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

Rapydtest®

CareUS™ Malaria

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) migrate to the liver where they mature. They are then released into the blood stream of the 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. ovale,* and *P. malariae*) 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 antibodies 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 sunlight. 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).

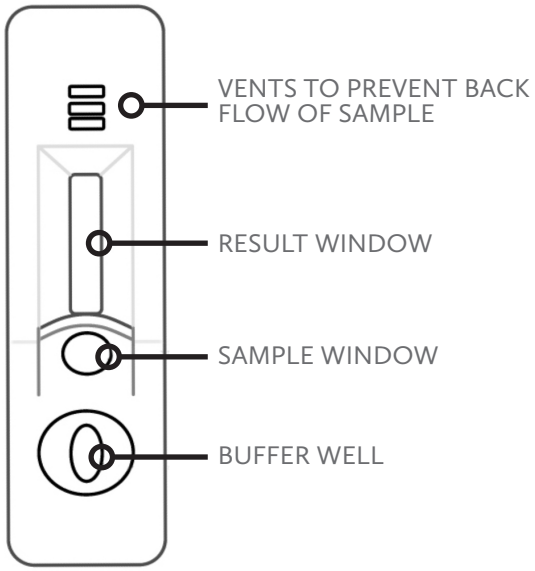
Accessories supplied

Sample pipette

Disposable capillary dropper

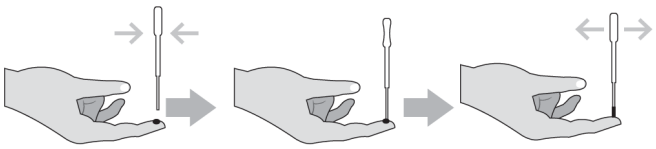
Capped Lancet

Alcohol pad

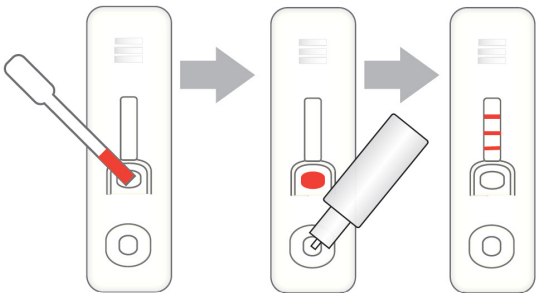


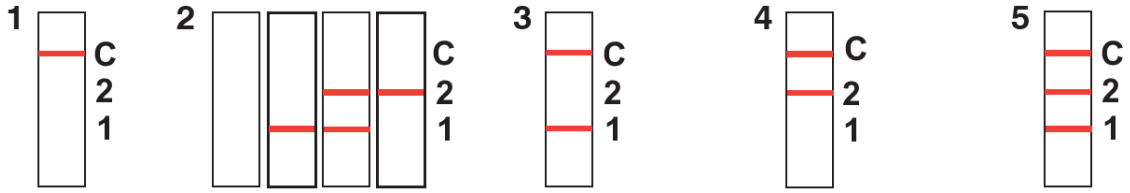
Test Procedure

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





NEGATIVE

INVALID

POSITIVE
P. falciparum

POSITIVE
P. vivax,
P. malariae or
P. ovale

POSITIVE
P. falciparum or
mixed infection

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. falciparum, P. vivax, P. ovale, or P. malariae. 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. falciparum, P. vivax, P. ovale, or P. malariae*. 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 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*, *P. vivax, P. ovale,* and *P. malariae*. 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.

