HIV Viral Load and Early Infant Diagnosis 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 EID 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

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/2
4.1	Is there a process in place for inventory control?	x				1
4.2	If no VL reagent/test kit stock-outs were experienced in the past 6 months record YES. If stock-outs have been experienced, record NO.			x	If NO, record frequency of stock-outs: ____ ≥1 x last 1 month __X_ ≥ 1 x last 3 months ____ ≥ 1 x last 6 months	0
4.3	Are SOPs in place for managing test kits and consumables?		x			0.5
4.0	**PROCUREMENT AND INVENTORY**					1.5

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 EID testing
Laboratory Technologist			
Laboratory Technician			
Laboratory Assistant			
Laboratory Clerk			
Others, please specify			

What is the average retention time for VL/EID testing personnel?	☐ <6 months ☐ 6 months – 1 year ☐ >1 year – 2 years ☐ >2 years
Comments:	

1.0	PERSONNEL	YES	PARTIAL	NO	COMMENTS	SCORE/12
1.1	Is the Viral Load (VL)/Early Infant Diagnosis (EID) training program based on the national policy?					
1.2	Have all laboratory personnel received comprehensive training on VL/EID testing using approved Standard Operating Procedures (SOPs)?					

1.3	Are laboratory personnel trained on using standardized VL/EID testing registers?					
1.4	Are laboratory personnel trained on sample management from collection to disposal?					
1.5	Are laboratory personnel trained on the quality control process?					
1.6	Are laboratory personnel trained on safety and waste management procedures and practices?					
1.7	Are laboratory personnel trained on routine preventive equipment maintenance?					
1.8	Are laboratory staff trained on use of laboratory information systems (LIS)?					
1.9	Are approved/signed records of all training for all laboratory personnel kept on file?					
1.10	Do records indicate all laboratory personnel were deemed competent before independently testing client VL/EID specimens?					
1.11	Are only trained/competent laboratory personnel allowed to perform VL/EID testing?					
1.12	Have all VL/EID 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 for VL/EID testing?					
2.2	Does testing area meet manufacturer's requirements for equipment installation?					
2.3	Is the VL/EID 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					
2.8	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 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 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?					
3.5	Is personnel protective equipment (PPE) always available to the VL/EID testing personnel?					
3.6	Do all laboratory personnel properly use PPE throughout the VL/EID 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	Is chemical waste handled, according to laboratory SOPs?					
3.12	Are containers for infectious and non-infectious waste emptied regularly in accordance with SOPs?					
3.0	**SAFETY**				**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/EID ordered?			
Comments			

4.0	PROCUREMENT AND INVENTORY	YES	PARTIAL	NO	COMMENTS	SCORE/8
4.1	Is there a SOP for inventory control?					
4.2	Were all VL reagents/supplies in stock in the last 6 months? If no or partial record frequency of stock outs in comment section.				Record frequency of stock-outs: ____1x last 1 month ___1x last 3 months ___ 1x last 6 months	
4.3	Were all EID reagents/supplies in stock in the last 6 months? If no or partial record frequency of stock outs in comment section.				Record frequency of stock-outs: ____1x last 1 month ___1x last 3 months ___ 1x last 6 months	
4.4	Are SOPs in place and followed for receipt, inspection and storage of reagent/supplies?					
4.5	Are reagents/supplies appropriate for molecular testing (e.g. filtered tips, RNAse/DNAse-free)?					
4.6	Are reagents/supplies labeled with the date received and initials?					
4.7	Are all reagents/supplies, currently in use, within the expiration period?					
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 specimen type(s) **received** for VL testing:	☐ DBS ☐ Plasma ☐ Whole blood
Identify specimen type(s) **received** for EID testing:	☐ DBS ☐ Plasma ☐ Whole blood
Identify specimen type(s) **used** for VL testing:	☐ DBS ☐ Plasma
Identify specimen type(s) **used** for EID testing:	☐ DBS ☐ Plasma ☐ Whole blood
Comments	

