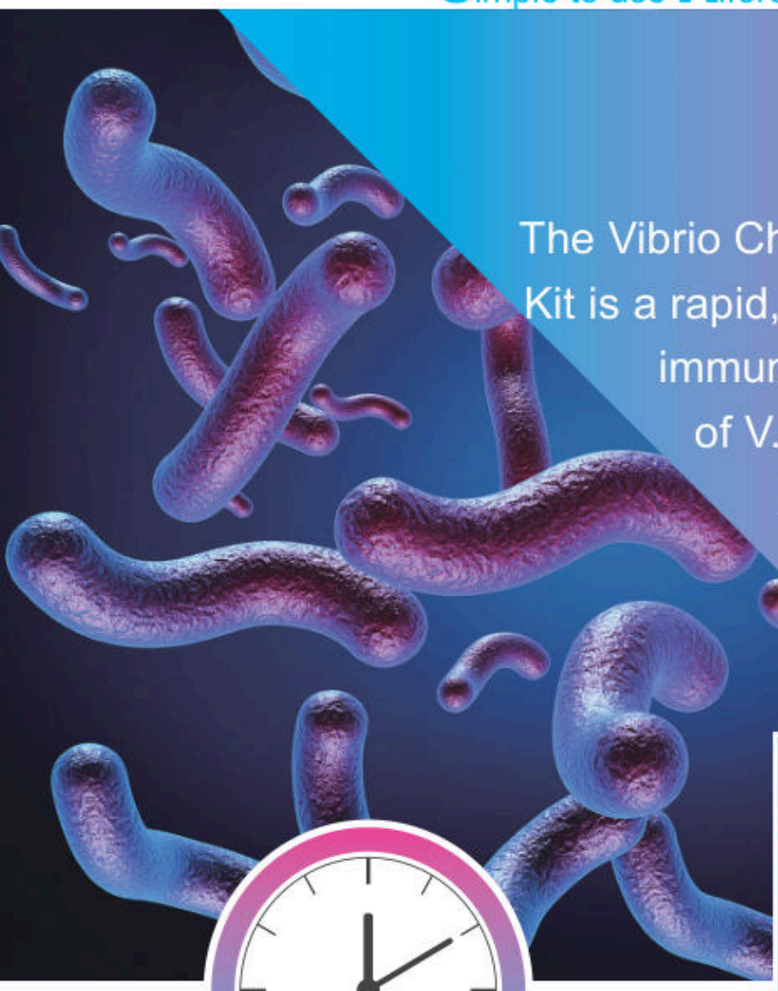
REAGEN

Vibrio cholerae O1/O139 Antigen Rapid Test Kit

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



EXPECTED USAGE

The Vibrio Cholerae O1/O139 Antigen Rapid Test Kit is a rapid, visual, lateral flow chromatographic immunoassay for the qualitative detection of V. cholerae O1 and/or O139 antigens in human fecal specimens as an aid in the diagnosis of V. cholerae O1 and O139 infection.





Results within 10 minutes

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

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1.Summary

Cholera epidemics, caused by V. cholerae serotype O1 and O139, continue to be a devastating disease of immense global significancein many developing countries. Clinically, cholera may range from asymptomatic colonization to severe diarrhea with massive fluid loss,leading to dehydration, electrolyte disturbances, and death. V. cholerae O1/O139 cause this secretory diarrhea by colonization of the small intestine and production of a potent cholera toxin. Because of the clinical and epidemiological importance of cholera, it is critical to determine as quickly as possible whether or not the organism from a patient with watery diarrhea is positive for V. cholera O1/O139.A fast, simple and reliable method for detecting V. cholerae O1/O139 is a great value for clinicians in managing the disease and for public health officials in instituting control measures.

2.Features



- Early detection and differentiation of Vibrio cholerae O1/O139.
- Higher sensitivity & higher accuracy.
- Simple operation and highly-efficient test.
- Suitable for massive scale testing.
- Rapid test results in 10 mins.

3.Storage and Stability

1.The test must remain in the sealed pouch until use. DO NOT FREEZE. Keep away from sunlight. Do not use after the expiration date.

2.Once the package of the test card pouch is opened, it must be used within 30 minutes.

3.The LOT and the expiration date were printed on the labeling.

4.Store as packaged in the sealed pouch at temperature (2-30℃).

5.Shelf life of sample diluent after open is 30 days.

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4.Product Information

Product Code	Product Name	Package	Storage Condition	Shelf Life	Qualification
RNS92164	Vibrio cholerae O1/O139 Antigen Rapid Test Kit	1T/Kit 20T/Kit	2-30℃	24 Months	CE

5.Components



6.Test Procedure



1. Collect feces samples and put them into diluent tube.
2. Tighten the lid and shake to mix the sample and diluent. Let it stand for 2 minutes.
3. Unscrew the cap and add 3 drops of diluent buffer to the test card.
4. Read result after 10 minutes.