CareUS™ Malaria
Rapydtest®

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	Sensitivity
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

1. Valecha N., Eapen A., Devi C. Usha, Ravindran J., Aggarwal A., and Subbarao 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., 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
- Expiry Date
- LOT Batch code
- Manufacturer
- REF Catalogue number
- Keep dry
- CE mark
- Quantity in Box
- IVD In-Vitro diagnostic medical device
- Storage Temperature limitation
- Consult instructions for use
- Do not use if package is damaged
- Keep away from sunlight
- EC REP Authorized representative in EU

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APA059WB - V2 08/2024

SAFETY DATASHEET
CareUS™ Malaria Rapydtest ®

This Safety Datasheet complies with the requirements of Regulation (EC) No 1907/2006

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/ MIXTURE AND THE COMPANY/UNDERTAKING

1.1 Product Identifier: 1629 / 16295
CareUS™ Malaria Rapydtest®

1.2 Relevant identified uses of the substance or mixture and uses advised against:

TEST: Medical device for professional in vitro diagnostic use only. Use for detection of malaria HRP2 and pLDH in human blood.
BUFFER: For use only with the supplied CareUS™ Malaria Rapydtest®.

1.3 Details of the supplier of the Safety Data Sheet:

Manufacturer: Wells Bio, Inc, 16 Magokjungang 8-ro 1-gil, Gangseo-gu, Seoul, 07795, Republic of Korea

EU representative: MDSS GmbH, Schiffaraben 41, 30175 Hanover, Germany
Distributed By: Apacor Limited, Unit 5 Sapphire Centre, Fishponds Road, Wokingham, Berkshire, RG41 2QL, UK
+44 (0) 118 979 5566
technical@apacor.com

1.4 Emergency telephone number:

+44 (0)118 979 5566
(Monday-Friday 0900-1700 excluding UK Public Holidays)

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

No significant health effects are anticipated from using this product when used under normal operating conditions and in accordance with the kit specific instructions for use. The following are not considered as hazardous at the amounts shown below according to the latest edition of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS):

Monoclonal antibody (0.4µg/25 tests)

Monoclonal antibody-dye conjugate (0.12µg/25 tests)

Sodium Azide less than 0.1%

Repeated or prolonged exposure is not known to aggravate any medical condition.

2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]: Non-hazardous

Eye Contact: Irritation. Tears.

Skin Contact: Irritation.

Ingestion: No known significant effect or critical hazard upon ingestion of assay buffer solution in the kit.

Inhalation: None known.

2.2 Label elements
Labelling according to Regulation (EC) No 1272/2008 [CLP]

Hazard statement(s): -

Precautionary statements: -

2.3 Other hazards
No information available.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures
Hazardous ingredients according to Regulation (EC) No 1272/2008
Component: Sodium Azide
CAS No: 26628-22-8
Concentration: <0.1%
Hazard statement: non-hazardous at this concentration

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures
If inhaled: remove to fresh air. Give artificial respiration to support vital functions.
In case of skin contact: wash off immediately with soap and plenty of water.
In case of eye contact: rinse thoroughly with plenty of water for at least 15 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Consult a physician immediately.
If swallowed: Do not induce vomiting. Rinse mouth with water. Consult a physician immediately.
If symptoms persist, call a physician or poison control center.

4.2 Most important symptoms and effects, both acute and delayed
No data available

4.3 Indication of any immediate medical attention and special treatment needed
Treat symptomatically.

SECTION 5 FIRE FIGHTING MEASURES

5.1 Extinguishing media
Water spray, CO_2, dry chemical, halon, foam & abc class.

5.2 Special hazards arising from the substance or mixture
None.

5.3 Advice for firefighters
Wear approved self-contained breathing apparatus for firefighting if necessary and full protective gear.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Prevent contact with skin, eyes and clothes. Use personal protective equipment. Ensure adequate ventilation

6.2 Environmental precautions
Avoid release to the environment.

6.3 Methods and material for containment and cleaning up
Contain spillage, soak up with inert absorbent material then collect and place in container for disposal according to local regulations.

6.4 Reference to other sections
See Sections 8 and 13 as appropriate.

SECTION 7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Follow Good Laboratory Practice, wear disposable gloves. Avoid contact and contamination with skin, eyes and clothes. Wash hands and any other exposed area with soap and water before eating, drinking, smoking, and leaving work place.

