

EctgUwt vJ TR4'O cmtk Test

Whole Blood, Plasma or Serum

TEST INSTRUCTIONS



1. Remove the test device from the foil pouch, and place it on a flat, dry surface.



2. Add 5ul of sample to the sample well. If you're using the included micro-capillary tube to measure the sample size, simply pinch the sides of the tube between your fingers and place the tip into the sample, slowly release your fingers to draw the sample into the tube up to the black line printed on the end.



3. Touch the end of the microcapillary tube to the sample pad and pinch the tube once again to release the sample. Make sure that you do not use more than 5ul of sample. If using whole blood, allow sample to absorb for 1-2 minutes before adding the diluent.



4. Slowly add 5 drops of TB sample diluent to the sample well allowing each drop to fully absorb before adding the next drop. If required, add one more drop to fully clear the test window.
NOTE: full absorption of each drop is necessary to allow the sample to flow through the special filter in the sample well.



5. Start the timer.



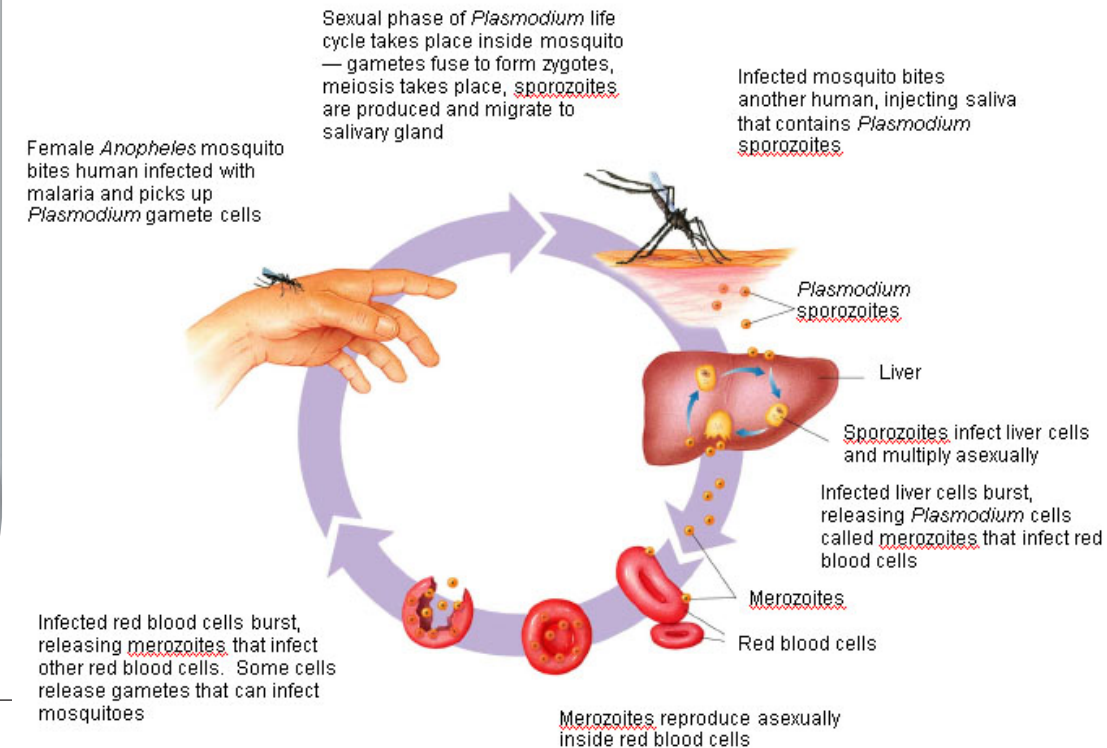
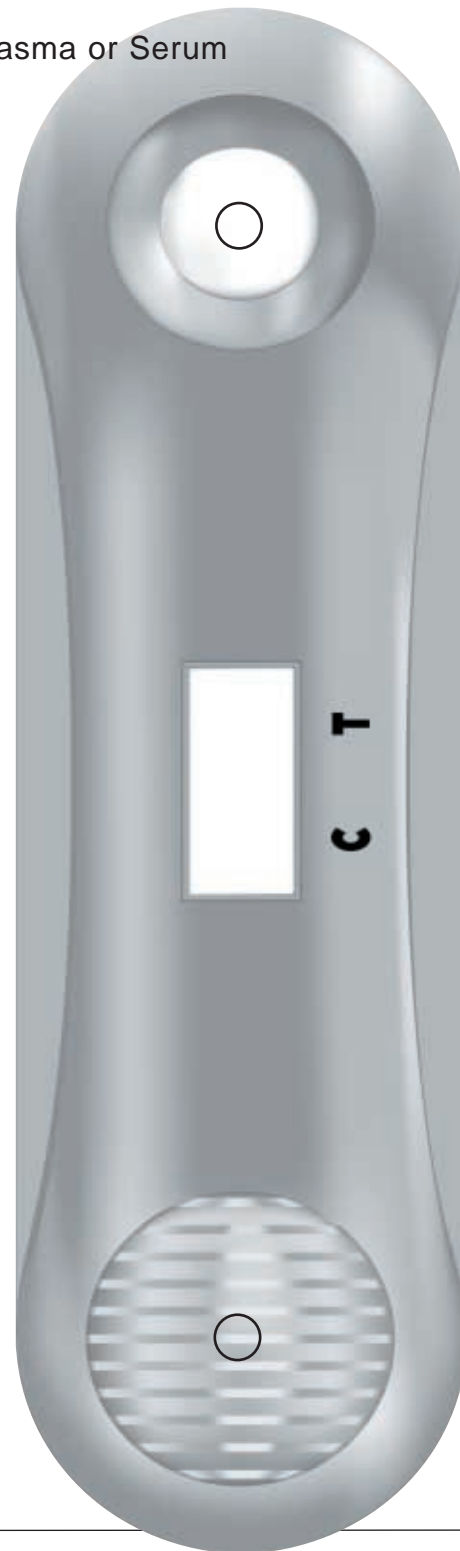
6. As the test begins to work, you will see purple color move across the Result Window in the center of the Test Device.

