REAGEN

Monkeypox Virus Antigen 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 monkeypox virus antigen in human lesion exudate, scab or oropharyngeal swab samples. It is suitable for the early aid of monkeypox virus infection diagnosis and screening.





Results within 10 minutes

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

www.reagen.cn www.reagen.us

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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1.Background

Monkeypox is an infectious disease caused by the monkeypox virus. Both humans and animals can be infected (such as monkeys, etc.). The main features include fever, fatigue and blisters similar to chickenpox on the skin. Since the global outbreak of monkeypox in 2022, the number of cases has continued to increase. In August 2024, the World Health Organization (WHO) once again classified monkeypox as a "Public Health Emergency of International Concern" and launched a global strategic response plan, with an estimated investment of 135 million US dollars for prevention and control, driving a sharp increase in the demand for testing, vaccines and treatments. As of 2025, the fatality rate of monkeypox cases in the Democratic Republic of the Congo has reached 3.5%, and the risk of the epidemic spreading beyond Africa has intensified.

2.Features



- Early detection and differentiation of Monkeypox Virus.
- Higher sensitivity & higher accuracy.
- Simple operation and highly-efficient test.
- Suitable for massive scale testing.
- Rapid test results in 10 mins.

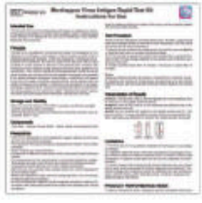
3.Components



Test Card


Sample Buffer


Swab


IFU



Biosafety Bags

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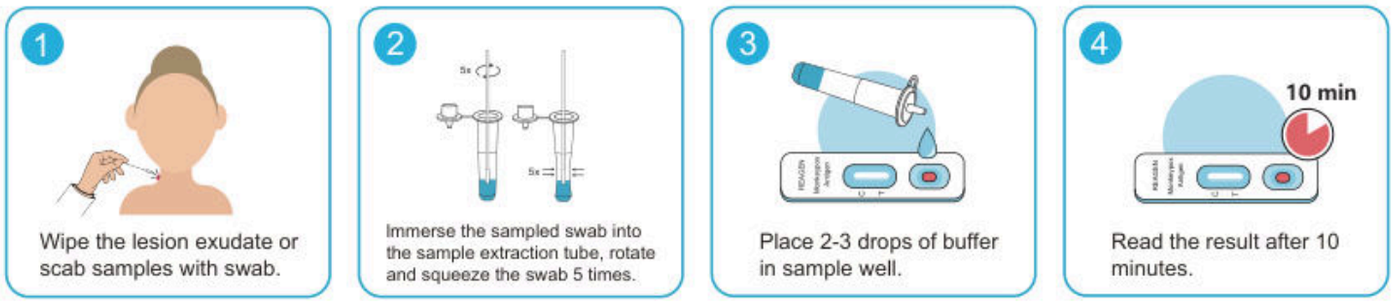
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4.Product Information

Product Code	Product Name	Package	Storage Condition	Shelf Life	Qualification
RNS92125	Monkeypox Virus Antigen Rapid Test Kit	1T/Kit	2-30℃	24 Months	CE

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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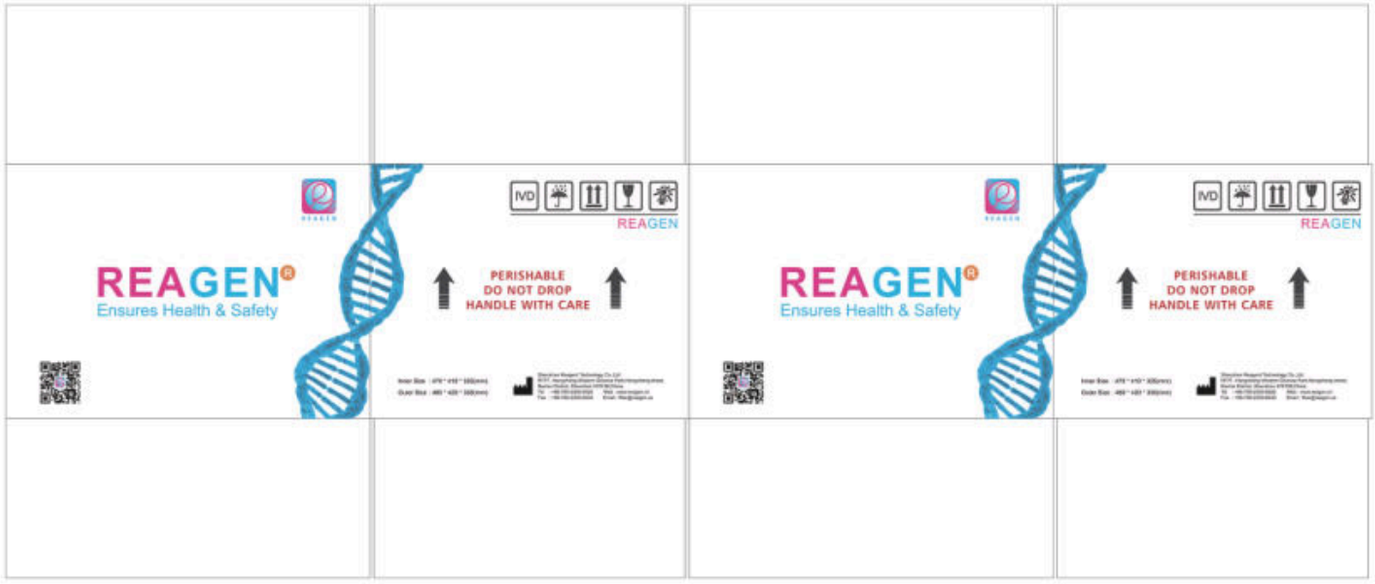
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8.Packing Specification

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

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9.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: 28th of October 2025
Manuel Mateos
Chief Executive Officer

Expiration date: 8th of December 2028
Certificate #: ECREP20251028.7
Ver: CERT-EC-2407
cmcmedicaldevices.com

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EU REP

CMC

Medical Devices Spain

Fluorescence PCR Detection Kit					
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
Multi-Drug Screen Test Cup (Urine)	IVDD - Directive 98/79	IVD OTHERS	M:Test cup	RPS/2301/2025	Registered with AEMPS
Mycobacterium Tuberculosis Real-Time Fluorescence PCR Detection Kit	IVDD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/2301/2025	Registered with AEMPS
Myoglobin/ CK-MB/ Troponin I Combo Test Kit (Colloidal Gold)	IVD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2301/2025	Registered with AEMPS
NS1/Pf Antibody Combo Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2301/2025	Registered with AEMPS
Neisseria Gonorrhoeae Real-Time Fluorescence PCR Detection Kit	IVD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/584/2023	Obsolete
Nine Respiratory	IVDD -	IVD OTHERS	M:Test card	RPS/2301/2025	Registered with

Expiration date: 8th of December 2028
Certificate #: ECREP20251028.7
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 : Deng Xingchao

Company Address : R7777, 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 : R7777, Hangcheng Wisdom Science Park,Hangcheng street,Bao'an District, Shenzhen 518128,China.

Warehouse Address : R7777, 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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High-tech Enterprise

Certificate

Company Name: Shenzhen Reagent Technology Co., Ltd. **Certificate No.**: GR202244206194

Date of Issuance: December 19, 2022 **Period of Validity**: Three years

Approval Authority:

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