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

SPI-RRT Checklist

Version S.4.0
(Amended to include Recency study only components - Section S.0 Study Protocol and Section D.0 Study Data Indicators. Version S.4.0 is for sites implementing recency under a study protocol only)

6/5/2020

PART A: CHARACTERISTICS OF THE FACILITY OR TESTING POINT AUDITED

Before completing the checklist, it is important to characterize the testing point to be audited. Please provide relevant information in the summary table below.

<table>
<tr><td colspan="2">Date of Audit (dd/mm/yyyy):</td><td colspan="2">Audit Start Time (hh:mm) :</td><td>Audit Round No:</td></tr>
<tr><td colspan="3">Testing Facility Name:</td><td colspan="2">Testing Facility ID (if applicable)</td></tr>
<tr><td colspan="5">Type of testing point (Circle One)
VCT/HTC PITC PMTCT TB clinic Laboratory Treatment Center Other (Specify)</td></tr>
<tr><td colspan="5">Physical Address:</td></tr>
<tr><td colspan="3">Level (Circle One and specify name)
□ Sub-national 1:
□ Sub-national 2:
□ Sub-national 3:
□ Sub-national 4:
□ Other (Please specify to reflect country context):</td><td colspan="2">Affiliation (Circle One)
□ Government
□ Private
□ Faith-based Organization
□ Non-governmental organization
□ Other:</td></tr>
<tr><td colspan="3">Number of Testers at Site:</td><td colspan="2">Number of clients tested for HIV:

Past Month: Past Quarter:</td></tr>
<tr><td colspan="3">Number of newly identified HIV positives:

Past Month: Past Quarter:</td><td colspan="2">Number of HIV negatives:

Past Month: Past Quarter:</td></tr>
<tr><td colspan="3">Number of newly identified HIV positives tested by RTRI:

Past Month: Past Quarter:</td><td colspan="2">Number of Recent by RTRI or RITA:

Past Month: Past Quarter:</td></tr>
<tr><td colspan="3">Name of the Auditor 1:</td><td colspan="2">Name of the Auditor 2:</td></tr>
</table>

PART B. SPI- RRT Checklist

For each of the sections listed below, please check **Yes, Partial or No**, where applicable. Indicate "**Yes**" only when all elements are satisfactorily present. Provide comments for each "**Partial**" or "**No**" response. State N/A (not applicable) in the comments field of the Section 8.0 questions (*) if the testing site has not implemented the Rapid Test for Recent Infection (RTRI).

SECTION		YES	Partial	NO	Comments	Score
1.0 PERSONNEL TRAINING AND CERTIFICATION						**10**
1.1	Have all testers received a comprehensive training on HIV rapid testing using the nationally approved curriculum?					
1.2	Are the testers trained on the use of standardized HIV testing registers/logbooks?					
1.3	Are the testers trained on external quality assessment (EQA) or proficiency testing (PT) process?					
1.4	Are the testers trained on quality control (QC) process?					
1.5	Are the testers trained on safety and waste management procedures and practices?					
1.6	Have all testers received a refresher training within the last two years?					
1.7	Are there records indicating all testers have demonstrated competency in HIV rapid testing prior to client testing?					
1.8	Have all testers been certified through a national certification program?					
1.9	Are only certified testers performing HIV rapid testing at the site?					
1.10	Are all testers re-certified periodically (e.g., every two years)?					

1.0 PERSONNEL TRAINING AND CERTIFICATION SCORE						
2.0 PHYSICAL FACILITY						**5**
2.1	Is there a designated area for HIV testing?					
2.2	Is the testing area clean and organized for HIV rapid testing?					
2.3	Is sufficient lighting available in the designated testing area?					
2.4	Are the test kits stored according to manufacturers' instructions?					
2.5	Is there sufficient storage space for test kits and other consumables?					
2.0 PHYSICAL FACILITY SCORE						
3.0 SAFETY						**10**
3.1	Are there SOPs and/or job aides in place to implement safety practices?					
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?					
3.4	Is personal protective equipment (PPE) always available to testers?					
3.5	Is PPE properly used by all testers consistently throughout the testing process?					
3.6	Is there clean water and soap available for hand washing and is it consistently used?					
3.7	Is there an appropriate disinfectant to clean the work area available?					
3.8	Is the disinfectant solution available properly labeled with content, date of preparation and date of expiration?					

