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CE

P.f. Malaria Rapid test

Detection of pf Malaria LDH antigen in human blood

REF

Catalog No.R6-530

IVD

For in vitro diagnostic use only
For export use only

Intended Use

The Pf Malaria Rapid Test for *Plasmodium falciparum* (pf) infection is a rapid immunochromatographic strip assay for the qualitative detection of plasmodium lactate dehydrogenase (pLDH) in human blood as an aid in the diagnosis of Malaria infection. This test is intended for *in vitro* diagnostic use only.

Summary and explanation

Four *Plasmodium* species cause human disease, *P. falciparum (P.f), P. vivax (P.v), P. ovale (P.o),* and *P. malariae (P.m)*. Of these, *P. falciparum* remains by far the most severe form, is resistant to many common drugs, and is responsible for nearly all deaths from malaria (1). Extreme exhaustion and a sudden febrile illness, sweats, shaking, chills, and anemia characterize the disease. The WHO estimates that that 40% of the world's population is at risk of malaria, a disease that was once thought to be under control, but is now resurgent in many developing countries, causing >300 million acute illnesses and upwards of one million deaths annually. Diagnosis of malaria (2-6) has traditionally been done by microscopic examination of blood. Microscopy, however, is time-consuming, particularly in patients with low parasitemias, since the microscopist must carefully scan 50-100 fields to ensure a slide is negative. Other diagnostic methods have included fluorescence microscopy, including the Quantitative Buffy coat method using acridine orange to stain intracellular parasites, and the polymerase chain reaction (PCR) to detect parasite DNA from whole blood. Immunospec has developed a pLDH based rapid diagnostic tests for malaria in the lateral-flow format that can be used with finger-stick or venous blood. *Presence of pLDH can be used for monitoring therapeutic efficacy as only dividing cells produce the LDH.*

Principle

The pf*Malaria* p-LDH antigen test contains a membrane strip, which is pre-coated with a pf LDH specific monoclonal antibody across a test strip (T line). The conjugate pad is dispensed/dried with a different anti-LDH monoclonal antibody. Once the blood sample is applied, the blood and anti- LDH antibody gold mix then migrate upward on the membrane to react with the T line representing p.f malaria reactivity. Presence of this red line indicates a positive result, while its absence indicates a negative result.

Regardless of the presence of pLDH, as the mixture continues to migrate across the membrane towards the immobilized control region (C line) region, a red line at the control line region will always appear. The presence of this red line serves as verification for sufficient sample volume and proper flow and as a control for the reagents.

Kit contents

1. Test device, individually pouched.
2. Vial of Chase Buffer solution.

Optional:

- Extra assay Buffer
- Sample Pipette
- Lancet (Optional)
- Alcohol Swab (Optional)

Precautions

- For *in vitro* diagnostic use only. Do not use after expiration date.
- Handle all sera and kits used as if they contain infectious agents. Observe established precautions against microbiological hazards while performing all procedures and follow the standard procedures for proper disposal of sera and used kits.
- Wear protective clothing, eye protection and disposable gloves while performing the assay. Wash hands thoroughly when finished.
- Avoid all contact between hands and eyes or mucous membranes during testing.
- Do not eat, drink or smoke in the area where the sera and kits are handled.
- The Chase Buffer contains a preservative; avoid all possible contact with skin and mucous membranes.
- Clean up spills thoroughly using an appropriate disinfectant.

Storage

The sealed pouch or vial containing the test strip cassette is designed to be stored at room temperature (8°C-30°C) for the duration of its shelf life.
The bottle containing the Chase Buffer is designed to be stored at room temperature
for the duration of its shelf life. Exposure to temperatures

over 30°C can impact the performance of the test and should be minimized. The strips should not be frozen. The test should be used within 15 minutes after removal from the pouch or vial to prevent exposure to humidity.

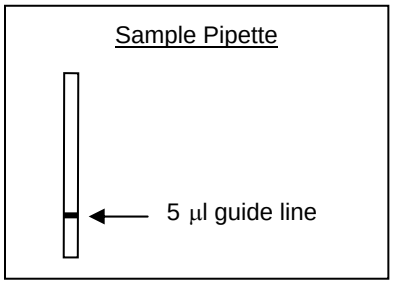
Specimen Collection and Storage

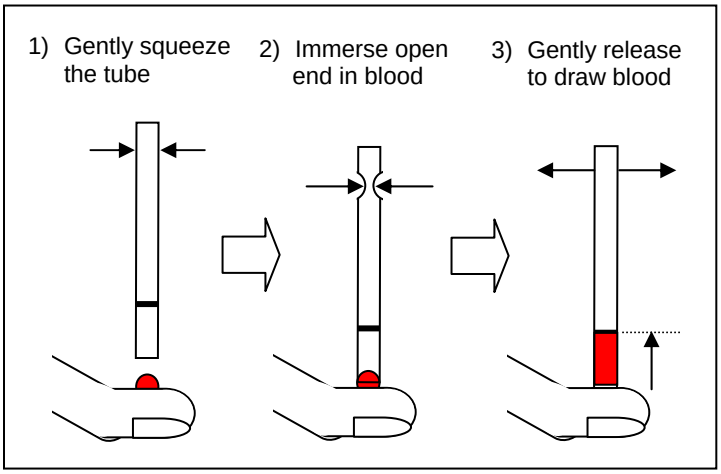
[Collection by venipuncture]

