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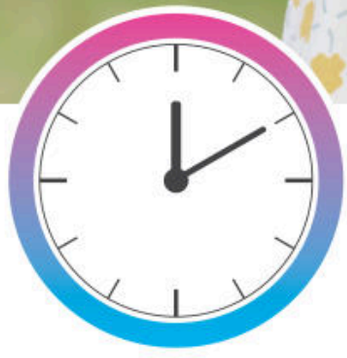
Dengue NS1 Antigen&IgG/IgM Antibody Combo Rapid Test Kit

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



INTENDED USE

This kit is used for qualitative detection of dengue virus NS1 antigen, IgG antibody and IgM antibody in human serum, plasma and whole blood samples in vitro, which plays an important role in the early diagnosis and treatment of dengue infection, and can assist in the diagnosis of dengue virus infection in clinical practice.





Results within 10 minutes

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

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

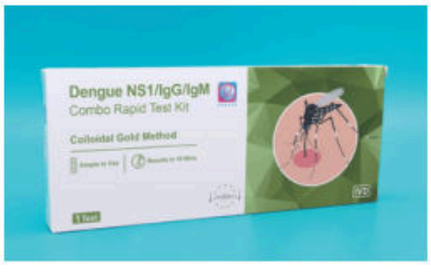
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1.Summary

Dengue virus belongs to the genus Flavivirus in the Flaviviridae family. Infection with it can cause dengue fever. In the past, dengue fever was classified into dengue fever, dengue hemorrhagic fever and dengue shock syndrome based on whether there was bleeding and shock. The latter two had dangerous clinical manifestations and a high mortality rate. The dengue virus is mainly transmitted by Aedes aegypti and Aedes albopictus. It has a strict geographical distribution and is mainly prevalent in tropical and subtropical regions, with the highest incidence rate in Southeast Asia. The World Health Organization (WHO) estimates that about 390 million people are infected each year, among which 96 million show clinical symptoms. The fatality rate of severe dengue fever (dengue hemorrhagic fever/ dengue shock syndrome) can reach 20%, but it can be reduced to less than 1% through early treatment.

2.Features



- It is convenient for the early detection and identification of Dengue NS1 Antigen&IgG/IgM Antibody.
- Simple operation and highly-efficient test.
- Suitable for massive scale testing.
- 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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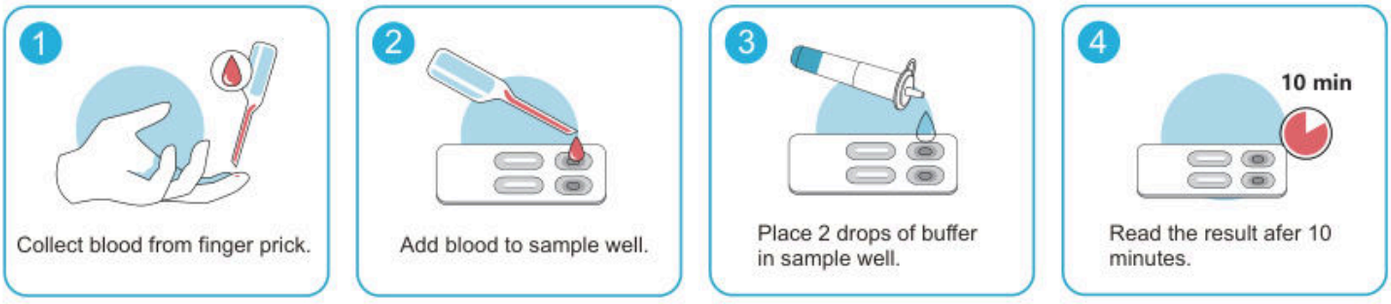
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4.Product information

Product Code	Product Name	Package	Storage Condition	Shelf Life
RNS92199	Dengue NS1 Antigen& IgG/IgM Antibody Combo Rapid Test Kit	1T/Test	2-30℃	24 Months

