

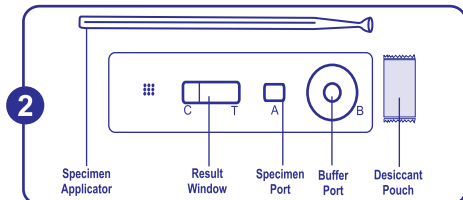


RAPID TEST FOR *P. FALCIPARUM* MALARIA (Ver.3)

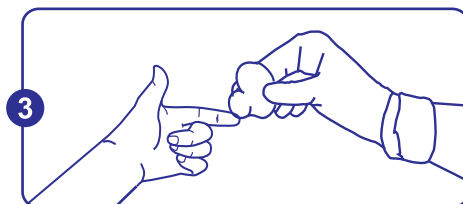
Test Procedure



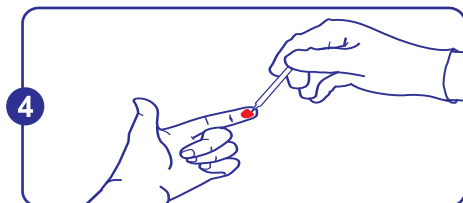
Open pouch at cut mark and remove all the contents; the device, disposable specimen applicator & desiccant pouch. Once opened, the device must be used immediately.



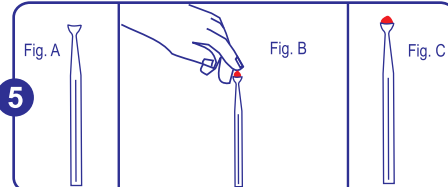
Component details are shown above. Check the colour of the desiccant. It should be blue, if it has turned colourless or pink, discard the device & use a new device.



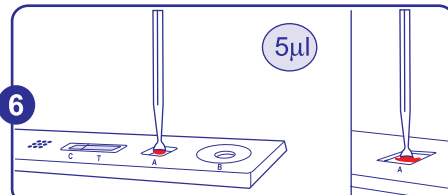
Clean finger to be pricked with an alcohol swab. Allow it to dry.



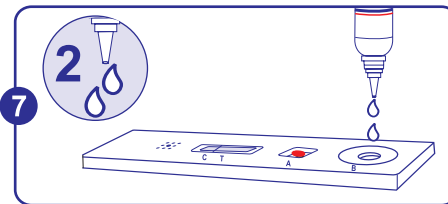
Take a lancet & prick the finger with the pointed end of the lancet.



For blood collection, hold the specimen applicator vertically as shown above Fig A. With the pricked finger facing downwards towards the specimen applicator, allow the blood drop to touch the cup side of specimen applicator, Fig.B. Ensure that the cup full of blood is retrieved Fig C.



Blot the collected blood (5µl) on the specimen port 'A' by touching the applicator vertically straight on the sample port. Ensure that the blood from the applicator has been completely taken up at the specimen pad.

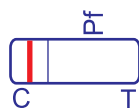


Hold the clearing buffer vial vertically straight over the buffer port 'B' & add exactly 2 drops of buffer onto the buffer port. Start the stop watch.

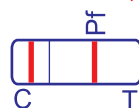


Read the test Results at the end of 20 minutes.

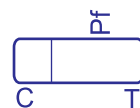
Interpretation of Results



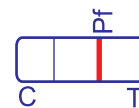
Band on 'C' Area
NEGATIVE
for *P.f.* Malaria



Band on 'C' & 'T' Area
POSITIVE
for *P.f.* Malaria



No band on 'C' & 'T' Area
INVALID
Repeat the test



No band on 'C', Band on 'T' Area
INVALID
Repeat the test

Precautions in Malaria RDT Procedure

Do's

- Once opened use the device immediately.
- Always check the colour of desiccant immediately after opening the pouch. It should be blue in colour, if it has turned colourless or pink, discard the device and use a new device.
- In case of anti-coagulated venous blood, ratio of blood & anticoagulant (1:9) should be accurate as recommended.
- In case test device pouches have been stored at 2°C To 8°C, they must be allowed to come to ambient temperature before pouches are opened.
- Always evenly mix anti-coagulated blood specimen gently before testing.
- Always make sure that the blood from specimen applicator/applicator has been completely transferred to the specimen pad.
- Stored cold whole blood specimen must be allowed to come to ambient temperature before testing.
- Read the result only at the end of recommended reading time of 20 minutes.
- Always lay the device horizontally on a flat surface before testing.
- Users, who interpret the test result must be trained to read the test band signals with low analyte concentration specimens.

Don'ts

- Do not use blood specimens, stored more than 72 hours.
- In case device pouches has been stored at 2°C To 8°C, do not open the pouches immediately after retrieval from 2°C To 8°C storage. Cold devices will attract moisture rush thereby altering migration properties of the membrane.
- Do not use the cold whole blood specimen (<25°C) as test specimen. Use of cold blood may affect the clearance of test window and also affect the sensitivity and specificity of the RDTs.
- Do not use clotted, partially clotted, lysed, or contaminated whole blood specimens.
- Do not reuse the specimen applicator.
- Do not intermix the buffer and device of different lots.
- Do not dispense excess/less drops of buffer in the buffer port than those recommended in test procedure. This could affect the reaction kinetics between target antigen and capture elements of test system.
- Do not move the device during the assay. It could affect the buffer flow.
- Do not compare test band intensity with control band intensity.
- Do not repeatedly freeze/thaw test specimens. Freeze/thaw accelerates target antigen denaturation and hampers test's performance.



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Orchid Biomedical Systems

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