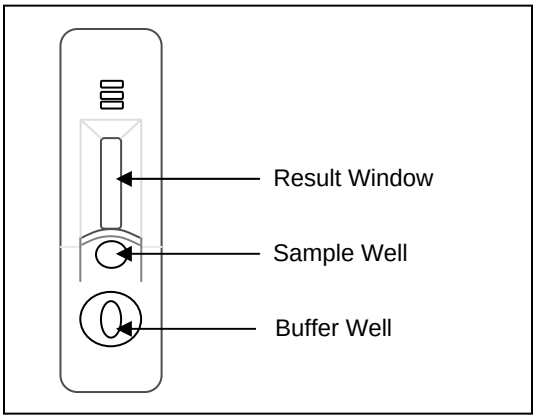
1. Collect the whole blood into the collection tube (containing EDTA, citrate or heparin) by venipuncture.
2. **<u>For best results use freshly drawn blood.</u>** If specimens are not immediately tested, they should be refrigerated at 2 ~ 8°C. For storage periods greater than three days, freezing is 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 reaction.
3. When storage at 2 ~ 8°C, the whole blood sample should be used within three days.
4. If samples are to be shipped, they should be packed in compliance with Federal Regulations covering transportation of infectious agents.

[Collection using a lancet]

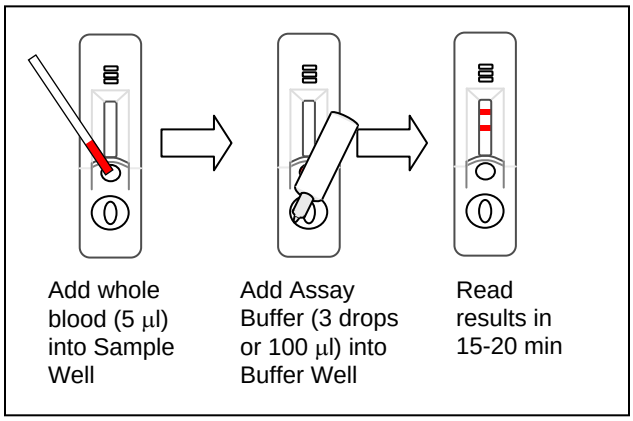
1. Clean the area to be lanced with an alcohol swab.
2. Squeeze the end of the fingertip and pierce with a sterile lancet provided.
3. Wipe away the first drop of blood with sterile gauze or cotton.
4. Take a dropper provided, while gently squeezing the tube, immerse the open end in the blood drop and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



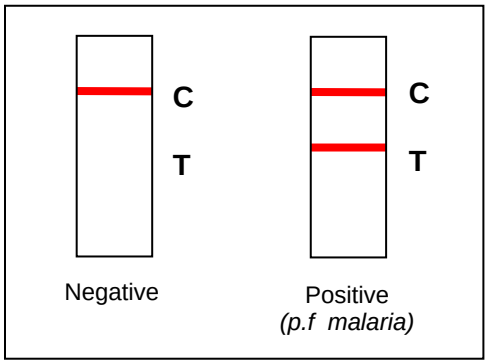




1) Add 5 µl of whole blood into Sample Well using a single channel micropipette, or a sample pipette provided (**sample well**; **DO NOT USE MORE THAN 5 µl OF BLOOD**).
2) Add three drops (100 µl) of assay buffer into buffer well (**<u>add buffer slowly</u>**).
3) Read the test result in 15 – 20 min.



Interpretation of the test



Positive reaction

The presence of two color bands (C and T lines) indicates a positive result for *Plasmodium falciparum* infection. The pLDH present in the sample reacts with the anti-pLDH conjugate and move through the test strip where the pLDH is captured by a different *p.f*-specific, anti-pLDH monoclonal antibody.

Negative reaction

The presence of only one band in **C** area within the result window indicates a negative result.

Invalid

The test is invalid if the line in **C** area does not appear (not shown). If this occurs, the test should be repeated using a new strip.

Performance Characteristics

The pf*Malaria* pLDH antigen detection rapid assay has been tested with purified recombinant LDH, and infected human blood.

Limitation

- This test will only indicate the presence of pLDH in whole blood and should not be used as the sole criterion for the diagnosis of malaria (as with all diagnostic tests, all results must be considered with other clinical information available to the clinicians).
- If the result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended.
  A negative result does not preclude the possibility of malaria.
- Do not use samples containing any glycerol or other viscous materials. This will compromise the sensitivity of the assay dramatically.
- Most blood samples clear within 15 minutes. However, with some fresh and also with old blood samples, clearance may take additional 15 minutes. In these situations, allow additional 15 minutes for final reading.
- The test is limited to the detection of antigen to Malaria <u>*Plasmodium falciparum*</u>.
- Although the test is very accurate in detecting pLDH, a low incidence of false negative 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

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PIE6-530
Effective date: 07/09
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