3.9	Are sharps, infectious and non-infectious waste disposed of according to the segregation instructions?					
3.10	Are infectious and non-infectious waste containers emptied regularly per the SOP and/or job aides?					
3.0 SAFETY SCORE						
4.0 PRE-TESTING PHASE						**13**
4.1	Are there national HIV testing guidelines available at the testing point?					
4.2	Is the national HIV testing algorithm(s) consistently being used at the testing site?					
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?					
4.4	Are SOPs and/or job aides on HIV rapid test procedures and the national testing algorithm up-to-date and accurate?					
4.5	Are only nationally approved HIV rapid test kits available for use?					
4.6	Are all the test kits currently in use within the 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?					
4.8	Is there a process in place for stock management?					
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.)?					
4.10	Are job aides on finger prick or venous blood collection available and posted at the testing point?					
4.11	Are there sufficient supplies available for finger prick or venous blood collection (i.e. lancet, gauze, alcohol swab, etc.)?					

4.12	Are there SOPs and/or job aides describing how client identification should be recorded in the HIV testing register?					
4.13	Are client identifiers recorded in the HIV testing register and on test devices per SOPs and/or job aide?					
4.0 PRE-TESTING PHASE SCORE						
5.0 TESTING PHASE						9
5.1	Are SOPs and/or job aides on HIV testing procedures and the national testing algorithm being referred to and followed during testing?					
5.2	Are there timers available and used for HIV rapid testing?					
5.3	Are sample collection devices (e.g., capillary tube, loop, disposable pipettes, etc.) used accurately to perform the test?					
5.4	Are testing procedures adequately followed?					
5.5	Are external positive and negative quality control (QC) specimens routinely used (e.g., daily, weekly or monthly) according to SOPs or guidelines?					
5.6	Are QC results properly recorded?					
5.7	Are incorrect and/or invalid QC results properly recorded?					
5.8	Are appropriate steps taken and documented when QC results are incorrect and/or invalid?					
5.9	Are QC records reviewed by the person in charge routinely?					
5.0 TESTING PHASE SCORE						
6.0 POST TESTING PHASE - DOCUMENTS AND RECORDS						9
6.1	Is there a national standardized HIV rapid testing register/logbook that includes all of the key quality elements available and in use?					

6.2	Are all the elements in the register/ logbook recorded/captured correctly? (e.g., client demographics, kit names, lot numbers, expiration dates, tester name, individual and final HIV results, etc.)?					
6.3	Is the total summary at the end of each page of the register/logbooks complied accurately?					
6.4	Are invalid test results recorded properly in the register/logbook?					
6.5	Are appropriate steps taken and documented when a result is invalid?					
6.6	Are the register/logbook pages routinely reviewed for accuracy and completeness by the person in charge?					
6.7	Are all client documents and records securely kept throughout all phases of the testing process?					
6.8	Are all registers/logbooks and other documents kept in a secure location when not in use?					
6.9	Are registers/logbooks properly labeled and archived when full?					
6.0 POST TESTING PHASE - DOCUMENTS AND RECORDS SCORE						
7.0 EXTERNAL QUALITY ASSESSMENT (PROFICIENCY TESTING/EQA AND SITE SUPERVISION)						**8**
7.1	Is the testing point enrolled in an EQA/PT program?					
7.2	Do all testers at the testing point test the EQA/PT samples?					
7.3	Does the person in charge at the testing point review the /PT results before submission to NRL or designee?					
7.4	Is an EQA/PT report received from NRL and reviewed by testers and/or the person in charge at the testing point?					
7.5	Does the testing point implement corrective action in case of unsatisfactory results?					
7.6	Does the testing point receive periodic supervisory visits?					

