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Guidelines on
Quality Monitoring System
for Outsourced Viral Load Tests

NACO

National AIDS Control Organisation
Ministry of Health & Family Welfare, Government of India

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February 2018

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1 Background

National AIDS Control Organization (NACO), Ministry of Health and Family Welfare (MoHFW), Govt. of India is implementing fourth phase of National AIDS Control Programme (NACP-IV). There are nearly one million PLHIV on ART at more than 530 ART Centers. All patients on first line ART are monitored by six monthly CD4 count testing to see the response to ART. Those with immunological failure or suspected treatment failure are evaluated for treatment failure. Viral load test is recommended to confirm the treatment failure and switch to second line ART if viral load (VL) is more than 1,000 copies.

Currently, NACO is implementing targeted HIV Viral Load testing in the program through 10 Viral Load Testing Centers in the government run facilities across the country and around 14,000 tests are done annually (2016).

WHO 2013 treatment guidelines recommends VL testing as a preferred test for monitoring Anti-Retroviral Treatment and early diagnosis of treatment failure thereby improving clinical outcomes and reducing accumulation of treatment related mutations. Aligned with the WHO guidelines, GOI has laid down a policy to provide VL test to all the PLHIV on ART. NACO pl¬ans to roll out routine VL testing in a phased manner over three years on a turnkey model engaging the private sector. NACO has formed a national viral load committee to provide technical guidance to scale up VL testing in the country and set up systems for assuring quality in VL testing services.

Scope

This document provides guidelines and tools for monitoring quality of the outsourced VL test results. The document aims to serve as a reference for all stakeholders viz., NACO, SACS, Private Lab, ART centre etc. engaged in the national viral load testing scale up, guiding them through different methods to monitor quality of tests.

Specifically, the document defines

1- Processes and procedures for monitoring of Viral Load testing in outsourced labs
2- List of quality indicators and monitoring checklist for assuring quality of services

2 Monitoring Mechanisms for Private Labs Conducting Viral Load Testing

HIV Viral Load testing is currently available at 10 Viral Load Testing Centers in the government run facilities across the country and around 14,000 tests are done annually. These centers are supported and monitored by NACO. With the scale-up of VL testing through private partnerships the role of NACO and the government run viral load testing facilities expands to include monitoring of quality in these select private testing facilities.

NACO will provide guidance and directions to the private labs on requisite quality parameters and processes. It will also monitor the private labs through periodic review of reports and supervisory visits.

An outline of the three major methods for monitoring is provided in Figure-1.

