Viral Load Scale-Up Clinical Facility Readiness Assessment

Version 1.0

9/12/2016

Objectives

Part 1: Facility Profile and Scorecard

- To gather situational analysis information regarding the facility's readiness to provide routine VL monitoring for patients on ART
- To assess clinical systems in place for implementation of routine viral load (VL) testing and interpretation
- To serve as scorecard for monitoring and documenting improvements

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

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

Instructions for Assessors

- Familiarize yourself with the scorecard
- Explain the objectives of the scorecard to facility in-charge, ART clinicians, laboratory manager/officer, monitoring and evaluation (M&E) officer/data clerk or designee prior to completing the scorecard
- Administer sections 1 and 2 to the ART clinician (facility in-charge may provide input)
- Administer section 3, 4, 5 (where applicable) to the laboratory manager/officer
- Administer section 8 to the monitoring and evaluation (M&E) officer/data clerk (may need input from ART clinician)
- Complete the scorecard by going through all the sections
- Debrief scorecard findings with facility in-charge, ART clinicians, laboratory manager, quality officer and/other staff
- Discuss any corrective actions and/or recommendations with facility in-charge, ART clinicians, laboratory manager, 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
- 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 the situation and exclude from scoring
- Sections 2 and 3 contain questions that require observation of materials for score = Yes; these questions are indicated by the icon  .
- Tally the total points for each section and transcribe to table in Part 2: Scoring and Summary

PART 1: Basic Site and Assessment Information & Facility Characteristics

Please provide relevant information in the summary table below.

<table>
<tr><td colspan="2">Date of Assessment (DD/MM/YYYY):</td><td>First assessment?
Yes ☐ No ☐</td></tr>
<tr><td>Start Time:</td><td>End Time:</td><td>If No:
Date Last Assessed (DD/MM/YYYY):</td></tr>
<tr><td colspan="2">Facility Name:</td><td>Facility Level (Circle one)
Regional/Provincial/Zonal
Referral center/Center of Excellence
District
Health center
Dispensary
Health Post
Other (Please specify to reflect country context):</td></tr>
<tr><td colspan="2">Region/Province/Zone:</td><td>Affiliation (Circle one)
Government
Private
Faith-based organization
Non-governmental organization
Other:</td></tr>
<tr><td colspan="2">Assessor Name #1:</td><td>Assessor Name #2:</td></tr>
</table>

1.0 FACILITY CHARACTERISTICS			
Administer sections 1 and 2 to the ART clinician (facility in-charge may provide input).			
			Response
When did VL testing begin at this facility? (MM/YYYY)			
How many patients are currently on ART?			
How many patients are on 2nd line ART?			
	Number	**Service outlets**	**Comments**
Total number of Expert Clients (EC)			
Provide any additional comments on challenges that you have with relation to human resources available for HIV treatment and HIV-related testing (e.g., VL) in the comments			

PART 2

For each of the sections listed below, please check **Yes, Partial or No**, where applicable. Indicate "**Yes**" only when all elements are satisfactorily present. Provide comments for each "**Partial**" or "**No**" response. State N/A in the comments section if "not applicable". Some questions require observation of materials for score = **"Yes"** and are indicated by the icon 👁**.**

	SECTION	YES	PARTIAL	NO	Comments	Score/Total (excluding NA)
2.0	**CLINICAL CARE RELATED QUESTIONS**					**Points**
	Type of Testing, Testing Algorithms, and Staff Responsibilities					
2.1	Is your facility requesting/ordering VL testing? ☐ Targeted (tick PARTIAL and enter to whom in comments) ☐ Routine (score YES, if all populations; score = partial for only specific sub-populations)					
👁 **2.2**	Are VL testing algorithm job aids posted for the following populations?					
	2.2.1 Adults?					
	2.2.2 Adolescents (10-19 years)?					
	2.2.3 Children (less than 10 years)?					
	2.2.4 Pregnant/breastfeeding women?					
2.3	Are there clinic staff tasked with the following activities?					
	2.3.1 A focal person identified at the ART clinic who is responsible for VL-related activities?					
	2.3.2 Completion of the VL requisition form?					
	2.3.3 VL sample collection?					
	2.3.4 Documents receipt of VL test results from the lab (clarify whether processing lab vs. on site mini-lab?)? (Note: mini-lab refers to a location staffed by a lab technician/technologist with capacity for sample					