7. While results can often be seen within 2-3 minutes, interpret the test results at 7 to 8 minutes. Very weak samples may appear at 15 minutes. **Do not interpret test result after 20 minutes.**

Caution: The above interpreting time is based on reading the test results at room temperature of 15 to 30 degrees C. If your room temperature is significantly lower than 15 degrees C, then the interpreting time should be properly increased.

INTERPRETATION OF THE TEST

Positive	Invalid
C T	C T
Negative	Invalid
C T	C T



ASSAY
INNOVATION





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.

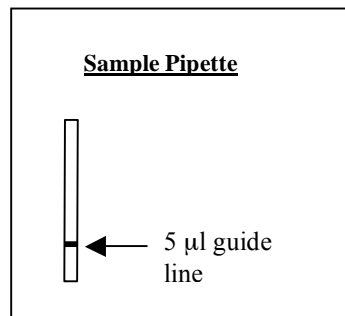
Specimen Collection and Storage

[Collection by venipuncture]

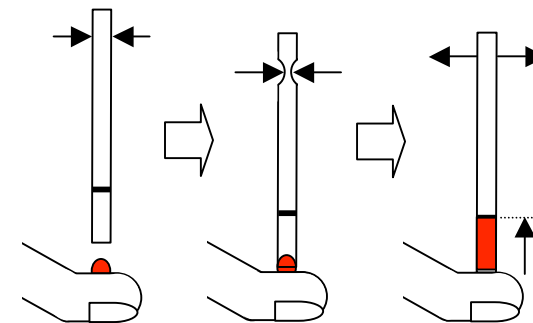
- 1) Collect the whole blood into the collection tube (containing EDTA, citrate or heparin) by venipuncture.
- 2) If specimens are not immediately tested, they should be refrigerated at 2 ~ 8°C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature 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]

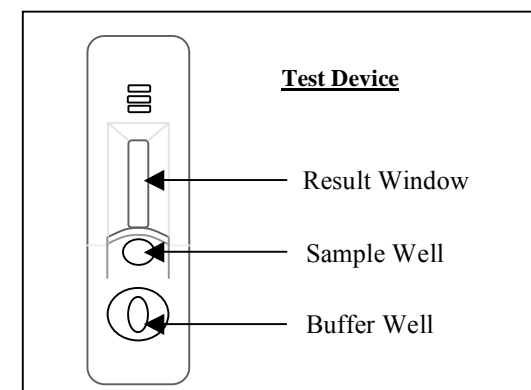
- 1) Clean the area to be lanced with an alcohol swab.
- 2) Squeeze the end of the fingertip and pierce with a sterile lancet provided.
- 3) Wipe away the first drop of blood with sterile gauze or cotton.
- 4) Take a **sample pipette** provided, while gently squeezing the tube, immerse the open end in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



