

SARS-CoV-2 Antigen Rapid Test

WVIZ

Instruction for USE



SARS-CoV-2 ANTIGEN RAPID TEST

BRIEF INTRODUCTION

Intended Use	Detection of SARS-CoV-2 Antigen
Package	20 tests/Box
Storage	2-30 °C
Specimen Type	Oropharyngeal/nasopharyngeal swab

FEATURE

Rapid testing for SARS-CoV-2 in 15 minutes
High sensitivity and Specificity
Detect 2-3 days after contracted virus

Step1

Extraction Solution Preparation



1. Label for tube
2. Add 10 drops solution
3. Lay aside

Step2

Sample Collection Oropharyngeal Swab

Nasopharyngeal Swab



1. Open mouth widely and make a sound of "ah"
2. Insert the Oropharyngeal swab
3. Wipe both sides of pharyngeal tonsils back and forth for at least 3 times, then wipe the posterior pharyngeal wall up and down for at least 3 times



1. Hold the patient's head with one hand
2. Insert the swab into the nostril and slowly go deep along the bottom of the lower nasal passage
3. Rotate it for one round (Pause for a moment if reflex cough), and then slowly remove the swab

Step3

Detection Procedure



1. Dip the swab head into the extraction solution, and rotate the swab close to the extraction tube wall for about 10 seconds/times
2. Squeeze the tip of the swab along the inner wall of the extraction tube
3. Tighten tube cover

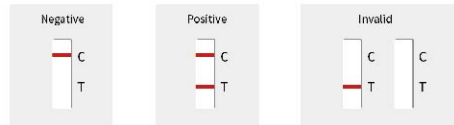


4. Stand by
5. Place the test device on a clean, flat surface
6. Add 2 drops sample solution to the well



7. Read the result in 15-20 minutes

RESULT INTERPRETATION



Xiamen Wiz Biotech Co., Ltd.
 Add: 3-4 Floor, NO. 16 Building, Bio-medical Workshop, 2030 Wengjiao Xi Road,
 Haicang District, Xiamen City, Fujian Province, 361026, P.R. China.
 Web: www.wizbiotech.com Tel: 0086-592-6800278
 E-mail: jessiewang@wizbiotech.com

Features



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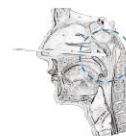


SPECIMEN COLLECTION

Oropharyngeal swab specimen collection: open mouth widely and make a sound of "ah", use the disposable swab to cross the tongue base. Wipe both pharyngeal tonsils back and forth at least three times, then wipe the posterior pharyngeal wall up and down for at least 3 times.



Nasopharyngeal swab specimen collection: carefully insert the swab into the nostril, slowly go deep along the bottom of the lower nasal passage. When the top of the swab reaches the back wall of the nasopharyngeal cavity, rotate it for one round (pause for a moment once reflex cough), then slowly remove the swab.



ASSAY PROCEDURE

Sample Preparation

- 1 Add 10 drops of extraction solution to the specimen extract tube.
- 2 Dip the swab head into the extraction solution rotate the swab close to the specimen extraction tube wall for about 10 seconds or 10 times.
- 3 Squeeze the tip of the swab along the inner wall of the specimen extraction tube. Remove and discard the swab. Then tighten tube cover and stand by.



Test Procedure

- 1 Take out the test device from the foil bag, and place it horizontally on the test table.
- 2 Vertically invert the specimen extraction tube (the extraction tube with processed specimens), add 2 drops vertically into the sample well of the test device.
- 3 Read the result within 15 to 20 minutes, invalid if more than 30 minutes.
- 4 Visual or instrument interpretation can be used in the interpretation.

INSTRUMENT SET

According to different requirements, reagents can be matched with different instruments to achieve different solutions.



RESULT INTERPRETATION

- ✓ **Negative:** The red line in the "C" control line region appears. No line appears in the "T" test line regions.
- ✓ **Positive:** The red line in the "C" control line region appears and a red line appears in the "T" test line region.
- ✓ **Invalid:** The red line in the "C" control line region doesn't appear.





XIAMEN WIZ BIOTECH CO.,LTD.

