HIV VIRAL LOAD AND INFANT VIROLOGIC TESTING SCORECARD

HIV Viral Load and Infant Virological 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
- Send copy of scorecard to site in advance of visit for site to get ready (e.g. prepare documentation for assessors) for the assessment
- 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

PART 1 LABORATORY PROFILE AND SCORECARD

Country	UGANDA	District/Province/Region	KAMPALA	
Laboratory Name	CENTRAL PUBLIC HEALTH LABORATORIES	City/Town	KAMPALA	
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	10/09/2018	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	37	34	3
Laboratory Technician	12	11	1
Laboratory Assistant	2	2	
Laboratory Clerk	25	22	3
Others, please specify	Senior laboratory technologists= 2 Laboratory managers = 3 Laboratory director = 1 Logistics officers = 8 Sample archivists = 2 Customer care officers = 3 Records officers = 7 ICT officers = 14		

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**	**YES**	**PARTIAL**	**NO**	**COMMENTS**	**SCORE/11**
1.1	Is the Viral Load (VL)/Infant Virological Testing (IVT) training program based on national policy?	✓			ART guidelines 2018	
1.2	Have all laboratory personnel received comprehensive training on VL/IVT testing using approved Standard Operating Procedures (SOPs)?	✓			Read, understood and signed all SOPs	

1.0	PERSONNEL	YES	PARTIAL	NO	COMMENTS	SCORE/11
1.3	Are laboratory personnel trained on using standardized VL/IVT testing registers/log book/LIMS?	✓				
1.4	Are laboratory personnel trained on sample management from collection to disposal?	✓				
1.5	Are laboratory personnel trained on routine preventive equipment maintenance?	✓				
1.6	Are laboratory personnel trained on the quality control process?	✓				
1.7	Are laboratory personnel trained on safety and waste management procedures and practices?	✓				
1.8	Are only trained/competent laboratory personnel allowed to perform VL/IVT testing?	✓				
1.9	Are approved/signed records of all trainings for all laboratory personnel kept on file?	✓				
1.10	Do records indicate all laboratory personnel were deemed competent before independently testing client VL/IVT samples?	✓				
1.11	Have all VL/IVT testing personnel received refresher training, according to the approved training program?	✓			Please specify refresher training frequency:	
1.0	**PERSONNEL**				**total:**	

2.0	PHYSICAL FACILITY / ENVIRONMENT	YES	PARTIAL	NO	COMMENTS	SCORE/14
2.1	Is there a designated area exclusively for VL/IVT testing?	✓				
2.2	Does testing area meet manufacturer's requirements for equipment installation?	✓				
2.3	Is the VL/IVT testing area clean, and organized?	✓				
2.4	Are reagents/supplies kept in a temperature controlled environment according to manufacturer's instructions?	✓				
2.5	Are SOPs in place and followed for temperature monitoring?	✓				
2.6	Are acceptable temperature ranges defined for temperature dependent equipment?	✓				
2.7	Are temperatures recorded daily for? - Freezers - Refrigerators - Room temperature	✓				

2.0	PHYSICAL FACILITY / ENVIRONMENT	YES	PARTIAL	NO	COMMENTS	SCORE/14
2.8	Is there documentation of corrective action taken in response to out of range temperatures?	✓				
2.9	Are UPS in place for testing equipment?	✓				
2.10	Is there a functional back-up generator?	✓				
2.11	Is there secure cold chain storage space?	✓				
2.12	Is there secure backup cold chain storage space?	✓				
2.13	Is there secure storage space for consumables?	✓				
2.14	Are SOPs for cleaning work areas in place and followed?	✓				
2.0	**PHYSICAL FACILITY**				**total:**	

3.0	SAFETY / WASTE MANAGEMENT	YES	PARTIAL	NO	COMMENTS	SCORE/12
3.1	Are SOPs in place and followed for personnel safety practices?	✓				
3.2	Are SOPs in place and followed for disposal of 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?	✓				
3.5	Is personnel protective equipment (PPE) always available to the VL/IVT testing personnel?	✓				
3.6	Do all laboratory personnel properly use PPE throughout the VL/IVT testing process?	✓				
3.7	Are clean water and soap available for hand washing?	✓				
3.8	Are eye wash and/or safety shower facilities readily accessible to laboratory personnel?	✓				
3.9	Is an appropriate disinfectant available to clean the work area and equipment?	✓				
3.10	Are sharps, infectious and non-infectious waste handled properly?	✓				
3.11	Are SOPs in place and followed for proper handling of chemical waste?	✓				
3.12	Are containers for infectious and non-infectious waste emptied regularly in accordance with SOPs?	✓				
3.0	**SAFETY / WASTE MANAGEMENT**				**total:**	

