Stepwise Process for Improving the Quality of HIV Rapid and Recency Testing (SPI-RRT) Checklist

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

Version 4.0

3/3/2020

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 and Recency Testing (SPI-RRT)*** checklist has been developed. The checklist provides guidance on quality assurance (QA) practices for sites using HIV rapid tests to diagnose HIV infection and for sites using the rapid test for recent infection (RTRI) to determine whether a newly HIV diagnosed person has been infected within the past 12 months. The SPI-RRT checklist sets minimum standards for all HIV RT/RTRI testing points and provides guidelines for continuous quality improvement (CQI). Working through the SPI-RRT Checklist will enable the individuals in charge of the HIV RRT/RTRI 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-RRT checklist, the HIV rapid and recency 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 RT/RTRI testing point is well-managed and is adhering to quality practices; and 3) identify areas for improvement.

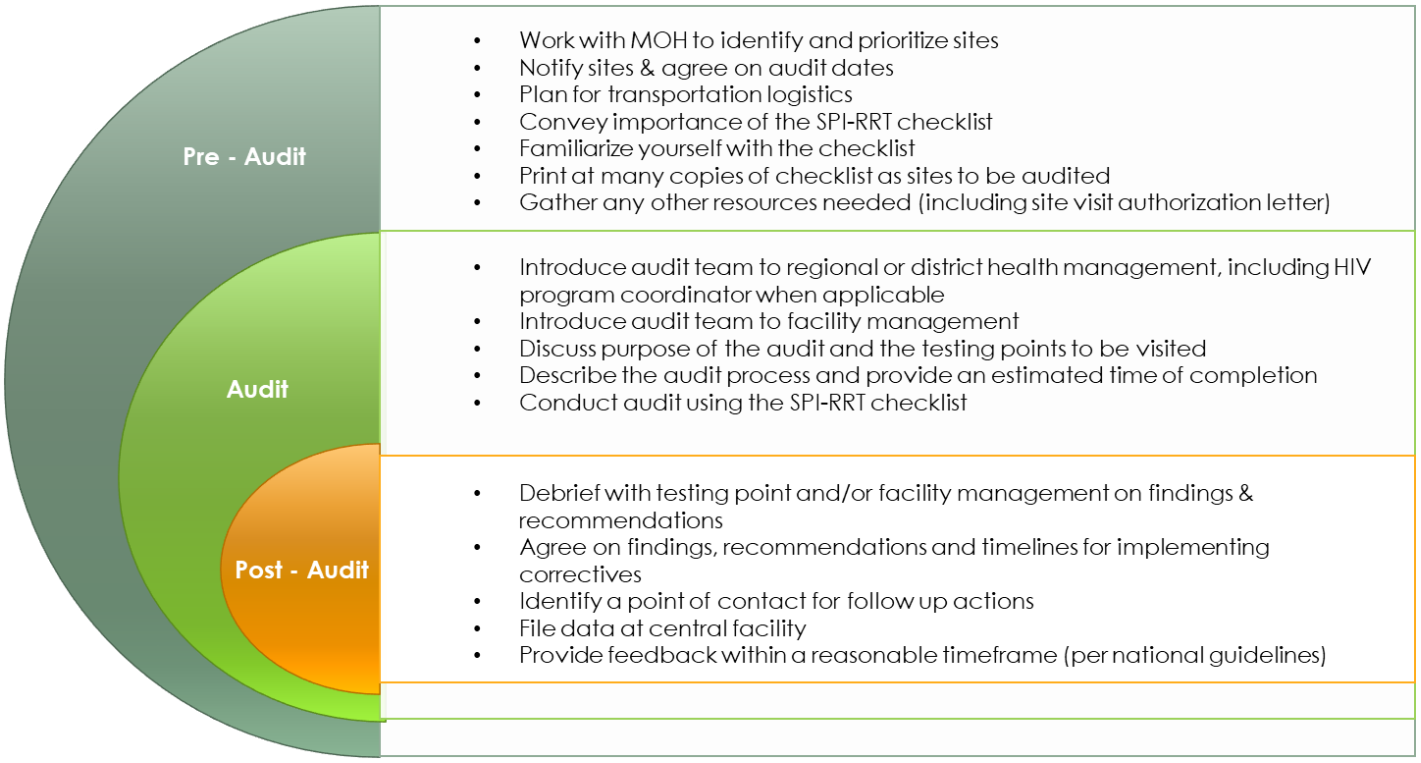
II. Purpose of the Users' Guide for SPI-RRT Checklist

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-RRT 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 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 to assess whether or not there is compliance.**
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 outside the purview of the testing point personnel. However, the data collected from these audits will be used for advocacy and decision making at a higher level.