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2030 Wengjiao West Road,Haicang District,361026,Xiamen,China

Tel: +86-592-6808278
Fax: +86-592-6808279

Specifications

20Tests/Kit	Specification		MOQ/T	
	Per Box	GW/g	300	1000
		MEAS/mm	160x145x80	
	Per Carton (470x360x450mm)	Boxes	30	
		GW/kg	10.15	
	Tests	600		
 <p data-bbox="220 1332 651 1390">Optional: Oropharyngeal swab or Nasopharyngeal swab</p>	Per Carton	MEAS/mm	GW/g	
		240x175x190	As per quantity	

CE certificate SARS-CoV-2 Antigen Rapid Test

EC declaration of conformity **CE**

According to Directive 98/79/EC, Concerning In-Vitro Diagnostic medical device

 **Manufacturer:** Xiamen Wiz Biotech CO., LTD.
Address: 3-4 Floor, NO. 16 Building, Bio-medical Workshop, 2030 Wengjiao Xi Road, Haicang District, Xiamen City, Fujian Province, 361026, P.R.China

 **EU representative:** WellKang Ltd
Address: Address: 16 Castle St, Dover, Kent, CT16 1PW, England, UK.

Product Name: SARS-CoV-2 Antigen Rapid Test

Product Type: 1 Test/kit, 2 Tests/kit, 3Tests/kit, 5 Tests/kit, 10Tests/kit, 20Tests/kit, 25Tests/kit, 30Tests/kit, 40Tests/kit, 50Tests/kit, 100Tests/kit, 200Tests/kit

Product Classification: Other IVD device

We hereby state that:
Those above products with CE marking which are manufactured by our company all comply with EU Medical Device Directives IVDD98/79/EC, and realize their expected uses. All CE files have been certified by the company, consequently their authenticity has been guaranteed.

Directive we are following:
In-Vitro Diagnostic medical device:
DIRECTIVE 98/79/EC OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 October 1998 on *In-Vitro Diagnostic medical device.*

Standards we are implementing:
EN 13612:2002/AC: 2002 EN ISO 13485:2016 EN ISO 14971:2012
EN ISO 23640:2015 EN 13641:2002 EN ISO 15223-1:2016
EN ISO 18113-1:2011 EN ISO 18113-2:2011

Xiamen Wiz Biotech CO., LTD.

XiaMen. China August 10, 2020

Place date


Signature Title

MHRA SARS-CoV-2 Antigen Rapid Test



Medicines & Healthcare products
Regulatory Agency



Medicines & Healthcare products
Regulatory Agency

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London
E14 4PU
United Kingdom

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gov.uk/mhra

Wellkang Ltd
16 Castle St
DOVER
CT16 1PW
United Kingdom

17 September 2020

Dear **Edward Wang**

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **16 September 2020** has been reviewed:

Application reference: **2020091601185081**

Manufacturer organisation: **Xiamen Wiz Biotech Co., Ltd.**
Address:
**3-4 Floor, No.16 Building, Bio-medical Workshop,
2030 Wengjiao Xi Road,
Haicang District,
Xiamen City, Fujian Province,
361026
China**

Manufacturer registration status: **Registered**

Device(s):

GMDN term	Status	MHRA comment
64787 - SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	

Please note this letter **does not** represent any form of accreditation, certification or approval by the UK Competent Authority.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:

1. **company/organisation information e.g. name and address**
2. **additional devices (GMDN code or term)**

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/discontinuation of a device (GMDN) or product from your registration record, change of contact person, telephone number and/or email address, for which payment of our statutory fee does not apply.

Please note that the name and address of manufacturers and authorised representatives and their devices that have been registered will be published on our [Public Access Registration Database \(PAR\)](#). This applies to non-in vitro diagnostic devices only.

The account number for your company/organisation is **0000010576**.

Yours sincerely,



Ngozi Onyeukwu
 Device registrations service
 Devices division
 MHRA

Registration in Italy

SARS-CoV-2 Antigen Rapid Test



Ministero della Salute

Stampa | Scarica

dispositivi medici

ricerca:

Denominazione fabbricante:
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM: **1988738**
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:30/08/2020

DISPOSITIVO MEDICO/ASSEMBLATO							FABBRICANTE/ASSEMBLATORE						
IDENTIFICATIVO				NOME			DATA FINE			PARTITA			
LOGIA	DI	ISCRITTO AL	CODICE ATTRIBUITO DAL	COMMERCIALE	CND	CLASSE	DATA PRIMA	IMMISSIONE	RUOLO	DENOMINAZIONE	CODICE	IVA/VAT	N
OSITIVO	REGISTRAZIONE	REPERTORIO	FABBRICANTE/ASSEMBLATORE	E MODELLO		CE	PUBBLICAZIONE	IN	AZIENDA		FISCALE	NUMBER	
	BD/RDM							COMMERCIO					
positivo	1988738	S	51232012	SARS-COV-2 ANTIGEN RAPID TEST	W0105040619 - CORONAVIRUS	IVD - Altro tipo di IVD	28/08/2020		FABBRICANTE	XIAMEN WIZ BIOTECH CO., LTD			
									MANDATARIO	WELLKANG LTD		GB4740528	

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