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ONE STEP MALARIA TEST - LATERAL FLOW

(Whole Blood)

FOR *IN VITRO* DIAGNOSTIC USE ONLY

INTENDED USE

The One Step Malaria (p.f.) Test is a Colloidal Gold rapid Immunochromatographic Assay for testing, *in vitro*, the presence of Plasmodium Falciparum Malaria in the blood. The test is an Antigen-Capture Assay detecting the presence of a specific soluble protein, Plasmodium Lactate Dehydrogenase (LDHp), 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

The antigen, LDHp, is present in the blood of patients infected with Plasmodium Falciparum, but not uninfected individuals, binds to a specific antibody which has been conjugated to colloidal gold forming a reddish colored complex. As this complex migrates along the test strip, if LDHp is present, it will be captured by a second antibody which has been immobilized on the Nitrocellulose test strip forming a reddish colored band.

REAGENTS AND MATERIALS SUPPLIED

1 Test slide and test strips sealed in a foil pouch with a desiccant

1 Plastic dropper

1 Sample diluent

1 Alcohol Swab

1 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 should be observed in specimen handling.
5. Dispose of used lancets, capillary tubes and cassettes, in designated biohazard disposal containers.
6. Devices used for testing should be autoclaved before disposal.
7. Do not use kit materials beyond their expiration dates.
8. Do not interchange reagents from different lots of test kits.
9. Keep out of reach of children.

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. Sodium Azide can be added to the specimen as preservative, to a final concentration of 0.1%, without affecting the results of the assay.

BEFORE TESTING

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

- ✓ Wash hands thoroughly with soap and warm water. Dry completely. If your hands are cold, rub them together to warm them.
- ✓ Select the finger from which you will obtain the blood sample. Make sure your finger is warm and callous-free.
- ✓ If you are right-handed, select the “middle” or “ring” finger of your left hand.
- ✓ If you are left-handed, select the “middle” or “ring” finger of your right hand.
- ✓ Wipe the selected finger with the alcohol prep pad provided. To increase blood flow, let your arm hang down at your side while the alcohol dries.

Obtain Blood Sample

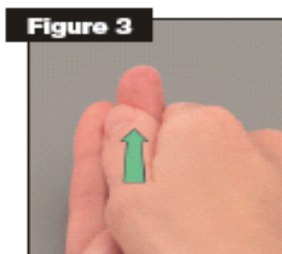


Figure 3

a. **Place selected finger flat on the tabletop.** With the thumb of your opposite hand. Massage or “milk” the selected finger, five or six times, to push blood to the tip (**Figure 3**).

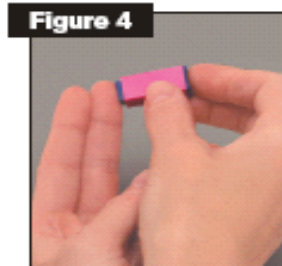


Figure 4

b. Place the raised end of the lancet firmly against the **side of the selected finger.**

Press the lancet against your finger until you hear a “click” You may feel a slight sting. (**Figure 4**).

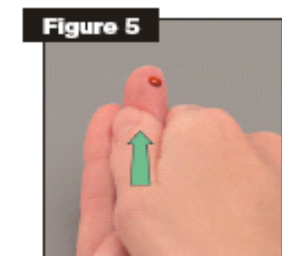


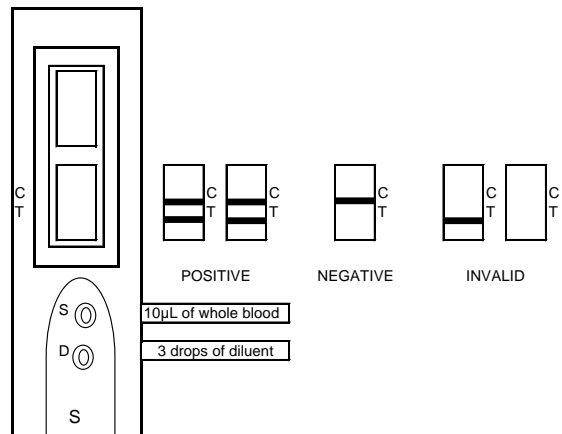
Figure 5

c. With the thumb of your opposite hand, massage or “milk” your finger until a **large drop of blood forms.** (**Figure 5**).

- ✓ Collect your blood using the plastic dropper provided

ASSAY PROCEDURE

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



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 the sample well.*
2. *A positive results could appear as soon as 1 minute for a sample with high levels of LDHp.*
3. *Do not interpret your result after 30 minutes.*

READING THE TEST RESULTS

1. Positive:

Both, a reddish test line and a reddish control line appear on the membrane. The lower the LDH concentration, the weaker the test band.

2. Negative:

Only the reddish control line appears on the membrane. The absence of a reddish test line indicates a negative result.

3. Invalid:

There should always be a reddish control line in the control region regardless of the test result. If the control line 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 line with very strong positive samples, as long as it is distinctly visible.

PERFORMANCE CHARACTERISTICS

The following data was generated from previously frozen whole blood samples. The test results were evaluated by comparison to standard thick and thin smear microscopic examination with discrepancies evaluated via PCR. Retrospective study results are summarized below:

Site	Pos.	Neg.	Test Positive	Test Negative
India	66	86	64 (97%)	86 (100%)
Senegal	8	10	8 (100%)	10 (100%)
Various Origins	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%)

Note: 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 at room temperature .
2. The test slide should be used immediately after being taken from the package. Avoid exposing the test strips to air for prolonged periods prior to use.
3. The test slide may be stored at room temperature under dry condition. If refrigerated, the strips should be brought to room temperature before testing.
4. Although the test is very accurate, a low incidence of false positive or negative 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

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HEALTH-CHEM DIAGNOSTICS LLC,
POMPANO BEACH, FLORIDA
Website: www.healthchemdiagnostics.com
ISO 13485 & US FDA Certified Facility
FDA – Establishment Registration No.: 1048532