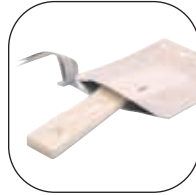


CareStart pLDH Malaria Test

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

C T



Invalid

C T



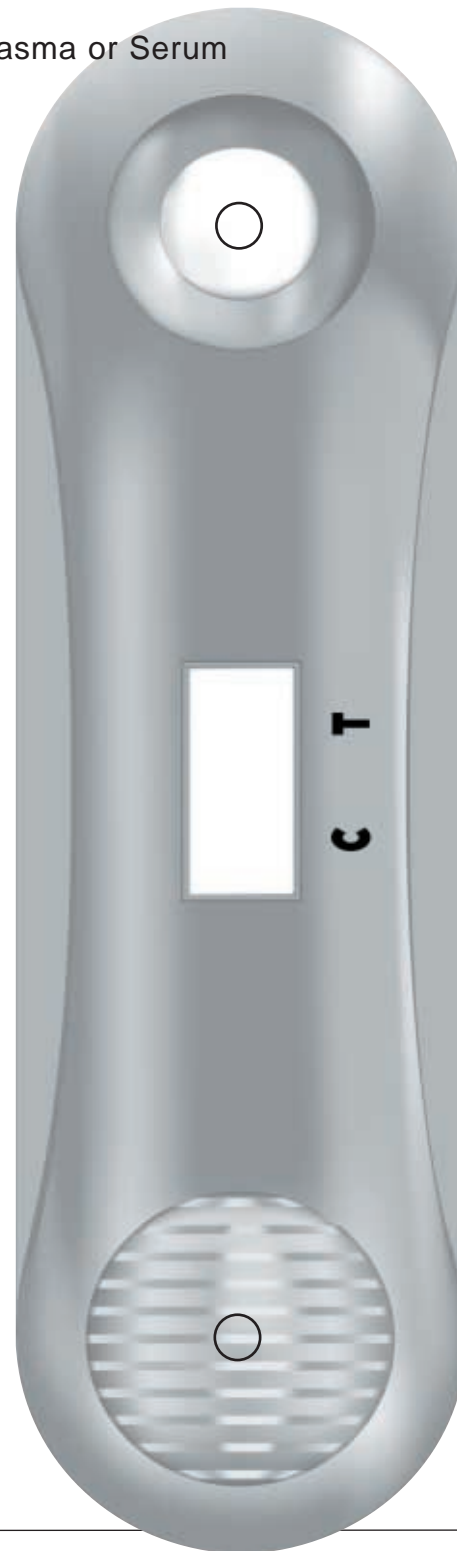
Negative

C T



Invalid

C T



ASSAY

INNOVATION

ISO 9001

ISO 13485

EN 46001

GMP

QSR





CareStart™ Malaria pLDH

Rapid One Step Malaria LDH Rapid Test

A rapid test for the detection of Malaria LDH in human blood

For in vitro test use only

Intended Use

For the rapid qualitative determination of Malaria lactate dehydrogenase (LDH) in human blood as an aid in the diagnosis of Malaria infection

Summary

Malaria is a serious 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 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 will be put onto a microscope slide and stained so that the parasites will be visible under a microscope.

The **CareStart™ Malaria Antigen Test** contains a membrane strip, which is pre-coated with two monoclonal antibodies as two separate lines across a test strip. One monoclonal antibody (test line 1) is specific to the lactate dehydrogenase of *P. falciparum* and another monoclonal antibody (test line 2) is pan specific to the lactate dehydrogenase of *Plasmodium* species (*P. falciparum*, *vivax*, *malariae*, *ovale*). Conjugate pad is dispensed with monoclonal antibody, which is pan specific to the lactate dehydrogenase of *Plasmodium* species.

So the **CareStart™ Malaria Antigen Test** is designed for the differential diagnosis between *Plasmodium falciparum* and the other *Plasmodium* species.

Materials Provided

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

Test Device

- Package Insert
- Instruction Card
- Assay Buffer
- Sample Pipette (Optional)
- Lancet (Optional)
- Alcohol Swab (Optional)

Precautions

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

- 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.

