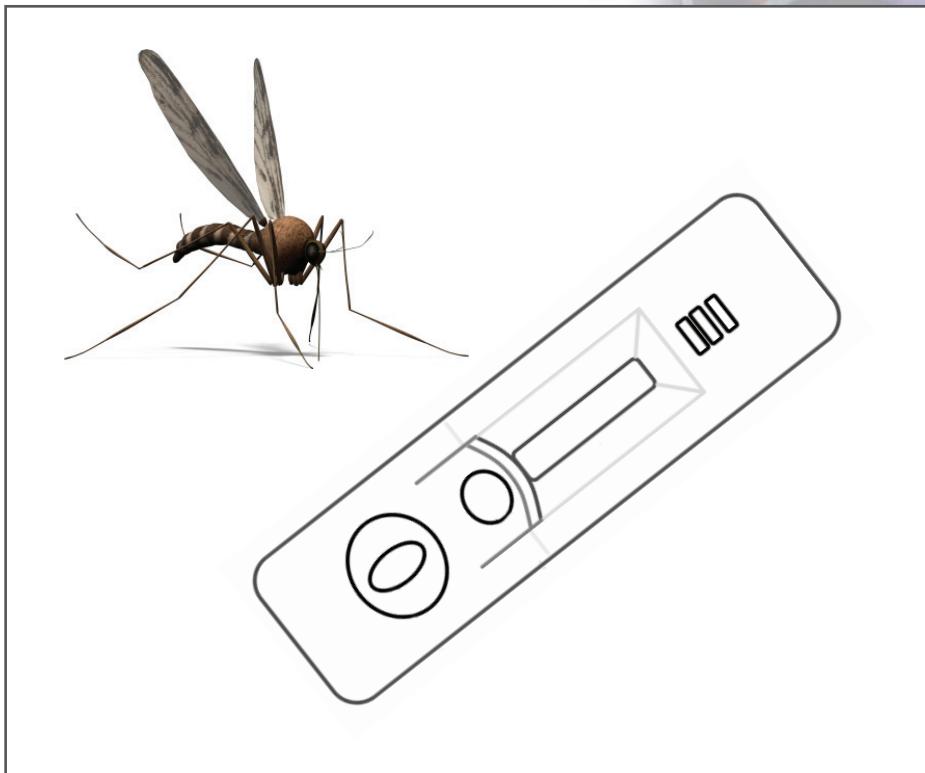


CareStart™ Malaria PF/VOM Combo Rapydtest

HRP2 for *P. falciparum* pLDH for Vivax, Ovale, Malariae
A rapid test for the detection of Malaria LDH
and HRP2 in human blood

Single use device for in vitro diagnostic use only



Benefits at a glance

- Distinguishes between a mixed infection and a falciparum
- Isolates Plasmodium falciparum HRP2 and Vom
- Specific LDH (Pv, Po, Pm) on separate test lines
- Combined antigen technology gives you increased accuracy
- User friendly cartridge format for ease of use and storage
- Integral vents prevent sample 'back flow' interference
- Results in 20 minutes

CareStart™ Malaria

Intended Use

For the rapid qualitative determination of Malaria Histidine-rich Protein 2 (HRP2) (*P. falciparum*) and lactate dehydrogenase (pLDH) (*P. vivax*, *P. ovale* and *P. malariae*) 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.

The CareStart™ Malaria PF/VOM Combo 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 VOM) is specific to pLDH of *Plasmodium vivax*, *Plasmodium ovale* and *Plasmodium malariae*. The other line (test line Pf) is printed with a monoclonal antibody specific to HRP2 of *Plasmodium falciparum*. The conjugate pad is dispensed with monoclonal antibodies, which are specific to pLDH (*Plasmodium vivax*, *Plasmodium ovale* and *Plasmodium malariae*) and *P. falciparum* specific to HRP2.

