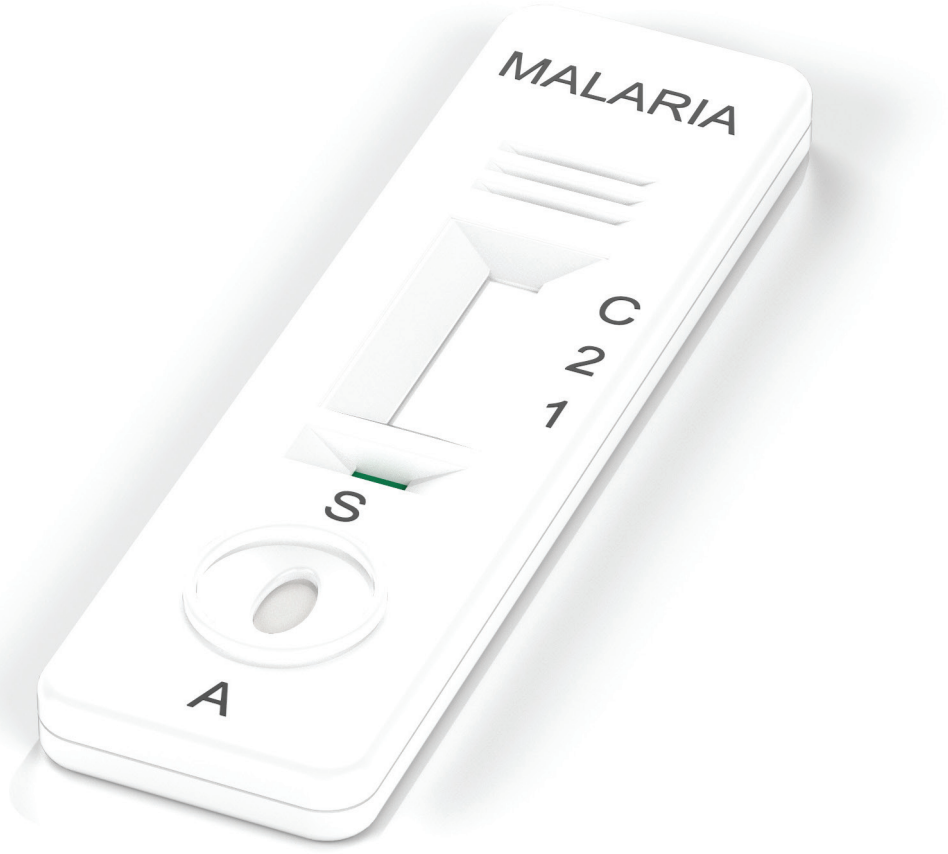
RAPYDTEST® USING

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



APACOR

CareUS™ Malaria

Rapydtest®

PARASITOLOGY

SINGLE USE IN VITRO DIAGNOSTIC DEVICE

careUS™ Malaria

Rapydtest®

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 detection of malaria HRP2 (histidine-rich protein 2) of P. falciparum and pLDH (plasmodium lactate dehydrogenase) of P.falciparum, 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. It is caused by a bite of infected Anopheles mosquitoes resulting transmission of protozoan parasite to human. There are four types of human malaria: Plasmodium falciparum, P. vivax, P. ovale, and P. malariae. When infected, the parasites (called sporozoites) migrated to the liver where they mature and then they are released to the blood stream of human infecting the red blood cells. Malaria infection occurs in more than 90 countries worldwide, but is mostly prevalent in sub-Saharan Africa. It is estimated that there are over 500 million clinical cases and 2.7 million malaria-caused deaths per year.

The careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag contains a membrane strip, which is pre-coated with two monoclonal antibodies as two separate lines across the test strip. One monoclonal antibody (test line 2) is PAN specific to pLDH of the Plasmodium species (P.falciparum, P.vivax, P.malariae, and P.ovale) and the other line (test line 1) consists of a monoclonal antibody specific to HRP2 of the P.falciparum. The conjugate pad is dispensed with an2bodies absorbed on gold particles, which are specific to pLDH of PAN and specific to HRP2 of P. falciparum.

The careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag is designed for the differentiated diagnosis of P.falciparum, P.vivax, P.malariae, and P.ovale infection.

Precautions

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

- Test kits are for in vitro diagnostic and professional use only.
- Read the provided instructions for use before using the test kit and follow the provided information when using the test kit.
- Wash the hands thoroughly before and after using the test kit.
- Wear the protective gloves at all times while using the test kits and dispose the gloves immediately after each testing.
- Change the gloves and wash hands when contacted with potentially infectious materials.
- Do routine clean-up using an appropriate disinfectant.
- Do not eat or smoke while using the test.
- Use the test cassette and accessory components (lancet and alcohol swab) immediately after opening its package.
- All provided materials are single-use. Do not re-use any of the materials.
- Do not use the materials from different lots.
- Do not use a test cassette, if the packaging of the test cassette is compromised.
- Do not use the test kit if the expiration date has past.
- Lancet is sterile. If a lancet cap is loose and/or damaged, do not use the lancet.
- Do not swallow the assay buffer solution.
- Do not us the alcohol swab if the package is damaged.
- Observe the storage condition indicated on the packaging and box.
- Do not freeze the test kit. The refrigerated test cassettes need to be equilibrated to the room temperature prior to use.
- Dispose of waste in accordance with the local regulations.
- The buffer bottle should be lightly closed after each use and stored in a cool area avoiding direct sun light. Discard the buffer solution and bottle after the expiration date indicated on the bottle.
- The test may produce a false positive result for a patient with acute schistosomiasis.

