


Supero-Produkt Wiztech – Selbsttest

- ✓ Endlich ein Test ohne negative Schlagzeilen;
- ✓ BfArM zugelassen, PEI empfohlen, EU-RA-gelistet, mit CE;
- ✓ Nasal; Flüssigkeit vorgefüllt; Sensibility: 96,3%(!!), Speciality: 100% (!!);
- ✓ Effektiv gegen OmiCron- und Delta-Varianten;
- ✓ 1er verpackt, 400 Tests / Karton (615x315x370mm, 14kg).





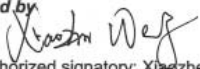

EC Declaration of Conformity

Manufacturer	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
European Representative	Qarad EC-REP BV Pas 257, 2440 Geel, Belgium
Product	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)
Model	1 test/kit, 2 tests/kit, 5 tests/kit, 10 tests/kit.
Catalogue number	51332801, 51332802, 51332803, 51332804
Classification	Self-Test
Conformity assessment route	Annex III including Section 6

We, the manufacturer, herewith, declares that the product(s) as specified above meet(s) the applicable provisions of the European Directive 98/79/EC on *in vitro* Diagnostic Medical Devices. All supporting technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the Authorized Representative in Europe.

General applicable directive:
Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

Notified Body: Polish Centre for Testing and Certification
Identification number: CE1434
EC Certificate No.: 1434-IVDD-492/2021
Start of CE Marking: 2021-11-22
Signed on 22/(Day) 11/(Month) of 2021. Place Xiamen.

Represented by
Signature:  Seal/Stamp: 
Name of authorized signatory: Xiaozhen Wang
Position held in the company: General Manager
Rev.3

CERTIFICATE


CERTIFICATE

EC Certificate No. 1434-IVDD-492/2021
EC Design-examination
Directive 90/269/EEC 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)
S1332001, S1332002, S1332003, S1332004

In terms of design documentation, comply with requirements
of Annex II (Section II) to Directive 90/269/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC
validity of the Certificate: From 22.11.2021 to 27.04.2024
The date of issue of the Certificate: 22.11.2021
The date of the first issue of the Certificate: 02.11.2021

CE 1434
Based under the Contract No. 1434/2021
Approved File: 1434/2021
Certificate covers the qualified original use
Module A1

Vizus@pbc.pl

POLISH CENTRE FOR TESTING AND CERTIFICATION Sp. z o.o. ul. Wolności 100/101, 01-652 Warszawa, Poland, tel. +48 22 624 20 00, info@pbc.pl, pbc.pl

Certificate (20190211)

SGS

The management system of
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

has been assessed and certified to meet the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following address:

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 26 August 2020 until 3 September 2022
and remains valid subject to satisfactory surveillance audits.
The certification audit date before 26 July 2022
Issue 2, Certified since 4 September 2019

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

Authorised by:


SGS
Personnel Services P.O. Box 40000, CH-1214, Geneva, Switzerland
T +41 22 717 7361 F +41 22 717 90 00
www.sgs.com

Page 1 of 2

SGS

Certificate (20190211) continued

SGS

Xiamen Wiz Biotech Co., Ltd.

ISO 13485:2016
EN ISO 13485:2016

Issue 2

Issued scope

Design and manufacture of in vitro diagnostic medical devices
including hormone marker test kit, kidney disease marker test kit,
tumor marker test kit, infectious disease marker test kit,
gastrointestinal inflammation marker test kit, cardiac marker test kit,
immunochromatography analysis.

Issued address

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

Authorised by:


SGS
Personnel Services P.O. Box 40000, CH-1214, Geneva, Switzerland
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www.sgs.com