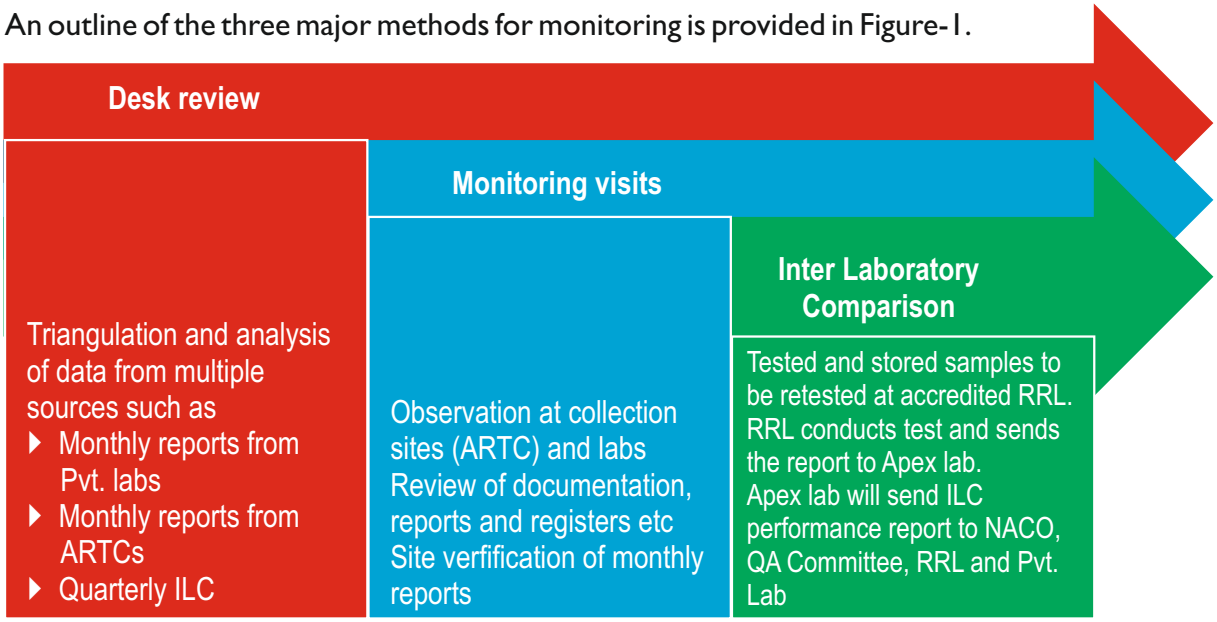

Figure-1: Methods for monitoring private HIV VL testing laboratories

QA committee: A viral load QA committee will be formed to review the adherence of outsourced lab to the NACO's slated QA processes and procedures. The committee is formed with representatives from NACO, VL Reference Laboratories (VL labs under NACP with NABL accreditation) and other experts as nominated by NACO (2).

- The committee will meet quarterly initially to review the QA status of the outsourced labs. Based on need the frequency can be changed as per the committee's decision.
- Review the triangulated data from different sources as detailed in the illustration above, site visit report and reports from the ILC-using split sample analysis.
- Provide recommendations to NACO based on the desk review for corrective actions to be taken by the lab, if any

I. Desk Review

Process

1. Monthly Review

The CST and LSD of NACO will receive monthly report from the private labs and the ARTCs based on Monthly Report Format for Desk Review of Private Laboratories and ARTC (Annexures 1 and 2). These reports will be compiled by NACO and a broad dashboard of three indicators as mentioned below will be monitored by NACO and feedback will be provided to the private labs.

Core Indicators for Monthly review by NACO:

- Turn Around Time (TAT) - This indicator provides time from of sample collection, transportation, receipt, reporting to issue of results for clinical decision making.
- Collection coverage and achievement- This indicator provides information on the saturation of the designated collection sites.
- Monthly Percentage Coefficient of Variation (CV %)- an indicator of good quality control in the lab

2. Quarterly review

In addition to monthly review by NACO, the QA committee will undertake a comprehensive review each quarter and provide feedback to DDG laboratory services.

The monthly data received from multiple sources; the private laboratory, VL reference laboratory and ART centres will be triangulated, reviewed and analyzed by the QA committee.

