MEDICAL DIAGNOSTECH

# MD Malaria *P.f./Pan* (pLDH)

**Rapid test for the detection of Pf/Pan (pLDH) in human Whole blood**

**Product Code: MDMALLDH001**
**Version: 210412**

## INTENDED USE

The MD Malaria Pf/Pan (pLDH) device is a rapid visual immunoassay for the qualitative detection of *Plasmodium falciparum* (P.f.), *Plasmodium vivax* (P.v.), *Plasmodium malariae* (P.m.) and *Plasmodium ovale* (P.o.) antigens in whole blood. It is intended for professional use to accurately diagnose Malaria and to avoid over or under treatment.

Using combined HRP2 and pLDH technology for the differential diagnostic of *Plasmodium falciparum* and the other *plasmodium* species, the MD Malaria Pf/Pan (pLDH) device is highly sensitive in accordance with WHO standards (>95% sensitivity) for the detection of *falciparum* malaria infections when the parasitomia is as low as 100p/µl.

Using pLDH technology, this test can be used for monitoring therapeutic response after anti-malarial therapy; the pLDH line will become faint and eventually disappear in response to therapy.

## PRINCIPLE OF THE TEST

The MD Malaria Pf/Pan (pLDH) device (whole blood) detects Malaria P.f./P.m./P.o./P.v. through visual interpretation of colour development on the membrane. Capture monoclonal antibodies (anti HRP2 for P.f. (T1) and anti pLDH for P.f./P.m./P.o./P.v. (T2) are immobilized on the nitrocellulose membrane. The red blood cells are lysed by the reaction buffer releasing plasmodium specific antigens which bind selectively to these antibodies as the blood is wicked up the strip. The colloidal gold signal reagent is coated with specific Malaria antibodies which bind with the antibody-antigen complexes formed on the membrane, producing a red line. Presence of coloured bands at the test line region indicate a positive result, while their absence indicates a negative result. The presence of an upper red line (the procedural control line (C) demonstrates that the test has been performed correctly.

## REAGENTS AND MATERIALS PROVIDED IN THE KIT

| Units | Components |
|---|---|
| 25 | Single pouched test cassettes with desiccant |
| 25 | Disposable blood collection devices (10µl) |
| 25 | Sterile Wipes |
| 25 | Lancets |
| 25 | Reaction Buffer (used to lyse blood and ensure the flow) |
| 1 | Instructions for use |

***Timer required but not provided.***

## STORAGE CONDITIONS AND SHELF LIFE

The following indications must be followed to ensure accurate test performance:

1. Store kits at room temperature between 4 and 40°C.
2. Store in a dry place, humidity can affect test performance.
3. The test devices must remain pouched until usage.
4. The kits will have a shelf-life of 24 months after manufacturing.
5. The expiration date printed on the kits and pouches must be verified prior to use.
6. Kits must not undergo freezing conditions.

## Precautions and warnings

1. For in vitro diagnostic use only.
2. All tests are for single use; do not re-use.
3. Follow the test procedure exactly as shown in this insert in order to get accurate results.
4. Do not open the sealed pouch, unless ready to conduct the test.
5. Verify the expiration date, do not use expired tests.
6. Do not mix reagents and components of different lots.
7. Do not use the test if pouch is damaged or seal is broken.
8. Do not eat, drink or smoke while handling specimens and test devices.
9. Wear protective gloves and eye protection while handling specimens.
10. Respect standard procedures to dispose specimens and potentially contaminated material, in biohazard containers.
11. The MD Malaria Pf/Pan (pLDH) does not present any risk to the user if used as recommended.

## Specimen collection and storage

**Collection by venipuncture**

1. Collect the whole blood into the collection tube (containing EDTA, citrate, or heparin) by venipuncture.
2. If specimens are not immediately tested, they should be refrigerated at 2 - 8°C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use. Using the specimen in the long-term keeping more than three days can cause non-specific reactions.
3. When storage at 2 - 8°C, the whole blood sample should be used within three days.

**Collection using a lancet**

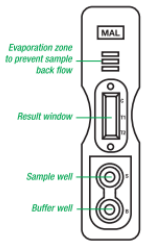
1. Clean area to be lanced with an alcohol swab.
2. Squeeze the end of the fingertip and pierce with a sterile lancet.
3. Wipe away the first drop of blood with sterile gauze or cotton.
4. Take a sample pipette provided, and while gently squeezing the tube, immerse the open end in the blood drop and then gently release the pressure to draw blood into the sample pipette up to the first line (5µl).

