reference laboratory and PPHLs for enrolment of all HIV testing sites to the HIV EQAS program.

We would like to thank NSCAC, PPHLs, WHO, Save the Children – Global Fund, FHI360/EpiC Nepal and technical experts for contributing to the development and finalization of this important guideline.

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Acronyms and abbreviations

AIDS	Acquired Immunodeficiency Syndrome
CPD	Citrate Phosphate Dextrose
CPDA	Citrate Phosphate Dextrose Adenine
DBS	Dried Blood Spot (specimen)
DTS	Dried Tube Specimen
EDTA	Ethylene Diamine Tetra-acetic Acid
EIA	Enzyme Immuno-Assay
ELISA	Enzyme-linked immunosorbent assay
EQA	External Quality Assessment
FFPE	Formalin-fixed Paraffin embedded
HIV	Human Immunodeficiency Virus
ISO	International Organization for Standardization
MOH	Ministry of Health
MOSD	Ministry of Social Development.
MRSA	Methicillin resistant *Staphylococcus aureus*
NAT	Nucleic Acid testing
NCASC	National Center for AIDS and STD Control
NEQAS	National External Quality Assurance Scheme
NPHL	National Public Health Laboratory
PBS	Phosphate Buffered Saline
PCR	Polymerase Chain Reaction
PPHL	Provincial Public Health Laboratory
PT	Proficiency Testing
POC	Point of Care
QC	Quality Control
RDT	Rapid diagnostic test
R&D	Research and Development
SD	Standard Deviation
STD	Sexually Transmitted disease
TOT	Training of Trainers
WHO	World Health Organization

Contents

1. Introduction

Quality assured diagnosis of HIV is crucial for national HIV program as appropriate care and treatment of people living with HIV (PLHIV) primarily depends on the accurate diagnosis of HIV. Quality assured testing is also key to successful implementation of HIV prevention interventions. In Nepal, diagnosis of HIV is principally done through HIV serological testing. A national HIV testing algorithm has been developed and implemented for the diagnosis of HIV.[1] Rapid HIV antibody detection test kits prequalified by World Health Organization (WHO) are used for diagnosing HIV following the national HIV testing algorithm. Basic and refresher trainings and intermittent monitoring and supervision visits are conducted from different levels to ensure the quality of rapid HIV testing. However, not all HIV testing sites in Nepal have yet been successfully enrolled to the national External Quality Assessment (EQA) scheme for HIV serology testing.

The term "External Quality Assessment (EQA)" is used to describe a method/process that allows testing conducted by a laboratory, testing site or individual user to be compared to that of a source outside the laboratory – of a peer group of laboratories or a reference laboratory or a testing site. Successful participation of a testing site in an EQA program provides objective evidence of the competence of testing service for customers, accrediting bodies and regulatory agencies, and serves as a unique source of information that is not easily obtainable in other ways. Importantly, participation in an EQA program allows for a "peer-review" process towards solving technical and methodological problems to improve the quality of service for each individual testing site as well as to achieve comparability of results among different testing services. For accrediting bodies and regulatory agencies, EQA provides objective data on the quality of delivered services and has been shown to reflect the quality of testing of patients' specimens. [2]An EQA program may be organized on a sub-national, national, regional or international basis. National EQA programs are effective for most performed assays and are very useful in providing data on the accuracy of testing.