7.2 Conditions for safe storage, including any incompatibilities

Store at room temperature, not above 40°C and not below 1°C.

7.3 Specific end use(s)

No other specific uses are specified apart from those listed in Section 1.2.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

No data available

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday. Specimen collection and preparation: all the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

8.2.2 Personal protective equipment

(a) Eye/face protection:

Tightly fitting safety goggles. Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

(b) Skin protection:

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves should satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

(c) Body Protection:

The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

(d) Respiratory protection:

No specific requirement when used under normal operating conditions.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a) Appearance Test: White solid reaction strip in a plastic cassette.
Buffer: brown liquid.
b) Odour No data available
c) Odour threshold Not applicable
d) pH Buffer: 9.2
e) Melting point / freezing point Not applicable
f) Initial boiling point and boiling range Buffer 100°C
g) Flash point Not applicable
h) Evaporation rate Not applicable
i) Flammability (solid, gas) Not applicable
j) Upper/lower flammability or explosive limits Not applicable
k) Vapour pressure Not applicable
l) Vapour density Not applicable
m) Relative density No data available
n) Solubility (ies) No data available
o) Partition coefficient: n-octanol/water No data available
p) Auto-ignition temperature Not applicable
q) Decomposition temperature Not applicable
r) Viscosity No data available
s) Explosive properties No risk
t) Oxidising properties Not applicable

9.2 Other information

No data available

SECTION 10 STABILITY AND REACTIVITY

10.1 Reactivity

Not applicable.

10.2 Chemical stability

Under storage at normal ambient temperatures the product is stable.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

None.

10.5 Incompatible materials

None.

10.6 Hazardous decomposition products

None.

SECTION 11 TOXICOLOGICAL INFORMATION

11.1 Information of toxicological effects

Acute toxicity: Product does not present an acute toxicity hazard based on known or supplied information.
Skin corrosion/irritation: irritation.
Serious eye damage/eye irritation: irritation.
Respiratory or skin sensitisation: no data available
Germ cell mutagenicity: no effects are known.
Carcinogenicity: no effects are known.
Reproductive toxicity: no effects are known.
Specific target organ toxicity - single exposure: no data available
Specific target organ toxicity - repeated exposure: no data available
Aspiration hazard: no data available

SECTION 12 ECOLOGICAL INFORMATION

12.1 Toxicity
No data available. The product should be discarded in a proper biohazard container after testing. Do not allow product to reach ground water, water bodies or sewage system.

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential
No data available

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
No data available

12.6 Other adverse effects
No data available

12.7 Additional information
Do not allow to enter waters, drains or soil.

SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
This material is not regarded as hazardous waste.

Product: Dispose of in accordance with all federal, state, and local regulations.

Contaminated packaging: Dispose of as unused product.

Sodium azide (<0.1%) may react with lead or copper found in plumbing drains to form explosive compounds. Drain with copious amount of water to dilute solutions to prevent the buildup of shock sensitive compound.

SECTION 14 TRANSPORT INFORMATION

14.1 UN number: -

14.2 UN proper shipping name: Not dangerous goods.

14.3 Transport hazard class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user: -

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
Not intended to be transported in bulk.

SECTION 15 REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/ legislation specific for the substance or mixture
This product does not require special labelling, in accordance with the appropriate EC directives. This product is for in vitro diagnostic use therefore must comply with the European Directive 98/79/EC regarding bearing the CE label prior to placing on the market.

15.2 Chemical Safety Assessment
No chemical safety assessment has been carried out for this product.

SECTION 16 OTHER INFORMATION

For professional in vitro diagnostic use only. Consult instructions for use.

References: Directives 1999/45/EC, 98/79/EC, 91/155/EC, 67/548/EEC

Amended sections are indicated by a line in the border.

The information supplied in this SDS is correct to the best of our knowledge. We do not accept any liability for loss, injury or damage, which may result from its use.

EC REP

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