III. Steps and Requirements of the Audit



IV. Tips on How to Conduct the Audit

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

Observe the HIV RT/RTRI 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 and/or RTRT 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 or RTRI procedure whenever possible, from specimen collection through testing, analyzing, and result reporting.

V. Structure of the SPI-RRT Checklist

The SPI-RRT Checklist contains four distinct parts. Detailed instructions are provided below on how to use the checklist to audit HIV RT and/or RTRI 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.
Physical Address: Provide the complete location or address of the testing facility.
Level: Circle the most appropriate sub-national level of the health tiered systems; if not listed, specify under "other". Sub-national levels vary from country to country. Therefore, in some instances, countries will have to customize to reflect the country context.
Affiliation: circle the most appropriate one; if not listed, specify under "other"
Number of testers: Specify the number of individuals performing testing in the testing point at the time of the audit.
Number of clients tested for HIV: Provide the number of clients tested for HIV for the past month and quarter
Number of newly identified HIV positives: Provide the number of newly diagnosed HIV positives for the past month and quarter.
Number of HIV negatives: Provide the number of clients that tested HIV negative for the past month and quarter.
Number of newly identified HIV positives tested by RTRI: Provide the number of newly diagnosed HIV positives tested by RTRI.
Number of Recent by RTRI or RITA: Provide the number of recent clients by the rapid test for recent infection only or the recent infection testing algorithm (RTRI +viral load)
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-RRT Checklist

The SPI-RRT Checklist is laid out in sections that align with standard requirements. The checklist contains eight (8) main sections specific to HIV rapid and recency 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
- Section 8 HIV-1 Recent Infection Surveillance Using the Rapid Test for Recent Infection (RTRI)

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 or there is no evidence of compliance.
- When marking **"Partial"** or **"No"**, provide comments for each "**Partial**" or "**No**" response.
- State N/A (not applicable) in the comments field of the Section 8.0 questions (*) if RTRI is not implemented.

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 describes 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 has not implemented RTRI (**Section 8.0 questions 8.1 - 8.11**) or 75 points if the program does include RTRI.

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	13
Section 5	Testing Phase	9
Section 6	Post-Testing Phase	9
Section 7	External Quality Assessment	8
Section 8	HIV-1 Recent Infection Surveillance	11
TOTAL SCORE		**64/75**

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 point operations using the SPI-RRT Checklist and will document findings in detail using the ***Auditor's Summation Report for SPI-RRT 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 11 questions related to RTRI. If so, the total score should 75, 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.
The correct pre-certification level should be indicated for each site audited.

In the summary table, gaps and areas for improvement 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 be 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? - Documentation of training (e.g., certificates) for all testers including any refresher training - 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 correctly by the tester(s) ***Note:** Mark "Yes" if all testing QA elements are accurately documented* *Mark "Partial", if inconsistent or inaccurate documentation of QA elements* *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 tester(s) training record on external quality assessment (EQA) or proficiency (PT) process ***Note:** Mark "Yes", if EQA and PT module is included in training and tester PT result are satisfactory*

			Mark "Partial", if EQA and PT module is included training, but tester 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 by the tester in QC logs or HIV testing register ***Note:*** *Mark "Yes", tester is able to accurately describe procedure and logs are properly documented by the tester* *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 by the tester*
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 or cannot accurately describe procedure* *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*
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 performing HIV rapid testing at the site?	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 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 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 but the space is not adequate or 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 not consistently clean and organized* *Mark "No" if the area is dirty and/or cluttered which could result in a safety hazard or contamination of items in the testing area*
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 area does not have adequate light for testing*
2.4.	Are the test kits stored according to manufacturers' instructions?	Ask the following: - To see where test kits and other supplies are being stored?	- Verify storage conditions are appropriate - Verify if kits are stored in an area where temperature requirements are being met (e.g., 2- 30°C) and is