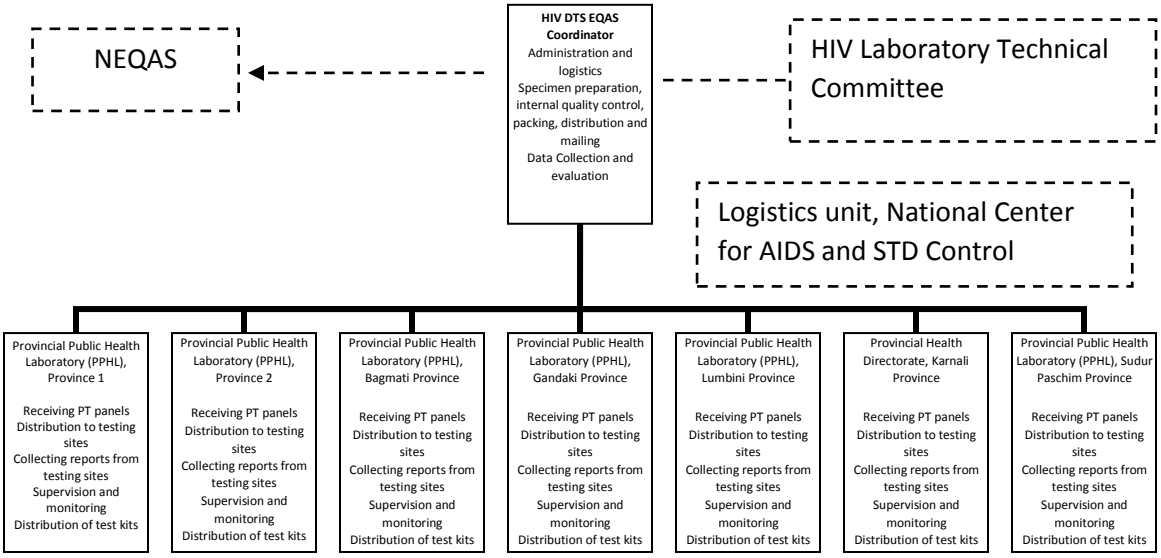
This document provides guidance to the laboratories of different levels for organizing and implementing the EQA of HIV testing in Nepal using Dried Tube Specimens (DTS) proficiency testing (PT).

Proficiency testing may be commercially acquired or locally prepared. The choice of materials is usually guided by availability, as well as by funding, human resources, the expertise required to prepare the items locally, and the number of participating testing sites.

1. National HIV testing and Treatment Guidelines, National Center for AIDS and STD Control (2020)

[2] https://www.who.int/diagnostics_laboratory/guidance/160622_eqa_manual_2016.pdf

2. Structure of the HIV DTS EQAS organizing center at NPHL



3. Establishment and implementation of the HIV DTS PT panel serology EQA

3.1 Identification of HIV testing sites recognized by the National HIV program

The HIV EQAS unit of NPHL obtains an updated list of HIV testing facilities for each province. The list will include only those healthcare facilities which perform HIV confirmatory testing following national HIV testing algorithm. A unique identifier will be provided to each HIV testing site for the purpose of EQAS which will use DTS as proficiency panels, commonly called DTS EQAS hereafter.

3.2 Supplies required for HIV DTS EQAS

Supplies required for national HIV DTS EQAS will be included in national HIV commodities forecasting and quantification. However, to initiate the proficiency testing as earlier as possible, first lot of proficiency panels will be prepared and distributed with the commodities available at NPHL.

3.3 Frequency of proficiency testing rounds

Proficiency panels will be dispatched to HIV testing sites twice a year.

3.4 Number of samples for each proficiency testing round

Each round of proficiency panels will comprise five blinded samples. Of five blinded samples, HIV EQAS unit of NPHL will determine the number of known positive and number of known negative samples to be included in each round of the PT panels.

EQAS unit of NPHL will prepare a panel package consisting of a validated panel of five blinded samples for each HIV testing site following the standard guidance provided in the section 10 of this document. Each proficiency panel package will contain an instruction sheet and a form to record the results.

3.5 Packaging

The following materials are required for packaging the DTS-PT panels.

a. Panel of five blinded dried tube specimens
b. 2 ml tube with Tween 20 phosphate buffer
c. Small zip-lock bags
d. Large zip lock bags
e. Bubble envelope
f. Instruction sheet
g. Reporting form
h. Parafilm tape

Each proficiency panel package will be prepared according to the following procedures.

