伊仕生物
EGENS

SARS-CoV-2

Antigen Rapid Test

(Colloidal Gold Immunochromatography)

For Self-testing

IVD CE 1434

Nantong Egens Biotechnology Co., Ltd

Email: Egens@Egens-bio.cn

Web address: www.egens-bio.cn

2022 Edition I

SARS-CoV-2 Antigen Rapid Test

for Self-testing

Product Features

- Specimen type:Nasal Aspirate Fluid/Nasal Swab/
- Easy to collect samples,simple operation, without professional equipment and laboratory
- Testing time:15-20 minutes
- convenient transportation
- Applicable to self- testing at home

Sensitivity And Specificity

SARS-CoV-2 Antigen Rapid Test	RT-PCR		TOTAL
	Positive	Negative	
Positive	205	1	206
Negative	14	599	613
Total	219	600	819

Sensitivity=205/219×100%=93.61%
(Wilson 95%CI: 89.51% - 96.46%)

Specificity=599/600×100%=99.83%
(Wilson 95%CI: 99.07% - 100.00%)

Total accuracy=(205+599)/819×100%=98.17%
(Wilson 95%CI: 97.00% - 98.97%)

Kit Components

1 Test/Box	5 Tests/Box	25 Tests/Box
1 Test Cassette	5 Test Cassettes	25 Test Cassettes
1 Sterilized swab	5 Sterilized swabs	25 Sterilized swabs
1 Extraction Tube with Buffer	5 Extraction Tubes with Buffer	25 Extraction Tubes with Buffer
1 Biosafety bag	5 Biosafety bags	25 Biosafety bags
1 Instructions for use	1 Instructions for use	1 Instructions for use
1 cardboard rack	1 cardboard rack	1 cardboard rack

伊仕生物
EGENS

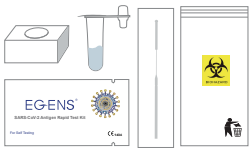
SARS-CoV-2 Antigen Rapid Test for Self-testing

Specimen Requirements and Test Procedure

1

Wash your hands before starting the test.

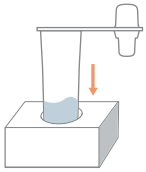
2



Check all components for possible damage and that all materials supplied are complete. Lay all the supplied materials on a clean, dry and flat surface.

3

Pinch the upper of the extraction tube and shake it more times to make buffer drop to the bottom of the tube completely.
Tear off the aluminum foil seal of the extraction tube containing the buffer solution carefully.
(*Note: Keep your distance away with your face)

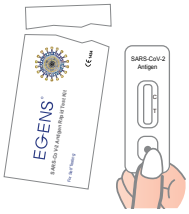


4

Insert the extraction tube into the circular hole of cardboard rack.

5

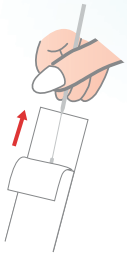
Take out the test cassette from the sealed foil pouch and place it on a clean and level surface.

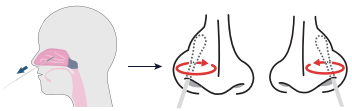


6

Please remove excess mucus in the nasal cavity before sampling by swab.

Unpack the swab package, being careful NOT to touch the soft end, which is the absorbent tip.



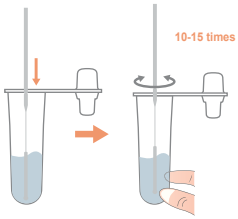


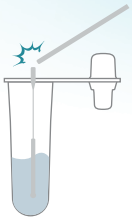
7

Gently insert the swab into your nasal cavity 1-1.5cm deep (generally 1cm for children aged 2-14 years). Do not inserting deeper, avoid hurting your nostril. Slowly rotate the swab in the inside walls of nostril 5 times or more to collect more nasal secretions. Repeat steps in the other nostril using the same swab.

8

Insert the swab into the extraction tube with buffer, gently pick up the tube from cardboard rack, and then rotate the swab for 10~15 times to mix the collected specimen with the buffer as much as possible.



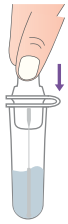


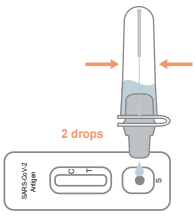
9

Pull the swab breaking position near the mouth of the extraction tube, pinch the swab head with one hand across the outer wall of the extraction tube, and bend the swab to break it gently with another hand.

10

Close the cap of the extraction tube and press firmly.



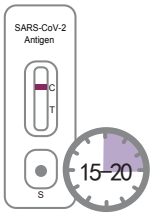


11

Add 2 drops of the treated sample vertically into the sample well of the test cassette. And start the timer.

