

EzDx™ Malaria Pan Test Procedure

1. FIRST, read carefully the Product Insert on how to use the EzDx™ Malaria Pan kit.
2. Now open the kit and look for the following.

1) Test device individually foil pouched with a desiccant.



2) Buffer Solution or Buffer Ampoule



3) Product Insert

4) Sample Dropper



Additional accessories in Complete Single Test Kit.

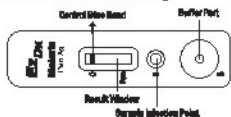
1) Lancet



2) Alcohol Swab



Open the pouch and look for the following.

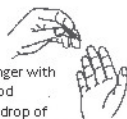


3. Next, look at the expiry date at the back of the pouch. Use another kit, if expiry date has passed.

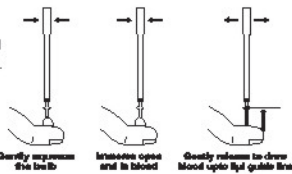
4. Clean the patient's finger. The alcohol MUST be dried before pricking, or test may not work.



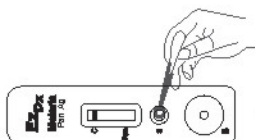
5. Prick the patient's finger with the lancet to get blood (Wipe away the first drop of blood with sterile gauze or cotton)



6. With the help of Sample Dropper provided draw 5 µl of blood upto the indicated mark.

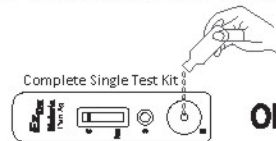


7. Add 5 µl blood into sample injection point (S).



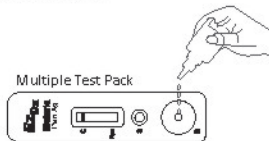
Add 5 µl of whole blood

8. Add Buffer Solution into the Buffer Port (B) of the test device



Add 5 to 6 drops (110 µl ± 5 µl) of buffer solution with even pressure

OR



Add 4 drops (110 µl ± 5 µl) of buffer solution with even pressure

9. INTERPRET TEST RESULTS AT THE END OF 20 MINUTES.

CAUTION: Do not read test after 30 minutes, since it may give incorrect results.



10. Interpretation of Test Results.

Negative For Malaria	Positive For Pan	Invalid
<p>Only one red-purple Control band appears in the result window</p>	<p>In addition to Control band red-purple "Pan" band appears in the result window</p>	<p>If no red-purple Control band appears in the result window the test is considered invalid.</p>

(4)

EzDx™

MALARIA Pan

Rapid Malaria Ag Detection Test
Detection of Pan(pLDH) Antigen

Ref. No.: 002RMA010KI-2

Product Code: RK MAL 002

INTRODUCTION

EzDx™ Malaria Pan is a rapid qualitative, chromatographic immunoassay for the detection of malaria infection in human blood sample indicating *Plasmodium* species (*Pan, pLDH*) (*P. falciparum, P. vivax, P. ovale* and *P. malariae*).

CLINICAL SIGNIFICANCE

Malaria is a serious, sometimes fatal, parasitic disease. It is characterized by fever with chills, anemia and is caused by *Plasmodium* parasite that is transmitted from one human being to another by the bite of infected *Anopheles* mosquitoes. Four species of the *Plasmodium* parasite are responsible for malaria infections in humans viz. *P. falciparum, P. vivax, P. ovale* and *P. malariae*. Of these, *P. falciparum* and *P. vivax* are the most prevalent. Early detection and differentiation of malaria is of paramount importance due to incidence of cerebral malaria and drug resistance associated with *falciparum* malaria causing most of the morbidity and mortality worldwide.

PRINCIPLE

EzDx™ Malaria Pan test utilizes the principle of immuno-chromatography. It has the test strip coated with Monoclonal Anti pLDH, Pan antibodies (test line Pan) specific to the lactate dehydrogenase of *plasmodium* species (*P. falciparum, P. vivax, P. ovale* and *P. malariae*). As the test sample flows through the membrane assembly of the device after addition of the buffer solution, the colored colloidal gold, anti-pLDH antibody conjugate complexes with the lysed blood sample. The Malarial antigens get immobilized on the test line on the nitrocellulose membrane which leads to the formation of red/purple colored band/s. The unreacted conjugate and unbound complex if any moves further on the membrane and are subsequently immobilized at the control "C" region forming a red/purple band. This control band serves to validate the test performance and should always appear. This test is intended for professional use and must be used by a trained personnel.

MATERIALS PROVIDED

EzDx™ Malaria Pan kit contains the following items to perform the assay:

1. EzDx™ Malaria Pan Test Device in individually foil pouched with a Desiccant.
2. Sample Dropper
3. Alcohol Swab (Provided in Complete Single Test Kit)
4. Lancet (Provided in Complete Single Test Kit)
5. Buffer Solution.
6. Product Insert.

PRECAUTIONS

1. Read this Insert carefully before carrying out the test and instruction must be followed exactly together accurately.
2. The Device is sensitive to humidity as well as to heat. Therefore take out the Device from sealed pouch just before carrying out the test.
3. Store the EzDx™ Malaria Pan kit at the temperature mentioned on the kit in a dry atmosphere.
4. Do not use the kit after the expiration date.
5. Do not mix reagents from different lots.
6. For *In Vitro* diagnostic use only.
7. Wear protective gloves while handling samples and wash hands thoroughly after performing the test.
8. Dispose all the samples and kits properly as per the instructions after test in accordance with GLP.
9. Do not pipette reagents or blood samples by mouth.
10. When transporting or storing the kits, avoid exposure to high temperature (over 45°C) for a period longer than 1 week.