1. Each DTS will be kept separately in a small plastic zip-lock bag.
2. Tube with Tween 20 phosphate buffer will also be sealed in another small plastic zip-lock bag.
3. All small zip-lock bags with DTS and Tween 20 phosphate buffer will be further kept in a larger plastic zip-lock bag, based on number of sample requirement, sample containing larger zip lock bag will be kept in a bubble envelop.
4. An instruction sheet and a reporting form will also be kept in the same envelope.
5. The envelope will be labelled with the address of the respective PPHL. The number envelopes in the package depends on the number HIV testing sites in a province

3.6 Shipment

Proficiency panels will be dispatched from NPHL to PPHLs (in case of Karnali province, to Provincial Health Directorate) through courier. A courier agent designated by NPHL for transporting the proficiency test items will be engaged to work with the EQA organizer to ensure timely dispatch and delivery of the items.

3.7 Dates of mailing of proficiency test items

The PT panels will be dispatched from NPHL to each PPHL by the first week of Ashwin and the second lot will be dispatched by the first week of Chaitra in a year.

4. Role of Provincial Public Health Laboratory (PPHL)

From Provincial Public Health Laboratory (PPHL), the panels will be distributed to peripheral HIV testing sites at room temperature within one week of sample arrival. Resource needs to be allocated by PPHL to ensure the transportation of the panels to the peripheral testing sites. The panels need to be tested by the testing sites within the deadline specified by NPHL of the shipment of the panels.

5. EQA Documents

Letter sent by NPHL to PPHL: Letter format from NPHL to PPHL is added in Annex-1.

Address labels: Address labels with name and address of the participating sites are prepared by respective PPHL.

Instructions and process checklist: Participants will receive adequate instructions regarding proficiency test item characteristics and handling requirements, procedures for recording results, process for returning results and due date. Relevant notes and instructions, biohazard warnings, storage requirements, reconstitution method, recommended method for disposal. Instruction and process checklist is added in Annex-2.

Form to record results by the peripheral HIV testing sites: Participants will be provided with a sheet to record results. Data such as participant reference number, batch number, proficiency test item(s) number(s), test method will be included in the form. The unique identifier of the participating laboratory will be placed on all recording forms; this will be confidential to the participant and the EQA organizing center and not divulged to any third party. Report format for testing site is added in Annex-3

Performance report from NPHL to HIV testing sites: Participants will be provided the evaluation result of their individual performance after the submission of their result. Performance report format is added in Annex-4.

6. EQAS reporting mechanisms

Participating laboratories will send the PT results recording form back to the concerned PPHL (in case of Karnali Province, to the Provincial Health Directorate) within a week of the receipt of the proficiency panels.

PPHL will review the completeness of the PT results record forms received from all the HIV testing sites and send them to NPHL by the end of next week through email/fax/courier.

NPHL will analyze the results received from all the laboratories and send the EQAS reports for all participating HIV testing sites to PPHL within one month of receiving the reports from PPHL.

PPHL will send the reports received from the NPHL to participating HIV testing sites within a week of the receipt of the reports from NPHL.

7. Training

ToT for PPHL laboratory officials and MoSD focal person will be organized by NPHL.

Provincial training on DTS EQAS will be conducted by PPHL for participating HIV testing sites.

8. Supervision and monitoring

Regular supervision and monitoring of the peripheral HIV testing sites will be conducted by PPHL in coordination with NPHL. In case of any discrepant results, PPHL will conduct an immediate visit to the concerned HIV testing site, investigate to find the possible reasons for the discrepancy and help the site resolve the issue.

