**Malaria P.f. / Pan Rapid Test Cassette (Whole Blood) Package Insert**

A rapid test for the qualitative detection of circulating antigens of *P. falciparum* (P.f.), *P. vivax* (P.v.), *P. ovale* (P.o.), and *P. malariae* (P.m.) in whole blood.

**INDICATIONS**

- Test of clinical specimens from patients suspected of having malaria.
- Diagnosis of malaria in areas where no biological methods are available.

**CONTRAINDICATIONS**

- This test is not intended for use on blood from patients with toxoplasmosis.
- This test should not be used on blood from patients who have been treated with antimalarial drugs within the last 30 days.

**PRECAUTIONS**

- This test should be used as a diagnostic aid, not as the sole criterion for the diagnosis of malaria infection.
- False-negative results may occur with low-density infections.

**SPECIMEN COLLECTION AND PREPARATION**

- **Whole Blood:** Collect the specimen in a sterile, anticoagulated tube.
- **Blood Films:** Prepare thick and thin blood films from the specimen.

**PROCEDURE**

- Place the cassette on a clean and level surface.
- Open the sealed pouch and use it as soon as possible.
- Completely thaw and mix the specimen before testing.
- Ensure the test cassette is stored at room temperature (15-30°C) or refrigerated (2-8°C).
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Wash the patient's hand with soap and warm water or clean with an alcohol swab.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.

**INTERPRETATION OF RESULTS**

- **POSITIVE:** Two or three distinct colored lines appear.
- **NEGATIVE:** No line or only one line appears in the control region, one line appears in the P.f. line region, and one line appears in the Pan line region.

**QUALITY CONTROL**

- Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct processing.

**LIMITATIONS**

- This test should be used for the detection of P.f., P.v., P.o., and P.m. antigens in whole blood.
- False-negative results may occur with low-density infections.

**EXPECTED VALUES**

- **Sensitivity:** The Malaria P.f. / Pan Rapid Test Cassette (Whole Blood) has been tested with microscopy on clinical samples. The results show that the sensitivity of the Malaria P.f. / Pan Rapid Test Cassette (Whole Blood) is 99.9% when compared to results obtained with microscopy.

**PERFORMANCE CHARACTERISTICS**

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**INTERPRETING RESULTS**

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**PRODUCT USE**

- This product is intended for use in vitro diagnostic use only.
- Do not use other specimen types.
- Do not use the test if the expiration date has passed.
- Do not exceed the expiration date.

**STORAGE AND STABILITY**

- The kit can be stored at room temperature or refrigerated (2-8°C). The test cassette is stable for at least 12 months when stored at 2-8°C.
- This product is not intended for use on blood from patients with toxoplasmosis.
- This product should not be used on blood from patients who have been treated with antimalarial drugs within the last 30 days.

**SUMMARY**

- The Malaria P.f. / Pan Rapid Test Cassette (Whole Blood) is a rapid test for the qualitative detection of circulating antigens of *P. falciparum* (P.f.), *P. vivax* (P.v.), *P. ovale* (P.o.), and *P. malariae* (P.m.) in whole blood.
- The test utilizes gold and anti-HRP-II antibodies to detect *P. falciparum* antigens and anti-Plasmodium-specific antibodies to detect non-*P. falciparum* antigens.
- The test cassette is intended for use with whole blood or thin blood films.
- The kit can be stored at room temperature or refrigerated (2-8°C).
- The test cassette is stable for at least 12 months when stored at 2-8°C.

**REFERENCES**