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?		Quarterly				
Comments:						
4.0	**PROCUREMENT AND INVENTORY**	**YES**	**PARTIAL**	**NO**	**COMMENTS**	**SCORE/8**
4.1	Have all reagents been in stock during the past 6 months? If no or partial record the number of stock outs in comment section.	✓			VL _____ IVT _____	
4.2	Have all consumables/supplies been in stock during the past 6 months? If no or partial record number of stock outs in comment section.	✓			VL _____ IVT _____	
4.3	Is there a SOP for inventory control?	✓				
4.4	Are SOPs in place and followed for receipt, inspection and storage of reagent/supplies?	✓				
4.5	Are reagents/supplies labeled with the date received and initials?			✓		
4.6	Are all reagents/supplies, currently in use, within their expiration period?	✓				
4.7	Are reagents/supplies appropriate for molecular testing (e.g. powder-free gloves, filtered tips, RNAse/DNAse-free)?	✓				
4.8	Are SOPs for disposal of reagents and consumables in place and followed?	✓				
4.0	**PROCUREMENT AND INVENTORY**				**total:**	

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	54,021	448
VL – DBS	46,831	214
VL - Other	N/A	N/A
IVT – Whole Blood	N/A	N/A
IVT – DBS	12,642	135

5.0	SAMPLE MANAGEMENT	YES	PARTIAL	NO	COMMENTS	SCORE/8
5.1	Are SOPs in place and followed for sample transport and processing in the laboratory?	✓				
5.2	Does the laboratory highlight issues with sample processing/transport to implementing partner or referring facilities for remediation?	✓				
5.3	Are SOPs in place and followed for evaluating sample acceptability upon receipt in the laboratory?	✓				
5.4	Are requesters notified of rejected samples within 24 hours according to SOPs?	✓			If YES by: ☐ Phone ☐ Email ☒ Others, specify :Results reports with rejection reasons If NO: Avg: Range:	
5.5	Does a sample transport form accompany samples and does it account for chain of sample custody?	✓				
5.6	Are sample transport time and conditions maintained according to assay requirements from collection until reception in laboratory?	✓				
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 contacted to address the issue(s)?	✓			Rejection reason: Records indicate IP/hub/facility was contacted for remediation? ☐ Yes ☐ No	
5.8	Are SOPs for sample storage written according to manufacturer's requirements, in place and followed?	✓				

5.0	SAMPLE MANAGEMENT	total:	

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.	Viral Load _90,000_____ (Range:73,000-100,852)	IVT _____12,000___ (Range: 11,000-13,000)
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: _2,155_____ IVT: _2,383_____
Comments:		
With current testing schedule, what is the laboratory's current instrument testing capacity per day?	Viral Load_____7,698___	IVT ____990_____
How many shifts per day does the lab operate?	3 shifts	
How long are these shifts (in hours)?	8 hours	
How many days per week does the lab operate?	6 days	
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?	N/A	
If yes, what was the reason for the backlog?	N/A	
How many VL tests has the laboratory performed?	100,852	N/A
How many VL results have been reported?	100,852	
How many of these VL tests were virally suppressed? (<1000 cp/ml)	89,557	
How many of these VL tests were virally non-suppressed? (≥1000 cp/ml)	11,295	
How many IVT tests were performed?	N/A	12,536
How many IVT results have been reported?		12,536
How many IVT tests were positive?		406