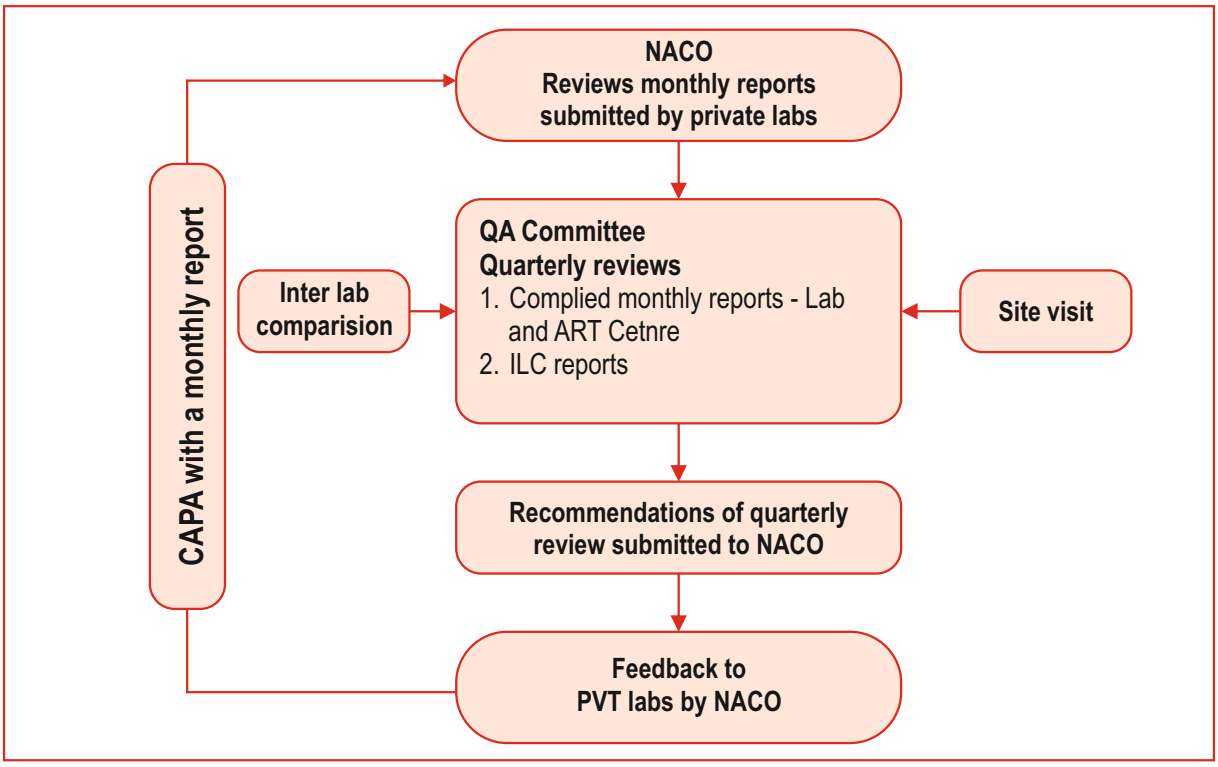

Figure-2: Process of Desk review

The observations of the desk review will be made available to the Technical Assistance partners as well as referral laboratories. Based on these regional/state wise plan of action for private laboratories will be prepared, the implementation of which will be supervised by NACO, SACS and reference laboratories. The findings of the desk review may further support the monitoring supervision visits. Refer Annexure 3 Indicators (Quality and Program Indicators) for Desk Review by the QA committee.

II. Monitoring Visits

Periodic supervisory visits are critical to ensure continuance of quality practices and identify gaps. These visits maybe scheduled in advance with the private laboratory or be unannounced visits. The process of structuring effective supervisory visits is provided below.

Monitoring Team: A team of auditors will consist of representatives from NACO, VL Referral laboratories and Technical Assistance partners like, CDC, SHARE INDIA and other organizations engaged in laboratory strengthening. The team will be trained on the use of the checklist and they will conduct assessments of outsourced VL testing labs.

The Technical Officers of SRL/NRL will monitor ART centers attached to their institute from where samples will be collected for testing by outsourcing model every month and send the report to NACO every month using a checklist (Annexure 4).

Assessment checklist: Through consultations with a core team of experts, a checklist is developed to assess the compliance of the outsourced labs to the technical and the quality requirements. The TO checklist (Annexure 4) covers the important indicators that require monthly monitoring while the monitoring team checklist (Annexure 5) covers four domains- Pre-Analytical Procedure, Analytical Procedure, Post Analytical Procedure and Quality Assurance. A snapshot of domain wise indicators for monitoring team's checklist is provided below.

Domain 1 Pre Analytical Procedure	Domain 2 Analytical Procedure	Domain 3 Post Analytical Procedure	Domain 4 Quality Assurance
▸ Specimen Collection ▸ Specimen transportation ▸ Sample Reception	▸ Equipment ▸ Testing process ▸ Staff, Facility and Infrastructure ▸ Inventory Management	▸ Reporting ▸ Sample storage & Safety ▸ Information Management ▸ Confidentiality and data storage	▸ EQAS and ILC using split samples ▸ QC

Figure-3: Domains in the Monitoring Visit Checklist

Considering the usefulness of multiple data collection as opposed to a single method for the review, different methods (observations, interviews and review of records) for data collection from different sources were systematically integrated. Combining these three methods, the checklist captures both quantitative and qualitative data.

As per the monitoring team's checklist (Annexure 3), the maximum score attainable is 126 and the following scoring scheme will be used:

- Each item is assigned a score of 2
- Score of 0 (zero) is given when there is a complete gap in the requirement /availability
- Partial compliance of an item is scored as "1" and explanation is assigned to it

Based on the cumulative scores, the grading will be done as shown in Table 1.

