Viral Load Scale-Up Facility Readiness Assessment Checklist

Facility Name: _____ Region: _____ Date: _____

Assessors Names: 1. _____ 2. _____

Interview Start Time: _____ Interview End Time: _____

Instructions:

- *Please read and make sure you understand the contents of the checklist.*
- *Discuss the objective of the assessment with the senior nurse and doctor.*
- *Request a meeting with the antiretroviral therapy (ART) nurse and laboratory personnel to jointly interview and complete the checklist.*
- *For underlined items, look for evidence and ask for copies/take pictures of the materials, as specified in the checklist.*
- *Document complete responses provided by the interviewees.*

1. Facility Characteristics:	Number	Comments
Total number of doctors		
Total number of doctors providing ART		
Total number of nurses		
Total number of nurses trained on nurse-initiated and managed ART		
Total number of expert clients (EC)		
Total number of lay counselors		
Total number of phlebotomists		
Total number of lab technologists		
Provide any additional comments on challenges you have regarding the human resources available for HIV care and HIV-related testing		

2. Staff Interview	Comments
A. Clinical Care-related Questions *(Ask the senior nurse or doctor in the facility)*	
Is your facility conducting viral load (VL) testing? ☐Yes ☐No *If yes, choose all that apply:* ☐Targeted ☐ Routine	
To whom is VL testing offered in your facility? *Tick that all apply:* ☐ Suspected treatment failure ☐ Pregnant women/option B+ ☐ Children <10 years ☐ Adolescents 10–19 years ☐ Other *(specify in comments)*	
From response above, is VL testing prioritized for any specific population? *Tick that all that apply:* ☐ Suspected treatment failure ☐ Pregnant women/option B+ ☐ Children <10 years ☐ Adolescents 10–19 years ☐ Other *(specify in comments)*	
Is there a dedicated VL point-of-contact identified for the ART clinic? ☐Yes ☐No *If yes, who? (name and cadre)* _____ **Are there dedicated individuals for VL testing activities?** ☐Yes ☐No *If Y\yes, tick all that apply:* ▪ **Designated individual who identifies which patient(s) require a VL test:** ☐EC ☐ART nurse ☐Visiting doctor ☐Resident doctor ☐Laboratory technologist ☐Phlebotomist ▪ **Requisition form completed by:** ☐EC ☐ART nurse ☐Visiting doctor ☐Resident doctor ☐ Laboratory technologist ☐Phlebotomist ▪ **Sample collection performed by:** ☐EC ☐ART nurse ☐Visiting doctor ☐Resident doctor ☐ Laboratory technologist ☐Phlebotomist	

▪ **VL test results from the lab received by:** ☐EC ☐ART nurse ☐Visiting doctor ☐Resident doctor ☐ Laboratory technologist ☐Phlebotomist ▪ **VL test results that have not been received from the lab (pending or outstanding results) are noted by:** ☐EC ☐ART nurse ☐Visiting doctor ☐Resident doctor ☐ Laboratory technologist ☐Phlebotomist ▪ **VL test results are documented in the patient record (chronic care file) by:** ☐EC ☐ART nurse ☐Visiting doctor ☐Resident doctor ☐ Laboratory technologist ☐ Phlebotomist ▪ **VL test results are reviewed for patient management by:** ☐EC ☐ART nurse ☐Visiting doctor ☐Resident doctor	
Is there a facility-level VL literacy education program? ☐Yes ☐No *If yes, tick all that apply:* ☐ Morning talk ☐ Supply of IEC materials ☐ One-on-one counseling ☐ *Other (specify in comments)*	
Is there a community education program on VL literacy (i.e., health care worker presentation to promote community awareness? ☐ Yes ☐ No *(If yes, specify in comments)*	
How are VL test results delivered from the central/hub lab to your facility? ☐National Sample Transport System (NSTS) ☐SMS ☐ LIS ☐ Other *(specify in comments)* **How long does it take to get results back to your facility from the time the VL sample is sent to the hub or central lab?** ☐ Less than 1 week ☐ 1–2 weeks ☐ 2–4 weeks ☐ >4 weeks	

Once the VL test result is received from the central lab/hub, is there a system for clinical providers in your facility to review the results?
☐Yes ☐No *If yes, continue with the following questions:*

