Malaria Plasmodium Falciparum (P.f.) Rapid Test Kit Instructions For Use

PRODUCT NAME

FRENOVO Malaria Plasmodium Falciparum (P.f.) Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

FRENOVO Malaria Plasmodium Falciparum (P.f.) Rapid Test is a qualitative test for the detection of histidine-rich protein 2 antigen (HRP-2) of P.f. in human whole blood.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Malaria is one of the world's most prevalent parasitic diseases and ranks third in the world among major infectious diseases in terms of mortality. The protozoal parasites that cause malaria are from the Plasmodium genus. Four species of Plasmodium protozoa cause malaria: Plasmodium falciparum, Plasmodium vivax, Plasmodium malariae and Plasmodium orale. Transmitted principally by the Anopheles mosquito, malaria infections may also occur from contacting infected blood, such as from blood transfusions. P. falciparum accounts for the majority of infections and is the most lethal. P. vivax, P. malariae and P. orale cause a less severe form of malaria with intermittent fever which is usually neither debilitating nor fatal. Classic symptoms of malaria include fever, headaches, chills, vomiting, shiver- ing and convulsions. In some rare forms of falciparum malaria, chills and fever may be absent and the patient may present with delirium or coma. Remission periods can last from a few weeks to several months. Severe anemia is often attributed to the cause of death from a malaria infection. Malaria is a curable disease with a host of drugs that can be used in both its treatment and prevention. Two of the best known and most commonly used are chloroquinine and quinine. The early detection of P falciparum malaria is of great importance due to rising levels of drug resistance now being associated with this disease.

FRENOVO Malaria Plasmodium Falciparum (P.f.) Rapid Test is a rapid, in-vitro immunodiagnostic test for the detection of circulating P.f. antigen in whole blood. The test uses antibodies that are specific for the histidine-rich protein 2 antigen (HRP-2) of P.f. Whole blood (10 uL) is applied to the sample pad where the red blood cells are lysed with a specially formulated solution. The label pad that is next to the sample pad on the strip is impregnated with gold conjugation that has an anti- HRP-2 antibody coupled to it. The label pad is also impregnated with gold conjugation that is coupled to a control antibody. A second anti-HRP-2 antibody is immobilized on the test strip at the test line region. A control material is immobilized on the strip at the control line region. When a positive sample is applied to the sample pad, P.f. antigen in the sample contacts the gold-labeled antibody and binds to it. A washing buffer then added to sample well, as the liquid flows along the length of the strip, any antigen-gold complexes also migrate with the liquid. These complexes are captured by their respective antibodies at the test and control line regions. If a sample contains P.f. antigen, a red line will form in the test region. If no P.f. antigen is present, no line will form in the test region. A control line will always appear in the control region if the test has been properly performed.

MATERIALS PROVIDED

Each kit contains:

1. test cassettes: 20 pieces test cassettes individually pouched.
2. Wash Buffer Solution: 3.0 ml in dropper bottle.
3. Droppers: 20 pieces droppers of 10 ul.
4. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing
- Micro-pipette

WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kits for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. FRENOVO Malaria Plasmodium Falciparum (P.f.) Rapid Test Kit is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The kit is intended for *in vitro* diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke,eat,drink,apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of solution, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate dropper and device for each specimen tested.

Handling Precautions

1. Do not use if the kit safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix wash buffer solution/test cassettes from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 10 minutes incubation time following the addition of specimen and wash buffer solution. Do not read results beyond 15 minutes.

STORAGE INSTRUCTIONS

1. The kit should be stored between 2-30°C and the shelf life is 24 months.
2. The kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the wash buffer solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

SAMPLE COLLECTION AND PREPARATION

1. Applicable samples： Whole Blood
2. Testing should be performed immediately after the specimens have been collected as soon as possible . Do not leave the specimens at room temperature for prolonged periods.
3. Whole blood collected by venipuncture should be stored at 2~8℃ if the test is to be run within 2 days of collection.
4. Do not freeze whole blood specimens.
5. Bring specimens to room temperature prior to testing.
6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
7. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

QUALITY CONTROL

An internal procedural control is included in the test. a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

TEST PROCEDURE

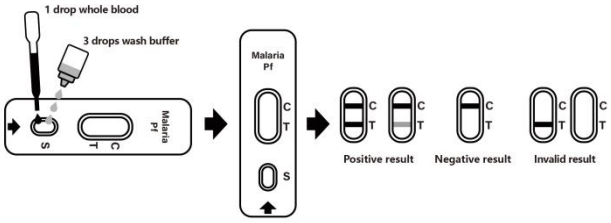
Allow the test cassette, specimen, buffer solution to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface.

