Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) Checklist

Users' Guide for Site Audit Using the for SPI-RT Checklist

Version 3.0

10/1/2015

I. Background

The expansion of HIV/AIDS testing, care, and treatment services has been driven by the increasing need for HIV services including HIV rapid testing, the increasing provision of antiretroviral (ARV) drugs to treat persons living with HIV, and the demonstrated effectiveness of ARVs taken consistently to prevent further transmission (e.g. prevention of mother-to-child transmission (PMTCT), discordant couples, etc.). Considerable effort and resources have focused on expanding and decentralizing HIV testing services (HTS), PMTCT, and HIV care and treatment services so that HIV testing is performed at both facility and non-facility levels. As such, a continuous and systematic approach is needed to ensure good quality, accuracy and reliability of rapid HIV diagnostics for HTS.

To assist ministries of health and national programs, a ***Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT)*** checklist has been developed. The checklist provides guidance on quality assurance (QA) practices for sites using HIV rapid tests to diagnose HIV infection. The SPI-RT checklist sets minimum standards for all HIV testing points and provides guidelines for continuous quality improvement. Working through the SPI-RT Checklist will enable the individuals in charge of the HIV testing points and facilities to recognize quality gaps and shortcomings, identify areas for improvement and where additional resources may be needed to achieve national certification.

Using the SPI-RT checklist, the HIV rapid testing site audits are intended to be effective means to 1) determine if a testing point is providing accurate and reliable results; 2) determine if HIV rapid testing point is well-managed and is adhering to quality practices; and 3) identify areas for improvement.

II. Purpose of the Users' Guide for SPI-RT Checklist

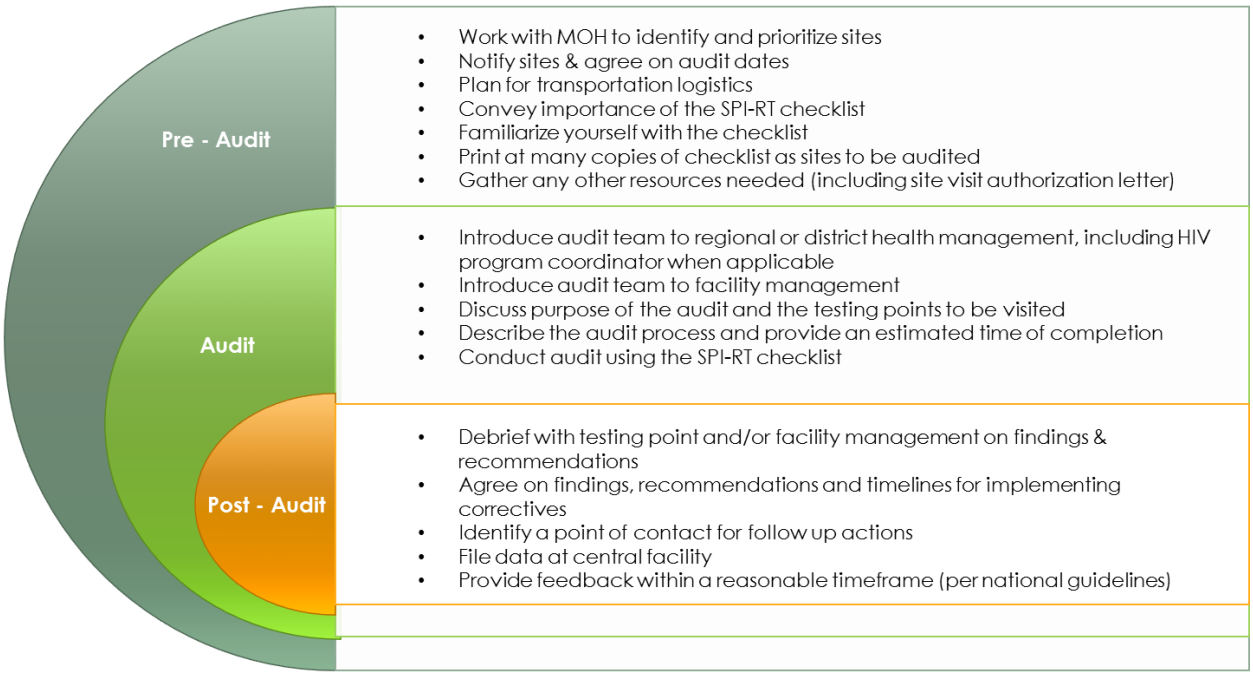
The users' guide has been developed to provide instructions on how to implement the associated checklist in an accurate and standardized way. The information should also provide testing point personnel with a clear indication of the requirements for compliance and some direction on the SPI-RT auditors' expectations.

The rationale for each standard and the methods that should be used to assess them are explained in this users' guide. Specifically, the users' guide outlines of the steps and requirements throughout an audit and provides a description of how and what data should be collected. For elements that require reviewing records and documents and/or verifying and confirming evidence of compliance, the user's guide also explains how it should be done. **In some instances, an observation may be sufficient for**
Examples are used to illustrate the methods described in **Section IV. Tips on How to Conduct the Audit.**

It is recognized that some of the questions related to personnel competency (**Section 1.0**) or the HIV testing registers (**Section 6.0)** may be out outside the purview of the testing point personnel. However, the data collected from these audits will be used for advocacy and decision making at higher level.

It should also be noted that the checklist only audits one testing point per program area in the same facility. For example, in a facility where more than one HIV HTC or PMTCT testing areas are operated by different tester, only one testing area will be audited. However, findings shared with and recommendations will have be provided to all testers for this particular testing point**.**

III. Steps and Requirements of the Audit



IV. Tips on How to Conduct the Audit

Review HIV rapid testing/site records to verify that the HIV rapid testing site guidelines, supervisory visit reports, incident reports, logs, Standard Operating Procedures (SOPs), and job aides are complete, current, and accurate.

Observe the HIV rapid testing site operations to ensure:

- All testing follows written procedures in pre-analytic, analytic and post-analytic phases of testing;
- The HIV rapid testing procedures are appropriate for the test performed;
- Deficiencies and nonconformities identified are adequately investigated and resolved within the established timeframe and documented.

