Malaria Pf/Pan Rapid Test (WB)

Labgene biotech

INTENDED USE

Labgene Malaria Pf/Pan Rapid test kit is a lateral flow chromatographic immunoassay designed for the qualitative detection of Malaria Pf (Plasmodium falciparum) and Malaria Pan antigen in human whole blood samples.

ORDER INFORMATION AND MATERIALS PROVIDED

Cat No.	Test Devices	Assay Buffer	Dropper & Sillica Gel	Lancets & Alcohol Swabs
LG008-10T	10	1 X 2 mL	01 in an individual pouch	-
LG008-25T	25	1 X 3 mL		
LG008-30T	30	1 X 3 mL		
LG008-40T	40	2 X 2 mL		
LG008-50T	50	2 X 3 mL		
LG008-100T	100	4 X 3 mL		
LG008LS-10T	10	1 X 2 mL		10
LG008LS-25T	25	1 X 3 mL		25
LG008LS-30T	30	1 X 3 mL		30
LG008LS-40T	40	2 X 2 mL		40
LG008LS-50T	50	2 X 3 mL		50
LG008LS-100T	100	4 X 3 mL		100
*IFU: O1 in an individual carton box				

INTRODUCTION

Labgene Malaria is caused by a protozoan which invades human red blood cells. Malaria is one of the world's most prevalent diseases. According to the WHO, the worldwide prevalence of the disease is estimated to be 300-500 million cases and over 1 million deaths each year. Most of these victims are infants, young children. Over half of the world's population lives in malarious areas. Microscopic analysis of appropriately stained thick and thin blood smears has been the standard diagnostic technique for identifying malaria infections for more than a century. The technique is capable of accurate and reliable diagnosis when performed by skilled microscopists using defined protocols. The skill of the microscopist and use of proven and defined procedures, frequently present the greatest obstacles to fully achieving the potential accuracy of microscopic diagnosis. Although there is a logistical burden associated with performing a time-intensive, labor-intensive, and equipment-intensive procedure such as diagnostic microscopy, it is the training required to establish and sustain competent performance of microscopy that poses the greatest difficulty in employing this diagnostic technology. The Malaria P.f./Pan Rapid Test (Whole Blood) is a rapid test to qualitatively detect the presence of P. falciparum - specific HRP-II and four kinds of circulating plasmodium falciparum(P. falciparum (P.f.), P. vivax (P.v.), P. ovale (P.o.), and P. malariae (P.m.)). The test utilizes colloid gold conjugate to selectively detect P.f-specific and Pan-malarial antigens (P.f., P.v., P.o. and P.m.) in whole blood.

PRINCIPLE

Labgene Malaria Pf/Pan Rapid test kit is a lateral flow chromatographic immunoassay. The strip in the test cassette consists of: 1) a burgundy colored conjugate pad containing monoclonal anti-pHRP-II antibody conjugated with colloidal gold(pHRP-II-gold conjugates), monoclonal anti pLDH antibody conjugated with colloidal gold and 2) a nitrocellulose membrane strip containing two test lines (Pan and Pf lines) and a control line (C line). The pan line is pre-coated with anti-pLDH antibody for the detection of infection with any of the four species of plasmodium, the Pf line is pre-coated with anti-p HRP-II antibodies for the detection of Pf infection, and the C line is coated with a control line antibody.

During the assay, an adequate volume of the blood specimen is dispensed into the sample well (S) of the test cassette, and a lysis buffer is added to the buffer well (B). The buffer contains a detergent that lyses the red blood cells and releases various plasmodium antigens which migrate by capillary action across the strip held in the cassette.

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container
- Timer
- Centrifuge
- Micropipette

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not use if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves or eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- The used test should be discarded according to local regulations.
- Do not use expired lancet.
- Do not share used lancet.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch either at room temperature or refrigerated (2°C-30°C).
- DO NOT FREEZE.
- The test device is stable through the expiration date printed on the sealed pouch.
- The test device must remain in the sealed pouch until use.

SPECIMEN COLLECTION AND PREPARATION

Whole Blood :

Venipuncture:

- Collect the whole blood into the collection tube (containing EDTA, citrate or heparin) by Venipuncture.
- Transfer the sample to sample well of device using sample pipette.
- Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The whole blood must be tested within 24 hours of collection.

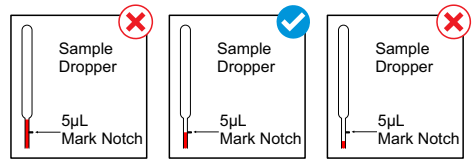
Collection using a lancet:

- Clean the area to be lanced with the alcohol swab
- Squeeze the fingertip then prick the lateral side of the finger with a lancet provided .
- Wipe away the first blood drop. And immerse the open end of a micropipette and release the pressure to draw blood into it.

PROCEDURE

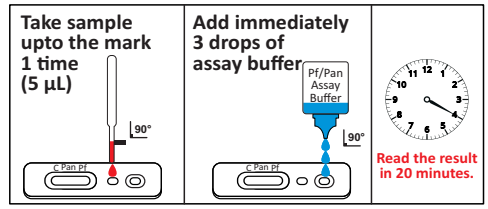
1. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
2. When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
3. Be sure to label the device with specimen's ID number.
4. **For whole blood specimen :** Hold the dropper vertically and **take the sample specimen upto the mark (5µL)** as shown in the diagram below and **transfer the sample to the specimen well (S)** of the test device, then **add 3 drop of Assay buffer to the well (B) immediately**.
5. Set up timer.
6. Read the result in 20 minutes. Read result as shown under interpretation of result.

⚠ **Do not read results after 25 minutes. To avoid confusion, discard the test device after interpreting the result.**



Incorrect Sample Volume | **Correct Sample Volume** | Incorrect Sample Volume

WHOLE BLOOD:



INTERPRETATION OF RESULTS

POSITIVE: Two distinct colored lines appear. One line should be in the control line region (C) and another line should be in the test line regions (Pf & Pan).

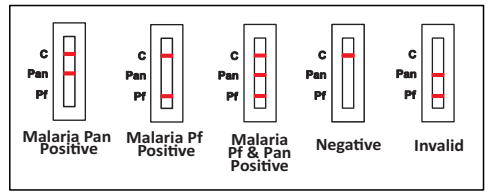
Pan Positive: If both C and Pan line appear, the test indicates the presence of detectable Pan Malarial antigen in the specimen. The result is Malaria Pan positive or reactive.

Pf Positive: If both C and Pf line appear, the test indicates the presence of detectable Malaria Pf antigen in the specimen. The result is Malaria Pf positive or reactive.

NEGATIVE: Only one colored line appears in the control line region ©. No apparent colored line appears in the test line regions (Pf &Pan).

INVALID: No visible band appears at the control region ©. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

RESULTS:



LIMITATIONS

- The Malaria Pf/Pan Rapid test is for in vitro diagnostic use only.
- Humidity and temperature can adversely affect results.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity studies were carried out in-house on fresh as well as frozen samples, from low risk as well as high risk groups.

Malaria Pf Samples	Positive	Negative	Total
Positive	30	00	30
Negative	00	100	100
Total	30	100	130