			being monitored regularly using a thermometer - Check if kits are being stored away from direct sunlight or away from an area with high humidity, etc. - if applicable, check if kits are being stored in functioning refrigerator. If test kit is stored in refrigerator then the tester takes it out for at least 30 mins to reach room temp prior to testing ***Note:*** *Mark "Yes" if all storage conditions are met* *Mark "Partial" if some of the storage conditions are met* *Mark "No" if none of the storage conditions are met*
2.5	Is there sufficient storage space for test kits and other supplies?		- Verify storage space is sufficient, accessible, and organized ***Note:*** *Mark "Yes", if storage space (room, cabinets or drawers) is sufficient for all test kits and supplies* *Mark "Partial" if storage space is limited* *Mark "No", if storage space is insufficient, not accessible and/or disorganized*
	SECTION QUESTIONS	**WHAT TO ASK FOR?**	**WHAT TO LOOK FOR?**
3.0	**SAFETY**	**The testing site 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	- Review all documents, SOP, and/or job aides for safety including proper disposal of infectious and non-infectious waste, manage blood and other body fluids. - Verify handling infectious and noninfectious waste
3.2	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?		

3.3	Are testers and those visiting the testing area following the safety practices outlined in the SOPs and/or job aides?	▪ Exposure management procedures	- Verify handling spills - Verify post-exposure prophylaxis ***Note:*** *Mark "Yes", if the SOP/job aides clearly outline the different safety procedures and practice; and these are understood and implemented by the tester and anyone that visits the testing area* *Mark "Partial", if the SOP/job aides do not clearly outline the different safety procedures and practice; or they are not understood or implemented by the tester or those visiting the testing area* *Mark "No" if there are no SOP/job aides outlining safety practices*
3.4	Is personal protective equipment (PPE) always available to testers?	Ask the following: - To see where PPEs (gloves, apron, laboratory coats, etc.) are stored - To ask for the stock card or see the supply inventory database	- Verify PPEs (apron, gloves, laboratory coats, etc.) - Review the stock card or inventory database 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*
3.5	Is PPE properly used by all testers consistently throughout the testing process?	Ask the following: - How and when is PPE 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*
3.6	Is there clean water and soap available for hand washing and is it consistently used?	Ask the following: - Availability of soap and water - 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 testers wash their hands before and after each client* *Mark "Partial", if soap and running water are available but testers are not consistently washing their hands before and after testing each client* *Mark "No" if soap and water are not available*
3.7	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*

3.8	Is the disinfectant solution used properly labeled with content, date of preparation and date of expiration?		- Verify that bleach (e.g., JIk) and/or alcohol are properly labeled with content, date of preparation, date of expiration and initials of who prepared it ***Note:*** *Mark "Yes" if disinfectant is properly labeled* *Mark "Partial", if disinfectant is not properly labeled (i.e., some elements missing from label)* *Mark "No", if there is no label identifying the product as a disinfectant and no content, date of preparation, expiration or initials of who prepared it.*

3.9	Are sharps, infectious and non-infectious waste disposed of according to the segregation instructions?	Ask the following: - To see how the site manages waste, is it properly segregated? - To see where sharps, infectious, and non-infectious wastes are stored prior to disposal	- 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 - Observe where sharps, infection and non-infectious waste are stored prior to disposal (i.e., incineration, etc.) ***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*
3.10	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 whether 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 overflowing 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 HIV testing guidelines available at the testing point?	Ask the following: - To see the national guidelines outlining HIV testing and QA procedures	- Verify that national testing guidelines provided are current ***Note:*** *Mark "Yes" if national guidelines are available, current and understood by testers* *Mark "Partial" if national guidelines are available but not current and/or understood by testers* *Mark "No" if national guidelines are not available*
4.2	Is the national HIV testing algorithm(s) consistently being used at the testing site?	Ask the following: - To describe the testing algorithm used at the sites - To ask if there is an approved alternative algorithm in case of stock out issues - 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 - If there is an alternative algorithm, document in the comments section what the approved algorithms are. ***Note****: Mark "Yes" if the national algorithm is being used and accurately implemented* *Mark "Partial": if national algorithm is being used but not consistently implemented due to stock issues or other reasons (Note: please document reasons algorithm is not followed)*

