REAGEN

HIV Antigen/Antibody Rapid Test Kit

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

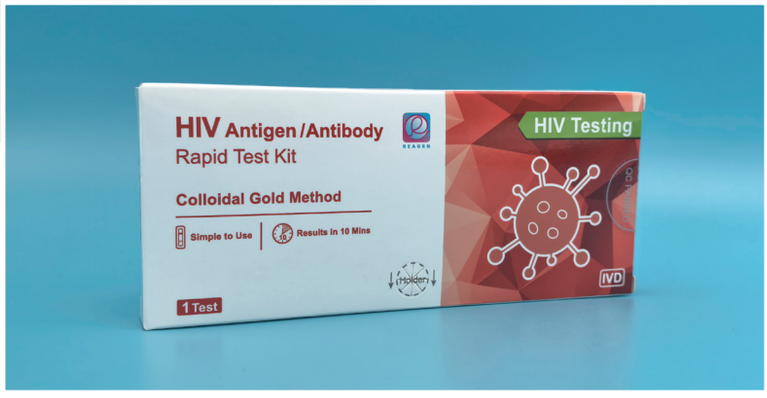


EXPECTED USAGE

This test kit is a serological, lateral flow chromatographic immunoassay for the qualitative detection of human immunodeficiency virus type 1 (HIV-1) p24 antigen, human immunodeficiency virus type 1antibody and type 2 antibody in human whole blood, serum and plasma samples



Results within 10 minutes



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

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Shenzhen Reagent Technology Co.,Ltd.
0755-2300-6699 info@reagenus.com
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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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rich@homehealthbrands.com
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1.What is HIV?

HIV or Human Immunodeficiency Virus, is transmitted sexually, through blood exposure and drug use by contaminated needles and during pregnancy from an infected mother to her unborn child. It can also be transmitted by breastfeeding. HIV virus attacks and impairs immune cells, causing progressive weakness of the immune system and can further progress to a condition called AIDS.

2.Symptom of infection

After being infected with HIV, there are no symptoms at the beginning. At this time, it is in a window period of HIV, and the virus cannot be detected by testing. This period generally lasts for about 2 to 6 weeks, and then Entering the acute phase of HIV, at this time patients will appear:



This situation will last for about a week to three weeks, and then enter an asymptomatic period. Many people can have HIV for many years and not feel sick. The only way to know if you have HIV is to take a test.Early detection of infection can effectively reduce the spread of HIV and early treatment can prevent progression to AIDS.

3.Features



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

4.Product information

Product Code	Product Name	Package	Storage Condition	Shelf Life
RNS92289	HIV Antigen/Antibody Rapid Test Kit	1T/Test	2-30℃	24 Months

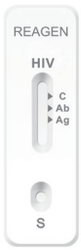
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5.Components



Test Card


Dropper


Instruction for Use



Alcohol Pad

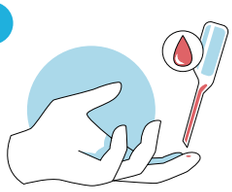

Sample Diluent

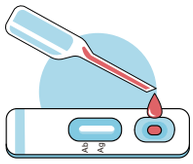

Disposable Sterile Lancets



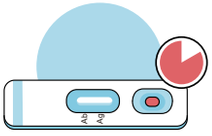
Biosafety Bags

6.Test Procedure


1 Collect blood from finger prick.


2 Add 1 drop of blood to sample well.


3 Place 3 drops of buffer in sample well.

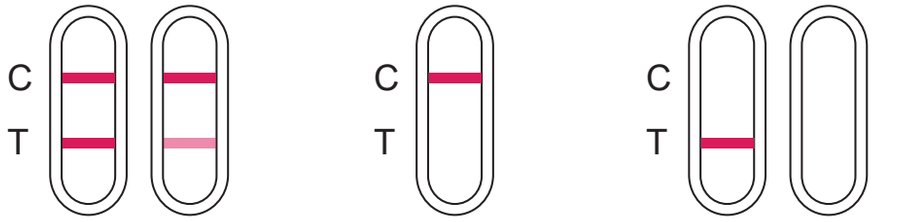

4 Read the result afer 10 minutes.

7.Test Results

Positive: Two red lines, that is, one red reaction line in the detection area (Ag or Ab) and one in the quality control area (C).

Negative: One red line, that is, a red response line appears only in the quality control area (C).

Invalid: No red reaction line appears in the quality control area (C). The test is invalid, it is recommended to re-test with a new test card at this time, especially pay attention to whether the added sample is enough.



POSITIVE NEGATIVE INVALID

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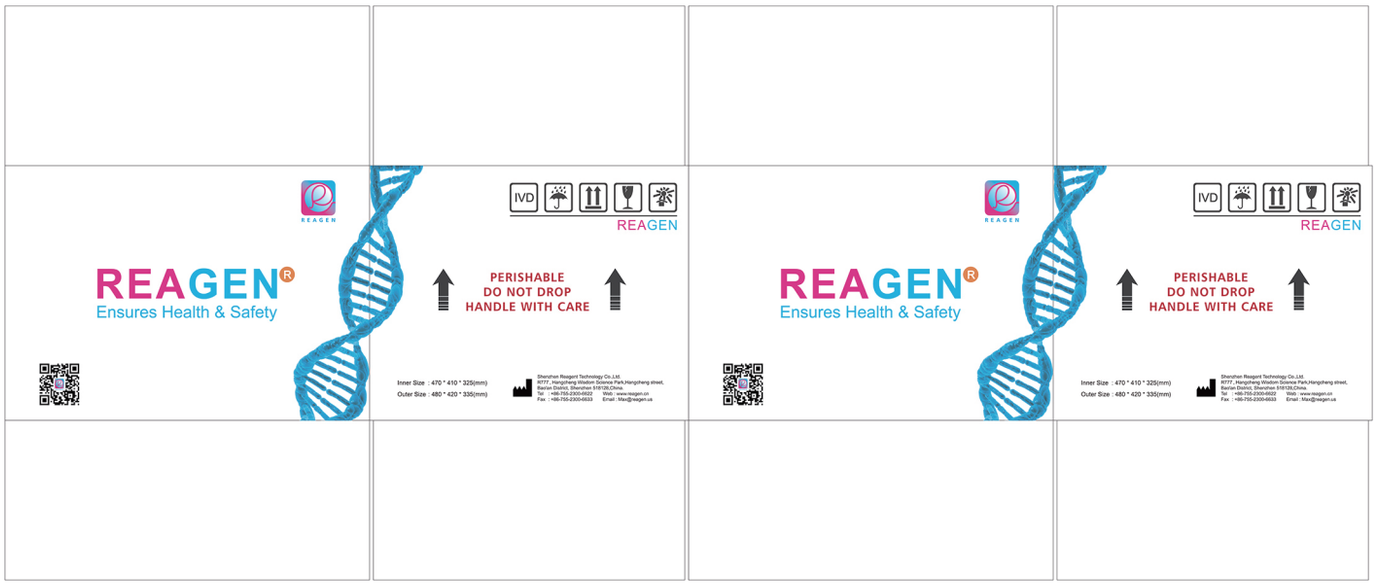
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8.Packing Specification

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

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9.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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