7.7	Is feedback provided during supervisory visit and documented?					
7.8	If testers need to be retrained, are they being retrained during the supervisory visit?					
7.0 EXTERNAL QUALITY ASSESSMENT (PROFICIENCY TESTING/EQA AND SITE SUPERVISION) SCORE						
If the country has implemented HIV-1 Recent Infection Surveillance and the testing site provides the Rapid Test for Recent Infection (RTRI) proceed with questions 8.1-8.11. Otherwise, STOP here.						
8.0 HIV-1 RECENT INFECTION SURVEILLANCE USING THE RAPID TEST FOR RECENT INFECTION						**11**
8.1*	Have all testers received a comprehensive training on RTRI?					
8.2*	Are there records indicating all testers have demonstrated competency in RTRI prior to testing?					
8.3*	Are all current versions of recency/RTRI SOPs and/or job aids readily available at the site?					
8.4*	Is there a sufficient supply of RTRI tests available at the site? Please provide number of tests currently available…….					
8.5*	Are the test kits kept in a temperature-controlled environment based on the manufacturers' instructions?					
8.6*	Are RTRI testing procedures being followed (i.e. right volume of sample using correct sample application device, correct read time, correct result interpretation)?					
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 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?					

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 person in charge?					
8.10*	Are appropriate steps taken and documented according to the SOP or guidelines when RTRI QC results are incorrect?					
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……					
8.0 HIV-1 RECENT INFECTION SURVEILLANCE USING THE RAPID TEST FOR RECENT INFECTION SCORE						
If the country has implemented HIV-1 Recent Infection Surveillance under a study protocol proceed with Section S.0 and D.0 Otherwise, STOP here. Please note that Section S.0 and D.0 are for study purposes only and are not to be included in the overall SPI-RRT score.						
S.0 HIV-1 RECENT INFECTION SURVEILLANCE STUDY PROTOCOL						
S.1*	Are counselors adhering to the study protocol for eligibility, consent, and counseling?					
S.2*	Are counselors following the study protocol for confirming new diagnosis?					
S.3	For those patients with RTRI recent, are VL tests requested, samples collected and sent to VL testing lab, and VL test requests recorded in the recency VL order form?					
S.4*	Are processes in place and well documented (Job Aid, SOP, etc.) for returning RTRI results? (if applicable)					
S.5*	Are RITA results returned to the facility/client within 2 weeks (dependent on protocol)?					
S.6*	Are protocol violations documented?					
S.7*	Are appropriate steps taken and documented according to the study procedures when a protocol violation occurs?					

D.0 HIV-1 RECENT INFECTION SURVEILLANCE USING DATA INDICATORS	Number	Denominator	Score		

D.1*	Number of persons aged > 15 newly diagnosed with HIV at service delivery point during review period					
D.2*	Number of candidates screened for participation in RTRI at service delivery point during review period		(see number for D.1)			
D.3*	Number of total eligible candidates at service delivery point during review period		(see number for D.2)			
D.4*	Number of eligible candidates at service delivery point who declined during review period		(see number for D.3)			
D.5*	Number of candidates with documented reason for refusal at service delivery point during review period		(see number for D.4)			
D.6*	Number of participants enrolled in RTRI testing at service delivery point during review period		(see number for D.3)			
D.7*	Number of participants incorrectly enrolled (i.e. ineligible) at service delivery point during review period					
D.8*	Number of eligible participants enrolled with correct consent documentation at service delivery point during review period		(see number for D.3)			

*Those marked with an asterisk are only applicable to sites where RTRI testing is being performed.

Audit End Time (hh:mm):

PART C: SCORING CRITERIA

Each element marked will be assigned a point value:

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

Total points scored for each section should be tallied and recorded at the end of the section. The total number of points expected for all eight sections is 75. If section 8.0 is not applicable then the total number of points expected for seven sections is 64.

The overall total points obtained by each HIV testing point audited will be weighed to correspond to a specific performance level.

Levels	% Score	Description of results

Level 0	Less than 40%	Needs improvement in all areas and immediate remediation
Level 1	40% - 59%	Needs improvement in specific areas
Level 2	60%-79%	Partially eligible
Level 3	80%-89%	Close to national site certification
Level 4	90% or higher	Eligible to national site certification

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

Facility Name:
Site Type:
Site code (if applicable):
Staff Audited Name:

No. of Tester(s):
Audit Start Time (hh:mm) :
Audit End Time (hh:mm):
Duration of Audit:

Section	1	2	3	4	5	6	7	8	Total
Score Received									a =
Expected Score	10	5	10	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):