	centrifugation and where other diagnostics are performed such as gram stain, AFB smear, urinalysis, etc.)					
	2.3.5 Reviews VL test results and separates VL <1000 vs ≥1,000 copies/mL?					
	2.3.6 Documents VL test results in the patient record?					
	2.3.7 Follows up on VL test results that have not been received from the lab (i.e., pending or outstanding results)?					
SECTION		**YES**	**PARTIAL**	**NO**	**Comments**	**Score/Total (excluding NA)**
Pre-Test						
👁 **2.4**	Is there a national- or site-level specific VL sample requisition form?					
👁 **2.5**	Is the VL sample requisition form well-stocked (i.e., >3 months)?					
👁 **2.6**	Are SOPs developed for ordering VLs and collecting VL samples that include the following?					
	2.6.1 Filling out the VL sample requisition form?					
	2.6.2 Collecting VL samples?					
2.7	Is there a facility-level VL literacy education program for patients?					
👁 **2.8**	Do you have patient education materials on VL literacy?					
Post-Test						
2.9	Is there a community education program on VL literacy (i.e., presentations to promote community awareness)?					
2.10	Once the VL test results are received from the central lab/hub, is there a system to review the results in your facility?					
2.11	When the VL results are reviewed are they routinely separated into VL ≥1,000 copies/mL vs <1,000 copies/mL?					

		YES	PARTIAL	NO	Comments	Score/Total (excluding NA)
2.12	Is there a process to ensure patients receive their results?					
👁 **2.13**	Are SOPs developed for recording of VL test results upon return to sites in the following?					
	2.13.1 Patient chart					
	2.13.2 High VL register					
2.14	Are patients receiving their results in a specified time period? If yes, score based on average period of time: ☐ within 1 month (score= yes) ☐ > 1 month-3 months (score= partial) ☐ > 3 months (score= no)					
👁 **2.15**	Is there an SOP for managing patients defined as having virologic suppression (<1,000 copies/mL)?					
👁 **2.16**	Is there an SOP for managing patients defined as having virologic failure (≥1,000 copies/mL)?					
👁 **2.17**	Is there tools to track patients with VL ≥1000 copies/mL?					
2.18	Is there a process for enhanced adherence counseling for patients with VL ≥1000 copies/mL?					
Enhanced Adherence Counseling						
👁 **2.19**	Are there job aids for use during enhanced adherence counseling for patients with VL ≥1000 copies/mL specific to the following populations?					
	2.19.1 Adults?					
	2.19.2 Adolescents (10-19 years)?					
	2.19.3 Children (less than 10 years)?					

		YES	PARTIAL	NO	Comments	Score/Total (excluding NA)
	2.19.4 Pregnant/breastfeeding women?					
2.20	Is there a process in place for patients who do not return for enhanced adherence counseling sessions?					
Managing Virologic Failure						
2.21	Is there a system for expert consultation to manage patients on 1st line with virologic failure (≥1,000 copies/mL; 1st line regimen failure)?					
2.22	Is there a standardized process for switching of ARV regimens for patients failing 1st line?					
2.23	Is there a system of consultation with experts for management of patients on 2nd line with virologic failure (≥1,000 copies/mL; 2nd line regimen failure)?					
2.24	Is there a standardized process for switching of ARV regimens for patients failing 2nd line?					
2.25	Are second-line ARV regimens available at this site for the following populations?					
	2.25.1 Adults?					
	2.25.2 Children?					
2.26	Have CD4 count practices for monitoring of patients on ART changed at this site in the past 6 months?					
2.0 CLINICAL SCORE						
						Score/Total (excluding NA)

SECTION		YES	PARTIAL	NO	Comments	Score/Total (excluding NA)
3.0 LAB RELATED QUESTIONS						**Points**
Administer section 3, 6, 7 (where applicable) to the laboratory manager/officer. *Answer the respective questions based on the type of sample collected: for whole blood only collection, complete questions 3.1 - 3.7 and 3.10 - 3.26; for DBS only collection, complete questions 3.1 - 3.2 and 3.8 - 3.26. (*Note: if your site collects both DBS and plasma, proceed with *all questions 3.1 - 3.26). If sites do not have a mini-lab, (Note: a mini-lab has a trained technician or technologist), skip 3.4 - 3.7.* Some questions require observation of materials for score = **"Yes"** and are indicated by the icon 👁**.**						
3.1	Do you have a phlebotomist?					
3.2	Is there an individual who is capable of collecting venous samples for the following populations?					
	3.2.1 Adults ≥ 15 years?					
	Children					
	3.2.2 < 5 years?					
	3.2.3 5-10 years?					
	3.2.4 11 < 15 years?					
3.3	Does your site have a mini-lab? (Note: a mini-lab has a trained technician or technologist) If no, skip questions 3.4-3.7.					
3.4	Do you have a working centrifuge to separate plasma?					