5.0	SAMPLE MANAGEMENT	YES	PARTIAL	NO	COMMENTS	SCORE/10
5.1	Are SOPs in place and followed for specimen transport and processing in the laboratory?					
5.2	Does the laboratory provide specimen collection and transport training and/or information to referring facilities?					
5.3	Are SOPs in place and followed for evaluating specimen acceptability upon receipt in the laboratory?					
5.4	Does a specimen transport form accompany specimens and does it account for chain of specimen custody?					
5.5	Are SOPs in place and followed for specimen rejection?					
5.6	Are specimen rejection criteria defined according to VL/EID assay requirements?					
5.7	Are specimen transport time and conditions maintained according to assay requirements from collection until received in laboratory?					
5.8	Is the monthly specimen rejection rate <3%? If NO please provide specimen rejection rate by sample type in comments. Note most common reason(s) for rejection in comments section.					
5.9	Are requesters notified of rejected specimens within 24 hours according to SOPs?				If YES by: ☐ Phone ☐ Email ☐ Others, specify_____	

					If NO: If NO: __1-3 days ___4 – 7 days Other:_____	
5.10	Are SOPs for specimen storage written according to manufacturer's requirements, in place and followed?					
5.0	**SAMPLE MANAGEMENT**				**total:**	

TESTING PHASE

EFFICIENCIES		
Is the work flow from specimen reception to releasing results optimal?		Yes ☐ No ☐ Comments ☐
Comments		
Is a lab information system (LIS/LIMS) used for both receiving specimens, testing and reporting in the lab? If no, please explain.		Yes ☐ No ☐ Comments ☐
Comments		
Are instrument barcode scanners used as recommended during testing?		Yes ☐ No ☐ Comments ☐
Comments		
How many specimens are tested per week?	**Viral Load** ☐ <100 specimens ☐ 100 – 300 specimens ☐ 300 - 500 specimens ☐ 500 – 1000 specimens ☐ Others, specify_____	**EID** ☐ <100 specimens ☐ 100 – 300 specimens ☐ 300 - 500 specimens ☐ 500 – 1000 specimens ☐ Others, specify_____
Comments		
Do you receive specimens for VL/EID testing from outside facilities (referral testing?) • If yes, for how many facilities do you provide VL/EID testing services? _____		Yes ☐ No ☐
Comments		
What is the laboratory's current testing capacity per day?	Viral Load_____	EID _____
Comments		

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				
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**	**YES**	**PARTIAL**	**NO**	**COMMENTS**	**SCORE/5**
6.1	Are Instrument Manuals for all VL/EID equipment available to the laboratory?					
6.2	Is all equipment, required for VL/EID testing, present?					
6.3	Is all equipment, required for VL/EID testing, functional?					

6.4	Do equipment records include documentation of routine preventive maintenance?					
6.5	Are equipment maintenance contracts in place?					
6.0	**EQUIPMENT**				**total:**	

7.0	**PROCESS CONTROLS**	**YES**	**PARTIAL**	**NO**	**COMMENTS**	**SCORE/24**
7.1	Are VL and EID testing job aids and/or SOPs available at the testing site?					
7.2	Are SOPs in place and followed for running, recording, and reviewing quality control (QC) results?					
7.3	Do records indicate equipment performance was verified prior to beginning VL/EID testing?					
7.4	Are QC specimens routinely used according to manufacturer's instructions?					
7.5	Are QC results properly recorded, including invalid and incorrect results?					
*7.6	Are appropriate steps taken and documented when QC results are incorrect and/or invalid?	[5]				
7.7	Does a supervisor routinely review quality control records?					
7.8	Is the laboratory enrolled in Proficiency Testing (PT) for VL?				If yes: Name of PT program _____ _ ☐ 1x/yr ☐ 2x/yr ☐ 3x/yr	
7.9	In the past 12 months, has the laboratory passed all PT for VL?					
7.10	Is the laboratory enrolled in PT for EID?				If yes: Name PT program _____ ☐ 1x/yr ☐ 2x/yr ☐ 3x/yr	
7.11	In the past 12 months, has the laboratory passed all PT for EID?					
7.12	Is PT testing rotated among all VL/EID testing staff?					
7.13	Are PT samples tested in the same manner as patient samples?					
7.14	Is there a supervisor review of PT result prior to submission?					
7.15	Do records indicate that lab staff review PT result reports prior to submission?					

