

**Directorate of Malaria Control,
Ministry of Inter Provincial Coordination**

Checklist for RDT Center

A. Geographical information

Province	District	Facility	Date of visit

B. Facility information

Medical Officer/In-charge	District Lab. Supervisor	Catchment area population	Date (Last visit)

C. Stock update

RDTs available in stock	CQ tablets available in stock	CQ syrups available in stock	ACT adult doses available in stock	ACT child doses available in stock

Tab. Primaquine 15 mg available in stock	Tab. Primaquine 7.5 mg available in stock	Inj. Artemether 80 mg available in stock	Inj. Artemether 40 mg available in stock

D. Store and storage

Sr. No.	Item	Observation		
		Available	#	3-month supply
1	RDT stored in a cool, shaded area			
2	RDT protected from heat, fire, rain, pests, etc.			
3	RDT sufficient stock			
4	Lancets			
5	Alcohol			
6	Cotton			
7	CQ tabs			
8	CQ syrup			
9	Tab. Primaquin 15 mg			
10	Tab. Primaquin 7.5 mg			
11	Inj. Artemether 80 mg			
12	Inj. Artemether 40 mg			
13	ACTs adult doses			
14	ACTs child doses			

E. Quality assurance

Sr. No.	Item	Observation	
		Yes	No
1	FM 1 register complete, up-dated and includes monthly summary?		
2	HW attended a formal training on RDT?		
3	HW has been supervised at least once during past one month by the facility in-charge?		

Guidelines on checklist for Rapid Diagnostic Test (RDT) Center

A. Geographical Information

Write down the name of province, district, malaria rapid diagnostic Test (RDT) facility and date of visit.

B. Facility information

Write down the name of in-charge of facility and in-charge of lab. Give the catchment area population and date of last visit conducted by the visiting officer/official, along with designation.

C. Stock Update

Give the available no. of following items in the stock from stock register malaria program and physical validation of the items against the no. in the stock register (Book balance should be equal to the physical balance)

1. RDTs
2. CQ Tablets
3. CQ Syrups
4. ACT Adult doses
5. ACT child doses
6. Tab. Primaquine 15 mg
7. Tab. Primaquine 7.5 mg
8. Inj. Artemether 80 mg
9. Inj. Artemether 40 mg

D. Store and Storage

(By observation, tick Yes or No column for the following points)

1. RDT stored in a cool, shaded area.
2. RDT protected from heat, fire, rain, pests, theft etc.

(Following stock should be available for 3 months. It can be calculated by multiplying daily average consumption with 90.)

3. Sufficient stock availability of RDT for 3 months
4. Lancets available and adequate for 3 months
5. Alcohol available and adequate for 3 months
6. Cotton available and adequate for 3 months
7. CQ tabs received available and adequate for 3 months
8. CQ syrup available and adequate for 3 months
9. Tab. Primaquin 15 mgTab.
10. Primaquin 7.5 mg
11. Inj. Artemether 80 mg
12. Inj. Artemether 40 mg
13. ACTs adult doses
14. ACTs child doses

E. Quality assurance

(By observation, tick Yes or No for the following points)

1. FM 1 register complete, up-dated and includes monthly summary?
Check the register and find the status of accuracy and completeness of the register.

2. HW attended a formal training on RDT?
Check for the training completion certificate/record of health worker on RDT.
3. HW has been supervised at least once during past one month by the facility in-charge?
Check the signatures of facility in-charge in the register on FM1 register.
4. HW has been supervised at least once during past 3 months by the DLS or an external senior supervisor?
Check the signatures and visit notes of any senior officer or district laboratory supervisor in the FM1 register during specified period.
5. Procedure manual/job aid available in the testing site?
Check for the availability of any such document. The generic instructions, job-aids and training manual have been developed with the aim of improving accuracy of RDT diagnosis and blood safety during the diagnostic procedure.
6. Manual/job aid regularly used by the health worker?
Manual should always be in easy access of the HW at all the times.
7. Guidelines on treatment and management of RDT outcomes available?
Check for the availability of such guidelines in laboratory.
8. RDT expiry date checked before performing test?
Lab. person should always check the expiry date of RDT. At the time of supervisory visit, no expired RDT should be present on the table or dustbin.
9. RDT device labeled properly?
Check the label on device. The RDT devices (cassette or cardboard housing the nitrocellulose strip) are to be assessed for clearness of design and construction including referral to the RDT kit's name. The space allocated for sample identification is evaluated for dimensions and ease of writing. A space of minimal 0.5 cm height and 4 cm wide is considered as adequate for handwriting of sample identification. The labeling of buffer wells, sample wells and reading windows including the places of appearance of the control and test lines (further referred to as reading label) are assessed for visibility and unambiguous interpretation.
The buffer vials are assessed for leak-proof closure, and their labels for quality of adherence and print. The information displayed on the label is assessed for the presence of RDT kit name, lot number, and expiry date and storage conditions.
10. Proper timing observed before reading test result?
Observe a couple of tests being performed by the staff. Write the *correct* time (e.g., 15 minutes) after adding buffer before *reading test results*. There are several different platforms commonly used to build rapid diagnostic tests. The relative utility of common RDT platforms is summarized below.
Lateral flow tests are the simplest type of RDT, requiring only very minimal familiarity with the test and no equipment to perform, since all of the reactants and detectors are included in the test strip. In a lateral flow test, the sample is placed into a sample well and migrates across the zone where the antigen or antibody is immobilized. The results are read after a certain amount of time has passed. Another type of RDT, a flow-through test, obtains results even faster than lateral flow tests, but requires an added wash and buffer step, which can limit its portability and stability.
An agglutination test works simply by observation of the binding of carrier particles and target analyses into visible clumps, seen either through a microscope or with the naked eye. However, if the binding of the particles is weak, the results of the test can be inconclusive.

Dipstick format RDTs (with binding sites to test for multiple antigens) work by placing the dipstick in a sample. The dipstick is then washed and incubated to prevent non-specific binding. These additional steps can limit their usability in low-resource point of care settings.

11. Test result interpreted correctly?
Read some of the results and check for their correctness.
12. Appropriate container available for used lancets, cotton and other infectious wastes?
Discard the lancet in a sharps-only container immediately after using it. Never put the lancet down before discarding it. Never discard the lancet in a non-sharps container. Check also for the other infectious material, where it is being discarded.
13. Patient details in RDT cross-checked with details in FM1 register before reporting of the result?
Compare both the entries and if these match with each other, tick in the column of yes or otherwise.
14. Test result recorded in patient FM1 register?
Check the FM1 register for few test records.
15. Action taken on RDT results correct?
Check what action has been taken on RDT results. The *result* of an *RDT* should always be interpreted in the light of the clinical picture of the patient, and *taking* into account the limitations of the test.

COMMENTS

Monitor will write down his/her comments, any issue noticed by him or raised by staff or by patient. The monitor should also give his recommendations to improve the work of center.

In the last, monitor will write down his name, designation and sign along with date of visit.