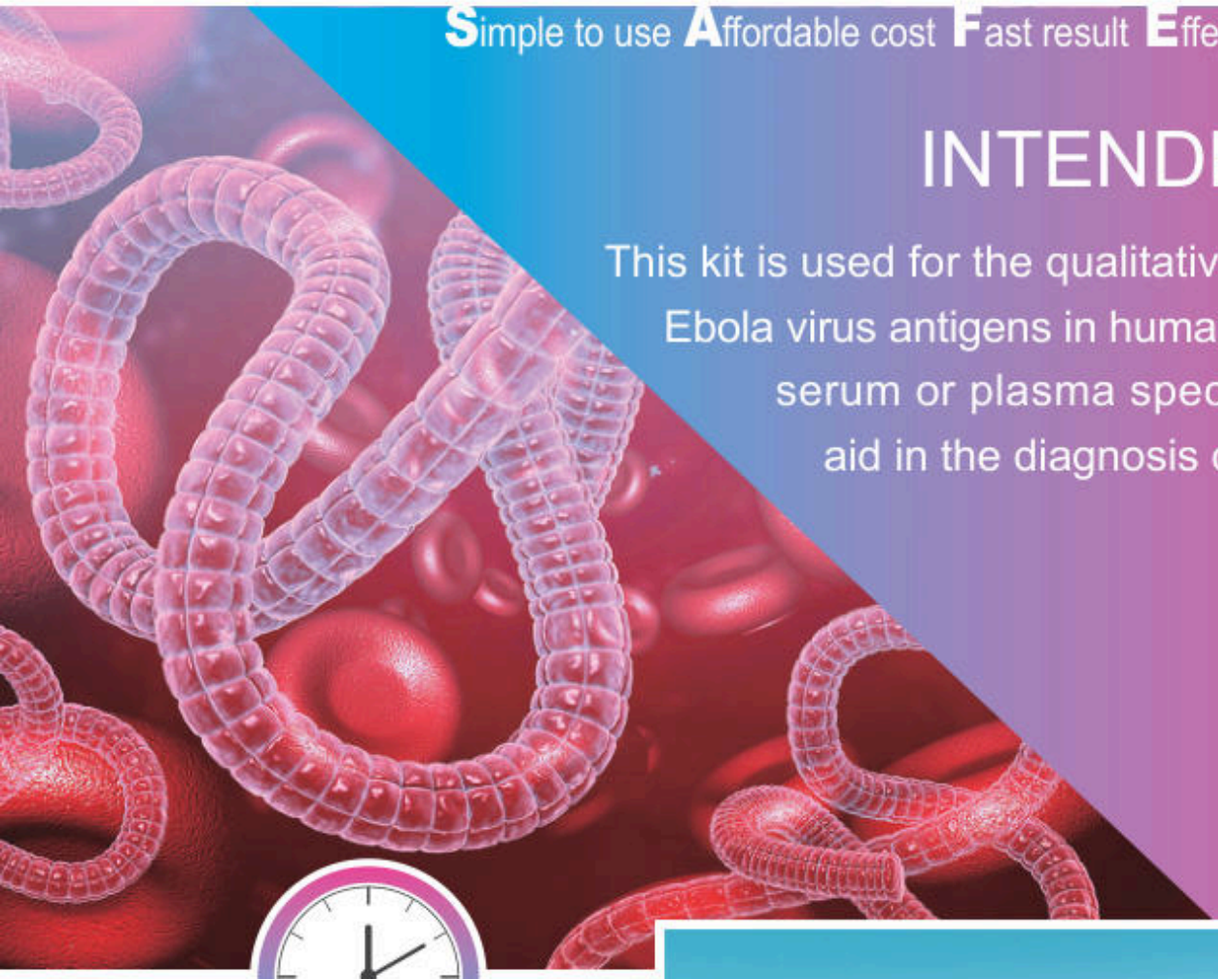
REAGEN

Ebola Virus Antigen Rapid Test Kit

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



INTENDED USE

This kit is used for the qualitative detection of Ebola virus antigens in human whole blood, serum or plasma specimens as an aid in the diagnosis of Ebola virus infection.