Table 1: Grading pattern based on cumulative scores

Total Score: ..... Maximum Score: ..... Percentage (%):				
Grade 5 Excellent (90-100%)	**Grade 4 Very Good (75-89%)**	**Grade 3 Good (55-74%)**	**Grade 2 Average (30-54%)**	**Grade 1 Poor (0-29%)**

Monitoring Visit: The audit visits will be scheduled on such dates that there is a scheduled specimen collection at an ARTC within 30 km radius of the private lab. The auditors will start the visit at the ARTC collection site where they will observe the collection process, and hold discussions with the ART MO and team, basis the checklist. The team will then proceed to the private laboratory and conduct the requisite document reviews and interviews with POC and staff. The audit will be completed in one day.

Data Analysis: Post the audit and within 2 working days of the visit the auditors will send a completed signed copy of the checklist to NACO Laboratory Services Division. The report will also include key action points for the audited lab and propose timelines for the same.

Follow up Plan: Based on the assessment report, NACO will issue an OM to the Pvt. Lab for actions and charge penalty for any deviations mentioned in the contract.

III. Inter Lab Comparison

NACO recommends the use of Inter laboratory comparison (ILC) using split samples for quality assurance of outsourced tests. An ILC will consist of re-testing of previously tested samples with an accredited Reference Regional VL lab. ILC will be initiated with an accredited Regional Reference lab with comparative test method and equipment. The Regional Reference VL lab will be considered as the reference lab for the purpose of ILC.

For the purpose of repeat testing by ILC, the private laboratory will store the tested samples for a period of one year under appropriate storage conditions. Upto 1 % of randomly selected samples to cover the dynamic range. The samples for ILC will be blinded to the Regional Reference Lab.

The results of retesting and previously tested samples will be evaluated by the Apex lab for acceptability. A copy of the ILC report will be sent by Apex lab to NACO, RRL, QA Committee and Private lab.

ILC, will be conducted quarterly. The cost for transporting the samples for ILC will be borne by the outsourced agency/private lab.

Consideration for matching platforms for ILC – As far as possible matching testing platforms should be selected for ILC.

IV. Acceptance criteria

- 0.5 log difference is accepted

Non Conformance and Penalty 3

Based on the programmatic needs NACO has defined a set of procedures for accessing viral load test and utilization of results for patient care. Deviation from the defined procedures and in particular as listed in table no. 2 will amount to non-conformances with associated penalty.

Table 2: Performance indicators and acceptance criteria

S No.	Performance Indicators	Acceptance criteria	Penalty Provisions	Source Monthly Reports
1	Providing soft copy of the test report to concerned ART Centre	24 hours from receipt of samples at testing facility	Deduction of 2% of the testing charges for every hour of delay beyond 24 hours subject to maximum of 100% of testing charges.	Private Lab (column no. 8) 95 % of the reports should meet the TAT
2	Non-availability of sample collection facility to patient upon his / her visit to ART Centre.	1% cases in a year (measured each quarterly performance review)	Deduction of amount equivalent to 1% of the performance security submitted by the Agency for every 1% case of default beyond 1% in a year.	ART Centre
3	Percentage of test results found to be unsatisfactory in the proficiency testing done by NACO or an organization on its behalf	PT failure on two consecutive occasions	Deduction of double the amount of value of tests found inaccurate.	Private Lab

Other Non-Conformances

The QA committee will monitor the performance on the other indicators though not associated with penalty, refer Table no. 3

Table 3: Additional performance indicators

S No.	Performance criteria / Indicators
1	Sample not collected as per the frequency defined in the contract (daily/weekly/bi-weekly)
2	Sample not collected as per the sample collection plan defined in the contract
3	Daily reports sent to NACO by e-mail (Y/N) for each ARTC
4	Monthly reports sent to NACO by e-mail (Y/N) for each ARTC

Annexures

Monthly Report Format for Desk Review of Private Laboratories

Name of the Laboratory: ..... Reporting Month/Year: M M Y Y Y Y

Platform used for VL testing: .....

Number of ARTC allotted by NACO for sample collection: ..... Total samples received for testing: .....

Number of ARTC from where sample collected: .....

