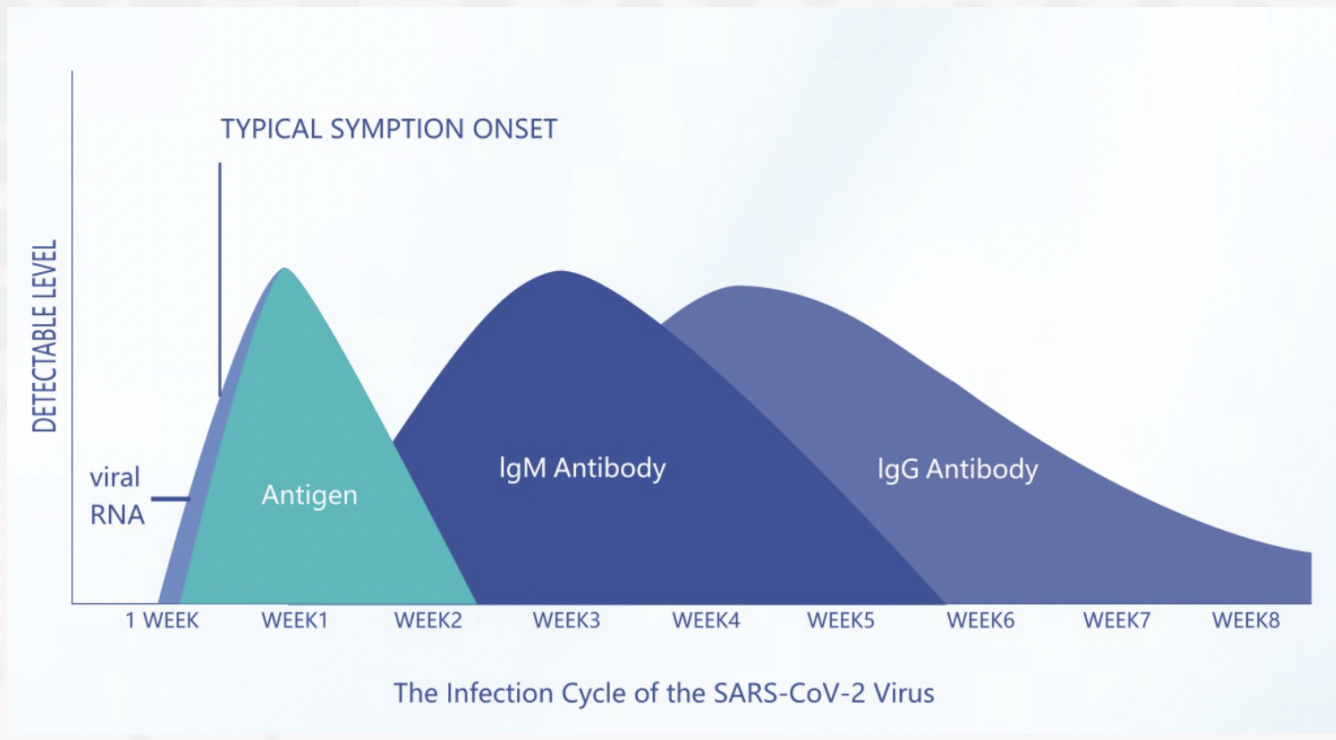
SkyPro

Rapid COVID-19 Antigen Test (Colloidal Gold) /Nasal Swab for self-testing

About SkyPro

SkyPro is a Hong Kong-based enterprise founded in 2002. We have been a supplier of medical consumables for Hong Kong Hospital Authority since 2003. The company has successfully passed the Medical and Industrial Production System Certification, including Medical Device Quality Management System (ISO13485), Medical Device License, US FDA, FFP2, EU CE Certification, etc. Our products have been sold to more than 40 countries and regions, occupying a large market share.

High Detectability



The Infection Cycle of the SARS-CoV-2 Virus

Antigen-detection diagnostic tests are designed to directly detect SARS- CoV-2 proteins produced by replicating virus in respiratory secretions and have been developed as both laboratory-based tests, and for near-patient use, so-called rapid diagnostic tests, or RDTs.

Highly Accurate

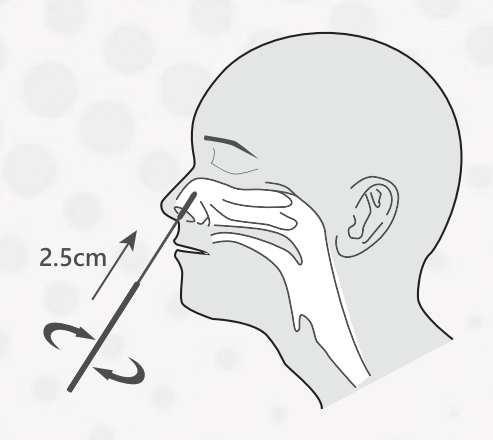
The clinical performance of the test was determined by examining 300 positive and 700 negative samples for SARS-CoV-2 antigen with a sensitivity of 99.00% (95% CI: 97.11% -99.79%) and a specificity of 100.00%. (95% CI: 99.47% - 100%).

