ACCUCARE

One Step Malaria Pf/Pv Ab Detection Test

(Serum, Plasma, Whole Blood)

INTENDED USE

For the rapid qualitative determination of Malaria antibodies 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 ACCUCARE Malaria Pf/Pv test is an immunochromatographic (rapid) test for the qualitative detection of antibodies of all isotopes (IgG, IgM, IgA) specific to Plasmodium falciparum and Plasmodium vivax simultaneously in human serum, plasma or whole blood. The ACCUCARE Malaria Pf/Pv test contains a membrane strip, pre-coated with recombinant malaria Pf capture antigen (MSP, CSP) on test band 1 region and with recombinant malaria Pv antigen (MSP, CSP) on test band 2 region. The recombinant malaria Pf/Pv antigen (MSP, CSP) - colloid gold conjugate and serum sample moves along the membrane chromatographically to the test regions (1,2) and forms a visible line as the antigen-antibody-antigen gold particle complex forms with high degree of sensitivity and specificity.

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 (4-30°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 :

Materials Provided :

Test Device
Assay Buffer
Package Insert
10 µl Dropper

Materials Not Provided:

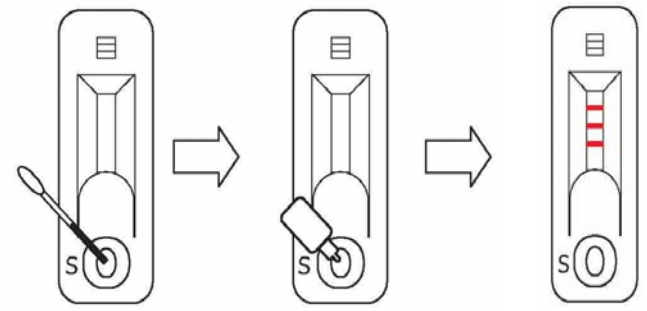
Pipette
Timer

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.

Direction for Use:



Add 10 µl of serum plasma or 20 µl of whole blood to the sample well "S"

Add 1 drop of the assay chase buffer.

Read Result in 20 mins

- **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 10µl (1 drop) of serum / plasma or 20µl (2 drops) of whole blood to the sample well "S".
2. Add 1 drop of the assay chase buffer.
3. Interpret test results in 10 to 20 minutes. Do not interpret test result after 30 minutes.

INTERPRETATION OF RESULTS

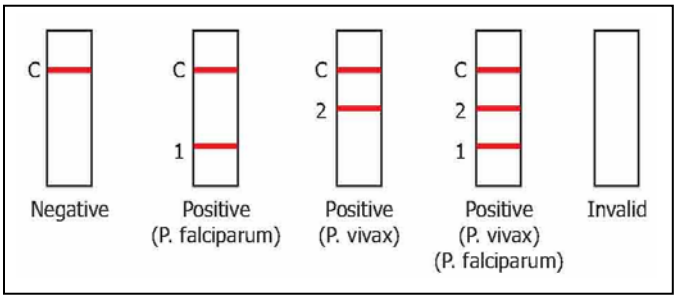
1. **P. falciparum Positive reaction**
   The presence of a color band at 1 & C indicates a positive result for P. falciparum. The antibody present in the sample reacts with the CSP, MSP conjugate and moves through the test strip where the antibody is captured by both P. falciparum specific CSP, MSP antigens.

2. P. vivax Positive reaction

The presence of a color band at 2 & C indicates a positive result for P. vivax. The antibody present in the sample reacts with the CSP, MSP conjugate and moves through the test strip where the antibody is captured by both the P. vivax specific CSP, MSP antigens.

3. Negative reaction

The presence of only one band at the C indicates a negative result.



4. Invalid

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

As no true standards have been established for determining the absence or presence of Malaria (P. falciparum) in whole blood specimens, it is recommended that the performance of the kit be compared to established panels or reference materials if found available.

LIMITATIONS

The test is limited to the detection of antibodies to Malaria both Plasmodium falciparum and Plasmodium Vivax simultaneously. Although the test is very accurate in detecting antibodies to Malaria Pf/Pv, 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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3. Price DL : Procedure Manual for the Diagnosis of Intestinal Parasites. CRC Press, 1994.
4. Voller A : Immunoassay for Tropical Parasitic Infections Trans R Soc. Trop Med Hyg 1993;87:497.
5. World Health Organisation Committee on Malaria, 20th Rep. Report Series 892. WHO 2000.

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