			Mark "no" If the national algorithm is not implemented or does not exist, and the site is implementing their own
4.3	Are SOPs and/or job aides on HIV rapid test procedures and the national HIV rapid test algorithm(s) available and easily accessible at the testing site?	Ask the following: - For the SOPs and/or job aides for the national testing algorithm and for each of the HIV rapid test kits used in the algorithm	- Verify that SOP and/or job aides for the test kits and algorithm are available and easily accessible ***Note**: Mark "Yes" job aides are available* *Mark "Partial" if only some job aides are available* *Mark "No" if job aides are not available*
4.4	Are SOPs and/or job aides on HIV rapid test procedures and the national testing algorithm up-to-date and accurate?		- Verify that SOP and/or job aides for the test kits and algorithm are the most current version and that the information is based on the manufacturer's most recent package insert ***Note**: Mark "Yes" job aides are up-to-date and accurate* *Mark "Partial" if only some job aides are up-to-date and accurate* *Mark "No" if none of the job aides are up-to-date or accurate or there are none available*
4.5	Are only nationally approved HIV rapid test kits available for use?	Ask the following: - To see each of the HIV rapid tests currently in use	- Verify that test kits available are currently approved for HIV rapid testing in-country, including test kits for the nationally approved alternative algorithm ***Note**: Mark "Yes" if all the test kits available currently are the ones approved by the national program.* *Mark "Partial" if only some of the test kits available are part of the ones approved by the national program.* *Mark "No" if none of the test kits available are nationally approved*

4.6	Are all the test kits currently in use within the expiration date?		- 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 expired* *Mark "No" if none of the test kits used currently are within expiration date*
4.7	Are all required test kit components (i.e., test device, buffer, sample collection device, etc.) and supplies available prior to testing?	Ask the following: - To see each of the HIV rapid tests currently in use - To see documentation of receipt of kits (i.e., stock card, inventory form, or kits labeled with date received and initials, etc.) - 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 that each test kit contains the required components (i.e., Sample collection device, buffer, test device, etc.), - Review the test kits in the testing area to ensure no component is missing. - Please note sample collection device means loop, disposable pipette, or capillary tube ***Note**: Mark "Yes" if the correct components required for each kit are present in the test kit package (i.e., correct sample collection device, test device and buffer) and all supplies are available prior to testing* *Mark "Partial" if only some of the supplies are available* *Mark "No" if supplies are not available prior to testing and/or test kit components are mixed up with other kits (i.e., Determine chase buffer mixed in with UniGold test kit, etc.)*
4.8	Is there a process in place for stock management		- Verify process in place including stock documents and/or inventory database (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 the stock management process and practice does not include quantification of stock or an ordering system or documentation consistently* *Mark "No" if there is no evidence that the process and practice include quantification of stock, an ordering system or documentation*
4.9	Is there a documented inventory system in place at the testing point for test kits received (i.e., who received them, date of receipt, etc.)??		- Verify that the testing point has documentation that kits are received, what lot number/expiration, who received and date of receipt - Verify that test kits are properly labeled with date received and initials ***Note**: Mark "Yes" if there is documentation of inventory system for kits received* *Mark "Partial" if documentation is not consistent* *Mark "No" if there is no documentation*
4.10	Are job aides on finger prick or venous blood 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 blood 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, up-to-date, accurate and accessible 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 accurate or adhered to consistently *Mark "No" if there are no job aides available or posted*
4.11	Are there sufficient supplies available for finger prick or venous blood collection (i.e., lancet, gauze, alcohol swab, etc.)?	Ask the following - To see all the supplies for specimen collection. - To see stock card	- Based on testing volume, verify the site has enough supplies for blood 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 amounts* *Mark "Partial" if there is evidence that some the supplies are insufficient* *Mark "No" if there is evidence that supplies are not sufficient and there are frequent stock outs*
4.12	Are there SOPs and/or job aides 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 or site level guidelines on how to document client identification (e.g., client name vs. code)?* *Mark "Partial" if there is evidence of inconsistence adherence to national or site level guidelines on how to document client identification* *Mark "No" if there is no evidence of adherence to the national or site level guidelines on how to document client identification*

4.13	Are client identifiers recorded in the HIV testing register and on test devices per SOPs and/or job aide?	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 and the national testing algorithm being referred to and followed during testing?	Ask the following: - If the site has SOPs/job aides on HIV testing - To see the location of the job aides at the testing point	- Verify that the job aide is current, accurate and complete and follows the national testing algorithm - If testing can be observed during audit, verify that the tester refers to the job aide during testing and the procedures followed Note: Mark "Yes" if job aides are referred and adhered to during testing. Mark "Partial" if job aides are not adhered to consistently during testing. Mark "No" if job aides are not being adhered to during testing.