Rapid COVID-19 Antigen Test (Colloidal Gold) Result	PCR Result		
	Positive	Negative	Total
Positive	297	0	297
Negative	3	700	703
Total	300	700	1000

Coincidence rate and 95% confidence interval		
	Coincidence	95% Confidence Interval
Clinical sensitivity	99.00%	97.11%~99.79%
Clinical specificity	100.00%	99.47%~100.00%
Total coincidence rate	99.70%	99.13%~99.94%

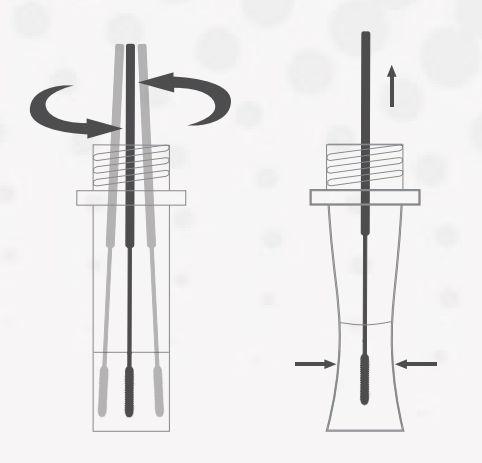
Instructions for Use

1



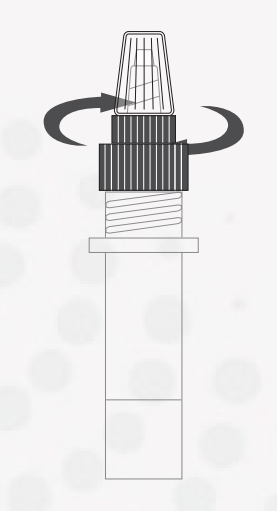
Insert the swab into both nostrils to a depth of 2.5cm, and rotate the swab for at least 5 times.

2



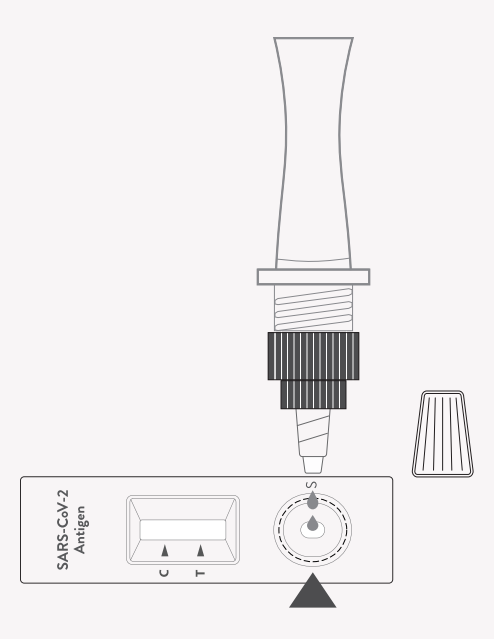
Unscrew violet cap. Plug in the swab and swirl for 10-15 times. Squeeze against sides of the tube and remove the swab.

3



Screw the cap.