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
www.reagen.us www.reagen.cn www.reagen.eu
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
kelly@homehealthbrands.com

1.Summary

Ebola virus is a highly contagious disease that can cause Ebola hemorrhagic fever in humans and primates. It was discovered in 1976 in the Ebola River region of southern Sudan and the Democratic Republic of Congo. It is mainly transmitted through close contact. Fruitbats, as natural hosts, transmit the virus to wild animals such aschimpanzees and monkeys. Humans are infected by contact withthese animals and their bodily fluids, excreta, etc. The incubation period, that is, the time interval from infection with the virus to onset of symptoms is 2 to 21 days. Humans are not infectious until they develop symptoms. First symptoms are the sudden onset of fever fatigue, muscle pain, headache and sore throat. This is followed by vomiting, diarrhoea, rash, symptoms of impaired kidney and liver function, and in some cases, both internal and external bleeding (e.g., oozing from the gums, blood in the stools).

2.Features



- It can detect Ebola viruses antigens.
- 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 Buffer



Sterile Lancets

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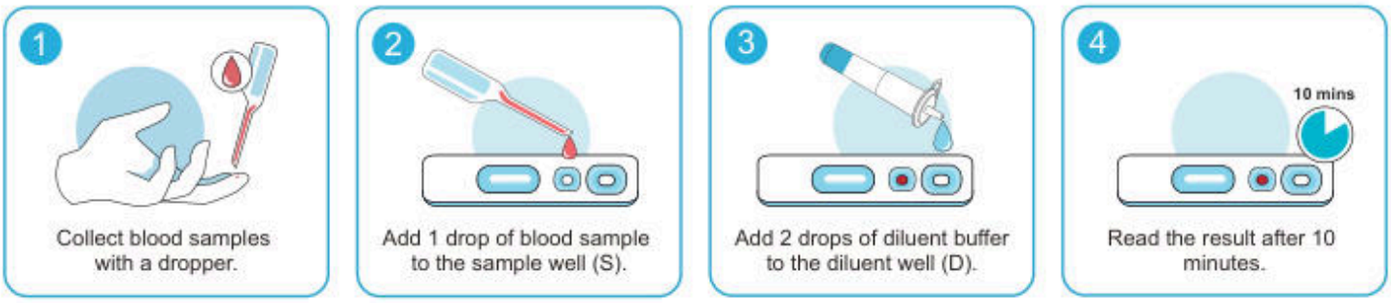
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4.Product Information

Product Code	Product Name	Package	Storage Condition	Shelf Life
RNPT96029-01 RNPT96029-20	Ebola Virus Antigen Rapid Test Kit	1T/Kit 20T/Kit	2-30℃	24 Months

5.Test Procedure

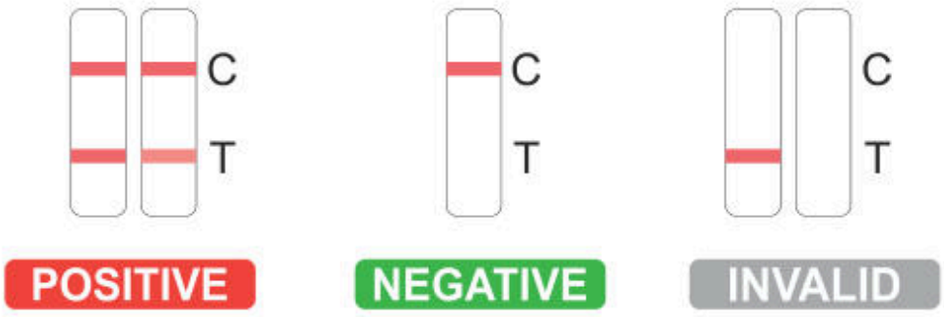


6.Test Results

POSITIVE: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).

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, stop using the test kit immediately and contact your local distributor.