Storage & Stability

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. This product is stable for 30 months.

Specimen collection and storage

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).

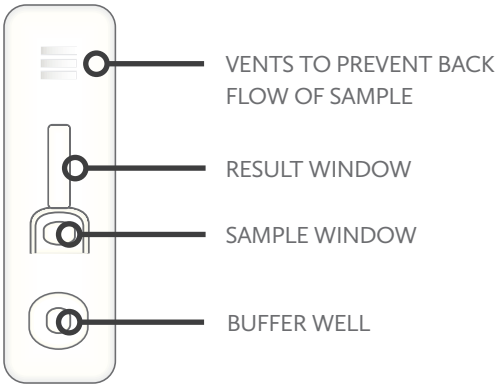
Accessories supplied

Sample pipette

Disposable capillary dropper

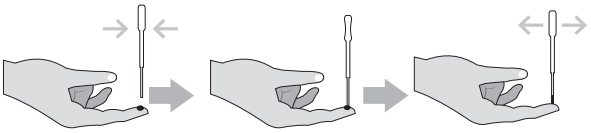
Capped Lancet

Alcohol pad

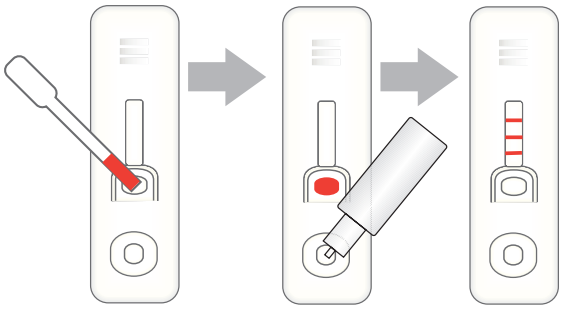


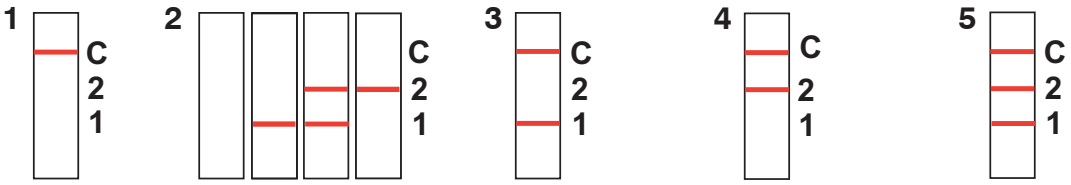
Test Procedure

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



Bulb type





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 "I" areas) or two bands (one band in the Control Area and another band in the "I" 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 falciparum or mixed infection of P. falciparum and other species.

Limitation and interferences

- The following anticoagulants have been validated for use with this test: heparin, EDTA and citrate.
- This test is designed to detect HRP2 and pLDH antigens of Malaria P. falciparum and P. vivax. A definitive clinical diagnosis should not be made based on the result of this test, but should only be made by a qualified physician after all clinical and laboratory findings have been evaluated.
- The prozone effect may cause false-negative result.
- Positive result with faint test line or false-negative is possible due to low parasite density.
- This test may produce a positive result after successful anti-malarial treatment. Therefore its use is not recommended for monitoring response to anti-malarial treatment.
- If specimens cannot be tested immediately, they should be refrigerated at 2-8°C for up to 3 days.

Performance Characteristics

The careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag has been tested with positive and negative clinical samples conformed by microscopic examination.

Precision

Within- and between-run precisions have been evaluated 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%.

Specimen	Positive	Negative	Sensitivity
P.falciparum	98	2	98%
P.vivax	96	4	96%

Specimen	Positive	Negative	Specificity
Negative	5	195	97.5%

95% CI, (97.05, 100) for P. falciparum positive result, (92.16, 99.84) for P. vivax positive results and (94.64, 99.36) for negative result.

References

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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., Wellems 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
5. 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
CareUS™ Malaria Rapydtest®, 30 individually wrapped strips, complete with Assay Buffer, Lancet, Pipette and Alcohol Swabs	30	1629
CareUS™ Malaria Rapydtest®, 5 individually wrapped strips, complete with Assay Buffer, Lancet, Pipette and Alcohol Swabs	5	16295

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

Visit our website for all the latest information www.apacor.com or e-mail on: orders@apacor.com

Description of Symbol Used

	Single use		Quanity in Box
	Expiry Date	IVD	*In-Vitro* diagnostic medical device
LOT	Batch code		Storage Temperature limitation
	Manufacturer		Consult instructions for use
REF	Catalogue number		Do not use if package is damaged
	Keep dry		Keep away from sunlight
CE	CE mark	EC REP	Authorized representative in EU

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