A rapid test for the qualitative detection of circulating antigens of P. falciparum (P.f.) and P. vivax (P.v.) in whole blood.

**INTENDED USE**
The Malaria P.f./P.v. Rapid Test Cassette (Whole Blood) is a rapid chromatographic immunassay for the qualitative detection of two kinds of circulating plasmodium falciparum(P.f.) and plasmodium vivax (P.v.) in whole blood.

**SUMMARY**
Malaria is caused by a protozoan which invades human red blood cells. Malaria is one of the world's most prevalent diseases. At the end of the 20th century, the prevalence of the disease is estimated to be 300-500 million cases and over 1 million deaths each year. Most of these deaths are in children under 5 years of age. The 10,000 to 15,000 cases of P. falciparum infections reported in the United States each year is an underestimate of the actual number of cases. S. falciparum is the most virulent species of malaria. In the United States, malaria is considered a notifiable disease due to the high mortality rate (20%).

**Materials Provided**
- Test Cassette
- Buffer
- Materials Required But Not Provided
- Pipette and disposable tips (optional)
- Lancets (for fingerstick whole blood only)

**DIRECTIONS FOR USE**
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Open the pouch to room temperature before opening it. Remove the test cassette from the sealed package and use as soon as possible.

2. Place the cassette on a clean and level surface. For Whole Blood specimen:

   a. Insert a sample. To transfer 5 μl of whole blood to the specimen well, then add 3 drops of buffer (approximately 180μL).

   b. If no line appears in the control region, discard the device.

   c. Hold the dropper vertically, draw up the specimen up to the Fill Line as shown in the illustrated below (optional). Transfer the specimen to the cassette's sample well, then add 3 drops of buffer (approximately 180μL), and start the timer. Wait for 15 minutes. Read results at 10 minutes. Do not interpret the result after 20 minutes.

3. Be sure to add sufficient buffer to the cassette's sample well. Invalid result may occur if inadequate volume of buffer is added.

4. Wash the patient's hand with soap and warm or cold with an alcohol swab. Allow to dry.

5. Grasp the hand without touching the puncture site by rubbing down the hand against the edge of the fingerstrip.

6. Punch the skin with a sterile lancet. Wipe away the first sign of blood.

7. Gently rub the hand from wrist to palm to form a rounded drop of blood over the puncture site.

8. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collection venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below 20°C. Whole blood collected by fingerstick should be tested immediately.

9. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly for more than three times.

**INTERPRETATION OF RESULTS**
POSITIVE: Two or Three distinct colored lines appear.

Non-falciparum Plasmodium species infection, one line appears in the control region, and one line appears in P.f. line region.

**LIMITATIONS**
1. The Malaria P.f./P.v. Rapid Test Cassette (Whole Blood) is for in vitro diagnostic use only. This test should be used for the detection of P.f. and P.v. antigens in whole blood specimens only. Neither the quantitative value nor the rate of parasitemia in P.f. and P.v. concentration can be determined by this qualitative test.

2. The Malaria P.f./P.v. Rapid Test Cassette (Whole Blood) will only indicate the presence of antigens of Plasmodium sp. (P.f.+P.v.) in the specimen and should not be used as the sole criterion for the diagnosis of malaria infection.

3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at all preclude the possibility of malaria infection.

**EXPECTED VALUES**
The Malaria P.f./P.v.-rapid Test Cassette (Whole Blood) has been compared with microscopy on clinical samples. The sensitivity of the Malaria P.f./P.v. Rapid Test Cassette(Whole Blood) is >99.9% when compared to results obtained with microscopy.

**PRECAUTIONS**
- Do not perform tests on patients with known allergy to any component of the test.
- Do not use beyond the expiration date.
- Do not exchange or mix buffer and test cassettes from kits of different lot numbers.
- Be sure to add sufficient buffer to the cassette's sample well. Invalid result may occur if inadequate volume of buffer is added.
- Wash the patient's hand with soap and warm or cool with an alcohol swab. Allow to dry.
- Grasp the hand without touching the puncture site by rubbing down the hand against the edge of the fingerstrip.
- Punch the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to form a rounded drop of blood over the puncture site.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collection venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below 20°C. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly for more than three times.

**CONFIDENCE INTERVALS**
Minimum Detection Level

- **Precision-Within** Run precision has been determined by using 15 replicates of four specimens: a negative, a P.f. positive, a P.v. positive and a P.f./P.v. dual positive. The specimens were correctly identified >99% of the time.

- **Inter-Assay**

**Cross-reactivity**

- The following potentially interfering substances were added to Malaria negative and positive samples. The specimens were correctly identified >99% of the time.

**BIBLIOGRAPHY**