



ABOUT US

Xiamen Wiz Biotech Co., Ltd. is a high-tech biomedical company, devoted to the field of rapid diagnostic reagents and instrument. Wiz is located in Xiamen, China, established in July 2013, which is a listed enterprises in National Equities and Quotations. As a technology-driven company that prides itself on its scientific excellence, Wiz focused on technological innovation and roduct innovation with 15 authorized patents, each of our products embodies the creativity of our excellent scientists, who are working hard to continuously bring novel products to the China and world markets. SARS-CoV-2 rapid detection series of products, including SARS-CoV-2 antigen, antibody and influenza differential detection, are produced by Wizbiotech, which can easily and quickly carry out screening of SARS-CoV-2 in a large number of people, adding strength to epidemic prevention and control.

Xiamen Wiz Biotech Co., Ltd.

COVID-19 Antigen Self-Testing Kit



Self-testing



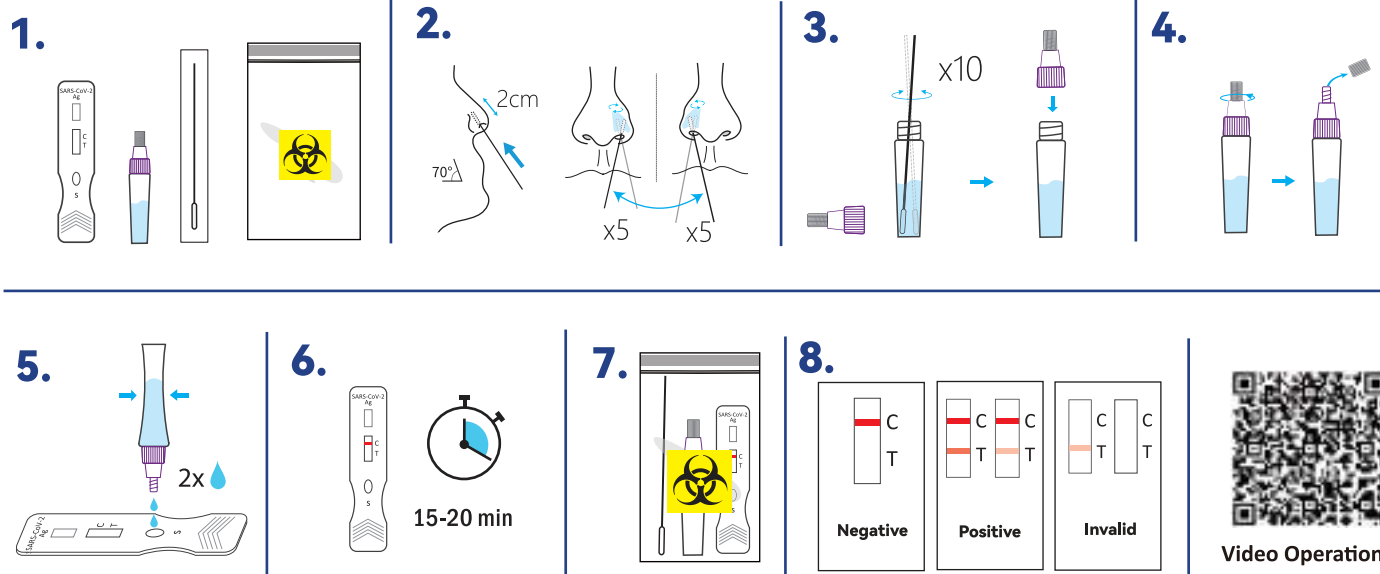
SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)

- ✓ Anterior nasal swab specimen, noninvasive
- ✓ Very simple to use
- ✓ Convenient, no instrument required
- ✓ Rapid, results within 15~20 minutes
- ✓ Cost-efficient

<http://en.wizbiotech.com/>

CE 1434

QUICK REFERENCE GUIDE



CLINICAL PERFORMANCE

Test Results	Reference PCR Results		
	Positive	Negative	Total
Positive	113	0	113
Negative	2	456	458
Total	115	456	571

Sensitivity: **98.26%** (95% C.I. 93.86%~99.79%)
 Positive Predictive Value: **100%** (95% C.I. 96.79%~100.00%)
 Overall Percent Agreement: **99.65%** (95% C.I. 98.74~99.96%)

Specificity: **100.00%** (95% C.I. 99.19%~100.00%)
 Negativity Predictive Value: **99.56%** (95% C.I. 98.43%~99.95%)

PACKING INFORMATION

Specification	Box size(mm)	Carton size(mm)	Carton G.W.(kg)	Boxes/Carton	Tests/Carton
1Test	150*70*15mm	615*315*370mm	14kg	400	400
2Tests	150*65*30mm	675*320*320mm	11kg	200	400
5Tests	170*80*40mm	420*360*340mm	9kg	80	400
10Tests	150*100*80mm	420*320*420mm	7kg	40	400
20Tests	210*140*70mm	440*300*370mm	7kg	20	400

CERTIFICATE


CERTIFICATE

EC Certificate No. 1434-IVDD-492/2021
EC Design-examination
Directive 98/79/EC concerning
in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies
that manufactured by:

Xiamen Wiz Biotech Co., Ltd.,
3-4 Floor, NO.16 Building, Bio-medical Workshop,
2030 Wengjiao Xi Road, Haicang District, Xiamen City,
Fujian Province, 361026, P.R. China

in vitro diagnostic medical devices
for self-testing

SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)
51332801, 51332802, 51332803, 51332804

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 22.11.2021 to 27.05.2024
The date of issue of the Certificate: 22.11.2021
The date of the first issue of the Certificate: 22.11.2021

 **1434**

Issued under the Contract No. MD-77/2021
Application No: 130/2021
Certificate bears the qualified signature.
Warsaw, 22/11/2021
Module A1

Vice-President

POUSH CENTRE FOR TESTING AND CERTIFICATION 02-844 Warsaw, 469 Pulawska Street, tel. +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl



Certificate No. 1434-IVDD-492/2021

The registered address
Xiamen Wiz Biotech Co., Ltd.
3-4 Floor, NO. 16 Building, Bio-medical Workshop, 2030 Wengjiao Xi Road,
Haicang District, Xiamen City, Fujian Province, 361026, P.R. China

The last inspection method is described on page 2 of this certificate

ISO 13485:2016
EN ISO 13485:2016

For the following sector:
The scope of registration appears on page 2 of this certificate.

This certificate is valid from 28 August 2020 and 3 September 2022
and remains valid subject to satisfactory surveillance audits
by certification body due before 28 Aug 2022
(Issue 1, Certified since 4 September 2019)

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Signed by:




UKAS
MEDICAL DEVICES
0004

UKAS is a not-for-profit organisation
Registered Charity No. 2744796
Limited by guarantee. Registered in England
Company No. 02052914

In more detail visit us at
Page 1 of 1

 **SGS**      



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FACTORY

Our one hundred thousand grade clean and dust-free workshop is operated strictly under ISO 13485:2016 and GMP guidelines. With the automatic production line, efficient production process, strict quality control, we always produce the products timely to meet customers' request.



