CE
IVD

Malaria Pf/Pv Antigen Rapid Test Kit (Colloidal Gold)

Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of Human Malaria Pf/Pv in human blood specimen.*For professional medical institutions use only,Not for self testing.*

PRODUCT NAME

Malaria Pf/Pv Antigen Rapid Test Kit (Colloidal Gold)

SPECIFICATION

25 tests/kit; 5 tests/kit;1 test/kit

INTENDED USE

The Malaria Pf/Pv Ag Rapid Test is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of Plasmodium falciparum (Pf) and vivax (Pv) antigen in human blood specimen. This device is intended to be used as a screening test and as an aid in the diagnosis of infection with plasmodium. Any reactive specimen with the Malaria Pf/Pv Ag Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION THE TEST

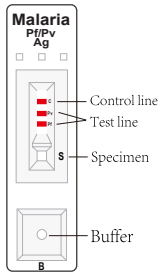
Malaria is a mosquito-borne, hemolytic, febrile illness that infects over 200 million people and kills more than 1 million people per year. It is caused by four species of Plasmodium: P. falciparum, P. vivax, P. ovale, and P. malariae. These plasmodia all infect and destroy human erythrocytes, producing chills, fever, anemia, and splenomegaly. P. falciparum causes more sever disease than the other plasmodial species and accounts for most malaria deaths. P. falciparum and P. vivax are the most common pathogens, however, there is considerable geographic variation in species distribution.

Traditionally, malaria is diagnosed by the demonstration of the organisms on Giemsa stained thick smears of peripheral blood, and the different species of plasmodium are distinguished by their appearance in infected erythrocytes. The technique is capable of accurate and reliable diagnosis, but only when performed by skilled microscopists using defined protocols, which presents major obstacles for the remote and poor areas of the world.

The Malaria Pf/Pv Ag Rapid Test is developed for solving these obstacles. It utilizes antibodies specific to P. falciparum Histidine Rich Protein-II (pHRP-II) and to P. vivax Lactate Dehydrogenase (Pv-LDH) to simultaneously detect and differentiate infection with P. falciparum and P. vivax. The test can be performed by untrained or minimally skilled personnel, without laboratory equipment

PRINCIPLE

The Malaria Pf/Pv Ag Rapid Test is a lateral flow chromatographic immunoassay. The strip test components consist of: 1) a burgundy colored conjugate pad containing mouse anti-Pv-LDH antibody conjugated with colloid gold (Pv-LDH-gold conjugates) and mouse anti-pHRP-II antibody conjugated with colloid gold (pHRP-II-gold conjugates), 2) a nitrocellulose membrane strip containing two test bands (Pv and Pf bands) and a control band (C band). The Pv band is pre-coated with another mouse anti-Pv-LDH specific antibody for the detection of Pv infection, the Pf band is pre-coated with polyclonal anti-pHRP-II antibodies for the detection of Pf infection, and the C band is coated with goat anti-mouse IgG.



During the assay, an adequate volume of the blood specimen is dispensed into the sample well (S) of the test cassette, a lysis buffer is added to the buffer well (B). The buffer contains a detergent that lyses the red blood cells and releases various antigens, which migrate by capillary action across the strip held in the cassette. Pv-LDH if presents in the specimen will bind to the Pv-LDH-gold conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-Pv-LDH antibody, forming a burgundy colored Pv band, indicating a Pv positive test result. Alternatively, pHRP-II if presents in the specimen will bind to the pHRP-II-gold conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-pHRP-II antibodies, forming a burgundy colored Pf band, indicating a Pf positive test result. Absence of any test bands suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti- mouse IgG / mouse IgG (anti-Pv-LDH and anti-pHRP-II)-gold conjugates regardless of the color development on any of the test bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

Components	25tests/kit	5tests/kit	1test/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution with dropper	25tubes (300ul/tube)	5tubes (300ul/tube)	300ul/tube
Transfer tube	25 pcs	5 pcs	1 pcs
Package insert	1	1	1

