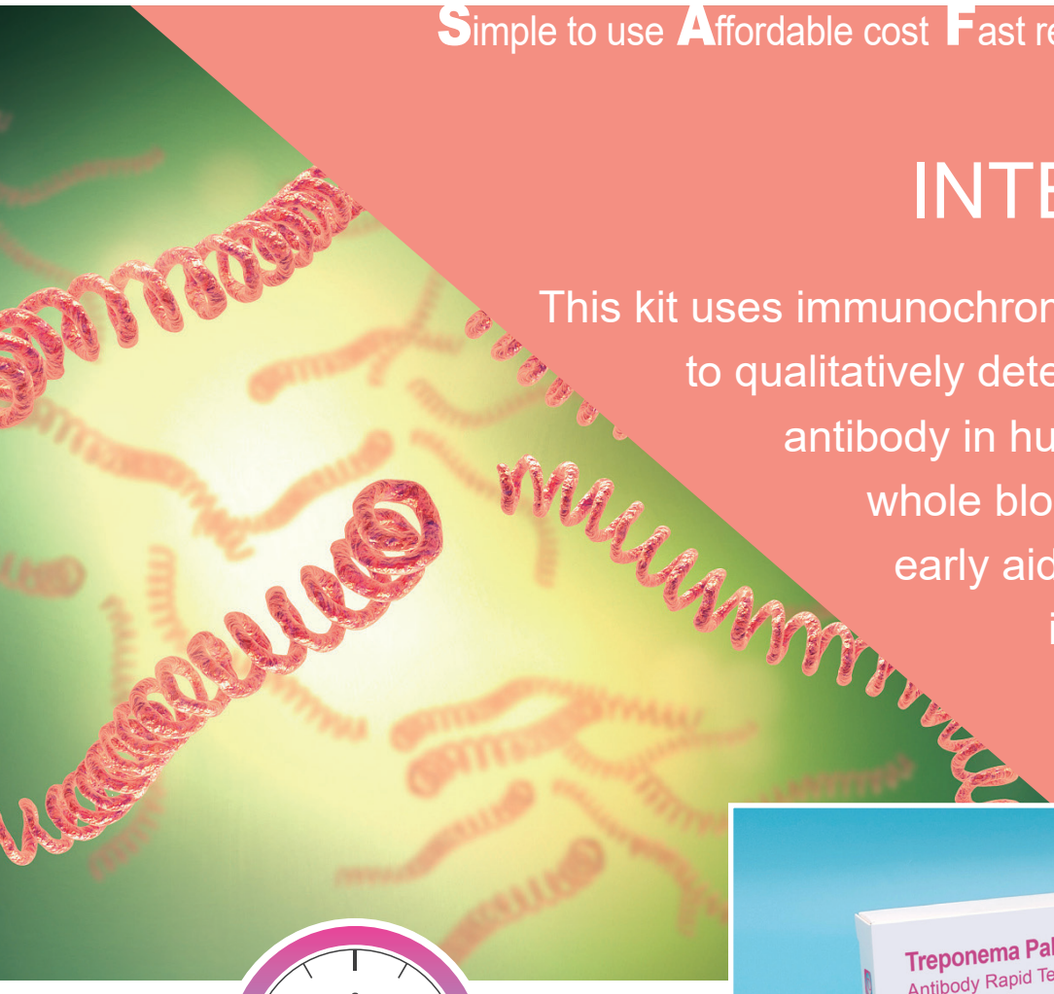
Treponema Pallidum Antibody Rapid Test Kit

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



INTENDED USE

This kit uses immunochromatography technology to qualitatively detect treponema pallidum antibody in human serum, plasma or whole blood. It is suitable for the early aid of treponema pallidum infection diagnosis and screening.



Results within 10 minutes

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

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1.Summary

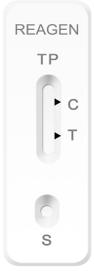
Treponema pallidum is a small spiral-shaped microorganism that often progresses insidiously. In the early stage, it is often manifested as rashes, erosions and ulcers on the external genitalia, as well as painless swelling of the lymph nodes. If the disease continues to progress, it can cause syphilis rash all over the body and also damage multiple organs throughout the body, such as the heart, central nervous system, blood vessels, kidneys, etc. Each year, there are approximately 12 million new cases of syphilis infection worldwide, among which 2 million are pregnant women. The risk of vertical transmission from mother to child is significant. In recent years, the incidence of syphilis has been on a continuous upward trend, with developing countries being particularly prominent. For instance, the number of cases in China has been increasing by an average of 11% annually. By 2023, the number of reported cases had reached 3 million, ranking first in the world.

