recombigen

CLEAR SCAN PLUS

One Step Malaria Pf/Pv Antigen Test (Whole Blood)

INTENDED USE

For the rapid qualitative determination of Malaria P.falciparum specific histidine rich protein-2 (Pf HRP-2) and Malaria P.vivax specific lactate dehydrogenase (pLDH) in human blood as an aid in the diagnosis of Malaria infection.

SUMMARY

Malaria is a serious parasitic disease characterized by fever, chills and anaemia and is caused by a parasite that is transmitted from one human to another by the bite of infected Anopheles mosquitoes. There are four kinds of malaria that can infect humans: Plasmodium falciparum, P. vivax, P. Ovale, and P.Malariae. In humans, the parasites (called sporozoites) migrate to the liver where they mature and release another form, the merozoites. The disease now occurs in more than 90 countries worldwide, and it is estimated that there are over 500 million clinical cases and 2.7 million malaria-caused deaths per year. At present, malaria is diagnosed by looking for the parasites in a drop of blood. Blood will be put into a microscope slide and stained so that the parasites will be visible under a microscope.

The Malaria Antigen Test contains a membrane strip, which is pre-coated with one monoclonal antibodies as one line across a test strip. One monoclonal antibody (test line 1) is specific to the P. falciparum histidine rich protein-2 (Pf HRP-2) and another monoclonal antibody test line 2) is P.vivax specific to the lactate dehydrogenase of plasmodium vivax species. Conjugate pad is dispensed with monoclonal antibodies conjugated to the colloidal gold, which specific to P.falciparum histidine rich protein-2 (Pf HRP-2) and P.vivax specific to the lactate dehyogenase of plasmodium species. The Malaria Antigen Test is designed for the diagnosis of Plasmodium falciparum and Plasmodium vivax.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.

STORAGE & STABILITY

The kit can be stored at room temperature or refrigerated (1-40°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

Materials Provided:

Test Device, Assay Diluent and Sample loop

SPECIMEN COLLECTION & PREPARATION

(Collection by venipuncture)

1. Collect whole blood into a collection tube containing EDTA, citrate or heparin) by venipuncture.
2. If specimens are not immediately tested, they should be refrigerated at 2~8°C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use. Using the

Specimen after long-term storage more than three days can cause non-specific reaction.

3. When stored at 2~8°C, the whole blood sample should be used within three days.

(Collection using a lancet)

1. Clean the area to be lanced with an alcohol swab.
2. Squeeze the end of the fingertip and pierce with a sterile lancet provided.
3. Wipe away the first drop of blood with sterile gauze or cotton.
4. Take a sample pipette provided, and while gently squeezing the tube, immerse the open end in the blood drop and then gently release the pressure to draw blood into the sample pipette up to the black Optimal assay performance requires strict adherence to the assay procedure described in this instruction sheet and any deviations from the procedure may lead to aberrant results.

DIRECTIONS FOR USE

1. Add 5µl of whole blood into sample well ("S" small well) with the help of sample loop provided with kit. (Do not use excess blood).
2. Add 3 drops or 90-110 µL of assay buffer into developer well ("A").
3. Read the test result at 20 minutes.

NOTE: DO NOT INTERPRET RESULT AFTER 30 MINUTES.

INTERPRETATION OF RESULTS

1) P. falciparum Positive reaction

The presence of two color bands (C and 1) indicates a positive result for P.falciparum.

2) P.vivax Positive reaction

The presence of two color bands (C and 2) indicates a positive result for P.vivax.

3) P. falciparum/ P.vivax Positive reaction

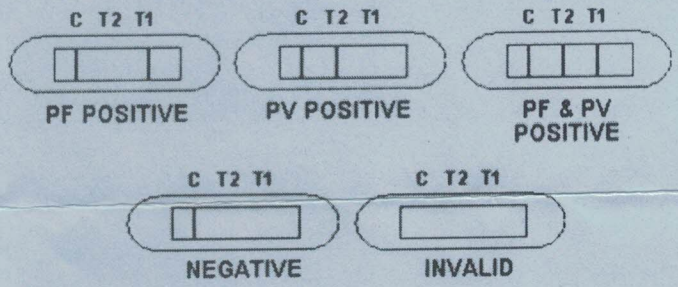
The presence of three color bands indicates a positive result for P.falciparum and P.vivax.

4) Negative reaction

The presence of only one band within the result window indicates a negative result.

5) Invalid

The test is invalid if the C line does not appear. If this occurs, the test Should be repeated using a new cassette.



LIMITATIONS

1. The test procedure, precautions and interpretation of results for this test must be followed during testing.
2. Anti-coagulants. heparin, EDTA, and citrate do no affect the test result
3. This test kit detects Plasmodium lactate dehydrogenase in patient whole blood and is useful as a screening procedure for malaria diagnosis.
4. Do not mix reagent of different lots.
5. The test is limited to the detection of antigen of Malaria Plasmodium falciparum and vivax. Although the test is very accurate in detecting pLDH, 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.

BIBLIOGRAPHY

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