Humasis

Malaria P.f/Pan Antigen Test

Please read the instructions carefully before use!

For professional use

[INTENDED USE]

Humasis Malaria P.v/P.v Antigen Test is a one step in vitro diagnostic test based on an immunochromatographic assay. It is designed for qualitative detection of HRP-II (specific to Plasmodium falciparum) and pLDH (specific to Plasmodium vivax, Plasmodium ovale, and Plasmodium malariae) in human venipuncture and finger puncture blood.

[SUMMARY AND EXPLANATION]

Malaria is one of the worldwide diseases known as a mosquito-borne infectious disease. It is accompanied by the symptom such as high fever, shivering, arthralgia (joint pain), vomiting, and etc. The typical symptom of malaria is cyclical occurrence of sudden coldness followed by rigor and fever and sweating. The seriousness depends on the type and the most serious form is caused by Plasmodium falciparum which needs the fast treatment. Otherwise it may be fatal to death. Four species of the Plasmodium parasites are responsible for malaria infections in human viz. P. 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 maybe 2 million malaria-caused deaths per year.

[PRINCIPLE OF THE TEST]

Humasis Malaria P.f/Pan Antigen Test is an immunochromatographic assay. As the test sample flows through the membrane assembly, after addition of the clearing buffer, the colored colloidal gold conjugates of monoclonal anti P. falciparum(HRPII specific) and monoclonal anti-pan(pLDH specific) complexes the HRPII/corresponding pLDH in the lysed sample. This complex moves further on the membrane to the test region where it is immobilized by the monoclonal anti HRPII and monoclonal anti pLDH specific antibody coated on the membrane leading to formation of pink-purple colored band, which confirms a positive test result. Absence of colored bands in the test region indicates a negative test result.

[CONTENTS]

- Humasis Malaria P.f/Pan Antigen Test
- Specimen collection inverted cup
- Buffer
- Lancet (optional)
- Alcohol swab (optional)

[COMPOSITION]

- Mouse monoclonal antibody to Plasmodium falciparum HRPII-1
- Mouse monoclonal antibody to Pan pLDH-1
- Mouse monoclonal antibody to Plasmodium falciparum HRPII-2
- Mouse monoclonal antibody to Pan pLDH-2
- Goat anti-mouse immunoglobulin G

[STORAGE AND SHELF-LIFE]

1. Store the test device packaged in a sealed foil pouch at 1~30℃(34~86℉). Do not freeze.
2. Shelf-life: 24 months from manufacturing date

[PRECAUTIONS]

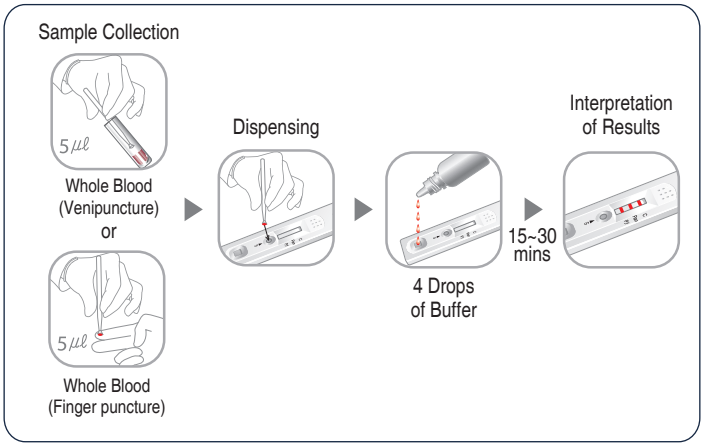
1. For *in vitro* diagnostic use only
2. Do not use the test device beyond the expiration date.
3. Do not use the test device if the pouch is damaged or the seal is broken.
4. The test result should be used in conjunction with other clinical information such as clinical signs and symptoms and other test results to diagnose Plasmodium falciparum, Plasmodium vivax, Plasmodium ovale and Plasmodium malariae.
5. Specimen Handling and Storage
   1) Test the whole blood specimen within an hour after sampling.
   2) Handle all specimens as potentially infectious.
   3) Specimens with high level of hemolysis should be avoided as it can give inaccurate result.
   4) If the specimen was kept in the fridge before, it should be left in room temperature for fifteen minutes before testing it.
6. Keep it sealed until usage, and once opened use it quickly.
7. Do not re-use the device that has already been used.
8. The test result of the Pan (pLDH) should be used in conjunction with other clinical or test results as there is a possibility of false negative caused by Plasmodium malariae and Plasmodium ovale.