5.Test Procedure

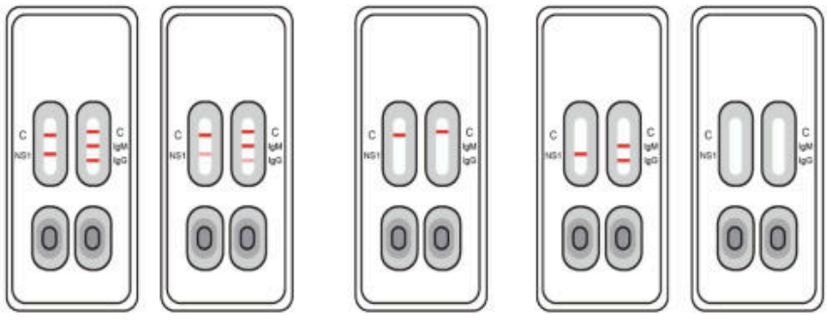


6.Test Results

Positive: Two red lines appear. One red line should always appear in the control line region (C), and another one apparent red line should appear in the T line region.

Negative: One red line appears in the control region(C). No apparent red line appear in the T line region.

Invalid: Control line fails to appear. Insufficient sample 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.



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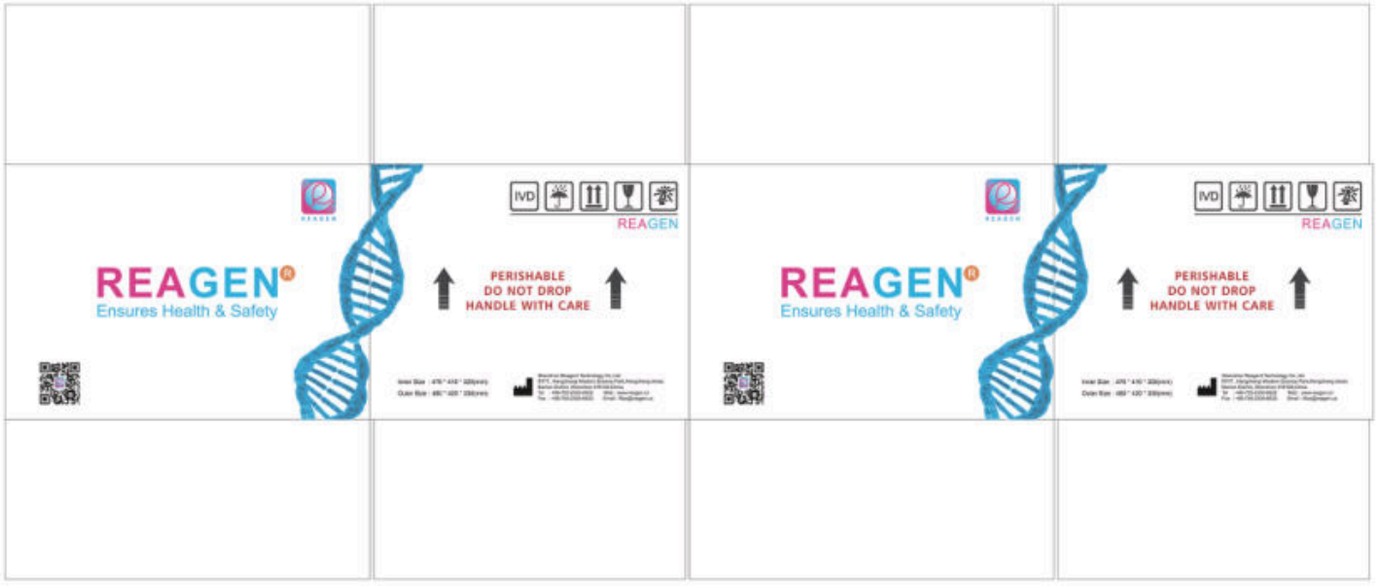
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7.Packing Specification

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) /9.5kg	350boxes * 1T = 350PCS

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8.Qualification

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 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.

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

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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