

## Vedlegg 3.5 – Pakningsvedlegg for CareStart™ Malaria Rapydtest

### Pakningsvedlegg

- 1) CareStart™ Malaria Rapydtest pakningsvedlegg, engelsk



## RAPYDTEST<sup>®</sup> USING

COMBINED HRP2 / PLDH TECHNOLOGY FOR THE DIFFERENTIAL  
DIAGNOSIS OF PLASMODIUM FALCIPARUM AND THE OTHER  
PLASMODIUM SPECIES



APACOR

RAPYDTEST<sup>®</sup>  
CareStart<sup>™</sup>  
Malaria



# PARASITOLOGY

SINGLE USE IN VITRO DIAGNOSTIC DEVICE

## Performance Benefits

- Isolates Plasmodium falciparum HRP2 and Pan
- Specific LDH (Pf, 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

## Intended Use

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

## Summary

Malaria is a serious parasitic disease characterized by fever, chills, and anaemia and is caused by a parasite that is transmitted 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 100 countries worldwide, and it is estimated that there are over 280 million clinical cases and nearly one million malaria-caused deaths per year.

At present Malaria is diagnosed microscopically using thick and thin blood films. These require expert knowledge to correctly identify the species, not always available 24hrs a day. This is where a reliable support test becomes invaluable.

The CareStart™ Malaria HRP2/pLDH Combo 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 2) is pan specific to lactate dehydrogenase (pLDH) of the Plasmodium species (P. falciparum, vivax, malariae, ovale) and the other line (test line 1) consists of a monoclonal antibody specific to Histidine-Rich Protein 2 (HRP2) of the Plasmodium falciparum species. The conjugate pad is dispensed with monoclonal antibodies, which are pan specific to pLDH and P. falciparum specific to HRP2.

So, the CareStart™ Malaria HRP2/pLDH Antigen Test is designed for the differential diagnosis between Plasmodium falciparum and the other Pan specific species.

## 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.

## Storage

The sealed pouch containing the test strip is designed to be stored at 1°C - 40°C for the duration of its shelf life. The bottle containing the Assay Buffer is designed to be stored at 1°C - 40°C for the duration of its shelf life. Exposure to temperatures over 40°C can impact the performance of the test and should be minimized. The strips should not be frozen. The test should be used within 15 minutes after removal from the pouch to prevent exposure to humidity.

## 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 stored 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 sterile gauze or cotton.
4. Take a sample pipette provided, and collect the blood sample (5µl).

