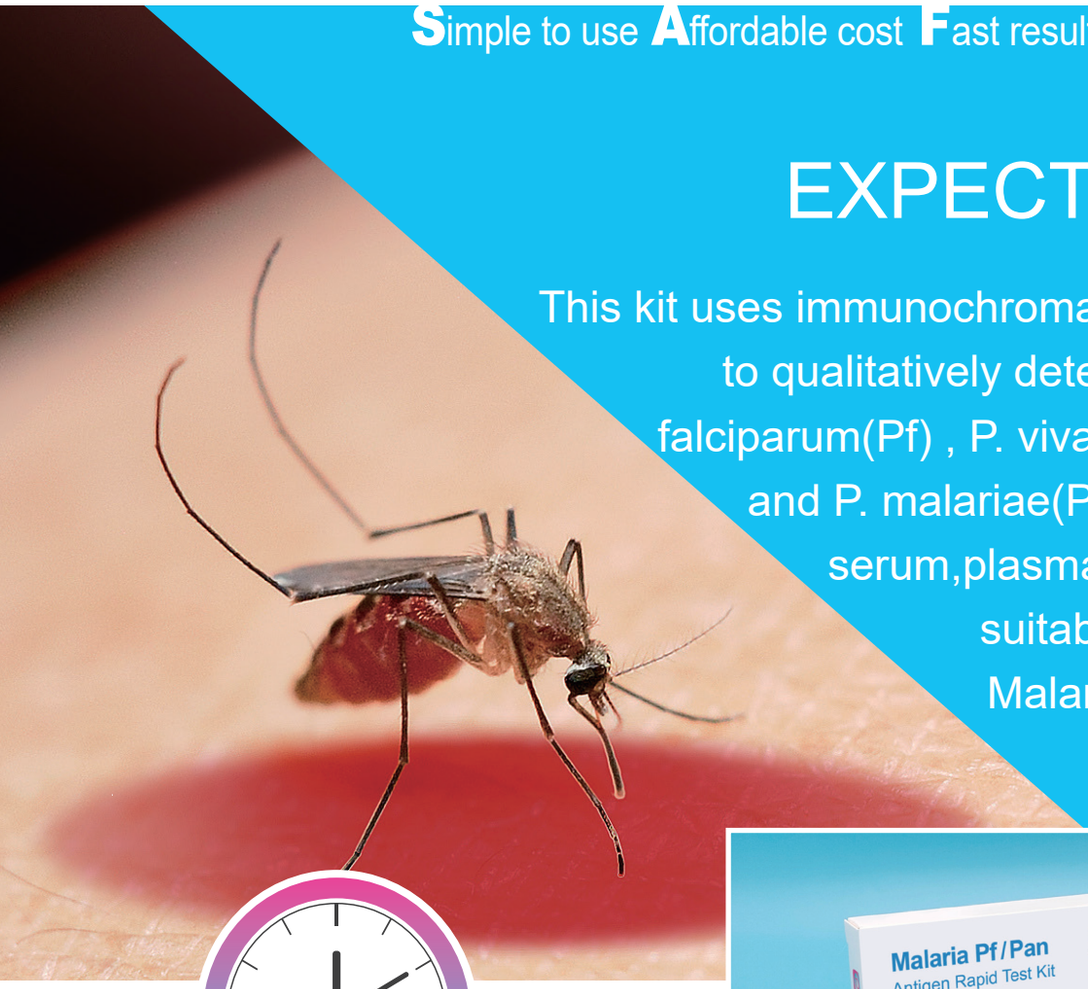
REAGEN

Malaria Pf/Pan Antigen Rapid Test Kit

Simple to use **A**ffordable cost **F**ast result **E**ffective virus testing



EXPECTED USAGE

This kit uses immunochromatography technology to qualitatively detection of Plasmodium falciparum(Pf) , P. vivax (Pv), P. ovale (Po), and P. malariae(Pm) antigen in human serum,plasma or whole blood. It is suitable for the early aid of Malaria nfection diagnosis and screening.