2. To use a dropper: Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (one drop/approximately 10ul), then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

   To use a micro-pipette: Pipette and dispense 10ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer.

3. Wait for the colored line to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

Negative result: if there is only a quality control line C, the detection line is colorless, indicating that the Malaria P.f. has not been detected and the result is negative.

Positive result: if both the quality control line C and the detection line appear, the Malaria P.f. has been detected and the result is positive.

Invalid result: Control line fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE: The intensity of the color in the test line region(s) will vary depending on the concentration of Malaria P.f. in the specimen.

LIMITATIONS

1. The kit is for in vitro diagnostic use only. The test should be used for the detection of Malaria P.f. in whole blood specimens only.
2. FRENOVO Malaria Plasmodium Falciparum (P.f.) Rapid Test may give positive malaria results for up to 2 weeks following chemotherapy and parasite clearance as confirmed by microscopy.
3. As with all diagnostic tests, the result must be correlated with clinical findings. If the test result is negative and malaria infection suspicion still exists, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of an early malaria infection.
4. A negative result at any time does not preclude the possibility of an early malaria infection.
5. A final diagnosis should be based on these test results in conjunction with other clinical and laboratory findings.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Clinical study was performed to compare the results obtained by The kit and PCR. The results indicated that The kit has a high sensitivity and specificity as summarized below:

Method		PCR		
FRENOVO Malaria P.f. Rapid Test	Results	Positive	Negative	Total Results
	Positive	54	8	62
	Negative	1	318	319
Total Results		55	326	381

Summary Results:

Clinical sensitivity =98.18% (95%CI*90.28%～99.75%)

Clinical specificity = 97.55% (95%CI*95.22%～98.93%)

Accuracy=97.64% (95%CI*95.56%～98.91%)

.

Interference Substances

The following potential interfering substances were added to Malaria negative and positive specimens. None of the substances at the concentration tested interfered in the assay.

Substance	Tested Concentration
Hemoglobin	6 mg/ml
Bilirubin	0.4 mg/ml
Triglycerides	15 mg/ml
Cholesterol	4 mg/ml
Human Anti-mouse Antibody (HAMA)	100 IU /ml
Rheumatoid Factor	1500 IU/ml
Antinuclear Antibody (ANA)	100 IU/mL
Acetaminophen	20 mg/dL
Caffeine	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Gentisic Acid	20 mg/dL
Ascorbic Acid	2 g/dL
Albumin	2 g/dL
Creatin	200 mg/dL
Bilirubin	1g/dL
Oxalic Acid	60 mg/dL

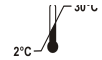
Minimum Detection Level

The minimum detection limit for FRENOVO Malaria Plasmodium Falciparum (P.f.) Rapid Test is 200 Parasites/ul.

Cross Reaction

FRENOVO Malaria Plasmodium Falciparum (P.f.) Rapid Test has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, Syphilis, HIV, HCV, H. Pylori, MONO, CMV, Rubella, HSV and TOXO positive specimens. The results showed no cross-reactivity.

INDEX OF SYBOML

	In vitro diagnostic medical device		single-use,Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
	Temperature limit		Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don’t use the product when the package is damaged
	CE mark		Biological risks

Hangzhou FRENOVO Biotech Co., Ltd.
Address: Room 401,Building 36,No.488-1,Donghu North Road, Donghu Street, Yuhang District, Hangzhou City, Zhejiang Province, China.
Tel: 86-0571-89170657
Email： business@frenovo.com

EC REP
Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Email： peter@lotusnl.com

INSTRUCTION APPROVAL AND REVISION DATE

Revision Date:
Date of Issue: