Malaria Pf/Pv Rapid Test (WB)

Labgene biotech

INTENDED USE

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

ORDER INFORMATION AND MATERIALS PROVIDED

Cat No.	Test Devices	Assay Buffer	Dropper & Sillica Gel	Lancets & Alcohol Swabs
LG007-10T	10	1 X 2 mL	01 in an individual pouch	-
LG007-25T	25	1 X 3 mL		
LG007-30T	30	1 X 3 mL		
LG007-40T	40	2 X 2 mL		
LG007-50T	50	2 X 3 mL		
LG007-100T	100	4 X 3 mL		
LG007LS-10T	10	1 X 2 mL		10
LG007LS-25T	25	1 X 3 mL		25
LG007LS-30T	30	1 X 3 mL		30
LG007LS-40T	40	2 X 2 mL		40
LG007LS-50T	50	2 X 3 mL		50
LG007LS-100T	100	4 X 3 mL		100
*IFU: O1 in an individual carton box				

INTRODUCTION

Malaria is a serious parasitic disease characterized by fever, chills, and anemia and is caused by a parasite that is transmitted from one human to another by the bite of infected Anopheles mosquitoes. There are four kinds of malaria that can infect humans: Plasmodium falciparum, P. vivax, P. ovale, and P. malariae. In humans, the parasites (called sporozoites) migrate to the liver where they mature and release another form, the merozoites. The disease now occurs in more than 90 countries worldwide, and it is estimated that there are over 500 million clinical cases and 2.7 million malaria-caused deaths per year. At the present, malaria is diagnosed by looking for the parasites in a drop of blood. Blood will be put onto a microscope slide and stained so that the parasites will be visible under a microscope.

PRINCIPLE

Labgene Malaria Pf/Pv Rapid test kit is a lateral flow chromatographic immunoassay designed for the qualitative detection of Malaria Pf/Pv antigen in human whole blood samples. When a whole blood sample is dispensed into the sample well, red blood cells ruptures by the in-built system. The sample flows through the filter efficiently after adding buffer solution. The gold-antibody conjugate will bind to Malaria HRP II & Pv-LDH antigens if present in the sample specimen which in turn will bind with anti-HRP II & anti-Pv-LDH antibodies coated on the membrane as two separate lines in the test region as the reagent move across the membrane. The anti-HRP II & anti-Pv-LDH antibodies on the membrane will bind the malaria antigen-gold antibody complex at the relevant Pv and or Pf test lines causing pale or dark pink or red lines to form at the Pv or Pf region of the test membrane. The intensity of the lines will vary depending upon the amount of antigen present in the sample. The appearance of the colored line in a specific test region (Pv or Pf) should be considered as positive for that particular malaria type (Pv or Pf). If no band is present in the Control area, the test is invalid and another test must be run using a fresh device, regardless of the presence or absence of band in the Test area.

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.

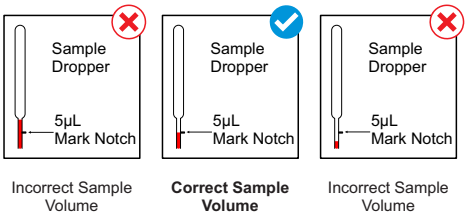
Collection using a lancet:

- 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

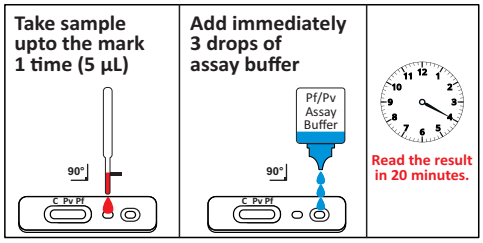
1. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
2. When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
3. Be sure to label the device with specimen's 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 & Pv).

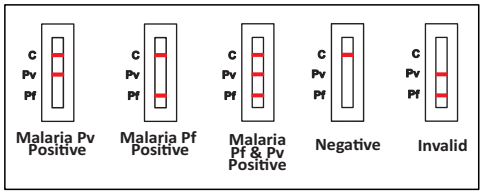
Pv Positive: If both C and Pv line appear, the test indicates the presence of detectable Pv Malarial antigen in the specimen. The result is Malaria Pv positive or reactive.

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 (C). No apparent colored line appears in the test line regions (Pf &Pv).

INVALID: No visible band appears at the control region (C). 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/Pv 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

Relative Sensitivity: 100%,
Relative Specificity: 100%,
Overall agreement: 100%

Malaria Pv Samples	Positive	Negative	Total
Positive	40	00	40
Negative	00	100	100
Total	40	100	140

Relative Sensitivity: 100%,
Relative Specificity: 100%,
Overall agreement: 100%

REFERENCES

1. Leonard K. Basco, Frederique Marquet, Michael M. Makler, and Jacques Le Bras. : Plasmodium falciparum and Plasmodium vivax: Lactate Dehydrogenase Activity and its Application for in vitro Drug Susceptibility Assay. Experimental Parasitology 80, 260-271 (1995)
2. David L. Vander Jagt, Lucy A. Hunsaker and John E. Heidrich: Partial Purification and Characterization of Lactate Dehydrogenase from Plasmodium falciparum. Molecular and Biochemical Parasitology, 4 (1981) 255-264.
3. David J. Bzik, Barbara A, Fox and Kenneth Gonyer : Expression of Plasmodium falciparum lactate dehydrogenase in Escherichia coli Molecular and Biochemical Parasitology, 59(1993) 155-166
4. Cameron R. Dunn, Mark J. Banfield, John J. Barker, Christopher W. Highm, Kathleen M. Moreton, Dilek Turgut-Balik, R. Leo Brady and J. John Holbrook. The Structure of lactate dehydrogenase from Plasmodium falciparum reveals a new target for anti-malarial design. Nature Structural Biology 3(11)1996, 912-915.

INDEX OF SYMBOLS

REF	Product Reference No.	ISO 13485	International Organization or Standardization
	Manufacturer		Keep out of Sunlight
	Expiry date	IVD	For invitro diagnostic use only
LOT	Lot (batch) number		Read product insert before use.
2°C 30°C	Store between 2-30°c		Do not use if package is damaged
	Do not reuse		Keep Away From Moisture
	Contains sufficient for test	ART/IFU-007-03	

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