In some instances, a simple observation may be sufficient to assess whether or not there is compliance. Questions should be asked for clarification.
For example, Question 4.4. will only be asked if the job aides are not available or outdated

Ask open-ended questions to clarify documentation seen and observations made. Ask questions like, "show me how…" or "tell me about…". It is often not necessary to ask all the checklist questions verbatim. An experienced auditor can often learn to answer multiple checklist questions through open-ended questions with the testing staff.

Follow a specimen through the HIV rapid testing procedure whenever possible, from specimen collection through testing, analyzing, and result reporting.

V. Structure of the SPI-RT Checklist

The SPI-RT Checklist contains four distinct parts. Detailed instructions are provided below on how to use the checklist to audit HIV testing points.

Part A. Characteristics of the Facility or Testing Point Audited
Part A is a summary table that gathers general information on the testing point to be audited. Because the nomenclature of the health facilities and the types of testing points vary from country to country, it is recommended to provide the most accurate information about the facility or testing points to be audited according to the national guidelines.

Date of audit: Provide the date of the audit, using the format provided.
Audit round: Audit round corresponds to the number of times the testing point was audited, as of the day of the audit.
Testing facility name: Provide the official name of the facility.
Testing facility ID: Some countries have a listing of the facilities with unique ID assigned, if available provide the number.
Type of testing point: Circle the type of testing point to be audited that is the most appropriate one; if not listed specify under "other". HIV programmatic areas vary from countries to countries. Therefore in some instances, countries will have to customize to reflect the program types available in country.
Location/Address: Provide the complete location or address of the testing facility.
Level: Circle the most appropriate level of the health tiered systems; if not listed, specify under "other". Health tiered system varies from countries to countries. Therefore in some instances, countries will have to customize to reflect the reflect country context.
Affiliation: circle the most appropriate one; if not listed, specify under "other"
Number of testers: Specify the number of individuals performing testing at the testing point at the times of the audit.
Average tested per month: Provide an estimate of number of individuals tested per month.
Name of the auditor 1: Provide the name of the auditor.
Name of the auditor 2: If more than one auditor, provide the name of the second auditor.

Part B. SPI-RT Checklist
The SPI-RT Checklist is laid out in sections that align with standard requirements. The checklist contains seven (7) main sections specific to HIV rapid testing.

- Section 1 Personnel Training and Certification
- Section 2 Physical Facility
- Section 3 Safety
- Section 4 Pre-Testing Phase
- Section 5 Testing Phase
- Section 6 Post-Testing Phase
- Section 7 External Quality Assessment

Part C. Scoring Criteria
This section briefly outlines the scoring criteria

For each of the sections listed below, responses to all questions must either be, "**Yes**", **"Partial**", or "**No**".

- Indicate **"Yes"** only when **all** elements are present, and the evidence of compliance is present in a tangible and/or observable form (e.g., written material, physical items, etc.)
- Indicate **"Partial"** if the testing point has a written procedure but there is no evidence of consistent implementation or if there is evidence of non-adherence.
- Indicate **"No"** when an element (e.g., SOP or job aides) requires a written procedure but it is not available at the testing point.
- When marking **"Partial"** or **"No"**, provide comments for each "**Partial**" or "**No**" response.
- State N/A in the comments section for the questions marked (*), if "not applicable"

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.

At the end of each section, total points scored for the section should be reported.

The table below describe the total score expected for each section of the checklist. The possible maximum score a testing point can obtain is either 64 points, if the country external quality assessment does not include a Retesting program (**Section 7.0 questions 7.10-7.14**) or 70 points if the program does include Retesting.

Audit Score Sheet		
Section	**Section Name**	**Total Points**
Section 1	Personnel Training and Certification	10
Section 2	Physical Facility	5
Section 3	Safety	11
Section 4	Pre-Testing Phase	12
Section 5	Testing Phase	9
Section 6	Post-Testing Phase	9
Section 7	External Quality Assessment	8/14
TOTAL SCORE		**64/70**

The percent score obtained by the audited testing point will correspond to a specific performance level as described in the table below.

This checklist consists of five different levels to indicate status toward national certification.

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%	Partially eligible
Level 3	80%-89%	Close to national site certification
Level 4	90% or higher	Eligible to national site certification

Part D. Summary of Audit Findings

Auditors complete this audit using the methods outlined above to evaluate testing points operations per SPI-RT Checklist items, and will document findings in detail using the ***Auditor's Summation Report for SPI-RT Audit***. A copy of the summation report will be made available to the head of facility or testing sites at the end of the audit.

The Auditor's summation report should include the following information:
Facility name as provided before the audit, the site type, the name of the staff audited. It should also include the number of testers at the testing point and the time it took to complete the audit.

The overall total points obtained by each HIV testing point audited will be weighed using the following formula:
Total points scored (exclude all N/A) = a. The auditor will compute all the points obtained for each section
Total score expected = b. The auditor will decide whether or not to include the 6 questions related to Retesting. If so the total score should 70, otherwise the total score to expected will be 64
% Score = (a/b) x 100. The total score obtained weighted in percentage. The percentage obtained by the testing point will be translated in level of performance.

In the summary table, issues and deficiencies should be documented. The section number should be referenced, immediate corrective actions by testing point or the facility or a follow up (e.g. higher level) should be noted. The auditor should provide some relevant comments and jointly with the testing point staffs, agree on actions to be taken, the timeline for completion and identify a person as point of contact.

The staff audited, the person in charge and the auditors should review, date and endorse the Auditor's Summation report. A copy should retained by the testing point and another copy by the auditor.