9. Establishment and Implementation Plan

	Activities	**Responsible**
1	Finalization of protocol for DTS EQAS	**NPHL/NCASC/WHO/Save the Children - Global Fund/FHI360-EpiC Nepal**
2	Finalization of recording and reporting tools for DTS EQAS	**NPHL/Save the Children - Global Fund/FHI360-EpiC Nepal**
3	Procurement of consumables and supplies required for DTS EQAS	**NCASC/Save the Children - Global Fund**
4	Training of Trainers (ToT) for PPHL and MoSD officials	**NPHL**
5	Provincial training for participating laboratories	**PPHL**
6	Shipment of DTS panels to PPHLs through air courier	**NPHL/NCASC**

7	Distribution of DTS panels to participating sites by PPHLs	**PPHL**
8	Testing of the panels by participating HIV testing sites	**HIV testing sites.**
9	Reporting the results to PPHL by peripheral HIV testing site	**HIV testing sites**
10	Compilation and review of the reports by the PPHL	**PPHL**
11	Sending the compiled reports to NPHL by PPHL	**PPHL**
12	Analysis of the reports received from PPHL by NPHL	**NPHL**
13	Preparation of EQA feedback report for each site	**NPHL**
14	Sending the feedback reports to PPHL for distribution	**NPHL**
15	Distribution of the reports to testing sites by PPHL	**PPHL**
16	Immediate onsite monitoring visit by PPHL to the HIV testing site in case of any discrepancy.	**PPHL**

10. Laboratory process for the preparation of dried tube specimen

10.1 Pooling of confirmed positive and negative serum samples

Pooling specimens involves mixing individual specimens together to create a mixed pooled specimen. Pooling has the benefit of extending the volume of material while seeking to maintain the reactivity of key constituents in the specimens contributing to the pool. Sometimes, pooled negative sera or plasma can show an increased tendency to false reactivity. Therefore, pooled materials, whether they are negative or positive, will be retested following HIV testing guideline before specimen dispatch.

10.2 Heat inactivation of pooled samples

The specimens used as proficiency test items will be inactivated to reduce the risk of contamination/infection of handlers. The heat inactivation process using a water bath at 56°C

for 60 minutes is adequate to inactivate. HIV negative specimens will not be heat-inactivated as this may cause false positive reactions EQA panels will be handled as potentially infectious, and all precautions required for handling potentially infectious blood specimens will be observed (Note: The temperature in the water bath will be monitored with a thermometer throughout the time required for this process).

10.3 Mixing specimen with green dyes

The pooled samples both Positive and Negative samples are mixed with 0.1% (vol/vol) green dye (i.e., food color). The addition of 0.1% green dye does not affect the HIV test results but allows visualization of the colored pellet at the bottom of the tube.

10.4 Filtration

Serum samples will be filtered using either vacuum or pressure filtration apparatus, in a stepwise reduction of pore size (pre-filter, 0.8 μm and 0.45 μm and a final 0.22 μm). Filtration will remove any micro-particulate matter, ranging from micro-clots to bacterial contamination.

10.5 Labelling and aliquoting samples

Each specimen tube will be labelled with unique sample id, and samples are added to specific tubes Dried tube specimens will be prepared by transferring 20 μL of serum premixed with 0.1% (vol/vol) green dye (i.e., food color), into a 2 mL cryovial. The tubes will be left open in a laminar flow hood at room temperature (18^0–25^0C) overnight to dry.

10.6 Preparation of Tween 20 Phosphate buffer

1) Take 3.8 liters of deionized water and add 1 vial of phosphate buffer power (phosphate buffer solution)
2) Add 1.9 ml of Tween 20 to 3.8 liters of phosphate buffer solution.
3) Mix properly with magnetic stirrer.
4) The following day DTS will be capped and stored at 4^0C until rehydrated prior to testing. Before testing, the DTS will be rehydrated with phosphate buffered saline (PBS) containing Tween 20 (PBS/Tween 20) buffer.

PBS–Tween buffer is prepared, aliquoted in 2 ml volumes to be used as rehydration buffer (also termed PT buffer). A day before testing, a DTS specimen will be rehydrated by adding 200 μL PBS-Tween with a precision pipette.

10.7 Testing of aliquoted samples for reconfirmation

After the sample aliquoting and drying, the sample are reconstituted using tween 20 phosphate buffer for overnight and testing using national HIV testing guideline.

The methodology for preparing DTS of HIV, using characterized serum specimens are summarized in Figure 2.