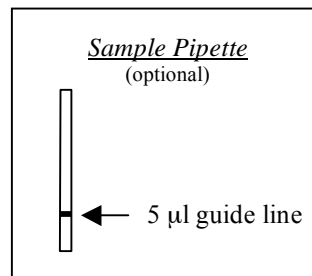
Specimen Collection and Storage

[Collection by venipuncture]

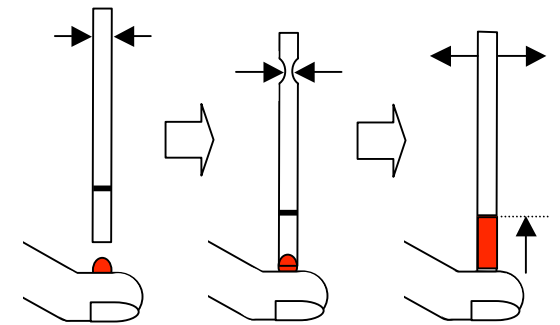
- 1) Collect the whole blood into the collection tube (containing EDTA, citrate or heparin) by venipuncture.
- 2) If specimens are not immediately tested, they should be refrigerated at 2 ~ 8°C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature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

[Collection using a lancet]

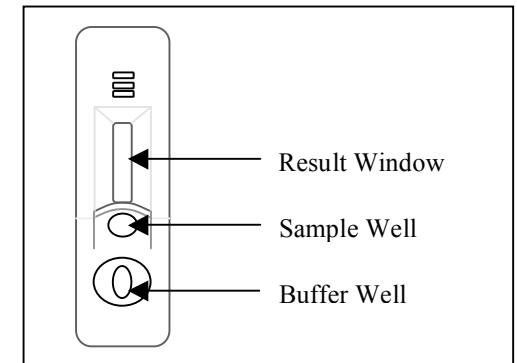
- 1) Clean the area to be lanced with an alcohol swab.
- 2) Squeeze the end of the fingertip and pierce with a sterile lancet provided.
- 3) Wipe away the first drop of blood with sterile gauze or cotton.
- 4) Using a pipette, gently squeeze the tube and immerse the open end in the blood drop. Then, gently release pressure to draw blood into the dropper.



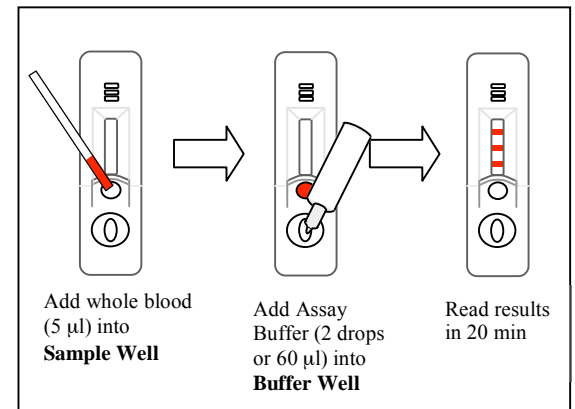
- 1) Gently squeeze the tube
- 2) Immerse open end in blood
- 3) Gently release to draw blood



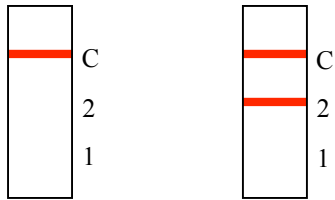
Test Procedure



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

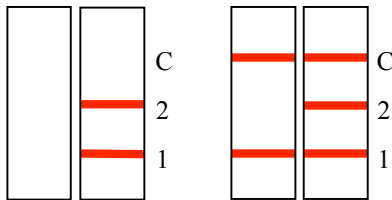


Interpretation of the test



Negative

Positive
(*P. vivax*)



Invalid

Positive
(*P. falciparum*)

1) *P. falciparum* Positive reaction

The presence of three color bands (three bands in all C, 1 and 2 areas) or two bands (one band in C area and another band in 1 area) indicates a positive result for *P. falciparum*. The pLDH present in the sample reacts with the pan anti-pLDH conjugate and move through the test strip where the pLDH is captured by both *P. falciparum*-specific anti-pLDH and pan specific anti-pLDH.