- **When reviewing VL results, do you routinely separate results that are ≥1,000 copies/mL from those that are <1,000 copies/mL?**
  ☐Yes ☐ No *If yes, within what period of time are the results reviewed and separated?* ☐ within 1 week ☐ 1–2 weeks ☐ 2–4 weeks ☐ >4 weeks
- **Is there a process to ensure patients receive their results?**
  ☐ Yes ☐ No ☐Other *If yes, specify the method of communication:* ☐ Phone call ☐ SMS ☐ Home visit ☐ Other *(specify in comments)*
- **Are patients receiving results within a specified time**? ☐Yes ☐No
  - *If yes, specify the time if the VL result is ≥1,000*: ☐ Within 1 week ☐ 1–2 weeks ☐ 2–4 weeks ☐ >4 weeks
  - *If yes, specify the time if the VL result is <1,000:* ☐ Within 1 week ☐ 1–2 weeks ☐ 2–4 weeks ☐> 4 weeks
- **Is there a tool to track patients with VL ≥1000?** ☐Yes ☐No *<u>If yes, obtain a copy or take a picture of it</u>*
- **Provide any additional comments on challenges or weaknesses with VL test ordering and results management** *(in comments)*

Is there a process for stepped-up adherence counseling for patients with VL ≥1000? ☐Yes ☐No *If yes, who is responsible for the:* ▪ **First session**? ☐EC ☐ART nurse ☐ Visiting doctor ☐ Resident doctor ☐ Laboratory technologist ☐ Phlebotomist ▪ **Second session**? ☐EC ☐ART nurse ☐ Visiting doctor ☐ Resident doctor ☐ Laboratory technologist ☐ Phlebotomist ▪ **Third session**? ☐EC ☐ART nurse ☐ Visiting doctor ☐ Resident doctor ☐ Laboratory technologist ☐ Phlebotomist ▪ **Is there an average duration for the stepped-up adherence counseling?** ☐Yes ☐No *If yes, specify time:* ☐ <15 minutes ☐ 15–30 minutes ☐ >30 minutes ☐ Other *(specify in comments)* ▪ **Is there a specific duration between the stepped-up adherence counseling?** ☐Yes ☐No *If yes, specify time?* ☐ 1 month ☐ 1–2 months ☐ >2 months ▪ **Is there specific content (job aids or tools) used for the stepped-up adherence counseling?** ☐Yes ☐No. *If yes, obtain a copy or take a picture* **Provide any additional comments on challenges or weaknesses of stepped-up adherence counseling** *(in comments)*	
Is there a system for expert consultation to manage patients with virologic failure (≥1,000 copies/ml; first-line regimen failure)? ☐Yes ☐No *If yes, answer the following:* ▪ **Is there a standardized process for switching of ARV regimens for patients with virologic failure?** ☐Yes ☐No *If yes, who is doing the switch to second line regimens?* ☐EC ☐ART nurse ☐Visiting doctor ☐ Resident doctor ☐ Laboratory technologist ☐ Phlebotomist	

▪ *If yes, when does the actual switch take place and specify relative to what (e.g., within 2 weeks of the second VL > 1000, etc.)* ? ☐ Within 1 week ☐ 1–2 weeks ☐ 2–4 weeks ☐ >4 weeks *(specify in comments relative to what)* **Provide any additional comments on challenges or weaknesses of the process of switching ARV regimens** (*in comments)*	
Is there a system of consultation with experts for management of patients on second-line with virologic failure (≥1,000 copies/ml; second-line regimen failure)? ☐Yes ☐No *If yes, answer the following:* ▪ **Is there a standardized process for switching of ARV regimens for patients failing second-line?** ☐Yes ☐No • *If yes, who is making the ART regimen change?* ☐EC ☐ ART nurse ☐ Visiting doctor ☐ Resident doctor • *If yes, when does the actual switch taking place?* ☐ Within 1 week ☐ 1–2 weeks ☐ 2–4 weeks ☐ >4 weeks • **Provide any additional comments on challenges or weaknesses of the process of managing patients who experience second-line regimen failure** *(in comments)*	
Are second-line ARV regimens available for first-line treatment failure? ▪ **For Adults?** ☐Yes ☐No ▪ **For Pediatrics?** ☐Yes ☐No **Is there a second-line ARV regimen inventory?** ☐Yes ☐No *If yes, check it.* **How many patients do you have on second-line ARV drugs?** ▪ **For pediatrics: _____** ▪ **For adults: _____**	

Have CD4 count test ordering practices changed at this site in the past six months? ☐Yes ☐No *If yes, choose one:* ☐ Increased ☐ Reduced ☐ Remained the same ☐ Interrupted ☐ Other *(specify in comments)*	
B. Lab-related Questions *(Ask laboratory personnel)*	
How is this site receiving VL test results? *Tick all that apply:* ☐NSTS ☐Phone call ☐ Email ☐ Post ☐ Courier ☐ SMS ☐ *Other (specify in comments)*	
What is the average time from when you collect the VL sample to when you receive the result at your site (i.e., turnaround time for receiving VL results back to your site)? ☐ Within 1 week ☐ 1–2 weeks ☐ 2–4 weeks ☐ >4 weeks	
• **Does your site have a mini-lab?** ☐Yes ☐No • **Do you have a phlebotomist?** ☐Yes ☐No • **Can you centrifuge the sample?** ☐Yes ☐No • **Can you store samples?** ☐Yes ☐No • **Specify any challenges to sample collection, storage, packaging, etc.** *(in comments)*	
Who is capable of collecting venous samples for: ▪ **Adults ≥15years:** ☐EC ☐ART nurse ☐ Visiting doctor ☐ Resident doctor ☐ Laboratory technologist ☐ Phlebotomist ▪ **Children:** • **0– ≤5 years?** ☐EC ☐ART nurse ☐ Visiting doctor ☐ Resident doctor ☐ Laboratory technologist ☐ Phlebotomist • **5–10 years?** ☐EC ☐ART nurse ☐ Visiting doctor ☐ Resident doctor ☐ Laboratory technologist ☐Phlebotomist • **11– <15 years?** ☐EC ☐ART Nurse ☐ Visiting doctor ☐ Resident doctor ☐ Laboratory technologist ☐Phlebotomist	