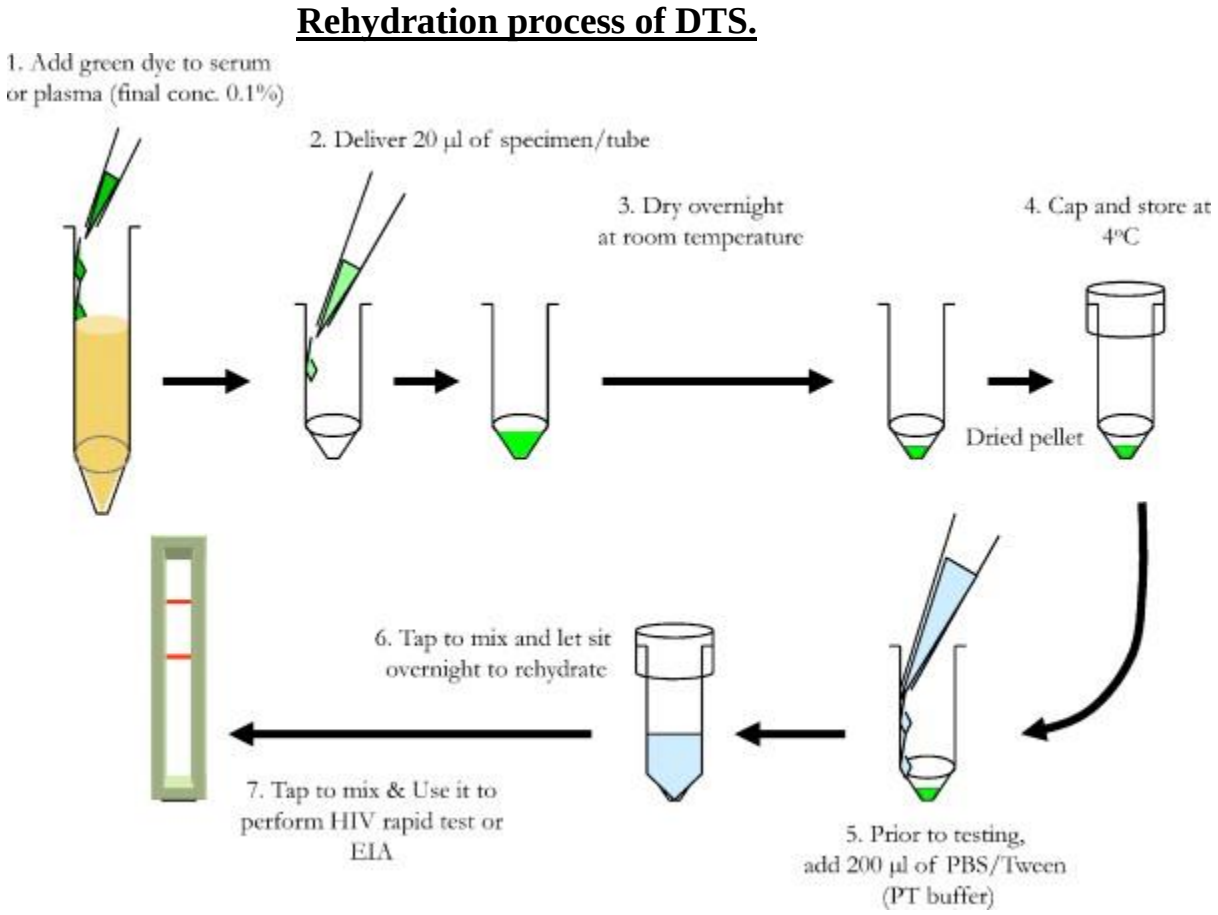


Figure 2: Summary procedures for preparation and testing of DTS specimens

11. Proficiency panel testing at peripheral laboratories and reporting back to reference laboratories

After receiving the PT panels from NPHL, PPHL will check all the inventory and documents to ensure that the DTS sample is properly packaged and dispatched by NPHL. In case of any issues on the samples sent by NPHL, PPHL will record such issues and communicate with NPHL immediately.

