Malaria Total Quick Test

For the qualitative detection of Plasmodium falciparum (P.f.), Plasmodium vivax (P.v.), Plasmodium malariae (P.m.) and Plasmodium ovale (P.o.) antigens in whole blood.

Test Procedure:
1. Ensure all test components warm to room temperature prior to use. Just prior to use, remove the cassette from foil pouch. Lay the cassette flat on the work surface.
2. Prick the finger with the lancet and transfer 5 µl of blood into the round sample well of the test cassette using a sample loop provided. A visible test line on the device only located in the Pan zone indicates a positive test result for Plasmodium falciparum. The control line must also be present.
3. Add 4 drops of assay diluent into square-shaped diluent well.
4. Wait a minimum of 15 minutes (up to 30 minutes) and read the results. Don’t read test results after 30 minutes, this can give false results.

Results Interpretation:
This cassette contains two test result lines: a test line that solely detects Malaria P.f. (line P.f) and a test line that detects all four Malaria Plasmodium species: P.f., P.v., P.o. and P.m. (line Pan). A positive result is indicated when any visible line forms in the result window next to the P.f. or Pan zone together with a line in the C zone.

Plasmodium falciparum detection
1. A visible test line on the strip located in the P.f. zone indicates a positive test result for Plasmodium falciparum. The control line must also be present.
2. A visible test line on the strip located in the P.f. zone and the Pan zone indicates a positive test result for Plasmodium falciparum. The control line must also be present.

Plasmodium vivax, Plasmodium ovale or Plasmodium malariae detection
A visible test line on the device only located in the Pan zone indicates a positive test result for Plasmodium vivax, Plasmodium ovale or Plasmodium malariae. The test cannot distinguish between these three malaria subtypes. The control line must also be present.

Mixed infection:
A visible test line on the strip located in the P.f. zone and the Pan zone may indicate mixed infection of P.f and P.v (or P.o, P.m).

Quality control
- Cypress Diagnostic Malaria Total test includes a procedural control. A control line appearing in the control area indicates proper performance and reactive reagents.
- Good laboratory practice includes the use of external control to ensure proper kit performance.

Limitations of Procedure:
- This test kit detects P.f HRP-II and/or Pan specific pLDH in patient whole blood and is useful as a screening procedure of malaria diagnosis. Reactive samples should be confirmed by a supplemental assay such as microscopic examination of thin blood smear.
- The test is limited to the detection of antigen to Malaria Plasmodium species. Although the test is very accurate in detecting HRP-II of P. falciparum and pLDH of Plasmodium species (P.f., P.v., P.o. and P.m.), a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
- P.f HRP-II line may remain positive for up to 2 weeks following treatment and parasite clearance as confirmed by microscope. Pan line will become negative within days of successful treatment.
- Known interfering specimens, haemolytic samples, rheumatoid factors-contained samples and lipemic, icteric samples can impair the test results.

Performance characteristics:
- In a comparison of the Cypress Diagnostics’ Malaria Total Quick test versus microscopic examination, the results gave sensitivity of 99.7% (P.f.) and 95.5% (Pan), a specificity of 99.5%, and total agreement of 98.9%.

Materials Required but not Included:
- 25 sterile swabs
- 25 sterile lancets
- 25 capillary sample loops (5 µl)
- 25 sterile swabs

For the detection of circulating Plasmodium falciparum antigen (HRP-II) and an antigen (lactate dehydrogenase) that is common to all four species of malaria, Plasmodium falciparum (P.f.), Plasmodium vivax (P.v.), Plasmodium ovale (P.o.) and Plasmodium malariae (P.m.). So, the Cypress Diagnostics Malaria Total Quick Test is designed for the differential diagnosis between P.f. and the other Plasmodium species (P.v., P.m. and P.o.) in whole blood.

This kit is intended for professional use, as an initial screening test and reactive samples should be confirmed by a supplemental assay such as microscopic examination of thin blood smear.

Test Principle:
Cypress Diagnostics Malaria Total Quick Test contains a membrane strip, which is pre-coated with a mouse monoclonal antibody and a mouse polyclonal antibody as two separate lines across a test strip. The monoclonal antibody (test line P.f) is specific to the HRP-II of P.f. and the other polyclonal antibody (test line Pan) is pan specific to the lactate dehydrogenase of Plasmodium species P.f., P.v., P.m. and P.o. After a positive sample is applied, the antibodies on the test membrane will react specifically with the Malaria antigens present in the sample causing a direct sandwich reaction as the complex of membrane-antigen-conjugated antibody. The formed complex results in the appearance of a colored test line. The control line (anti-mouse IgG) is used for procedural control. Control line should always appear if the test procedure is performed properly and the reagents are working correctly.

Storage
The Malaria total test cassettes should be stored at room temperature between 8° and 40° C. Diluent can be stored between 1 and 40° C. The test device is sensitive to humidity and heat. Be sure to un-pouch only the number of cassettes that will be immediately used. The test kit may be used until its expiration date, which can be found on the package label.

Precautions and Warnings:
- Optimal results will be obtained by strict adherence to this protocol. Reagents must be added carefully to maintain precision and accuracy.

Timer

Specimen Collection:
A) To obtain capillary blood via puncture of a finger, clean the area with a sterile swab. Squeeze the end of the fingertip and puncture the skin with a sterile lancet. Wipe away the first drop of blood with sterile gauze or cotton. Take a 5 µl sample loop provided. Dip the circular end of the loop into the blood sample and carefully place the circular end of the loop into the round sample well of the test cassette.
B) Collect venous blood, by the standard venipuncture procedure, into a collection tube (containing EDTA, sodium citrate or heparin). If the test cannot be performed immediately, the blood may be stored for up to three days at 2° - 8°C or at -20°C. A longer storage period is required. Longer storage time at 2°-8°C can cause non-specific reactions. A testing of the sample after a storage of more than 3 days can cause non-specific reactions.