Quality Management Systems for non-laboratory settings – Toolkit

Testing provider competency-based assessment tool

World Health Organization

Testing provider competency-based assessment tool

At the end of the training period and before being authorized to perform testing for clients, it is crucial to ensure testing providers are recognized as competent to perform testing through a competency-based assessment. The objective of the competency-based assessment is to determine whether participants have understood the content of the training and can safely and accurately perform testing, from sample collection, to test result reporting and recording.

The competency-based assessment should be carried out by an authorized trainer/assessor, at the end of the initial training using nationally validated standardized tools. It should be composed of a theoretical and practical test and a final score should be provided to each candidate.

1. The theoretical test is a written questionnaire composed of 25-30 multiple-choice questions covering the entire training session contents.

2. The practical test consists of:

   - Direct Observation (using a standardized checklist) of candidates performing the entire national algorithm correctly and reporting adequate results on the national register template and any other relevant reporting forms using a panel of 4-6 unknown samples (containing at least one positive and one negative sample). In addition, sample collection practice should also be assessed. Trainees could perform the sample collection procedure (and only sample collection) on consenting trainees under trainers' direct observation. To note: If appropriate and allowed, it might also be possible to observe trainees performing the entire test procedure and sample collection on consenting clients attending the testing site.

   - Proficiency test: To be successful the candidate should provide the correct result for each of the 4-6 unknown samples.

The unknown samples could be either DTS samples provided from the national/subnational level or stored samples from the closest testing site.

To pass the competency-based assessment, candidates will be required to have minimum passing scores of 80% on the theoretical test and 90% on direct observation part and 100% for the proficiency test.

An authorization of practice/work letter must be provided by the trainers to all successful candidates.

An example of Competency-based assessment theoretical and practical tests can be found on the RT-CQI website (https://rtcqi.org/resources/tester-certification#training-packages) and bellow.

Materials needed to conduct competency-based assessments:

- All test kits included in the algorithm for each disease the testing provider is to test (including the 3 tests included in the national HIV testing algorithm)
- Tests SOPS, bench aids and IFUs
- Sample collection materials: lancet or sterile swabs for each participant to perform sample collections
- Personal protective equipment (PPE), including gloves, gowns, eye protection or face shields and medical masks
- Unknown samples: DTS, or stored samples based on the country's decision
- Permanent pens for marking or labelling
- Household bleach, ethanol, and paper towels to clean the workstation and hands and other IPC materials
- Soap for handwashing
- leak-proof biohazard bags for containing or moving biohazard waste and waste bins
- timers
- Stationary material
- testing Logbook, registers, and any other relevant reporting forms
- Blank written test questionnaire forms
- Blank direct observation checklists
- Blank authorization of practice/work letters

1. Theoretical Test

Instructions:

- The moderator will provide the tester with this test form.
- The tester will be required to answer 25-30 multiple-choice questions on the content presented in the training in 45 minutes.
- The tester will obtain 1 point for each question answered correctly.
- to be successful the testing provider should obtain a score of minimum 80%

The theoretical test can be designed/adapted by countries/ external partners based on the training content and testing providers requirements, and type of test kits and testing strategies used in the country.

In the table below you can find example of questions:

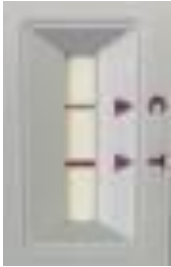| Question No	Question	Answer Key
1	Who is responsible for the quality of testing at the testing site? A. everyone B. Testing provider C. Testing site supervisor C. Quality officer D. National Reference Laboratory personnel	A
2	Which of the following statements best describes what you do during the post-testing phase? A. Record test results into a standardized testing register B. Add the sample to test device C. Add the buffer to the test device D. Write the client's name on the test device	A
3	Which factor may compromise the quality of rapid testing? A. Testing quality control samples on a regular basis B. Store rapid tests as manufacturer's instructions (IFU) C. Checking the expiration date of the test kit prior to use D. Recording a non-reactive result after 13 minutes, although the manufacturer requires the test to be read between 15-30 minutes	D
4	When can you use expired rapid test kits to test a client? A. When the control line is present B. When you run out test kit and you have clients waiting to be tested C. When the kit has been properly stored D. You never use an expired test kit to test a client	D
5	What is the first thing you would do if there is no control line visible, but the test line is reactive? A. Repeat the test using a new device B. Check temperature records for storage and testing areas C. Record the result as reactive D. Report the result to the client	A
6	If the control line is extremely faint, the test is A. Invalid B. Valid C. Damaged D. Non-reactive	B