S. No.	Name(s) of ARTC from where samples are received	Frequency of sample collection from each ARTC	Number of samples collected at ARTC	Number of samples received from each ARTC	Number of samples rejected from ARTC	Number of samples tested from each ARTC	Number of reports missed TAT (soft copy released in 24 hours of sample receipt)	Number of reports missed TAT within 10 days from sample collection to issue of results)

Other Quality Indiactors for monthy review of Pvt. Lab , as applicable:

- % CV
- PT Report
- ILC Report

Annexure II

Monthly Report Format for Desk Review of ARTC			
Name of ARTC: ..... Frequency of sample collection as per contract:		Reporting Month/Year:	Data verified with Pvt Lab monthly report
S No.	**Indicator**		
1	Were samples collected as per the prescribed schedule? (Yes or No) If No, give details		
2	Number of patients referred for VL testing by MO		
3	Number of patients turned back due to non-availability of sample collection facility		
4	Number of specimens collected by Private lab at ARTC		
5	Number of specimens transported to Private lab for testing		
6	Number of reports (Soft copy) missed TAT		
7	Number of reports (soft copy) received within 10 days of sample collection		

Signature of MO at ARTC

QA Committee Checklist

Quality Indicators

S No.	Indicator	Source	Frequency	Remarks
1	**Accreditation status**			
1.1	Valid ISO 15189 accreditation for performing HIV-1 Viral Load quantitative Assay using the proposed method	Labs to share the NABL accreditation certificate and scope of accreditation every year	Annually	
2	**EQA / PT**			
2.1	Enrolled in a PT programme, for the Viral Load test?	Lab to share last PT report	Bi-Annually	
2.2	PT performance reports are accessible to NACO?	Lab to share PT report as well as login ID and password to access the reports –	Bi-Annually	
2.3	Enrolled in a PT program accredited as per ISO 17043 standards?	Appropriate document to be shared with NACO	Annually	
3	**ILC**			
3.1	ILC performance report	APEX lab to provide data	Quarterly	
4	**IQC**			
4.1	Monthly IQC data with % CV and CAPA for outliers	Labs to share the monthly LJ chart and % CV	Monthly	
4.2	Number of samples rejected in the reporting month		Monthly	
4.3	Reasons for sample rejection		Monthly	

Program Indicators

1	**Site Saturation and Frequency**			
1.1	Is the lab maintaining coverage & frequency of sample collection as per the contract	ARTC to provide data –monthly Pvt lab to provide data-monthly:		
		Frequency of collection	Number of centers as per contract	Actual collection centers
		Daily		
		Twice a week		
		Weekly		
		Total		

S No.	Indicator	Source
1	**Site Saturation and Frequency**	
1.2	Proportion of samples not meeting the TAT. ▸ Number of reports (24 hours Soft copy) missed TAT Number of reports (10 days from sample collection to issue of results) missed TAT Acceptance criteria : 95% should meet the TAT criteria	Pvt. Lab to provide data- monthly
1.3	Is a summary of daily, monthly/ quarterly/ half-yearly/ yearly testing reports of all tests shared with NACO? *soft copy/access to LIMS*	Pvt. Lab to provide data
1.4	Proportion of patients non-availability of sample collection facility to patient upon his / her visit to ART Centre	Record to be maintained at ARTC and reported in MPR (Monthly Performance Report)
2	**IVR**	
2.1	Number of calls received during the month	Pvt. Lab to provide data – monthly
2.2	Evidence for nature of the call and redressal	

Checklist for Monitoring Visit by TO			
Name of the Lab/Institution			
Name of the Reviewer(s)			
Signature of Reviewer			
Date of review			
S No.	**Description**	**Source**	**Observations by TO**
1	Is staff responsible for sample collection and transportation competent on these procedures?	Observe at the collection site	
2	Are the specimens collected at prescribed frequency?	Review the records and verify the frequency with the MOU	
3	Are all consumables required for specimen collection including plasma tubes, evacuated EDTA Blood collection tubes, needles and syringes (within shelf-life), single use spirit swabs, sterile gauze with sticking tape & tourniquet collection, tube holder etc. provided by the Pvt. lab?	Observe at the ARTC specimen collection site and interview with the CD4 lab in-charge/ART MO	
4	Is whole blood processed for plasma separation within 4-6 hours of blood-draw	Observe at ARTC specimen collection site	
5	Is plasma transported at 2-8°C (with temperature logger)?	Observe at ARTC specimen collection site and Review the Record	
6	Are the reports provided to ARTC within 10 days of sample collection?	Review last two weeks data	
7	Is Biomedical waste discarded as per the existing national guidelines	Observe at ARTC	
8	Is ARTC sending monthly reports to NACO	Observe at ARTC	
9	Number of patients turned back due to non-availability of sample collection facility in last two weeks	Review record at ARTC	

