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National Health Laboratory

Guidelines on National External Quality Assessment (NEQA) for HIV Viral Load Testing

Version 1.0

NATIONAL HEALTH LABORATORY
DEPARTMENT OF MEDICAL SERVICES
MINISTRY OF HEALTH
MYANMAR

Guidelines on

National External Quality Assessment (NEQA)

For HIV Viral Load Testing

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June 2025

National Health Laboratory

Department of Medical Services

Ministry of Health

Myanmar

These guidelines (Version 1.0 : June 2025) has been jointly developed by the National Health Laboratory and ICAP at Columbia University, Myanmar.
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ACKNOWLEDGEMENTS

The guidelines on National External Quality Assessment for HIV Viral Load Testing (Version 1.0) represent a remarkable collaborative achievement, and we convey our heartfelt appreciation to all who contributed to the development of these guidelines.

We are deeply grateful to ICAP at Columbia University for their invaluable support and significant contributions, which made these guidelines possible. Their expertise and dedication were crucial in ensuring the successful completion of this work. We also acknowledge our colleagues in the HIV NEQAS section for their dedication, collaboration, and invaluable input, which were pivotal in laying the foundation for these guidelines.

We trust that these guidelines will serve as a valuable resource in ensuring the reliability and quality of HIV viral load testing, ultimately contributing to improved patient outcomes and global efforts to combat HIV/AIDS.

National Health Laboratory
Department of Medical Services
Ministry of Health

PREFACE

Maintaining the quality of HIV Viral Load (VL) testing is essential to ensure the ongoing effectiveness of HIV treatment programs. As diagnostic technologies advance and testing networks expand, the provision of quality-assured testing services becomes increasingly critical. Accurate and reliable VL testing is vital for the effective management of HIV infection to receive optimal treatment for HIV-infected patients.

External Quality Assessment (EQA) is important for the improvement of the laboratory quality management system, as it is a measure of laboratory performance. To support continuous quality improvement in HIV VL testing laboratories, the National Health Laboratory has implemented the HIV Viral Load External Quality Assessment Scheme since 2024. Consequently, these HIV VL EQA guidelines have been developed as a reference for the laboratory personnel, to sustain the continuous quality improvement of HIV VL testing services. These guidelines provide a structured, step-by-step approach for laboratories to enhance the quality of HIV VL testing services, including detailed procedures for testing VL EQA panel samples and conducting site assessments using the VL scorecard assessment tool.

By adhering to these guidelines, HIV Viral Load testing laboratories can establish and maintain continuous quality improvement practices, ensuring the delivery of high-quality, reliable results that contribute to improved patient care and health outcomes. Together, through the commitment to quality testing, we are building a stronger foundation to support the health and wellbeing of people living with HIV across Myanmar.

Dr. Swe Setk
Deputy Director General
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ABBREVIATIONS

AIDS/STD	Acquired Immune Deficiency Syndrome/ Sexually Transmitted Disease
ART	Antiretroviral therapy
CAPA	Corrective and Preventive Action
CDC-ILB	The Centers for Disease Control and Prevention – International Laboratory Branch
DBS	Dried Blood Spot
DTS	Dried Tube Specimen
e-PT	electronic Proficiency Testing
EQA	External Quality Assessment
EQAS	External Quality Assessment Scheme
GX	GeneXpert
HIV	Human Immune Deficiency
HTP	High Throughput Platform
INGO	International Non-Government Organization
ISO	International Organization for Standardization
LIMS	Laboratory Information Management System
MSF-CH	Médecins Sans Frontières (Switzerland)
N/A	Not Applicable
NCs	Nonconformities
NEQA	National External Quality Assessment
NEQAS	National External Quality Assessment Scheme
NGO	Non-Government Organization
nIQR	Normalized Interquartile Ratio
NHL	National Health Laboratory
NRL	National Reference Laboratory

PBS	Phosphate Buffer Saline
PCR	Polymerase Chain Reaction
PDCA	Plan Do Check Act
PLHIV	People living with HIV
PHL	Public Health Laboratory
PNCs	Potential Nonconformities
POC	Point-of-Care
PSI	Population Service International
PT	Proficiency Testing
TAT	Turnaround Time
TND	Target Not Detected
VL	Viral Load
VL-IVT	Viral Load and Infant Virological Testing
WHO	World Health Organization

TERMS AND DEFINITIONS

Assigned Value	Value attributed to a particular property of a proficiency test item
Corrective Action (CA)	Action to eliminate the cause of a detected nonconformity
Nonconformities (NCs)	Situation in which a service, product, or process does not meet specificed requirements or industry standards
PDCA	The Deming Plan-Do-Check-Act (PDCA) cycle shows how to achieve continual improvement in any process
Point-of-care testing	Examination performed near or at the site of a patient
Potential nonconformities (PNCs)	A situation that is leading to the occurrence of a nonconformity
Preventive Action (PA)	An approach that, rather than being a reaction to the identification of problems or complaints, takes an active, proactive role in identifying opportunities for improvement.
RealTime PCR	The continuous collection of fluorescent signal from polymerase chain reaction throughout cycles
Turnaround Time	Length of time that a sample's final result issued to the ordering physician
z score	Standardized measure of performance, calculated using the participant result, assigned value and the standard deviation for proficiency assessment

1. INTRODUCTION

HIV Viral Load testing (VL) is a key indicator to monitor the effectiveness of antiretroviral therapy (ART) and confirm treatment failure in people living with HIV (PLHIV), preventing unnecessary therapy switches. The World Health Organization (WHO) recommends VL testing as the gold standard to assess the efficacy of HIV treatment. Providing accurate and reliable viral load test result is essential, as it supports clinicians in making treatment decisions and facilitates timely adjustments to ART regimens, thereby preventing drug resistance.

In Myanmar, with the leadership of the National AIDS Programme (NAP) and National Health Laboratory (NHL), routine HIV viral load (VL) testing has been recommended as an approach to monitor people who are taking antiretroviral therapy (ART) since the launch of the National Strategic Plan (NSP III) 2016–2022.

HIV VL testing network in the country employs both high throughput platforms (Abbott and Biocentric) for centralized testing and GeneXpert platform for point-of-care (POC) testing. The National Health Laboratory (NHL) began HIV VL testing since 2010 with the manual extraction method using the Abbott RealTime platform, which was later upgraded to an automated extraction method in 2014. The Abbott platforms were expanded to Public Health Laboratory (PHL) in 2016 and the Specialized Hospital Mingalardon & Magway AIDS/STD team in 2017.

Parallel to these testing platforms, partner organizations supported the integration of Biocentric platforms into the national VL testing network in 2016. Additionally, the GeneXpert POC platforms have been installed at state and regional level hospitals and AIDS/STD teams to enhance the decentralized testing capacity and implement routine testing since 2017. As of 2025, Myanmar's VL testing network becomes 11 HTP platforms and 24 GeneXpert systems.

To provide accurate and reliable VL testing services across all testing platforms, the quality of testing service is of utmost importance. Although international external quality assessment (EQA) program for HTPs has been implemented since 2015 through the Centers for Disease Control and Prevention - International Laboratory Branch (CDC-ILB) and National Reference Laboratory (NRL) in Australia, there is still a requirement for the point-of-care (POC) platforms to enroll in the EQA program. Hence the National Health Laboratory (NHL) implemented the National EQA program for all VL platforms in 2024 as it is crucial for the improvement of the laboratory quality management system. These

NEQAS guidelines aim to provide information for the NEQA program for HIV VL testing at the NHL.

2. OBJECTIVES

The National External Quality Assessment Scheme for HIV Viral Load is important for the improvement of the laboratory quality management system, as it is a measure of laboratory performance. The NEQAS provides each participating laboratory with the opportunity to measure its performance through a confidential system of testing unknown samples and to determine its ability to perform HIV VL testing. The NEQAS samples are tested with similar testing methods used for routine samples and by the personnel who routinely perform the testing.

The main objectives of HIV VL NEQAS testing are as follows.

- Objective one: To assess the accuracy of HIV VL results produced by VL laboratories in Myanmar through the EQA samples
- Objective two: To support continuous quality improvement processes implemented at laboratories that provide HIV VL testing services
- Objective three: To identify major gaps and needs for capacity building at HIV VL laboratories

3. NEQAS FOR HIV-1 VIRAL LOAD TESTING

The HIV Virology Subsection of the National Health Laboratory (NHL) takes the role of EQA provider/organizer for HIV VL NEQAS testing. NHL is responsible for the production, distribution, and reporting of the NEQAS panels. The panels are made of HIV-1 VL Dried Tube Specimen (DTS). In June 2023, a pilot program for HIV VL NEQAS was conducted and 9 HTPs and 20 GeneXpert platforms were included.

NEQAS for HIV VL testing began in June 2024, with participating laboratories from public sectors and international non-governmental organizations (INGOs) using HTP platforms (Abbott and Biocentric) as well as the POC platform (GeneXpert) for HIV-1 VL testing. For the enrollment of the HIV VL NEQAS in 2024, there were a total of 37 participating laboratories: 4 using the Abbott platform, 7 using the Biocentric platform, and the remaining 26 were POCT sites using the GeneXpert platform.

4. STEPS INVOLVED IN HIV-1 VL DTS PANEL TESTING

4.1. Registration

There are two categories for HIV-1 VL NEQAS registration: mandatory and voluntary. Participation is mandatory for public laboratories and AIDS/STD control teams whereas private laboratories and INGOs/NGOs have the option to participate voluntarily. Voluntary participants are required to enroll each year, while mandatory participants are automatically enrolled without the need for an annual registration process. Annual registration usually opens in the first quarter of the calendar year. For new enrollment, laboratories are required to provide contact details, including the laboratory address, contact person's name, active email address, phone number, and a copy of the hospital or laboratory license.

4.2. Workshop

The National Health Laboratory (NHL) organizes an annual HIV Viral Load (VL) workshop to support continuous quality improvement of HIV VL testing laboratories. The primary objective of this workshop is to enhance the quality of HIV molecular testing across PCR laboratories. Additionally, the workshop includes a training session on the use of the e-PT system for the VL EQA scheme.

4.3. NEQAS event

The NHL conducts NEQAS rounds twice a year. Each panel includes the following:

1. two sets of five-coded dried tube specimen (DTS)
2. one tube containing 13 mL of Phosphate Buffer Saline (PBS) and
3. an instruction sheet

4.4. Panel preparation

Panel samples are prepared at the NEQAS unit, Virology section in the NHL. Details can be found in the "DTS preparation and validation procedure" in the appendices section.

4.5. Panel distribution

One week prior to panel distribution, the participating laboratories receive a notification email regarding panel shipment via the email address : nhleqas.vl@gmail.com.

4.6. Panel testing

Upon the receipt of the panel samples, the participant must carefully read the instruction sheet and adhere to the recommended practices for the handling and testing of the panel samples. If the laboratory has multiple testers, a tester rotation practice should be implemented to ensure the competency and capability of all staff members to perform HIV VL testing.

4.7. Result submission

Participants can submit their results electronically through the e-PT (electronic Proficiency Testing) system. Timely submission is crucial, as there is an assigned deadline for the submission process. Participants are required to complete all mandatory fields on the result submission page prior to submission.

The e-PT system is a multi-user, web-based platform designed to streamline the NEQAS process by automating workflow management and reducing turnaround time. All participating sites are provided with password-protected user accounts to access the e-PT system. Participants can edit their results in the e-PT system before the assigned deadline.

The system can be accessed on a computer via the webpage, which is reachable through the provided link: https://nhlmmr.org. For detailed instructions, refer to the "User instruction for the e-PT system."

4.8. Data analysis and evaluation

The NHL conducts data analysis and evaluation in the e-PT system after the assigned deadline. The scoring criteria are determined by the enrollment numbers of different VL testing platforms and there are separate scoring systems used in the HIV-1 VL DTS NEQAS program.

> 18 participants for the same VL platform: If the number of participants using the same VL platforms is more than eighteen, the results of participating laboratories are grouped together and analyzed for peer-comparison using the normalized Interquartile range (nIQR) method. Assigned value, robust standard deviation, standard uncertainty of the assigned value, z score and performance score are derived according to the Standard ISO 13528:2015 (E).

≤ 18 participants for the same VL platform: If the number of participants using the same VL platform is less than or equal to eighteen, the assigned value determined by the reference laboratory is used for the result comparison.

z score: The performance of the participating laboratories is determined based on the "z score," which is calculated for each reported result. The z score provides feedback on participant's performance, compared to the robust standard variation among peer-comparison laboratories for more than 18 participants and to the reference laboratory for less than or equal to 18 participants. The z score calculation is as follows.

$$z\ score = \frac{(x-\mu)}{\delta}$$

x = reported result from participants (log_{10} copies/mL)

μ = assigned value (log_{10} copies/mL) and

δ = robust standard deviation

Interpretation of z-scores is provided in the table below.

z Score		Results Interpretation	Recommended Action
z ≤ ± 3.0	z ≤ ± 2.0	Acceptable	No action required
	± 2.0 > z < ± 3.0	Warning	Closely monitor performance
z ≥ ± 3.0		Unacceptable	Perform corrective action

Table 1. z score interpretation

- A 20% score is given for each DTS result that is correctly reported within the "Acceptable" and "Warning" range (where the z score is ≤ ± 3.0). A full 100% score (20% x 5) is provided if all five DTS results meet the acceptable z score range.

4.9. Reports

The NHL sends a notification email via nhleqas.vl@gmail.com upon the completion of the data analysis and evaluation process to inform that the individual and summary feedback reports are ready to download through the e-PT system. Refer to the "User instruction for e-PT system" and "Example Reports" in the appendices section.

4.10. Certificates

Although feedback reports are provided for each NEQAS round, certificates are issued annually at the end of the second panel round within a calendar year, based on the following criteria.

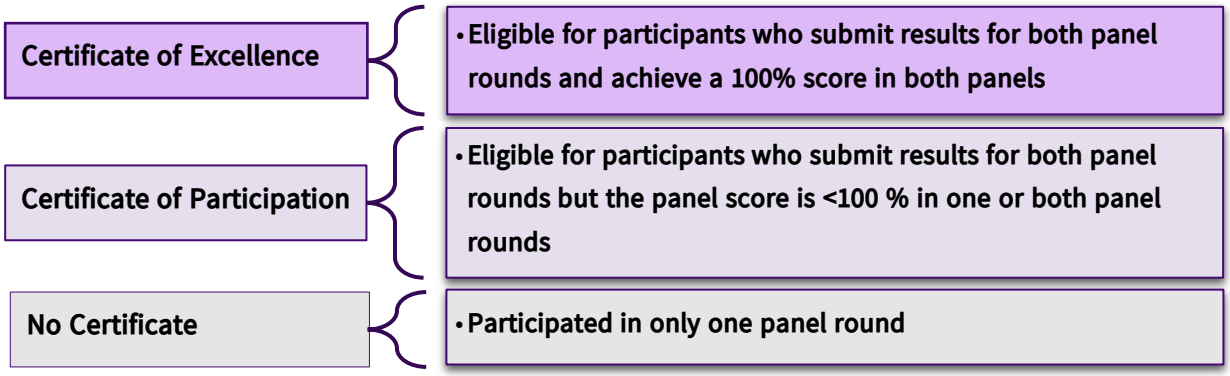


Figure. 1. Eligible criteria for annual certificate

4.11. Feedback and actions

The individual feedback report includes the suggested corrective actions for each participant. The participating laboratory must undertake self-evaluation as per the feedback report. Necessary corrective and preventive action (CAPA) are also required to implement at the laboratory to prevent potential nonconformities (PNCs), to resolve nonconformities (NCs) and to prevent reoccurrence. If the performance of the participating laboratory is unsatisfactory, the NHL may provide refresher training courses for that participating site.

4.12. Monitoring and supervisory visits

To sustain continual quality improvement of HIV VL testing laboratories, the HIV VL and Infant Virological Testing (VL-IVT) Scorecard and the users' guide has been developed by the United States, the Centers for Disease Control and Prevention (CDC) since 2017. It is a laboratory and clinic-based tool, to help, define, improve, and measure improvement of efficiencies across the VL testing spectrum. Since 2018, the VL-IVT scorecard has been utilized in Myanmar to assess the quality improvement of HIV VL testing laboratories in international non-government organizations (INGOs): Population Service International (PSI) and Médecins Sans Frontières, Switzerland (MSF-CH). During the same period, four Abbott laboratories in the public sectors were assessed by external assessors from CDC and NRL, Australia.

The VL-IVT scorecard assesses VL testing laboratories and acts as a valuable tool for external audits and internal monitoring. Through a point-based system the scorecard enables the individual responsible for the supervision of VL-IVT services to recognize gaps, identify areas for improvement, and take corrective actions as required. The users' guide which outlines how to conduct the audit process is also included in the appendices section.

It is suggested that each VL laboratory is assessed with the scorecard at least annually and the VL scorecard checklist including corrective actions if indicated, must be filed at the VL laboratory, and should be presented when the external monitoring team (such as NHL and technical experts) visit the laboratory.

To enhance the data analysis and review process, and to improve the efficiency of the continuous quality monitoring system, an electronic version of the HIV VL-IVT scorecard was developed by the NHL, with technical assistance from ICAP, in 2023. Unlike paper-based scorecard, which requires manual data review and analysis, the electronic version allows users to submit assessment findings and scores online. Instructions for using the electronic scorecard and the link for submitting assessment data online are also provided in the appendices section.

5. Appendices

5.1. Organogram for National External Quality Assessment Scheme

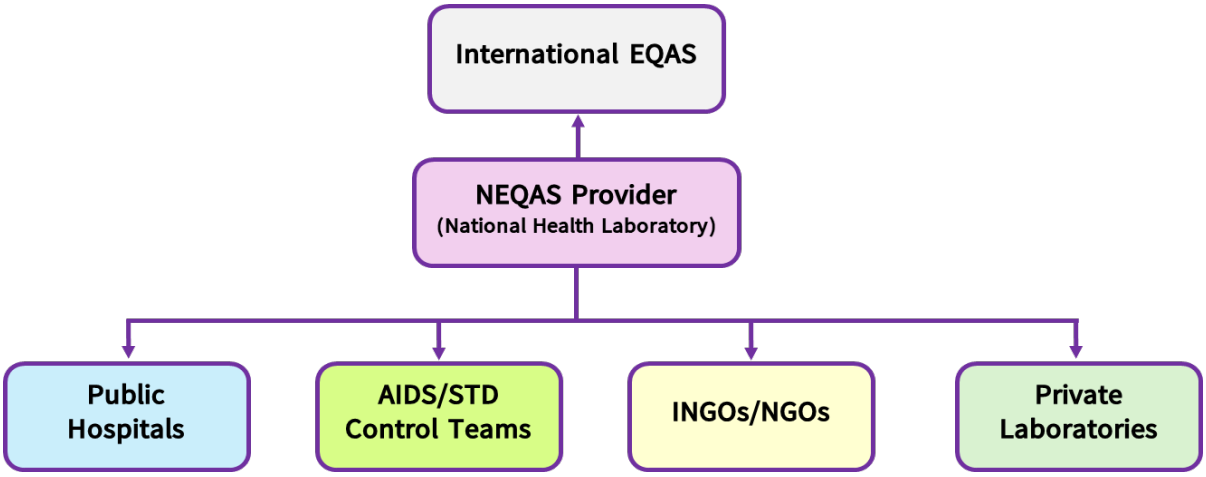
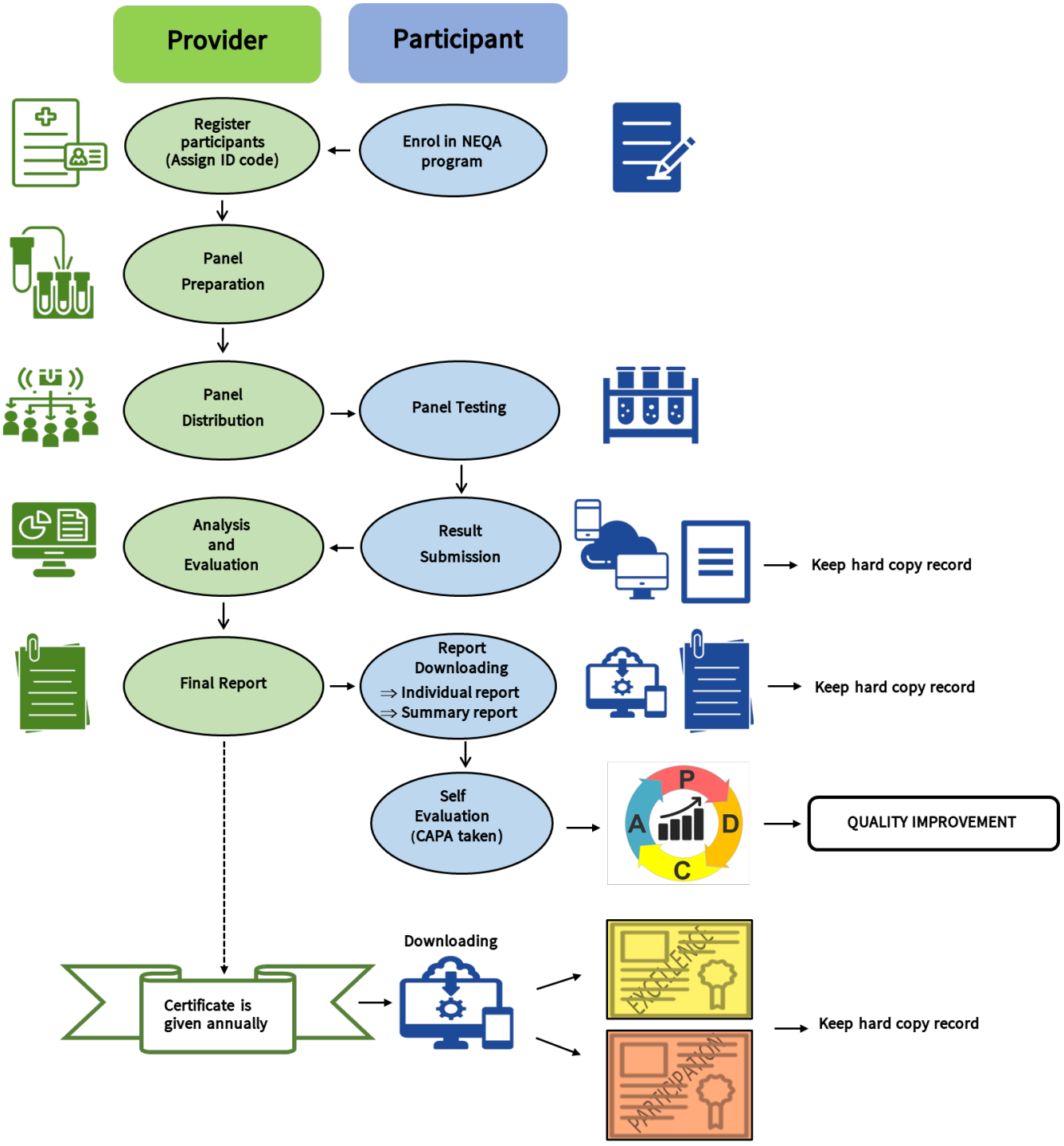