7.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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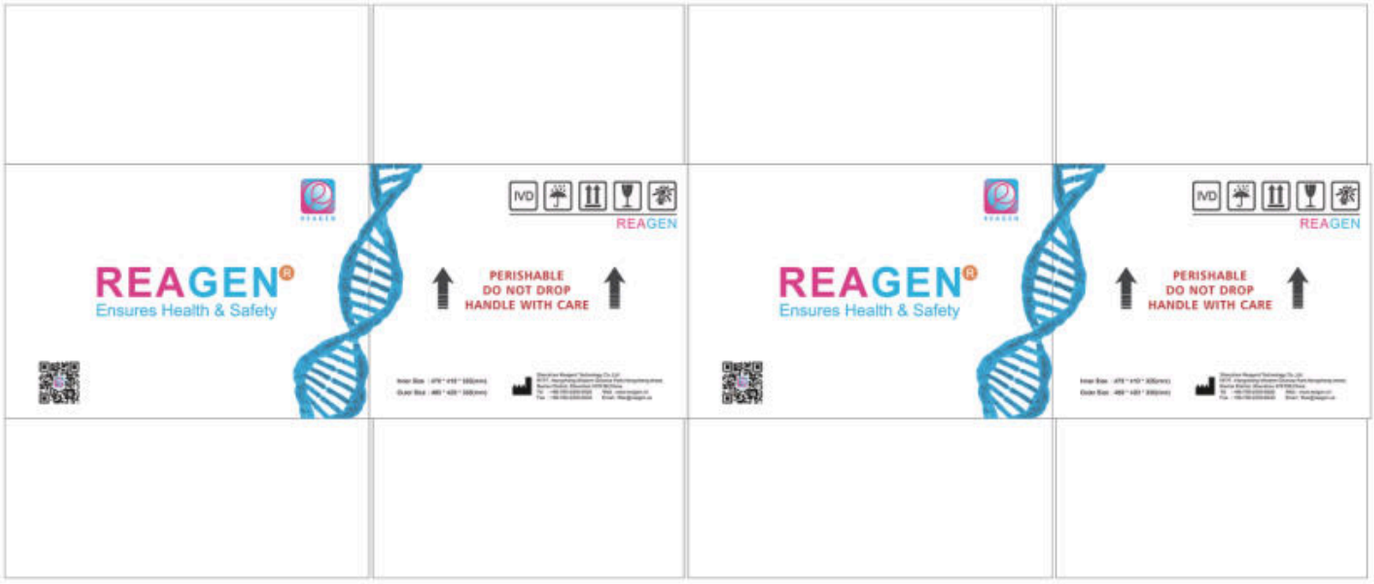
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8.Packing Specification

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

Antigen Rapid Test Kit					
SARS-CoV-2/ RSV/HMPV&Flu A/B Antigen Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2301/2025	Registered with AEMPS
SP10 Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2301/2025	Registered with AEMPS
Seven Respiratory Pathogens Antigen Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	R:	RPS/2301/2025	Registered with AEMPS
Seven Respiratory Pathogens Real-Time Fluorescence PCR Detection Kit	IVDD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/2301/2025	Registered with AEMPS
Ten Respiratory Pathogens Antigen Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2301/2025	Registered with AEMPS
Transferrin Rapid Test Kit (Colloidal Gold)	IVD - Directive 98/79	IVD OTHERS	M:Test card	RPS/584/2023	Obsolete
Typhoid IgG/IgM & Malaria Pf/Pv Ab Combo Rapid Test	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/1887/2025.	Obsolete
Typhoid IgG/IgM Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2301/2025	Registered with AEMPS
Vibrio Cholerae O1/O139 Antigen Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2301/2025	Registered with AEMPS
Vitamin D3 Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2301/2025	Registered with AEMPS
Zika Virus Antigen Rapid Test Kit	IVDD - Directive 98/83	IVD OTHERS	M:Test card	RPS/2301/2025	Registered with AEMPS
Zilpaterol ELISA Test Kit	IVD - Directive 98/88	CLASS IVD OTHERS	M:Reagent	RPS/543/2021	Obsolete
cTnI/PCT/HS-CRP Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2301/2025	Registered with AEMPS
hs-CRP+CRP Rapid Test Kit (Colloidal Gold) #82	IVD - Directive 98/79	CLASS IVD OTHERS	M:Test card	RPS/46/2022	Obsolete

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 May 10, 2028

Date of issuance: May 10, 2025

State Food and Drug Administration

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