IVD

Asan Easy Test® Malaria Pf/Pan Ag

ASAN

Diagnostic Kit for the malarial antigens against *P.falciparum* (HRP-II) and *Pan Plasmodium* (pLDH) in human whole blood

Immunochromatography

INTENDED USE

Asan Easy Test® Malaria Pf/Pan Ag is a chromato-graphic immunoassay for the rapid, qualitative differential detection of histidine-rich protein II (HRP-II) antigen and *Plasmodium* lactate dehydrogenase (pLDH) in human whole blood. This kit is intednded for the discriminational detection of Malaria P.f infection and other pan malaria (Non-P.f malaria) infections in human blood sample. This kit is for professional use and only for the initial screening test and reactive samples should be confirmed by a supplemental assay such as microscopic examination of thin blood smear.

EXPLANATION OF THE TEST

Asan Easy Test® Malaria Pf/Pan Ag is introduced 4 different monoclonal antibodies. Among them, two antibodies are detectable for P.f-HRP II and others is for pLDHs. anti-P.f-HRP II and anti-pLDH antibody were dispensed and immobilized on the test line 1 for anti-HRP II and test line 2 for anti-pLDH of nitrocellulose membrane. Colloidal gold were also conjugated another antibodies for HRP2 and pLDH. This rapid diagnostic system can be achievable to differentially diagnose *P.falciparum* and other species of malaria. Malaria antigens, LDH(Lactate dehydrogenase) and anti-aldolase monoclonal antibody-coupled gold conjugate followed by reaction with anti-LDH or anti-HRP Ⅱ monoclonal antibody in the test lines. When the bloood sample is infected with malaria, a visible line appears in the test region on the membrane.

MATERIALS PROVIDED

Asan Easy Test® Malaria Pf/Pan Ag contains following items to perform the assay.

1. Test device in aluminium pouch with a dessicant.
2. Assay solution
3. Disposable sample applicator
4. Instructions manual for use

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. The test kit should remain in the sealed pouch until ready for use.
3. The test kit is sensitive to humidity and to heat.
4. Do not smoke, eat or drink in areas where specimens or kit component are handled.
5. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infection agent.
6. Wear protective gloves while handling samples and wash hands thoroughly after the assay is complete.
7. Avoid any contact with the eyes, broken skin or mucous membranes.
8. The test device and all materials should be discarded in a proper biohazard container after testing.

SPECIMEN COLLECTION AND STORAGE

1.Specimen Collection and Storage

[Whole blood] Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture.

If blood specimens are not immediately tested, they should be refrigerated at 2~8℃ and should be used within 3days or at -20℃ for longer period.

2.Precaution

1) Anticoagulants such as heparin, EDTA, and citrate do not affect the test result.

2) Use separately disposable capillay pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous result.

TEST PROCEDURE

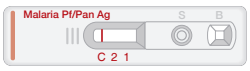
1. All materials should be equilibrated to room temperature before performing the test.
2. Remove the test device from its protective pouch.
3. Add 5㎕ of whole blood into the sample well(S) of the test device.
4. Dispense 4drops (about 120㎕) of assay solution into the buffer dropping well(B) of the test device.
5. Interpret test results at 30 minutes after placement of blood and assay solution. Do not interpret after 30 minutes.

INTERPRETATION OF THE TEST

1. A color band will appear in the upper section("C" zone) of the window to show that the test is working properly. This band is the control band.
2. The down section("T" zone: 1 and 2) of the window indicates the test results, test band. If another color band appears in the down section of the window, this band is the test band.

A. NEGATIVE RESULTS:

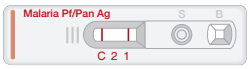
The presence of only one purple color band("C" band) within the window indicates a negative result.



B. POSITIVE RESULTS:

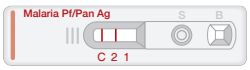
- Positive for HRP-II of *P.falciparum* :

The presence of two color bands ("T1" band and "C" band) within the result window regardless of which band appears first indicates a positive result .



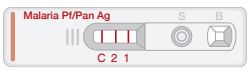
- Positive for pLDH of *Pan Plasmodium* :

The presence of two color bands ("T2" band and "C" band) within the result window regardless of which band appears first indicates a positive result .



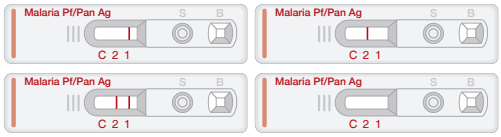
- Positive for HRP-II of *P.falciparum* and pLDH of *Pan Plasmodium* :

The presence of two color bands ("T1","T2" band and "C" band) within the result window regardless of which band appears first indicates a positive result .

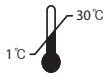


C. INVALID RESULTS:

If no band is visible within the window after performing the test, the result is considered invalid . Some causes of invalid results are not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.



STORAGE & EXPIRATION



1. Asan Easy Test® Malaria Pf/Pan Ag should be stored between 1 to 30℃ (33.8~86 °F).
2. Expiration date of this kit is 24 months after its manufacture date.

PERFORMANCE CHARACTERISTICS

This clinical test was performed using a total of 371 specimens. Each specimen was tested with Asan Easy Test® Malaria Pf/Pan Ag and Blood Smear. The results are summarized in the following tables.

n= 371		Blood Smear		Total
		Positive	Negative	
Asan EasyTest® Malaria Pf/Pan Ag	Positive	266	1	267
	Negative	5	99	104
Total		271	100	371

※ Relative Sensitivity : P.falciparum(98.1%), P.viviax(98.3%), Povale(97.1%), P.malaria(100%), Relative Specificity : 99%

※ Detection limit : Pf 50parasites/㎕, Pv 75parasites/㎕

LIMITATIONS OF THE TEST

Other clinically available tests are required if questionable results are obtained. As all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but be made by the physician after all clinical and laboratory findings have been evaluated.

ASAN

ISO13485:2003

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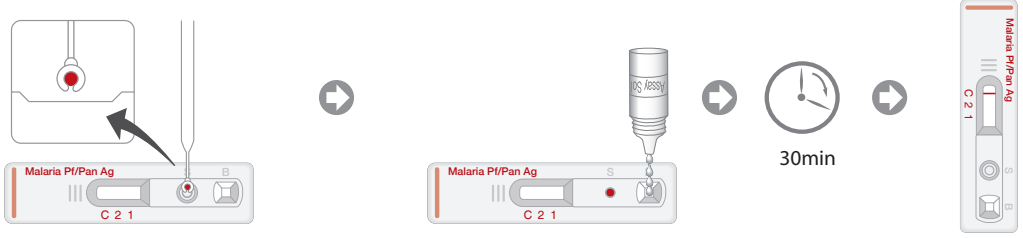
REF Code No.: 24651
Document Code: AMPAN0-S0E00



Add 5㎕ of whole blood

4drops of assay solution

Reading