AG- MALARIA PAN/Pf/Pv Ag RAPID TEST KIT

INSTRUCTION FOR USE

AstraGene - Malaria Pan/Pf/Pv Ag Rapid test kit **i**s a rapid chromatographic immunoassay for the qualitative detection of four kinds of circulating *Plasmodium falciparum* (P.f.), *P. vivax* (P.v.), *P. ovale* (P.o.), and *P. malariae* (P.m.) in whole blood.

PRINCIPLE

AstraGene - Malaria Pan/Pf/Pv Ag Rapid test kit is a qualitative, membrane based immunoassay for the detection of P.f., P.v., P.o. and P.m. antigens in whole blood. The membrane is pre-coated with anti-HRP-II antibodies, anti-p.v. LDH and anti-pan LDH antibodies. During testing, the whole blood specimen reacts with the dye conjugate, which has been pre-coated on the test cassette. The mixture then migrates upward on the membrane by capillary action, reacts with anti-Histidine-Rich Protein II (HRP-II) antibodies on the membrane on P.f. test line region, with anti-p.v.LDH antibodies on the membrane on P.v. line region and with anti-pan LDH antibodies on the membrane on Pan line region. If the specimen contains HRP-II, p.v. LDH and/or pan LDH, colored line (s) will appear in P.f. line region, P.v. and/or Pan line region. The absence of the colored lines in P.f. line region, P.v. line region and/or Pan line region indicates that the specimen does not contain HRP-II, P.v. LDH and/or Plasmodium-specific LDH. To serve as a procedure control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

PACKAGE CONTENTS

Description	10 tests	1 test
Test Cassette	10	1
Disposable Specimen Dropper	10	1
Buffer.	01×2.0mL	01×0.2mL
Instructions for use	1	1

Catalogue Number	10 tests	1 test
Cassette Model	AG/RTK/MALAg/24/01	AG/RTK/MALAg/24/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Calibrated micropipette capable of delivering 5µl specimen accurately, disposable micropipette tips.
- Permanent marker Pen/pencil, disposable gloves, timer.
- Biosafety sharps container and Biohazard waste container (for potentially infectious waste).
- Venipuncture blood collection kit (if whole blood is collected by venepuncture).
- Anti-coagulant tube containing heparin, EDTA or sodium citrate for collection of venous whole blood, Lancet.

STORAGE &STABILITY

- Store the sealed pouch and the buffer provided in the kit at 2-40°C out of the direct sunlight for the duration of it Shelf life. Do not open the foil pouch until you are ready to perform the test. Close the buffer cap tightly after using, and then store it at 2-40°C out of the direct sunlight. It is stable until the expiry date of the kit and the buffer label after opening its cap, if it is tightly closed

SPECIMEN COLLECTION & PREPARATION

- AstraGene - Malaria Pan/**Pf/Pv** A**g** Rapid test kit can be performed using whole blood.
- Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
- To collect Fingerstick Whole Blood specimens:

1. Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
2. Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger
3. Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
4. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.

- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20°C. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly for more than three times
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

PROCEDURE

Allow the test, specimen, buffer and/or controls to reach room temperature (15- 30°C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
- Place the cassette on a clean and level surface.

 Use a pipette: To transfer 5 uL of whole blood to the specimen well (S), then add 3 drops of buffer (approximately 180 uL) to the buffer well (B) and start the time.

 Use a disposal specimen dropper: Hold the dropper vertically; draw the specimen up to the upper end of the nozzle as shown in illustration below (approximately 5 uL). Transfer the specimen to the specimen well (S), then add 3 drops of buffer (approximately 180 uL) to the buffer well (B) and start the timer.

- Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.

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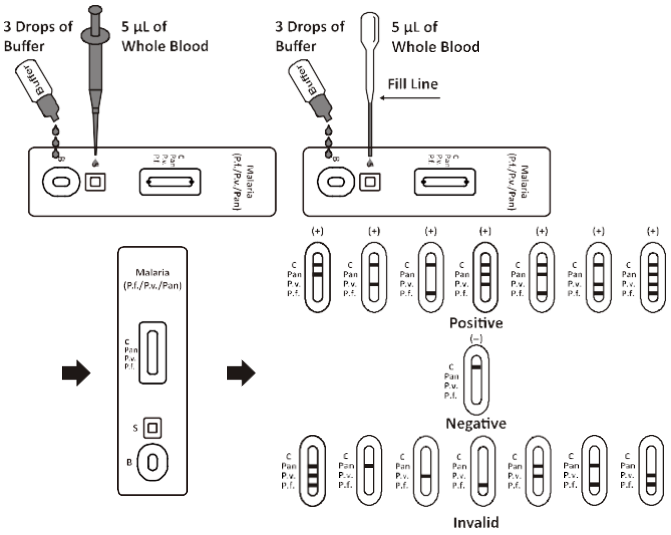

RESULT INTERPRETATIONS

POSITIVE:* Two or Three or Four colored lines appear.

- **P. falciparum Infection (Either of the results):**
  - One line appears in the control region, one line appears in P.f. line region.
  - One line appears in the control region, one line appears in P.f. line region and one line appears in Pan line region.
- **P. vivax Infection (Either of the results):**
  - One line appears in the control region, one line appears in P.v. line region.
  - One line appears in the control region, one line appears in P.v. line region and one line appears in Pan line region.
- **Non-P. falciparum/Non-P. vivax Infection:**
  - One line appears in the control region, one line appears in Pan line region.
- **Mixed malaria infection:**
  - One line appears in the control region, one line appears in P.f. line region, and one line appears in P.v. line region.
  - One line appears in the control region, one line appears in P.f. line region, one line appears in P.v. line region and one line appears in Pan line region.

***NOTE:** The color intensity of P.f., P.v. or Pan Test lines may vary depending on the concentration of antigens, viz., HRP-II, P.v. LDH or Plasmodium-specific LDH present in the specimen.

NEGATIVE: Only one colored line appears in the control region.

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

SENSITIVITY & SPECIFICITY

AstraGene - Malaria Pan/**Pf/Pv Ag** Rapid test kit has been tested with microscopy on clinical samples. The Kits sensitivity is >98.7% and specificity is >99.0%, when compared to results obtained with microscopy.

LIMITATION OF THE PROCEDURE

- AstraGene - Malaria Pan/**Pf/Pv A**g Rapid test kit is for *in vitro* diagnostic use only. This test should be used for the detection of P.f., P.v., P.o., P.m. antigens in whole blood specimens only. Neither the quantitative value nor the rate of increase in P.f., P.v., P.o., and P.m. concentration can be determined by this qualitative test.
- AstraGene - Malaria Pan/**Pf/Pv A**g Rapid test kit will only indicate the presence of antigens of Plasmodium sp. (P.f., P.v., P.o., P.m.) in the specimen and should not be used as the sole criterion for the diagnosis of malaria infection.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of malaria infection.

WARNING AND PRECAUTION

- For professional in vitro diagnostic use only. Do not use after expiration date.
- For whole blood specimen use only. Do not use other specimens.

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- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- Do not exchange or mix buffer and test cassettes from kits of different lots.
- Caution must be taken at the time of specimen collection. Inadequate volume of specimen may lead to lower sensitivity.
- Be sure to add sufficient buffer to the cassette's sample well. Invalid result may occur if inadequate buffer is added.

SYMBOLS

 Do not use if package is damaged  Manufacturer  Batch Code

 CE mark of Conformity  Refer to the instructions  ISO  GMP

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