Viral Load Lab Checklist

Name of the Lab/Institution	
Name of the Reviewer(s)	
Signature of Reviewer	
Date of review	

Section	Score Obtained	Maximum Score	%
Pre Analytical Procedure		36	29
Analytical Procedure		30	24
Post Analytical Procedure		34	27
Quality Management Systems		26	20
Overall Score		**126**	**100**

Summary (Include best practices)

Challenges and Suggestions for mitigation

S.No	Description	Source	Max Score	Score obtained	Remarks
1	**Pre Analytical Procedure**				
1.1	**Specimen Collection**	**Source**	**Max Score**	**Score obtained**	**Remarks**
1.1.1	Are procedures for sample collection and transportation documented and available in the lab?	Observe at Lab	2		
1.1.2	Is staff responsible for sample collection and transportation trained on these procedures?	Observe at Lab	2		
1.1.3	Does the Lab have defined sample collection plan as per NACOs contract? (Review list of ARTCs assigned to the lab by NACO and compare it with the list of ARTCs from which samples are collected, also verify for the accuracy of the monthly report).	Observe at Lab (LIMS/monthly report)	2		
1.1.4	Are the specimens collected at prescribed frequency? (Look for 'daily' collection at ART Centers with more than 2500 eligible patients (>10 samples per day) and on 'weekly' basis at ART Centers with less than 2500 eligible patients (<10 samples per day, also verify for the accuracy of the monthly report).	Observe at Lab and ARTC specimen collection site (IMS/LMIS/monthly report)	2		
1.1.5	Are all consumables required for specimen collection including plasma EDTA tubes, evacuated EDTA Blood collection tubes, needles and syringes (sterile within shelf-life), single use spirit swabs, sterile gauze with sticking tape & tourniquet collection, tube holder etc. provided by the agency?	Observe at the ARTC specimen collection site or interview with the CD4 lab in-charge/ART MO	2		

1.1.6	Does the lab ensure collection of valid specimen for the assay: (Look for appropriate use of vacutainers, disposable pipettes recommended sample type as approved by NACO for HIV-1 Viral Load test)	Observe at ARTC specimen collection site	2		
1.1.7	Are the samples uniquely labelled for sample identification and tracking. (*At least two identifiers for manual labelling or barcodes)*	Observe at ARTC specimen collection site	2		
	Sub Total		**14**		
1.2	**Specimen Transportation**	**Source**	**Max Score**	**Score obtained**	**Remarks**
1.2.1	Is there a documented procedure for specimen transportation SOP (including requirements for temporary storage)?	Observe at ARTC specimen collection site (Review SOP)	2		
1.2.2	Is there a system for specimen tracking? (Look for a copy of documentation of specimen collection, transportation and receipt provided to ART Centre or an online system of specimen tracking)	Observe at ARTC specimen collection site (Review documentation)	2		
1.2.3	Is there a defined process for temperature maintenance during transportation? (Look for plasma specimen transportation plan under cold chain, time period with appropriate temperature data loggers)	Observe at Lab	2		
1.2.4	Is plasma transported at 2-8°C (with temperature logger)?	Observe at ARTC specimen collection site	2		
1.2.5	Are temperature data loggers available with plasma transportation (to identify episodes of temperature excursions) till the sample reaches the testing laboratory?	Observe at ARTC specimen collection site	2		
1.2.6	Is the temperature data logger of the temperature range -10°C to 40°C and WHO-prequalified approved? (Look for technical specifications and	Observe at lab	2		

