Genrui

CE 1434

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

Self Testing

Soft Pack

Genrui Biotech Inc.

CERTIFICATE

EC Certificate No. 1434-IVDD-487/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Genrui Biotech Inc.
4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China

in vitro diagnostic medical devices
for self-testing

SARS-CoV-2 Antigen Test Kit (Colloidal Gold)
52104097, 52112086, 52026094, 52104115

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 13.11.2021 to 27.05.2024

The date of issue of the Certificate: 12.11.2021

The date of the first issue of the Certificate: 02.08.2021

CE 1434

Issued under the Contract No. MD-75/2021
Application No: 147a/2021
Certificate bears the qualified signature.
Warsaw, 12.11.2021
Module A1

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.11.12 13:42:38 +01'00'

Vice-President

Genrui

Declaration of Conformity

Manufacturer:

Genrui Biotech Inc.

4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China.

Tel: +86 755 26835560 Fax: +86 755 26678789

European Representative:

Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Product Name:

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

Specification: 1 T/kit, 5 T/kit, 25 T/kit

REF: 52104097, 52112086, 52026094, 52104115

Classification:

Self-testing

Conformity Assessment Route:

IVDD 98/79/EC Annex III (Section 6)

We here with declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices.

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.

Compliance of the designated product with the Directive 98/79/EC has been assessed and certified by the Notified Body

POLISH CENTRE FOR TESTING AND CERTIFICATION

469 Puławska Street, 02-844 Warsaw, Poland

Certificate No: 1434-IVDD-448/2021

Validity of the Certificate: from 13.11.2021 to 27.05.2024

Standards Applied:

EN ISO 13485:2016	EN ISO 23640:2015	EN ISO 14971:2012	EN ISO 18113-1:2011
EN ISO 15223-1:2016	EN 13612:2002	EN 62366-1:2015	EN ISO 18113-4:2011
EN ISO 17511:2003	EN 13641:2002	EN 13532:2002	

CE 1434

Place, Date of Issue: Shenzhen, Nov.15th, 2021

Position Held in Company Management Representative

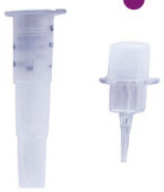
Signature: LiYiping

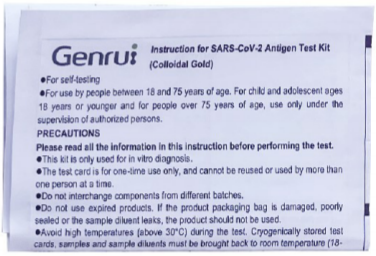
Sample Diluent

Biohazard Sample Bag

Test Kit

Dripper





Swab

Test Card

IFU

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

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

TÜV SÜD
Product Service

Certificate

No. Q5 112784 0001 Rev. 00

Holder of Certificate: **Genrui Biotech Inc.**
4-10F, Building 3, Geya Technology Park
Guangming District
518106 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Instruments, including Biochemistry Analyzers, Electrolyte Analyzers, Hematology Analyzers, Coagulation Analyzers, Specific Protein Analyzers, Quantitative Immunoassay Analyzers, Chemiluminescence Immunoassay Analyzers, Fully-Auto Nucleic Acid Extraction Instruments, and In Vitro Diagnostic Test Kits, including Reagents, Calibrators and Controls Used for Determination of Immune Status, Detection of Respiratory Infectious Disease, Determination or Monitoring of Physiological Markers, Confirmation of Specific Disorders/Impairments, Confirmation of Non-infectious Pathologies, Non-infectious Disease Staging, Detection of Pregnancy or Fertility.**

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 112784 0001 Rev. 00

Report No.: GZ2145901

Valid from: 2021-10-29
Valid until: 2024-10-28

Date, 2021-10-29

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany
TÜV®

Genrui

– Self Test

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

The most suitable RDT to combat COVID-19

Nasal swab sample for self test is now available!

Application

- Self test at home
- Multiple specifications for different needs
- Auxiliary to PCR, serological test, CT, etc.
- Used at hospitals, schools, borders, stations, etc.

Genrui Biotech Inc.