2.Features



- It is convenient for the early detection and identification of Treponema Pallidum.
- 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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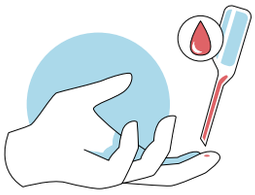
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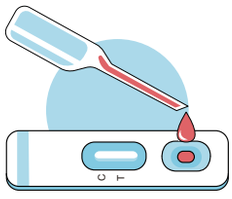
4.Product information

Product Code	Product Name	Package	Storage Condition	Shelf Life
RNS92135	Treponema Pallidum Antibody Rapid Test Kit	1T/Test	2-30℃	24 Months

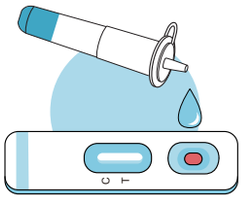
5.Test Procedure



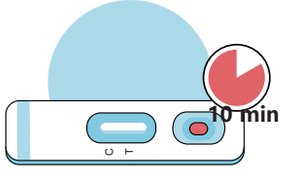
1 Collect blood from finger prick.



2 Add blood to sample well.



3 Place 2-3 drops of buffer in sample well.



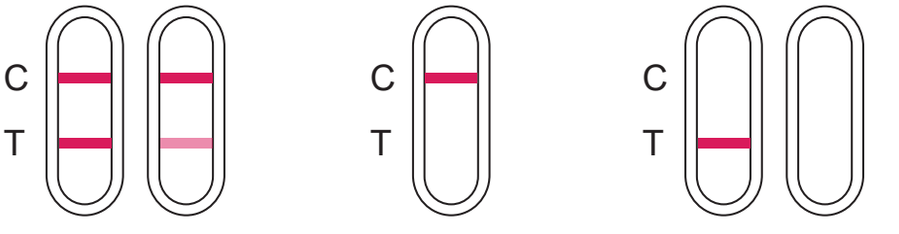
4 Read the result afer 10 minutes.

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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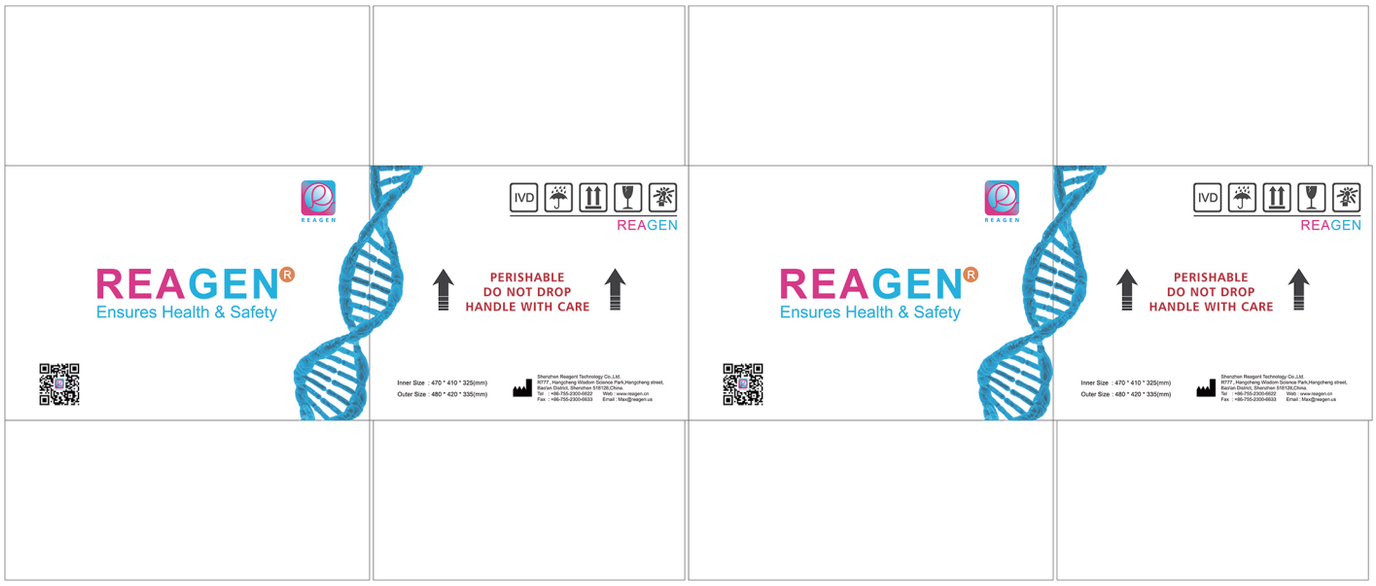
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7.Packing Specification

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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10.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 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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