	approval status as above)				
1.2.7	Is plasma transported at 2-8°C and reaching the testing laboratory within 24 hrs of separation or as per manufacturer's instructions?	Data from LIMS	2		
1.2.8	Is whole blood processed for plasma separation within 4-6 hours of blood-drawn when kept/transported at 2-25°C or as per manufacturer's instructions?	Observe at specimen collection site	2		
	Sub Total		**16**		
1.3	**Sample Reception**	**Source**	**Max Score**	**Score obtained**	**Remarks**
1.3.1	Is there a sample accession procedure in place? (including date and time of receipt recorded in an accession book, or other comparable record?)	Observe at Lab	2		
1.3.2	Is a written criterion for rejection and acceptance of specimen available?	Observe at Lab	2		
1.3.3	Is there a written procedure for handling rejected specimen? (including retention and discard policy)	Observe at Lab	2		
1.3.4	What are the reasons for sample rejection observed				
	Sub Total		**6**		

Section Summary

S.No	Description	Source	Max Score	Score obtained	Remarks
2	**Analytical Procedure**				
2.1	**Equipment**	**Source**	**Max Score**	**Score obtained**	**Remarks**
2.1.1	Does the lab have a list of the equipment used for testing?	Observe at Lab	2		
2.1.2	Is functional back-up method/ equipment/ lab available for VL testing in case the primary method/ equipment/ lab is not able to perform the test?	Observe at Lab	2		
2.1.3	Is calibration done as per recommendation? (Look for congruence with the kit protocol)	Observe at Lab	2		
2.1.4	Are daily maintenance records available as per manufacturer's instructions	Observe at Lab	2		
2.1.5	Is AMC/CMC available?	Observe at Lab	2		
2.1.6	Is the lab equipped for storage of specimens up to one year at -70°C?	Observe at Lab	2		
	Sub Total		**12**		
2.2	**Testing Process**	**Source**	**Max Score**	**Score obtained**	**Remarks**
2.2.1	Is there an SOP for testing procedures?	Observe at Lab	2		
2.2.2	Is the SOP for testing, compliant with the manufacturer's instructions?	Observe at Lab	2		
2.2.3	Is sample identification ensured through all applicable phases of analysis? (through barcode, worksheet)	Observe at Lab	2		
2.2.4	Are nucleic acids extracted and purified as per the recommended methods of manufacturer	Observe at Lab	2		
2.2.5	Are results interpreted as per manufacturer's instructions?	Observe at Lab	2		
	Sub Total		**10**		
2.3	**Staff, Facility and Infrastructure**	**Source**	**Max Score**	**Score obtained**	**Remarks**
2.3.1	Is the person performing tests qualified, trained and competent?	Observe at Lab and review staff personnel file	2		

2.3.2	Is the facility and infrastructure suitable to support volume of testing required under the assignment? (Look for number of staff, equipment through put)	Observe at Lab	2		
2.3.3	Is unidirectional workflow followed	Observe at Lab	2		
	Sub total		**6**		
2.4	**Inventory Management**	**Source**	**Max Score**	**Score obtained**	**Remarks**
2.4.1	Is there a well-defined inventory management system to avoid stock-outs resulting in delay in testing? (look for inventory registers/ software/ stock outs in last year)	Observe at Lab (Review inventory policy or procedure)	2		
	Sub total		**2**		

Section Summary

S No.	Description	Source	Max Score	Score obtained	Remarks
3	**Post Analytical Procedure**				
3.1	**Reporting**	**Source**	**Max Score**	**Score obtained**	**Remarks**
3.1.1	Is there an SOP for interpretation of results?	Observe at Lab (Review the SOP)	2		
3.1.2	Is report reviewed and signed by the authorized personnel? (Look for recommendations of National Accreditation Board for Testing and Calibrating Laboratories (NABL)	Observe at Lab (Review the SOP)	2		
3.1.3	Are duly signed reports made available to ARTC in the format/software recommended by NACO?	Observe at Lab or ARTC (Review in random 10 patient reports)	2		
3.1.4	Are the reports provided to ARTC as soon as the report is available but not later than 24 hours of receipt of sample at testing facility laboratory?	Observe at ARTC (Review in random 10 patient reports)	2		
3.1.5	Is a hard copy of report for patient record made available to ARTC within 10 days of receipt of sample at testing facility?	Observe at ARTC (Review in random 10 patient reports)	2		
3.1.6	Are reports to NACO submitted in the format approved by NACO (through e-mail / Lab Information Management System)?	Observe at Lab (Review of Emails or LMIS)	2		
3.1.7	Has the lab's reporting system been automated?	Observe at Lab (If yes, verify the LIMS)	2		
3.1.8	Is the LIMS updated daily with results of tests carried out at the end of the day, every day, with all the patient details and the results?	Observe at Lab (Review 10 patient records at random from different days for input in IMS)	2		
	Sub Total		**16**		
3.2	**Sample storage and Safety**	**Source**	**Max Score**	**Score obtained**	**Remarks**
3.2.1	Is there a documented procedure for short term and long term storage of specimens?	Observe at Lab (Review SOP)	2		