7	Which statement best describes how the chase or running buffers should be used?	B
	A. Chase or running buffers from different rapid tests are interchangeable	
	B. Chase or running buffers from different rapid tests are not interchangeable	
	C. Chase or running buffers from the same rapid tests are interchangeable even if they have different lot numbers	
	D. Chase or running buffers can be replaced with saline if there is a stock out issue	
8	Which of the following is an immediate step taken when a test provider has a sharps injury:	B
	A. For injuries that break the skin, do not allow bleeding and wash with soap and water	
	B. For injuries that break the skin, allow bleeding for few seconds and wash with soap and water	
	C. Apply disinfectants into the wound	
	D. Inform another test provider of the exposure and the action taken	
9	An appropriate sharps container must have puncture-proof walls, leak proof sides and bottoms.	A
	A. True	
	B. False	
10	Which of the following items could be a risk for infection at a testing site?	A
	A. Used lancets	
	B. Alcohol swabs and gauzes	
	C. Sterile Gloves	
	D. New Apron or Lab coat	
11	What should a test provider do to ensure a valid sample is collected for rapid testing?	D
	A. Make sure the first drop of blood is collected	
	B. Use any sample collection device available	
	C. Ensure the sample is collected using any collection device	
	D. Ensure the correct sample volume is collected using the test specific collection device	
12	Why is it important to warm up the hand or finger to be pricked?	A
	A. To increase the blood flow	
	B. To make the client comfortable	
	C. To make the provider comfortable	
	D. It does not really matter	

13	You run an RDT on a client sample. According to the test instructions for use, the maximum reading time is 15 min. You were distracted by your boss, who came to ask you a question, and you only read the result after 20 min. What would be your action if, when reading the RDT result, you see a faint line in front of 'T' (test line) and a line in front of 'C' (control)?	D
	A. Record the test as reactive	
	B. Record the test as negative	
	C. record the test as invalid	
	D. Repeat testing	
14	Using a serial three tests algorithm to diagnose HIV, the following results were recorded Test 1: Reactive; Test 2: Reactive. Test 3: non-reactive. What is the HIV status of the client?	A
	A. Client is HIV Positive	
	B. Client is HIV Negative	
	C. Client is Reactive	
	D. Client's result is Indeterminate	
15	When can HIV infection be diagnosed with 2 tests	D
	A. In the case of stockout of one of the tests included in the algorithm	
	B. During outreach campaign	
	C. During labour	
	D. Never	
16	Which of the following is TRUE about Recordkeeping?	A
	A. Helps to properly document and maintain the testing results	
	B. The standardized registry/logbook should be used to share with relatives of the patient	
	C. Cannot be used to track test kit consumption	
	D. Is used to record the information in different ways every time	
17	Which of the following is TRUE when storing a standardized HIV Test Register/Logbook?	A
	A. It is only accessible by authorized personnel	
	B. It is kept in a central location for client to view and sign	
	C. It kept in an unlocked cabinet when it is not in use	
	D. It is kept in a central location readily available for all staff	
18	A standardized Register/logbook allows a test site to do which of the following:	C
	A. Identify problems with the client	
	B. Determine test kit consumption only	
	C. Determine areas that need improvement	

	D. Provide information about the last training received by the test provider	
19	What is the CORRECT statement about corrective action?	A
	A. An action taken to resolve a problem	
	B. An action taken to create a problem	
	C. A disciplinary action taken against the test provider	
	D. A disciplinary action taken against the client	
20	Testing of unknown samples that you received from the national reference laboratory is known as:	B
	A. Quality Control (QC)	
	B. Proficiency testing (PT)/External Quality Assessment (EQA)	
	C. Quality performance	
	D. Quality assurance (QA)	
21	What should a test provider do when recommendations for improvement are provided by a supportive supervision team?	A
	A. Discuss with the person in charge of the test site how best to implement the recommendations	
	B. Discuss with the person in charge of the test site only the recommendations that can be implemented if time permits	
	C. Discuss with the person in charge of the test site that the recommendations are not relevant	
	D. Agree with the person in charge of the test site that the recommendations can be implemented when all testers are available	
22	What best describes the implication of a breach of confidentiality?	A
	A. Stigma towards to the client	
	B. Respect for client	
	C. Gain of trust	
	D. Improved communication skills	
23	Which of the following may be considered as a violation of professional ethics?	C
	A. Always following the national algorithm while performing HIV tests	
	B. Seeking permission before sharing a client's result with a relative	
	C. Using an expired test kit to perform client test	
	D. Referring a client to a nearby facility in case of stockout of test kits	
24	To ensure continuous tests availability, when does a test order need to be placed by a testing site?	D
	A. Always at the same period independently of the workload	
	B. Always at the same period independently of stock status	
	C. When requested by supervisor	