Results within 10 minutes

- ***Higher Sensitivity***
- ***Higher Specificity***
- ***Higher Accuracy***

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1.Introduction

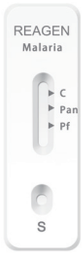
Malaria is an insect-borne infection caused by the infection of malaria parasites through the bite of Anopheles mosquitoes or through the transfusion of the blood of a malaria carrier. There are four species of Plasmodium that live in humans, namely Plasmodium vivax, Plasmodium malariae, Plasmodium falciparum and Plasmodium ovalis. The disease is mainly manifested as periodic regular attacks, the whole body chills, fever, hyperhidrosis, long-term multiple attacks, can cause anemia and spleen enlargement. The global prevalence of malaria remains high, with about 40 per cent of the world's population living in malaria-endemic areas. Malaria remains the most serious disease on the Africancontinent, with about 500 million people living in malaria-endemic areas, about 100 million people globally experiencing clinical symptoms of malaria each year, 90 per cent of them in Africa, and more than 2 million deaths per year. Southeast and central Asia are also areas where malaria is endemic. Malaria is still endemic in Central and South America.

2.Features



- It is convenient for the early detection and identification of Pf/Pan.
- Simple operation and highly-efficient test.
- Suitable for massive scale testing.
- Can protect privacy of customer.
- Rapid test results in 10 min.

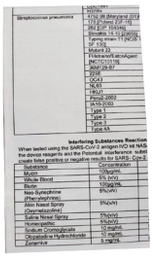
3.Components



Test Card



Dropper



Instruction for Use



Alcohol Pad



Sample Diluent



Disposable Sterile Lancets



Biosafety Bags

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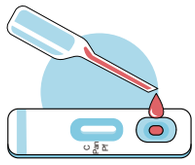
4.Product Information

Product Code	Product Name	Package	Storage Condition	Shelf Life	Qualification
RNS92162	Malaria Pf/Pan Antigen Rapid Test Kit	1T/Kit	2-30℃	24 Months	CE

5.Test Procedure



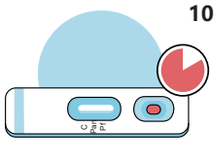
1. Collect blood samples with a dropper.



2. Add 1 drop of blood sample to the specimen well.



3. Unscrew the cap and add 2 drops of diluent buffer to the test card.



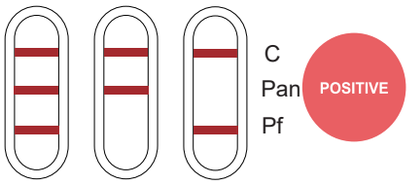
4. Read result after 10 minutes.

6.Test Procedure

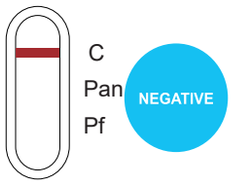
Positive: Two or Three distinct colored lines appear. One line should always appear in the control line region(C), and another line or Two line should appear in the test line region(Pan/Pf). The color intensity of the Test and Control lines may be different.

Negative: One red line appears in the control region(C).No apparent colored line appear in the test line region(Pan and Pf).

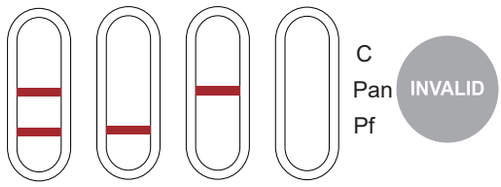
Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