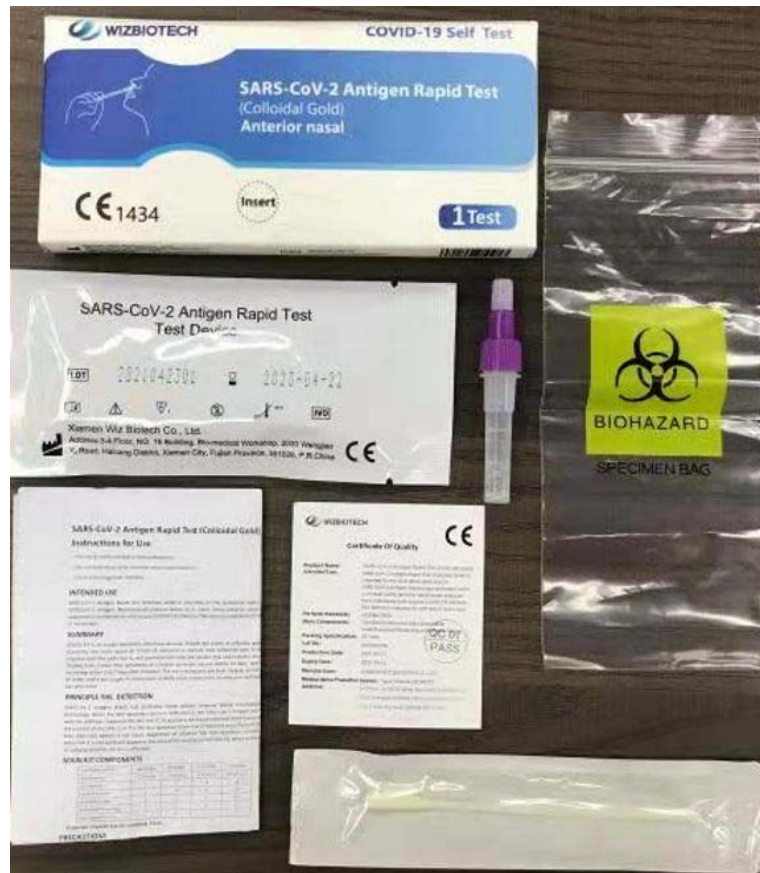
Page 2 of 2

SGS

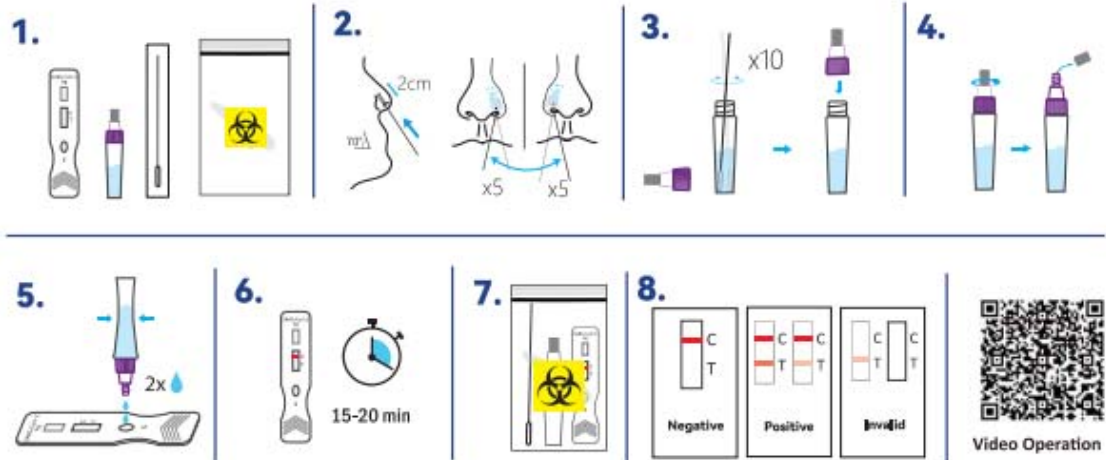
Verpackung



Inhalte



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

Specifacaton	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

Gegen OmiCron



厦门为正生物科技股份有限公司
XIAMEN WIZ BIOTECH CO.,LTD

Declaration on the detection validity of omicron variant

To Who It May Concern,

For the newly discovered variant of novel coronavirus Omicron (B.1.1.529), we have analyzed WIZ SARS-CoV-2 Antigen Rapid Test Kit and came to a conclusion: there is no off-target or missing detection occurred in the latest test for variant of Omicron (B.1.1.529). WIZ SARS-CoV-2 antigen rapid test adopts double antibody sandwich method to detect Nucleocapsid protein of SARS-CoV-2 viruses, Omicron NP protein mutation sites were P13L, 31-33, R203K, G204R. WIZ SARS-CoV-2 antigen rapid test detectable sites are not at these mutation sites. Our team will continue to track the latest variant of novel coronavirus to ensure stable supply.

XIAMEN WIZ BIOTECH CO.,LTD

2021.11.30 单证专用章

地址：厦门市海沧区新阳街道翁角西路 2030 号海沧生物医药通用厂房 16# 厂房 3-4 层 邮编：361026
Add: 3-4 Floor, NO.16 Building, Bio-medical Workshop, 2030 Wengjiao Xi Road, Haicang District, Xiamen City,
Fujian Province, 361026, P.R. China 361026
[Tel:+86-592-6808278](tel:+86-592-6808278) Fax: +86-592-6808279
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Gegen Delta



厦门为正生物科技股份有限公司
XIAMEN WIZ BIOTECH CO., LTD

Statement for the detection of the S glycoprotein mutant strain

Spike glycoprotein exist on the surface of novel coronavirus and easily mutated such as Delta mutant.

The viral nucleocapsid is composed of nucleocapsid protein (N protein for short) and RNA. The N protein is relatively stable, the largest proportion in viral structural proteins and high sensitivity in detection.

Based on the features of N protein, Monoclonal antibody of N protein against novel coronavirus was chosen in the development and design of our product named 'SARS-CoV-2 Antigen Rapid Test' that is intended for the qualitative detection of SARS-CoV-2 Antigen in oropharyngeal swab and nasopharyngeal swab specimens in vitro through the detection of N protein.

That is to say, the current spike glycoprotein mutant strain Delta mutant was not affected by detection.

XIAMEN WIZ BIOTECH CO., LTD

2021.06.23 单证专用章

地址：厦门市海沧区新阳街道翁角西路 2030 号海沧生物医药通用厂房 16# 厂房 3-4 层 邮编：361026
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