Figure. 2. Organogram for NEQAS

5.2. Role of NEQAS Provider and Participant in NEQAS Process



**CAPA = Corrective and Preventive Actions / PDCA = Plan-Do-Check-Act*

Figure. 3. Role of PT provider and participants in NEQAS

5.3. Dried Tube Specimen Preparation and Validation

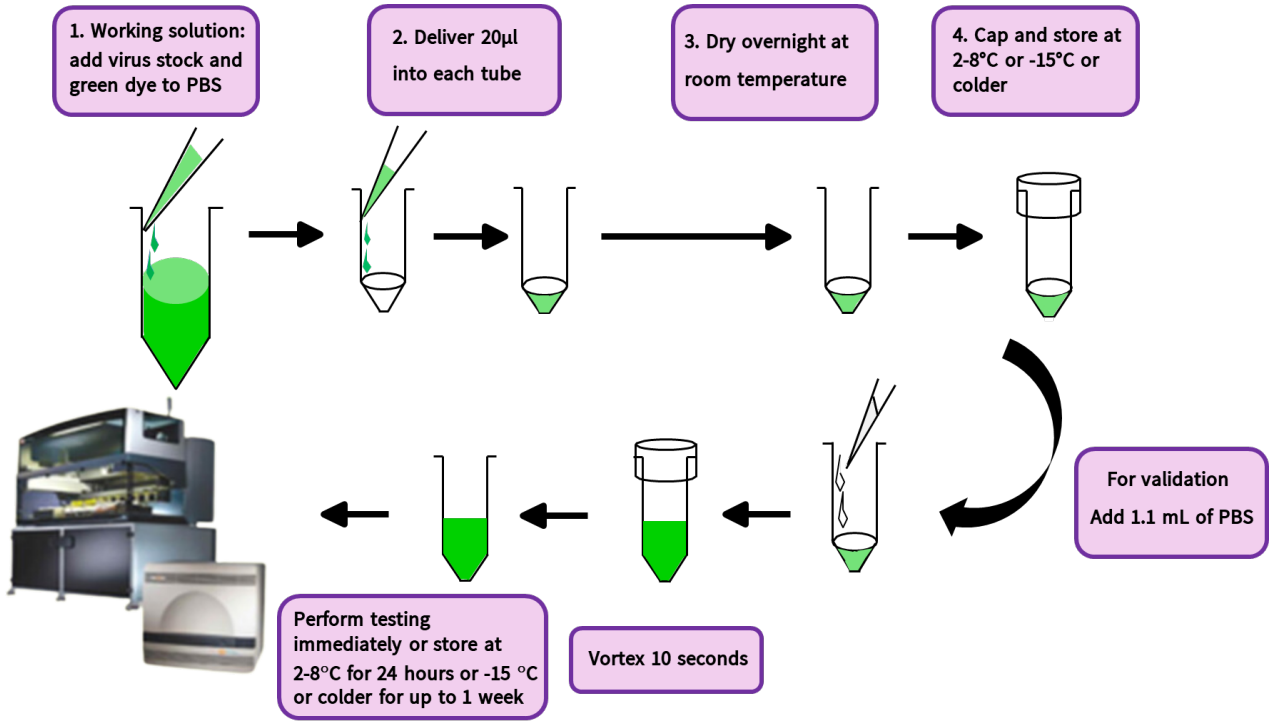


Figure. 4. DTS preparation and validation

5.4. Dried Tube Specimen Testing

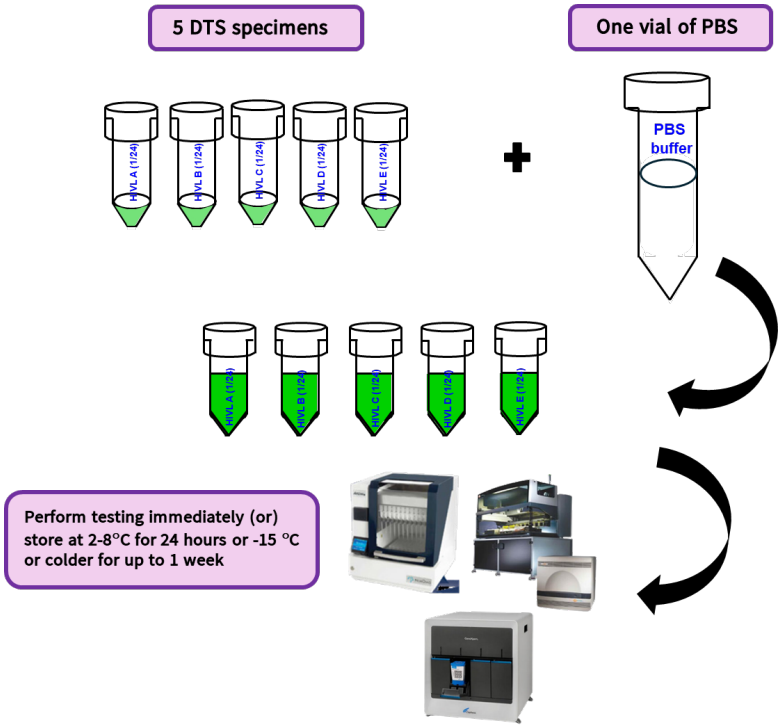


Figure. 5. DTS Testing

5.5. Form A: Instruction for HIV Viral Load NEQAS Panel Testing

Read carefully prior to performing the HIV VL NEQAS panel.

The panel package for HIV VL NEQAS consists of

- Two identical sets of 5-coded dried tube specimens (DTS); use one set for NEQAS panel testing and another set is provided for retesting in case it is needed.
- One tube of 13 mL Phosphate Buffer Saline (PBS) for reconstitution of DTS

Handling

- If any components of the NEQAS package are missing or damaged, notify the National Health Laboratory.
- Store panels at 2-8°C until day of testing. Panel samples must be at room temperature before opening the vials. Each vial should be tested once and then discarded.

Precaution

- Panel specimen may contain infectious material and must be handled using standard laboratory safety precautions.
- Wear personal protective equipment when handling all the components of the panels.
- Dispose of all waste according to local regulations.

Specimen preparation and testing

- Add 1.1 mL of PBS to each DTS specimen to reconstitute and vortex for 10 seconds.
- Reconstituted specimens should be green in color, free of particulate matter and use immediately. If needed, the rehydrated DTS specimen can be stored at 4°C for 24 hours or -20 °C or colder for up to one week, with no more than one freeze-thaw.
- Perform the testing according to your laboratory's Standard Operating Procedure along with your patients' specimen into your daily workflow, so test results are truly indicative of your laboratory's daily performance.

Result submission

- Submit the results online via the e-PT website at https://nhlmmr.org/auth/login
- Results must be reported in log $_{10}$ copies/mL.
- Verify all fields are complete. Check for transcription errors.
- The result sheet provided in the package of DTS NEQAS panel can be used for recording information before submission via the e-PT system. Retain the result sheet at your laboratory.
- The deadline for result submission is **(DD-MM-YY)**. Submit the result before the assigned deadline.

HIV VL NEQAS Panel Testing အတွက် ညွှန်ကြားချက်များ

HIV Viral Load NEQAS panel စစ်ဆေးမှုမပြုလုပ်ခင် သေချာစွာ ဖတ်ရှုပါရန်။

HIV Viral Load NEQAS panel အထုပ်တွင်

- ကုဒ်နံပါတ်တပ်ထားသော Dried Tube Specimen (DTS) ဓာတ်ခွဲနမူနာ (၅) ခုပါသည့် panel (၂) စုံ ပါပါသည်။
- ဓာတ်ခွဲစစ်ဆေးမှုပြုလုပ်ရန် panel (၁) စုံကို အသုံးပြုပါ။ ကျန် (၁) စုံသည် ပြန်လည်စစ်ဆေးမှုပြုလုပ်ရန် လိုအပ်ပါက အသုံးပြုနိုင်ရန် ထည့်ပေးထားခြင်းဖြစ်သည်။
- DTS ဓာတ်ခွဲနမူနာများကို ဖျော်ရန်အတွက် Phosphate Buffer Saline (PBS) 13 mL ပါဝင်သော tube (၁) ချောင်းပါပါသည်။

ကိုင်တွယ်ခြင်း

- အကယ်၍ ဓာတ်ခွဲနမူနာများ ပျောက်ဆုံးခြင်း၊ ပျက်စီးခြင်းများဖြစ်ပါက National Health Laboratory သို့ အကြောင်းကြားပါ။
- ဓာတ်ခွဲနမူနာများအား စစ်ဆေးမှုချက်ချင်းမပြုလုပ်နိုင်ပါက **2-8°C** ၌ သိမ်းဆည်းထားရမည်။ စစ်ဆေးမှုပြုလုပ်ခါနီးတွင် ၎င်းတို့ကို အခန်းအပူချိန်သို့ ရောက်စေရန် သတိပြုရမည်။
- ဓာတ်ခွဲနမူနာတစ်ခုကို စစ်ဆေးမှုတစ်ကြိမ် ပြုလုပ်ပြီးနောက် စွန့်ပစ်ရမည်။

ကြိုတင်ကာကွယ်ခြင်း

- ဓာတ်ခွဲနမူနာများသည် ရောဂါကူးစက်နိုင်ပါသဖြင့် ဓာတ်ခွဲခန်းတွင် သတ်မှတ်ထားသောစည်းကမ်းများအတိုင်း သတိထားကိုင်တွယ်ရမည်။ ဓာတ်ခွဲနမူနာများ ကိုင်တွယ်နေစဉ်တစ်လျှောက်လုံး တစ်ကိုယ်ရေအကာအကွယ်ပစ္စည်းများ ဝတ်ဆင်ရမည်။
- ဓာတ်ခွဲခန်းမှထွက်သော အမှိုက်များအားလုံးကို ရောဂါပိုးကူးစက်မှုကာကွယ်ထိန်းချုပ်ရေးလုပ်ငန်းလမ်းညွှန်မှ သတ်မှတ်ထားသည့်အတိုင်း စနစ်တကျစွန့်ပစ်ရမည်။

ဓာတ်ခွဲနမူနာများအား ပြင်ဆင်ခြင်းနှင့် စစ်ဆေးခြင်း

- DTS tube တစ်ခုစီသို့ PBS reconstitution buffer 1.1 mL ထည့်ဖျော်ပြီး ကောင်းစွာပျော်ဝင်စေရန် vortex mixer တွင် (၁၀) စက္ကန့်ကြာ ထားပါ။
- အရည်ဖျော်ထားသောဓာတ်ခွဲနမူနာသည် အစိမ်းရောင်ဖြစ်ပြီး ကောင်းစွာပျော်ဝင်နေရမည်။ ထိုဓာတ်ခွဲနမူနာအား ချက်ချင်းစစ်ဆေးမှုပြုလုပ်ပါ။ လိုအပ်ပါက ဖျော်ထားပြီးသောဓာတ်ခွဲနမူနာအား 4°C တွင် 24 hours ကြာ သိမ်းထားနိုင်ပြီး -20 °C နှင့် ၎င်းအောက်အပူချိန်တွင် တစ်ပတ်ကြာသိမ်းထားနိုင်သည်။ အရည်ဖျော်ထားသော ဓာတ်ခွဲနမူနာကို Freeze and Thaw တစ်ကြိမ်သာ လုပ်ခွင့်ရှိသည်။
- NEQAS panel ဓာတ်ခွဲနမူနာများကို နေ့စဉ်လူနာများ၏ ဓာတ်ခွဲနမူနာများနှင့်အတူ စစ်ဆေးမှုပြုလုပ်ရမည်။ သို့မှသာ ရရှိလာသော အဖြေများသည် သက်ဆိုင်ရာဓာတ်ခွဲခန်း၏ နေ့စဉ်လုပ်ဆောင်မှုများကို မှန်ကန်စွာညွှန်ပြနိုင်လိမ့်မည်။

အဖြေများ ပေးပို့ခြင်း

- အဖြေများအား internet အသုံးပြုပြီး e-PT website “https://nhlmmr.org” မှတစ်ဆင့် ပြန်လည်ပေးပို့ရမည်။ အဖြေများအား log $_{10}$ copies/mL ဖြင့် အဖြေထုတ်ပါ။
- အဖြေမပေးပို့မီ ဖြည့်ထားသောအချက်အလက်များ မှားယွင်းမှုမရှိစေရန် ပြန်စစ်ပါ။
- NEQAS panel အထုပ်နှင့်အတူပို့လိုက်သော အဖြေဖြည့်ရမည့်စာရွက်သည် e-PT system တွင်အဖြေမဖြည့်မီ မှတ်သားထားရန်ဖြစ်ပြီး ဓာတ်ခွဲခန်းတွင်မှတ်တမ်းမှတ်ရာအဖြစ် သိမ်းဆည်းထားရန်အတွက်ဖြစ်သည်။
- အဖြေဖြည့်ရန် သတ်မှတ်ထားသော နောက်ဆုံးသတ်မှတ်ရက်သည် (ရက်၊လ၊နှစ်) ဖြစ်သည်။ အဖြေများကို သတ်မှတ်နောက်ဆုံးရက် Deadline မတိုင်မီ ပေးပို့ရမည်။

THE GOVERNMENT OF THE REPUBLIC OF THE UNION OF MYANMAR
MINISTRY OF HEALTH
DEPARTMENT OF MEDICAL SERVICES
NATIONAL HEALTH LABORATORY
35, HMAW KUN DAIK STREET, YANGON

5.6. Form B: Result sheet

RESULT SHEET

National External Quality Assessment Scheme for HIV-1 Viral Load Testing

DISTRIBUTION NUMBER # (#/Year)

Laboratory Name …… Identification No ……..

Received date ……..…….... Receiver ……

Is the panel delivered to you in a good condition? ☐ Yes ☐ No

Specimen volume used for testing .....

	For High Throughput Platform (Abbott, Biocentric, etc.)		For Point of Care Platform (GeneXpert)
	Extraction	**Amplification**	
Kit Name			
Kit Lot No			
Expiry Date (DD,MM,YY)			
Date of Performance			
Lower Limit of Detection			

Sample/Analyte	**Result (log_{10} copies/mL)**	**Interpretation**	**Remark (if any)**
HIVL A-2 (2/24)			
HIVL B-2 (2/24)			
HIVL C-2 (2/24)			
HIVL D-2 (2/24)			
HIVL E-2 (2/24)			
Operator Signature: ……		Operator Name: ……	
Supervisor Signature: ……		Supervisor Name: ……	

Date of Submission: ……

Name of contact person: …… Tel: ……..

Fax: …… E-mail: ……

The result sheet is to be used for recording information before the result submission via electronic proficiency testing (e-PT) system via the website "https://nhlmmr.org". No need to send this result sheet copy to the National Health Laboratory.

5.7. Form C: Certificate of Participation

CERTIFICATE OF PARTICIPATION

This certificate is presented to

Lab Name

For participation in

the National External Quality Assessment Scheme for

HIV Viral Load Testing

Organized by
National Health Laboratory
Department of Medical Services
Ministry of Health (Myanmar)
Year

Deputy Director General
National Health Laboratory

Figure. 6. Certificate of Participation

5.8. Form D: Certificate of Excellence

CERTIFICATE OF EXCELLENCE

This certificate is presented to

Lab Name

For participation and excellent performance in

the National External Quality Assessment Scheme for

HIV Viral Load Testing

Organized by
National Health Laboratory
Department of Medical Services
Ministry of Health (Myanmar)
Year

Deputy Director General
National Health Laboratory

Figure. 7. Certificate of Excellence

5.9. Form E: User instruction for e-PT system

HIV Viral Load NEQAS Panel result submission using Laptop/ Desktop

HIV Viral Load NEQAS Panel အဖြေများအား Laptop/ Desktop ဖြင့် ဖြည့်သွင်းခြင်း

Follow step-by-step instructions to submit PT results in the e-PT system.

PT အဖြေများအား e-PT system တွင် ဖြည့်သွင်းပုံအဆင့်ဆင့်ကို အောက်ပါအတိုင်း ပြုလုပ်နိုင်ပါသည်။

1. Go to the e-PT website "https://nhlmmr.org" to submit PT results.
   PT အဖြေများ ဖြည့်သွင်းရန် e-PT website "https://nhlmmr.org" သို့ ဝင်ရောက်ပါ။

2. Select "**PARTICIPANT LOGIN**" from e-PT program homepage. (Fig. 8. e-PT Homepage)
   e-PT program ၏ ပင်မစာမျက်နှာရှိ "**PARTICIPANT LOGIN**" ကို နှိပ်ပါ။ (Fig. 8. e-PT Homepage)

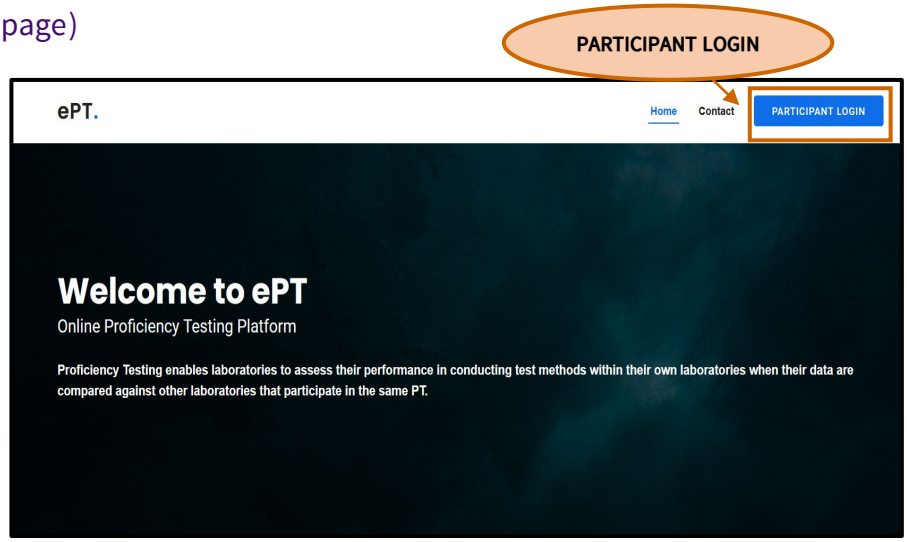


Figure. 8. e-PT Homepage

3. Enter the **e-mail/username** and **password** provided for the e-PT system.
   Enter text from the image box to **sign in**. (Fig. 9. Participant Login).
   e-PT system အသုံးပြုရန် ပေးထားသော **e-mail/username** နှင့် **password** တို့ကို ဖြည့်ပါ။
   Image box တွင် ပေါ်လာသော စာလုံးအတိုင်း ရိုက်ထည့်ပြီး **sign in** ဝင်ပါ။ (Fig. 9.Participant Login)

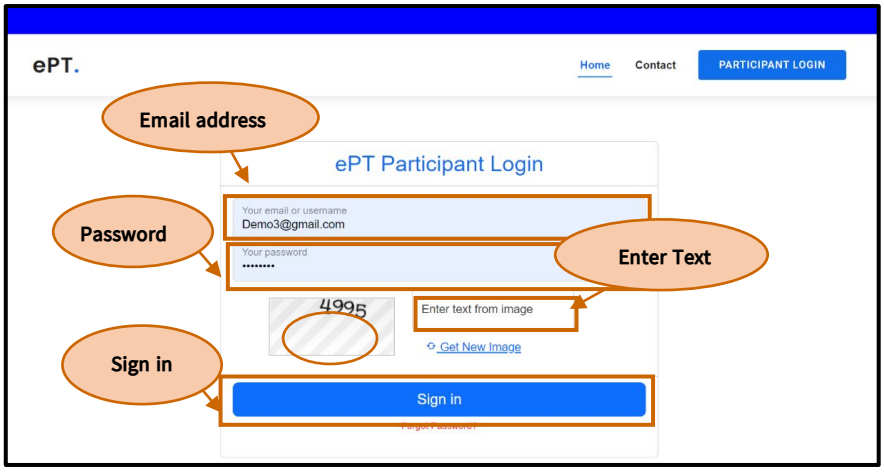


Figure. 9. Participant Login

4. Select “**PT Result Submission**” at the left side of “Dashboard” page to submit results. (Fig. 10. PT Result submission)

“Dashboard” Page ဘယ်ဘက်ခြမ်းရှိ “**PT Result Submission**” ကို နှိပ်ပါ။ (Fig. 10. PT Result submission)