SECTION NO	SECTION QUESTIONS	WHAT TO ASK FOR?	WHAT TO LOOK FOR?
1.0	**PERSONNEL TRAINING AND CERTIFICATION**	**HTS should be offered by only testers with adequate and documented training, competent skills, and certified to administer tests and interpret the results, in accordance with national guidelines, policy and regulations.**	
1.1.	Have all testers received a comprehensive training on HIV rapid testing using the nationally approved curriculum?	Ask the following: - How many testers are on site - How many are trained - For documentation of training (e.g., certificates) for all testers including any refresher training - For training manual or training competency criteria	- Verify dates of trainings - Verify training contents including hands-on sessions ***Note**: Mark "Yes", if training documents are available and content include all quality elements* (e.g., safety, EQA/PT, waste management, inventory, QC documents and records, testing procedures, etc.) *Mark "Partial", if training documents are available but content does not include all quality elements* *Mark "No", if training documents are not available*
1.2.	Are the testers trained on the use of standardized HIV testing registers/logbooks?		- Verify a copy of HIV testing register and check all required elements are filled out ***Note:** Mark "Yes", if all testing QA elements are accurately documented* *Mark "Partial", if some testing elements are documented* *Mark "No", if no testing QA elements are documented*
1.3.	Are the testers trained on external quality assessment (EQA) or proficiency testing (PT) process?		- Verify the testers' training record on external quality assessment (EQA) or proficiency (PT) process ***Note:** Mark "Yes", if EQA and PT module is included in training and PT result are satisfactory* *Mark "Partial", if EQA and PT module is included training but PT results are unsatisfactory*

			Mark "No", if tester was not trained on EQA and PT
1.4.	Are the testers trained on quality control (QC) process?		- Verify the testers know about QC procedures - Verify how QC results are documented in QC logs or HIV testing register ***Note:*** *Mark "Yes", tester is able to accurately describe procedure and logs are properly documented* *Mark "Partial", tester is able to describe procedure but QC logs are not properly documented* *Mark "No", if tester cannot describe procedure and QC logs are not properly documented*
1.5.	Are the testers trained on safety and waste management procedures and practices?		- Verify procedures for safe handling and disposal of waste ***Note:*** *Mark "Yes", tester is able to accurately describe procedure and there is a training module on safety and waste management* *Mark "Partial", if safety and waste management are part of the national training curriculum but the tester is not following the safety and waste management procedures* *Mark "No", if tester cannot describe or follow the procedures and are not trained on safety and waste management*
1.6.	Have all testers received refresher training within the last two years?		Verify date (if more than 2 years, document in the comments field) ***Note:*** *Mark "Yes", testers have received refresher training the last 2 years* *Mark "Partial", some testers have refresher training the last 2 years*

			Mark "No", if none of the testers had refresher training the last 2 years or if refresher training was provided for more than 2 years
1.7.	Are there records indicating all testers have demonstrated competency in HIV rapid testing prior to client testing?	Ask the following: - For documentation of competency assessment for all testers	- Verify documentation of direct observation of the tester performing HIV rapid testing by in charge or supervisor (e.g., signature and date) - Verify personnel training log indicating the trainer or supervisor signature and date ***Note:*** *Mark "Yes", if demonstrated competency is well documented for all testers* *Mark "Partial", if demonstrated competency is well documented for some of the testers* *Mark "No", if there is no documentation of demonstrated competency*
1.8.	Have all testers been certified through a national certification program?	Ask the following: - If testers are enrolled in the national certification program - For certification of all testers currently performing testing	- Verify documented evidence of enrollment in national certification program - Verify a copy of the tester certification ***Note:*** *Mark "Yes", if there is evidence of enrollment of all testers in certification program* *Mark "Partial", if there is evidence of enrollment of some testers in certification program* *Mark "No", if there is no evidence of enrollment*

1.9.	Are only certified testers allowed to perform HIV testing?	Ask the following: - For evidence for documentation of national certification (e.g., certificate of competency, national guidelines) - Ask how many testers are on site and how many are certified	- Verify date of issuance certificate of competency and validity - Verify requirements for certification in the national guidelines if available - Verify testers signature on the HIV testing register to confirm that only certified testers are performing testing ***Note:*** *Mark "Yes", if there is evidence that only certified testers perform testing* *Mark "Partial", if there is evidence that only some testers performing testing are certified* *Mark "No", if none of the testers performing testing are certified*
1.10.	Are all testers required to be re-certified periodically (e.g., every two years)?	Ask the following: - For documentation of re-certification of all testers currently performing testing	- Verify the date of the most recent certification ***Note:*** *Mark "Yes", if there is evidence of recertification of all testers* *Mark "Partial", if there is evidence of recertification of some testers* *Mark "No", if there is no evidence of recertification*
	SECTION QUESTIONS	**WHAT TO ASK FOR?**	**WHAT TO LOOK FOR?**
2.0	**PHYSICAL FACILITY**	**The testing site is adequate to provide a safe and effective HTC services.**	
2.1.	Is there a designated area for HIV testing?	Ask the following: - To see where the HIV rapid testing occurs	- Verify that space is adequate for testing, ensures safety and client's confidentiality (e.g., all clients' information, a partition is present, etc.) ***Note:*** *Mark "Yes", if there is a designated area for HIV testing* *Mark "Partial", if there is evidence of a designated area for HIV testing and the*

			space is adequate but does not ensure safety or client confidentiality *Mark "No", if there is no evidence of a designated area for HIV testing*
2.2.	Is the testing area clean and organized for HIV rapid testing?		- Verify that the space is clean and organized (not cluttered) ***Note:*** *Mark "Yes", if testing area is clean and well organized* *Mark "Partial", if testing area is somehow clean and organized* *Mark "No", if there is not clean or organized*
2.3.	Is sufficient lighting available in the designated testing area?		- Verify that the primary light source (e.g., natural or lamp) is adequate for testing ***Note:*** *Mark "Yes", if testing area is well lit* *Mark "Partial", if testing area has a primary light source but the lighting is not consistent* *Mark "No", if testing are does not have adequate light for testing*
2.4.	Are the test kits kept in a temperature controlled environment based on the manufacturers' instructions?	Ask the following: - To see where test kits and other supplies are being stored?	- Verify storage conditions are appropriate (e.g., not too hot/cold, not too close to the ceiling, away from direct sunlight) - if applicable, in functioning refrigerator ***Note:*** *Mark "Yes", if all storage conditions are met* *Mark "Partial", if some storage conditions are met* *Mark "No", if none of the storage conditions are met*
2.5	Is there sufficient and secure storage space for test kits and other supplies?		- Verify storage space is sufficient, accessible, secured, and organized ***Note:*** *Mark "Yes", if storage space*

			(room, cabinets or drawers) is sufficient for all test kits and supplies and kept locked *Mark "Partial", if storage space is limited but locked* *Mark "No", if storage space is insufficient and not locked*
	SECTION QUESTIONS	**WHAT TO ASK FOR?**	**WHAT TO LOOK FOR?**
3.0	**SAFETY**	**The testing sites implements infection prevention and control processes.**	
3.1	Are there SOPs and/or job aides in place to implement safety practices?	Ask the following: - To see the safety related SOPs/job aides for: ▪ Overall safety guidelines ▪ Disposal of infectious and non-infectious waste ▪ Spill management procedures ▪ Exposure management procedures	- Review all documents, SOP, and/or job aides for safety - Verify handling infectious and noninfectious waste - Verify handling spills - Verify post-exposure prophylaxis ***Note:*** *Mark "Yes", if the SOP/job aides clearly outlines the different safety procedures and practice; and these are understood and implemented by the tester* *Mark "Partial", if the SOP/job aides do not clearly outline the different safety procedures and practice; or they are understood or implemented by the tester* *Mark "No", if there is no SOP/job aides outlining safety practices*
3.2	Are there SOPs and/or job aides in place on how to dispose of infectious and non-infectious waste?		
3.3	Are there SOPs and/or job aides in place to manage spills of blood and other body fluids?		
3.4	Are there SOPs and/or job aides in place to address accidental exposure to potentially infectious body fluids through a needle stick injury, splash or other sharps injury?		
3.5	Is personal protective equipment (PPE) always available to testers?	Ask the following: - To see where PPEs (gloves, apron, laboratory coats, etc.) are stored	- Verify PPEs (apron, gloves, laboratory coats, etc.) - Review the stock card and current stock ***Note:*** *Mark "Yes", if there are appropriate PPEs (i.e. gloves, apron/lab coats, etc.) available for the providers* *Mark "Partial", if there are gloves, apron/lab coats available but insufficient*

			Mark "No", if gloves, aprons/lab coats are not available for providers
3.6	Is PPE consistently used by all testers?	Ask the following: - How and when PPE is used?	- Observe if PPE is properly used by all testers during testing ***Note:*** *Mark "Yes", if gloves and apron/lab coats are properly worn at all times during testing procedure and gloves changed between clients* *Mark "Partial", if gloves and apron/lab coats are inconsistently worn during testing procedure and gloves not consistently changed between clients* *Mark "No", if no PPE is worn or if handling personal items (e.g., cell phone, key, etc.) with contaminated gloves*
3.7	Is PPE properly used by all testers through the testing process?		
3.8	Is there clean water and soap available for hand washing?	Ask the following: - Do the testers wash their hands	- Check that soap and running water are available - Check that sinks are functional and/or bucket (with a faucet, if applicable) contains water ***Note:*** *Mark "Yes", if soap and running water are available and consistently used* *Mark "Partial", if soap and running water are available and but not consistently used* *Mark "No", if soap and water are not available*

3.9	Is there an appropriate disinfectant to clean the work area and equipment available?	Ask the following: - To see their disinfectant - To describe how and when they use it - To describe the cleaning procedure after spills and end of day	- Verify that bleach (e.g., JIk) and/or alcohol are available and properly labeled (expiration date, initials) ***Note:*** *Mark "Yes", if disinfectant is available and properly used to clean testing area* *Mark "Partial", if disinfectant is available but not properly used to clean testing area* *Mark "No", if disinfectant is not available for routine cleaning of testing area*
3.10	Are sharps, infectious, and non-infectious waste handled properly?	Ask the following: - To see where sharps, infectious, and non-infectious wastes	- Verify that waste is properly managed (sharps in sharp containers, infectious vs. noninfectious disposed of per national guidelines (e.g., using correct waste bins and bags) - Observe that sharps, infectious, and non-infectious wastes are properly disposed ***Note:*** *Mark "Yes", if wastes and sharps are properly segregated and handled throughout testing procedure* *Mark "Partial", if wastes or sharps are inconsistently segregated and handled throughout testing procedure* *Mark "No", if wastes or sharps are not segregated and handled properly throughout testing procedure*
3.11	Are infectious and non-infectious waste containers emptied regularly per the SOP and/or job aides?	Ask the following: - How frequently the waste containers are emptied, by whom and how. - To see where the infectious waste is disposed	- Verify that waste containers are full or not - Verify where the wastes are disposed ***Note:*** *Mark "Yes", if there is evidence that wastes and sharps containers emptied regularly* *Mark "Partial", if there is evidence that*

			wastes or sharps containers are inconsistently emptied *Mark "No", if wastes or sharps containers are not overflown and evidence of poor waste management*
	SECTION QUESTIONS	**WHAT TO ASK FOR?**	**WHAT TO LOOK FOR?**
4.0	**PRE-TESTING PHASE**	**All safety and specimen collection procedures are followed, test kits and consumables are adequate to provide accurate and reliable test results**	
4.1	Are there national testing guidelines specific to the program (e.g. HTS, PMTCT, TB, etc.) available at the testing point?	Ask the following: - To see the program related guidelines outlining HIV testing and QA procedures	- Verify that national testing guidelines provided are current ***Note:*** *Mark "Yes", if program specific guidelines are available, current and understood by testers* *Mark "Partial", if program specific guidelines are available but not current and/or understood by testers* *Mark "No", if program specific guidelines are not available*
4.2	Is the national HIV testing algorithm being used?	Ask the following: - To describe the testing algorithm used at the sites - To see the job aides for testing algorithm	- Verify that the algorithm described is correct - Verify that job aides are current and correct - Review HIV testing register ***Note****: Mark "Yes" if national algorithm is being used and accurately implemented* *Mark "Partial": if national algorithm is being used but not consistently implemented* *Mark "no" If the national algorithm is not implemented or does not exist, and the site is implementing their own*