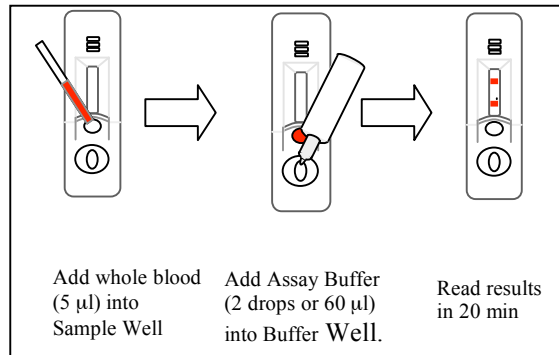
- 1) Gently squeeze the tube
- 2) Immerse open end in blood
- 3) Gently release to draw blood



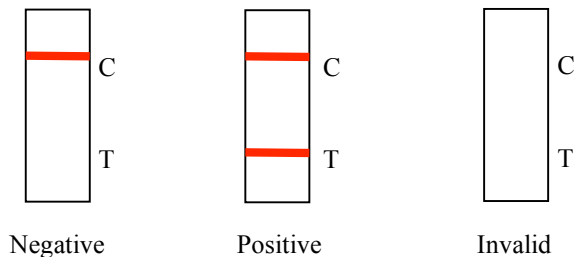
Test Procedure



- 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.



Interpretation of the test



1) Positive reaction

The presence of two color bands indicates a positive result.

2) Negative reaction

The presence of only one band within the result window indicates a negative result.

3) Invalid

The test is invalid if the C line does not appear. If this occurs, the test should be repeated using a new strip.

Limitations and Interferences

- 1) The test procedure, precautions and interpretation of results for this test must be followed when testing.
- 2) Anti-coagulants such as heparin, EDTA, and citrate do not affect the test result.

- 3) This test kit detects *Plasmodium* HRP2 in patient whole blood and is useful as a screening procedure of malaria diagnosis.
- 4) Do not mix reagent of different lots.
- 5) The test is limited to the detection of antigen to Malaria *Plasmodium falciparum*. Although the test is very accurate in detecting HRP2, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

Performance characteristics

The **CareStart™** Malaria Antigen rapid test kit has tested with positive and negative clinical samples tested by microscopic examination of whole blood.

1) Malaria *P. falciparum* evaluation results

	<i>P.f</i> -positive confirmed specimen		Sensitivity
	Positive N	egative	
CareStart™ Malaria Ag Rapid	98 2		98/100 x 100% = 98%

2) Malaria-negative normal human specimen evaluation results

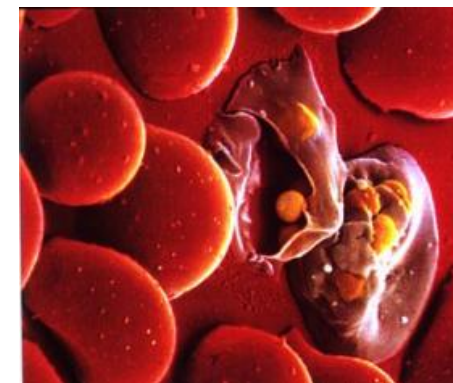
	Random normal human specimen		Specificity
	Positive N	egative	
CareStart™ Malaria Ag Rapid	5 195		195/200 x 100% = 97.5%

Precision

Within-run and between-run precisions have been determined by the testing 10 replicates of three specimens: a negative, a low positive and a strong positive. The agreement between the test results and the expected results were 100%.

References

1. Valecha N., Eapen A., Devi C. Usha, Ravindran J., Aggarwal A., and Subba rao S. K. (2002). Field evaluation of the ICT Malaria P.f./P.v. immunochromatographic test in India. *Annals of Tropical Medicine & Parasitology*. 96: 333-336
2. Iqbal J., Hira P. R., Sher A., and AL-Enezi A. A. 2001. Diagnosis of imported Malaria by Plasmodium Lactate Dehydrogenase (pLDH) and Histidine-Rich Protein 2 (PfHRP2)-based immunocapture assays. *American Journal of Tropical Medicine and Hygiene*. 64: 20-23
3. Tjitra E., Suprianto S., Dyer M., Currie B. J. and Anstey N. M. (1999). Detection of Histidine-rich Protein 2 and panmalarial ICT MALARIA P.f./P.v. test antigens after chloroquine treatment of uncomplicated falciparum malaria does not reliably predict treatment outcome in eastern Indonesia. *Journal of Clinical microbiology*. 37: 2412-2417
4. Panton L. J., PcPhie P., Maloy W. L., Wellem T. E., Taylor D. W. and Howard R. J. (1989). Purification and partial characterization of an unusual protein of *Plasmodium falciparum*: histidine-rich protein II. *Molecular and Biochemical Parasitology*. 35: 149-160



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