5.2	Are timers available and used them for HIV rapid testing?	Ask the following: - To see the timers or stopwatch at the testing site - For a demonstration on how to use the timer - If the timer is not available what do they use to time the test?	- Verify that a timer or stopwatch is available and in good operating conditions ***Note**: Mark "Yes" if timer or stopwatch is available, working and the tester knows how to use them* *Mark "Partial" if timer or stopwatch is available but it is not working, or the tester does not know how to use it.* *Mark "No" if timer or stopwatch is not available or used for testing.*
5.3	Are sample collection devices (e.g., capillary tube, loop, disposable pipettes, etc.) used accurately to perform the test?	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). - Please note sample collection device means loop, disposable pipette, or capillary tube ***Note**: Mark "Yes" if specimen collection devices are available for all test kits and used accurately* *Mark "Partial" if specimen collection devices are available for only some of the test kits and used accurately* *Mark "No" if no specimen collection device is available or used accurately*
5.4	Are testing procedures adequately followed?	Ask the following:	If testing can be observed during audit, verify the following:

		- For a description of the testing procedure from the time client is received, if testing cannot be observed.	- 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 or if they are using one or more monitoring time device - The right volume of sample is being added - The right buffer and buffer 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 external positive and negative quality control (QC) specimens routinely used (e.g., daily, weekly, monthly) 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 or monthly, 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.*

		- Note correct terminology of QC based on country context. Some countries term it IQC.	
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 and/or 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. If testers state that they never had an incorrect/invalid QC result, they should be able to describe what it looks like and how would they record it if it happens* *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 and/or tester does not know what*

			an incorrect/invalid QC result is or how to document it.
5.8	Are appropriate steps taken and documented 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 steps taken to troubleshoot QC failures as well as results of retesting. If testers state that they never had a QC failure, they should be able to describe what steps to take to troubleshoot* *Mark "Partial" if there is evidence of inconsistent documentation of steps to troubleshoot QC failures as well as results of retesting.* *Mark "No" if there is no evidence of documentation of steps taken to address QC failures as well as results of retesting. Or tester does not know what steps to take to troubleshoot and document QC failures.*
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 an 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 is not available or not used*
6.2	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.)?		- 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	Is the total summary at the end of each page of the register/logbooks complied accurately?		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 or INCONCLUSIVE 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	Are invalid test results recorded properly in the register/logbook?	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 invalid results were recorded - Verify that the invalid result was properly recorded and repeated ***Note**: Mark "Yes" if there is evidence that invalid results are being recorded consistently in the logbook as well as results of repeat testing. If testers state that they never had an invalid, the tester should be able to describe the procedure for troubleshooting an invalid result.*
6.5	Are appropriate steps taken and documented when a result is invalid?		

			Mark "Partial" if there is evidence of inconsistent documentation of invalid results including results of repeat testing *Mark "No" if there is no evidence of documentation of invalid results including results of repeat testing and/or tester does not know how to handle an invalid result*
6.6	Are the register/logbook pages routinely reviewed for accuracy and completeness by the person in charge?	Ask the following: - To see the HIV testing register/logbook	- Verify that the supervisor or person in-charge reviews and signs at the end of each logbook page ***Note**: Mark "Yes" if there is evidence of consistent review by supervisor or person in-charge.* *Mark "Partial" if there is evidence of inconsistent review of the logbook/register pages by the supervisor or person in-charge* *Mark "No" if there is no evidence of documentation of review by supervisor or person in-charge*
6.7	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 inconsistent practice to ensure client confidentiality* *Mark "No" if there is evidence that the clients' information is not treated as confidential (e.g., clients demographic and HIV register accessible to all) and may result in a confidentiality breach.*

6.8	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 of a secure location (locked cabinet, drawer, etc.) to store documents and records but they are not kept secure consistently.* *Mark "No" if there is no evidence that the documents and records are properly handled and kept secure (locked cabinet, drawer, etc.).*
6.9	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 label and archive system when registers/logbooks are full*
	SECTION QUESTIONS	**WHAT TO ASK FOR?**	**WHAT TO LOOK FOR?**
7.0	**EXTERNAL QUALITY ASSESSMENT (PROFICIENCY TESTING AND SITE SUPERVISION)**	**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., DTS from the National Reference Laboratory (NRL) for testing and returns the results to	- Verify if EQA/PT program is either site specific or tester specific