4.3	Is there a process in place for an alternative HIV testing algorithm in case of expired or shortage of test kit(s)?	Ask the following: - If the site has an alternative or different algorithm from the nationally approved algorithm - To describe to alternative algorithm	- Verify that the algorithm is per national guidelines (if it exists) ***Note**:* *Scenario 1: Mark "Yes" if the country guidelines recommend the alternative algorithm and it is implemented consistently.* *Mark "Partial" if the country guidelines recommend the alternative algorithm and it is not implemented consistently* *Mark "No" if the country guidelines recommend the alternative algorithm and it is not implemented* *Scenario 2: Mark "Yes" if the country guidelines do not recommend the alternative algorithm and the site is not implementing an alternative algorithm* *Mark "No" if the country guidelines do not recommend the alternative algorithm and the site is implementing their own*
4.4	Are there SOPs and/or job aides in place for each HIV rapid test used in the testing algorithm?	Ask the following: - For the SOPs and/or job aides for each of the test kits	- Verify that SOP and/or job aides of the test kits used are at the site ***Note**: Mark "Yes" job aides are available, current, referred and adhered to during testing.* *Mark "Partial" if job aides are available, current, but not adhered to consistently during testing.* *Mark "No" if job aides are not available or not current.*
4.5	Are only nationally approved HIV rapid test kits available for use currently?	Ask the following: - To see each of the HIV rapid tests currently in use	- Verify that test kits used are currently approved for HIV testing, including test kits for the nationally approved alternative algorithm ***Note**: Mark "Yes" if all the test kits used*

			currently are the ones approved by the national program. *Mark "Partial" if some of the test kits used currently are part of the ones approved by the national program.* *Mark "No" if none of the test kits used currently are nationally approved*
4.6	Are all the test kits in use within the expiration date currently?		- Verify that test kits currently used are not expired. ***Note**: Mark "Yes" if all the test kits currently used are within expiration date.* *Mark "Partial" if some of the test kits currently used are within expiration date.* *Mark "No" if none of the test kits used currently are within expiration date*
4.7	Are test kits labeled with date received and initials?		- Verify that test kits are properly labeled with date received and initials ***Note**: Mark "Yes" if all the test kits currently used* are *properly labeled with date received and initials* *Mark "Partial" if some of the test kits currently used are properly labeled with date received and initials* *Mark "No" if none of the test kits used currently are properly labeled with date received and initials*
4.8	Is there a process in place for stock management?	Ask the following: - To describe process in place to manage stock of test kits and supplies at testing point - If there is a designated person to manage stock, if so ask to speak to that person	- Verify process in place including stock documents (e.g., stock card, order form) ***Note**: Mark "Yes" if there is evidence that the process and practice include proper quantification of stock, an ordering system and documentation* *Mark "Partial" if there is some evidence*

			that the process and practice include quantification of stock or an ordering system or documentation *Mark "No" if there is no evidence that the process and practice include quantification of stock, an ordering system or documentation*
4.9	Are job aides on client sample collection available and posted at the testing point?	Ask the following: - To see the SOP and/or job aides that describe specimen collection	- Verify that job aides for specimen collection (e.g., finger-prick, venous blood, etc.) are available at the testing site - Verify that the job aides are current and accurate ***Note**: Mark "Yes" if job aides are available and posted and there is evidence that they are adhered to* *Mark "Partial" if job aides are available and posted but there is evidence that they are not adhered to* *Mark "No" if there are no job aides available or posted*
4.10	Are there sufficient supplies available for client sample collection?	Ask the following - To see all the supplies for specimen collection.	- Based on testing volume, verify the site has enough supplies for specimen collection (e.g., lancets, gauze, alcohol swabs, plaster, tubes, DBS cards, etc.) ***Note**: Mark "Yes" if there is evidence that all the supplies are in sufficient amount* *Mark "Partial" if there is evidence that some the supplies are insufficient* *Mark "No" if there is evidence that there is frequent stock out*
4.11	Are there national guidelines describing how client identification should be recorded in the HIV testing register	Ask the following - To see testing SOP and/or job aides	- Verify that the SOP and/or job aide describes how to record the client identification in logbooks and on the test devices ***Note**: Mark "Yes" if there is evidence of*

			adherence to national guidelines on how to document client identification (e.g. client name vs. code)? *Mark "Partial" if there is evidence of inconsistence adherence to national guidelines on how to document client identification* *Mark "No" if there is no evidence of adherence to the national guidelines on how to document client identification*
4.12	Are client identifiers recorded in the HIV testing register per national guidelines and on test devices?	Ask the following: - To see the logbook - What unique client identifiers are used - How the client test devices are labelled	- Verify that the client identifier matches the logbook - If possible, observe testing procedure and verify that test devices are labelled with correct client identifier ***Note**: Mark "Yes" if there is evidence of adherence to national guidelines on how to document client identification (e.g. client name vs. code) and that test devices are properly labelled?* *Mark "Partial" if there is some evidence of inconsistence adherence to national guidelines on how to document client identification and test device are inconsistently labelled* *Mark "No" if there is no evidence of adherence to national guidelines on how to document client identification or test devices not labelled*
	SECTION QUESTIONS	**WHAT TO ASK FOR?**	**WHAT TO LOOK FOR?**
5.0	**TESTING PHASE**	**All safety and testing procedures are implemented during throughout testing**	
5.1	Are SOPs and/or job aides on HIV testing procedures available and posted at the testing point?	Ask the following: - If the site has SOPs/job aides on HIV testing - To see the location of the job aides at the	- Verify that the job aide on HIV testing is available. - Verify that the job aide is current, accurate and complete and follows