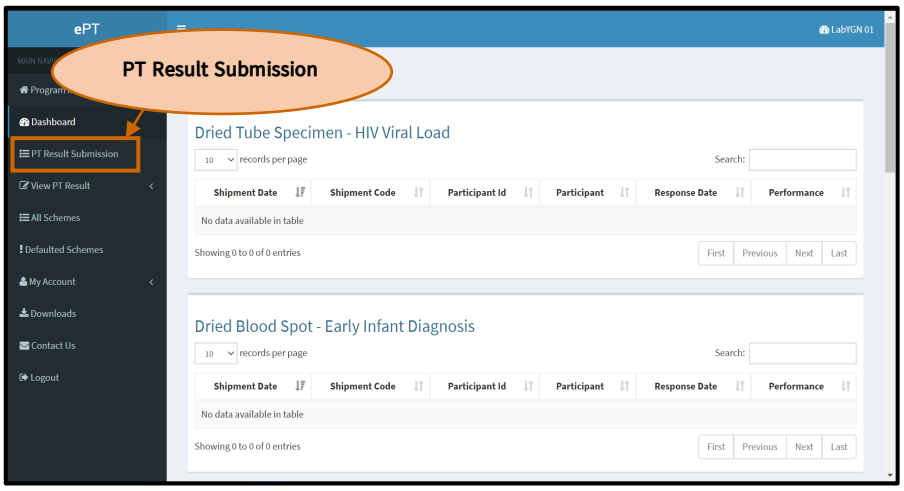


Figure. 10. PT Result Submission

5. Click “**Enter Response**” in the HIV Viral Load scheme on the “Report PT Data” page. (Fig. 11. Enter Response)

“Report PT Data” Page တွင် HIV Viral Load scheme ၏ “**Enter Response**” button ကိုနှိပ်ပါ။ (Fig. 11. Enter Response)

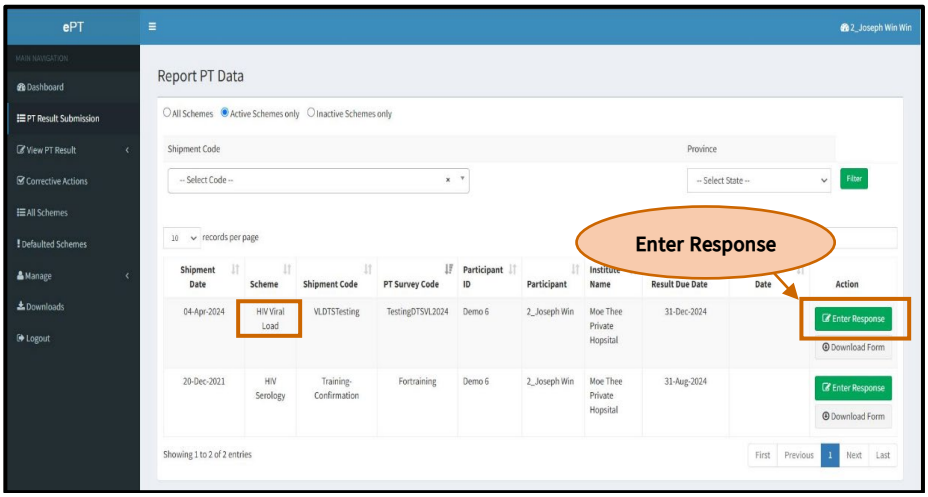


Figure. 11. Enter Response

6. Complete all required fields on the “HIV Viral Load” page. Choose the VL testing platform in “**Viral Load Assay**”. (Fig. 12. Select VL Assay)

“HIV Viral Load” page တွင် လိုအပ်သော အချက်အလက်များကို ဖြည့်ပါ။ “**Viral Load Assay**” နေရာတွင် အသုံးပြုသော VL platform ကို ရွေးချယ်ပါ။ (Fig. 12. Select VL Assay)

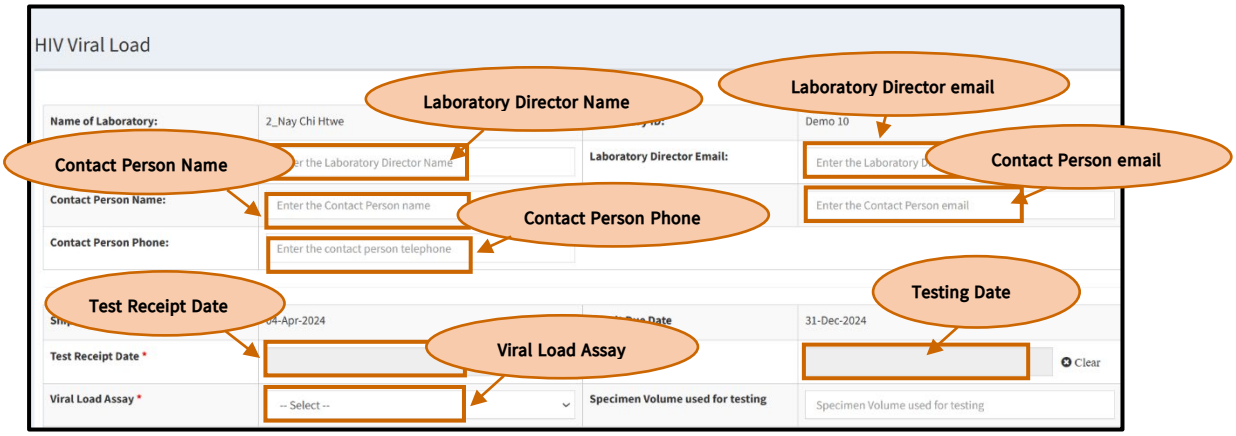


Figure. 12. Select VL Assay

6.1.Complete the following information if the high throughput (HTP) platform either Abbott (or) Biocentric is selected in “Viral Load Assay”. (Fig. 13. HTP information)

- Add the specimen volume used for testing
- Complete “Assay lot, expiration, date of last instrument calibration and instrument serial number” in both EXTRACTION and AMPLIFICATION section

Viral Load Assay နေရာတွင် high throughput platform (Abbott (သို့မဟုတ်) Biocentric) ဖြစ်ပါက အောက်ပါတို့ကို ဖြည့်ပါ။ (Fig. 13. HTP information)

- စမ်းသပ်မှုပြုလုပ်ရာတွင် အသုံးပြုသော ဓာတ်ခွဲနမူနာပမာဏ
- EXTRACTION နှင့် AMPLIFICATION နေရာတွင် အသုံးပြုသော reagent kit များ၏ Lot no., expiration date ၊ အသုံးပြုသောစက်များ၏ serial no နှင့်နောက်ဆုံး calibration ပြုလုပ်ထားသော ရက်စွဲများကို ဖြည့်ပါ။

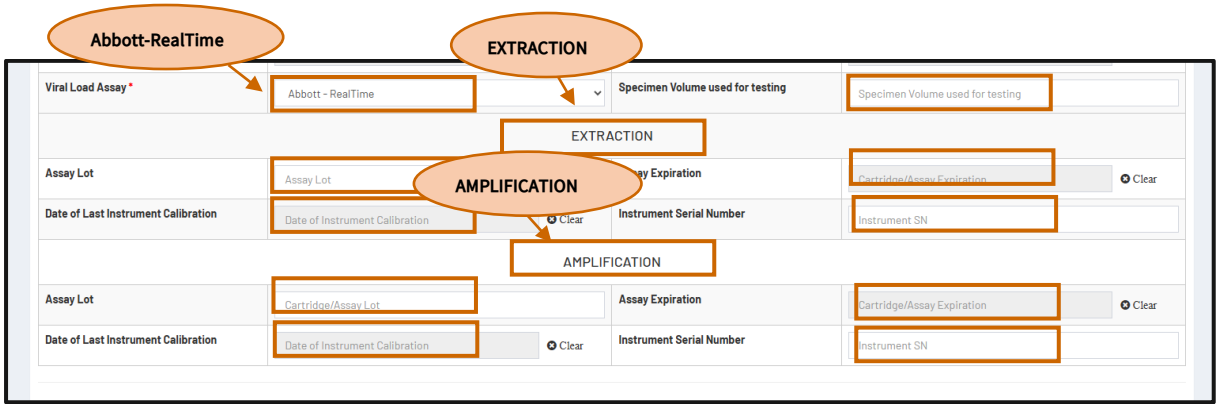


Figure. 13. HTP information

Complete PT results in the designated column. Tick the rectangular box in the TND (Target Not Detected) column if the result is TND. (Fig. 14. HTP result entry)

PT အဖြေများကိုသတ်မှတ်ထားသောနေရာတွင် ဖြည့်ပါ။ Target Not Detected အဖြေ ဖြစ်ပါက (Target Not Detected) နေရာရှိ box ထဲတွင် ☑ လုပ်ပေးပါ။ (Fig. 14. HTP result entry)

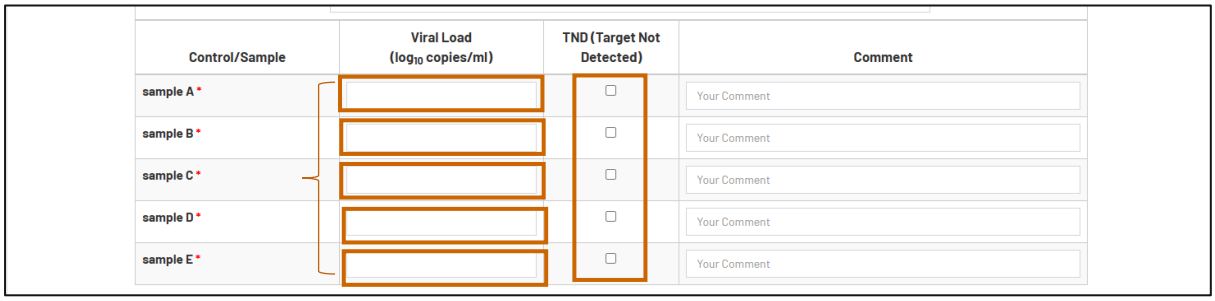


Figure. 14. HTP result entry

6.2.Complete the following information if GeneXpert platform “GeneXpert HIV-1” is selected in “Viral Load Assay”. (Fig. 15. GX information)

- Add the specimen volume used for testing
- Complete “cartridge lot, cartridge expiration, date of last instrument calibration and instrument serial number

Viral Load Assay နေရာတွင် GeneXpert platform (GeneXpert HIV-1) ဖြစ်ပါက အောက်ပါတို့ကို ဖြည့်ပါ။ (Fig. 15. GX information)

- စမ်းသပ်မှုပြုလုပ်ရာတွင် အသုံးပြုသော ဓာတ်ခွဲနမူနာပမာဏ
- အသုံးပြုသော GX cartridge များ၏ Lot no., expiration date ၊ အသုံးပြုသောစက်များ၏ serial no နှင့်နောက်ဆုံး calibration ပြုလုပ်ထားသော ရက်စွဲများကို ဖြည့်ပါ။

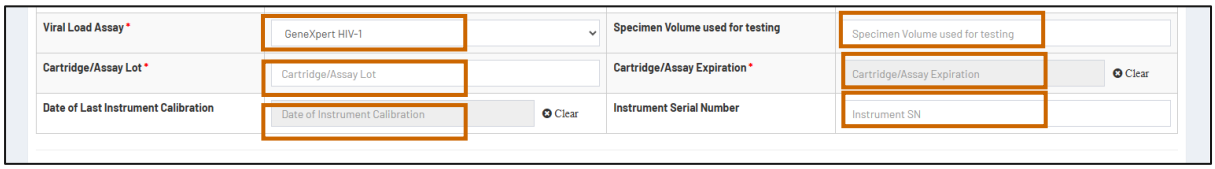


Figure. 15. GX information

Complete PT results in the designated column. Tick the rectangular box in the TND (Target Not Detected) column if the result is TND.

- Select “Invalid” for the invalid specimen
- Select “Error” and add Error code & related module for the error specimen. (Fig. 16. GX result entry)

PT အဖြေများကိုသတ်မှတ်ထားသောနေရာတွင် ဖြည့်ပါ။Target Not Detected အဖြေ ဖြစ်ပါက (Target Not Detected) နေရာရှိ box ထဲတွင် ☑ လုပ်ပေးပါ။

- Invalid အဖြေရရှိပါက “Invalid/Error” Drop-down listမှ Invalid ကို ရွေးပါ။
- Error အဖြေရရှိပါက “Invalid/Error” Drop-down list မှ “Error” ကို ရွေးပြီး Error code နှင့် Error အဖြေထွက်သော Module numberကို ဖြည့်ပါ။ (Fig. 16. GX result entry)

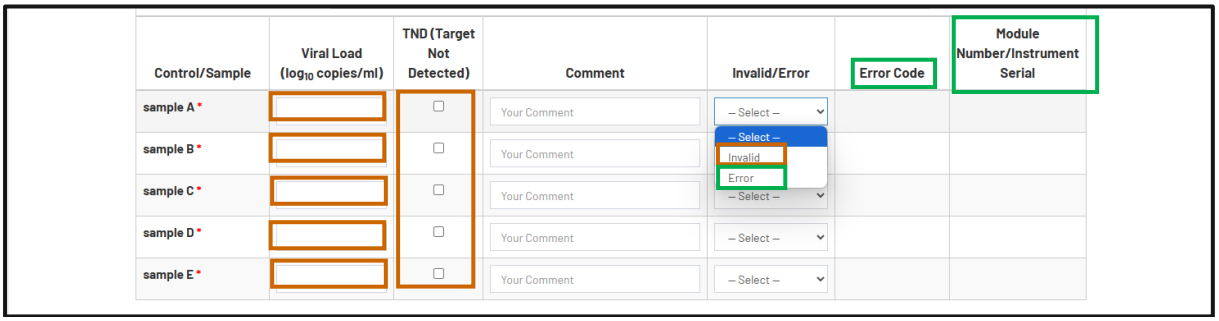


Figure. 16. GX result entry

7. Select "**Yes**" and enter the supervisor's name if PT results are reviewed by the supervisor. Select "**No**" if they are not reviewed. Then, click the "**Submit**" button. (Fig. 17. Submit results)

   အဖြေများကို Supervisor Review လုပ်ပါက "Supervisor Review" နေရာတွင် Yes ကို ရွေးပြီး Name နေရာတွင် အမည်ရေးပါ။ Review မလုပ်ပါက "No" ကိုရွေးပါ။ ထို့နောက် "Submit" button ကိုနှိပ်ပါ။ (Fig. 17. Submit results)

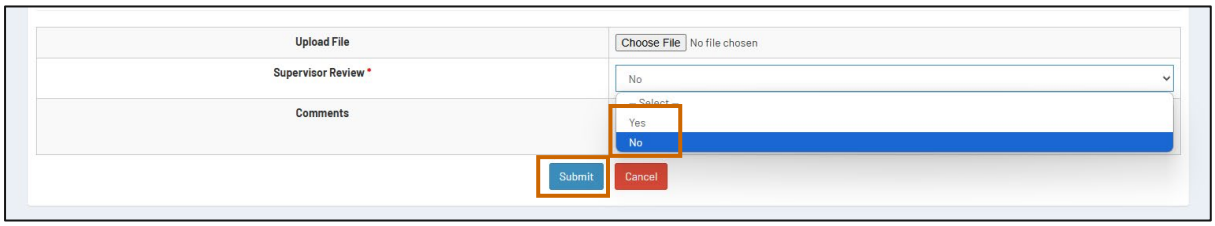


Figure. 17. Submit results

8. Confirm your response message appears and click "OK" to confirm the response. (Fig. 18. To confirm your response)

   "Confirm your response" စာကြောင်းပေါ်လာပါက OK ကိုနှိပ်ပါ။ (Fig. 18. To confirm your response)

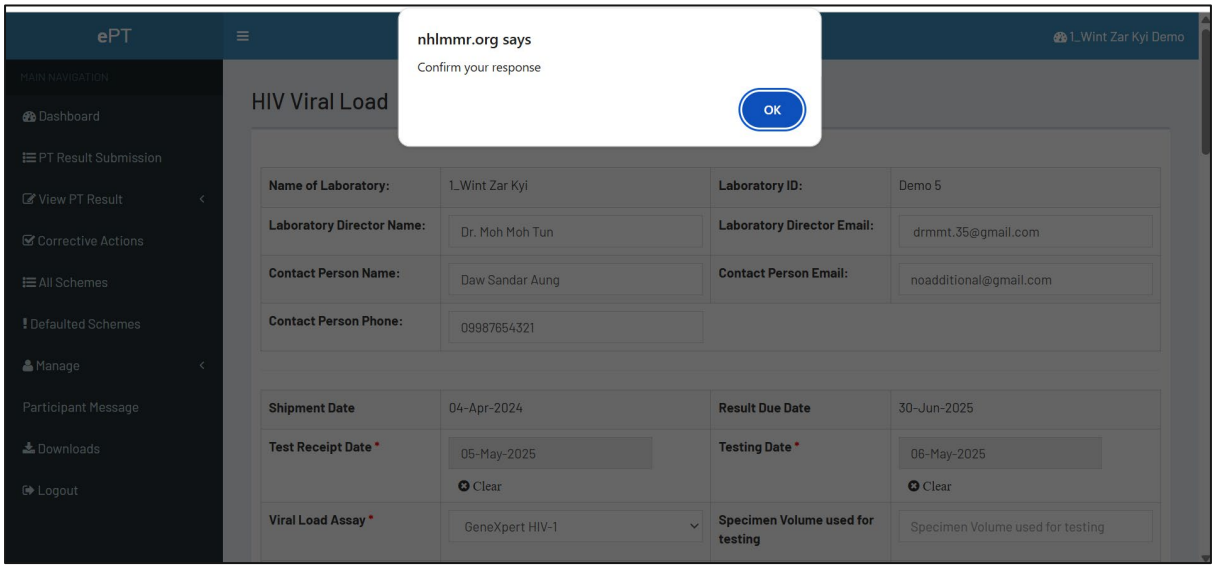


Figure. 18. To confirm your response

9. Then, click “Confirm Response” to submit PT results to the e-PT system. (Fig. 19. Confirm response)

ထို့နောက် “Confirm Response” ကိုနှိပ်ပြီး PT အဖြေများကို e-PT system သို့ ဖြည့်ရန် အတည်ပြုပါ။ (Fig. 19. Confirm response)

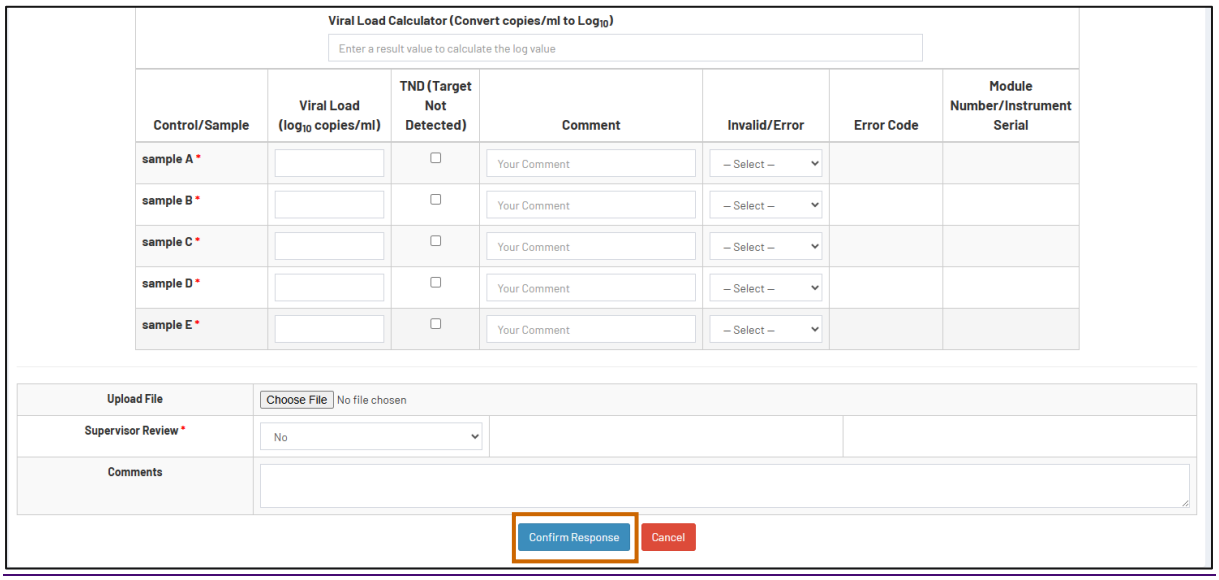


Figure. 19. Confirm response

10. Click “OK” when the confirmation message of result submission process completed. (Fig. 20. Completion of result submission)

e-PT system သို့ အဖြေဖြည့်သွင်းမှု ပြီးစီးကြောင်း စာတန်းပေါ်လာပါက “OK” ကိုနှိပ်ပါ။ (Fig. 20. Completion of result submission)

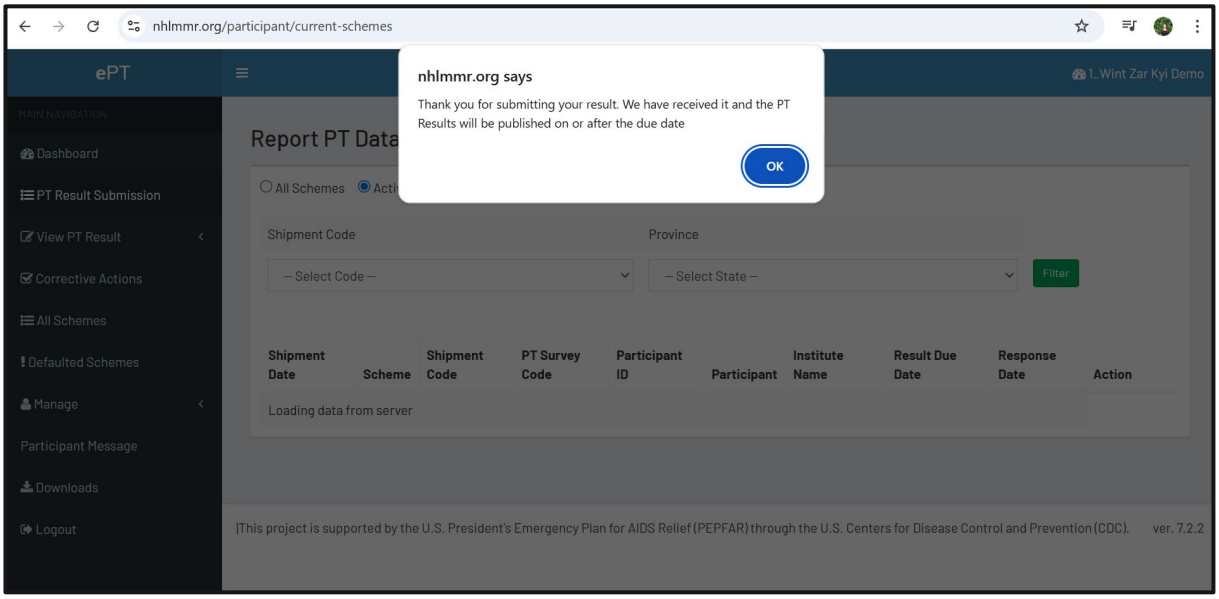


Figure. 20. Completion of result submission

11. After submission, it is possible to edit results before the assigned deadline. Enter your e-PT email and password as in the result submission process and edit via the "**View/Edit**". (Fig. 21. Edit Response)

