

ONE STEP MALARIA (p.f.) TEST

(Whole Blood)

FOR IN VITRO DIAGNOSTIC USE ONLY

INTENDED USE

The One Step Malaria (p.f.) Test is A Colloidal Gold Enhanced, Rapid Immunochromatographic Assay for testing, in vitro , the presence of Plasmodium falciparum malaria in blood. The 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 instruments.

PRINCIPLE OF THE PROCEDURE

A capture monoclonal antibody is immobilized on the nitrocellulose strip. The red blood cells are lysed releasing HRP-II which binds 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 black line. The presence of an upper black line (the procedural control line) demonstrates the test has been performed correctly.

REAGENTS AND MATERIALS SUPPLIED

- Test cards/ test strips individually foil pouched with a desiccant
- Plastic dropper
- Sample Diluent
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Positive and negative controls

STORAGE AND STABILITY

- The kit must be stored at 2 - 30°C.

WARNINGS AND PRECAUTIONS

1. ALL positive results must be confirmed by an alternative method.
2. Treat all specimens as though potentially infectious.
3. Wear gloves and protective clothing when handling specimens.
4. Standard safety precautions in the handling of biohazardous material.
5. Should be observed in specimen handling. Dispose of used lancets.
6. Capillary tubes and cassettes in designated biohazard disposal containers.
7. Devices used for testing should be autoclaved before disposal.
8. Do not use kit materials beyond their expiration dates.
9. Do not interchange reagents from different lot of kit.

SAMPLE COLLECTION AND STORAGE

1. Collect whole blood specimens following regular clinical laboratory procedures.
2. Storage: A specimen should be refrigerated if not used the same day of collection. 0.1% of sodium azide can be added to specimen as preservative without affecting the results of the assay.

BEFORE TESTING

1. Bring the device, sample diluent, and specimens to room temperature.
2. Remove test card from the sealed pouch.



Select the finger for puncture, usually the side of the third or fourth finger. Clean with antiseptic and allow to air dry.



Puncture the finger with a sterile lancet.

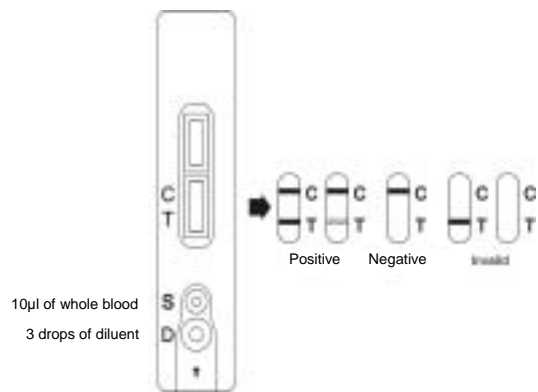


Blood will well to the surface. Redo Procedure on another finger if necessary. Collect the blood using the plastic dropper provided.

ASSAY PROCEDURE

1. Dispense 1 drop (10µl) of whole blood to the “S” well of the test card using the plastic dropper provided according to the figure.
2. Add three drops of Sample Diluent to the “D” well after the specimen is added.
3. Interpret test results at 15 minutes.

Invalid



Notes:

1. Applying sufficient amount of sample diluent is essential for a valid test result. If migration (the wetting of membrane) is not observed in the test window after one minute, add one more drop of diluent to sample well.
2. The positive results could appear as soon as 1 minute for a sample with high levels of Malaria.
3. Do not interpret result after 30 minutes.

4. Although the test is very accurate, a low incidence of false results may occur.
5. If questionable results are obtained, the test should be repeated on a fresh whole blood, serum or plasma specimen using a new device.

BIBLIOGRAPHY

1. WHO. World malaria situation in 1994 .Part I. Population at risk [J] .Wkly Epidemiol Rec, 1997, 72(36):269-74
2. Quintana M, Piper R, Boling HL, et al. Malaria diagnosis by dipstick assay in Honduran population with coendemic *Plasmodium falciparum* and *Plasmodium vivax* [J] . Am J Trop Med Hyg, 1998, 59(6): 868-871

READING THE TEST RESULTS

1. *Positive*: Both black test band and black control band appear on the membrane. The lower the HRP-II concentration, the weaker the test band.
2. *Negative*: Only the black control band appears on the membrane. The absence of a test band indicates a negative result.
3. *Invalid*: There should always be a black control band in the control region regardless of test result. If control band is not seen, the test is considered invalid. Repeat the test using a new test device.

Note: It is normal to have a slightly lightened control band with very strong positive samples as long as it is distinctly visible.

PERFORMANCE CHARACTERISTICS

The following data was generated by 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	Pos	Neg	Test Pos	Test Neg
India	66	86	64(97%)	86(100%)
Senegal	8	10	8(100%)	10(100%)
Varied Origin	48	53	46(95.8%)	53(100%)
South Africa	102	150	99(97%)	149(99.3%)
TOTAL	224	299	217(96.9%)	298(99.7%)

The Malaria Test did not cross-react with any of the following species of malaria: *P.malariae*, *P.ovale*, and *P.vivax*

LIMITATIONS

1. The assay should be performed in normal room temperature.
2. Test cards should be used immediately after being taken from the package. Avoid exposing the test strips in the air for too long before use.
3. The test cards may be stored under room temperature and dry condition. If refrigerated, the strips should be brought to room temperature before testing.