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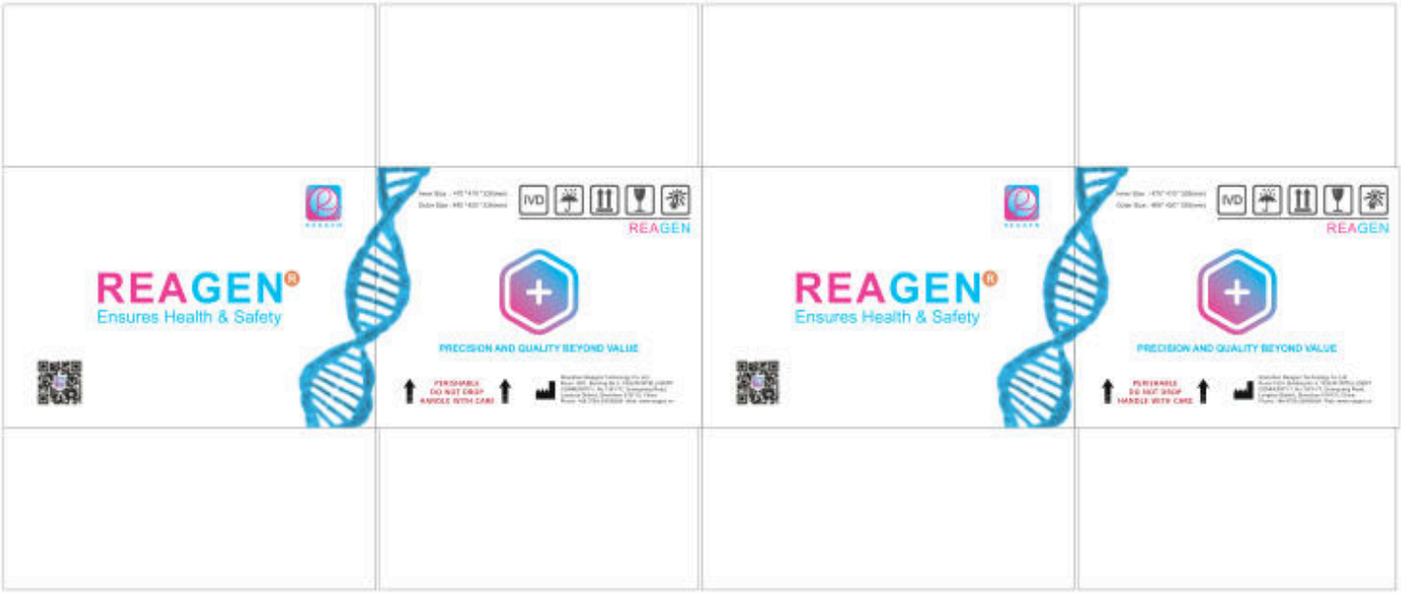
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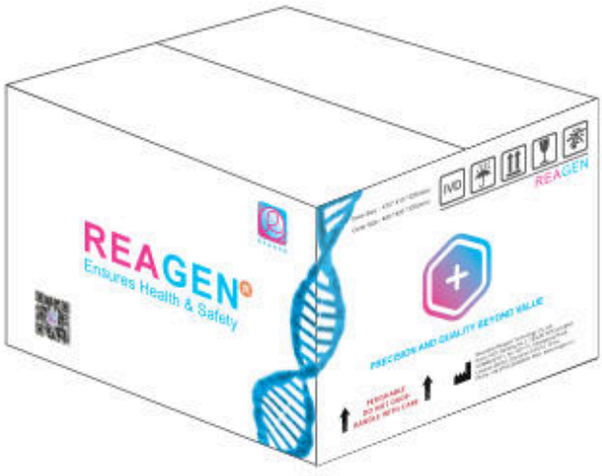
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7.Packing Specification

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) / 12kg	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 N18, 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: 15th of April 2026

Manuel Mateos

Chief Executive Officer

Expiration date: 8th of December 2028
Certificate #: ECREP20260415.7
Ver: CERT-EC-2407
cmcmedicaldevices.com

10 YEARS ANNIVERSARY

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Certificate CN21/42019

The management system of

Shenzhen Reagent Technology Co., Ltd.

Room 1601, Building 3 and 8F, Building 2, Yesun Intelligent Community I, No. 1301-77, Guanguang Road, Guanlan Street, Longhua District, Shenzhen, Guangdong, 518110, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016

Medical devices - Quality management systems - Requirements for regulatory purposes

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 29 January 2026 until 06 January 2027 and remains valid subject to satisfactory surveillance audits.

Issue 5. 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

Unified Social Credit Identifier : 914403006911615909

Company Name : Shenzhen Reagent Technology Co., Ltd.

Legal Representative : Deng Xinggang

Mode of operation : wholesale and retail

CEO : Wang Xinxin

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

Business Scope : 2002 Catalogue (Class III): 6804, 6815, 6821, 6822, 6823, 6824, 6825, 6826, 6828, 6830, 6832, 6833, 6840, 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 (Class III) : 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 : Room 1601, Building No.3, YESUN INTELLIGENT COMMUNITY I, No. 1301-77, Guanguang Road, Longhua District, Shenzhen 518110, China.

Warehouse Address : 201, 2nd Floor, Room 1601, Building No.3, YESUN INTELLIGENT COMMUNITY I, No.1301-77, Guanguang Road, Longhua District, Shenzhen 518110, China.

Lssuing Department : Shenzhen Administration For Market Regulation

Limited period: From Nov.14, 2025 to April 25, 2030

Date of issuance: November 14, 2025

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