12

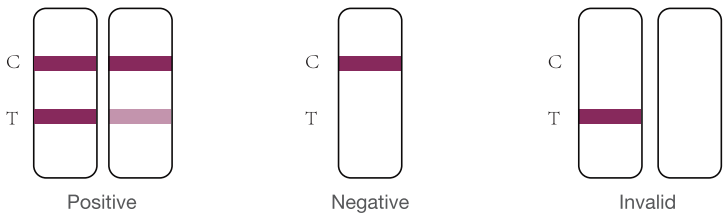
Read the result 15-20 minutes after adding the sample. Result got after 20 minutes is invalid.



13

All used test components should be put into the biosafety bag, sealed and discarded. (According to local garbage classification regulations)
*Note: After completing all steps, wash hands with hand sanitizer.

Interpretation of result



Packing information

Product Code	D0101TE	D0501EE	D2501AT
Format	1 Test/box,400 Box/Ctn	5 Test/box,200 Box/Ctn	25 Test/box,40 Box/Ctn
Box Size	13.5*7*2CM	15*7*4CM	19.5*13.2*8.5CM
Carton Size	57*38*43CM	63*38*43CM	55.5*41*45.5CM
G.W.	12.0KGS	16.0KGS	14.0KGS

SARS-CoV-2 Antigen Rapid Test for Self-testing

CERTIFICATE

EC Certificate No. 1434-IVDD-231/2022
EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

**Nantong Egens Biotechnology Co., Ltd.
Building 15, Building 12 (west), No. 1692 Xinghu Avenue, Nantong Economy &Technology Development Zone, 226010 Nantong, PEOPLE'S REPUBLIC OF CHINA.**

in vitro diagnostic medical devices
for self-testing

SARS-CoV-2 Antigen Rapid Test Kit
The list of medical devices covered by this certificate is provided in the annex 1

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 25.05.2022 to 27.05.2025

The date of issue of the Certificate: 25.05.2022

The date of the first issue of the Certificate: 25.05.2022

CE 1434

Issued under the Contract No. MD-171/2021
Application No: 332/2021
Certificate bears the qualified signature.
Warsaw, 25/05/2022
Module A1

Director
Medical Device Certification
Department

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

ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE
No. 1434-IVDD-231/2022

List of medical devices covered by the certificate:
1 Test/ Box – REF. D0101TE
5 Tests/ Box – REF. D0501EE
25 Tests/ Box – REF. D2501AT

CE 1434

Issued under the Contract No. MD-171/2021
Application No: 332/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2022

Director
Medical Device
Certification Department

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 063367 0018 Rev. 01

Holder of Certificate: **Nantong Egens Biotechnology Co., Ltd.**
Building 15, Building 12 (west)
No. 1692 Xinghu Avenue
Nantong Economy & Technology Development Zone
226010 Nantong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Rapid Test Kit for the Detection of Fertility Function Hormones, Pregnancy, Tumor Markers, Drug of Abuse, Infectious Disease, Sperm Concentration and Clinical Chemistry, Blood Glucose Monitoring System**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: TAM/SH1924115

Valid from: 2019-09-01
Valid until: 2022-08-31

Date, 2019-08-31

Stefan Preiß
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Page 1 of 2
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany NTYS-Y-1

Consultas

ANVISA - AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA

Consultas / Produtos para Saúde / Produtos para Saúde

Detalhes do Produto

Nome da Empresa	Domo Salute Consultoria Regulatória Ltda		
CNPJ	26.263.959/0001-03	**Autorização**	8.14.647-5
Produto	Kit Teste Rápido de Antígeno SARS-CoV-2		

Apresentação/Modelo
EGCOVAG-25 - 25x Cassete de teste; 25x500microlitro Diluente; 25x Tubo de extração; 25x Swab estéril

Tipo de Arquivo	**Arquivos**	**Expediente, data e hora de inclusão**
INSTRUÇÕES DE USO OU MANUAL DO USUÁRIO DO PRODUTO	IFU_Kit Teste Rápido de Antígeno SARS-CoV-2.pdf	3753365/21-1 - 23/09/2021 - 06:17

Nome Técnico	CORONAVÍRUS
Registro	81464750072
Processo	25351.366078/2020-97
Fabricante Legal	• FABRICANTE: NANTONG EGENS BIOTECHNOLOGY CO., LTD. - CHINA, REPÚBLICA POPULAR
Classificação de Risco	III - Classe III: produtos de alto risco ao indivíduo e ou médio risco à saúde pública
Vencimento do Registro	12/11/2030