POSITIVE



NEGATIVE



INVALID

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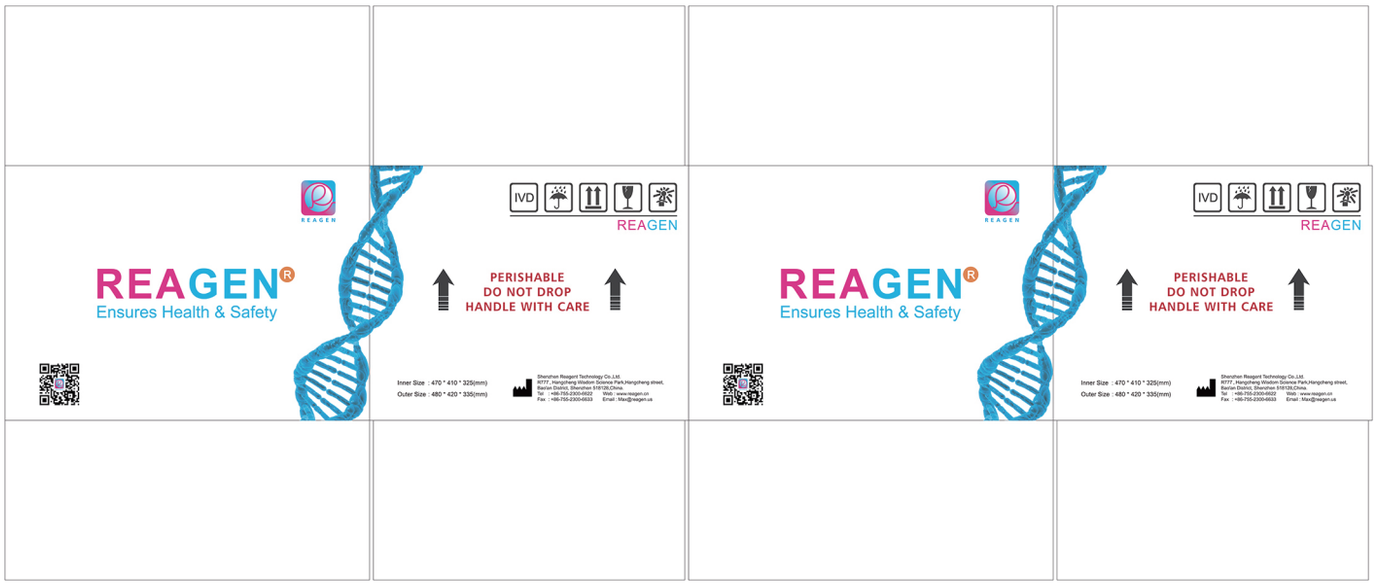
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7.Packing Specification

Outer Size: 480*420*335 (mm) Inner Size: 470*410*325 (mm)







PCS PER BOX	BOX DIMENSIONS	BOXES PER EXPORT CARTON	EXPORT CARTON EXTERNAL DIMENSIONS	QUANTITY PER CARTON
1 pcs (test)	155*65*15(mm)	350 boxes	480*420*335 (mm) / 10.7kg	350boxes * 1T = 350PCS

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8.Qualification

EU REP

CMC

Medical Devices Spain

Hereby confirms that CMC Medical Devices & Drugs S.L.located in C/Horacio Lengo, 18, 29006, Málaga, Spainand with SRN ES-AR-000000293is the Authorised Representative (EC REP) of

Shenzhen Reagent Technology Co.,Ltd.

Room 1601, Building No.3, YESUN INTELLIGENT COMMUNITY I, No.1301-77, Guanguang Road, Longhua District, Shenzhen 518110, China.

The certificate remains valid until the expiration date of the EC REP agreement or until manufacturing conditions, the quality system or relevant legislation are modified.

The validity is subject to positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with the applicable directive/regulation mentioned in Annex I of this certificate and the applicable standards.

After fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to the relevant models of the medical devices mentioned below.

The table in the Annex I lists, where applicable, the registration status with the Spanish MOH (AEMPS) and their registration number (RPS).