Until PPHLs have full-fledged capacity for the diagnosis of HIV and participate in EQA program, they only redistribute the PT-panel to the testing sites. Once the testing site receive the samples, they need to store the samples at 4-8^{0}C until processed for testing and report back to PPHL.

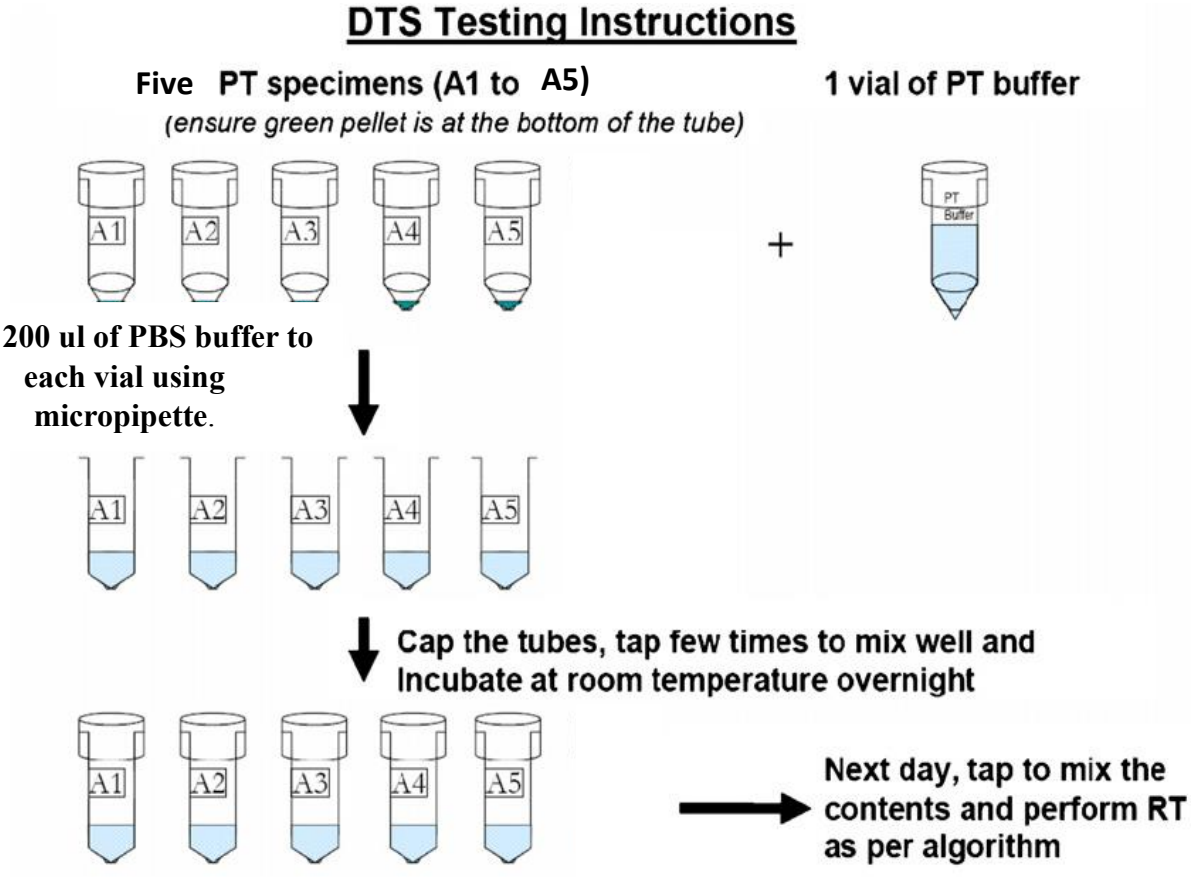


Figure 3: DTS testing instructions

12. Proficiency testing feedback

12.1 Report dispatch timing

All the testing sites must send the report to PPHL within 14 days of receiving panels and PPHL will send the final report by compiling all the reports from the testing sites to NPHL within 15 days.

