

**NATIONAL LEVEL MONITORING AND EVALUATION CHECKLIST FOR
HIV QUALITY IMPROVEMENT INITIATIVE**

Summary

The Quality Improvement (QI) Initiative is a comprehensive approach to HIV rapid test quality assurance that addresses the following key areas of testing: 1) Policy engagement, 2) HR development through training and certification, 3) proficiency testing, 4) logbook use for quality assurance (QA) purposes, and 5) lot-release testing for rapid test post-marketing surveillance.

This brief survey will help gather baseline data of the key areas identified for this initiative serve to develop framework for strategic planning and work plans and determine timelines and budgets. In addition, the checklist will allow monitoring the progress throughout the implementation of activities related to the key QI areas. Individual countries are encouraged to provide up to date information and assign a numeric score to the level of implementation for each QI area.

A. General Information

Country Name:	
Date of baseline assessment (MM/DD/YYYY): ____/____/____	Name of assessor:
Date of follow-up assessment (MM/DD/YYYY): ____/____/____	Name of assessor:
In country Laboratory POC	Name: Affiliation: Contact:
In country HTC POC	Name: Affiliation: Contact:
In country PMTCT POC	Name: Affiliation: Contact:
In country Supply Chain POC	Name: Affiliation: Contact:

B. Country background information

Country Name:	Overall national program	PEPFAR supported program
<p>Number of individuals tested by rapid testing (previous year) <i>(Please check the appropriate box(es) and provide total number of HTC, PMTCT, PITC, etc.)</i></p>	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):
<p>Number of laboratories/sites using rapid testing <i>(Please check the appropriate box(es) and provide total number of HTC, PMTCT, PITC, etc.)</i></p>	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):
<p>Cadres authorized to offer HIV testing and counseling services <i>(Please check box(es) where applicable)</i></p>	<input type="checkbox"/> Counselor <input type="checkbox"/> Nurse <input type="checkbox"/> Laboratory <input type="checkbox"/> Lay workers <input type="checkbox"/> Doctors <input type="checkbox"/> Midwife <input type="checkbox"/> Others	<input type="checkbox"/> Counselor <input type="checkbox"/> Nurse <input type="checkbox"/> Laboratory <input type="checkbox"/> Lay workers <input type="checkbox"/> Doctors <input type="checkbox"/> Midwife <input type="checkbox"/> Others
<p>Current approved testing algorithm <i>(Please check box(es) where applicable)</i></p>	<input type="checkbox"/> Serial <input type="checkbox"/> Parallel	<input type="checkbox"/> Serial <input type="checkbox"/> Parallel
<p>Current approved test kits of testing algorithm <i>(specify the name of each test used)</i></p>	<p>Screening or 1st line: Confirmatory or 2nd line: Tie-breaker or 3rd test (if applicable):</p>	<p>Screening or 1st line: Confirmatory or 2nd line: Tie-breaker or 3rd test (if applicable):</p>

C. Current National Quality Assurance Program

Country Name:	Overall national program	PEPFAR supported program
<p>Number of individuals trained (2013) <i>(Please check the appropriate box(es) and provide total number of HTC, PMTCT, PITC, etc.)</i></p>	<p><input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):</p>	<p><input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):</p>
<p>Number of individuals certified or re-certified by national certification program for rapid testing <i>(Please check the appropriate box(es) and provide total number of HTC, PMTCT, PITC, etc.)</i></p>	<p><input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):</p>	<p><input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):</p>
<p>Cadres authorized to offer HIV testing and counseling services <i>(Please check box(es) where applicable)</i></p>	<p><input type="checkbox"/> Counselor <input type="checkbox"/> Nurse <input type="checkbox"/> Laboratory <input type="checkbox"/> Lay workers <input type="checkbox"/> Doctors <input type="checkbox"/> Midwife <input type="checkbox"/> Others</p>	<p><input type="checkbox"/> Counselor <input type="checkbox"/> Nurse <input type="checkbox"/> Laboratory <input type="checkbox"/> Lay workers <input type="checkbox"/> Doctors <input type="checkbox"/> Midwife <input type="checkbox"/> Others</p>
<p>Current approved testing algorithm <i>(Please check box(es) where applicable)</i></p>	<p><input type="checkbox"/> Serial <input type="checkbox"/> Parallel</p>	<p><input type="checkbox"/> Serial <input type="checkbox"/> Parallel</p>
<p>Current approved test kits of testing algorithm <i>(specify the name of each test used)</i></p>	<p>Screening or 1st line: Confirmatory or 2nd line: Tie-breaker or 3rd test (if applicable):</p>	<p>Screening or 1st line: Confirmatory or 2nd line: Tie-breaker or 3rd test (if applicable):</p>

- 1. Policy Engagement:** Engage with MOH and other stakeholders to develop a framework to address supply chain, regulatory and national policy issues that will strengthen the quality and monitoring of HIV RTs and testing.