	D. Always at the same period and if the testing site reach the alert stock	
25	What should a test provider do when he/she suspects a false result? A. give result to the client B. give result to the client and contact his/her supervisor to discuss this case C. re-do testing with another test D. Stop testing and contact the supervisor	C
26	What is an alert stock? A. A stock quantity that indicates that an order needs to be placed without delays to avoid stock out B. A workload level which indicates the testing site fulfil his objectives C. A stock quantity which indicates test kits are almost expired C. A stock quantity which indicates a donation to another site needs to be planned	A
27	What is the recommended frequencies for External Quality Control (known samples tested in the testing site) A. Every year when requested by the national reference laboratory B. Every new batch, every new user and every storage condition concerning events C. When time allowed D. During supervision visits	B
28	Observe the test results has shown by the pictures below and for each picture, indicate what is the result?	
29	A. Reactive B: Negative C: invalid D: none of the above.	B
30	A. Reactive B: Negative C: invalid D: none of the above.	C

31	A. Reactive B: Negative C: invalid D: none of the above.	A
32	A. Reactive B: Negative C: invalid D: none of the above.	B
33	A. Reactive B: Negative C: invalid D: none of the above.	A

Score	Nb of correct (yes) answers	%
	X	(X/25 or 30) * 100

Moderator's name: _____   Date (dd/mm/yy): __ __/__ __/__ __

2. Practical Test:

   a. Instructions: direct observation

- Testers should wear adequate PPE.
- Testers should prepare the workspace and all necessary materials
- Testers should conduct testing in accordance with the SOPs, bench aids and Instructions for Use (IFUs).
- Assessor should observe the tester and fill the standardize checklist (example below)
- The tester must perform the tasks outlined in the checklist correctly. If not, the answer should be "NO," and the testing provider will obtain 0 points. A comment should be included in the last column.
- For each correctly performed item, the tester will obtain 1 point.
- To be successful the tester should obtain a score of minimum 90%

   . Direct observation sample collection and conduct testing on samples (DTS, store samples, or clients) using observation check list

Testing provider name: _____   Date (dd/mm/yy): __ __/__ __/__ __

		YES	NO	comments
TEST PREPARATION				
1	Is the testing area sufficiently light?			
2	Is the testing area clean and organized?			
3	Are all materials put out ready for use before testing starts (test strip, capillary tube, buffer, timer, lancet, alcohol pad, cotton)?			
4	Has the operator checked and documented the expiration date before using the test?			
5	Is adequate time allowed for the test kit to reach room temperature before testing begins? (if store in the fridge)?			
HYGIENE AND BIOSAFETY				
6	Is the testing area clean?			
7	Does the operator wear clean gloves (when working in a lab) or new gloves (for each new sample collection procedure on client)?			
8	Does the operator use an infectious waste bin for infectious materials?			
9	does the operator use a sharps container for sharp items (needle, lancet...)?			
SAMPLE COLLECTION AND TEST PERFORMANCE				
10	Is there a SOP and/or job aid available to the tester?			
11	Is the patient's identity checked?			

12	Is the test strip/cassette/tube clearly labelled with the client's ID?			
13	Is the protection of the strip/cassette removed just before performing the test?			
14	Is the finger well dry before pricking?			
15	Is the first drop of blood removed before collecting blood?			
15	Is the capillary tube/collection item filled with the correct amount (refer to IFU) with blood without bubbles?			
16	Is the correct amount of sample dispensed delicately on the sample pad (refer to IFU)?			
17	Does the operator adhere to the correct timing for the procedure? (refer to IFU)?			
18	is timer set and used correctly for the test (refer to IFU)?			
READING AND REPORTING RESULTS				
19	Is the test interpreted within the reading time after buffer application (refer to IFU)?			
20	Is the presence of the control band checked before interpreting the test?			
21	Is a negative result interpreted correctly?			
22	Is a positive result, even a faint band, interpreted as positive?			
23	Is an invalid result repeated and recorded?			
24	Does the operator record the result on the client's file and in the register correctly?			

Score	Nb of correct (yes) answers	%
	X	(X/24) * 100

Moderator's name: _____   Date (dd/mm/yy): __ __/__ __/__ __

b. Proficiency testing exercise

Instructions:

Tester should test 4-6 unknown samples using appropriate tests and algorithms and record the results obtained on appropriate forms

sample	Tester result	Expected result	good (1)/ wrong (0)
Sample 1			
Sample 2			
Sample 3			
Sample 4			
Sample 5			
Sample 6			

Score	Nb of correct (good) results	%
	X	(X/6) * 100

Moderator's name: _____   Date (dd/mm/yy): __ __/__ __/__ __

C. Final score and Conclusion

Tester's name: _____   Date (dd/mm/yy): __ __/__ __/__ __

Performance targets met?			If NO, add comment
Score Part A (written test): ≥ 80%?	θYES	θNO	
Score Part B (direct observation): ≥ 90%?	θYES	θNO	
Score Part C (proficiency testing exercise): =100%?	θYES	θNO	
Conclusion: Tester passed competency assessment	θYES	θNO	

Tester can only pass the competency test if the scores for individual Parts A, B and C, are ALL met.

Assessor's name: _____   Date (dd/mm/yy): __ __/__ __/__ __

For all successful candidates, an authorization of work/practice should be provided

For non-successful candidates, assessors should explain what was missed and what should the tester improve to be successful in the future.