12.2 Evaluation of results

All samples will be tested in a range of assays to confirm their reactivity.

Evaluations of results reported by participants using the same test method will be grouped for analysis.

Qualitative Evaluation Results reported by participants for assay interpretations and status (where applicable) will be compared with the relevant reference results.

A score of 1 point is allocated for each of three test kits (Determine HIV 1/2, UniGold HIV, and HIV 1/2 Stat-Pak), thus making a total of 4 points for each sample.

- A score of zero point will be given for any incorrectly reported Test.
- A score of zero is also given in case there is no answer/wrong answer or in case of non-participation (NP).

SNO:	Sample ID	Determine1/2 result	Unigold 1/2 result	HIV 1/ 2Statpak result	Final Result
1	A	1 point	1 point	1 point	1 point
2	B	1 point	1 point	1 point	1 point
3	C	1 point	1 point	1 point	1 point
4	D	1 point	1 point	1 point	1 point
5	E	1 point	1 point	1 point	1 point

Table: 1 Point allocation for the individual test result

One batch consists of 5 samples, hence total points for each batch would be 3 test kits x 5 samples= 15, and 5 points for the "final result". A total of 20 points is assigned for the batch result. The points will be expressed in percentage and calculated as obtained points/total points x 100.

12.3 Evaluation of performance

The scores obtained by participating HIV testing laboratories will be summed up and

scored will be calculated to evaluate the performance as below:

Score	Performance status
100%	Excellent performance
90-100%	Need to be improve performance (Action required to troubleshoot the underlying problem)
Less than 90%	Unacceptable performance (Urgent action needed to review the technical competency of the HTC and upgrade the quality of performance)

Table 2: Performance evaluation based on score.

12.4 Assessment for comparison

To assess the performance in comparison with other participant HTCs, the total score, an average score for all HTC and the maximum score obtained by an HTC will be calculated and notified in the feedback report. A laboratory may be excluded from the EQAS for non-participating/non-responding in two successive proficiency panels. Supportive supervision and monitoring will be performed by the NPHL/PPHL to rule out the reason for discontinuation for participation.

13. References:

1.National HIV testing and Treatment Guidelines, National Center for AIDS and STD Control (2020)

2. http://www.who.int/diagnostics_laboratory/160622_eqa_manual_2016_vl.pdf

Annex 1: Letter from NPHL to PPHL

Annex 2: Instruction and processing Checklist

Annex 3: Report format for testing site

Annex 4: Performance report format for NPHL.

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स्वास्थ्य तथा जनसंख्या मन्त्रालय
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राष्ट्रिय जनस्वास्थ्य प्रयोगशाला
टेकू काठमाडौं ।

फोन नं.: ४२५२४२१
फ्याक्स ४२५२३७५

प.सं.:
च.न.

मिति :

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श्री प्रदेश जनस्वास्थ्य प्रयोगशाला, जनकपुर, प्रदेश नं. २
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श्री प्रदेश जनस्वास्थ्य प्रयोगशाला, भैरहवा, लुम्बिनी प्रदेश
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विषय: **DTS EQAS को Sample पठाइएको बारे ।**

प्रस्तुत विषयमा DTS EQAS को **Sample** यसै पत्रसाथ संलग्न राखी पठाइएको छ । उक्त नमुना सम्बन्धीत HIV Testing प्रयोगशालाहरुमा वितरण गरी उक्त परीक्षणको नतिजा **E-mail address ……..** मा पठाई सहयोग गरीदिनु हुन आदेशानुसार अनुरोध छ ।