So, the CareStart™ Malaria PF/VOM Combo Antigen Test is designed for the differential diagnosis between *Plasmodium falciparum* and other *Plasmodium* species (*Plasmodium vivax*, *Plasmodium ovale* and *Plasmodium malariae*).

Precautions

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

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

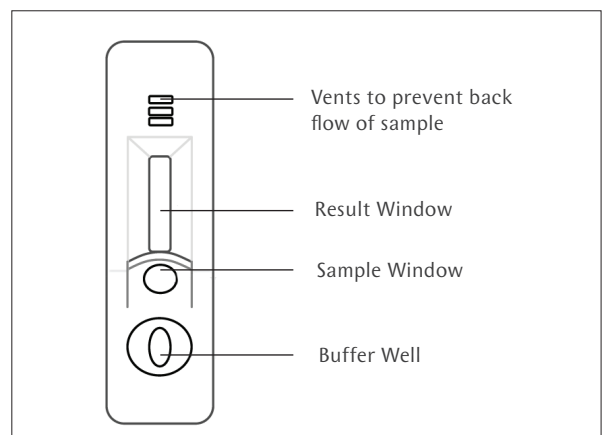
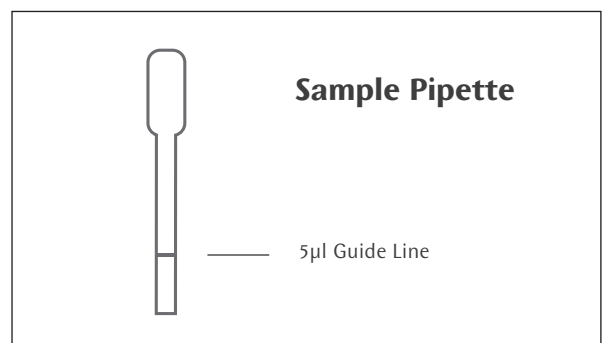
Specimen collection and storage

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 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 alcohol swab.
4. Take a sample pipette provided, and 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 the black line.

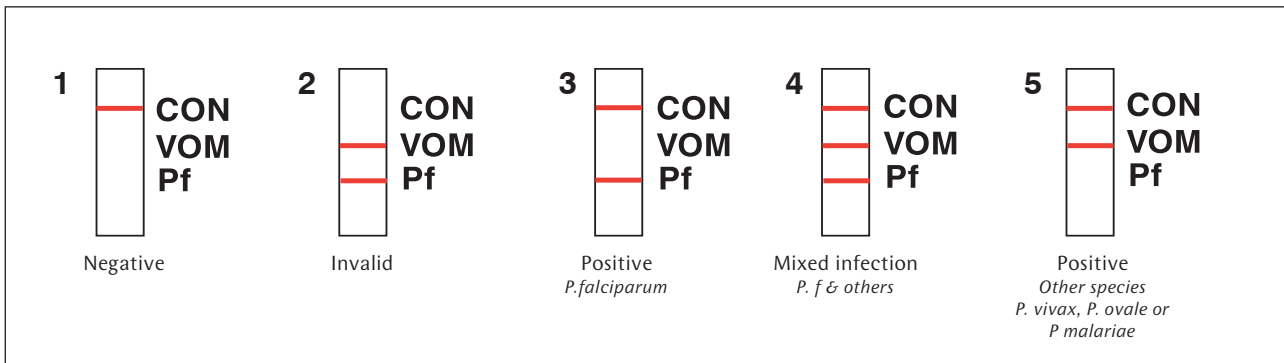
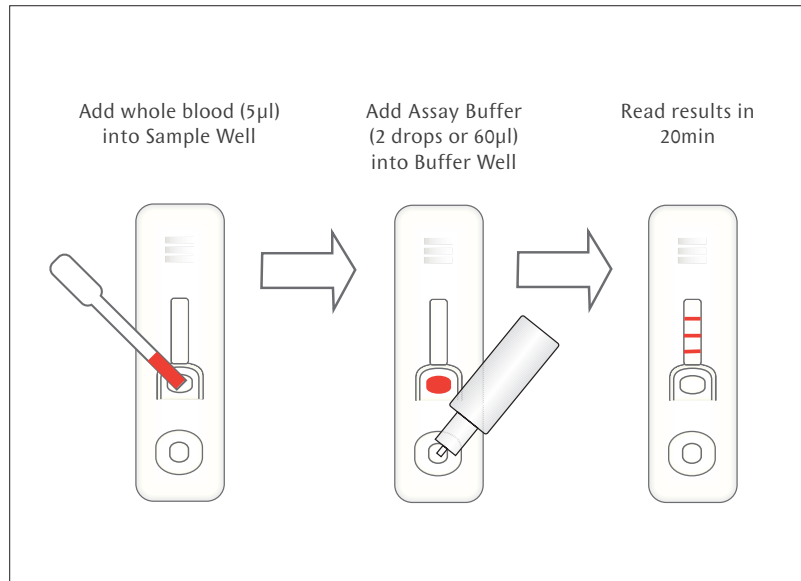
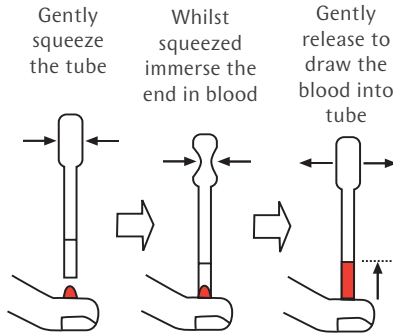