Who is capable of preparing a sample for VL at this site? ▪ **DBS from venous blood:** ☐ EC ☐ ART nurse ☐ Visiting Doctor ☐ Resident doctor ☐Laboratory technologist ☐Phlebotomist ☐ Not applicable (DBS not currently collected) ▪ **DBS from finger prick/heel prick**: ☐ EC ☐ ART nurse ☐ Visiting doctor ☐ Resident doctor ☐Laboratory technologist ☐ Phlebotomist ☐ Not applicable (DBS not currently collected) ▪ **Plasma:** ☐EC ☐ART nurse ☐ Visiting doctor ☐Resident doctor ☐ Laboratory technologist ☐ Phlebotomist	
How do you package whole blood samples? Please describe *(probe for the use of a cooler box, for maintenance at 2–25° C, and for use of cushion and ice pack at higher ambient temperatures)*	
How do you package plasma samples? Please describe *(probe for the use of a cooler box, for maintenance at 2–25° C, and for use of cushion and ice pack at higher ambient temperatures)*	
How do you prepare and pack DBS samples? *Tick responses:* ▪ **☐ Not applicable (DBS not currently collected)** ▪ **How many blood spots do you collect per DBS card?** ☐ 1 ☐ 2 ☐ 3 ☐ 3–5 ▪ **How many hours do you allow your DBS samples to dry before packaging?** ☐ 1 hour ☐ 2–4 hours ☐ 4 hours ☐ >4 hours ▪ **How many DBS cards do you pack in one bag?** ☐ 1 ☐ 2–5 ☐ 6–10 ☐ >10 ▪ **Do you separate your DBS cards with glassine paper if you package multiple cards?** ☐Yes ☐ No ▪ **How many desiccant packets per card are included in your packaging?** ☐1 ☐ 2 ☐3 ☐Other *(specify in comments)* ▪ **Do you include a humidity indicator card in your DBS package?** ☐ Yes ☐ No ▪ *Specify any challenges to DBS and/or plasma sample collection, storage, packaging, etc. in comments*	

What is the current VL specimen transport system to the hub? *Circle all that apply.* ☐NSTS ☐Motor bikes ☐Courier ☐Other *(specify in comments)*	
What is the current VL result delivery system from the central lab to your site? *Circle all that apply.* ☐NSTS ☐SMS ☐ Phone call ☐Courier ☐Other *(specify in comments)*	
Does your specimen transport system support cold chain? ☐Yes ☐No **If yes, what do you use for maintaining cold chain?** ☐NSTS refrigerated cars ☐ Use of cold boxes ☐ Other *(specify in comments)* *Specify any challenges to sample transport in the comments.*	
C. Tools	
Are VL testing algorithm job aids posted? *(If yes, obtain a copy or take a picture of them)* ▪ **For adults?** ☐Yes ☐No ▪ **For adolescents?** ☐Yes ☐No ▪ **For pediatrics?** ☐Yes ☐No ▪ **For pregnant/breastfeeding women?** ☐Yes ☐No	
Are job aids available for use during stepped-up adherence counseling for patients with VL ≥1000? ☐Yes ☐No *(If yes, obtain a copy or take a picture of them)*	
Is there a job aid to guide the time interval for routine VL monitoring? ▪ **For adults?** ☐ Yes ☐No *If yes, obtain a copy or take a picture of it* ▪ **For adolescents (10–19 years)?** ☐ Yes ☐No *If yes, obtain a copy or take a picture of it* ▪ **For pediatrics (<10 years)?** ☐ Yes ☐No *If yes, obtain a copy or take a picture of it* ▪ **For pregnant/breastfeeding women?** ☐ Yes ☐No *If yes, obtain a copy or take a picture of it*	