အဖြေများကို e-PT system ထဲသို့ ဖြည့်ပြီးနောက် အဖြေပြန်ပို့ရန် နောက်ဆုံးသတ်မှတ်ရက် မတိုင်မီအထိ ဝင်ရောက်ပြင်ဆင်နိုင်သည်။ အဖြေဖြည့်သွင်းသည့်အတိုင်း username/ password နှင့် ဝင်ရောက်ကာ "**View/Edit**" မှတစ်ဆင့် ပြန်လည်ပြင်ဆင်နိုင်ပါသည်။ (Fig. 21. Edit Response)

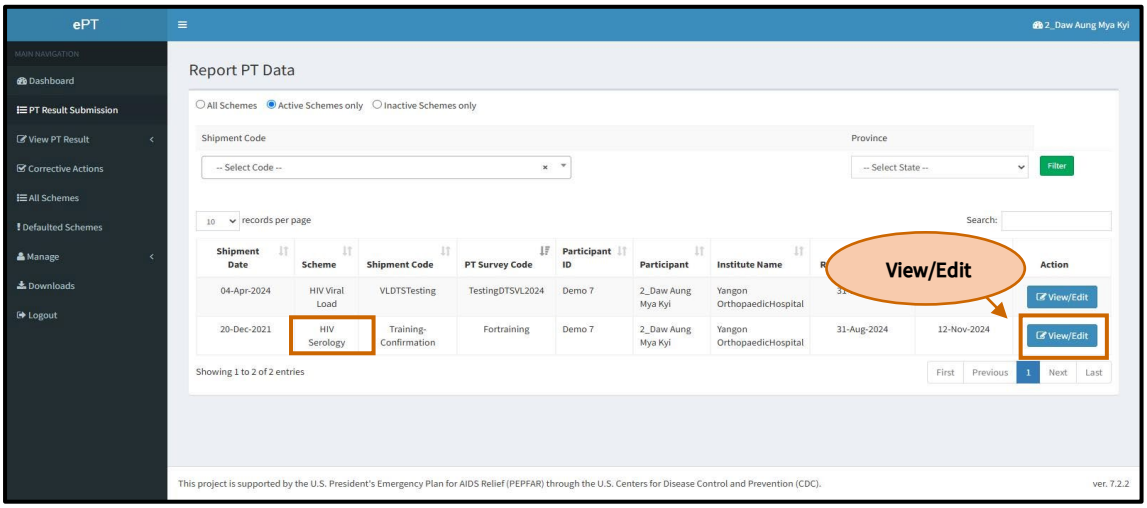


Figure. 21. Edit Response

HIV Viral Load NEQAS Panel report downloading using Laptop/ Desktop
HIV Viral Load NEQAS Panel report များအား Laptop/ Desktop ဖြင့် download ရယူခြင်း

Follow step-by-step instructions to download PT reports from the e-PT system.

PT report များအား e-PT system တွင် အောက်ပါအဆင့်များအတိုင်း download ရယူနိုင်ပါသည်။

1. Go to e-PT website "https://nhlmmr.org" and login with username and password in e-PT participant homepage.

   e-PT website "https://nhlmmr.org" တွင် e-PT အသုံးပြုရန်ပေးထားသော username နှင့် password အသုံးပြု၍ Login ဝင်ရောက်ပါ။

2. PT reports are available for the evaluated shipments reviewed by PT provider (NHL).

   PT provider (NHL)မှ အကဲဖြတ်စစ်ဆေးပြီးသော shipments များ အတွက်သာ PT report များ ရရှိပါမည်။

3. Click “**View PT Result**” button. Choose “**Individual Report**” and get report by clicking “**Report**” button in “HIV Viral Load” scheme. (Fig. 22. Individual Report Downloading)

“**View PT Result**” button ကို နှိပ်ပါ။ “**Individual Report**” ကိုရွေးပြီး “HIV Viral Load” scheme ရှိ သက်ဆိုင်ရာ Shipment code တွင် “**Report**” button ကို နှိပ်ကာ download ရယူနိုင်ပါသည်။ (Fig. 22. Individual Report Downloading)

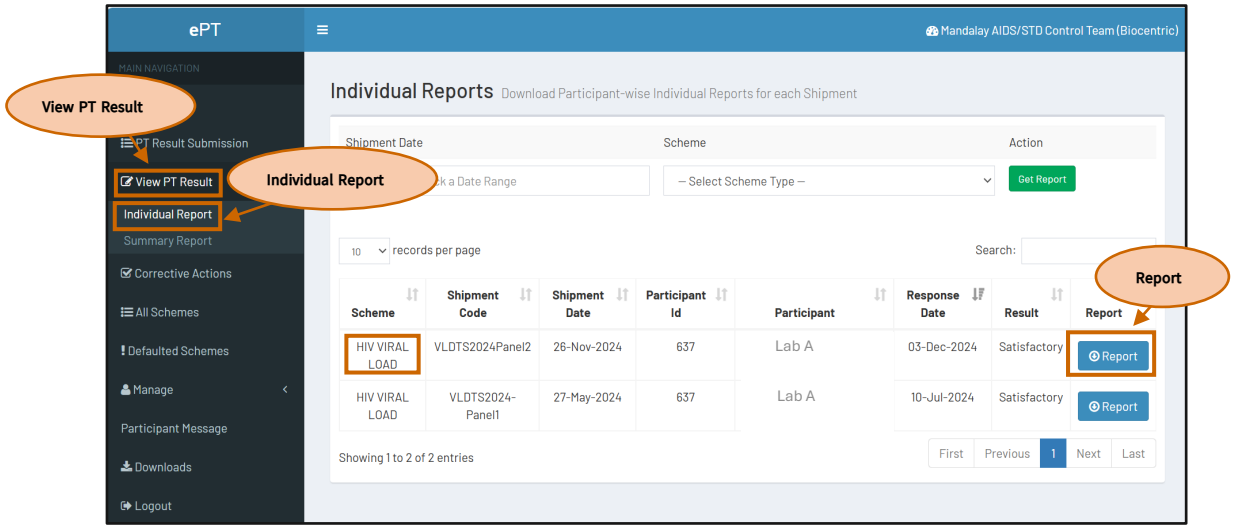


Figure. 22. Individual Report Downloading

4. Click “**View PT Result**” button. Choose “**Summary Report**” and get report by clicking “**Download Report**” sentence in “HIV Viral Load” scheme. (Fig. 23. Summary Report downloading)

“**View PT Result**” button ကို နှိပ်ပါ။ “**Summary Report**” ကိုရွေးပြီး “HIV Viral Load” scheme ရှိ သက်ဆိုင်ရာ Shipment code တွင် “**Download Report**” စာတမ်းကို နှိပ်ကာ download ရယူနိုင်ပါသည်။ (Fig. 23. Summary Report downloading)

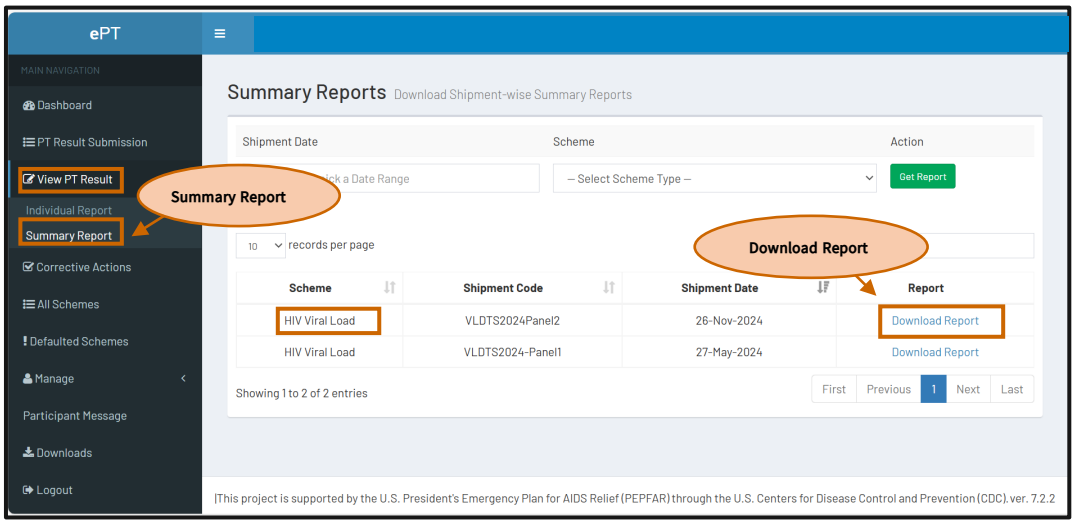


Figure. 23. Summary Report Downloading

Changing e-PT account password using Laptop/ Desktop
e-PT account password အား Laptop/ Desktop ဖြင့် ပြောင်းခြင်း

1. Go to the e-PT website and login with username and password to change current account password.
   e-PT system အတွက် လက်ရှိသုံးနေသော account password အား ပြောင်းလဲလိုပါက website သို့ login ဝင်ရောက်ပါ။

2. Select "**Manage**" on the left side of e-PT participant home screen and click "**Change Password**".
   Page ဘယ်ဘက်ခြမ်းရှိ "**Manage**" ကို နှိပ်ပြီး "**Change Password**" ကို နှိပ်ပါ။

3. Type "Your Current/Default Password" in "**Old Password**" box. Enter "New Password" that you would like to change in "**New Password**" box and "**Confirm New Password**" box and then click "**Change Password**". (Fig. 24. To change password)
   "**Old Password**" နေရာတွင် ယခုလက်ရှိအသုံးပြုနေသော Password ကို ရိုက်ထည့်ပါ။ အသစ်ပြောင်းလိုသော password အား "**New Password**" နှင့် "**Confirm New Password**" နေရာတွင် ရိုက်ထည့်ပြီး "**Change Password**" ကို နှိပ်ပါ။ (Fig. 24. To change password)

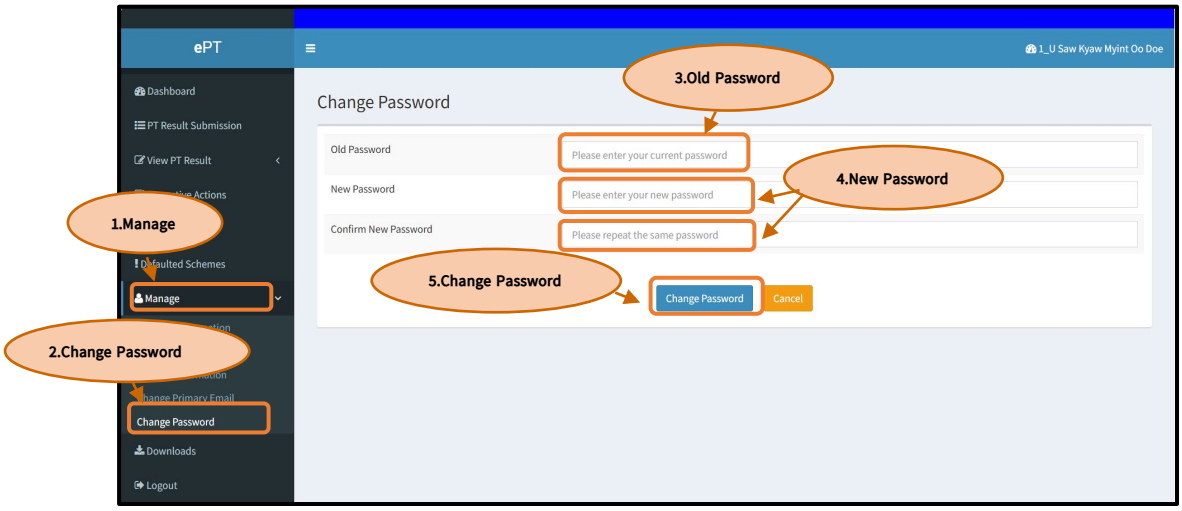


Figure. 24. To change password

5.10. Form F: User instruction for VL scorecard electronic tool

Submission of HIV VL scorecard assessment using Laptop/ Desktop

HIV VL scorecard assessment အား Laptop/ Desktop မှ တစ်ဆင့် ဖြည့်သွင်းခြင်း

1. Use any preferred browser to access the provided link.
   https://nhlmmricapvl.org//single/hmw4fXqH0Dgf70esr6eghRpEGqT1dqK?st=oBrzg6W1hP1PW4YrAzstvTi2vLB5gDbDmEp9eoMxdqxI1uWM5GZrFYXfSfRFIecr
   မိမိနှစ်သက်ရာ browser မှတစ်ဆင့် ပေးထားသော link ကို ဝင်ရောက်ပါ။
   https://nhlmmricapvl.org//single/hmw4fXqH0Dgf70esr6eghRpEGqT1dqK?st=oBrzg6W1hP1PW4YrAzstvTi2vLB5gDbDmEp9eoMxdqxI1uWM5GZrFYXfSfRFIecr

2. In the first entry page of electronic tool, select "**Next**" to start assessment submission. (Fig. 25. Scorecard homepage)
   Assessment စတင်ဖြည့်သွင်းရန် electronic tool ၏ ပထမစာမျက်နှာရှိ "**Next**" ကို နှိပ်ပါ။ (Fig. 25. Scorecard homepage)

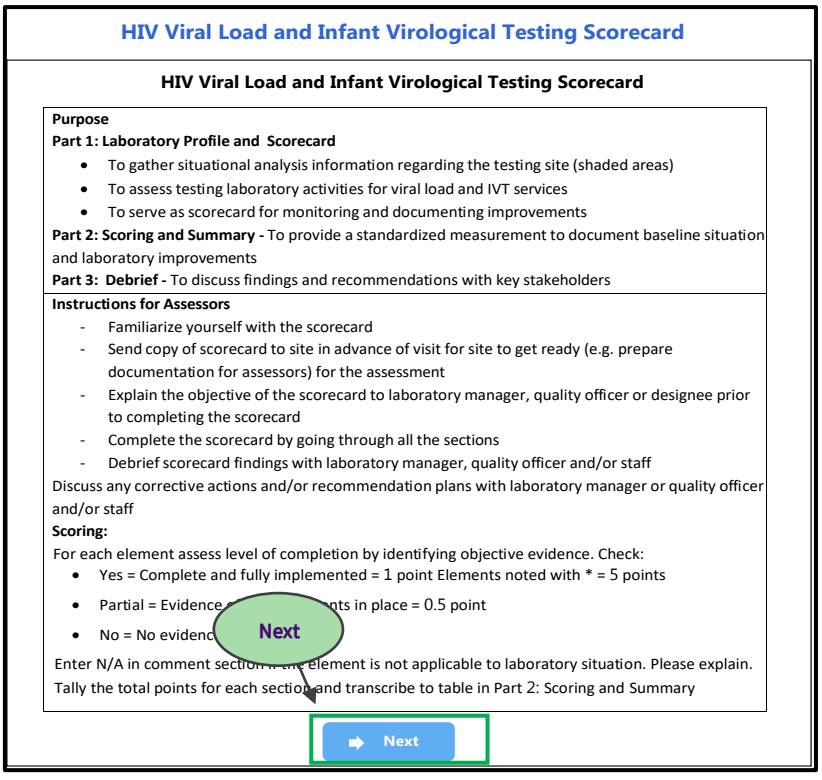


Figure. 25. Scorecard Homepage

3. On the "Part1 Laboratory Profile and Scorecard" page, select "**Country, State/Region and City/Town**" where the Viral Load Laboratory is located.
   "Part1 Laboratory Profile and Scorecard" စာမျက်နှာတွင် assessment ပြုလုပ်မည့် Viral Load ဓာတ်ခွဲခန်းရှိသော "**Country, State/Region and City/Town**" ကိုရွေးပါ။

4. In the “**Type of VL Platform**”, select the type of Viral Load Platform used in the laboratory. Select the name of laboratory in the “Laboratory Name”. Then, complete the assessment questions.

   “**Type of VL Platform**” နေရာတွင် ဓာတ်ခွဲခန်းဌ အသုံးပြုသော Viral Load Platform အမျိုးအစားကို ရွေးပါ။ “Laboratory Name” နေရာတွင် ဓာတ်ခွဲခန်းအမည်ကို ရွေးပါ။ ထို့နောက် assessment မေးခွန်းများကို ဖြေဆိုပါ။

5. Select **Yes** (or) **No** (or) **Partial** icon for the assessment questions in each section.
   If there is any specific comment, write in the “Comments:” box. (Fig. 26. To provide score)

   Section (ခ) ခုစီရှိ assessment မေးခွန်းများကို အမှတ်ပေးရန် **Yes** (သို့) **No** (သို့) **Partial** သင်္ကေတကို ရွေးချယ်ပါ။ မှတ်ချက်ပေးလိုပါက “Comments:” နေရာတွင်ရေးပါ။ (Fig. 26. To provide score)

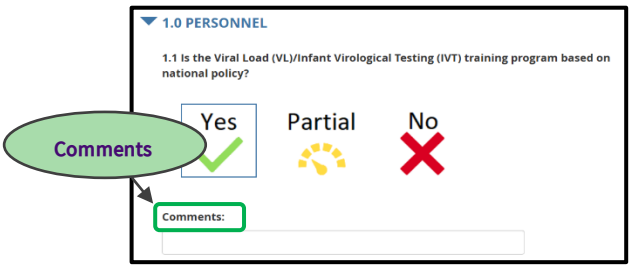


Figure. 26. To provide score

Notes: After completing each section, check the section score. If **NaN/section score** appears, it indicates that one or more questions have not been answered. It is required to review that section to ensure all questions are completed. (Fig. 27. Section score)

သတိပြုရန်။ section တစ်ခုဖြည့်ပြီးတိုင်း ရရှိသောအမှတ်ကို စစ်ဆေးပါ။ အမှတ်မပေါ်ပဲ **NaN/section score** ဟု ပေါ်နေပါက မေးခွန်းတစ်ချို့ဖြေဆိုရန်ကျန်ခဲ့ခြင်းဖြစ်သဖြင့် ထို section ရှိ မေးခွန်းများအား ပြန်စစ်ဆေးရန် လိုအပ်ပါသည်။ (Fig. 27. Section score)

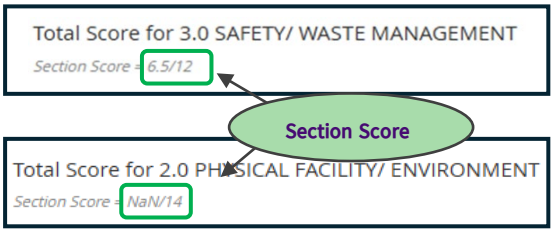


Figure 27. Section score

6. Click “**+**” symbol to add more information in some question. Select “**Next**” if there is no additional information. (Fig. 28. To add more information)

   တစ်ချို့သောမေးခွန်းများတွင် အချက်အလက်များ ထပ်မံဖြည့်စွက်ရန် လိုအပ်ပါက “**+**” သင်္ကေတကို နှိပ်ပါ။ မလိုအပ်ပါက “**Next**” ကို နှိပ်ပါ။ (Fig. 28. To add more information)

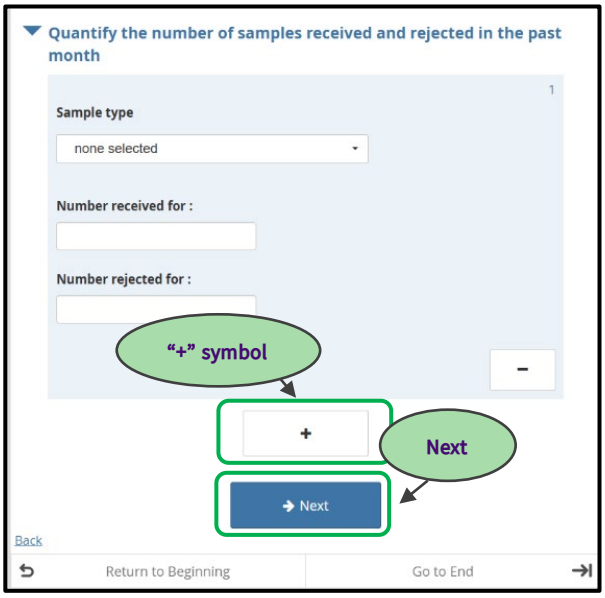


Figure. 28. To add more information

7. After all sections (5 sessions in Pre-Testing Phase, 2 sections in Testing Phase and 2 sections in the Post-Testing Phase) are completed, the summary score appears.
   Section အားလုံး (Pre-Testing section တွင် 5 sections ၊ Testing section တွင် 2 sections နှင့် Post-Testing section တွင် 2 sections) ဖြည့်ပြီးပါက summary score ရရှိပါသည်။

8. If there are any comments by the auditor, write in each section or sub-section in the Auditor's Summary Report page.
   Auditor မှ မှတ်ချက်ပေးရန် လိုအပ်ပါက Auditor's Summary Report စာမျက်နှာရှိ သက်ဆိုင်ရာ section (သို့မဟုတ်) sub-section တွင်ရေးသားပါ။

9. In "PART 3: Debrief" section, enter the name, position, and signature of all individuals who participated in the debriefing.
   "PART 3: Debrief" section တွင် assessment တွေ့ရှိချက်များကို ဆွေးနွေးခဲ့ရာတွင် ပါဝင်ခဲ့သူများ အားလုံး၏အမည်၊ ရာထူးနှင့်လက်မှတ်များကို ဖြည့်ပါ။

10. Click printer icon at the right corner of the page to save the assessment findings as PDF document.
    Assessment ပြုလုပ်ထားသော document ကို "PDF" file အနေဖြင့် သိမ်းဆည်းထားလိုပါက စာမျက်နှာညာဘက်ထောင့် အပေါ်ရှိ printer icon ကိုနှိပ်ကာ Save as PDF အနေနှင့် PDF file ကို ရယူနိုင်ပါသည်။