MATERIALIS REQUIRED BUT NOT PROVIDED

Clock or Timer

WARNINGS AND PRECAUTIONS

For in Vitro Diagnostic Use

1.This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2.Do not open the sealed pouch, unless ready to conduct the assay.
3.Do not use expired devices.
4.Bring all reagents to room temperature (15°C-30°C) before use.
5.Do not use the components in any other type of test kit as a substitute for the components in this kit.
6.Do not use hemolized blood specimen for testing.
7.Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8.Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9.Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10.Dispose of all specimens and materials used to perform the test as biohazardous waste.
11.Handle the Negative and Positive Control in the same manner as patient specimens.
12.The testing results should be read within 25 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 25 minutes may give erroneous results.
13.Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them with standard biosafety procedures.

Collect whole blood in a clean container containing anti-coagulant (EDTA, citrate or heparin) by venipuncture. Blood can be obtained by finger tip puncture as well.

Whole blood specimen should be stored in refrigeration (2°C-8°C) if not tested immediately for up to 3 days. The specimen should be frozen at -20°C for longer storage. Avoid repeat freeze and thaw

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed. Blood will be hemolyzed after thawing.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

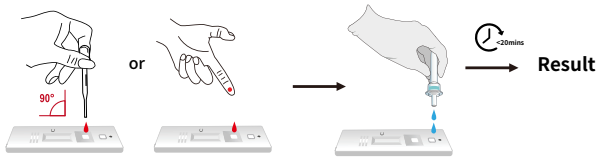
Step 3: Be sure to label the device with specimen's ID number.

Step 4: Fill in the mini plastic dropper with the blood specimen not to exceed the specimen line as showed in the following image. The volume of the specimen is around 5 μL.

Note: Practice a few times prior to testing if you are not familiar with the mini dropper. For better precision, transfer specimen by pipette capable to deliver 5μL of volume.

Holding the dropper vertically, dispense all of the specimen into the center of the sample well making sure that there are no air bubbles.

Then add 3 drops (about 100-150 μL) of Lysis Buffer immediately.



Step 5: Set up timer.

Step 6: Results can be read in 20 minutes. Positive results can be visible in as short as 1 minute.

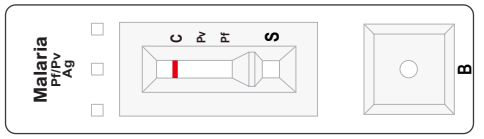
Don't read results after 30 minutes.To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

Using individual Pf / Pv Malaria Ag Rapid Test cassettes as described in the Assay Procedure
above, run 1 positive control and 1 Negative Control under the following circumstances to monitor test performance:
1.A new operator uses the kit, prior to performing testing of specimens.
2.A new test kit is used.
3.A new shipment of kits is used.
4.The temperature used during storage of the kit fall outside of 2°C-30°C.
5.The temperature of the test area falls outside of 15°C-30°C.
Expected results are as follows:

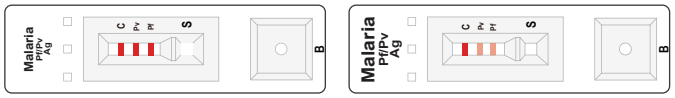
Negative Control

Only the C band shows color development, the two Test bands (Pv and Pf) show no color development.



Positive Control

The C band and two Test bands (Pv and Pf) show color development.

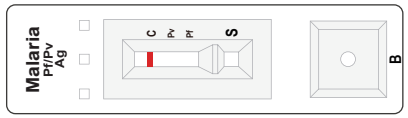


The appearance of any burgundy color in the test bands, regardless of intensity, must be considered as presence of the band.

INTERPRETATION OF ASSAY RESULT

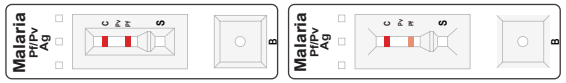
Negative Control

If only the C band is present, the absence of any burgundy color in the both test bands (Pv and Pf) indicates that no plasmodium antigens are detected. The result is negative.

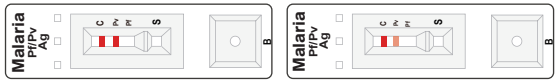


Positive Control

Pf Positive: In addition to the presence of C band, if only Pf band is developed, the test Indicates for the presence of pHRP-II antigen. The result is Pf positive.