		testing point	the national testing algorithm ***Note**: Mark "Yes" if job aides are available, current, referred and adhered to during testing.* *Mark "Partial" if job aides are available, current, but not adhered to consistently during testing.* *Mark "No" if job aides are not available or not current.*
5.2	Are timers available and used routinely for HIV rapid testing?	Ask the following: - To see the timers at the testing site - For a demonstration on how to use the timer - If the is timer not available what do they use to time the test?	- Verify the timer is available and in good operating conditions ***Note**: Mark "Yes" if timers or time tracking system are available and routinely used during testing* *Mark "Partial" if timers or time tracking system are available but not routinely used during testing* *Mark "No" if timers or time tracking system are not available or not used.*
5.3	Are sample collection devices (capillary tube, loop, disposable pipettes, etc.) used accurately?	Ask the following: - For a description of the sample collection device and how to use it (e.g., correct specimen collection device used from the kit, correct volume collected), if testing cannot be observed	- If testing can be observed during audit, verify to see if sample collection devices are appropriately used according to manufacturer's instructions (e.g., correct specimen device used from kit, correct volume collected, avoidance of bubbles in loop or disposable pipette, sample collected up to the appropriate mark on the capillary tube). ***Note**: Mark "Yes" if specimen collection devices are available for all test kits and used accurately* *Mark "Partial" if some specimen collection devices are available for all test kits and used accurately* *Mark "No" if no specimen collection*

			device is available or not used accurately
5.4	Are testing procedures adequately followed?	Ask the following: - For a description of the testing procedure from the time client is received, if testing cannot be observed.	If testing can be observed during audit, verify the following: - Testing procedure is followed - Tester does not have multiple test devices at the time they are testing one client - Tester has pre-set their timer if they are using one or monitor time - The right volume of sample is being added - The right buffer and volume is being added - Adherence to the required read time ***Note**: Mark "Yes" if there is evidence of consistent adherence to all testing procedures.* *Mark "Partial" if there is evidence of inconsistent adherence to all testing procedures.* *Mark "No" if there is evidence of non-adherence to all testing procedures.*
5.5	Are positive and negative quality control (QC) specimens routinely used (e.g., daily or weekly) according to country guidelines?	Ask the following: - If the National Reference Laboratory (NRL) or facility laboratory provides controls for testing, as recommended by country guidelines? - When do they receive QC from NRL or facility laboratory (e.g., weekly, monthly in a batch, etc.)? - What type of QC is being used (e.g., serum, plasma, DTS)? - How often QC is performed based on country guidelines (e.g., weekly, every new lot, environmental conditions change)?	Verify the following: - Positive and negative controls are available - Expiration date of QC material - Frequency of QC used according to country guidelines ***Note**: Mark "Yes" if there is evidence of consistent use of QC samples per guidelines.* *Mark "Partial" if there is evidence of inconsistent use of QC samples.* *Mark "No" if there is no evidence of QC samples being tested.*

5.6	Are QC results properly recorded?	Ask the following: - To see the quality control logs or testing register/logbook	Verify the following: - Quality controls results are documented in the QC log or testing register/logbook - How the QC results are recorded and interpreted (Negative/Positive or non-reactive/reactive)? - Who does the QC testing? ***Note**: Mark "Yes" if there is evidence of consistent documentation of QC results.* *Mark "Partial" if there is evidence of inconsistent documentation of QC results.* *Mark "No" if there is no evidence of documentation of QC results.*
5.7	Are incorrect/invalid QC results properly recorded?		Verify the following: - Quality controls that have incorrect/invalid results are documented in the QC log or testing register/logbook ***Note**: Mark "Yes" if there is evidence of consistent documentation of incorrect/invalid QC results.* *Mark "Partial" if there is evidence of inconsistent documentation of incorrect/invalid QC results.* *Mark "No" if there is no evidence of documentation of incorrect/invalid QC results.*
5.8	Are appropriate steps documented and taken when QC results are incorrect and/or invalid?	Ask the following: - To describe the actions taken to address failed or invalid controls received by the lab - To see the quality controls log or testing register/logbook	Verify the following: - Procedures or guidelines on how to handle QC failures - Documentation of QC failure and corrective action ***Note**: Mark "Yes" if there is evidence of consistent documentation of incorrect/invalid QC results as well as*

			results of retesting. *Mark "Partial" if there is evidence of inconsistent documentation of incorrect/invalid QC results as well as results of retesting.* *Mark "No" if there is no evidence of documentation of incorrect/invalid QC results as well as results of retesting.*
5.9	Are QC records reviewed by the person in charge routinely?	Ask the following: - To see the quality controls log or testing register/logbook to ensure routine review by the person-in-charge or facility lab technician - How often they are supposed to review it and when it is actually done?	- Verify the signature of the person-in-charge or facility lab technician ***Note**: Mark "Yes" if there is evidence of consistent review of QC records by the in-charge or facility lab technician.* *Mark "Partial" if there is evidence of inconsistent review QC results by the in-charge or facility lab technician.* *Mark "No" if there is no evidence of review of QC results by the person in charge or facility lab technician*
	SECTION QUESTIONS	**WHAT TO ASK FOR?**	**WHAT TO LOOK FOR?**
6.0	**POST TESTING DOCUMENTS AND RECORDS**	**Documents and procedures (SOPs/job aides) regarding reporting and reviewing results are implemented**	
6.1	Is there a national standardized HIV rapid testing register/logbook available and in use?	Ask the following: - If the site has a HIV testing register/logbook - To see the HIV testing register/logbook	Verify the following: - Tester is aware of the national standardized HIV testing register/logbook - National standardized HIV testing register/logbook is being used ***Note**: Mark "Yes" if the nationally approved register is available and properly used* *Mark "Partial" if the nationally approved register is available but inconsistently used* *Mark "No" if the nationally approved register not available or not used*

6.2	Does the HIV testing register/logbook include all of the key quality elements?		- Key elements such as, kit names, lot numbers, expiration dates, client demographics, tester name, unique ID, individual and final HIV results ***Note**: Mark "Yes" if the nationally approved register captures all key QA elements* *Mark "Partial" if the nationally approved register captures some key QA elements* *Mark "No" if the nationally approved register does not capture key QA elements*
6.3	Are all the elements in the HIV rapid testing logbook/register recorded/captured correctly? (e.g., kit names, lot numbers, expiration dates, client demographics, tester name, individual and final HIV results, etc.)?		Verify the following: - All of the fields are accurately completed and the QA elements (e.g., kit names, lot numbers, expiration dates, client demographics, tester name, individual and final HIV results, etc.) are captured correctly - Results recorded consistently the same way every time - Results recorded based on country guidelines (e.g., NR/R/INV for individual results and NEGATIVE/POSITIVE/ INDETERMINATE for the final result) - Results are written legibly, if they are not pre-printed in the testing register/logbook ***Note**: Mark "Yes" if all key QA elements are documented consistently and is properly used and maintained* *Mark "Partial" if key QA elements are documented inconsistently but is properly maintained*

			Mark "No" if key QA elements are not documented or is not properly maintained
6.4	Is the total summary at the end of each page of the register/logbooks complied accurately?		- Verify page totals are compiled accurately, as recommended by national guidelines ***Note**: Mark "Yes" if there is evidence that pages total summaries are consistently accurate.* *Mark "Partial" if page total summaries are not consistently accurate.* *Mark "No" if there are no page total summaries documented.*
6.5	Are invalid test results recorded in the register/logbook, and then repeated?	Ask the following: - If tester has recently encountered any invalid results - To describe the procedure for addressing and documenting invalid test results - To see the logbook/testing register/logbook	- Verify that the invalid result was properly recorded and repeated ***Note**: Mark "Yes" if there is evidence of consistent and proper documentation of invalid results as well as results of repeat testing.* *Mark "Partial" if there is evidence of inconsistent and proper documentation of invalid results as well as results of repeat testing.* *Mark "No" if there is no evidence of documentation of invalid results as well as results of repeat testing.*
6.6	Are all client documents and records securely kept throughout all phases of the testing process?	Ask the following: - To describe the measures taken to ensure confidentiality of client information throughout each phase of testing (e.g., pretesting, testing, post-testing)	- Verify the client information is handled to ensure confidentiality ***Note**: Mark "Yes" if there is evidence all clients' information is properly handled to ensure confidentiality.* *Mark "Partial" if there is evidence of some clients' information is not properly handled and may result in a confidentiality breach.* *Mark "No" if there is evidence that clients' information is not treated as*

			confidential (e.g. clients demographic and HIV register accessible to all)
6.7	Are all registers/logbooks and other documents kept in a secure location when not in use?	Ask the following: - To describe where registers/logbooks and other testing documents are kept when they are not testing (e.g., on short breaks, when testing is completed for the day)	- Verify location where documents are stored to ensure they are secure when testing is not being done. ***Note**: Mark "Yes" if there is evidence all documents and records are properly handled and kept secure (locked cabinet, drawer, etc.).* *Mark "Partial" if there is evidence some documents and records are not properly handled or kept secure (locked cabinet, drawer, etc.).* *Mark "No" if there is no evidence that the documents and records are properly handled and kept secure (locked cabinet, drawer, etc.).*
6.8	Are registers/logbooks properly labeled and archived when full?	Ask the following: - To describe the procedure and show where the registers are archived once they are full	- Verify that the registers are organized, properly labeled and easily retrievable (good filing system) ***Note**: Mark "Yes" if there is evidence all registers/logbooks are properly labeled and archived when full.* *Mark "Partial" if there is evidence some registers/logbooks are not properly labeled and archived when full.* *Mark "No" if there is no evidence that registers/logbooks are properly labeled and archived when full.*
	SECTION QUESTIONS	**WHAT TO ASK FOR?**	**WHAT TO LOOK FOR?**
7.0	**EXTERNAL QUALITY AUDIT (PT, SITE SUPERVISION AND RETESTING)**	**Testing sites are periodically audited for performance and Audited if quality assurance procedures are followed and documented**	
7.1	Is the testing point enrolled in an EQA/PT program?	Ask the following: - If the site receives specimens (e.g., Dried Tube Specimens or DTS) from the National	- Verify if EQA/PT program is either site specific or tester specific - Verify documentation of EQA/PT

		Reference Laboratory (NRL) for testing and returns the results to NRL (e.g., central lab in the capital) for scoring - If the EQA/PT panels are rotated among multiple testers - If EQA/PT program is specific to individual testers	participation (e.g., HIV testing register, QC log, EQA/PT forms) - Verify the most recent EQA/PT results, and if more than one year, document in the comments field to follow-up with the NRL ***Note**: Mark "Yes" if there is evidence that testing point or all testers are enrolled and participate regularly in EQA/PT program.* *Mark "Partial" if there is evidence testing point or some testers are enrolled but do(es) not participate regularly in EQA/PT program.* *Mark "No" if there is no evidence of enrollment or participation.*
7.2	Do all testers at the testing point test the EQA/PT samples?	Ask the following: - How many testers have performed EQA/PT testing - Documentation of EQA/PT test results	- Verify which testers participated in the most recent round; if no one participated, document why in the comment field. ***Note**: Mark "Yes" if all HIV rapid testers at the site have had an opportunity to tested EQA/PT panels and returned results to the NRL.* *Mark "Partial" if not all HIV rapid testers at the site have had an opportunity to tested EQA/PT panels and returned results to the NRL.* *Mark "No" if none of the testers at the site have ever participated in the PT program.*
7.3	Does the person in charge at the testing point review the EQA/PT results before submission to NRL or designee?	Ask the following: - If results of EQA/PT samples received from NRL (e.g., DTS) are reviewed by the person in charge or the facility lab	- Verify that the person in charge or the facility lab technician reviews the results (e.g., signature and date) ***Note**: Mark "Yes" if there is evidence of*

		technician - To see results form, if available or QC/QA log	*review of EQA/PT results every EQA/PT distribution.* *Mark "Partial" if there is evidence of review of EQA/PT results for some EQA/PT distributions.* *Mark "No" if there is no evidence of review of EQA/PT results for every EQA/PT distribution.*
7.4	Is an EQA/PT report received from NRL and reviewed by testers and/or the person in charge at the testing point?	Ask the following: - If NRL sends reports on site performance - If the report received by testing point is reviewed by testers and person in charge - To see documentation of review of the EQA/PT reports	- Verify tester and person in charge review of the report (e.g., signature and date) ***Note**: Mark "Yes" if there is evidence of review of site or testers' performance for every EQA/PT distribution.* *Mark "Partial" if there is evidence of inconsistent review of site or testers' performance.* *Mark "No" if there is no evidence of review of site or testers' performance.*
7.5	Does the testing point implement corrective action in case of unsatisfactory results?	Ask the following: - To describe procedures to implement corrective actions in case of a low score - To see if there is evidence of corrective actions being implemented - To indicate how long it takes to implement the corrective actions taken after report is received	- Verify what corrective actions were taken, when, and by whom. - Verify evidence of improvement if a low score was obtained prior to the last round. ***Note**: Mark "Yes" if there is evidence that corrective action is implemented consistently every EQA/PT distribution.* *Mark "Partial" if there is evidence that corrective action is implemented inconsistently.* *Mark "No" if there is no evidence that corrective action is implemented.*
7.6	Does the testing point receive periodic supervisory visits?	Ask the following: - If the site receives a supervisory visit from the region or NRL/Program.	- Verify the site visit report - Verify in the site report if direct