11. After completing all the sections, enter the completion time for the assessment, and then click "**Submit**".
    Section အားလုံး ဖြေဆိုပြီးပါက assessment ပြုလုပ်မှုပြီးဆုံးချိန်ကို ရိုက်ထည့်ပါ။ ထို့နောက် "**Submit**" ကို နှိပ်ပါ။

Submission of HIV VL scorecard assessment using android mobile application
HIV VL scorecard assessment အား ဖုန်းအသုံးပြုပြီး ဖြည့်သွင်းခြင်း

1. Download the “ODK Collect” application from Play Store to install on an andriod mobile phone. Click “**Configure with QR code**” and scan the VL Scorecard QR to access the new form. (Fig. 29. VL scorecard android mobile application)

   ODK Collect application ကို Google Play Store မှ download ရယူပြီး ဖုန်းတွင် install လုပ်ပါ။ “**Configure with QR code**” ကို နှိပ်ပြီး Form အသစ်ကို ရယူရန် VL Scorecard QR code ကို scan ဖတ်ပါ။ (Fig. 29. VL scorecard andriod mobile application)

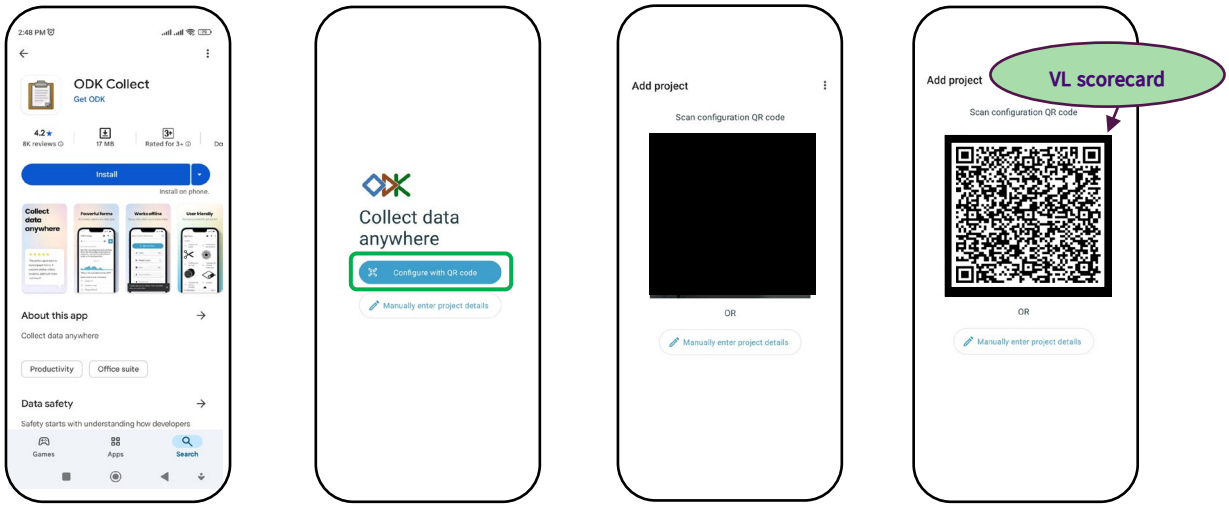


Figure. 29. VL scorecard andriod application

2. Click “**+ Start new form**” on the content page and then click "**HIV Viral Load and Infant Virological Testing Scorecard**” on the next page.

   “**+ Start new form**” ကို နှိပ်ပါ။ ထို့နောက် နောက်စာမျက်နှာရှိ "**HIV Viral Load and Infant Virological Testing Scorecard**” ကို နှိပ်ပါ။

3. On the “Part1 Laboratory Profile and Scorecard” page, select “**Country, State/Region and City/Town**“ where the Viral Load Laboratory is located.

   “Part1 Laboratory Profile and Scorecard” စာမျက်နှာတွင် assessment ပြုလုပ်မည့် Viral Load ဓာတ်ခွဲခန်းရှိသော “**Country, State/Region and City/Town**” ကိုရွေးပါ။

4. In the “**Type of VL Platform**”, select the type of Viral Load Platform used in the laboratory.

   “**Type of VL Platform**” နေရာတွင် ဓာတ်ခွဲခန်း၌ အသုံးပြုသော Viral Load Platform အမျိုးအစားကို ရွေးပါ။

5. Select the name of the laboratory in the "**Laboratory Name**". Then, complete the assessment questions. (Fig. 30. Laboratory profile and scorecard information)

   "**Laboratory Name**" နေရာတွင် ဓာတ်ခွဲခန်း၏အမည်ကို ရွေးပါ။ ထို့နောက် assessment မေးခွန်းများကို ဖြေဆိုပါ။ (Fig. 30. Laboratory profile and scorecard information)

Figure 30. Laboratory profile and scorecard information

6. Select **Yes** (or) **No** (or) **Partial** icon for the assessment questions in each section. If there is any specific comment, write in the "Comments:" box.

   Section (ခ) ခုစီရှိ assessment မေးခွန်းများကိုအမှတ်ပေးရန် **Yes** (သို့) **No** (သို့) **Partial** သင်္ကေတကို ရွေးချယ်ပါ။ မှတ်ချက်ပေးလိုပါက "Comments:" နေရာတွင်ရေးပါ။

7. Click "**Add**" button to add more information in some question. Select "**Do not add**" button if there is no additional information.

   တစ်ချို့သောမေးခွန်းများတွင် အချက်အလက်များ ထပ်မံဖြည့်စွက်ရန်လိုအပ်ပါက "**Add**" button ကို နှိပ်ပါ။ မလိုအပ်ပါက "**Do not add**" ကို နှိပ်ပါ။

8. After all sections (5 sessions in Pre-Testing Phase, 2 sections in Testing Phase and 2 sections in the Post-Testing Phase) are completed, the summary score appears. (Fig. 31. VL scorecard assessment)

   Section အားလုံး (Pre-Testing section တွင် 5 sections ၊ Testing section တွင် 2 sections နှင့် Post-Testing section တွင် 2 sections) ဖြည့်ပြီးပါက summary score ရရှိပါသည်။ (Fig. 31. VL scorecard assessment)

   Notes: After completing each section, check the section score. If **blank/section score** appears, it indicates that one or more questions have not been answered. It is required to review that section to ensure all questions are completed.

   သတိပြုရန်။ section တစ်ခုဖြည့်ပြီးတိုင်း ရရှိသောအမှတ်ကို စစ်ဆေးပါ။ အမှတ်မပေါ်ပဲ **blank/section score** ဟု ပေါ်နေပါက မေးခွန်းတစ်ချို့ဖြေဆိုရန်ကျန်ခဲ့ခြင်းဖြစ်သဖြင့် ထို section ရှိ မေးခွန်းများအား ပြန်စစ်ဆေးရန် လိုအပ်ပါသည်။

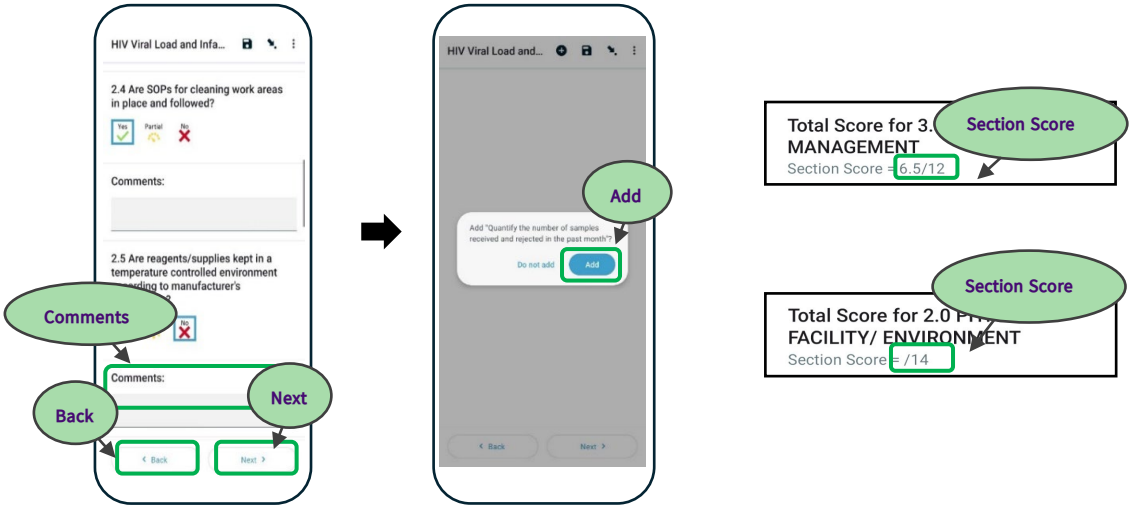


Figure. 31. VL scorecard assessment

9. If there are any comments by the auditor, write in each section or sub-section in the Auditor's Summary Report page.
   Auditor မှ မှတ်ချက်ပေးရန် လိုအပ်ပါက Auditor's Summary Report စာမျက်နှာရှိ သက်ဆိုင်ရာ section (သို့မဟုတ်) sub-section တွင်ရေးသားပါ။

10. In "PART 3: Debrief" section, enter the name, position, and signature of all individuals who participated in the debriefing.
    "PART 3: Debrief" section တွင် assessment တွေ့ရှိချက်များကို ဆွေးနွေးခဲ့ရာတွင် ပါဝင်ခဲ့သူများ အားလုံး၏ အမည်၊ ရာထူးနှင့်လက်မှတ်များကို ဖြည့်ပါ။

11. After completing all the sections, enter the assessment completion time, and then click "**Send**". In mobile version, save as draft in the "**Drafts**" folder and edit before the final submission to the ODK server. (Fig. 32. Assessment submission)
    Section အားလုံးကို ဖြေဆိုပြီးပါက assessment ပြုလုပ်မှုပြီးဆုံးချိန်ကို ရိုက်ထည့်ပါ။ ထို့နောက် "**Send**" ကို နှိပ်ပါ။ ဖုန်း version တွင် ODK Server သို့ နောက်ဆုံးမဖြည့်သွင်းမီ "**Drafts**" folder တွင် ယာယီသိမ်းဆည်းထားပြီး ပြန်လည်ပြင်ဆင်နိုင်ပါသည်။ (Fig. 32. Assessment submission)

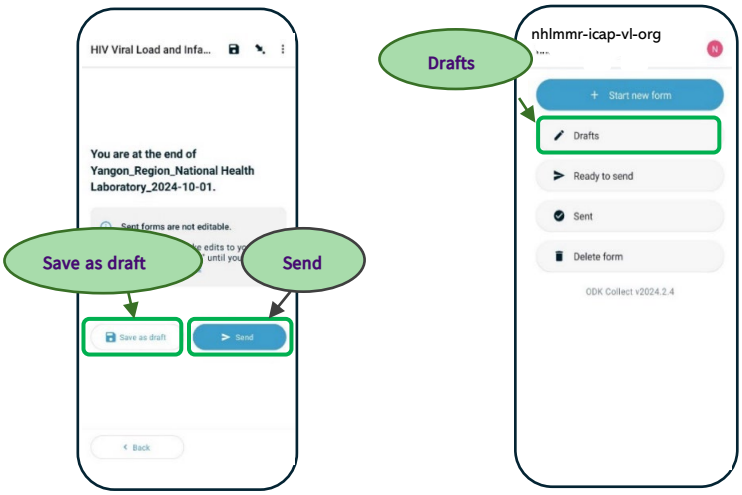


Figure. 32. Assessment submission

HIV VIRAL LOAD AND INFANT VIROLOGIC TESTING SCORECARD v3.1

Users' Guide for HIV Viral Load and Infant Virologic Testing Scorecard

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Version 2.0

HIV VIRAL LOAD AND INFANT VIROLOGIC TESTING SCORECARD

Purpose

Part 1: Laboratory Profile and Scorecard

- To gather situational analysis information regarding the testing site (shaded areas)
- To assess testing laboratory activities for Viral Load and IVT services
- To serve as scorecard for monitoring and documenting improvements

Part 2: Scoring and Summary - To provide a standardized measurement to document baseline situation and laboratory improvements

Part 3: Debrief - To discuss findings and recommendations with key stakeholders

Appendix A: Quarterly Monitoring Tool - To capture indicators of VL/IVT program implementation quarterly

Appendix B: Pre-Inspection Checklist - To prepare laboratory for inspection using Scorecard, to minimize the time of the on-site inspection

Instructions for Assessors

- Familiarize yourself with the scorecard
- Explain the objective of the scorecard to laboratory manager, quality officer or designee prior to completing the scorecard
- Complete the scorecard by going through all the sections
- Debrief scorecard findings with laboratory manager, quality officer and/or staff

Discuss any corrective actions and/or recommendation plans with laboratory manager or quality officer and/or staff.

Scoring:

For each element assess level of completion by identifying objective evidence. Check:

- Yes = Complete and fully implemented = 1 point Elements noted with * = 5 points
- Partial = Evidence of some elements in place = 0.5 point
- No = No evidence = 0 point
- Enter N/A in comment section if the element is not applicable to laboratory situation. Please explain.

Tally the total points for each section and transcribe to table in Part 2: Scoring and Summary

Example:

4.0		PROCUREMENT AND INVENTORY					
Who decides/quantifies lab supplies to be procured?		☐ Laboratory ☒ Pharmacy ☐ Other, specify_____					
4.0		**PROCUREMENT AND INVENTORY**	**YES**	**PARTIAL**	**NO**	**COMMENTS**	**SCORE/3**
4.1		Is there a SOP for inventory control?	x				
4.2		Have all reagents been in stock during the past 6 months? If no or partial record the number of stock outs in comment section.		x		VL __2__ IVT _____	
4.3		Have all supplies been in stock during in the past 6 months? If no or partial record number of stock outs in comment section.		x		VL __1__ IVT __1__	
4.0		**PROCUREMENT AND INVENTORY**					2

PART 1: LABORATORY PROFILE AND SCORECARD

Country		District/Province/Region	
Laboratory Name		City/Town	
Affiliation	☐ Government ☐ Private ☐ Faith-based organization ☐ Non-government organization ☐ Other (Please specify):	Level	☐ National Reference Laboratory ☐ Regional/Provincial Laboratory ☐ District Laboratory ☐ Other (Please specify):
Date DD/MM/YYYY		Start Time	
Assessor Name #1		End Time	

Assessor Name #2		First assessment? Yes ☐ No ☐	If no: Date of Last Assessment	

PRE-TESTING PHASE			
1.0 Personnel			
	Total Number	Number performing VL testing	Number performing IVT testing
Laboratory Technologist			
Laboratory Technician			
Laboratory Assistant			
Laboratory Clerk			
Others, please specify			
What is the average retention time for VL/IVT testing personnel?			☐ <6 months ☐ 6 months – 1 year ☐ >1 year – 2 years ☐ >2 years
Comments:			

1.0	PERSONNEL	WHAT TO ASK FOR?	WHAT TO LOOK FOR?
1.1	Is the Viral Load (VL)/Infant Virological Testing (IVT) training program based on national policy?	**Ask the following:** - National Policy - How many testers are in the lab? - How many are trained? - For training manual or training competency criteria	- Verify training content meets national policy requirements. **Note**: *Mark "Yes" if training documents are available and compliant with national policy. Mark "Partial" if training documents are available but content does not meet national policy.* *Mark "No" if training documents are not available.*

1.2	Have all laboratory personnel received comprehensive training on VL/IVT testing using approved Standard Operating Procedures (SOPs)?	**Ask the following:** - For documentation of competency assessment for all testers	- Verify dates of trainings. - Verify training contents including hands- on sessions. **Note**: *Mark "Yes" if training documents are available and content include all quality elements (*e.g., safety, EQA/PT, waste management, inventory, QC documents and records, testing procedures, etc.) *Mark "Partial" if training documents are available but content does not include all quality elements.* *Mark "No" if training documents are not available.*
1.3	Are laboratory personnel trained on using standardized VL/IVT testing registers /logbook/LIMS?	**Ask the following:** - Testing Registers/Logbook/LIMS	- Verify training content includes properly filling register. - Verify a copy of VL/IVT testing register and check all required elements are filled out. **Note:** *Mark "Yes" if all VL/IVT testing elements are accurately documented.* *Mark "Partial" if some testing elements are documented.* *Mark "No" if no testing elements are documented.*
1.4	Are laboratory personnel trained on sample management from	**Ask the following:** - For documentation of training on	- Verify SOPs for sample management. - Verify samples have been properly

	collection to disposal?	sample management	labelled and logged upon receipt in lab. - Verify SOPs contain proper disposal of samples, including logging the disposal appropriately. **Note:** *Mark "Yes" if laboratory personnel can describe sample management SOPs and samples are consistently properly labelled, logged and stored.* *Mark "Partial" if laboratory personnel can describe sample management SOP but samples are inconsistently labelled, logged, or stored.* *Mark "No" if laboratory personnel cannot describe sample management SOP or samples are not labelled, logged, or stored correctly.*
1.5	Are laboratory personnel trained on routine preventive equipment maintenance?	**Ask the following:** - For documentation of personnel training on routine preventive equipment maintenance	- Verify SOPs for routine preventative equipment maintenance, or that maintenance is included within the testing SOP. **Note:** *Mark "Yes" if laboratory personnel can describe SOPs for routine preventative equipment maintenance and logs are properly documented.* *Mark "Partial" if laboratory personnel can describe SOPs but logs are incomplete.* *Mark "No" if laboratory personnel cannot describe SOPs or logs are missing.*

1.6	Are laboratory personnel trained on the quality control process?	**Ask the following:** - For documentation of personnel training on preventive equipment maintenance	- Verify the laboratory personnel know about QC SOPs. - Verify how QC results are documented in QC logs or VL/IVT register/logbook /LIMS. **Note***: Mark "Yes" if laboratory personnel can describe QC SOPs and consistently document QC results in the appropriate log.* *Mark "Partial" if laboratory personnel can describe SOPs but logs are not properly documented.* *Mark "No" if laboratory personnel cannot describe SOPs and logs are not documented.*
1.7	Are laboratory personnel trained on safety and waste management procedures and practices?	**Ask the following:** - For documentation of personnel training on safety and waste management	- Verify SOPs for safe handling and disposal of waste. **Note***: Mark "Yes" if laboratory personnel can describe SOPs for safe disposal of waste.* *Mark "Partial" if laboratory personnel can describe but testing area shows improperly disposed of waste.* *Mark "No" if laboratory personnel cannot describe SOPs*
1.8	Are only trained/competent laboratory personnel allowed to perform VL/IVT testing?	**Ask the following:** - For documentation of competency assessment for all VL/IVT testers	- Verify SOP that describes method and frequency of competency assessment. - Verify competency documents are complete for all laboratory personnel. **Note***: Mark "Yes" if competency is well*

			documented for all laboratory personnel. Mark "Partial" if competency is well documented for some laboratory personnel but not all. *Mark "No" if there is no documentation of competency or no SOP.*
1.9	Are approved/signed records of all trainings for all laboratory personnel kept on file?	**Ask the following:** - For documentation of laboratory personnel training files	- Verify documentation of direct observation of the laboratorian performing VL/IVT testing by trainer or supervisor (e.g. signature and date). - Verify personnel training log indicating that trainers or supervisors trained all staff. **Note:** *Mark "Yes" if training logs fully indicate all laboratory personnel are trained. Mark "Partial" if logs indicate less than all laboratory personnel are trained.* *Mark "No" if logs do not indicate laboratory personnel are trained or are missing.*
1.10	Do records indicate all laboratory personnel were deemed competent before independently testing client VL/IVT samples?	**Ask the following:** - For documentation of laboratory personnel training files	- Verify SOP that describes method and frequency of competency assessment. - Verify competency documents are complete for all laboratory personnel. **Note:** *Mark "Yes" if competency is well documented for all laboratory personnel.* *Mark "Partial" if competency is well documented for some laboratory personnel but not all. Mark "No" if there is no documentation of competency*

			or no SOP.
1.11	Have all VL/IVT testing personnel received refresher training, according to the approved training program?	**Ask the following:** - For documentation of laboratory personnel refresher training files	- Verify if refresher training is included in the training and/or competency SOP. **Note***: Mark "Yes" if records indicate refresher training was performed for all laboratory personnel consistently.* *Mark "Partial" if records indicate refresher training was performed inconsistently.* *Mark "No" if no refresher training is performed or records do not exist.*

2.0	**PHYSICAL FACILITY / ENVIRONMENT**	**WHAT TO ASK FOR?**	**WHAT TO LOOK FOR?**
2.1	Is there a designated area exclusively for VL/EID testing?	**Ask for the following:** - To see all areas where VL/IVT testing occurs - For documentation of manufacturer's requirements for equipment installation. - Certificate of equipment installation by manufacturer	- Verify that the laboratory testing space is designated for only HIV VL/IVT testing. **Note***: Mark "Yes" if the laboratory is only used for VL/IVT testing.* *Mark "Partial" if the laboratory is used for other testing as well as VL/IVT.* *Mark "No" if all laboratory testing is performed in the same space.*
2.2	Does testing area meet manufacturer's requirements for equipment installation?	- To see all areas where VL/IVT testing occurs	- Manufacturer's equipment installation requirements or standards manual. - Check to see if testing area meet manufacturer's requirements for - equipment installation using the manual. - Verify manufacturer's equipment installation

			requirements in package insert or operator's manual. - Determine if laboratory space meets manufacturer's requirements (e.g. unidirectional workflow, extraction and amplification in separate areas, laboratory temperature control, space around the instruments, etc.) **Note***: Mark "Yes" if the laboratory meets or exceeds all manufacturer requirements.* *Mark "Partial" if the laboratory meets some of the manufacturer's requirements.* *Mark "No" if the laboratory is insufficient.*
2.3	Is the VL/IVT testing area clean, and organized?		- Verify that the laboratory space is clean and organized. **Note***: Mark "Yes" if the laboratory is clean and well organized.* *Mark "Partial" if the laboratory is somewhat clean and organized.* *Mark "No" if the laboratory is not clean or organized.*
2.4	Are reagents/supplies kept in a temperature controlled environment according to manufacturer's instructions?	**Ask for the following:** - To see where VL/IVT test kits and other supplies ae being stored	- Verify manufacturer's instructions from the VL/IVT testing package insert. - Verify storage conditions are appropriate (e.g. all temperatures are within required limits, away from direct sunlight, etc.)

