DISTRIBUTED BY:
American Screening Corporation
6658 Youree Dr Ste 180 PMB 404
Shreveport, LA 71105
Ph: 318-227-4994
Fax:318-227-4996
Toll Free: 1-866-526-2873
www.americanscreeningcorp.com

MALARIA RAPID DIPSTICK TEST

INTENDED USE
The Malaria Rapid Test is designed as a simple, rapid, qualitative and cost-effective method for testing the presence of *Plasmodium falciparum* malaria in blood.

INTRODUCTION
Malaria is a disease caused by protozoa, a parasite, carried by Anopheles mosquitoes. There are four species of malaria parasite. *Plasmodium falciparum* causes the most severe infections, which can often be fatal. Malaria is the most prevalent infection among humans, with 300 million to 500 million cases each year. In sub-Saharan Africa, more than 100 million cases occur each year, with an estimated one million deaths.

Malaria can be diagnosed by detecting the parasite in a smear made from blood. This test requires a small amount of blood, but a great deal of skill on the part of the person looking through the microscope. Falsely positive and falsely negative examinations happen frequently in developing countries. The Malaria Rapid test is an easy to use test that can replace microscopy as the primary screening method for malaria.

PRINCIPLE OF THE TEST
The Malaria Rapid test is an antigen capture assay detecting presence of a specific soluble protein, histidine-rich protein II (PfHRP-II), which is present in, and released from, infected red blood cells, The assay is intended for use with whole blood and does not require additional instrument.

A capture monoclonal antibody is immobilized on the microcellulose strip. The red blood cells are lysed, releasing PfHRP-II which bonds selectively to this antibody as the blood is wicked up the strip. The signal reagent is coated with specific antibodies, which bind with the antibody-antigen complex, producing a red line.

STORAGE AND HANDLING
Store the test kit between 4 – 28°C; DO NOT FREEZE. Refer to the expiration date for stability. Remove the foil cover from cassettes just prior to use. Do not use devices after the expiration date.

WARNINGS AND PRECAUTIONS
1. Malaria Rapid Test is for *in vitro* diagnostic use only.
2. Do not use the test beyond the expiration date printed on the pouch.
3. Good Laboratory Practice includes the use of external positive and negative control specimens to ensure proper test performance.

SPECIMEN COLLECTION AND STORAGE
The Malaria Rapid test is intended for use with either capillary or venous whole blood.
1. Follow standard clinical procedure to collect fresh whole blood specimens.
2. Clean skin thoroughly with antiseptic and allow to air dry before collection of sample.
3. Puncture the finger with a sterile lancet.
4. Touch the collection capillary to the blood spot and allow the blood to fill the capillary.
5. Fill the capillary to at least half full (approximately 5 – 10 µl)
6. In the case of venous blood being used, it should be treated with anticoagulant such as EDTA or Heparin, as neither of these has been shown to interact with the test.

TEST KIT COMPONENTS
Each kit contains following items to perform 25 tests:
1. Malaria Rapid Test – 25 dipsticks.

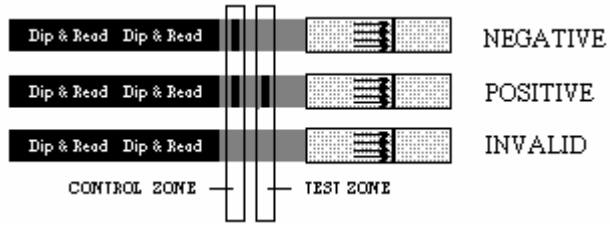
MATERIALS REQUIRED BUT NOT PROVIDED
1. Lancet
2. Capillaries
3. Sterile wipes

TEST PROCEDURE
NOTE: *Bring all patient samples and test components to room temperature (15-30° C) before assaying.*

1. Open the foil pouch at the notch and remove test strip
2. If the test sample is refrigerated, remove it from the refrigerator and allow it to come to room temperature.
3. Label the test device with patient name or identification number.
4. Add the specimen sample in the center of SAMPLE WELL using an accurate 5 or 10 µl pipette. Add 5 – 10 µl specimen into the sample well.
5. Invert the diluent bottle and hold it vertically (not at an angle) over the sample well. Add 4 drops (~200 µl) of diluent slowly dropwise with the provided dropper into the sample well.
6. Read results within 15 minutes after the addition of diluent.

Note: Some Rapid tests may develop a faint line upon drying. Results should not be read after 30 minutes.

INTERPRETATION OF RESULTS



1. **Positive:** Two burgundy colored lines appear, one in the Control region (C) and one in the Test region (T). A positive result indicates presence of *P. falciparum* histidine-rich protein II (PfHRP-II), which is present in infected red blood cells.

2. **Negative:** One burgundy colored line appears in the Control Region (C), with no apparent line in the Test Region (T). A negative result indicates there is no presence of PfHRP-II.

3. **Invalid:** No burgundy colored lines appear, or a line appears in the Test Region (T) but not in the Control Region (C). An invalid result may be due to improper testing procedures or deterioration of the test components. Repeat the assay sequence using a new device.

PERFORMANCE CHARACTERISTICS

The following data was generated from previously frozen whole blood samples, and was determined by correlation to standard thick and thin smear microscopic examination with discrepant evaluated via PCR.

Retrospective study results are summarized below:

Site	Positive	Negative	Positive Test	Negative Test
India	82	99	79 (96.3%)	99 (100%)
Senegal	7	6	7 (100%)	6 (100%)
Varied Origin	50	52	46 (92.0%)	51 (98%)
South Africa	134	160	130 (97.7%)	160 (100%)
Total	273	317	262 (96.0%)	316 (99.7%)

Malaria Rapid Test did not crossreact with any of the following species: *P. vivax*, *P. ovale*, and *P. malariae.*

LIMITATION OF PROCEDURE

Definitive clinical diagnosis should not be made until the physician has evaluated the result in combination with other clinical and laboratory findings.

REFERENCES

1. Howard, R. f Secretion of a malarial histidine-rich protein 2 (PfHRPII) from *Plasmodium falciparum* infected erythrocytes. J. Cell Bio, 103; 1269 – 1277 (1968)
2. Parra. M.E. Ed al. Identification of *Plasmodium falciparum* histidine rich protein 2 in the plasma of human with malaria. Clinical Microbiology, 18; 1627 – 1634
3. Multicentre Field Evaluation of a rapid immunochromatographic test (Cape Biotech for the diagnosis of *P. falciparum* Malaria (published document)

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