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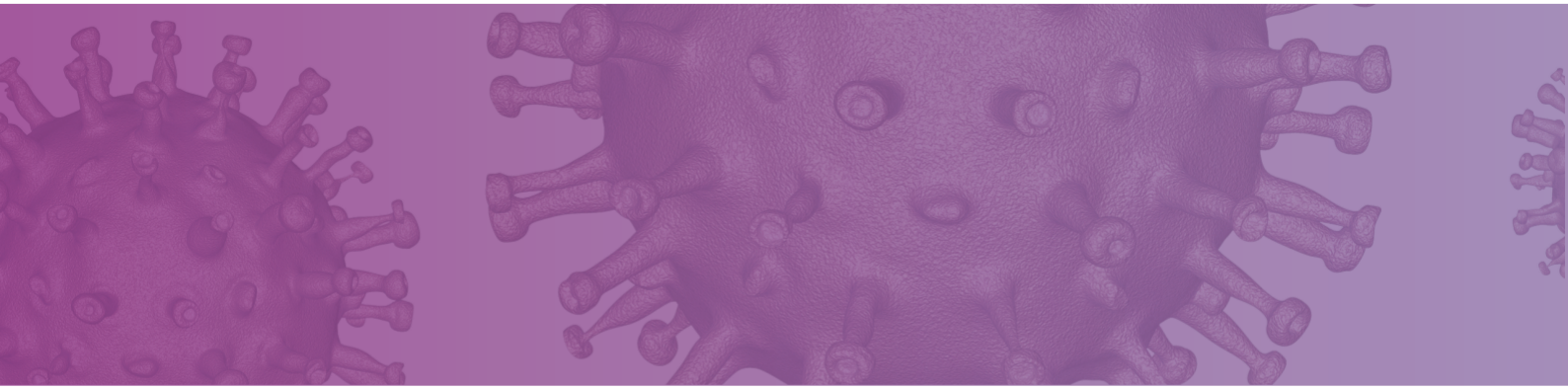
CE 1434



Advantages

- **Accessible** - Can be used in a wide variety of non-laboratory settings
- **User-friendly** - Easy-to-operate, less invasive and less discomfort
- **Economical** - No additional instruments required
- **High performance** - Fast identification of potentially contagious individuals

Characteristics

Method	Colloidal Gold
Test Time	15-20 min
Shelf Life	18 months
Sample Type	Nasal swab
Specification	Soft Pack for 1T
Storage	Room temperature (2-30℃)

Genrui

Instruction for SARS-CoV-2 Antigen Test Kit (Colloidal Gold)

REF: 52104115

- For self-testing
- For use by people between 18 and 75 years of age. For child and adolescent ages 18 years or younger and for people over 75 years of age, use only under the supervision of authorized persons.

PRECAUTIONS

Please read all the information in this instruction before performing the test.

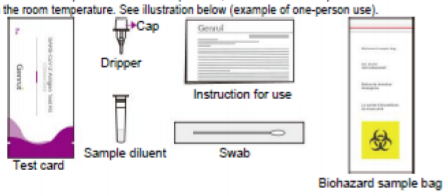
- This kit is only used for in vitro diagnosis.
- The test card is for one-time use only, and cannot be reused or used by more than one person at a time.
- Do not interchange components from different batches.
- Do not use expired products. If the product packaging bag is damaged, poorly sealed or the sample diluent leaks, the product should not be used.
- Avoid high temperatures (above 30°C) during the test. Cryogenically stored test cards, samples and sample diluents must be brought back to room temperature (18-28°C) prior to opening. Please do not perform the test in the following situations or scenarios: outdoors under the sunlight, temperatures above 30°C, in a moving vehicle or in places where stability cannot be guaranteed.
- Do not touch the reaction area of the test paper and keep the swab clean.
- For substances that contain or are suspected to contain sources of infection, appropriate biosafety assurance procedures should be followed. If the liquid splashes in your eyes or on your skin, rinse with plenty of water. If you feel unwell, go to a specialist for a checkup.

SAMPLE REQUIREMENTS

- Nasal swab can be used for testing.

PREPARATION BEFORE TEST

Take out all kit components at room temperature, make sure the sample diluent and test card reach the room temperature. See illustration below (example of one-person use).



SPECIMEN COLLECTION

Preparation

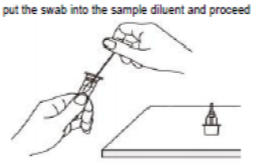
Use the dripper tip to pierce the sealed foil of the tube containing sample diluent, pull out the dripper tip and place the sample diluent on the table for later use. (Note: pierce the sealed foil all the way through, but there should be a gap between the dripper and the tube.)

Nasal swab collection

1. Tear the swab packaging bag, keep the swab tip clean and make sure it does not touch any surface before use.

2. Insert the entire swab tip (usually 2 cm) into left nostril.
3. Firmly brush against insides of nostril in a circular motion 5 times or more for at least 15 seconds.

4. Remove swab and insert it into right nostril, firmly brush against insides of nostril in a circular motion 5 times or more for at least 15 seconds.
5. Remove the dripper, put the swab into the sample diluent and proceed to sample processing.

