Stepwise Process for Improving the Quality of HIV-Related Point-of-Care Testing (SPI-POCT) Checklist

SPI-POCT Checklist (Instrument based)

Version 2.0

9/16/2014

SPI-POCT Checklist

Level (Specify all appropriate names) **Region/Province:** **District:** **Referral center:** **Health center:** **Dispensary:** **Health Post:** **Other:**	**Affiliation (Circle One)** **Government** **Private** **Faith-based Organization** **Non-governmental organization** **Other:**
Name of POCT Facility/ Site:	
Location/Address of POCT Facility/ Site:	
Location of Point-of-care Testing Service:	
Point-of-care Test offered (list all):	
POCT Facility/Site Supervisor or point of contact:	
Name of the Auditor:	
Signature of Auditor:	**Date of Audit:**

Levels	% Score	
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 site certification)**
Level 4 =	**90% or higher**	**(Eligible for certification)**

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 in the comments section if "not applicable" where appropriate (*).

SECTION		YES	Partial	NO	Comments	Score
1.0 Integration of POCT service for Patient Care ***POCT services should be offered so results are interpreted and utilized to support HIV+ patient care, in accordance with national/sub-national/facility guidelines, policy and regulations***						**6**
1.1.	Is there a testing algorithm/guideline at the facility/site for using POCT results for Patient Care?					
1.2.	Does the testing algorithm/guideline specify on which patients and when POCT should be performed?					
1.3.	Does the testing algorithm/guideline include steps for result interpretation?					
1.4.	Does the testing algorithm/guideline specify when to provide results to patient for medical review?					
1.5.	Is there a plan or policy for an alternative algorithm or testing facility in case the POCT facility/site is unable to provide POCT? (ie stockouts, expired reagent, equipment failures, etc.)					
1.6.	Are the testing algorithm/guidelines current? Have they been reviewed and/or approved within the last 2 years?					

2.0 Personnel Training, Competency, and Certification ***POCT services should be offered so results are interpreted and utilized to support HIV+ patient care, in accordance with national/sub-national/facility guidelines, policy and regulations.***						**9***
2.1.	Does the POCT facility/site have a policy specifying which cadre may perform POCT?					
2.2.	Does the POCT facility/site have a policy specifying the qualification of the POCT personnel?					
2.3.	Have all POCT personnel received training on specimen collection and processing for each POC test? Has the training been documented?					
2.4.	Have all POCT personnel received training on the POC test procedure? Has the training been documented?					
2.5.	Have all POCT personnel received training on results recording and interpretation? Has the training been documented?					
2.6.	Have all POCT personnel received training on QC testing and QC results interpretation? EQA/PT testing? Has the training been documented?					
2.7.	Does the POCT facility/site have a documentation to ensure that each POCT personnel annually maintain a satisfactory level of competency?					
2.8.	For competency assessment is direct observation of routine test performance, including, as applicable, patient identification and preparation, specimen collection and processing, testing procedure, and result recording?					
2.9.	For competency assessment is there a review of POCT personnel performance with results reporting and interpretation, QC testing, EQA result, and/or equipment maintenance?					
2.10.	*If available, are all POCT personnel certified to perform each specific POCT?					
3.0 Physical Facilities ***The POCT facility/site should be adequate to provide safe and effective POCT services.***						**5**

3.1	Are there designated areas for POCT?					
3.2	Are the designated POCT areas clean and organized for POCT?					
3.3	Are each of designated areas of adequate space, lighting and environmental control to perform POCT?					
3.4	Is there sufficient and secure storage for POCT reagent, supplies, and equipment?					
3.5	Is there environmental monitoring of temperatures at the POCT area and reagent storage?					
4.0 Safety ***The POCT facility/site should have organization and processes in place providing for safety of staff, patients, and community.***						**6**
4.1	Does the POCT facility/site have documented procedures for handling and disposable of biohazardous material?					
4.2	Does the POCT facility/site have documented procedures and/or policies for safety in the work place?					
4.3	Are there SOPs and/or job aides in place to manage spills of blood and other body fluids?					
4.4	Are all POCT personnel trained on handling biohazardous material, workplace safety, and spill management? Is there documentation of these trainings?					
4.5	Is Personnel Protective Equipment always available? Gloves or other PPE, as appropriate, must be available.					
4.6	Are biohazardous waste and sharps containers available and appropriately labeled?					
5.0 PRE-TESTING PHASE ***The POCT facility/site should provide for a standardize system for patient handling and identification, specimen collection and processing, and recording of patient/specimen information.***						6