.....
डा. रुणा झा
निर्देशक

HIV-1/2 Proficiency Testing Program for HIV Serology

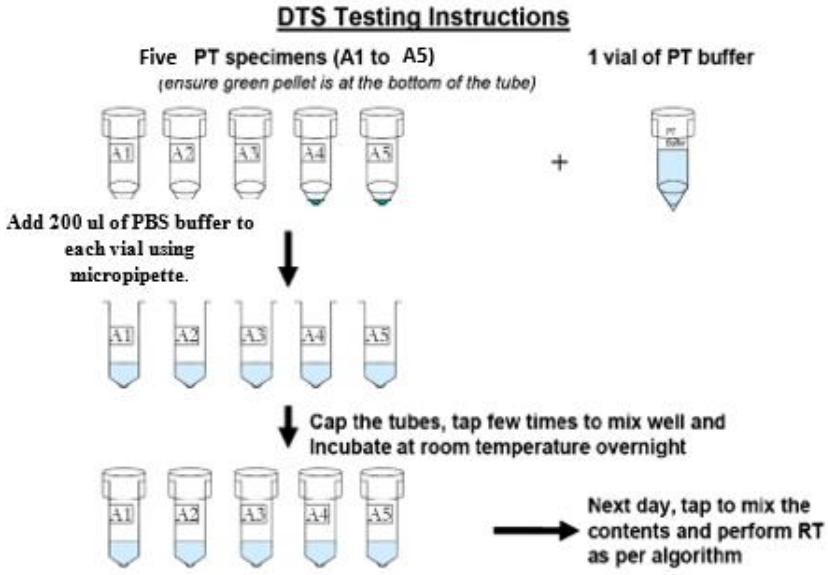
Instructions and process checklist

Upon receipt of PT material inspect each vial closely. If the sample are unacceptable, please notify National Public Health laboratory vial mail……Store PT samples at ambient temperature at 2-30^{0}C until the day of testing.

Checklist:

Please indicate with the date and your initials when PT materials were received. Your PT kit should include.

Initial	Date	Items
		5 vial of DTS samples
		1 vial of PBS buffer
		Instruction check list
		Report form



Result submission: The results for PT panel are due on ……. (date). Submit your PT results via email.

Effective date:

Note: These are clinical samples, kindly consider as biohazard and apply appropriate precaution. Dispose the specimens as infectious waste.

National Public Health Laboratory

Teku, Kathmandu,Nepal

Tel: 01-4252421; Fax: 01-4252375

HIV-1/2 Proficiency Testing for HIV serology

REPORTS

Batch number: DTS-HIV-PT- Serial number

Date samples dispatched from NPHL: **Received date……..(*yyyy/mm/dd)***

Report closing date:

Sample type: Dried Tube Specimen (DTS)

Sample condition ☐ **Acceptable**

☐ **Not acceptable (please specify……)**

Assayed date: **Time:**

	Assay 1: Determine HIV 1/2	**Assay 2: Uni-Gold HIV**	**Assay 3: HIV 1/2 STAT-PAK**	
	Lot no:	**Lot no:**	**Lot no:**	
	Expiry:	**Expiry:**	**Expiry:**	

Rapid HIV test Results

SNO	**Sample ID**	**Assay 1 Result**	**Assay 2 Result**	**Assay 3 Result**	**Final Result**
1					
2					
3					
4					
5					

Name of staff performing test:_____

Participating laboratory/testing site: _____

Address: _____

Phone No: _____ **Fax NO:** _____

Email: _____

National Public Health Laboratory

Performance Report

Laboratory Participant
Sample received Date :
Assayed Date :
Result Deadline:

Assay: **HIV-1/2 Rapid serology(Immunochromatograpy)**

SAMPLE ID	Determine Result		Unigold Result		Statpack Result		Final Result		Score
	Site Result	NPHL Result	Site Result	NPHL Result	Site Result	NPHL Result	Site Result	NPHL Result	

Peformance evaluation
Maximum score obtained by participant

Prepared by:

Verified by:

FLAGS: * - Aberrant

Discordent result may occur due to

Sample storage condition

Technical error

Interpretation error

Transcription error

Please troubleshoot accordingly for discordanct result.