

Appendix E: Sample quality assurance checklist for PMTCT HIV testing

Region/Provider _____

District _____

Site _____

Date _____

Assessor name _____

Assessment instructions: For each question, please write the number 1 if the answer is “Yes” and the number 0 if the answer is “No.” As a general standard, a facility score of 80% or higher in each phase category (pre-testing phase, testing phase and post-testing phase) would be considered to be within acceptable quality assurance parameters for HIV rapid testing

Pre-testing phase			
QUESTIONS	YES = 1	NO = 0	COMMENTS
1. Are there routine testing guidelines available which cover all HIV testing in the facility?			
2. Is the testing algorithm used at the facility current and updated according to the national guidelines?			
3. Are there signed records that all HIV testing procedures have been read and understood by HIV rapid testing personnel?			
4. Have all testing personnel received hands-on training in HIV rapid testing?			
5. Are all testing personnel trained in the use of standardized registers/logbooks?			
6. Are all testing personnel trained in safety and waste management procedures?			
7. Are only MOH-approved kits available for use?			
8. Are testing supplies stored in a secure cabinet or room?			
9. Are test kits stored according to the manufacturer's recommendations?			
10. Is the supply inventory updated periodically and expired materials discarded?			
11. When a kit in the algorithm is expired, and there are no kits available, is testing suspended until more kits become available?			
Total number of “Yes” answers ⇒			
Assessment score ⇒ (“Yes” answers divided by total number of questions)			

Testing phase			
QUESTIONS	YES = 1	NO = 0	COMMENTS
1. Is there a designated area for HIV testing at the facility?			
2. Is there clean water available for hand-washing?			
3. Is sufficient lighting available in the designated testing area?			
4. Is a first-aid kit available to testing personnel?			
5. Are safety gloves available to testing personnel?			
6. Are job aids on specimen collection available and posted?			
7. Are job aids on HIV testing procedures available and posted?			
8. Are job aids on testing algorithms available and posted?			
9. Are timers available and used routinely for HIV rapid testing?			
10. Are test kits used within the expiration date (first-to-expire, first-out [FEFO] principle)?			
11. Are test cartridges properly labelled (i.e. client ID) during use?			
12. Is the nationally standardized testing register/logbook in use?			
13. Are the kit names, lot numbers and expiration dates recorded for every test?			
14. Is the name of the person conducting the test recorded for each test?			
15. Are invalid tests recorded in a register/logbook, and then repeated?			
16. Are positive and negative quality control (QC) specimens routinely used (i.e. daily or weekly) according to country guidelines?			
17. Are QC specimen data recorded in a standardized logbook?			
18. Are appropriate steps documented and taken when QC specimens fail?			
Total number of "Yes" answers ⇒			
Assessment score ⇒ ("Yes" answers divided by total number of questions)			

Post-testing phase			
QUESTIONS	YES = 1	NO = 0	COMMENTS
1. Do testing supervisors routinely review testing logbooks/ registers (e.g. to identify high rates of discordant results between test 1 and test 2)?			
2. Are QC records routinely reviewed by a testing supervisor?			
3. Are registers/logbooks kept in a secure location?			
4. Are registers/logbooks properly labelled and archived when full?			
5. Is annual refresher training on HIV rapid testing offered to testing personnel?			
6. Is the testing site enrolled in an external quality assessment (EQA) programme (e.g. proficiency testing, site supervision, dried blood spot [DBS] retesting)? If yes, which one?			
7. Are proficiency samples tested by all personnel involved in HIV testing?			
8. Are testing personnel retrained when they fail an EQA activity?			
9. Is the site and/or testing personnel certified by the national certification system?			
10. Are sharps (e.g. lancets and needles) disposed of into appropriate containers?			
11. Are test cartridges disposed of into appropriate containers?			
12. Are waste containers emptied regularly?			
Total number of "Yes" answers ⇒			
Assessment score ⇒ ("Yes" answers divided by total number of questions)			

Recommendations/Comments:

Number of staff performing HIV tests _____

Name of: Facility supervisor _____

Nurse _____

Community counsellor _____

Others (please state) _____

Name of current kits in use

Expiration dates

_____	_____
_____	_____
_____	_____
_____	_____