BioSign™ Malaria Pf

For Professional Use

Immunoassay for the Qualitative Detection of Malarial *Plasmodium* Lactate Dehydrogenase(pLDH) in Blood

Intended Use

BioSign™ Malaria Pf test is an *in vitro*, qualitative, immunochromatographic assay for an infection by Malarial parasite (*Plasmodium falciparum*) in whole blood. **BioSign™ Malaria Pf** test can be used to monitor the course of the disease of which multidrug resistant patients can be identified within a few days.

Reagents

Materials Provided

- Test device:

  Each test device contains a membrane strip coated with specific monoclonal antibody to malarial

  pLDH(*Plasmodium falciparum*).
- Developer Solution
- Test tube for blood lysis.

Materials Required but Not Provided

- Micropipetter (0-200 µL) and tips

Warnings and Precautions

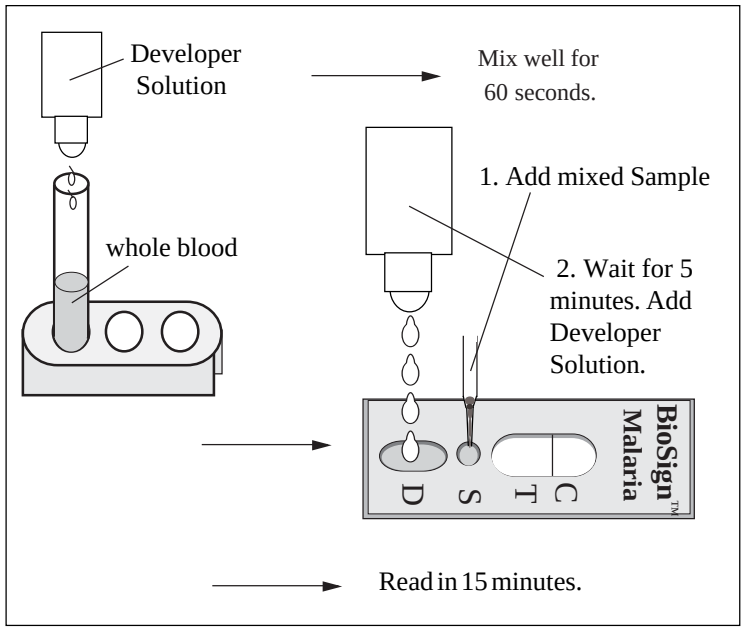
- For research use only.
- Do not interchange materials from different product lots and do not use beyond the expiration date.
- Use a fresh micropipette or tip for each specimen. Do not pipette by mouth.
- Do not smoke, eat or drink in areas in which specimens or kit reagents are handled.
- Wear disposable gloves while handling kit reagents or specimens and thoroughly wash hands afterwards.
- All specimens should be handled as if they are capable of transmitting disease. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Reagents in this kit contain sodium azide as a preservative, which may react with lead or copper in plumbing to form potentially explosive metal azides. Upon disposal, always flush with a large volume of water to prevent azide buildup in drains.
- The test device should remain in its original sealed pouch until ready for use. Do not use the test if the seal is broken or the pouch is damaged.

Test Procedure

STEP 1. Blood Lysis: Dispense 2 drops of Developer solution into test tube provided. Add 25 µl of whole blood and mix well for one minute.

STEP 2. Sample Application: Add 25 µl of mixed sample to the **Sample Well (S)** on the test device and allow sample to run up along the test strip for 5 minutes.

STEP 3. Visualizing: Add 4 drops of Developer solution to the **Developer Well (D)** on the test device. Read the result in 15 minutes.



Storage and Stability

The test kit is to be stored at 2–30 °C (36–86°F) in the sealed pouch. The storage conditions and expiration date given were established under normal laboratory conditions.

Procedural Notes

The instructions below must be followed to achieve optimal test reactivity with blood specimens. Follow the assay procedure and always perform the test under carefully standardized conditions.

- If specimens, kit reagents or test devices have been stored in the refrigerator, allow them to warm to room temperature before testing.
- Do not open the foil pouch until you are ready to perform the test.
- Several tests may be run at one time.
- To avoid contamination, do not touch the tip of the dropper bottle containing Developer Solution with your hands or to the device.
- Label the device with the specimen or control number.
- When the specimen is dispensed using a micropipetter, allow **the tip of the micropipette to touch lightly to the pad underneath the sample well (S) and dispense the specimen by pressing the micropipette lever slowly**. **Then wait for 5 min at least before adding Developer solution**.
- In case reddish background remains in the test window after 10 min of visualizing step, add 2 drops of developer solution to well (D).
- To add Developer solution, hold the dropper bottle in a vertical position above the solution well and dispense 4 full drops slowly into the well.

Interpretation of Results

Positive: Two colored lines, one at the Test position (**T**) and the other at the Control position (**C**), indicate that antigens of pLDH have been detected.

Negative: Only one colored line at the Control position, with no distinct colored line at Test position other than the normal faint background color, indicates that antigens of pLDH have not been detected.

Invalid: A distinctive colored line at the Control position should always appear. The test is invalid and should be repeated with a new test device if no line forms at the Control position.