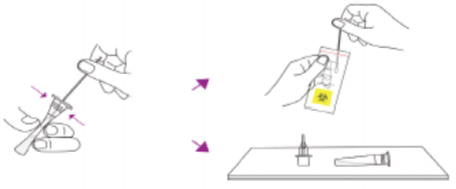


Note: It is recommended that specimens are tested at the time of collection. If the specimens are not tested immediately, please follow the sample cleanup procedure.

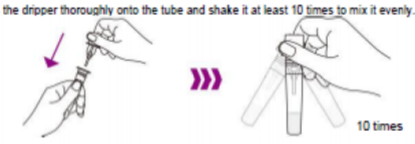
SAMPLE PROCESSING

1. Pinch the tube wall with fingers as shown below, meanwhile rotate the swab against the tube wall 5-6 times to allow the swab to soak well. After the sample is completely dissolved, let it stand for 1 minute.

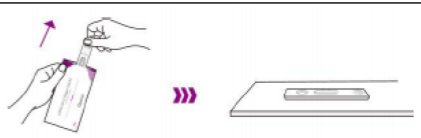
2. Pinch the tube wall to squeeze the swab gently to keep as much liquid in the tube as possible. Remove the swab and put it into a biohazard sample bag.



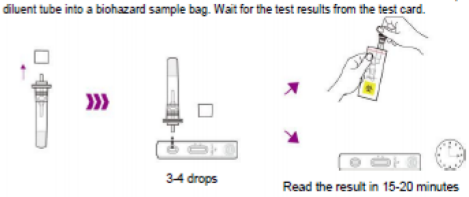
3. Press the dripper thoroughly onto the tube and shake it at least 10 times to mix it evenly.



4. Take out the test card from the package and lay it flat on a dry surface.



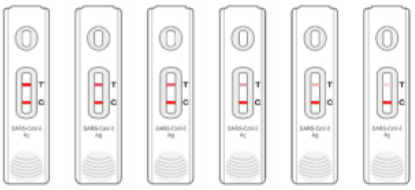
5. Remove the dripper cap at the top, drop 3 to 4 drops (about 0.1 mL) of evenly mixed solution vertically into the sample hole of the test card, close the dripper cap and put the used sample diluent tube into a biohazard sample bag. Wait for the test results from the test card.



Note: Read and interpret the test result at 15 minutes, the test result should not be read and interpreted after 20 minutes.

TEST INTERPRETATION AND ACTIONS

Positive Result: The appearance of both control line (C) and the test line (T) indicates that the SARS-CoV-2 antigen is positive. **Look very closely! The T line can be very faint. Any pink/purple line visible here indicates a Positive Result.**
Below are examples of the colors of T line.



POSITIVE

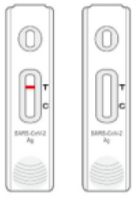
A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 were detected, and you are very likely to be infected with the virus and presumed to be contagious. Please follow your local self-isolation guidelines and contact your doctor/family doctor or local health authority immediately and have a COVID-19 nucleic acid PCR confirmatory test to confirm the infection.

Negative Result: The appearance of only the control line (C) and no test line (T) indicates a negative result.

NEGATIVE

A negative result does not rule out COVID-19 and should not be used as the sole basis for infection control decisions. Please continue to comply with all applicable rules and protective measures when in contact with others. There may be an infection, even if the test result is negative. If you suspect an infection (symptoms like headache, migraine, fever, loss of taste, etc.), then please repeat the test within 1-2 days, as the amount of virus at all stages of the infection may be too low to be reliably detected. Mutations in viral genes may lead to changes in antigenic determinants and result in negative results. Whilst variations in viral genes may lead to changes in antibody determinants and the new virus variants might cause false negative results.

Invalid Result: The control line (C) does not appear, it will be considered as invalid regardless of whether there is T line. The test should be repeated.



INVALID

The control line may be faulty due to insufficient sample volume or improper operation. Please review the procedure and repeat the test with a new test kit. If the problem persists, please stop using the current batch immediately, contact with the vender and/or contact your doctor or COVID-19 test center for professional opinions.

SAMPLE CLEANUP

1. Put the test card into the biohazard sample bag. Make sure that test card, sample diluent and swab are in the biohazard sample bag, then have it sealed.
2. Dispose of the sealed biohazard sample bag in accordance with local government regulations and then use the hand sanitizer.

INTENDED USE & BENEFITS

Genrui SARS-CoV-2 antigen test kit (colloidal gold) is an immunochromatographic assay for rapid and qualitative test of N protein of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) antigen detection in nasal swabs.

This test is applicable to all individuals suspected of being infected by SARS-CoV-2. The test will be used to assist in the diagnosis of the coronavirus infectious disease (COVID-19) caused by SARS-CoV-2.