2) *P. vivax* or other *Plasmodium* sp. Positive reaction

The presence of two color bands (one band in C area and another band in 2 area) indicates a positive result for *P. vivax*, *P. malariae*, or *P. ovale*. The pLDH present in the sample reacts with the pan anti-pLDH conjugate and move through the test strip where the pLDH is captured by pan specific anti-pLDH.

3) Negative reaction

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

4) Invalid

The test is invalid if the line in C area 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* lactate dehydrogenase 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* sp. Although the test is very accurate in detecting pLDH, 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 kit has tested with positive and negative clinical samples tested by microscopic examination of whole blood.

1) Malaria *P. vivax* evaluation results

	P.v-positive confirmed specimen		Sensitivity
	Positive N	Negative	
<i>CareStart™</i> Malaria Ag Rapid	964		96/100 x 100% = 96%

2) Malaria *P. falciparum* evaluation results

	P.f-positive confirmed specimen		Sensitivity
	Positive N	Negative	
<i>CareStart™</i> Malaria Ag Rapid	973		97/100 x 100% = 97%

3) Malaria-negative normal human specimen evaluation results

	Random normal human specimen		Specificity
	Positive N	Negative	
<i>CareStart™</i> Malaria Ag Rapid	3197		197/200 x 100%=98.5%

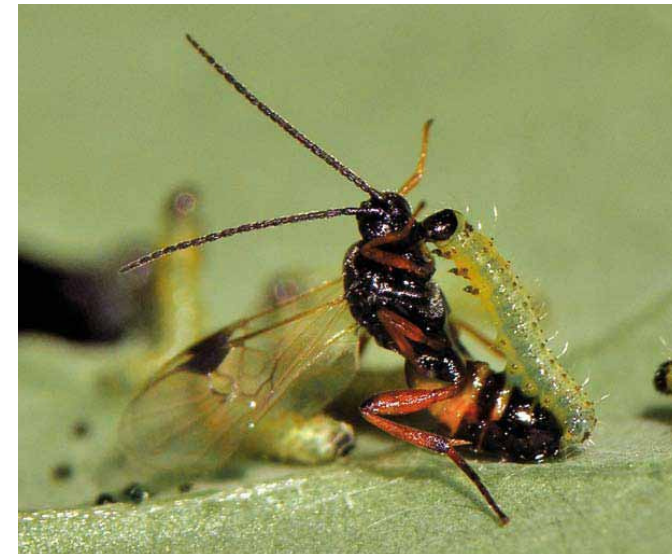
Precision

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) Leonard K. Basco, Frederique Marquet, Michael M. Makler, and Jacques Le Bras. : *Plasmodium falciparum* and *Plasmodium vivax* : Lactate Dehydrogenase Activity and its Application for in vitro Drug Susceptibility Assay. *Experimental Parasitology* 80, 260-271 (1995)
- 2) David L. Vander Jagt, Lucy A. Hunsaker and John E. Heidrich : Partial Purification and Characterization of Lactate Dehydrogenase from *Plasmodium falciparum*. *Molecular and Biochemical Parasitology*, 4 (1981) 255-264.

- 3) David J. Bzik, Barbara A. Fox and Kenneth Gonyer : Expression of *Plasmodium falciparum* lactate dehydrogenase in *Escherichia coli* *Molecular and Biochemical Parasitology*, 59(1993) 155-166
- 4) Cameron R. Dunn, Mark J. Banfield, John J. Barker, Christopher W. Hight, Kathleen M. Merton, Dilek Turgut-Balik, R. Leo Brady and J. John Holbrook. The Structure of Lactate dehydrogenase from *Plasmodium falciparum* reveals a new target for anti-malarial design. *Nature Structural Biology* 3(11)1996, 912-915



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