## Test Procedure

Prior to use, allow the test in the foil bag to reach room temperature.

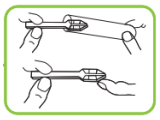
Open the foil bag to be used, only prior to conducting the test, exposing the cassette.

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



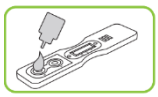

Puncture the finger with a sterile lancet. Blood will well to the surface, re-do procedure on another finger if necessary.

Touch the collection device supplied to the blood spot and allow the blood to fill up to the first (5µl) line.



**Step 1**
Transfer blood to the test cassette by gently touching the nozzle to the small sample well.

**Step 2**
Using the single buffer tube and dropper provided, add 4 drops of the reaction buffer into the buffer well



**Step 3**
Allow the reaction to proceed for 15-30 minutes.
Read the result and dispose of the cassette after use.

Manufactured by:
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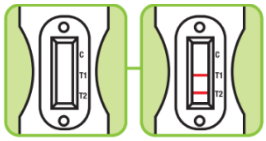
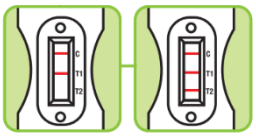
## Interpretation of results

***Invalid***:
Either no lines are observable or either test line without a control line. Improper test procedure was carried out or reagents have deteriorated. Re-test.

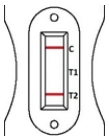


***Negative***:
The control line is present but neither test line, demonstrating the test was performed correctly but no malarial antigens are present.

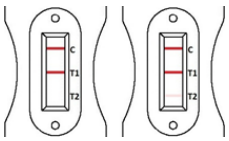
***Pf Positive***:
The middle and top (control) lines, or all three lines are evident. All three lines may also show in a mixed infection.



***PAN Positive and Pf Negative***:
The bottom and top (control) lines are evident.



***pLDH decrease***:
Post malaria treatment, the pLDH line in T2 area may decrease and disappear indicating treatment efficiency.



## Limitations of the test

1. The MD Malaria Pf/Pan (pLDH) test is for professional in vitro diagnostic use. It is intended to be used for the qualitative detection of Malaria P.f, P.m., P.o and P.v. antigens and/or for pLDH monitoring only.

2. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods (e.g. microscopic examination of the thick smear and thin blood films) is recommended. A negative result does not at any time rule out the existence of Malaria P.f./P.m./P.o./P.v. antigens in blood, because the antigens may be absent or below the minimum detection level of the test.

3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

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

## Internal quality control

The MD Malaria Pf/Pan (pLDH) immunoassay includes a control line which is used for procedural control. It should always appear confirming the test procedure has accurately been performed.

## Expected results

Shown below are comparative results to blood samples, previously evaluated with microscopy during in-house testing:

| Sample | #Pos | #Neg | MD-Test MALARIA Pos. | MD-Test MALARIA Neg. |
|---|---|---|---|---|
| Total non Pf Malaria specimens | 65 | 317 | 64 (98.5%) | 317 (100%) |
| Total Pf specimens | 273 | 317 | 270 (98.9%) | 316 (99.7%) |

**Sensitivity (Non-P.f. malaria):** 64/65 (98.5%)
**Sensitivity (P.f. Malaria):** 270/273 (98.9%)
**Specificity:** 316/317 (99.7%)

## References:


1. Wilson, M. (2012). Malaria Rapid Diagnostic Tests. Clin Infect Dis. (2012) 54 (11): 1637-1641
2. Fogg C, Twesigye R, Batwala V, Piola P, Nabasumba C, Kiguli J, Mutebi F, Hook C, Guillerm M, Moody A, Guthmann JP: Assessment of three new parasite lactate dehydrogenase (pan-pLDH) tests for diagnosis of uncomplicated malaria. Trans R Soc Trop Med Hyg 2008, 102:25-31.
3. Moody, A. (2002). Rapid Diagnostic Tests For Malaria Parasites. Clin Microbiol Rev. 2002 January; 15(1): 66–78.
4. Arai, M. Ishii, A. Matsuoka, H. (2004). Laboratory evaluation of the Rapid malaria P.f./PAN (pLDH) immunochromatographic test for detecting the panmalarial antigen using a rodent malaria model. Am J Trop Med Hyg. 2004 Feb;70(2):139-43


## Symbols

| | | | |
|---|---|---|---|
| IVD | For in-vitro diagnostic use only | | For single use only |
| Σ | Content | | Expiry date |
| LOT | Lot number | | Storage temperature |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