The test kit is simple, safe, effective and intended for self-testing, which is suitable for individuals to use in non-laboratory settings like homes, offices, schools, sports stadiums, airports, etc.

TEST PRINCIPLE

During the test, the processed samples to be tested are added to the sample holes. When the sample contains SARS-CoV-2 antigen, it first combines with the colloidal gold-labelled anti-SARS-CoV-2 antibody. Chromatography is then performed. When it binds to the anti-SARS-CoV-2 monoclonal antibody previously immobilized on another membrane, a purple-red band will appear in the test area (T). If there is no SARS-CoV-2 antigen in the sample, there will be no purple-red band in the test area (T). A purple-red band will appear in the quality control area (C) regardless of the presence of new coronavirus antigen in the sample, which is used as a criterion to determine whether there is sufficient sample or the chromatography is processed properly. It is also used as an internal control standard for the test kit.

MAIN COMPONENTS

- 1 test card, 1sample diluent (0.5 mL), 1 dripper, 1 swab, 1 biohazard sample bag and 1 Instruction for Use (IFU).
- The main components of the test card are foil pouch, desiccant, glass fiber membrane (colloidal gold labeled anti-novel coronavirus monoclonal antibody), nitrocellulose membrane (detection area coated with anti-novel coronavirus monoclonal antibody, quality control area coated with Goat anti Mouse IgG) and PVC plate.
- Sample diluent: the main component is phosphate buffer (PBS)
- Accessories required but not provided
  Timer.

STORAGE CONDITIONS

- The test kit can be stored at 2-30°C and the expiration date is 18 months. Once the foil pouch is opened, the validity period is 1 hour at a temperature of 18-28°C and humidity less than 65%.
- The sample diluent is valid for 1 month from the date of opening. The production date is shown on the outer box.

USE CONDITIONS

- Please make sure that the ambient temperature is 18-28°C when using.
- When the humidity level is below 65%, please use the product within one hour after opening the bag. And when the humidity is higher than 65%, please make sure to use the product immediately after opening it.

TRANSPORT CONDITIONS

Transport at 2-30 °C.

QUALITY CONTROL

Each test card has a built-in control. The purple-red band at the control line can be considered as an internal positive program control. If the procedure was performed correctly, the control line will appear. If no control line appears, then the test is invalid and a new test should be performed.

LIMITATIONS

- Test results cannot be used as a basis for diagnosis. Comprehensive judgments should be made based on clinical symptoms, epidemiological conditions and further clinical data.
- The accuracy of the test depends on the sample collection process. Improper sample collection will affect the test results.
- A positive test result does not rule out concurrent infection with other pathogens. The negative result may be caused by:

a) Improper sample collection, improper sample transfer or handling so that the amount of virus in the sample is too low.
b) The level of SARS-CoV-2 antigen is lower than the limit of detection.
c) Variations in viral genes may lead to changes in antibody determinants.

- There may be other unlisted reasons that cause the detection to be abnormal.
- This product can only qualitatively detect the SARS-CoV-2 antigen in the sample, but cannot determine the concentration of the antigen in the sample.

PERFORMANCE CHARACTERISTICS

Clinical performance

207 nasal swab samples, which include 107 confirmed as COVID-19 positive and 100 confirmed as COVID-19 negative by RT-PCR assay, were obtained for testing, and then compared the test results of Genrui SARS-CoV-2 Antigen Test Kit (Colloidal Gold) with that of RT-PCR. The results are shown below:

Positive Percent Agreement:

Ct value	Number of Sample	Number of true positive Rapid Test Samples	Number of false negative Rapid Test Samples	Sensitivity of SARS-CoV-2 Antigen Rapid Test (CI)
≤30	80	80	0	100%(96-100)
≤32	91	91	0	100%(96-100)
≤34	101	100	1	99%(94-99)
≤36	107	105	2	98.13%(93-99)

Negative Percent Agreement:

Number of Sample	Number of true negative Rapid Test Samples	Number of false positive Rapid Test Samples	Specificity of SARS-CoV-2 Antigen Rapid Test (CI)
100	100	0	100%(96-100)

MANUFACTURER

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IVD CE 1434 EC REP
Lotus NL B.V.
Koningin Julianaplein 10,1e Verd 2595AA, The Hague, Netherlands
Email: peter@lotusnl.com

INDEX OF SYMBOLS

	Do not re-use	IVD	*In vitro* diagnostic medical device
	Temperature limit		Consult instructions for use
LOT	Batch code	Σ	Contains sufficient for <n>tests
	Use-by date		Keep away from sunlight
	Keep dry		Do not use if packaging is damaged
	Manufacturer	EC REP	Authorized representative in the European community
	Production date		

DATE OF COMPILATION/APPROVAL

A/0 14/09/2021

OPERATION VIDEO