	Assessment Questions	For each of the questions, please check the appropriate box below				Comments
		Does not exist	In-development	Being implemented	Completed	
1	Is there a national technical working group for Laboratory Quality Assurance?					
2	Is there a national guideline or policy document for laboratory quality assurance in HIV testing?					
3	Is there a policy to empower national reference laboratory or designee to ensure quality of HIV test kits and testing?					
4	Is there a regulatory body approving the use of rapid testing?					
5	Does the national reference laboratory or designee evaluate/validate new HIV rapid tests for approval before their use in country?					
6	Is there a policy/guideline in place to identify and review HIV testing strategies and algorithms?					
7	Is there a national technical working group assisting the National HIV/AIDS Program in identifying and reviewing HIV testing strategies and algorithms?					
8	Is there a policy in place for new lot verification of RT kits and reagents?					
9	Is there a national policy requiring certification for personnel performing HIV rapid testing?					
10	Are there national policies requiring specific quality assurance measures such as <ul style="list-style-type: none"> - use of standardized logbooks at all testing sites? - participation in proficiency testing 					

	<p>program? - routine use of QC specimens?</p>					
11	<p>Are policies in place to assess the impact of quality assurance activities (e.g., training, logbooks, PT, etc.) on HIV testing and counseling services</p>					
12	<p>Does MOH engage key partners (e.g., WHO, implementing partners, etc.) in policy development for HIV testing and counseling services?</p>					

2. HR Development – Training and Certification: Provide information below for network of HIV rapid testers at various levels and link innovative hands-on training and re-training with certification process.

2.1. General background information

Country Name:	Overall national program	PEPFAR supported program
<p>Number of individuals trained (2013) <i>(Please check the appropriate box(es) and provide total number of HTC, PMTCT, PITC, etc.)</i></p>	<p><input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):</p>	<p><input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):</p>
<p>Number of individuals certified or re-certified by national certification program for rapid testing <i>(Please check the appropriate box(es) and provide total number of HTC, PMTCT, PITC, etc.)</i></p>	<p><input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):</p>	<p><input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):</p>
<p>Number of individuals of certified or re-certified by international certification program for rapid testing</p>	<p><input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):</p>	<p><input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):</p>

2.2. Assessment questions

	Assessment Questions	For each of the questions, please check the appropriate box below				Comments
		Does not exist	In-development	Being implemented	Completed	
1	Is there a <i>current</i> national level database of <i>all</i> HIV testing and counseling personnel?					
2	Is there a national institution and/or national reference laboratory responsible for hands-on training of key master trainers and field supervisors in the area of HIV rapid testing?					
3	Are key master trainers and field supervisors trained on QA aspects (e.g., testing procedures, logbook use, logbook data review and analysis, PT/QC, corrective actions etc.)?					
4	Are approved training curricula used for <i>all</i> training <i>across</i> program and by <i>all</i> partners?					
5	Are training curricula for HIV rapid testing standardized across programs and various testing settings?					
6	Is there a certification requirement for HIV testing and counseling personnel?					
7	Is the national certification system for HIV testing and counseling personnel governed by a national policy?					
8	Is the national certification system for HIV testing and counseling personnel based on approved criteria?					
9	Is there a current national database of all testing sites/laboratories?					
10	Is there a national registration system for HIV testing and counseling sites?					
11	Is the national registration system for testing sites based on approved criteria?					

3. Proficiency Testing and QC using DTS: Provide information on dried tube specimen (DTS)-based proficiency testing and quality control specimens as part of routine HIV RT testing and training.

3.1. General background information

Country Name:	Overall national program	PEPFAR supported program
Total number of sites enrolled in DTS PT program <i>(Please check the appropriate box(es) and provide total number of HTC, PMTCT, PITC, etc.)</i>	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):
Total number of sites participating (sites that submitted PT results) in each round <i>(Please check the appropriate box(es) and provide total number of HTC, PMTCT, PITC, etc.)</i>	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):
Total number of sites with satisfactory PT results <i>(Please check the appropriate box(es) and provide total number of HTC, PMTCT, PITC, etc.)</i>	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):
Total number of sites with unsatisfactory PT results that received corrective actions <i>(Please check the</i>	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT:	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT:

<i>appropriate box(es) and provide total number of HTC, PMTCT, PITC, etc.)</i>	PITC: ART clinic: STD clinic: TB clinic: Mobile/home based testing: Laboratory: Other (specify):	PITC: ART clinic: STD clinic: TB clinic: Mobile/home based testing: Laboratory: Other (specify):