Pv Positive: In addition to the presence of C band, if only Pv band is developed, the test indicates for the presence of Pv-LDH antigen. The result is Pv positive.

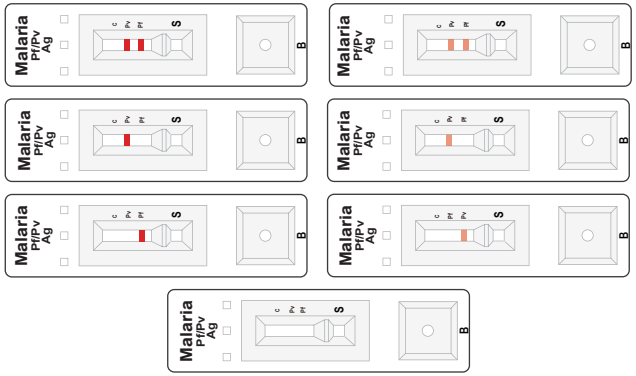


Pf/Pv Positive: In addition to the presence of C band, both Pv and Pv bands are developed, the test indicates for the presence of both Pv-LDH and pHRP-II antigens. The result is both Pv and Pf positive.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

INVALID:

If no C band is developed, the assay is invalid regardless of any burgundy color in the T bands as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

1. Clinical Performance with Pf positive specimen

A total of 400 samples from susceptible subjects were tested by the Malaria Pf/Pv Ag Rapid Test and by thick blood smear test. Comparison for all subjects is showed in the following table.

	Malaria Pf/Pv Ag Rapid Test		
Smear test	Positive	Negative	Total
Positive	135	1	136
Negative	2	262	264
Total	137	250	400

Relative Sensitivity:99.26% , Relative Specificity:99.24%, Overall Agreement: 99.25%

2. Clinical Performance with Pv positive specimen

A total of 500 samples from susceptible subjects were tested by the Malaria Pf/pv Ag Rapid Test and by thick blood smear test. Comparison for all subjects is showed in the following table.

	Malaria Pf/Pv Ag Rapid Test		
Smear test	Positive	Negative	Total
Positive	172	3	175
Negative	2	323	325
Total	174	326	500

Relative Sensitivity:98.29% , Relative Specificity:99.39%, Overall Agreement: 99%

3. External Evaluation

The Malaria Pf /Pv Ag rapid test was evaluated by the Research Institute for Tropical Medicine, a WHO affiliation in Philippines. The result is showed in the following table:

Quality control dilutions		Pf /Pv malaria Ag Rapid Test		
Sample ID	(parasites/μl)	Device tested	Positive result	% positive
P5F2 (Pf)	200	2	2	100%
	2000	1	1	100%
P5F4 (Pf)	200	2	2	100%
	2000	1	1	100%
P5F5 (Pf)	200	2	2	100%
	2000	1	1	100%
P5F8 (Pf)	200	2	2	100%
	2000	1	1	100%
P5V2 (Pv)	200	2	2	100%
	2000	1	1	100%
P5V5 (Pv)	200	2	2	100%
	2000	1	1	100%
P5V7(Pv)	200	2	2	100%
	2000	1	1	100%
P31(Pv)	200	2	2	100%
	2000	1	1	100%
		Device tested	Negative result	% negative
Negative control	0	1	1	100

LMITATIONS OF TEST

1.The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of plasmodium protozoa antigen in whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.

2.The Malaria Pf/Pv Ag Rapid Test is limited to the qualitative detection of plasmodium protozoa antigen in whole blood. The intensity of the test band does not have linear correlation with the antigen titer in the specimen.

3.A negative result for an individual subject indicates absence of detectable malaria plasmodium antigen. However, a negative test result does not preclude the possibility of exposure to or infection with plasmodium protozoa.

4.A negative result can occur if the quantity of the plasmodium protozoa antigen present in the specimen is below the detection limits of the assay, or the antigen that are detected are not present during the stage of disease in which a sample is collected.

5.Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

6.The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

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