## Accessories supplied

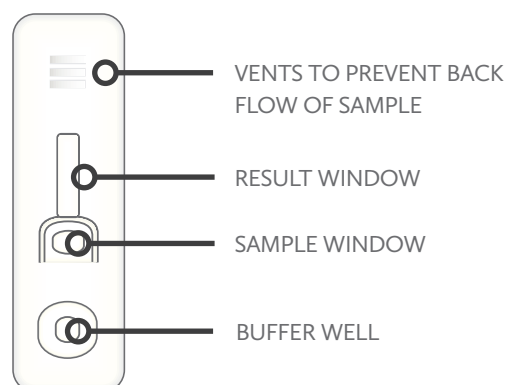
### Sample pipette



### Lancet

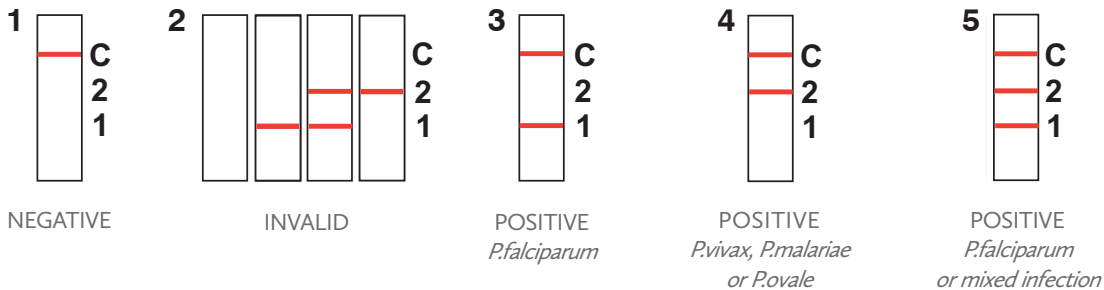
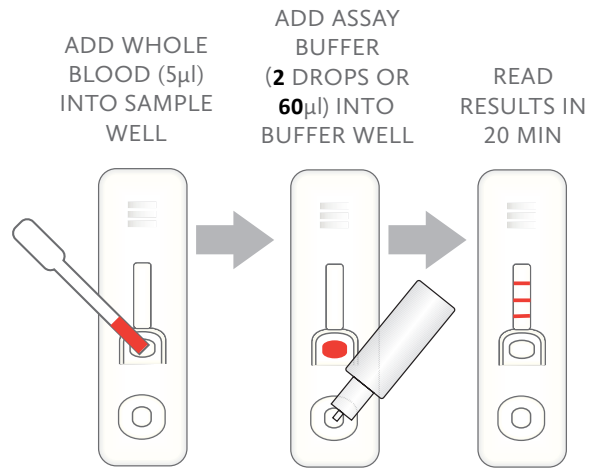
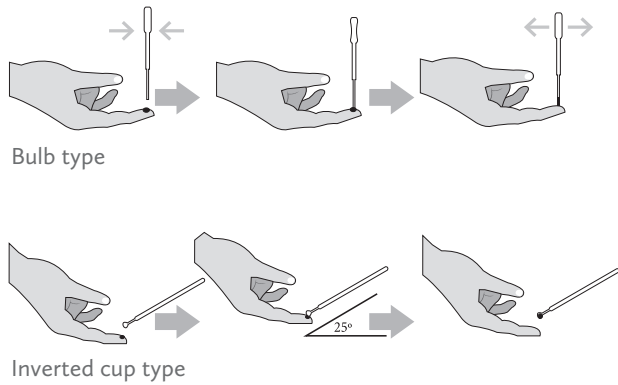


### Alcohol pad



## 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 (updated procedure).
3. Read test result in 20 minutes



## Results Interpretation of the test

1. **Negative reaction**  
The presence of only one band in the Control Area within the result window indicates a negative result.
2. **Invalid**  
The test is invalid if the line in the Control Area does not appear. If this occurs, the test should be repeated using a new strip.
3. **Positive reaction - *P. falciparum***  
The presence of three colour bands (three bands in the Control, "2" and "1" areas) or two bands (one band in the Control Area and another band in the "1" area) indicates a positive result for *P. falciparum*.
4. **Positive reaction**  
*P. vivax, P. malariae, or P. ovale.* The presence of two colour bands (one band in the Control Area and another band in the "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.

5. **Positive reaction - mixed infection of *P. falciparum* and other species**  
The presence of three colour bands (bands in the Control, "2" and "1" areas) indicates a positive result for *P. falciparum* or mixed infection of *P. falciparum* and other species.

## 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 HRP2 and 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 test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

### Performance Characteristics

The CareStart™ Malaria HRP2/pLDH combo kit has been evaluated with positive and negative clinical samples tested by microscopic examination of whole blood.

### Precision

Within-run and between-run precisions have been determined by 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%.

1. MALARIA P. VIVAX EVALUATION RESULTS	PV - POSITIVE CONFIRMED SPECIMEN		SENSITIVITY
	POSITIVE	NEGATIVE	
CARESTART™ MALARIA AG RAPID	96	4	96/100 X 100% = 96%

2. MALARIA P. FALCIPARUM EVALUATION RESULTS	P.F - POSITIVE CONFIRMED SPECIMEN		SENSITIVITY
	POSITIVE	NEGATIVE	
CARESTART™ MALARIA AG RAPID	98	2	98/100 X 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 X 100% = 97.5%

### References

- Valecha N., Eapen A., Devi C. Usha, Ravindran J., Aggarwal A., and Subbarao S. K. (2002). Field evaluation of the ICT Malaria PUP.v. immunochromatographic test in India. *Annals of Tropical Medicine & Parasitology*. 96: 333-336
- 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. (Pt-HRP2)-based immunocapture assays. *American Journal of Tropical Medicine and Hygiene*. 64: 20-23
- Tjitra E., Suprianto S., Dyer M., Currie B. J. and Anstey N.M. (1999). Detection of Histidine-rich Protein 2 and panmalarial ICT MALARIA PUP.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
- 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
- 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).

### Ordering Information

PRODUCT	PACK SIZE	CODE
CareStart™ Malaria Rapydtest®, 30 individually wrapped strips, complete with Assay Buffer, Lancet, Pipette and Alcohol Swabs	30	1630

Products can be ordered direct from Apacor or from an appointed distributor

Visit our website for all the latest information [www.apacor.com](http://www.apacor.com) or e-mail on: [sales@apacor.com](mailto:sales@apacor.com)