		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	- Verify documentation of EQA/PT 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 the testing point, or all testers are enrolled and participate regularly in EQA/PT program.* *Mark "Partial" if there is evidence the testing points and/or 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 test 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 has 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 technician - To see results form, if available or QC/QA log	- 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 review of EQA/PT results every EQA/PT distribution.* *Mark "Partial" if there is evidence of inconsistent review of EQA/PT results.* *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. - The frequency and purpose of the visits - To see the reports from the visits	- Verify the site visit report - Verify in the site report if direct 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 has implemented HIV-1 Recent Infection Surveillance and the site is performing the Rapid Test for Recent Infection (RTRI) proceed with questions 8.1-8.10. Otherwise, STOP here.			
8.0	**HIV-1 RECENT INFECTION SURVEILLANCE USING THE RAPID TEST FOR RECENT INFECTION**	**All safety, testing and documentation procedures are implemented during throughout the three phases of testing**	
8.1*	Have all testers received a comprehensive training on RTRI?	Ask the following:	- Verify dates of trainings - Verify training contents including hands-on sessions

		- How many testers are trained on RTRI? - For documentation of training (e.g., certificates) for all testers including any refresher training - For training manual or training competency criteria	***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 or not all testers at the site that are supposed to perform RTRI testing are trained* *Mark "No" if tester has not been trained or evidence of training is not available*
8.2*	Are there records indicating all testers have demonstrated competency in RTRI prior to testing?	Ask the following: - For documentation of competency assessment for all testers	- Verify documentation of direct observation of the tester performing RTRI testing by trainer, supervisor or person in-charge (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 but not all of the testers* *Mark "No" if there is no documentation of demonstrated competency*
8.3*	Are all current versions of recency SOPs and/or job aids readily available at the site?	Ask the following: - To see all relevant SOPs or job aides on the following: - RTRI testing - Enrollment and consent process - Counseling	- Verify that the relevant job aides and/or SOPs on recency testing process is available. - Verify that the job aides/SOPs are current, accurate and complete and follows testing algorithm (i.e., RTRI is run after national testing

		- Specimen collection and transport (if viral load testing is being implemented for Recent Infection Testing Algorithm [RITA]) - Return of results (if applicable) - Data collection and management	algorithm is completed or run in parallel with second test in HIV rapid test algorithm) - If testing can be observed during audit, verify that the tester refers to the job aides/SOPs during testing and the procedures followed Note: Mark "Yes" if job aides/SOPs are available, current, referred and adhered to during testing process. Mark "Partial" if job aides are available, current, but not adhered to consistently during testing process. Mark "No" if job aides are not available or current and not being adhered to.
8.4*	Is there a sufficient supply of RTRI tests available at the site? Please provide number of tests currently available…….	Ask the following - To see the supply of RTRI test kits - To see stock card - For estimated number of tests used per time period (e.g., per month) or check register to estimate number of patients tested within a particular time period (to compare to number of kits available & gauge whether sufficient numbers are available)	- Based on testing volume, verify the site has enough RTRI kits ***Note**: Mark "Yes" if there is evidence that the kits are in sufficient amount* *Mark "Partial" if there is evidence that supplies of the kits are insufficient or inconsistent* *Mark "No" if there is evidence that there is not enough test kit to perform testing at the time of audit and there are frequent stock outs*
8.5*	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 based on manufacturer's instructions (e.g., stored between 2-30°C, away from direct sunlight) - Thermometer is used to monitor temperature in storage area and temperatures are documented - if applicable, in functioning refrigerator. If test kit is stored in