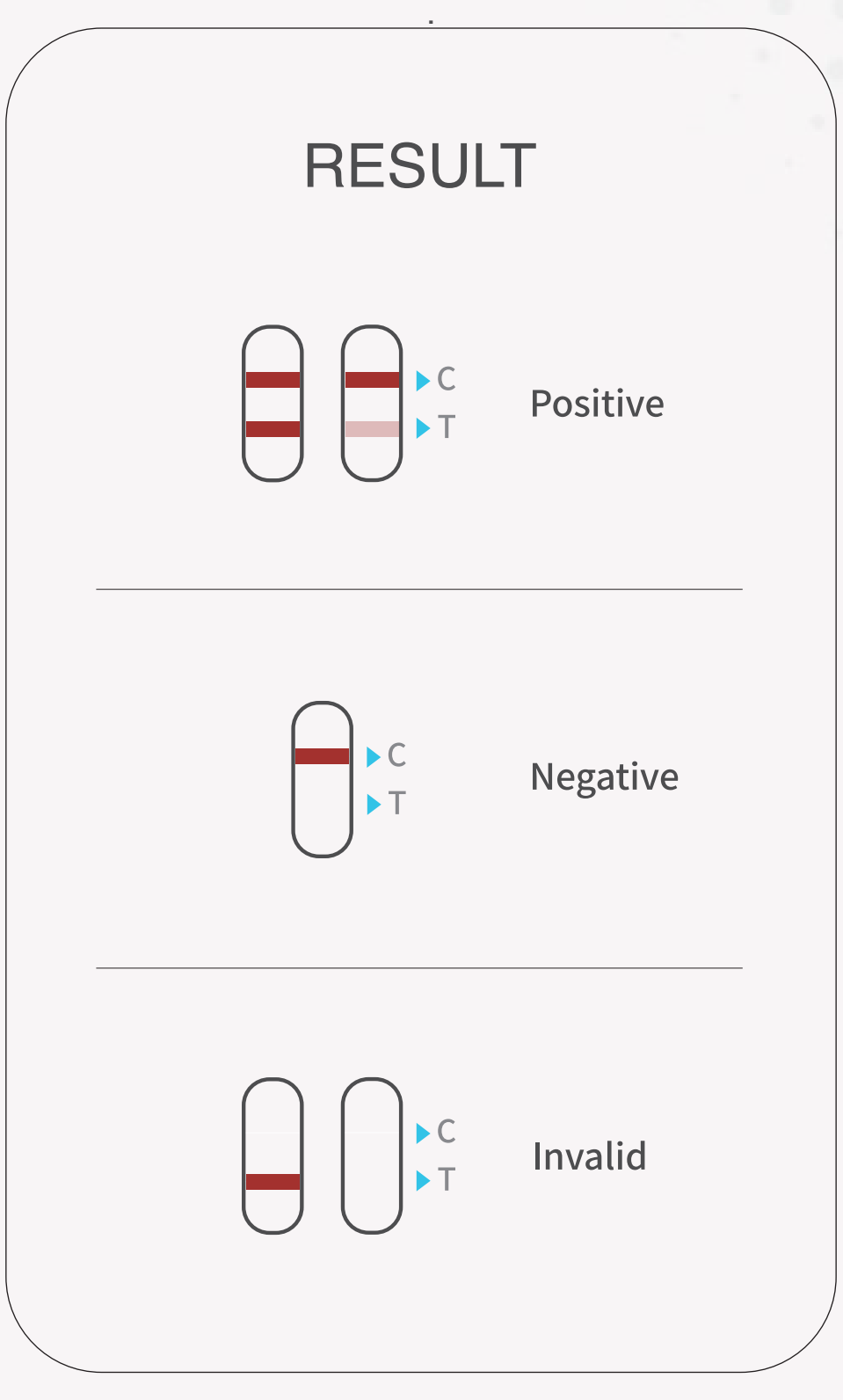
4



Squeeze 2 drops of liquid from the tube into the well of the Test Cassette (the circle next to "S").

5

The result will be displayed 15 minutes after the test. Please read the result between the 15th and 20th minutes after the test.



Certificate

CERTIFICATE

EC Certificate No. 1434-IVDD-451/2021
EC Design-examination
Directive 98/79/EC concerning
in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies that manufactured by:

Anbio (Xiamen) Biotechnology Co.,Ltd.
No.2016, Wengjiao West Road, Xinyang Street, Haicang District,361026 Xiamen, Fujian,China.

in vitro diagnostic medical devices for self-testing

Rapid COVID-19 Antigen Test (Colloidal Gold)/ Nasal Swab
A606101, A606102, A606103, A606104, A606105, A606106

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 16.08.2021 to 27.05.2024
The date of issue of the Certificate: 16.08.2021
The date of the first issue of the Certificate: 16.08.2021

CE 1434

Issued under the Contract No. MD-124/2021
Application No: 243/2021
Certificate bears the qualified signature.
Warsaw, 16/08/2021
Module A1

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.08.16 10:32:41 +02'00'
Vice-President
Mgr Anna Wyroba

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

For business use only

EC Certificate No.1434-IVDD-451/2021
Can be used in Europe

BUREAU VERITAS Certification

Anbio (Xiamen) Biotechnology Co., Ltd
No.2016, Wengjiao West Road, Xinyang Street, Haicang District, Xiamen City, P.R. China

Certified site:

NO.2016, WENGJIAO WEST ROAD, XINYANG STREET, HAICANG DISTRICT, XIAMEN CITY, P.R. CHINA

Bureau Veritas Italia S.p.A. certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

EN ISO 13485:2016
Scope of certification

Design and manufacture of fluorescence-based immunoassay reagent and devices, as an aid in clinical assessment of cardiovascular, gastric, inflammation, diabetic and infectious diseases detection, as well as hormone, vitamin testing. Design and manufacture of IVD reagents as an aid in clinical assessment of blood type testing.

Certificate awarded in conformity with the requirements of ACCREDIA DT 02-DC Rev.00

Original cycle start date:	**22/06/2020**
Expiry date of previous cycle:	**n.a.**
Certification / Recertification Audit date:	**17/05/2020**
Certification / Recertification cycle start date:	**22/06/2020**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **21/06/2023**

Certificate No. - Version: IT298645-1 Revision date: **22/06/2020**

GIORGIO LANZAFAME – *Local Technical Manager*

Certification body address:
Bureau Veritas Italia S.p.A., Viale Monza, 347 - 20126 Milano, Italia

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 009A

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation. To check this certificate validity please refer to the website www.bureauveritas.it

ISO 13485:2016