*7.16	Do records indicate that lab staff conduct investigation and corrective action for any failed PT results?	5				
7.0	**TESTING PHASE**				**total:**	

POST-TESTING PHASE

8.0	**M&E DOCUMENTS AND RECORDS – RESULTS REPORTING**
Is there a laboratory information system (LIS)? If yes, indicate the type/name of system:	Yes ☐ No ☐ If yes, functions include: ☐ Logging specimen receipt/specimen tracking ☐ Barcode labeling of specimens ☐ Interface with analyzers ☐ Results recording/reporting ☐ Others, specify_____
Comments	
How are results tracked to ensure they arrived at clinic sites?	
Comments	

8.0	**M&E DOCUMENTS AND RECORDS – RESULTS REPORTING AND DATA MANAGEMENT**	**YES**	**PARTIAL**	**NO**	**COMMENTS**	**SCORE/21**
8.1	Does the VL/EID register, log, or LIS at the laboratory include: Specimen ID, Test Name, Test Lot Number and Expiration Dates, Testing Staff Name, Testing Date, and Results?					
8.2	Can the lab track unique individuals (vs. number of tests)?					
8.3	Are invalid test results recorded in the register or logbook?					
*8.4	Are high VL test (> 1000 cp/ml) results identified at labs and reported as priority? Please note in comments section how high VL test results are reported.	5				
*8.5	Are VL/EID results returned from labs to clinic sites?	5			If yes, note method (check all that apply): ☐ Paper based ☐ Telephone ☐ SMS ☐ Email	

					☐ Others, specify _____	
8.6	Do lab records or documents indicate receipt of results at clinics?					
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?					
8.9	Are registers or logbooks in the lab properly labeled and archived when full?					
8.10	Are records or documents stored in accordance with national/local record retention requirements?					
8.11	Does the LIS security control unauthorized access to patient test results?					
8.12	Is the LIS routinely backed up according to SOPs?					
8.13	Is there a dashboard or tool for routine review of VL data in the LIS?					
	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/12**
9.1	Does the laboratory staff record non-conforming events associated with VL/EID sample receiving, testing, reporting, and supply chain?					
9.2	Do records indicate management reviews non-conforming events for trends?					
9.3	Do records indicate investigation of and 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 according to a planned schedule?					
9.6	Do records indicate corrective action is taken on audit findings?					
9.7	Does the laboratory identify and monitor quality indicators?					
9.8	Is the average turn-around-time (TAT) from specimen receipt to results release for VL within 1 week?				If no, please indicate in working days: ___ 1 – 2 weeks ___ 2 – 3 weeks ____Other:	

9.9	Is the average TAT from results reporting to confirmed receipt at clinic for VL within 1 week?				If no, please indicate in working days: ___ 1 – 2 weeks ___ 2 – 3 weeks ____Other:	
9.10	Is the average TAT from specimen receipt to results release for EID within 1 week?				If no, please indicate in working days: ___ 1 – 2 weeks ___ 2 – 3 weeks ____Other:	
9.11	Is the average TAT from results reporting to confirmed receipt at clinic for EID within 1 week?				If no, please indicate in working days: ___ 1 – 2 weeks ___ 2 – 3 weeks ____Other:	
9.12	Has the lab been recognized or accredited by any agency? If yes, name agency_____ Date _____					
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/EID LEVEL	SCORE / 118	% SCORE	DESCRIPTION OF RESULTS
0	< 65	< 55%	Needs improvement in all areas and immediate remediation
1	65 - 76	55 - 64%	Needs improvement in specific areas
2	77 - 88	65 - 74%	
3	89 - 99	75 - 84%	
4	100 - 111	85 – 94%	
5	≥112	≥ 95%	

SUMMARY: LABORATORY SCORECARD

	SECTION	TOTAL POSSIBLE POINTS	POINTS GIVEN	%	AUDITOR'S COMMENTS
Pre-Testing					
1	Personnel	**12**			
2	Physical Facility / Environment	**14**			
3	Safety / Waste Management	**12**			
4	Procurement / Inventory	**8**			
5	Sample Management	**10**			
Testing					
6	Equipment	**5**			
7	Process Controls	**24**			
Post-Testing					
8	M&E Documents/Records - Results	**21**			
9	Internal Quality Audits – Quality Indicators – Continual Improvement	**12**			
	OVERALL SCORE	**118**			

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