

# ASAN Easy Test<sup>®</sup> Malaria Pf/Pv Ab

Diagnostic kit for antibodies against *P. falciparum* and *P. vivax*

Immunochromatography

## EXPLANATION OF THE TEST

Asan Easy Test<sup>®</sup> Malaria Pf/Pv Ab is a chromatographic immunoassay kit for rapid qualitative detection of antibodies of all isotypes (IgG, IgM, IgA) specific to *Plasmodium falciparum* and *Plasmodium vivax* simultaneously and discriminately, in human serum, plasma or whole blood. This kit is intended for professional use, only for an initial screening test and malaria antibody positive samples should be confirmed by a supplemental assay such as a leading commercial malaria antibody detection ELISA or IFA. Finally, malaria Ab positive specimen by this kit should be confirmed by microscopic examination. Asan Easy Test<sup>®</sup> Malaria Pf/Pv Ab contains a membrane strip, which is pre-coated with recombinant malaria Pf-specific antigen (MSP) on test line 1 region and with recombinant malaria Pv-specific antigen (MSP) on test line 2 region. The recombinant malaria Pf/Pv antigen (MSP)-gold conjugate and serum sample moves along the membrane chromatographically with the gold conjugate and the antigen-antibody-gold particle complexes are formed in test line regions (1 and 2) with the high degree of sensitivity and specificity.

## MATERIALS PROVIDED

Asan Easy Test<sup>®</sup> Malaria Pf/Pv Ab kit contains the following item to perform the assay.

1. Test devices in aluminum pouch with a desiccant
2. Assay Solution
3. Instruction 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 °C and should be used within 3 days or at -20 °C for longer period.

**[Serum]** Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen or supernatant.

**[Plasma]** Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.

If serum or plasma specimens are not tested immediately, they should be refrigerated at 2~8 °C or -20 °C for longer period.

### 2. Precaution

- 1) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
- 2) Anticoagulants such as heparin, EDTA, and citrate do not affect the test result.
- 3) Use separately disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous result.

## TEST PROCEDURE

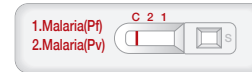
1. All materials should be equilibrated to room temperature before performing the test.
2. Remove the test device from its protective pouch.
3. Add 10  $\mu$ l of serum/plasma or 20  $\mu$ l of whole blood into the sample well(S) of the test device.
4. Dispense 3 drops (about 100  $\mu$ l) of assay solution into the sample well (S) of the test device.
5. Interpret test results at 5~20 minutes. Do not interpret after 20 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 result window indicates a negative result.

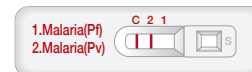


### B. POSITIVE RESULTS:

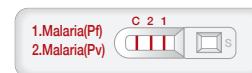
Along with the "C" band, if "1" band appears, the blood sample contains the antibodies against *P. falciparum*. If only "2" band appears, the blood sample contains the antibodies against *P. vivax*. If two bands in the "1" and "2" band, the sample contains the antibodies against both *P. falciparum* and *P. vivax*.



*P. falciparum* positive



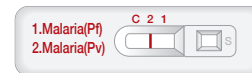
*P. vivax* positive



*P. falciparum* & *P. vivax* positive

### 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<sup>®</sup> Malaria Pf/Pv Ab should be stored between 2 °C to 30 °C (35.6~86 °F).
2. Expiration date of this kit is 24 months after its manufacture date.

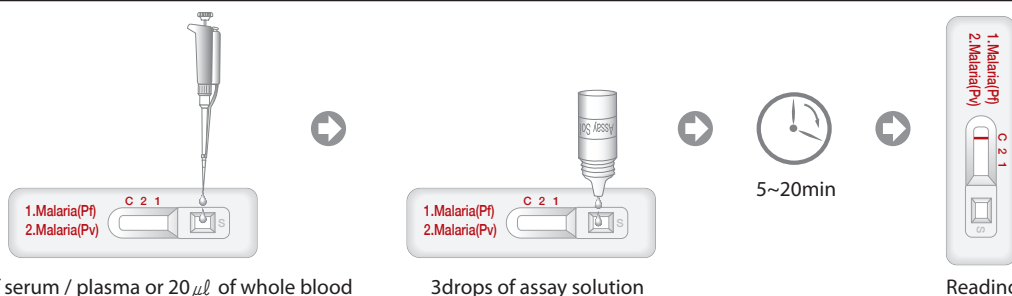
## LIMITATIONS OF THE RESULTS

Asan Easy Test<sup>®</sup> Malaria Pf/Pv Ab is designed for primary screening test of Malaria antibodies. This kit 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, refer to the result of this kit, please make a final decision with clinical manifestation, other test results, and doctor's view, collectively.



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**REF** Document Code: AHMAB0-S0E00



Add 10  $\mu$ l of serum / plasma or 20  $\mu$ l of whole blood

3drops of assay solution

Reading