		- The frequency and purpose of the visits - To see the reports from the visits	observation of client testing was conducted. - Verify if deficiencies are noted and corrective actions are taken. - Verify documentation of retraining where needed. ***Note**: Mark "Yes" if there is adequate evidence of supervisory visits and documentation of findings and corrective actions provided.* *Mark "Partial" if there is inadequate evidence of supervisory visits and documentation of findings and corrective actions provided.* *Mark "No" if there is no evidence of supervisory visits or documentation of findings and corrective actions provided.*
7. 7	Is feedback provided during supervisory visit and documented?	Ask the following: - If the visit of the supervisory team occurs during client testing - If so, ask if the team is in the room while HTC services are being offered to client	
7.8	If testers need to be retrained, are they being retrained during the supervisory visit?	Ask the following: - If during the supervisory team visit, , testers are retrained on specific aspects of HTC (e.g., counseling, specimen collection, testing, documentation, reporting results, etc.), if needed	
If the country external quality assessment program includes retesting of serum or DBS, proceed with questions 7.9 – 7.14. Otherwise, STOP here.			
7.9*	Does the site collect samples for retesting according to country guidelines (e.g., collection of DBS or serum sample of every 20th client)?	Ask the following: - If the site collects specimens (e.g., DBS or serum) and sends to referral lab for retesting - To see country guidelines for retesting	- Verify Quality log or HTC register documentation - Verify client ID, date sent and results from referral lab - Verify documentation of results comparison ***Note**: Mark "Yes" if there is evidence of consistent adherence to sample (e.g. DBS or serum) collection process for retesting per national guidelines.* *Mark "Partial" if there is evidence of inconsistent adherence to sample collection process (e.g. DBS or serum) for retesting per national guidelines.* *Mark "No" if there is no evidence of adherence to sample collection process*
7.10*	Are the DBS or serum samples collected for retesting properly documented?	Ask the following: - To see documentation for retesting	

			(e.g. DBS or serum) for retesting per national guidelines.
7.11*	Are DBS or serum samples collected properly (e.g., at least 3 complete circles or correct volume and correct tubes, etc.)?	Ask the following: - To describe the specimen (e.g., DBS or serum) collection process - To see DBS card to verify they are properly corrected	- If possible, observe preparation of DBS card and verify that DBS is properly prepared and/or useable according to an SOP/job aide if available. ***Note**: Mark "Yes" if there is evidence of consistent adherence to sample (e.g. DBS or serum) collection procedure for retesting* *Mark "Partial" if there is evidence of inconsistent adherence to sample collection procedure (e.g. DBS or serum)for retesting* *Mark "No" if there is no evidence of adherence to sample collection procedure (e.g. DBS or serum)for retesting*
7.12*	Are DBS samples stored properly (e.g., away from sunlight, separated by glassine paper, desiccant, or at 4oC or 20oC, etc.)?	Ask the following: - To see where samples (e.g. DBS cards or serum) are stored	- Verify if DBS cards are stored properly from sunlight, dust and insects, separated by glassine paper, desiccant, etc. ***Note**: Mark "Yes" if there is evidence that the samples (e.g. DBS or serum) are consistently stored properly.* *Mark "Partial" if there is evidence that the proper storage of samples (e.g. DBS or serum) is inconsistent* *Mark "No" if there is no evidence that the samples (e.g. DBS or serum) are stored properly*
7.13*	Are the identifiers of samples (e.g. DBS or serum) sent for retesting recorded?	Ask the following: - To see where information about DBS sent for retesting are recorded	- Verify the records of IDs of DBS samples sent for retesting

		- To review register/logbook for evidence of documentation of specimens sent for retesting	***Note**: Mark "Yes" if there is evidence of proper documentation samples (e.g. DBS or serum) sent for retesting* *Mark "Partial" if there is evidence of inconsistent documentation of samples (e.g. DBS or serum) sent for retesting* *Mark "No" if there is no evidence of documentation of samples (e.g. DBS or serum) sent for retesting*
7.14*	Are retesting samples (e.g. DBS or serum) results received from the referral lab properly documented and recorded in the HIV register/logbook?	Ask the following: - To see where samples (e.g. DBS or serum) results sent for retesting are recorded - To review register/logbook for documentation of retesting results	- Verify quality control log or HIV testing registers. - Look for results from most recent batch and how long ago it was tested (if it was tested more than six months ago, document in the comments field) ***Note**: Mark "Yes" if there is evidence of proper documentation of test results of samples (e.g. DBS or serum) sent for retesting* *Mark "Partial" " if there is evidence of inconsistent documentation of test results of samples (e.g. DBS or serum) sent for retesting* *Mark "No" if there is no evidence of documentation results of samples (e.g. DBS or serum) sent for retesting*

Part D. Auditor's Summation Report for SPI-RT Audit

Facility Name: Site Type: Staff Audited Name:	No. of Tester(s): Duration of Audit:	Total points scored (exclude N/A) = a Total score expected = b % Score = (a/b) x 100

Section No.	Deficiency/Issue observed	Correction Actions		Auditor's Comments	Recommendations	
		Immediate	Follow up		Actions	Timeline / Person responsible

Staff Audited Signature: Person in Charge Name and Signature:	Auditor Name and Signature: Date (dd/mm/yyyy):