			refrigerator then the tester takes it out for at least 30 mins to reach room temp prior to testing ***Note:*** *Mark "Yes" if all storage conditions are met and monitored on a routine basis* *Mark "Partial", if some storage conditions are met (i.e., kits located in temperature-controlled environment, but temperature is not being monitored on a regular basis)* *Mark "No" if none of the storage conditions are met*
8.6*	Are RTRI testing procedures being followed (i.e., right volume of sample using correct sample application device, correct read time using timer, correct result interpretation)?	Ask the following: - To observe client testing - 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 - The right volume of sample is being added using the correct specimen collection device - Right buffer and buffer volume Note: if buffer tube is required (i.e., Asante) - the test strip is placed correctly in the buffer tube (i.e. - sample pad down first) - 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.
8.7*	Are the RTRI results documented in the data capture form or logbook correctly (e.g., client demographics, kit name, lot number, expiration dates, tester name, RTRI visual results and recency interpretation) and reviewed by person in charge?	Ask the following: - To see the Recency data capture form or logbook	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, etc.) are captured correctly - Results recorded consistently the same way every time - Recency results recorded correctly (i.e., field checked for presence of control line, verification line and long-term line, - Final interpretation recorded correctly (i.e., Negative, Recent, Long-term) - Results are written legibly if they are not pre-printed in the testing register/logbook - Person in charge signs & dates review of register ***Note**: Mark "Yes" if all key QA elements are documented consistently and is properly used and maintained and person in charge signs & dates after review* *Mark "Partial" if key QA elements are documented inconsistently or no indication that document is reviewed by person in charge* *Mark "No" if key QA elements are not documented, is not properly maintained and/or not reviewed by the person in charge*

8.8*	Are external quality control (QC) specimens (i.e., long-term (LT), recent and negative) routinely used (i.e., monthly) for RTRI?	Ask the following: - If the National Reference Laboratory (NRL) or facility laboratory provides controls for RTRI testing - 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 (e.g., monthly, every new lot, environmental conditions change)?	Verify the following: - Long-term (LT), Recent and Negative controls are available for RTRI testing - Expiration date of QC material - Frequency of QC used according to SOP ***Note**: Mark "Yes" if there is evidence of consistent use of QC samples per SOP. Mark "Partial" if there is evidence of inconsistent use of QC samples. Mark "No" if there is no evidence of QC samples being tested.*
8.9*	Are QC results for RTRI properly recorded (e.g., kit name, lot number, expiration dates, tester name, RTRI visual results and recency interpretation for each level of QC) and reviewed by the person in charge?	Ask the following: - To see the quality control logs or testing register/logbook	Verify the following: - Quality control results are documented in the QC log or testing register/logbook - How the QC results are recorded and interpreted (field ticked for presence of control line, verification line and long-term line, - Final interpretation recorded correctly (i.e., Negative, Recent, Long-term) - Who does the QC testing (i.e., testing per site or per tester)? ***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.*
8.10*	Are appropriate steps taken and documented according to the SOP or		Verify the following: - Quality controls that have incorrect results (QC failure) are documented

	guidelines when RTRI QC results are incorrect?		in the QC log or testing register/logbook - Repeat testing of Quality controls are done if the results are incorrect ***Note**: Mark "Yes" if there is evidence of consistent documentation of QC failures results, repeat testing is done and recorded* *Mark "Partial" if there is evidence of inconsistent documentation of QC failures, repeat testing is done and recorded.* *Mark "No" if there is no evidence of documentation of QC failures and/or the tester does not know the steps to take if QC fails.*
8.11*	Are appropriate steps taken and documented according to the SOP or guidelines for invalid RTRI test results? If yes, how many in the last 3 months……	Ask the following: - To see register or data capture form - For a description of what is done if an invalid is obtained as a result, if no invalids are documented in the register or data capture form	Verify the following: - Invalid test results (if any) are documented in the test result register or data capture form - Invalids are repeated (based on SOP) ***Note**: Mark "Yes" if there is evidence of consistent documentation of invalids, repeat testing is done and recorded* *Mark "Partial" if there is evidence of inconsistent documentation of invalid results or repeat testing is not done and recorded.* *Mark "No" if there is no evidence of documentation of invalid results and the tester cannot articulate the proper procedure to perform when an invalid is obtained.*

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

Facility Name:	No. of Tester(s):
Site Type:	Audit Start Time (hh:mm):
Site code (if applicable):	Audit End Time (hh:mm):
Staff Audited Name:	Duration of Audit:

Section	1	2	3	4	5	6	7	8	Total
Score Received									a =
Expected Score	10	5	11	13	9	9	8	11	b =

% Score = (a/b) x 100 = (_____/_____) x 100 = _____%

Performance Level:

0 (<40%) 1 (40-59%) 2 (60-79%) 3 (89-90%) 4 (>90%)

Section No.	Deficiency/Issue observed	Auditor's Comments	Correction Actions		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):

Guidelines for SPI-RRT Checklist