D. Document Review	
Do you have a patient education program/materials on VL literacy? ☐Yes ☐No *If yes, please tick all that apply:* ☐ flyers ☐brochures ☐Audiovisual ☐Other *(specify in comments)*	
Is there a national or site-level specific VL requisition form? ☐Yes ☐No *If yes, obtain a copy or take a picture of it*	
Are the national lab forms well-stocked (for >3 months)? ▪ **Sample requisition form?** ☐Yes ☐No ▪ **Sample daily log/log book?** ☐Yes ☐No ▪ **Sample transmitter form/sample delivery checklist?** ☐Yes ☐No	
Is there an SOP for ordering VL and collecting VL specimen that includes the following? *(tick all that apply)* ▪ **Filling out the requisition form?** ☐Yes ☐No *If yes, obtain a copy or take a picture of it* ▪ **Collecting samples?** ☐Yes ☐No *If yes, obtain a copy or take a picture of it* ▪ **Entry of VL test ordered into the sample daily log sheet/log book?** ☐Yes ☐No *If yes, obtain a copy or take a picture of it* ▪ **Entry of VL test ordered into the sample transmitter form/sample delivery checklist?** ☐Yes ☐No *If yes, obtain a copy or take a picture of it*	
Is there a site-level sample daily log sheet/log book that allows documentation of each VL test ordered and sent to the lab? ☐Yes ☐No *If yes, obtain a copy or take a picture of it*	
Is the sample transmitter form/sample delivery checklist filled out to indicate the number of VL tests ordered? ☐Yes ☐No *If yes, obtain a copy or take a picture of it*	

Is there a feedback system to notify facilities of rejected/inadequate samples? ☐Yes ☐No ▪ **If yes, how do you receive notification?** ☐NSTS ☐SMS ☐ Phone call ☐ Courier ☐Other *(specify in comments)* ▪ **How long does it take for you to receive this notification?** ☐ Within 1 week ☐ 1–2 weeks ☐ 2–4 weeks ☐ >4 weeks ▪ **Does the timeline and process differ by sample type (DBS, whole blood, plasma)?** ☐Yes ☐No • **If yes, for DBS:** ☐ Within 1 week ☐ 1–2 weeks ☐ 2–4 weeks ☐ >4 weeks • **If yes, for whole blood:** ☐ Within 1 week ☐ 1–2 weeks ☐ 2–4 weeks ☐ >4 weeks • **If yes, for plasma:** ☐ Within 1 week ☐ 1–2 weeks ☐ 2–4 weeks ☐ >4 weeks	
Is there an inventory system in place for sample collection consumables? ☐Yes ☐No *If yes, check it and ask the following questions:* ▪ **Are VL sample collection consumables tracked?** *Tick all that apply:* By: ☐ Date received ☐ Lot number ☐ Expiration date ☐ Quantity ▪ **Are all VL sample collection consumables stored according to manufacturer's recommendations?** ☐Yes ☐No ▪ **Are all VL sample collection consumable used or discarded within their expiration date?** ☐Yes ☐No ▪ **Have you had a stock-out of VL sample collection consumables in the last year?** ☐Yes ☐No *If yes, specify in comments*	

Does your site have procedures for handling and disposing biohazardous material? ☐Yes ☐No *If yes, obtain a copy or take a picture of it* ▪ **Do you have spill kits?** ☐Yes ☐No *If yes, obtain a copy or take a picture of it* ▪ **Are there SOPs to manage blood spills?** ☐Yes ☐No *If yes, obtain a copy or take a picture of it* ▪ **Have you had spill kit stock-outs in the last one year?** ☐Yes ☐No ▪ **Is there documentation that the lab personnel have been trained on handling biohazardous material, workplace safety, and spill management?** ☐Yes ☐No *If yes, obtain a copy or take a picture of it* ▪ **Are gloves always available?** ☐Yes ☐No	
Is there an SOP to guide the time interval for routine VL monitoring? ▪ **For adults?** ☐ Yes ☐No *If yes, obtain a copy or take a picture of it* ▪ **For adolescents (10-19 years)?** ☐Yes ☐No *If yes, obtain a copy or take a picture of it* ▪ **For pediatrics (less than 10 years)?** ☐Yes ☐No *If yes, obtain a copy or take a picture of it* ▪ **For pregnant/breastfeeding women?** ☐Yes ☐No *If yes, obtain a copy or take a picture of it*	
Is there an SOP for patients defined as having virologic suppression (<1,000 copies/ml)? ☐Yes ☐No *If yes, obtain a copy or take a picture of it*	
Is there an SOP for patients defined as having virologic failure (≥1,000 copies/ml)? ☐Yes ☐No *If yes, obtain a copy or take a picture of it*	

How many VL tests do you think your site can handle per day (including ordering, sample collection, packaging, required documentation)?

Please provide any additional comments that would help us understand the challenges your site may have with VL scale-up, and anything you think is needed as we move to more routine VL testing of HIV patients on ART (please be as specific as possible).

Thank you very much for your time and responses!