			Note: *Mark "Yes" if all storage conditions are met. Mark "Partial" if some storage conditions are met. Mark "No" if none of the storage conditions are met.*
2.5	Are SOPs in place and followed for temperature monitoring?	**Ask for the following:** - Temperature monitoring logs/charts with defined acceptable temperature ranges - To see nonconforming event management sheets/logs	- Verify temperature monitoring SOP - Verify temperature logs, ensuring that all temperatures are with acceptable ranges, nonconforming events are noted, and that the supervisor reviews periodically, per SOP. **Note**: *Mark "Yes" if laboratory personnel can describe temperature monitoring SOP and logs are completely filled out.* *Mark "Partial" if laboratory personnel can describe SOP and logs are inconsistently filled out.* *Mark "No" if laboratory personnel cannot describe SOP, temperatures are not monitored, or logs are missing.*
2.6	Are acceptable temperature ranges defined for temperature dependent equipment?	**Ask for the following:** - Temperature monitoring logs/charts with defined acceptable temperature ranges - To see nonconforming event management sheets/logs	- Verify acceptable temperature ranges are defined for all temperature depending on equipment. - Verify that these ranges meet the manufacturer's requirements. **Note**: *Mark "Yes" if all temperature dependent equipment has an acceptable range defined that is within the manufacturer's requirements.*

			Mark "Partial" if some temperature dependent equipment does not have an acceptable range or the acceptable ranges are not within the manufacturer's requirements. *Mark "No" if no equipment has acceptable ranges or none of the acceptable ranges are within the manufacturer's requirements.*
2.7	Are temperatures recorded daily for? - Freezers - Refrigerators - Room temperature		- Verify temperature log monitors freezers, refrigerators, and testing spaces are recorded on a daily basis. - Verify that nonconforming events are properly noted. **Note***: Mark "Yes" if temperature monitoring logs are accurately completed.* *Mark "Partial" if logs are inconsistently completed or nonconforming events are not noted.* *Mark "No" if logs are missing or temperature monitoring is not performed daily.*
2.8	Is there documentation of corrective action taken in response to out of range temperatures?	**Ask for the following:** - Temperature monitoring logs/charts with defined acceptable temperature ranges - To see nonconforming event management sheets/logs	- Verify nonconforming event/corrective action SOP. - Verify that corrective action is documented when temperature nonconformity is reported. **Note***: Mark "Yes" if corrective action is documented and appropriate action is taken.*

			Mark "Partial" if documentation of corrective action is inconsistent but appropriate action is taken. *Mark "No" if documentation of corrective action is unavailable or inappropriate action is taken.*
2.9	Are UPS in place for testing equipment?	**Ask the following:** - List of all sensitive electrical equipment are connected to UPS system	- Verify sensitive electrical equipment are connected to UPSs (e.g. extraction equipment, amplification equipment, associated computers, etc.) - Verify utilized UPSs function. **Note:** *Mark "Yes" if all necessary equipment is connected to a functional UPS.* *Mark "Partial" if some necessary equipment is connected to a functional UPS.* *Mark "No" if necessary, equipment is not attached to UPSs or UPSs are not functional.*
2.10	Is there a functional back-up generator?	**Ask for the following:** - List of all sensitive electrical equipment is connected to a back-up generator. - For documentation of testing equipment to power system transfers (back-up generator). - For documentation of the tester how to deal with the loss of power	- Verify that all equipment required for VL/IVT testing and sample/ reagent storage are connected to a back-up generator. - Verify that the back-up generator is functional. - Verify that there is a sufficient fuel supply for the generator. **Note***: Mark "Yes" if all required equipment and sample/reagent storage are connected to a*

			functional back-up generator with sufficient fuel supply. *Mark "Partial" if some required equipment and sample/reagent storage are connected to a functional back-up generator with sufficient fuel supply.* *Mark "No" if generator is not functional or inadequate fuel supply prevents its use.*
2.11	Is there secure cold chain storage space?	**Ask for the following:** - To see cold chain storage space	- Verify cold chain storage space is sufficient, accessible, secured, and well organized. - Verify that samples and reagents are stored in separate spaces (e.g. samples and reagents in separate freezers/refrigerators) **Note***: Mark "Yes" if cold chain storage space is sufficient for all reagents/samples and kept secure.* *Mark "Partial" if cold chain storage space is limited but secure.* *Mark "No" if cold chain storage space is insufficient or unsecure.*
2.12	Is there a secure backup cold chain storage space?	**Ask for the following:** - To see back-up cold chain storage space is available and secured - To see storage space for	- Verify back-up cold chain storage space is sufficient, accessible, secured, and well organized (e.g. enough space for backlogged samples and reagents to test

		consumables is secured	the backlog in addition to normal inventory levels). **Note**: *Mark "Yes" if back-up cold chain storage space is sufficient and secure.* *Mark "Partial" if back-up cold chain storage space is limited but secure.* *Mark "No" if back-up cold chain storage space is insufficient or unsecure.*
2.13	Is there secure storage space for consumables?		- Verify storage space for consumables is sufficient and secure. **Note**: *Mark "Yes" if consumables storage space is sufficient and secure.* *Mark "Partial" if consumables storage space is limited but secure.* *Mark "No" if consumables storage space is insufficient or unsecure.*
2.14	Are SOPs for cleaning work areas in place and followed?	**Ask for the following:** - To see the laboratory cleaning checklist for work areas	- Verify SOPs for cleaning work areas and sufficient (e.g. work surfaces are treated with 10% bleach/JIK, deionized water, then 70% ethanol, or other appropriate disinfected in place of bleach/JIK, work areas are cleaned prior to and/or after use). - Verify work area cleaning logs. **Note**: *Mark "Yes" if SOPs for cleaning work areas are sufficient and logs indicate work areas are as*

			required. Mark "Partial" if SOPs for cleaning work areas are sufficient but logs do not adequately document work area cleaning. Mark "Partial" if SOPs are insufficient or logs are not filled out or missing.

3.0	SAFETY / WASTE MANAGEMENT	WHAT TO ASK FOR?	WHAT TO LOOK FOR?

3.1	Are SOPs in place and followed for personnel safety practices?	**Ask for the following:**
		- To see the safety/safety related SOPs/job aids for:
		  - Safety Manual/Guidelines
		  - Disposal of infectious and non-infectious waste
		  - Spill management procedures
		  - Exposure management procedures
			- Review all documents, SOPs, and/or job aides for safety.
			- Verify handling/disposal infectious and non-infectious waste.
			- Verify proper handling of spills.
			Note*: Mark "Yes" if the SOPs clearly outline the different safety procedures and practices, and that these are understood and implemented by the laboratory personnel.*
			Mark "Partial" if the SOPs do not clearly outline the different safety procedures and practices or they are not properly understood or implemented by the laboratory personnel.
			Mark "No" if there are no SOPs outlining safety procedures.

3.2	Are SOPs in place and followed for disposal for infectious and non-infectious waste?		
3.3	Are SOPs in place and followed to manage biohazardous spills, e.g. blood?		
3.4	Are SOPs in place and followed to address accidental exposure to potentially infectious body fluids through needle-stick injury, splash or other sharps injury?		- Verify SOP addressing accidental exposure. - Verify access to post-exposure prophylaxis. **Note***: Mark "Yes" if SOP clearly defines post-*

			exposure safety measures and laboratory personnel understand them. *Mark "Partial" if SOP clearly defines post-exposure safety measures but laboratory personnel do not fully understand them. Mark "No" if there is no SOP, laboratory personnel are unaware of post-exposure safety measures, or there is no access to post-exposure prophylaxis.*
3.5	Is personnel protective equipment (PPE) always available to the VL/IVT testing personnel?	**Ask for the following:** - To see where PPEs (gloves, aprons, laboratory coats, goggles, etc.) are stored - How and when PPE is used	- Verify PPEs (apron, gloves, laboratory coats, etc.) - Review the stock card and current stock **Note:** *Mark "Yes", if there are appropriate PPEs (i.e. gloves, apron/lab coats, etc.) available for the providers* *Mark "Partial", if there are gloves, apron/lab coats available but insufficient.* *Mark "No", if gloves, aprons/lab coats are not available for providers*
3.6	Do all laboratory personnel properly use PPE throughout the VL/IVT testing process?	**Ask for the following:** - How and when PPE is used.	- Observe if PPE is properly used by all laboratory personnel during testing **Note:** *Mark "Yes" if gloves and apron/ laboratory coats are properly worn at all times during testing.* *Mark "Partial" if gloves and apron/ laboratory coats are inconsistently worn during testing.*

			Mark "No" if no PPE is worn or if handling personal items (e.g. cell phone, key, etc.) with contaminated gloves.
3.7	Are clean water and soap available for hand washing?	**Ask for the following.** - Do the testers wash their hands?	- Check that soap and clean running water are available. - Check that sinks are functional. **Note***: Mark "Yes" if soap and clean running water are available and consistently used. Mark "Partial" if soap and clean running water are available but inconsistently used. Mark "No" if soap and/or clean running water are not available.*
3.8	Are eye wash and/or safety shower facilities readily accessible to laboratory personnel?	**Ask for the following:** - To see eyewash and shower station inspection checklist	- Verify eye wash unit/safety shower is in good operational condition. - Verify if laboratory personnel know the location and how to use the nearest eye wash unit/safety shower. - Verify if there is documentation of regular eye wash unit/safety shower inspection. **Note***: Mark "Yes" if eye wash unit/safety shower is available, in good operational condition, records show consistent inspection, and laboratory personnel know where it is and how to operate.* *Mark "Partial" if eye wash unit/safety shower is*

			available, in good operational condition, but records show inconsistent inspections and/or laboratory personnel do not know where it is or how to operate. *Mark "No" if eye wash unit/safety shower is unavailable or non-operational.*
3.9	Is an appropriate disinfectant available to clean the work area and equipment?	**Ask the following:** - How are work areas and equipment cleaned? How do you document work surface and equipment cleaning?	- Verify that appropriate disinfectant is being used and available (i.e. bleach/JIK as appropriate). - Work surfaces should be disinfected with 0.5% bleach, followed by DI water, then 70% ethanol. An appropriate alternate disinfectant may be used in place of bleach. - Note, some equipment is only regularly cleaned with water and ethanol. - Verify that records exist and are reviewed for work area and equipment cleaning. **Note***: Mark "Yes" if an appropriate disinfectant is available and laboratory personnel can properly describe how to disinfect work surfaces and equipment. Records show regular (i.e. every day of use) cleaning.* *Mark "Partial" if appropriate disinfectants are available but records do not show routine clean*

			work areas or equipment. *Mark "No" if disinfectants are not available, laboratory personnel cannot describe cleaning process, or records do not exist.*
3.10	Are sharps, infectious and non-infectious waste handled properly?	**Ask the following:** - Ask how often the waste containers are emptied, by who and how? To see where the infectious waste is disposed	- Verify that waste is properly managed (infectious vs. noninfectious disposed of per national guidelines (e.g., using correct waste bins and bags). - Observe that infectious, and non-infectious wastes are properly disposed. **Note:** *Mark "Yes" if wastes and sharps are properly segregated and handled throughout testing procedure.* *Mark "Partial" if wastes or sharps are inconsistently segregated and handled throughout testing procedure.* *Mark "No" if wastes or sharps are not segregated and handled properly throughout testing procedure.*
3.11	Is chemical waste handled, according to laboratory SOPs?	**Ask the following:** Ask how chemical waste is handled in the lab?	- Verify SOPs related to chemical waste management. - Observe chemical waste containers in laboratory (e.g. are they overfull, clean, etc.) **Note***: Mark "Yes" if laboratory personnel can describe SOP and evidence of*

			proper chemical waste handling in laboratory. *Mark "Partial" if laboratory personnel can describe SOP but evidence of inconsistent chemical waste handling in laboratory.* *Mark "No" if laboratory personnel cannot describe SOP, SOP missing, or mishandling of chemical waste in laboratory.*
3.12	Are containers for infectious and non- infectious waste emptied regularly in accordance with SOPs?	**Ask the following:** - How frequently the infectious and non- infectious waste containers are emptied, by whom and how? To see where the infectious waste is disposed	- Verify written SOP for the proper disposing infectious and non-infectious waste in the laboratory - Verify that waste containers are full or not - Verify where the wastes are disposed **Note***: Mark "Yes" if there is evidence that wastes and sharps containers are emptied regularly.* *Mark "Partial" if wastes and sharps containers are emptied inconsistently.* *Mark "No" if wastes or sharps containers are overfull and/or evidence of poor waste management.*

4.0	**PROCUREMENT AND INVENTORY**
Who decides/quantifies lab reagents/supplies to be procured?	☐ Laboratory ☐ Pharmacy ☐ Other, specify_____

What is the quantification based on?		☐ Inventory record ☐ Past consumption estimate ☐ Available budget	☐ Don't know ☐ Other, specify_____
How often are reagents/supplies for VL/IVT ordered?		VL: IVT:	
Comments:			
4.0	**PROCUREMENT AND INVENTORY**	**WHAT TO ASK FOR?**	**WHAT TO LOOK FOR?**
4.1	Have all VL/IVT reagents been in stock during the past 6 months? If no or partial record the number of stock outs in comment section.	**Ask the following:** - Check the procurement and management of supplies and equipment records	- Verify VL/IVT reagents have been in stock during the last 6 months from previous inventory records. **Note**: *Mark "Yes" if there have been no reagent stock-outs in the past 6 months.* *Mark "Partial" if there have been 1 or more reagent stock-outs that have not caused a backlog.* *Mark "No" if there have been multiple stock-outs that caused testing backlogs.*
4.2	Have all VL/IVT supplies been in stock during in the past 6 months? If no or partial record number of stock outs in comment section.	**Ask the following:** - To see all supplies for VL/IVT testing	- Verify VL/IVT reagents have been in stock during the last 6 months from previous inventory records. **Note:** *Mark "Yes" if there have been no reagent stock-outs in the past 6 months.* *Mark "Partial" if there have been 1 or more reagent stock-outs that have not caused a backlog.*

			Mark "No" if there have been multiple stock- outs that caused testing backlogs.
4.3	Is there a SOP for inventory control?	**Ask the following:** - To describe inventory control in place to manage stock of test kits and supplies in the laboratory	- Verify inventory control SOP. - Verify inventory documents. **Note***: Mark "Yes" if laboratory personnel can describe the inventory control SOP and inventory documents are up-to-date.* *Mark "Partial" if laboratory personnel can describe the inventory control SOP but inventory documents are not up-to-date.* *Mark "No" if there is no SOP or inventory documentation is missing.*
4.4	Are SOPs in place and followed for receipt, inspection and storage of reagent/supplies?	**Ask the following:** - To describe the purchasing, procurement - and inventory system used in the laboratory	- Verify SOP for receipt, inspection and storage of reagent/supplies (e.g. inspected, reagents/supplies are dated and initialed, and securely stored) **Note***: Mark "Yes" if laboratory personnel can describe SOP and it is sufficient.* *Mark "Partial" if laboratory personnel can describe SOP but it doesn't cover all required elements.* *Mark "No" if laboratory personnel cannot describe SOP or there is no SOP.*

4.5	Are reagents/supplies labeled with the date received and initials?	**Ask the following:** - To see reagents/supplies that currently in use	- Verify reagents/supplies in laboratory and storage have been initialed and dated. **Note***: Mark "Yes" if reagents/supplies are consistently initialed and dated.* *Mark "Partial" if reagents/supplies are inconsistently initialed and dated.* *Mark "No" if reagents/supplies are not initialed and dated.*
4.6	Are all reagents/supplies, currently in use, within the expiration period?	**Ask the following:** - To see each of the VL/IVT test that currently in use	- Verify reagents/supplies, currently in use in the laboratory, within the expiration period. If they are expired, are they properly labeled as expired and marked only for training use. **Note***: Mark "Yes" if reagents/ supplies, currently in use in the laboratory are consistently within expiration periods* *or marked for training use only.* *Mark "Partial" if reagents/supplies, currently in use in the laboratory are consistently within expiration periods, but are not consistently labeled for training use only if expired.* *Mark "No" if expired reagents /supplies are being used for non-training purposes.*

4.7	Are reagents/supplies appropriate for molecular testing (e.g. powder-free gloves, filtered tips, RNAse/DNAse-free)?	**Ask the following:** - Describe what reagents/supplies are used for molecular testing	- Verify appropriate reagents/supplies are present in laboratory. **Note**: *Mark "Yes" if all reagents /supplies are appropriate for molecular testing.* *Mark "Partial" if some reagents/ supplies are appropriate for molecular testing.* *Mark "No" if no reagents/supplies are appropriate for molecular testing.*
4.8	Are SOPs for disposal of reagents and consumables in place and followed?	**Ask the following:** - If the site has SOPs for disposal of reagents and consumables - To see the location of SOPs at the laboratory	- Verify that SOP is current and explains the required procedures for the disposal - Check whether the disposal process adheres to SOP **Note:** *Mark "Yes" if SOPs are available, current, and adhered to during the disposal* *Mark "Partial" if SOPs are available, current, but not adhered to consistently* *Mark "No" if SOPs are not available or not current.*

5.0	**SAMPLE MANAGEMENT**
Identify sample type(s) utilized for VL testing:	☐ DBS ☐ Plasma ☐ Other (specify):
Identify sample type(s) **utilized** for IVT testing:	☐ DBS ☐ Whole blood

Quantify the number of samples received and rejected in the past month			
Sample type		**Number received**	**Number rejected**
VL – Plasma			
VL – DBS			
VL – Other			
IVT – Whole Blood			
IVT – DBS			
5.0	**SAMPLE MANAGEMENT**	**WHAT TO ASK FOR?**	**WHAT TO LOOK FOR?**
5.1	Are SOPs in place and followed for sample transport and processing in the laboratory?	**Ask the following:** - To see the SOP and/ or job aids that describes specimen transport and processing	- Verify SOPs for sample transport and processing meet manufacturer's requirements per package inserts. - Verify laboratory personnel are aware of SOPs **Note:** *Mark "Yes" if SOPs meet all manufacturer requirements and laboratory personnel can describe the SOPs.* *Mark "Partial" if SOPs meet all manufacturer requirements and laboratory personnel can partially describe the SOPs.* *Mark "No" if SOPs do not meet manufacturer requirements.*
5.2	Does the laboratory provide sample collection and transport training or information referring to facilities?	**Ask the following:** - To see the SOP and/or job aids that describes the laboratory's training program for sample collection, transport	- Verify sample collection/ transport training materials provided to referring facilities. **Note***: Mark "Yes" if training or information*

		and use of referral lab facilities	*is consistently provided to referring facilities.* *Mark "Partial" if training or information is inconsistently provided to referring facilities.* *Mark "No" if no training or information is provided to referring facilities.*
5.3	Are SOPs in place and followed for evaluating sample acceptability upon receipt in the laboratory and for sample rejection?	**Ask the following:** - Describe how laboratory evaluate sample acceptability upon receipt in the laboratory.	- Verify sample acceptability SOP, ensuring that samples are rejected per manufacturer's recommendations. **Note***: Mark "Yes" if SOPs establish proper sample acceptability/rejection criteria and laboratory personnel can describe them for all sample types.* *Mark "Partial" if SOPs establish proper sample acceptability/rejection criteria but laboratory personnel cannot consistently describe them for all sample types.* *Mark "No" if SOPs do not establish appropriate criteria per manufacturer's requirements.*

5.4	Are requesters notified of rejected samples within 24 hours according to SOPs?	**Ask the following:** - To see sample rejection and notification records/logs	- Verify sample acceptability/ rejection SOP contains information about contacting requesters. - Verify in appropriate log that requesters were notified within 24 hours. **Note***: Mark "Yes" if laboratory personnel consistently notify requesters of rejected samples within 24 hours.* *Mark "Partial" if laboratory personnel inconsistently notify requesters within 24 hours.* *Mark "No" if requesters are not notified within 24 hours.*
5.5	Does a sample transport form accompany samples and does it account for chain of sample custody?	**Ask the following:** - To see sample transport requesting forms accompany all samples received in the laboratory	- Verify sample transport forms accompany all samples received. - Ensure sample transport forms are signed and dated every time samples are handed off from clinic to receipt in laboratory. **Note***: Mark "Yes" if sample transport form is consistently filled and contains chain of custody information.* *Mark "Partial" if sample transport form is consistently filled but does not contain chain of custody information.*

			Mark "No" if sample transport form is inconsistently filled.
5.6	Are sample transport time and conditions maintained according to assay requirements from collection until received in laboratory?	**Ask the following:** - Describe how sample transport time and conditions are maintained between the time of collection and the time of receipt in the laboratory. - To see the SOP for the specimen requirements that specify the requested volume, transport time, storage temperature, and any special handling	- Verify sample transport times and conditions are acceptable (e.g. transport times are within manufacturer's limits as noted on sample transport sheets, freezer packs are still ice cold to the touch, etc.) **Note:** *Mark "Yes" if laboratory personnel consistently verify sample transport time and conditions and can describe appropriate conditions.* *Mark "Partial" if laboratory personnel inconsistently verify sample transport time and conditions.* *Mark "No" if laboratory personnel do not verify sample transport time or conditions or cannot describe appropriate conditions.*
5.7	Is the monthly sample rejection rate <3%? If NO, please note most common reason(s) for rejection in comments section, and do records indicate the appropriate implementing partner, sample hub, or referring facility was	**Ask the following:** - To see the SOP for the calculation of sample rejection rate. - Describe how the monthly sample rejection rate is calculated.	- Calculate monthly sample rejection rate from above information, by sample type where appropriate. **Note:** *Mark "Yes" if monthly sample rejection rate is < 3% for all sample types.* *Mark "Partial" if monthly sample rejection*

	contacted to address the issue(s)?		*rate is ≤ 5% for all sample types.* *Mark "No" if monthly sample rejection rate is > 5% for any sample type.*
5.8	Are SOPs for samples storage written according to manufacturer's requirements, in place and followed?	**Ask the following**: - To see the SOP for the sample requirements that specify sample storage	- Verify SOPs require samples to be stored according to manufacturers' requirements. - Verify samples are stored according to SOP. **Note**: *Mark "Yes" if SOPs follow manufacturer's requirements and samples are consistently stored properly in the laboratory.* *Mark "Partial" if SOPs follow manufacturer's requirements but samples are inconsistently stored per SOP.* *Mark "No" if SOPs require inappropriate sample storage.*