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	9	9	Yes ☒ No ☐	Yes ☒ No ☐
2. -80°C Freezers	13	13	Yes ☒ No ☐	Yes ☒ No ☐
3. Refrigerators	08	08	Yes ☒ No ☐	Yes ☒ No ☐
4. Centrifuges	2	2	Yes ☒ No ☐	Yes ☒ No ☐
5. Biosafety cabinet	06	06	Yes ☒ No ☐	Yes ☒ No ☐
6. Abbott *m2000sp*	09	09	Yes ☒ No ☐	Yes ☒ No ☐
7. Abbott *m2000rt*	09	09	Yes ☒ No ☐	Yes ☒ No ☐
8. Roche COBAS AmpliPrep	05	05	Yes ☒ No ☐	Yes ☒ No ☐
9. Roche COBAS TaqMan 48	NA		Yes ☐ No ☐	Yes ☐ No ☐
10. Roche COBAS TaqMan 96	05	05	Yes ☒ No ☐	Yes ☒ No ☐
11. Biomerieux NucliSENS easyMag	NA		Yes ☐ No ☐	Yes ☐ No ☐
12. Biomerieux NucliSENS easyQ	NA		Yes ☐ No ☐	Yes ☐ No ☐
13. Emergency eyewash station	04	04	Yes ☒ No ☐	Yes ☒ No ☐
14. Pipettes	26	26	Yes ☒ No ☐	Yes ☒ No ☐
15. Incubator	NA		Yes ☐ No ☐	Yes ☐ No ☐
16. UV crosslink	NA		Yes ☐ No ☐	Yes ☐ No ☐
List any additional equipment used for protocol related assay				
17.Distiller	01	01	Yes ☒ No ☐	Yes ☒ No ☐
18.Hygrometer	26	26	Yes ☒ No ☐	Yes ☒ No ☐
19.Thermomixer	06	06	Yes ☒ No ☐	Yes ☒ No ☐
20.Dry block Heaters	05	05	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: Hologic evaluation before end of this year				

6.0	EQUIPMENT	YES	PARTIAL	NO	COMMENTS	SCORE/5
6.1	Is all equipment, required for VL/IVT testing, present?	✓				
6.2	Is all equipment, required for VL/IVT testing, functional?	✓				
6.3	Do equipment records include documentation of routine preventive maintenance?	✓				
6.4	Are equipment maintenance contracts in place?	✓				
6.5	Are Instrument Manuals for all VL/IVT equipment available to laboratory personnel?	✓				
6.0	**EQUIPMENT**				**total:**	

7.0	PROCESS CONTROLS	YES	PARTIAL	NO	COMMENTS	SCORE/21
7.1	Are VL/IVT testing job aids and/or SOPs available at the testing site?	✓				
7.2	Do records indicate equipment performance was verified prior to beginning VL/IVT testing per SOP?	✓				
7.3	Are SOPs in place and followed for running, recording, and reviewing quality control (QC) results?	✓				
7.4	Are QC results properly recorded, including invalid and out-of-range results?	✓				
*7.5	Are appropriate steps taken and documented when QC results are out-of-range and/or invalid per SOP?	✓				
7.6	Is there documented evidence of supervisor review of quality control records per SOP?	✓				
7.7	Is the laboratory enrolled in Proficiency Testing (PT) for VL/IVT?	✓			If yes: Name of PT programs: VL:VQA and CDC NEQAS IVT:VQA and CDC NEQAS Frequency: VL: ☐ 1x/yr ☒ 2x/yr ☐ 3x/yr IVT: ☐ 1x/yr ☒ 2x/yr ☐ 3x/yr	
7.8	In the past 12 months, has the laboratory passed all PT panels for VL?	✓				
7.9	Is PT testing rotated among all VL/IVT testing staff?	✓				
7.10	Are PT samples tested in the same manner as patient samples?	✓				
7.11	Are there records of supervisor review of PT result prior to submission?	✓				

7.12	Do records indicate that lab staff review PT result reports prior to submission?	✓				

7.0	PROCESS CONTROLS	YES	PARTIAL	NO	COMMENTS	SCORE/21
*7.13	Do records indicate that lab staff conduct investigation and corrective action for any failed PT results?	✓				
7.0	**TESTING PHASE**				**total:**	

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: E-LIMS	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	YES	PARTIAL	NO	COMMENTS	SCORE/19
Are the data elements below recorded in the laboratory?						

