



STANDARD OPERATING PROCEDURES (SOPs) FOR RDTs

UNITAID Private Sector RDT project

OVERVIEW OF THE SOPs FOR RDTs

AIM: These Standard Operational Procedures (SOPs) for malaria Rapid Diagnostic Tests (RDTs) are meant to define a standardized procedure to perform RDTs as agreed by private providers, trainers and supervisors enrolled in the UNITAID Private Sector RDT project.

AUDIENCE: Private providers, trainers and supervisors who are enrolled in the UNITAID Private Sector RDT project.

CONTENTS:

- Materials required to perform RDTs
- Preparing to perform the test
- RDT procedure.

MATERIALS REQUIRED TO PERFORM RDTs

- RDT kit (test cassette, buffer, blood collecting device),
- Sterile lancet,
- Alcohol swab,
- Pencil or pen for labeling,
- Gloves,
- Sharps container,
- Waste disposal container,
- Timer or clock,
- Instruction manual for the specific RDT,
- Dry cotton wool.



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PREPARING TO PERFORM THE TEST

1. Gather the necessary materials in the testing area,
2. Check the expiry date at the back of the test package. If the test kit has expired use another test,
3. Ensure the RDT packaging is not damaged by squeezing gently and feel/listen for air leakage.
Note: if the foil packaging is damaged, use another test kit,
4. Explain to the patient what the test is for and procedure,
5. Open the package tearing along the nick and look for the following
 - a. colour of desiccant (to be consistent with what indicated by the manufacturer),
 - b. cassette,
 - c. dropper,
6. Remove the cassette from the foil packaging and label it with patient particulars and reading time,
7. Wear a new pair of gloves,
8. Disinfect the puncture site (4th finger of the non-dominant hand) with an alcohol swab or appropriate disinfectant. The 4th finger is preferred because it's the least used and will cause least inconvenience even if it becomes sore.

RDTs PROCEDURE

1. Make a gentle prick towards the pulp (ball) of the 4th finger with a sterile lancet at the disinfected site. Pricking at the tip or midline is more painful. Discard the used lancet in an appropriate sharps container immediately after use. By applying gentle pressure to the finger express the first drop of blood and wipe it away with a dry piece of cotton wool. Make sure no strands of cotton remain on the finger to contaminate blood. Apply gentle pressure to the finger until a new blood drop appears. Emphasize the need for the right skills to ensure correct test performance and accurate results. The reason for wiping out the first drop is because it contains too much tissue fluid which might dilute the antigens and it might be contaminated with the alcohol used for wiping the finger.
2. Using the blood collection device (pipette, inverted cup or capillary tube) provided in the RDT kit, gently immerse the open end in the blood drop. Collect the required volume of blood as per manufacturer's instructions. Good blood collection and adequate amount of blood are fundamental to ensure good results. After pricking and collecting blood, apply a dry cotton wool at the puncture site to stop the bleeding. Discard the blood collection device in the box for infectious waste.
3. Transfer the collected blood to the sample well (as indicated on the RDT cassette by the manufacturer). It's important to put the sample in the right well as indicated by the manufacturer. Different manufacturers may have different labeling for the different wells. Discard the blood collection device in the box for infectious waste.
4. Holding the buffer bottle vertically, add the recommended number of drops of buffer into the buffer well. Put the exact amount of buffer as indicated by the manufacturer at the correct well of the test device and don't use any other buffer apart from the one provided and specified. Some test kits will come with a bottle of buffer for many tests and others will have enough buffer packed for a single test.

5. Time the test as recommended by the manufacturer. View the result window of the cassette for colour band(s).
 - a. **Negative** – The presence of only a control band, indicates a negative result for *P. falciparum* malaria. If RDT result is negative, alternative causes of fever should be investigated and treated appropriately. Note: Do not read the results before or after the set time. Don't treat any fever as malaria despite a negative result.
 - b. **Positive** – The presence of both a control band and a test band indicates a positive result. Refer to manufacturer's instructions to read positive results.
 - c. **Invalid** — If the test does not show the control band, even if there is test band, the test is invalid. Perform another RDT.
 - d. Refer to the “RDT Provider job-aid” for pictures of negative, positive and invalid results.
6. Report the results as “RDT Negative” or “RDT Positive” or “RDT Invalid” (in last case the RDT should be repeated. Record patient's information and RDT result in the appropriate register.'
7. Discard the cotton wool, RDT cassette and gloves into the box for infectious waste. Discard empty bottles/ampulla of buffer, instructions and RDT packaging into the box for non-infectious waste.

