

CareStart™ Malaria HRP2

Rapid One Step Malaria HRP2 Rapid Test

A rapid test for the detection of Malaria HRP2 in human blood
For *in vitro* test use only

Intended Use

For the rapid qualitative determination of Malaria Histidine-rich Protein 2 (HRP2) in human blood as an aid in the diagnosis of Malaria infection

Explanation of the Test

Malaria is a serious, sometimes fatal, parasitic disease characterized by fever, chills, and anemia and is caused by a parasite that is transmitted from one human to another by the bite of infected Anopheles mosquitoes. There are four kinds of malaria species that can infect humans: *Plasmodium 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 2.7 million malaria-caused deaths per year. At the present, malaria is diagnosed by looking for the parasites in a drop of blood. Blood is put onto a microscope slide and stained so that the parasites are visible under a microscope.

The CareStart™ Malaria HRP2 Test contains a membrane strip, which is pre-coated with a monoclonal antibody across a test strip. The monoclonal antibody (test line) is specific to the Histidine-rich Protein 2 of the *Plasmodium falciparum* species. Conjugate pad is dispensed with monoclonal antibody, which is specific to the Histidine-rich Protein 2 of the *Plasmodium falciparum* species.

Materials provided

CareStart™ Malaria Antigen Test Kit contains following items to perform the assay:

- Test Device
- Assay Buffer
- Sample Pipette

Precautions

In order to obtain reproducible results, the following rules must be followed:

- 1) For *in vitro* diagnostic use only.
- 2) Use disposable gloves while handling potentially infectious material and performing the assay. Wash hands thoroughly afterwards.
- 3) Do not use it beyond the expiration date
- 4) Do not eat or smoke while handling specimens.
- 5) Clean up spills thoroughly using an appropriate disinfectant.

Specimen Collection and Storage

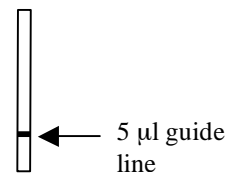
[Collection by venipuncture]

- 1) Collect the whole blood into the collection tube (containing EDTA, citrate or heparin) by venipuncture.
- 2) If specimens are not immediately tested, they should be refrigerated at 2 ~ 8°C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use. Using the specimen more than three days can cause non-specific reaction.
- 3) When storage is at 2 ~ 8°C, the whole blood sample should be used within three days.

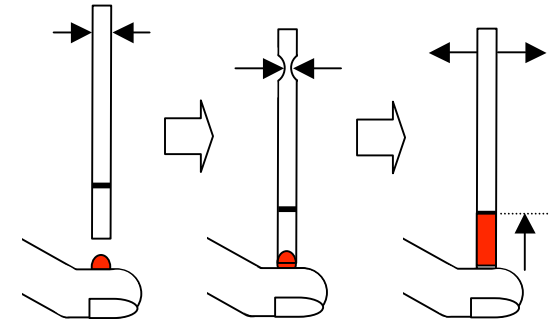
[Collection using a lancet]

- 1) Clean the area to be lanced with an alcohol swab.
- 2) Squeeze the end of the fingertip and pierce with a sterile lancet provided.
- 3) Wipe away the first drop of blood with sterile gauze or cotton.
- 4) Take a **sample pipette** provided, while gently squeezing the tube, immerse the open end in the blood drop and then gently release the pressure to draw blood into the **sample pipette up to black line**.

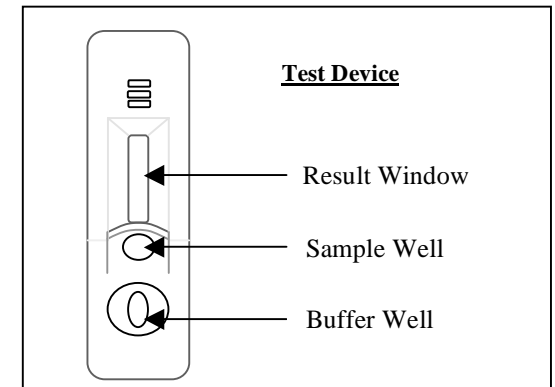
Sample Pipette



- 1) Gently squeeze the tube
- 2) Immerse open end in blood
- 3) Gently release to draw blood



Test Procedure



- 1) Add 5 µl of whole blood into **Sample Well** (small well) by squeezing **Sample Pipette**.
- 2) Add 2 drops (60 µl) of assay buffer into **Buffer Well**.
- 3) Read the test result in 20 min.