		VL/IVT Register	Laboratory Log Book	LIMS
	Select Scoring column:	☐	☐	☐
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' > 7 = Yes; 5 < 'Yes' ≤ 7 = Partial; 'Yes' ≤ 5 = 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 Score: Yes ☐ Partial ☐ No ☐
8.2	Unique patient ID	Yes ☒ Partial ☐ No ☐	Yes ☐ Partial ☐ No ☐	Yes ☒ Partial ☐ No ☐
				Q8.2 Score:

					Yes ☐ Partial ☐ No ☐	
8.0	**M&E DOCUMENTS AND RECORDS – RESULTS REPORTING AND DATA MANAGEMENT**	**YES**	**PARTIAL**	**NO**	**COMMENTS**	**SCORE/19**
8.3	Invalid Test Results	Yes ☐ Partial ☐ No ☐			Yes ☐ Partial ☐ No ☐	Yes ☒ Partial ☐ No ☐
					Q8.3 Score: Yes ☐ Partial ☐ No ☐	
*8.4	Are virally unsuppressed VL test results (≥1000 cp/ml) and positive IVT results identified at labs and reported as priority results to referring facilities? Please note in comments section how unsuppressed VL/positive IVT results are reported.	[5]✓				
*8.5	Are VL/IVT results returned from labs to clinic sites?	[5]✓			If yes, note method (check all that apply): ☒ Paper based ☐ Telephone ☐ SMS ☐ Email ☒ Others, specify _Dash board (Electronic Results Dispatch_____	
8.6	Do lab records or documents indicate receipt of results at clinics? Please indicate how in the comments.		✓			
8.7	Are all client documents and records securely kept throughout all phases of the testing process in the lab?	✓				
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?	✓				
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?	✓				
8.10	Are records or documents stored in accordance with national/local record retention requirements?	✓				
8.11	Is there a dashboard or tool for routine review of VL data in the LIS?	✓				
8.0	**M&E DOCUMENTS AND RECORDS – RESULTS REPORTING AND DATA MANAGEMENT**				**total:**	

9.0	INTERNAL QUALITY AUDITS – QUALITY INDICATORS – CONTINUAL IMPROVEMENT	YES	PARTIAL	NO	COMMENTS	SCORE/8
9.1	Does the laboratory staff record non-conforming events associated with VL/IVT sample receiving, testing, reporting, and supply chain?	✓				
9.2	Do records indicate management review of non-conforming events for trends?	✓				
9.3	Do records indicate investigation of corrective action taken for non-conforming events?	✓				
9.4	Does the laboratory have an internal audit SOP?	✓				
9.5	Do records indicate internal audits are performed per SOP?					
9.6	Do records indicate corrective action is taken on audit findings?	✓				
9.7	Does the laboratory identify and monitor quality indicators?	✓				
9.8	Has the lab been recognized or accredited by any agency? If yes, name agency_____SANAS_____ Date _____	✓			SANAS, WHO	

	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*)	4	2	7	5	1	7
Pre-test to test phase (*sample receipt to test initiation*)	01	0.5	1	0.5	0.5	1
Testing phase (*test initiation to test completion*)	01	0.5	1	0.5	0.5	1
Post-test phase 1 (*test completion to result release*)	01	0.5	1	0.5	0.5	1
Post-test phase 2 (*test release to clinic receipt*)	01	0.5	1	0.5	0.5	1

9.0	INTERNAL QUALITY AUDITS – QUALITY INDICATORS – CONTINUAL IMPROVEMENT	total:	

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	< 58	< 55%	Needs improvement in all areas and immediate remediation
1	59 - 67	55 - 64%	Needs improvement in specific areas
2	68 - 78	65 - 74%	
3	79 - 89	75 - 84%	
4	90 - 99	85 – 94%	
5	≥100	≥ 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	**8**			
	OVERALL SCORE	**106**			

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:**			
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 ☐	
Q2.1	**If yes, how many samples?**			
Q3	**Are there planned procurements within this fiscal year?**	Yes ☐	No ☐	

Q3.1	**If yes, please list:**	**Platform type:**	**Quantity:**	
		Planned location of placement:		
Q4	**Number of Early Infant Diagnosis test results reported by the lab:**			
Q4.1	**Number of Early Infant Diagnosis tests with positive result:**			
Q5	**Is there a backlog for Early Infant Diagnosis testing?**	Yes ☐ No ☐		
Q5.1	**If yes, how many samples?**			

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**
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?		
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 yes, what was the reason for the backlog?		
How many VL tests has the laboratory performed?		N/A
How many VL results have been reported?		
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	
How many IVT results have been reported?		
How many IVT tests were positive?		

		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/log books
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 mangement 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 runnings and monitoring results
33	Proper recording of invalid and incorrect results
34	Documentation noncomforming QC events and correcive 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 investigtion 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 single documents

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.