3.5	Were you trained to centrifuge blood tubes?					
3.6	Do you have a working refrigerator?					
3.7	Can you store samples at the recommended temperature for whole blood and plasma before transportation to the laboratory for VL testing?					
3.8	Is there an individual capable of preparing the following VL sample types at this site?					
	3.8.1 DBS from venous blood?					
	3.8.2 DBS from finger prick/heel prick?					
DBS Preparation and Packaging						
3.9	**3.9.1** Do you use powder-free gloves to collect DBS?					
	3.9.2 Do you prepare & pack DBS samples?					
	3.9.3 Do you collect at least 3 full blood spots per DBS card?					
	3.9.4 Do you dry DBS samples at least 4 hours before packaging?					
	3.9.5 Do you separate the DBS cards with glassine paper if you package multiple cards?					
	3.9.6 Do you seal the dried DBS cards in zip lock bags?					
	3.9.7 Do you include at least 1 desiccant packet per card in your packaging?					
	3.9.8 Do you include a humidity indicator card in your DBS package?					
Specimen Transport						
👁 **3.10**	**3.10.1** Is there a specimen transportation log?					
	3.10.2 Is the specimen transportation log reviewed for adherence to transport and time conditions?					

		YES	PARTIAL	NO	Comments	Score/Total (excluding NA)
	3.10.3 Does your specimen transport system support cold chain?					
	3.10.4 Is the specimen transport temperature monitored?					
Specimen Quality						
3.11	Do you track the monthly specimen rejection rate?					
👁 **3.12**	Can you show the monthly rejection rate for each of the past 3 months? Score = yes if % shown for each of the 3 months, score = partial if shown for 1-2 months. Note rates for any/or all months in comments.					
3.13	Was any rejection rate greater than 3% (e.g., 1 out of 30)? (Score = No if > 3%; score = Yes if < 3%)					
3.14	Is there a system for review of non-returned VL results?					
3.15	Is there a feedback system at your facility for rejected/inadequate samples?					
3.16	Do you routinely receive rejected/inadequate sample communications from the central testing lab?					
Consumables/Reagents						
3.17	Has there been a stock out of VL sample collection consumables in the last 3 months?					
3.18	**3.18.1** Is there an inventory system in place for all VL sample collection consumables?					
	3.18.2 Are all VL sample collection consumables stored according to manufacturer's recommendations?					

		YES	PARTIAL	NO	Comments	Score/Total (excluding NA)
	3.18.3 Are all VL sample collection consumables used or discarded within their expiration date?					
3.19	Is there adequate storage facilities for reagents?					
Laboratory Safety						
 **3.20**	**3.20.1** Does your site have procedures for handling and disposing biohazardous material?					
	3.20.2 Do you have blood spill kits?					
	3.20.3 Are there SOPs to manage blood spills?					
	3.20.4 Have you had spill kit stock outs in the last one year?					
	3.20.5 Is there documentation that the lab personnel have been trained on handling biohazardous material, workplace safety, and spill management? (if no lab personnel, score NA)					
	3.20.6 Are gloves always available?					
	3.20.7 Are other biohazard materials available (e.g., biohazard bag, sharp containers)?					
Logbooks, SOPs, and Job Aids						
 **3.21**	Is there a site level sample daily log sheet/log book that allows documentation of each VL test ordered and sent to the lab?					
 **3.22**	Is there an SOP for filling out the sample daily log sheet/log book?					
 **3.23**	Is the sample transmitter form/sample delivery checklist filled out to indicate the number of VL tests ordered?					

		YES	PARTIAL	NO	Comments	Score/Total (excluding NA)
👁 **3.24**	Is there an SOP for filling out the sample transmitter form/sample delivery checklist?					
👁 **3.25**	**3.25.1** Are there job aids for VL specimen storage?					
	3.25.2 Are there job aids for VL specimen packaging and transportation?					
	3.25.3 Are there job aids for VL specimen rejection?					
👁 **3.26**	Are national forms well-stocked (i.e., >3 months) for the following?					
	3.26.1 Sample daily log/log book?					
	3.26.2 Sample transmitter form/sample delivery checklist?					
	3.26.3 Specimen transportation log?					
3.0 LAB SCORE						Score/Total (excluding NA)

SECTION		YES	PARTIAL	NO	Comments	Score/Total (excluding NA)
4.0 FACILITIES WITH VL POC TESTING						**Points**
4.1	Is your facility and/ or mini-lab enrolled in EQA?					
	Identify the VL POC platform and average number of tests run per week?					
4.2	Did this facility pass the previous EQA?					
4.3	Is there an effective POC VL equipment maintenance contract in place?					
4.4	Was there equipment failure in the last year?					
4.5	Was the duration it took for the equipment to be repaired over 1 month?					
4.6	6.6.1 Have lab technicians been trained to perform VL testing?					
	6.6.2 Have all trained technicians who perform VL testing passed initial competency? (note: if NA, leave score blank)					
	6.6.3 Have all trained technicians who perform VL testing passed competencies? In the last year? (Note: if NA, leave score blank)					
4.7	Are there annual refresher trainings with records of such training?					
4.0 VL POC TESTING SCORE						
						Score/Total (excluding NA)