SPECIMEN COLLECTION, STORAGE & PRECAUTION

Collection by venipuncture

1. Collect the whole blood into the collection tube containing anticoagulant (EDTA, Citrate or Heparin) by venipuncture
2. If immediate testing is not possible then the samples may be stored at 2-8°C for upto 3 days. For storage more than 3 days, freezing is recommended. The samples should be brought to room temperature prior to use. Using the samples in the long term keeping more than 3 days can cause non-specific reactions.
3. Ideally samples when stored at 2-8°C, the whole blood samples should be used within 3 days.

(1)

Collection with lancet

1. Clean the fingertip area to be pricked with an Alcohol Swab (Provided in Complete Single Test Kit).
2. Squeeze the end of the fingertip and pierce with the Lancet (Provided in Complete Single Test Kit).
3. Wipe away the first drop of blood with sterile gauze or cotton.
4. While gently squeezing the Sample Dropper provided, immerse the open end in the blood drop and gently release to draw 5µl of blood up to the indicated mark with even pressure.
5. Then load 5µl of blood into the "Sample Injection Point (S)" on the test device.

Precaution

1. Anticoagulant such as Heparin, EDTA and Citrate do not affect the test results.
2. Use separate Sample Dropper (5µl) or fresh pipette tip for each sample to avoid cross-contamination and erroneous results.

TEST PROCEDURE

For Multiple test pack

1. Allow EzDx™ Malaria Pan kit components and specimens to attain room temperature.
2. Open the pouch and take out the Device from it.
Note : The Device contains a blue control line made up of water soluble dye that disappears as the test runs.
3. Tighten the bottle cap of the Buffer Solution provided with the kit in the clockwise direction to pierce the Dropper Bottle nozzle.
4. Evenly mix the anticoagulated blood sample by gently swirling and then dip the Sample Dropper (5µl) into the blood sample to draw 5µl of blood up to the indicated mark.

OR

In case of finger prick, clean the fingertip with an alcohol swab (Provided in Complete Single Test Kit) dry completely; prick the fingertip with a "Single Use Lancet" (Provided in Complete Single Test Kit). Wipe away the first drop of blood with sterile gauze or cotton; with the help of the Sample Dropper (5µl), provided, draw 5µl of blood up to the indicated mark.

5. Load 5µl of blood into the "Sample Injection Point (S)".
6. Add 4 drops (110µl ± 5µl) of Buffer Solution into the "Buffer Port (B)" on the Test Device.
7. Read the result at the end of 20 minutes.
8. Interpret the result. Refer to figure for interpretation of the result.

For Complete Single Test Kit

1. Allow EzDx™ Malaria Pan kit components and specimens to attain room temperature.
2. Open the pouch and take out the Device from it.
Note : The Device contains a blue control line made up of water soluble dye that disappears as the test runs.
3. For addition of Buffer Solution, break the neck of Buffer ampoule anticlockwise by twisting just before use.
4. Evenly mix the anticoagulated blood sample by gently swirling and then dip the Sample Dropper (5µl) into the blood sample to draw 5µl of blood up to the indicated mark.

OR

In case of finger prick, clean the fingertip with an Alcohol Swab dry completely; prick the fingertip with a "Single Use Lancet". Wipe away the first drop of blood with sterile gauze or cotton; with the help of the Sample Dropper (5µl), provided, draw 5µl of blood up to the indicated mark.

5. Load 5µl of blood into the "Sample Injection Point (S)".
6. Add 5-6 drops (110µl ± 5µl) of Buffer Solution into the "Buffer Port (B)" on the Test Device.
7. Read the result at the end of 20 minutes.
8. Interpret the result. Refer to figure for interpretation of the result.

CAUTION : Do not read test after 30 minutes, since it may give incorrect results.

INTERPRETATION OF THE RESULTS

Whole blood samples may cause red background to appear in the result window. If this is not masking the test line, the result remains valid.

NEGATIVE:

Only the control band appears. Negative result indicates no malaria antigens present in the blood sample, indicating no malaria infection or the number of malaria antigens present in the blood sample is below the detectable range.

POSITIVE:

Two bands ("Pan" Test line and "C" Control line) appears within the result window indicates infection with *Plasmodium* species (*P.falciparum*, *P.vivax*, *P. ovale* and *P. malariae*).

The shade of color / intensity of band may vary, but it should be considered positive whenever there is even a faint line.

INVALID:

If control band does not appear, the test is Invalid. In this case, please repeat the test using a fresh Device, and follow the test procedure exactly.

STORAGE & EXPIRATION

1. EzDx™ Malaria Pan kit should be stored between 4° to 30°C (39°-86°F) **DO NOT FREEZE**.
2. Expiration date of this kit is as indicated on the Kit Cartons as well as on individual Pouches.

LIMITATIONS OF THE TEST

EzDx™ Malaria Pan is designed for Primary screening of malaria infection. Although the test is accurate in detecting pLDH specific to *Plasmodium* in blood samples, 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.

REFERENCES

1. World Health Organization-Geneva (2000) New perspectives malaria diagnosis.
2. Jamshaid Iqbal; et al. Journal of Clinical Microbiology, 37 (1), 1999, 3644 – 3646.
3. Moody A, Clinical Microbiology Review 15 (1), 2002, 66-78.
4. Waqhrust, D.C., and J.E. Williams. 1996. Laboratory diagnosis of malaria J. Clin. Pathol. 49:533-538.

DISCLAIMER:

While every precaution has been taken to ensure the diagnostic ability and accuracy of this product, this product is used outside of the control of the manufacturer and the distributor and the result may accordingly be affected by environmental factors and / or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

WARNING:

The Manufacturers and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

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