3.2.2	Is the private laboratory storing samples for one year at the prescribed temperature	Observe at Lab (Review SOP)	2		
3.2.3	Are documented safety protocols/procedures available?	Observe at Lab (Review SOP)	2		
3.2.4	Are laboratory personnel trained for these safety protocols/procedures?	Review records at Lab	2		
3.2.5	Are there documented procedures for disposal of Biomedical Waste (BMW) generated during testing procedure?	Observe at Lab (Review SOP)	2		
	Sub Total		**10**		
3.3	**Information Management**	**Source**	**Max Score**	**Score obtained**	**Remarks**
3.3.1	Is a communication system available and is it appropriate to ensure proper and prompt communication between NACO staff, all ART Centres and team members of the Pvt. Lab (Look for communication mechanism devised by the Pvt. Lab including methods like telephone, online, call center etc.)?	Observe at Lab	2		
3.3.2	Has the lab set up a toll-free number for IVR?	Place calls to toll free number	2		
	Sub Total		**4**		
3.4	**Confidentiality and Data Storage**	**Source**	**Max Score**	**Score obtained**	**Remarks**
3.4.1	Does the lab have a plan to ensure patient and data confidentiality?	Observe at Lab (Review Plan)	2		
3.4.2	Does the lab have defined procedure to ensure data transfer to NACO and discarded from the Pvt. Lab at one year	Observe at Lab (Review reports)	2		
	Sub total		**4**		

Section Summary

S.No	Description	Source	Max Score	Score obtained	Remarks
4	Quality Assurance				
4.1	EQAS and ILC using spit samples	Source	Max Score	Score obtained	Remarks
4.1.1	Is laboratory enrolled in an External Quality Assurance (EQA) programme, for the test Viral Load test?	Observe at Lab (Review of EQA report)	2		
4.1.2	Is the EQA provider certified as per ISO 17043 standard for the same test?	Observe at Lab (Review of EQA report)	2		
4.1.3	Is the Lab NABL accredited for the HIV-1 Viral Load Assay using the proposed kit?	Observe at Lab (Review of NABL certification)	2		
4.1.4	Has the lab worked on the suggestions/observations made during the last assessment visit from NACO?	Observe at Lab (Review findings of the previous visit and corrective action taken henceforth)	2		
4.1.5	Based on directions from NACO has the lab participated in ILC with an accredited regional referral lab (RRL)?	Observe at Lab (Review reports)	2		
4.1.6	Did the Lab receive the results of ILC from Apex Lab	Observe at Lab (Review reports)	2		
4.1.7	Are the results being in concordance with the NACO designated public sector VL Lab	Observe at Lab (Review reports)	2		
4.1.8	Does the lab perform lot to lot kit verification?	Observe at Lab (Review reports)	2		
	Sub Total		**16**		
4.2	**QC**	**Source**	**Max Score**	**Score obtained**	**Remarks**
4.2.1	Is a Quality control procedure defined? Is this as per National Guidelines?	Observe at Lab and verify with monthly report	2		
4.2.2	Are kit controls used during each run?	Observe at Lab and verify	2		

4.2.3	Are control material/external controls used for QC?	Observe at Lab and verify	2		
4.2.4	Does the lab define control limits and monitor runs using defined criteria?	Observe at Lab and verify	2		
4.2.5	Is the lab regularly doing contamination check as per the manufacturer's instruction?	Observe at Lab and verify	2		
	Sub Total		**10**		

Section Summary

NACO Experts

Dr. NareshGoel, DDG, Lab Services
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Technical Experts

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