SECTION		YES	PARTIAL	NO	Comments	Score/Total (excluding NA)
5.0 FACILITIES WITH A LABORATORY						**Points**
5.1	Have lab personnel been trained to perform VL testing?					
5.2	Is the lab enrolled in EQA?					
5.3	Did your lab pass the previous EQA?				Provide previous EQA score.	
5.4	If your lab did not pass the previous EQA was corrective action taken?					
5.5	Is there an effective VL equipment maintenance contract in place?					
5.6	Was there equipment failure in the last year?					
5.7	Was the duration it took for the equipment to be repaired over 1 month?					
5.8	Is there a back-up generator?					
5.9	Are there annual refresher trainings with records of such training?					
5.10	Are equipment connected to UPS?					
5.0 FACILIITES WITH A LABORATORY SCORE						**Score/Total (excluding NA)**

SECTION		YES	PARTIAL	NO	Comments	Score/Total (excluding NA)
6.0 MONITORING AND EVALUATION (M&E)						**Points**
Administer this section to the monitoring and evaluation (M&E) officer/data clerk (may need input from an ART clinician).						
6.1	Do current patient cards (and/or electronic medical records) include field(s) to monitor VL test (including test ordered, and results)?					
6.2	Do current ART registers include field(s) to capture VL tests and result data (including Tx initiation month, date test was requested, and result)?					
6.3	Do current reporting tools (paper and/or electronic) from sites include fields to report on key variables including # of patients who received a VL test, # of patients who are virally suppressed, and for routine reporting on VL testing and outcomes?					
6.4	Can M&E systems and tools at sites track VL testing outcomes for cohorts of patients (e.g. VL tests results for patients 6 and 12 months after ART initiation)?					
6.5	Is there a high VL register (or specific register) on site to track patients who have high viral load results (≥ 1,000 copies/mL)?					
6.6	Is there a plan to train service providers, lab staff, M&E staff, and other site staff on the correct completion of M&E tools?					
6.7	Are there regular reviews (i.e. monthly, quarterly etc.) of VL data on site? If yes, score = Yes and describe in comments					
6.8	Is there a plan to mentor service providers, lab staff, M&E staff, and other site staff on performance of correct completion of M&E tools? Describe in comments					

		YES	PARTIAL	NO	Comments	Score/Total (excluding NA)
6.9	Are there plans to compare data from the laboratory information system (LIS) or laboratory data base for the site to data from site-level records/registers/logbooks etc.?					
6.10	Does the site receive routine reports from the LIS or laboratory database If yes, describe what variables are sent and how often.					
6.0 M&E SCORE						
						Score/Total (excluding NA)

PART 2: SCORING CRITERIA

Facility Name: _____ Assessment Date (DD/MM/YYY): _____

Each element marked will be assigned a point value:

- Items marked "Yes" receive 1 point each.
- Items marked "Partial" receive 0.5 point each.
- Items marked "No" receive 0 point each.

Total points scored for each section should be tallied and recorded at the end of the section.

The overall total points obtained by each facility assessed will be weighed to correspond to a specific performance level.

Total Points Given: _____ Overall % _____ Level_____

Levels	% Score	Description of results
Level 0	Less than 40%	Needs improvement in all areas and immediate remediation
Level 1	40% - 59%	Needs improvement in specific areas
Level 2	60% - 79%	Moderate readiness
Level 3	80% - 89%	Approaching readiness
Level 4	90% or higher	Meets readiness criteria

SECTION	POINTS GIVEN	TOTAL POSSIBLE POINTS (excludes NA responses)	% Score	Level	ASSESSOR'S COMMENTS
2.0 Clinical Care					
3.0 Lab Related					
4.0 VL POC Testing					
5.0 Facilities with a Lab					
6.0 Monitoring & Evaluation					
OVERALL READINESS SCORE					

Part 3. Assessor's Summation Report for VL Scale-Up Facility Readiness

Facility Name: Site Type:	Duration of Assessment:	Total points scored (exclude N/A) = a Total possible points = b % Score = (a/b) x 100

Section No.	Deficiency/Issue Observed	Corrective Actions		Assessor's Comments	Recommendations	
		Immediate	Follow-up		Actions	Timeline/Person Responsible

Person In-Charge Name: Signature:	Assessor(s) Name: Signature: Date (DD/MM/YYYY):