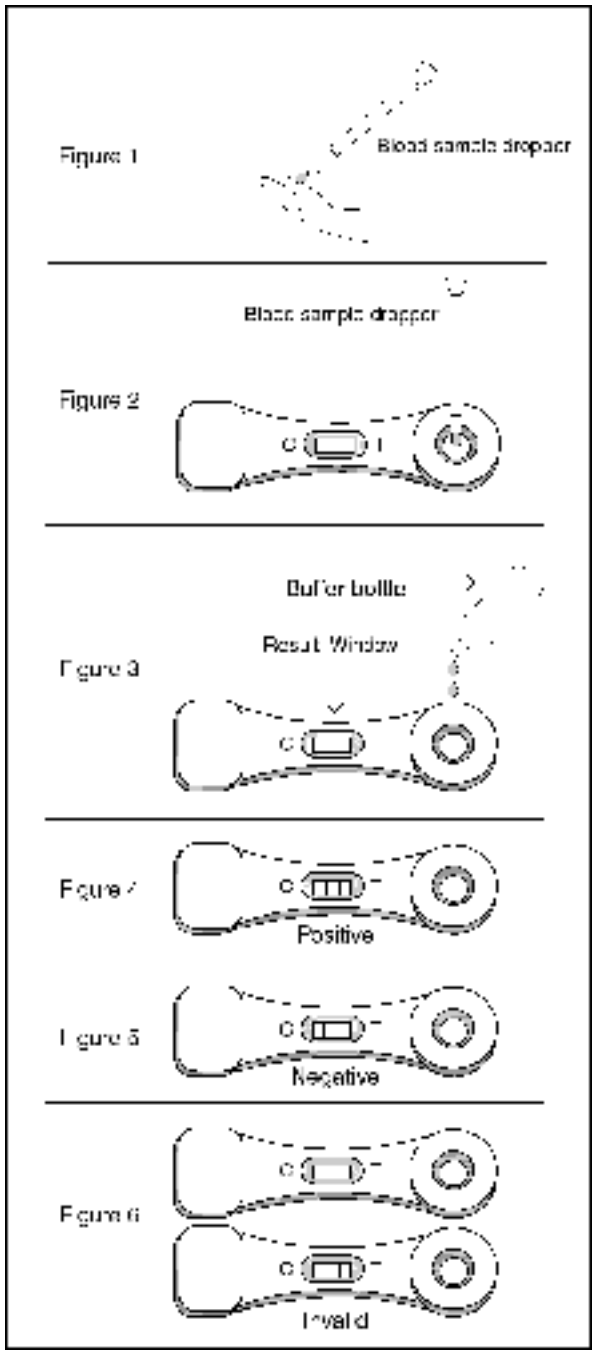
Rapid Malaria Test Disk
for Whole Blood
(Revised 2-21-2007)



Malaria is one of the most serious and complex health problems facing humanity. Over two billion people live in malaria-affected areas and each year approximately 300 million infections occur, resulting in up to 3 million deaths according to a report from World Health Organization. The definite diagnosis of Plasmodium Falciparum (PF) malaria continues to be based on clinical criteria supported by microscopic examination of whole blood. Microscopy is time consuming, labor intensive, expensive and requires considerable technical skills. For professional use only.

The Rapid Malaria Rapid Test is a breakthrough in detection of Malaria plasmodium falciparum. The Rapid Malaria Test is a chromatographic immunoassay for the qualitative detection of Malaria plasmodiumm falciparum in human whole blood.

MATERIALS PROVIDED
The Rapid Malaria test kit contains the following items to perform the assay;
1. Malaria test.
2. Instructions.
3. Disposable sample dropper.
4. Developing buffer.

PRECAUTIONS
The Rapid Malaria Test devices should be stored at room temperature 4-30ºC (40-86ºF). The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration.

SPECIMEN COLLECTION AND STORAGE
1. The test may be performed using human whole blood only.
2. If specimens are not immediately tested they should be refrigerated at 2-8ºC. For storage periods greater than three days, freezing is recommended.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

WARNINGS
1. For in vitro diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7. Do not use the test kit if the pouch is damaged or the seal is broken.

PROCEDURE
1. Remove the test disk from the foil pouch, and place it on a flat, dry surface.
2. Use the sample dropper to draw blood sample. Only draw the blood sample HALF way to the black line (the volume is about 5 ul as shown in Figure 1).
3. Slowly add 5 ul of blood sample to the sample well (Figure 2).
4. Then add 2 drops of the buffer (Figure 3). As the test begins to work, you will see purple color move across the Result Window in the center of the Test Disk.
5. Interpret test results at 10 to 15 minutes. Do not interpret test result after 20 minutes.

Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30 degrees C. If your room temperature is significantly lower than 15 degrees C, then the interpretation time should be properly increased.

INTERPRETATION OF THE TEST
1. A color band will appear in the left section of the Result Window to show that the test is working properly. This band is the Control Band.
2. The right section of the Result Window indicates the test results. If another color band appears in the right section of the Result Window, this band is the Test Band.

POSITIVE RESULT: TWO COLOR BANDS
The presence of two bands within the Result Window, regardless of which band appears first indicates a positive result (Figure 4).

NEGATIVE RESULT: ONE COLOR BAND
The presence of only one band within the Result Window indicates a negative result (Figure 5).

INVALID RESULT:
If after performing the test no band is visible within the Result Window, the result is considered invalid (Figure 6). The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

LIMITATIONS OF THE TEST
The test is limited to the detection of Malaria plasmodium falciparum. Although the test is very accurate in detecting Malaria plasmodium falciparum, 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.

PERFORMANCE CHARACTERISTICS
COMPARISON AND SENSITIVITY STUDIES
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.

SPECIFICITY AND INTERFERENCE STUDY
An in-house study is conducted with 3 separate lots of the One Step Malaria Test to determine the Specificity of One Step Malaria test. Compounds tested include: Serum with triglyceride concentrations up to 500 mg/ml, Serum with Bilirubin concentrations up to 10 mg/100ml, Prostatic acid phosphatase with concentrations up to 1000 mIU/ml and Albumin with concentrations up to 20 mg/ml. All of the above were analyzed and did not show interference or cross reactivity with the test.

REFERENCES

1. Gordon S,Brennessel DJ, Goldstein JA, et al., "Malaria: A City Hospital Experience" Arch Intern Med. 1988, 148(7); 1569-71.
2. Rickman LS, Long GW, Oberst R, et al, "Rapid Diagnosis of Malaria by Acridine Orange Staining of Contrifuged Parasites," Lancet, 1989,1 (8629):68-71.
3. Barker RH Jr. Suebsaeng L, Rooney W, et al, "Detection of Plasmodium falciparum infection in Human Patients: A comparison of the DNA Probe Method of Microscopic Diagnosis," Am J Trop Med Hyg, 1989, 41(3);266-72.

GRAPHICAL SYMBOLS USED

	Storage temperature	LOT	Lot number
IVD	In vitro diagnostic device		Expiry date
REF	Catalogue number		Contents
	Read instruction before use		Manufacturer

Avonchem Ltd
Macclesfield, Uk
www.avonchem.co.uk

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