TESTING PHASE		
EFFICIENCIES		
Are instrument barcode scanners used to enter specimen IDs?		Yes ☐ No ☐
Comments:		
On average, how many samples are tested per month? Please provide the average and range (min to max) per month over the last year.	VL _____(Range:)	IVT _____(Range:)
Comments:		

Do you receive samples for VL/IVT testing from outside facilities (referral testing?) - If yes, for how many facilities do you provide VL/IVT testing services?		Yes ☐ No ☐ VL: _____ IVT: _____
Comments:		
With current testing schedule, what is the laboratory's current instrument testing capacity per day?	VL _____*Max number of tests/days*	IVT _____*Max number of tests/days*
How many shifts per day does the lab operate?		
How long are these shifts (in hours)?		
How many days per week does the lab operate?	*Number of days from 1—7 that laboratory performs testing (e.g. Monday-Friday is 5)*	
Comments:		

	Viral Load	**Infant Virological Testing**
Is there currently a testing backlog (> 1 month testing volume)?	Yes ☐ No ☐	Yes ☐ No ☐
If yes, how many samples?		
If yes, what was the reason for the backlog?		
In the past month:		
How many VL tests has the laboratory performed?	*Number of tests performed during the past month.*	N/A
How many VL results have been reported?	*Number of test results that have been returned to the clinic during the past month.*	
How many of these VL tests were virally suppressed? (≤ 1000 cp/mL)		
How many of these VL tests were virally non-suppressed? (> 1000 cp/mL)		

How many IVT tests were performed?	N/A	*Number of tests performed during the past month.*
How many IVT results have been reported?		*Number of test results that have been returned to the clinic during the past month.*
How many IVT tests were positive?		*Number of test results in which HIV was detected.*

EQUIPMENT- INVENTORY				
Inventory and Location of laboratory Equipment: PMR = Preventive Maintenance Records EMC – Equipment Maintenance Contract				
Equipment Inventory	Quantity	Quantity Functional	PMR?	EMC?
1. -20°C Freezers			Yes ☐ No ☐	Yes ☐ No ☐
2. -80°C Freezers			Yes ☐ No ☐	Yes ☐ No ☐
3. Refrigerators			Yes ☐ No ☐	Yes ☐ No ☐
4. Centrifuges			Yes ☐ No ☐	Yes ☐ No ☐
5. Biosafety cabinet			Yes ☐ No ☐	Yes ☐ No ☐
6. Abbott *m2000sp*			Yes ☐ No ☐	Yes ☐ No ☐
7. Abbott *m2000rt*			Yes ☐ No ☐	Yes ☐ No ☐
8. Roche COBAS AmpliPrep			Yes ☐ No ☐	Yes ☐ No ☐
9. Roche COBAS TaqMan 48			Yes ☐ No ☐	Yes ☐ No ☐
10. Roche COBAS TaqMan 96			Yes ☐ No ☐	Yes ☐ No ☐
11. Biomerieux NucliSENS easyMag			Yes ☐ No ☐	Yes ☐ No ☐
12. Biomerieux NucliSENS easyQ			Yes ☐ No ☐	Yes ☐ No ☐
13. Emergency eyewash station			Yes ☐ No ☐	Yes ☐ No ☐
14. Pipettes			Yes ☐ No ☐	Yes ☐ No ☐
15. Incubator			Yes ☐ No ☐	Yes ☐ No ☐

16. UV crosslink			Yes ☐ No ☐	Yes ☐ No ☐
List any additional equipment used for protocol related assay				
17.			Yes ☐ No ☐	Yes ☐ No ☐
18.			Yes ☐ No ☐	Yes ☐ No ☐
19.			Yes ☐ No ☐	Yes ☐ No ☐
20.			Yes ☐ No ☐	Yes ☐ No ☐
21.			Yes ☐ No ☐	Yes ☐ No ☐
Describe backup plan(s) in place for prolonged non-testing due to, for instance, equipment breakdown?				
Comments:				

6.0	EQUIPMENT	WHAT TO ASK FOR?	WHAT TO LOOK FOR?
6.1	Is all equipment, required for VL/IVT testing, present?	**Ask the following:** - To see the SOP that specifies all necessary equipment to perform VL/IVT testing - To see the schedule and requirements for calibration, performance verification, and maintenance of testing instruments and equipment. - To see the calibration record sheets/logs. - To see the routine preventive maintenance record sheets/logs. - To see Equipment List in Maintenance Contract.	- Verify all necessary equipment to perform VL/IVT testing is present, per package insert. **Note***: Mark "Yes" if all required equipment is present.* *Mark "Partial" if some required equipment is present.* *Mark "No" if no equipment is present.*
6.2	Is all equipment, required for VL/IVT testing, functional?		- Verify that all required equipment is in good working order. **Note***: Mark "Yes" if all required equipment is functional.* *Mark "Partial" if some required equipment is functional. Mark "No" if no required equipment is functional.*

6.3	Do equipment records include documentation of routine preventive maintenance?		- Verify equipment records document routine preventative maintenance. - Verify that a supervisor or in-charge reviews these records periodically. **Note***: Mark "Yes" if equipment records show that routine preventative maintenance is consistently performed and that the logs are reviewed regularly.* *Mark "Partial" if equipment records show that routine preventative maintenance is consistently performed but logs are inconsistently reviewed.* *Mark "No" if equipment records show that routine preventative maintenance is inconsistently or not performed.*
6.4	Are equipment maintenance contracts in place?	**Ask the following:** - To see Maintenance contracts for all equipment.	- Verify equipment maintenance contracts. **Note***: Mark "Yes" if all equipment maintenance contracts are present.* *Mark "Partial" if some equipment maintenance contracts are present.* *Mark "No" if there are no maintenance contracts at the laboratory.*

6.5	Are instrument manuals for all VL/IVT equipment available to the laboratory?	**Ask for the following:** - To see availability of instrument manuals for VL/EID testing equipment	- Verify that complete instrument/equipment manuals are available to laboratory personnel. **Note***: Mark "Yes" if all manuals are available.* *Mark "Partial" if some manuals are available.* *Mark "No" if no manuals are available.*

7.0	**PROCESS CONTROLS**	**WHAT TO ASK FOR?**	**WHAT TO LOOK FOR?**
7.1	Are VL/IVT testing job aids and/or SOPs available at the testing site?	**Ask the following:** - If the testing site has SOPs/job aids on VL/IVT testing	- Verify that the job aids/SOPs on VL/IVT testing are available. - Verify that the job aids/SOPs are current, accurate and complete and follow the assay methods described in package inserts. **Note***: Mark "Yes" if job aids/SOPs are current, complete, and consistently available.* *Mark "Partial" if job aids/SOPs are current, complete, and inconsistently available.* *Mark "No" if job aids/SOPs are not current, not complete or not available.*
7.2	Do records indicate equipment performance was verified prior to beginning VL/IVT testing?	**Ask the following:** - To see the records of equipment performance characteristics/verification	- Verify instrument/method verification SOP. - Verify verification/validation

		prior to initiating the VL/ IVT testing	documentation checking if results met manufacturer's performance claims. **Note**: *Mark "Yes" if SOP is sufficient and documentation supports manufacturer's performance claims.* *Mark "Partial" if SOP is insufficient but documentation supports manufacturer's performance claims.* *Mark "No" if verification/validation was not performed prior to testing patient samples.*
7.3	Are SOPs in place and followed for running, recording, and reviewing quality control (QC) results?	**Ask the following:** - Describe how the QA/QC activities are organized, planned, and implemented for running, recording, and reviewing quality control (QC) results. - To see the quality control logs or testing register/logbook. - What type of QC is being used (e.g., serum, plasma, DTS) How often QC is performed?	- Verify QC SOP includes day-to-day running and monitoring of QC results. - Verify QC logs. **Note**: *Mark "Yes" if laboratory personnel can describe SOP and consistently run/record/monitor QC results.* *Mark "Partial" if laboratory personnel can describe SOP but inconsistently run/record/monitor QC results.* *Mark "No" if laboratory personnel do not run/record/monitor QC results.*

7.4	Are QC results properly recorded, including invalid and incorrect results?	**Ask the following:** - Describe how the QA/QC activities are organized, planned, and implemented for running, recording, and reviewing quality control (QC) results. - To see the quality control logs or testing register/logbook. - What type of QC is being used (e.g., serum, plasma, DTS) How often QC is performed?	- Verify QC SOP includes meeting manufacturers' requirements and recording inappropriate results. - Verify QC records (e.g. VL – LJ charts, IVT – QC monitoring chart). - Verify logs of QC related corrective actions. **Note***: Mark "Yes" if laboratory personnel can describe QC SOP and consistently log QC results.* *Mark "Partial" if laboratory personnel can describe QC SOP but inconsistently log QC results.* *Mark "No" if laboratory personnel do not log QC results or there is no SOP.*
*7.5	Are appropriate steps taken and documented when QC results are incorrect and/or invalid?		- Verify QC SOP includes nonconforming QC events and corrective actions. - Verify logs of QC related corrective action. **Note***: Mark "Yes" if laboratory personnel can describe QC SOP and consistently log/report inappropriate QC results.* *Mark "Partial" if laboratory personnel can describe QC SOP but inconsistently log/report inappropriate QC results.*

			Mark "No" if laboratory personnel do not log/report inappropriate QC results.
7.6	Does a supervisor routinely review quality control records?	**Ask for the following:** - To see the records of reviewing quality control results for VL/IVT	- Verify QC SOP includes routine supervisor review. - Verify QC logs for supervisor signature/initials and date of review. **Note***: Mark "Yes" if laboratory personnel can describe QC SOP and supervisor consistently reviews QC results.* *Mark "Partial" if laboratory personnel can describe QC SOP but supervisor inconsistently reviews QC results.* *Mark "No" if supervisor does not review QC results.*
7.7	Is the laboratory enrolled in Proficiency Testing (PT) for VL/IVT?	**Ask the following:** - To see the SOP for enrolling and testing PT for VL/IVT. - To see if PT samples are treated differently than patient specimens. - To see if the PT samples are rotated among other testers	- Verify VL/IVT PT enrolment documents for current year. **Note***: Mark "Yes" if the laboratory is currently enrolled in PT for VL/IVT.* *Mark "Partial" if the laboratory was previously enrolled in PT for VL/IVT, but isn't currently.* *Mark "No" if laboratory is not currently enrolled in PT.*

7.8	In the past 12 months, has the laboratory passed all PT for VL/IVT?	**Ask the following:** - To see the SOP for enrolling and testing PT for VL/IVT. - To see if PT samples are treated differently than patient specimens. - To see if the PT samples are rotated among other testers	- Verify VL/IVT PT results for previous 12 months. **Note***: Mark "Yes" if the laboratory passed all PT panels during prior 12 months. Mark "Partial" if the laboratory has failed no more than 1 PT panel during prior 12 months. Mark "No" if the laboratory has failed > 1 PT panel consecutively.*
7.9	Is PT testing rotated among all VL/IVT testing staff?	**Ask the following:** - If the EQA/PT panels are rotated among the testers - How many testers have performed PT testing - Documentation of PT test results	- Verify if the tester rotation is practiced or not by reviewing the record of the previous PT rounds **Note***: Mark "Yes" if the laboratory personnel can describe the documents for tester rotation. Mark "Partial" if the laboratory practices tester rotation but incomplete documentation Mark "No" if there is no tester rotation practice*
7.10	Are PT samples tested in the same manner as patient samples?	**Ask the following:** Have same people always do testing?	- Verify PT SOPs specify PT be run with general patient samples. - Verify from PT results submission information that PT panels were run with patient samples. **Note***: Mark "Yes" if laboratory personnel*

			can describe SOP and records indicate panel was run with patient samples. *Mark "Partial" if laboratory personnel can describe SOP but records indicate panel is inconsistently run with patient samples.* *Mark "No" if laboratory personnel cannot describe SOP or records do not indicate that panel is run with patient samples.*
7.11	Is there a supervisor review of PT result prior to submission?	**Ask the following:** - To see documentation of review of the PT reports	- Verify PT SOP includes supervisory review prior to results submission. - Verify PT records for supervisor signature and date. **Note***: Mark "Yes" if records indicate PT results are consistently reviewed by a supervisor prior to submission.* *Mark "Partial" if records indicated PT results are inconsistently reviewed by a supervisor prior to submission.* *Mark "No" if records do not indicate supervisor review prior to submission.*
7.12	Do records indicate that lab staff review PT result reports prior to submission?	**Ask the following:** - To see documentation of review of the PT reports by lab staff prior to final submission	- Verify PT SOP includes laboratorian review prior to results submission. - Verify PT records for laboratorian signature and date. **Note***: Mark "Yes" if records indicate PT*

			results are consistently reviewed by laboratory personnel prior to submission. Mark "Partial" if records indicate PT results are inconsistently reviewed by laboratory personnel prior to submission. Mark "No" if records do not indicate laboratorian review prior to submission.
*7.13	Do records indicate that lab staff conduct investigation and corrective action for any failed PT results?	**Ask the following:** - To describe procedures to implement actions in case of unacceptable PT results. - To see if there is evidence of corrective actions being implemented and monitored. - To indicate how long it takes to implement the corrective actions taken after report is received	- Verify PT SOP includes investigation/corrective action for failed PT results. - Verify documentation of investigation/corrective action taken, if applicable. **Note***: Mark "Yes" if laboratory personnel can describe failed PT investigation/ corrective action SOP and records indicate corrective action was taken. Mark "Partial" if laboratory personnel can describe failed PT investigation/ corrective action SOP but records inconsistently indicate corrective action was taken. Mark "No" if SOP makes no mention of investigating failed PT results.*

POST-TESTING PHASE		
8.0	**M&E DOCUMENTS AND RECORDS – RESULTS REPORTING**	
Is there a laboratory information management system (LIMS)? If yes, indicate the type/name of system:		Yes ☐ No ☐ If yes, functions include: ☐ Logging sample receipt/sample tracking ☐ Barcode labeling of samples ☐ Interface with analyzers ☐ Results recording/reporting Others, specify_____
Comments:		

8.0	**M&E DOCUMENTS AND RECORDS – RESULTS REPORTING AND DATA MANAGEMENT**	**WHAT TO ASK FOR?**	**WHAT TO LOOK FOR?**
Are the data elements below recorded in the laboratory?			
8.0	Elements 8.1.1 – 8.1.7, 8.2, and 8.3	**Ask the following:** To see the SOPs for M & E documents and recording – results reporting and data management	Verify the following: - All the data elements below are present. - Data elements are consistently and accurately recorded **Note***: Mark "Yes" if the data element is consistently and accurately recorded. Mark "Partial" if the data element is recorded, but inconsistently or inaccurately.*

			Mark "No" if the data element is not recorded.

		VL/IVT Register	Laboratory Logbook	LIMS
8.1.1	Sample ID	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐
8.1.2	Test Name	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐
8.1.3	Test Reagent Lot Number	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐
8.1.4	Test Reagent Expiration Dates	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐
8.1.5	Testing Staff Name	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐
8.1.6	Testing Date	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐
8.1.7	Result	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐
8.1.8	Date of Sample Receipt	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐
8.1.9	Date of Results Reported from Laboratory	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐
8.1.10	Date of Results Receipt in Clinic	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐
8.1 Total	'Yes' > 5 = Yes; 3 < 'Yes' ≤ 5 = Partial; 'Yes' ≤ 3 = No *****Please score only the most applicable log (IE: If you primarily use LIMS, only score the LIMS column), but please do indicate whether alternative logs contain the information*****		Q8.1 Summary: Yes ☐ Partial ☐No ☐	
8.2	Patient ID	Yes ☐ Partial ☐No ☐	Yes ☐ Partial ☐No ☐	Yes ☐ Partial ☐No ☐
			Q8.2 Summary: Yes ☐ Partial ☐No ☐	
8.3	Invalid Test Results	Yes ☐ Partial ☐No ☐	Yes ☐ Partial ☐No ☐	Yes ☐ Partial ☐No ☐
			Q8.3 Summary: Yes ☐ Partial ☐No ☐	

*8.4	Are high VL test (> 1000 cp/mL) and positive IVT results identified at labs and reported as priority? Please note in comments section how high VL/IVT results are reported.	**Ask the following:** - To describe how the laboratory establishes panic values/critical values for VL tests (> 1000 cp/mL) and how these results are reported	- Verify result reporting SOPs - Verify if VL > 1000 or positive IVT results are handled any differently than normal results. **Note***: Mark "Yes" if laboratory personnel*

			consistently report critical results as a priority to clinics per SOP. *Mark "Partial" if laboratory personnel inconsistently report critical results as a priority to clinics.* *Mark "No" if laboratory personnel never report critical results as a priority to clinics.*
*8.5	Are VL/IVT results returned from labs to clinic sites?	**Ask the following:** - To describe how VL/IVT test results get to clinic site from labs	- Verify result reporting SOP including how results are returned to clinics. **Note***: Mark "Yes" if laboratory personnel can describe result reporting SOP and consistently return results per SOP.* *Mark "Partial" if laboratory personnel can describe SOP but inconsistently report results per SOP.* *Mark "No" if laboratory personnel do not report results per SOP.*
8.6	Do lab records or documents indicate receipt of results at clinics? Please indicate how in the comments.	**Ask the following:** - To describe how the laboratory verifies the receipt of VL/IVT test results at clinics	- Verify results reporting SOP includes ensuring results are received at the clinic and that the receipt of results is recorded. - Verify records demonstrate receipt of results in clinics. **Note:** *Mark "Yes" if laboratory personnel can describe SOP and records consistently support confirmation of receipt of results.*

			Mark "Partial" if laboratory personnel can describe SOP and records inconsistently support confirmation of receipt of results. *Mark "No" if records do not indicate confirmation of results receipt.*
8.7	Are all client documents and records securely kept throughout all phases of the testing process in the lab?	**Ask the following**: - To describe how client documents and records are kept throughout all phases of the testing process in the laboratory. - To see the processes for capturing and maintaining evidence of and information about client documents in the form of records	- Verify records management/document control SOP. - Verify documents are stored securely when not actively in use. **Note***: Mark "Yes" if laboratory personnel can describe SOP and no patient documents/records are found unsecured.* *Mark "Partial" if laboratory personnel can describe SOP but some patient documents/records can be found unsecured.* *Mark "No" if patient documents are not stored securely.*
8.8	Are all lab registers or logbooks and other documents kept in a secure location when not in use? If applicable, does the LIMS prevent unauthorized access to patient results?	**Ask the following:** - To see where all lab registers or logbooks and other documents are kept in the laboratory	- Verify all laboratory registers/logbooks are securely stored when not actively in use. - Verify LIMS prevents unauthorized users from accessing system. **Note***: Mark "Yes" if laboratory personnel can describe SOP and no registers/ logbooks/ LIMS access are found*

			unsecured. *Mark "Partial" if laboratory personnel can describe SOP but some registers/ logbooks/ LIMS access can be found unsecured.* *Mark "No" if registers/logbooks/LIMS access are not stored securely.*
8.9	Are registers or logbooks in the lab properly labeled and archived when full? If applicable, does the LIMS get routinely backed-up according to an SOP?	**Ask the following**: - To describe the procedure and show where the registers are archived once they are full	- Written procedures for the document and records management and control system. - Verify registers or logbooks are properly labeled and achieved when full. - Verify that the registers are organized, properly labeled and easily retrievable (good filing system) - Verify that LIMS is routinely backed-up according to SOP. **Note***: Mark "Yes" if laboratorian can describe SOP and registers/logbooks/ LIMS are consistently archived in a secure location.* *Mark "Partial" if laboratory personnel can describe SOP but registers/logbooks/ LIMS are inconsistently archived in a secure location.* *Mark "No" if registers/logbooks/LIMS are*

			not archived in a secure location or missing.
8.10	Are records or documents stored in accordance with national/local record retention requirements?	**Ask the following:** - To see the records management SOP for meeting national/local record retention guide	- Verify that records management SOP is in accordance with national/local record retention requirements. **Note***: Mark "Yes" if SOPs consistently meet retention requirements.* *Mark "Partial" if SOPs inconsistently meet retention requirements.* *Mark "No" if SOPs do not meet retention requirements.*
8.11	Is there a dashboard or tool for routine review of VL/IVT data in the LIMS?	**Ask the following:** - To see a dashboard data or tool for routine review of results of VL/IVT data	- Verify VL/IVT dashboard use SOP. **Note***: Mark "Yes" if laboratory personnel can demonstrate use of dashboard.* *Mark "Partial" if dashboard exists, but no laboratory personnel know how to use it.* *Mark "No" if dashboard does not exist.*

9.0	**INTERNAL QUALITY AUDITS – QUALITY INDICATOR-CONTINUAL IMPROVEMENT**	**WHAT TO ASK FOR?**	**WHAT TO LOOK FOR?**
9.1	Does the laboratory staff record non-conforming events associated with VL/IVT sample receiving, testing, reporting, and supply chain?	**Ask the following:** - To describe the nonconforming event management program associated with VL/EID sample receiving, testing, reporting, and supply chain. - To see the nonconforming event	- Verify nonconforming event management SOP including identification and reporting, corrective action, investigation and documenting, action plan, classification, analysis and

		management forms/logs	presentation, management review and follow-up. - Examine a sample of nonconforming event report(s) **Note***: Mark "Yes" if SOP are sufficient and nonconforming events documents are consistently filled.* *Mark "Partial" if SOPs are sufficient but nonconforming events documents are inconsistently filled.* *Mark "No" if SOPs are insufficient or there is no documentation of nonconforming events.*
9.2	Do records indicate management reviews non-conforming events for trends?	**Ask the following:** - To see a trend analysis of nonconforming events in management review	- Examine a sample of nonconforming event report(s) showing trends **Note***: Mark "Yes" if records consistently indicate managerial review of nonconforming events for trends.* *Mark "Partial" if records inconsistently indicate managerial review of nonconforming events for trends.* *Mark "No" if no records are available or no evidence of managerial review.*
9.3	Do records indicate investigation of and corrective action taken for non-conforming events?	**Ask the following:** - To see the nonconforming event management forms/logs.	- Examine a sample of nonconforming event report(s) showing corrective actions taken.