5.1	Are SOPs and/or job-aids available for patient handling and patient identification?					
5.2	Are SOPs and /or job-aids for specimen collection and processing, including specimen storage conditions?					
5.3	Are there SOPs and / or job-aids for recording of patient/specimens? Including specimen identification?					
5.4	Are there standardized forms/registers/logbooks or /electronic files available for recording patient/specimen information?					
5.5	Are all standardized forms/registers/logbooks or /electronic files complete and legible?					
5.6	Are pre-testing procedures being adequately followed? Included safety practices and biohazardous disposable? (direct observation)					
6.0 TESTING PHASE ***The POCT facility/site should provide for a standardize system to perform POCT and included QC testing and troubleshooting guides***						**5**
5.1	Are SOPs and/or job-aids available for the POC testing procedures?					
5.2	Does the testing SOPs and/or job-aids specify how each sample is identified during the testing procedure and linked to patient/specimen?					
5.3	Does the testing SOPs and /or job-aids specify when and how to preform QC testing? Does the SOPs and /or job-aids include interpretation QC results and troubleshooting sets for failed QC results?					
5.4	Does the SOPs and or jo-aids include interpretation of patient results and troubleshooting sets for failed/invalid results?					
5.5	Are testing procedures adequately followed (direct observation)?					
7.0 POST-TESTING PHASE ***The POCT facility/site should provide for a standardize system for POCT results to be recorded and reported and include a system for recording QC results***						**5**

7.1	Are SOPs and/or job-aids available for recording and reporting of POCT results?					
7.2	Are there standardized forms/registers/logbooks or /electronic files available for recording POCT patient and QC results?					
7.3	Are all standardized forms/registers/logbooks or /electronic files for recording of POCT results complete and legible?					
7.4	Are SOPs and/or job-aids available or recording POCT QC results? Are the QC results recorded?					
7.5	Are all standardized forms/registers/logbooks or /electronic files properly labeled and kept in a secure location?					
8.0 Supplies, Reagents, and Equipment ***The POCT facility/site should provide for adequate and reliable stocks of supplies and reagents, and functional equipment and instruments.***						**5/8***
8.1	Are supplies available and in date for specimen collection? (ie.lancets, gauze, alcohol swabs, plasters, tubes, etc)					
8.2	Are POCT reagents and supplies available and in date?					
8.3	Are all POCT and specimen collection supplies and reagents stored as recommended by manufacturer?					
8.4	Are all POCT and specimen collection supplies and reagents inventoried monthly?					
8.5	Are there procedures and / or policies for ordering and receiving supplies and reagents?					
8.6*	Are all equipment and instruments functional?					
8.7*	Are there SOPs and job / aids available for maintaining of equipment and instruments? Including troubleshooting steps and procedures?					

8.8*	Is there document of equipment and instrument routine maintenance and troubleshooting /repairs?					
9.0 Monitoring Quality ***The POCT facility should provide for a quality monitoring system to ensure accurate and reliable POCT results.***						**6**
9.1	Are all POCT results regularly reviewed by a site supervisor or external monitor? Does this review included completeness and timing of patient result reporting, error/invalid test rates, interruption in testing, and individual POCT personnel performance?					
9.2	Does the POCT facility/sites verify the QC results for acceptability before reporting results?					
9.3	Are QC results regularly reviewed by a site supervisor or external monitor?					
9.4	Is the POCT facility/site enrolled in an EQA/PT program?					
9.5	Does the POCT facility/site report EQA/PT results to the program provider within the set timeframe?					
9.6	Is EQA/PT feedback report received and reviewed? Does the POCT facility/site implement corrective action in case of unsatisfactory results?					

*Those marked with an asterisk may be optional questions; please indicate N/A in the comments section if not applicable.

Auditor's Summation Report for SPI-POCT Assessment

POCT Facility/Site Name: _____
POC Tests offered: _____
Number of POCT Personnel: _____

Audit of Date: _____
Length of Audit: _____

Total Scored (a)=
Total Possible Score (b)=
% Score (a/b)=

Section No.	**Score**	**Possible Score** exclude NA	**Auditor's Comments**	**Recommendations**
1. Integration of POCT service for Patient Care		6		
2. Personnel Training, Compet and Certification		9-10		
3. Physical Facilities		5		
4. Safety		6		
5. Pre-Testing Phase		6		
6. Testing Phase		5		
7. Post-Testing Phase		5		
8. Supplies, Reagents and Equipment		5-8		
9. Quality Monitoring		6		

Auditor's Summation Report for SPI-POCT Assessment

Addition Auditor's Comments	Recommendations

Site Supervisor Name and Signature: _____ Date: _____

Auditor Name and Signature: _____ Date: _____