



**Self-testing**



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

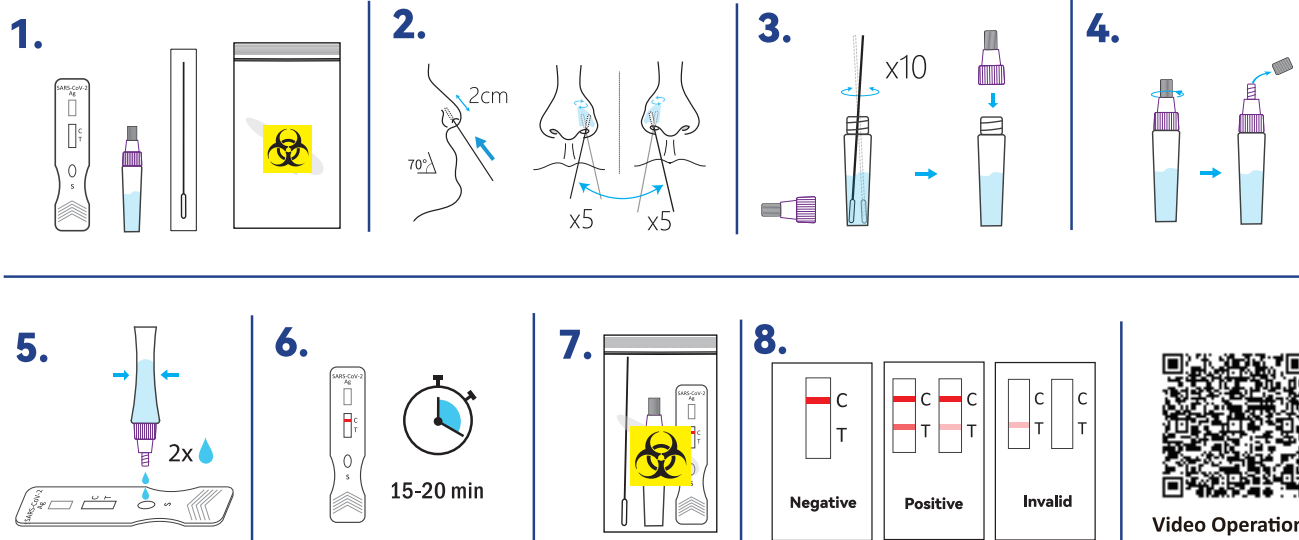
- ✓ Anterior nasal swab specimen, noninvasive
- ✓ Very simple to use
- ✓ Convenient, no instrument required
- ✓ Rapid, results within 15~20 minutes
- ✓ Cost-efficient

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



**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  
Tel:+86(592)6808 278 E-mail: sales@wizbiotech.com

## 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

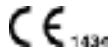
**SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)**  
51332801, 51332802, 51332803, 51332804

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



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