[SPECIMEN COLLECTION AND PREPARATION]

1. Finger puncture whole blood using lancet
   1) Clean the fingertip with an alcohol pad and let it dry.
   2) Take a lancet and make a quick deep stab on the side of the finger.
   3) Use the specimen collecting tool provided to collect the specimen. Avoid squeezing the fingertip to accelerate bleeding as this tends to dilute the blood with excess tissue fluid.
2. Venipuncture whole blood
   1) Use the tube with EDTA, heparin or sodium citrate anticoagulant.
3. Specimen storage
   1) In principle, test the specimen immediately after collection.
   2) If specimens are not immediately tested, they should be refrigerated at 2-8C up to 3 days. For storage periods longer than 3 days, freeze the specimen and store at below -20C.

[TEST PROCEDURE]

1. Place the specimen and test device on room temperature before testing for them to reach the room temperature.
2. Open the sealed pouch and take out the test device.
3. For fingerpuncture whole blood, take 5uL of whole blood using collection tool provided and drop the specimen in specimen insertion-hole(S). For venipuncture whole blood, use either the collection tool provided or micropipette to take 5uL of the specimen and drop in to the specimen insertion-hole(S).
4. Add 4 drops of buffer (approximately 120uL) in the buffer hole.
5. Wait for 15-30 minutes and then read the results. Do not interpret the test results after 30 minutes.



[INTERPRETATION OF RESULTS]

1. Negative

A colored band is visible only in the control region(C).

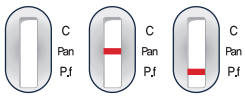
2. Positive

1) Positive for P.f :
Two colored bands are visible in the P.f region and control region(C).

2) Positive for Pan :
Two colored bands are visible in the Pan region and control region(C).

3) Positive for P.f and Pan :
Three colored bands are visible in the P.f region, Pan region and control region(C).

3. Invalid



If there is no color line in the control line region(C) , the result is invalid. This is due to deterioration of the test device or improper test procedure. Repeat the test with a new test strip.

[QUALITY CONTROL]

The appearance of the control line indicates that sufficient sample fluid was added for capillary flow to occur and all of the reagents in the test device are working properly. The absence of the control line may indicate that insufficient sample is added or the test device is inactivated.

[LIMITATIONS OF THE TEST]

1. Humasis Malaria P.f/Pan Antigen Test is designed for primary screening test of HRPII (P. falciparum) and pLDH(P. falciparum, P. vivax, P. ovale, P. malariae) in human blood.
2. This test can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative result caused by various factors. So, test result must be evaluated in conjunction with other clinical data available to the physician.
3. The device and buffer from different lots must not be used together.
4. In a few cases, where the result shows P.f(HRP-II)-positive and Pan-negative, it may indicate post-treatment phase. However, it may be also be an indication of malaria. In such cases, re-testing in 2 days is recommended.
5. In most cases the background will clear within the running time of the test. However, when using fresh samples and especially in stored samples, it may take another 15-20 minutes or longer for the background clearance.

[PERFORMANCE CHARACTERISTICS]

Sample			Humasis Malaria P.f/Pan Antigen Test	
			Positive	Negative
Positive	P. falciparum	50	50	0
	Pan	150	149	1
	Total	200	199	1
Negative		200	1	199
Sensitivity			99.5%(199/200)	
Specificity			99.5%(199/200)	

[REFERENCES]

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: Manufacturer	: Do not reuse	: Consult instructions for use
REF : Catalogue number	LOT : Lot number	IVD : *In vitro* diagnostic medical device
: Temperature limit	: Use by	: Contains sufficient for <n> tests
: Keep away from sunlight	: Keep dry	: Do not use if package is damaged
CE : This product fulfills the requirements for Directive 98/79/EC on *in vitro* diagnostic medical devices		EC REP : Authorized representative

Humasis Co., Ltd.

Rm. 114, 502, 504, 604, 604-1, B03-01, B03-02, 88, Jeonpa-ro,
Dongan-gu, Anyang-si, Gyeonggi-do, 14042, Republic of Korea
TEL: +82-31-8085-6200, FAX: +82-31-8085-6249
Email: question@humasis.com
www.humasis.com

EC REP **MT Promedt Consulting GmbH**

Altenhofstr. 80, 66386 St. Ingbert, Germany
TEL: +49 6894 581020
FAX: +49 6894 581021
Email: info@mt-procons.com
www.mt-procons.com

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