CE

CMC

Issue date: 7th of November 2025

Manuel Mateos

Chief Executive Officer

Expiration date: 8th of December 2028
Certificate #: ECREP20251107.2
Ver: CERT-EC-2407
cmcmedicaldevices.com

10 YEARS ANNIVERSARY 2014-2024

EU REP

CMC

Medical Devices Spain

Rapid Test Kit	Directive 98/79				AEMPS
Human Chorionic Gonadotropin(HCG) Rapid Test Kit(Colloidal Gold)	IVD - Directive 98/79	CLASS IVD OTHERS	M:Test card	RPS/2296/2025	Registered with AEMPS
Human Metapneumovirus Antigen Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2301/2025	Registered with AEMPS
Human Papilloma Virus (HPV) Types 16 and 18 Real-Time Fluorescence PCR Detection Kit	IVD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/2301/2025	Registered with AEMPS
Influenza A/B and Respiratory Syncytial Virus Real-Time Fluorescence PCR Detection Kit	IVDD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/2301/2025	Registered with AEMPS
Influenza A/B and Respiratory Syncytial Virus Real-Time Fluorescence PCR Detection Kit	IVDD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/2301/2025	Registered with AEMPS
MET/THC/AMP/MOP Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2301/2025	Registered with AEMPS
MOP/MET Combo Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2301/2025	Registered with AEMPS
MOP/MET/KET Combo Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2301/2025	Registered with AEMPS
Malaria Pf/Pan Antigen Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2301/2025	Registered with AEMPS
Monkeypox Virus Antigen Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2301/2025	Registered with AEMPS
Monkeypox Virus IgM/IgG Antibody Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2301/2025	Registered with AEMPS
Monkeypox Virus Real-Time Fluorescence PCR Detection Kit	IVD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/2296/2025	Registered with AEMPS

Expiration date: 8th of December 2028
Certificate #: ECREP20251107.2
Ver: CERT-EC-2407
cmcmedicaldevices.com

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Certificate CN21/42019

The management system of

Shenzhen Reagent Technology Co., Ltd.

No. 777, Building A, Hangcheng Wisdom Science Park, Sanwei Community, Hangcheng Street, Bao'an District, Shenzhen, Guangdong, 518128, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities
Design, development, manufacture and distribution of in-vitro diagnostic test kits for clinic chemistry, immunochemistry, infectious pathogens, genetic testing, molecular diagnosis, detection of monkeypox virus and detection of COVID-19

This certificate is valid from 11 February 2025 until 06 January 2027 and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 07 January 2021

L. Moran

Authorised by
Liz Moran
Business Manager

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0) 151 350-6666 - www.sgs.com

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Medical Device Business License

Permit Number : Yueshen Food and Drug Administration
Approval No. 20200224

Company Name : Shenzhen Reagent Technology Co., Ltd.

Legal Representative : Deng Xinggang

Mode of operation : wholesale and retail

CEO : Wang xinxin

Company Address : R777, Hangcheng Wisdom Science Park,Hangcheng street,Bao'an District, Shenzhen 518128,China.

Business Scope : 2002 Catalogue (three categories): 6804, 6815, 6821, 6822, 6823, 6824, 6825, 6826, 6828, 6830, 6832, 6833, 6840 (except in vitro diagnostic reagents), 6840 (diagnostic reagents do not require low-temperature refrigerated transportation Storage), 6845, 6854, 6858, 6863, 6864, 6865, 6866, except for implants and interventional products included in the above categories, except for contact lenses and hearing aid products included in the above categories 2017 Classification Catalog (three categories) : 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 14, 16, 17, 18, 20, 21, 22, 6840 In vitro diagnostic reagents (no need for cryogenic storage and transportation), the above categories Except for implants and interventional products included in the above categories, except for contact lenses, hearing aid products included in the above categories

Business Premises : R777, Hangcheng Wisdom Science Park,Hangcheng street,Bao'an District, Shenzhen 518128,China.

Warehouse Address : R777, Hangcheng Wisdom Science Park,Hangcheng street,Bao'an District, Shenzhen 518128,China.

Lssuing Department : Shenzhen Stadtverwaltung für Marktregulierung

Limited period: until April 25, 2030

Date of issuance: April 21, 2025

State Food and Drug Administration

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