		- To see the procedure that establishes the process to identify, track, investigate, and correct nonconformities within laboratory	**Note***: Mark "Yes" if the sample shows corrective action was consistently taken. Mark "Partial" if the sample shows corrective action was inconsistently taken. Mark "No" if the sample shows no corrective actions.*
9.4	Does the laboratory have an internal audit SOP?	**Ask the following:** - To describe the procedure/standard spells out the procedure for planning audits, conducting audits, reporting results, scheduling audits, and maintaining records. - To describe how the laboratory conducts internal audits.	- Verify SOPs for internal audits in the laboratory. - Examine a complete record of internal audits in the past two years. The report should include, name(s) of the auditor(s), Date of audit, reference number, the activities, areas or items, any nonconformities found, any recommendations and timescales for corrective action, responsibilities for corrective action, any recommendations for preventive action, date and signature of confirmation of completion of corrective and preventive action. **Note***: Mark "Yes" if records indicate audits were consistently thorough and all needed actions were taken. Mark "Partial" if records indicate audits*

			were inconsistently thorough or not all needed actions were taken. *Mark "No" if there are no records of audits.*
9.5	Do records indicate internal audits are performed according to a planned schedule?	**Ask the following:** - To describe the procedure/standard spells out the procedure for planning audits, conducting audits, reporting results, scheduling audits, and maintaining records. - To describe how the laboratory conducts internal audits.	- Verify SOP includes regularly scheduled audits. - Examine previous audit reports. **Note***: Mark "Yes" if SOPs include regularly scheduled audits and evidence shows they were consistently performed.* *Mark "Partial" if SOPs include regularly scheduled audits but evidence shows they were inconsistently performed.* *Mark "No" if SOPs do not include regularly scheduled audits or no evidence of performance of audits.*
9.6	Do records indicate corrective action is taken on audit findings?	Ask for the following: - To see previous internal audit reports	- Examine previous audit reports indicating corrective action taken on audit findings. **Note***: Mark "Yes" if records consistently indicate corrective action was taken on audit findings.* *Mark "Partial" if records inconsistently indicate corrective action was taken on audit findings.* *Mark "No" if no records are available or*

			records indicate corrective actions have not been taken on audit findings within prescribed time frame.
9.7	Does the laboratory identify and monitor quality indicators?	**Ask the following:** - To describe how the laboratory use quality indicators to monitor the quality of laboratory services. - A trend analysis of quality indicators used in the lab	- Verify SOPs including continuous monitoring and evaluation of quality indicators. - Examine a sample of reports showing monitoring of quality indicators. **Note***: Mark "Yes" if documents show quality indicators were consistently monitored.* *Mark "Partial" if documents show quality indicators were inconsistently monitored.* *Mark "No" if SOPs do not include quality indicator monitoring or documents do not indicate that they are being monitored.*
9.8	Has the lab been recognized or accredited by any agency? If yes, name Agency_____ Date _____	**Ask the following:** - To see if the laboratory is accredited by international accreditation agencies (ISO, CAP, IQMH, KENAS, SANAS, etc.) - To see the laboratory's certificate of accreditation if accredited by international accreditation bodies	- Verify accreditation documents. **Note***: Mark "Yes" if documents show the laboratory is currently accredited.* *Mark "Partial" if documents show that the laboratory has been accredited but is not currently or if the laboratory is currently going through the accreditation process.* *Mark "No" if the lab has never been accredited.*

	Viral Load			Infant Virological Testing		
Turnaround time (TAT)	Avg no. days	Min no. days	Max no. days	Avg no. days	Min no. days	Max no. days
Pre-test phase (*sample collection to sample receipt*)						
Pre-test to test phase (sample receipt to test initiation)						
Testing phase (test initiation to test completion)						
Post-test phase 1 (test completion to result release)						
Post-test phase 2 (test release to clinic receipt)						

PART 2: SCORING AND SUMMARY

Laboratory Name: _____Audit Date: _____

Auditor(s): _____

Total Points Given: _____Overall % _____Level_____

VL/IVT LEVEL	SCORE/111	% SCORE	DESCRIPTION OF RESULTS
0	< 61	< 55%	Needs improvement in all areas and immediate remediation
1	61 - 71	55 - 64%	Needs improvement in specific areas
2	72 - 82	65 - 74%	
3	83 - 93	75 - 84%	
4	94 - 104	85 – 94%	
5	≥105	≥ 95%	

SUMMARY: LABORATORY SCORECARD

	SECTION	TOTAL POSSIBLE POINTS	POINTS GIVEN	%	AUDITOR'S COMMENTS
Pre-Testing					
1	Personnel	**11**			
2	Physical Facility /Environment	**14**			
3	Safety / Waste Management	**12**			
4	Procurement / Inventory	**8**			
5	Sample Management	**8**			
Testing					
6	Equipment	**5**			
7	Process Controls	**21**			
Post-Testing					
8	M&E Documents/Records - Results	**19**			
9	Internal Quality Audits – Quality Indicators – Continual Improvement	**13**			
	OVERALL SCORE	**111**			

AUDITOR'S SUMMARY REPORT FOR ASSESSING THE STEP-WISE PROCESS FOR IMPROVING THE QUALITY OF VIRAL LOAD/IVT TESTING

	Section	Summary Comments / Recommendations	Timeline
	Pre-Testing		
1	Personnel		
2	Physical Facility / Environment		
3	Safety / Waste Management		
4	Purchasing / Inventory		
5	Sample Management		
	Testing		
6	Equipment		
7	Process Controls		
	Post-Testing		
8	M&E Documents/Records - Results and Data Management		
9	Internal Quality Audits – Quality Indicators – Continual Improvement		

PART 3: DEBRIEF

- Review laboratory assessment findings with lab manager, quality officer and/or lab staff
- Identify and put in place remedial actions with assigned individuals or partner, and timelines

Laboratory Name: _____Audit Date: _____

Auditor(s): _____

Total Points Given: _____Overall % _____Level_____

Individual/partner present at debrief session

Name	**Position**	**Signature**	**Date**
Name	**Position**	**Signature**	**Date**
Name	**Position**	**Signature**	**Date**
Name	**Position**	**Signature**	**Date**
Name	**Position**	**Signature**	**Date**

Appendix A: Quarterly Monitoring Tool

Country: _____Region/Province: _____City: _____

Laboratory Name: _____

Name, title, email of POC reporting: _____

Date (DD/MM/YYYY): _____Reporting quarter: ☐ Q1 ☐ Q2 ☐ Q3 ☐ Q4

	Question	Value		Comments
Q1	Number of Viral Load tests reported by the lab:			*Number of viral load test results returned to clinics during the previous quarter.*
Q1.1	Of the number of VL test results reported by the lab how many were:	≤ 1,000 copies/mL:	> 1,000 copies/mL:	
	Gender:			
Q1.2	Male			
Q1.3	Female			
Q1.4	Total			
	Age:			
Q1.5	<15			
Q1.6	≥15			
Q1.7	Total			
Q1.8	Pregnant Women:			
Q1.9	Women that are breastfeeding:			
Q2	Is there a backlog for Viral Load testing? (greater than one week testing volume)	Yes ☐	No ☐	*Viral load testing that has yet to be performed that is in excess of the number tests that can be completed in one week.*

Q2.1	**If yes, how many samples?**		*Number of samples that need to be tested in excess of samples arriving that week.*	
Q3	**Are there planned procurements within this fiscal year?**	Yes ☐ No ☐	*Are there plans to procure new testing equipment during the current fiscal year? (e.g. new CAPCTM96 /m2000/etc.)*	
Q3.1	**If yes, please list:**	**Platform type:**	**Quantity:**	*List any VL/IVT testing platforms (e.g. CAPCTM/m2000/etc.) that will be procured and note quantity.*
		Planned location of placement:		*List the locations that the above testing platforms will be placed.*
Q4	**Number of Early Infant Diagnosis test results reported by the lab:**			*Number of early infant diagnosis test results returned to clinics during the previous quarter.*
Q4.1	**Number of Early Infant Diagnosis tests with positive result:**			*Number of early infant diagnosis results in which HIV was detected.*
Q5	**Is there a backlog for Early Infant Diagnosis testing?**	Yes ☐	No ☐	*Early infant diagnosis testing that has yet to be performed that is in excess of the number of tests that can be completed in one week.*
Q5.1	**If yes, how many samples?**			*Number of samples that need to be tested in excess of samples arriving that week.*

Appendix B: Pre-Inspection Checklist

Please gather the following information, in advance of your laboratories inspection.

Identify sample type(s) **utilized** for VL testing:	☐ DBS ☐ Plasma
Identify sample type(s) **utilized** for IVT testing:	☐ DBS ☐ Whole blood

Quantify the number of samples received and rejected in the past month		
Sample type	**Number received**	**Number rejected**
VL – Plasma		
VL – DBS		
IVT – Whole Blood		
IVT – DBS		
What is the laboratory's current testing capacity per day?	**Viral Load**	**Infant Virological Testing**
	Number of specimens that can be tested in a normal workday	*Number of specimens that can be tested in a normal workday*
How many shifts per day does the lab operate?	*Does the laboratory run multiple shifts per day? If so, please note how many shifts (i.e. 1,2,3)*	
How long are these shifts (in hours)?	*How many hours are these shifts (8, 10, 12 hours, etc.)*	
How many days per week does the lab operate?	*From 1 to 7, how many days a week does the laboratory typically perform testing? (e.g. operating Monday – Friday would be 5)*	
Comments:		
In the past month:	**Viral Load**	**Infant Virological Testing**
Is there currently a testing backlog (>1 month testing volume)?	Yes ☐ No ☐	Yes ☐ No ☐
If yes, how many samples?	*If a testing backlog exists, how many samples currently need to be tested to catch up to normal demand?*	*If a testing backlog exists, how many samples currently need to be tested to catch up to normal demand?*
If yes, what was the reason for the backlog?	*What caused the backlog (e.g. equipment failure, reagent stock out,etc.)*	*What caused the backlog (e.g. equipment failure, reagent stock out,etc.)*
How many VL tests has the laboratory performed?	*Number of tests performed during the past month.*	
How many VL results have been reported?	*Number of test results that have been returned to the clinic during the past month.*	

How many of these VL tests were virally suppressed? (≤1000 cp/mL)		N/A
How many of these VL tests were virally non-suppressed? (>1000 cp/mL)		
How many IVT tests were performed?	N/A	*Number of tests performed during the past month.*
How many IVT results have been reported?		*Number of test results that have been returned to the clinic during the past month.*
How many IVT tests were positive?		*Number of tests results in which HIV was detected.*

	Viral Load			**Infant Virological Testing**		
Turnaround time (TAT)	Avg no.days	Min no. days	Max no. days	Avg no. days	Min no. days	Max no. days
Pre-test phase (*sample collection to sample receipt*)						
Pre-test to test phase *(sample receipt to test initiation)*						
Testing phase *(test initiation to test completion)*						
Post-test phase 1 *(test completion to result release)*						
Post-test phase 2 *(test release to clinic receipt)*						

Please also have the following list of SOPs and records readily available. If the SOPs are available in an electronic format, please send them as it will decrease the amount of time needed for document review on the day of your laboratories inspection.

No.	SOP Title
1	Comprehensive personnel training on VL/IVT testing
2	Personnel training on using standardized VL/IVT testing registers/logbooks
3	Sample management
4	Routine preventative equipment maintenance
5	Personnel training on the QC process
6	Safe handling and disposal of waste
7	Competence assessment of lab personnel
8	Refresh training in competency assessment
9	Temperature monitoring for lab equipment
10	Occurrence management in nonconforming event/corrective action
11	Cleaning work areas
12	Personnel safety practices
13	Disposal for infectious and non-infectious waste
14	Management of biohazardous spills including blood
15	Management of accidental exposure including post-exposure prophylaxis
16	Management of post-exposure prophylaxis
17	Proper use of PPE throughout the VL/IVT testing
18	Management of chemical waste
19	Proper disposal of infectious and non-infectious waste in the lab
20	Procurement and management of supplies and equipment records
21	Inventory control
22	Purchasing, procurement and inventory system
23	Sample transport and processing
24	Sample acceptability in the lab
25	Sample rejection and notification
26	Calculation of sample rejection rate
27	Proper management and storage of samples
28	Specification of all necessary equipment to perform VL/IVT testing
29	Schedules for calibration, performance verification and maintenance of testing equipment
30	VL/IVT testing job aids

31	Method verification/verification
32	Day-to-day QC running and monitoring results
33	Proper recording of invalid and incorrect results
34	Documentation non-conforming QC events and corrective actions
35	Supervisor 's routine review of QC records
36	Enrolling, testing and evaluating PT for VL/IVT
37	Running PT panels with patient samples
38	Supervisory review before results submission
39	Laboratorian review before results submission
40	Conducting investigation and corrective action for any failed PT results
41	M & E documents, recording and data management
42	Establishment of panic values
43	Documentation of results returning from labs to clinic sites
44	Record management and document control
45	Logbooks or registers are backed up and archived
46	Record retention guide
47	Dashboard tool for routine review of VL/IVT data in the LIMS
48	Management reviews of nonconforming events for trends
49	Conducting internal audit and schedules
50	Continuous monitoring and evaluation of quality indicators
51	Recording of TAT for VL/IVT

Please note, many of the above SOPs may be combined into a single document.

Finally, on the day of your laboratories inspection we will need the laboratory supervisor or designee, a representative of the Quality Assurance team, and a representative of the laboratory testing personnel available during the duration of the inspection.

Example 1: Individual Report for GeneXpert Platform

Government of the Republic of the Union of Myanmar

Ministry of Health

Department of Medical Services

National Health Laboratory

35, Hmaw Kun Daik Street, Dagon Township, Yangon, Myanmar

Individual Participant Results Report

Laboratory ID: 456

Laboratory Name: Lab B

PT Panel Name: 2024-02-HIVViralLoadDTS(26-Nov-2024)

Panel Received Date: 06-Dec-2024

Results Due Date: 27-Dec-2024

Panel Tested Date: 11-Dec-2024

Platform/Assay Name : GeneXpert HIV-1

Results Submitted Date : 27-Dec-2024

GeneXpert HIV-1 (Peer-Comparison)					Your Laboratory Performance		
Specimen ID	Your Results (log_{10} copies/mL)	Number of Participants	Assigned Value (log_{10} copies/mL)	Robust Standard Deviation	z Score	Your Grade	Score
HIVL A-2 (2/24)	2.83	23	2.74	0.19	0.47	Acceptable	100%
HIVL B-2 (2/24)	3.27	23	4.43	0.43	-2.72	Warning	
HIVL C-2 (2/24)	3.33	23	3.36	0.23	-0.13	Acceptable	
HIVL D-2 (2/24)	0.00	23	0.00	0.00	0.00	Acceptable	
HIVL E-2 (2/24)	3.34	23	3.39	0.19	-0.26	Acceptable	

0.00 indicated Target Not Detected (TND) results and NA for Not Applicable

z Score = (x - μ) / σ
where : x = Your reported Viral Load result (log10 copies/mL), μ = Assigned Value (log10 copies/mL) and σ = Robust Standard Deviation

Results Interpretation and Recommended Actions

z Score		Results Interpretation	Recommended Action
z ≤ ± 3.0	z ≤ ±2.0	Acceptable	No action required
	± 2.0 > z < ± 3.0	Warning	Closely monitor performance
z ≥ ± 3.0		Unacceptable	Perform corrective action

Confidentiality: The identities of participants are kept confidential and known only to the staff involved in the implementation of the Proficiency Testing. Each participant has been assigned a unique identification number for the purposes of database management.

Report approved by

Date of approval: 20 May 2025

This is a system generated report. No signature required

- End of final report -

Example 2: Individual Report for High throughput Platform

Government of the Republic of the Union of Myanmar

Ministry of Health

Department of Medical Services

National Health Laboratory

35, Hmaw Kun Daik Street, Dagon Township, Yangon, Myanmar

Individual Participant Results Report

Laboratory ID: 123

Laboratory Name: Lab A

PT Panel Name: 2024-02-HIVViralLoadDTS(26-Nov-2024)

Panel Received Date: 28-Nov-2024

Results Due Date: 27-Dec-2024

Panel Tested Date: 06-Dec-2024

Platform/Assay Name : Abbott - RealTime

Results Submitted Date : 16-Dec-2024

Reference Laboratory Result				Your Laboratory Performance		
Specimen ID	Your Results (log_{10} copies/mL)	Assigned Value (log_{10} copies/mL)	Robust Standard Deviation	z Score	Your Grade	Score
HIVL A-2 (2/24)	2.48	3.38	0.50	-1.80	Acceptable	100%
HIVL B-2 (2/24)	3.41	4.33	0.53	-1.74	Acceptable	
HIVL C-2 (2/24)	3.38	3.76	0.32	-1.17	Acceptable	
HIVL D-2 (2/24)	0.00	0.00	0.00	0.00	Acceptable	
HIVL E-2 (2/24)	3.45	3.91	0.32	-1.42	Acceptable	

0.00 indicated Target Not Detected (TND) results and NA for Not Applicable

z Score = (x - μ) / σ
where : x = Your reported Viral Load result (log10 copies/mL), μ = Assigned Value (log10 copies/mL) and σ = Robust Standard Deviation

Results Interpretation and Recommended Actions

z Score		Results Interpretation	Recommended Action
z ≤ ± 3.0	z ≤ ±2.0	Acceptable	No action required
	± 2.0 > z < ± 3.0	Warning	Closely monitor performance
z ≥ ± 3.0		Unacceptable	Perform corrective action

Confidentiality: The identities of participants are kept confidential and known only to the staff involved in the implementation of the Proficiency Testing. Each participant has been assigned a unique identification number for the purposes of database management.

Report approved by

Date of approval: 20 May 2025

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- End of final report -

Example 3: HIV VL NEQA Summary Report

Government of the Republic of the Union of Myanmar
Ministry of Health
Department of Medical Services
National Health Laboratory
35, Hmaw Kun Daik Street, Dagon Township, Yangon, Myanmar

National External Quality Assessment for HIV-1 Viral Load Testing

PT survey
2024-02-HIVViralLoadDTS (27-Dec-2024)

Shipment Code
VLDTS2024Panel2

GeneXpert HIV-1

Specimen ID	Number of Participants	Assigned Value (log_{10} copies/mL)	Participants with Passing Results (z ≤ ± 3.0)	
HIVL A-2 (2/24)	23	2.74	22	96%
HIVL B-2 (2/24)	23	4.43	23	100%
HIVL C-2 (2/24)	23	3.36	22	96%
HIVL D-2 (2/24)	23	0.00	23	100%
HIVL E-2 (2/24)	23	3.39	23	100%

High Throughput Platforms

Specimen ID	Number of Participants	Assigned Value (log_{10} copies/mL)	Participants with Passing Results (z ≤ ± 3.0)	
HIVL A-2 (2/24)	11	3.38	11	100%
HIVL B-2 (2/24)	11	4.33	11	100%
HIVL C-2 (2/24)	11	3.76	11	100%
HIVL D-2 (2/24)	11	0.00	11	100%
HIVL E-2 (2/24)	11	3.91	11	100%

Sample set notes: Sample C and E are duplicate samples.

Number of Participants for each VL platform (Total):
Point-of-care platform: GeneXpert HIV-1(n=23),
High Throughput platform: Biocentric - Generic HIV Charge Virale(n=7), Abbott - m2000 RealTime (n=4)

Information with respect to compliance with standards ISO 13528:2015(E)

Preparation of Proficiency Test items: The proficiency test items were prepared by trained staff using inactivated cultured HIV-1, following institutional SOPs. The PT samples were issued with instructions to report on detection using routine methods. The PT samples were tested for homogeneity prior to shipment and met program requirements.

Procedures used to establish the assigned value:

For the number of participants using the same VL platform was more than eighteen, the results of participating laboratories were grouped together and analyzed for peer-comparison using the Normalized interquartile range (nIQR) method. Assigned value, Robust Standard Deviation, Standard Uncertainty of assigned value, z score and performance score were derived as per the Standard ISO13528:2015(E). For VL platforms with less than eighteen participants, the assigned value determined by the reference laboratory was used for result comparison.

Z score

The performance of participating laboratories is determined based on the "z score," which is calculated for each reported result. The z score provides feedback on participant performance, compared to the robust standard variation. The z score calculation is as follows.

$$z\ score = \frac{(x - \mu)}{\delta}$$

x = reported result from participants (log10 copies/ml)

μ = assigned value (log10 copies/ml) and

δ = robust standard deviation

Interpretation of z-scores is provided in the table below.

z Score		Results Interpretation	Recommended Action
z ≤± 3.0	z ≤ ± 2.0	Acceptable	No action required
	± 2.0 > z < ± 3.0	Warning	Closely monitor performance
z ≥± 3.0		Unacceptable	Perform corrective action

A 20% score is given for each DTS result that is correctly reported within the "Acceptable" and "Warning" range (where the z score is ≤ ±3.0). A full 100% score (20% x 5) is provided if all five DTS results meet the acceptable z score range.

Confidentiality: The identities of participants are kept confidential and known only to the staff involved in the implementation of the Proficiency Testing. Each participant has been assigned a unique identification number for the purposes of database management.

Report approved by

Date of approval: 13 Jan 2025

This is a system generated report. No signature required

- End of report -

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ACTIVITY PHOTOS

Training on National External Quality Assessment scheme for HIV Viral Load Testing - 2024

Training on National External Quality Assessment scheme for HIV Viral Load Testing-2024