3.2. Assessment questions

	Assessment Questions	For each of the questions, please check the appropriate box below				Comments
		Does not exist	In-development	Being implemented	Completed	
1	Is there a national policy in place requiring participation of <u>all</u> HIV testing personnel/sites/laboratories in proficiency (PT) testing programs and for the use of QC for HIV testing?					
2	Is there a national/regional QA officer responsible for the oversight of all EQA activities for HIV?					
3	Does the QA guideline or policy document include collaboration with regions to scale-up the PT/QC programs for HIV testing?					
4	Is there adequate staff to analyze PT program data and generate reports for timely feedback and corrective actions to the testing sites?					
5	Does the NRL or designee collaborate with regions to decentralize and scale-up PT/QC programs?					
6	Does the NRL collaborate with regional					

	laboratories to produce and/or distribute PT panels (e.g. DTS, etc.) to HIV testing sites/laboratories, in their regions?					
7	Are resources (e.g., funding, staff, laboratory infrastructures, etc.) available to support PT/QC activities at regional level?					
8	Does the NRL or designee provide oversight and monitor performance of the regions?					
9	Are adequate logistics (e.g., result reporting paper-based, computer based, phone, fax, local courier, etc.) available for PT data collection and feedback to sites?					

4. Use of Standardized Logbook: Provide information on the use of standardized logbook or register for the purposes of quality assurance of HIV rapid testing.

Country Name:	Overall national program	PEPFAR supported program
Total number of sites using the standardized logbook <i>(Please check the appropriate box(es) and provide total number of HTC, PMTCT, PITC, etc.)</i>	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):
Total number of sites reporting logbook stock out <i>(Please check the appropriate box(es) and provide total number of HTC, PMTCT, PITC, etc.)</i>	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/>	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/>

	Laboratory: Other (specify):	Laboratory: Other (specify):
Total number of sites with consistent agreement rate between Test 1 and Test 2 (>98%). <i>(Please check the appropriate box(es) and provide total number of HTC, PMTCT, PITC, etc.)</i>	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):
Total number of the logbook data reviewed at all levels and across programs <i>(Please check the appropriate box(es) and provide total number of HTC, PMTCT, PITC, etc.)</i>	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):
Total number of sites that received corrective actions based on the review of logbook data <i>(Please check the appropriate box(es) and provide total number of HTC, PMTCT, PITC, etc.)</i>	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):	<input type="checkbox"/> HTC: <input type="checkbox"/> PMTCT: <input type="checkbox"/> PITC: <input type="checkbox"/> ART clinic: <input type="checkbox"/> STD clinic: <input type="checkbox"/> TB clinic: <input type="checkbox"/> Mobile/home based testing: <input type="checkbox"/> Laboratory: <input type="checkbox"/> Other (specify):
Total number of district or regions with capacity and resources to manage and analyze logbook data for monitoring and improving the quality of RT <i>(Please check the appropriate box(es) and provide total number of HTC, PMTCT, PITC, etc.)</i>		

	Assessment Questions	For each of the questions, please check the appropriate box below				Comments
		Does not exist	In-development	Being implemented	Completed	
1	Is there a policy in place requiring use of standardized logbook at <u>all</u> testing sites/laboratories?					
2	Are HIV testing logbooks or registers harmonized across different testing programs?					
3	Has a strategy been developed to roll out a standardized HIV logbook or register?					
4	Are there resources available to ensure uninterrupted supply of logbook at all testing sites/laboratories?					
5	Is there a mechanism in place for a timely data analysis using adequate tools (i.e., reporting forms, software, etc.)?					

5. Lot Release Testing for HIV Rapid Test Post-Market Surveillance: Provide information on indigenous regional or national approach, wherever possible, for new lot testing prior to lot release of HIV RTs.

	Assessment Questions	For each of the questions, please check the appropriate box below				Comments
		Does not exist	In-development	Being implemented	Completed	
1	Is there a policy in place for quality verification of new RT kit lots coming into your country?					
2	Is there a practice in place to quality check new lots of test kits coming into your country?					
3	Is there a formal supply chain management system in place for test kits?					

4	Has the NRL or designee been mandated to oversee/undertake kit lot verification?					
5	Is the laboratory performing the kit lot verification accredited? If yes, which accreditation?					
6	Has the NRL or designee established a procedure for the implementation kit lot verification?					
7	Have procedures been developed by NRL or designee for specimen panels preparation and characterization for kit lot verification?					
8	Has a specimen repository been established by the NRL or designee for kit lot verification?					
9	Has the NRL or designee established reference test kits to compare against new lots?					
10	Is there a MOH policy in place to address disposition of failed lots of RT kits that are out of established and acceptable ranges?					
11	Is there a communication mechanism in place between procurement agency (e.g., Central Pharmacy, Central Medical Store etc.) to notify the NRL or designee of arrival of new lots in country?					
12	Is there a mechanism in place to disseminate the results of kit lot verification?					