CareStart™ Malaria



Test Procedure

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



Results

Interpretation of the test

1. Negative reaction

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

2. Invalid

The test is invalid if the line in the “CON” area does not appear. If this occurs, the test should be repeated using a new strip.

3. *P. falciparum* - Positive reaction

The presence of two bands (one band in the “CON” area and another band in the “Pf” area) indicates a positive result for *P. falciparum*.

4. *P. f & others* – Mixed Infection

The presence of three color bands (bands in the “CON” area, “Pf” area and “VOM” area) indicates a positive result of mixed infection for *P. falciparum* and others (*P. vivax*, *P. ovale* or *P. malariae*).

5. *P. vivax/P. ovale/P. malariae* - Positive other species

The presence of two color bands (one band in the “CON” area and another band in the “VOM” area) indicates a positive result for *P. vivax*, *P. ovale* or *P. malariae*.

Limitation and interferences

- The test procedure, precautions and interpretation of results for this test must be followed when testing.
- Anti-coagulants such as heparin, EDTA, and citrate do not affect the test result.
- Do not mix reagent of different lots.
- The test is limited to the detection of antigen to Malaria Plasmodium sp. Although the test is very accurate in detecting pLDH and 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.



CareStart™ Malaria

Performance Characteristics

The CareStart™ Malaria PF/VOM Combo kit has tested with positive and negative clinical samples tested by microscopic examination of whole blood.

1. Malaria <i>P. vivax</i> evaluation results	Pv/Po/Pm-positive confirmed specimen		Sensitivity
	Positive	Negative	
CareStart Malaria Ag Rapid	96	4	$96/100 \times 100\% = 96\%$
2. Malaria <i>P. falciparum</i> evaluation results	Pf-positive confirmed specimen		Sensitivity
	Positive	Negative	
CareStart Malaria Ag Rapid	98	2	$98/100 \times 100\% = 98\%$
3. Malaria negative normal human specimen evaluation results	Random normal human specimen		Specificity
	Positive	Negative	
CareStart Malaria Ag Rapid	5	195	$195/200 \times 100\% = 97.5\%$

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

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Ordering Information

Product	Pack Size	Ordering Code
CareStart™ Malaria PF/VOM Combo kit	30	1631

Order product direct from DiaSys or appointed distributor



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