Virusee®

SARS-CoV-2 Antigen Rapid Test

Offers the Best Protection for Your Staff and Your Enterprise

Can accurately detect Omicron and Delta viruses

- Reasonably Priced
- High Accuracy and Sensitivity
- Included in the HSC Common List
- CE Certified
- Nasal/Saliva Sample Collection

Germany's Most Authoritative
Testing Lab Paul Ehrlich Institute
Latest Test Result

Cq≤25 Sensitivity 100%
Cq 25-30 Sensitivity 95%

Overall Sensitivity 86%,
Scored Top Spots in Overall Sensitivity
High Level Sensitivity in High Cq Level
Which Avoids Mistakes and Delay
Endorsed by German Enterprises

Hong Kong Distribution Agent:
Prunus Jade Creation Limited (Established in 2016)
www.jademedicals.com
Telephone: 5508-1331

Virusee®

Product Code: **CoVSLFA-01**

SARS-CoV-2 Antigen Rapid Test
(Colloidal Gold)
Summary Data

Genobio Pharmaceutical Co., Ltd.

目录

(Contents)

喜诺
Genobio

Virusee®

SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) (Saliva/Swab)

Product code : CoVSLFA-01 1 test/kit
CoVSLFA-20 20 tests/kit

Obtain result in 15 min

Overview

SARS-CoV-2, also known as Novel Coronavirus, causes acute pneumonia and is easily transmitted person to person and person to objects. After emerging, patients infected by SARS-CoV-2 have been successively discovered all over the world in a short time, and is still spreading rapidly. Nowadays, the diagnosis method widely used in clinical is real-time PCR. However, nucleic acid detection often gives false negative results due to sampling methods, virus titers, etc.
An accurate and rapid detection is crucial in weathering the SARS-CoV-2.

Epidemiology

Source of infection: The novel coronavirus infected patients, asymptomatic patients can also be a source of infection
Transmission: Respiratory droplets and close contact transmission (Mainly), Aerosol transmission
Susceptible population: Generally susceptible

Product Characteristics

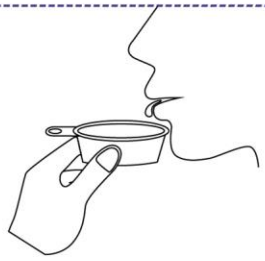
Name	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)
Method	Colloidal Gold
Specification	20 tests/kit, 1 test/kit
Sample type	Saliva, Nasopharyngeal Swab, Oropharyngeal Swab
Detection time	15 min
Stability	Stable for 18 months at 2-30 ℃
Sensitivity	96.23%
Specificity	99.26%

Product Advantages

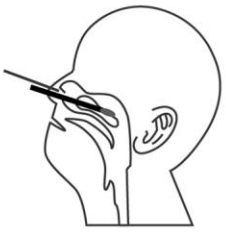
- **Flexible:** The sample type is optional between saliva and swab, convenient and meets different needing
- **Rapid:** Obtain result within 15 min
- **Simple:** Easy to use, without complicated operation
- **Intuitive result:** There is no need for calculation and instrument, visual reading result
- **Economic:** Product can be transported and stored at room temperature, reducing costs
- **Low risk:** Testing saliva or swab samples, reducing the risk of sampling process

Operation Procedure

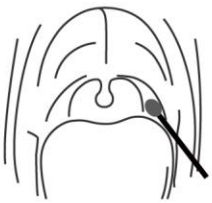
1. Sample Collection



Saliva Sample



Nasopharyngeal Swab



Oropharyngeal Swab

Swab Sample

- **Saliva sample:** Spit at least 1 mL CLEAR saliva into the sample collection bag. The bag must not touch the mouth.
- **Swab sample:** Use sterilized swab to obtain a nasopharyngeal swab sample or oropharyngeal swab sample.

2. Sample Preparation

- **Saliva sample:**

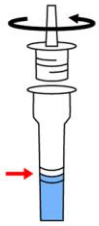
a.

Take the saliva sample with a dropper, avoid generating foam in it.

b.

Add 8-10 drops (about 300μL) of saliva into the extraction tube to the second mark.

c.



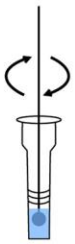
Tighten the cap firmly onto the extraction tube.

d.

Mix well by swirling the extraction tube at least 20 times.

- **Swab sample:**

a.



Insert the swab into the extraction tube, roll the swab at least 6 times while pressing the head against the bottom and side of the tube.

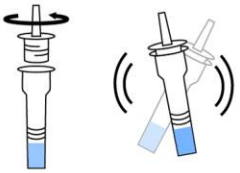
b.

Let the tube with the swab stand for 1 min.

c.

Squeeze the sample tube on the outside to make reagent immerse the swab.

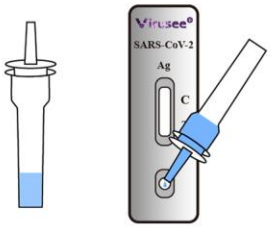
d.



Remove the swab and tighten the cap firmly onto the extraction tube. Mix well.

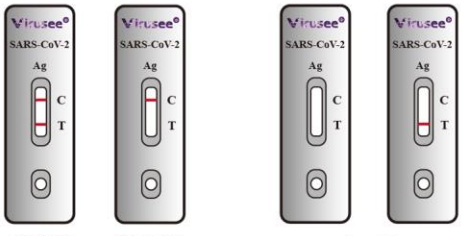
3. Test Procedure

1



2

15 min



Positive Negative Invalid

Add 5 drops to the specimen well (s).

Read the result at 15 min.

Innovation for Better Health

Tel: +86(22)60978609 ext. 8605/8606/8608/8609

Fax: +86(22)60978609-804

E-mail: marketing@era-bio.com / customer@era-bio.com

Web: www.era-bio.com

喜瑞 Genobio Genobio Pharmaceutical Co., Ltd.

Add: 2-1,2,3-101, No.2 Zone, Binlv Industrial Park, Binhai Tourism Area, Binhai New Area, Tianjin 300480, P. R. China

Tianjin Era Biology Technology Co., Ltd.

Add: 1601, Building C2, TEDA MSD-C, No. 79, 1st Avenue, Tianjin Economic-Technological Development Area, Tianjin 300457, P. R. China

Genobio is wholly-owned subsidiary of Era Biology Group

Company Profile

Era Biology Group, started business operation in 1997, is one of the leaders and pioneers of invasive fungal disease diagnosis around the world. Now we have eight subsidaries: Beijing Gold Mountainriver Tech Development Co., Ltd., Genobio Pharmaceutical Co., Ltd., Era Biology (Shanghai) Co., Ltd., Era Biology (Guangzhou) Co., Ltd., Era Biology (Suzhou) Co., Ltd., Beihai Sinlon Biotech Co., Ltd., Era Biology Group, LLC., and Era Biology (Canada) Co., Ltd.. Era Biology has passed the authentications of CMD ISO 9001, ISO 13485, Korea GMP and North America MDSAP, and has most products certificated by CE, NMPA and FSC.

In China, Era Biology, joint National Center for Clinical Laboratories etc, successfully drafted the industrial standard of "Fungus (1-3)-β-D-Glucan Test" in 2017. There are totally 2433 tertiary-level hospitals across the country, over 80% of which are users of our products. Globally, our products are exported to more than 60 countries and regions around the world. Our products are rapid, easy to use, quantitative, and accurate, which are of great value in early diagnostics for invasive fungal infection.

As a professional supplier in invasive fungal disease detection, we are not only providing quality products, but also focusing on customized services, which allow us to meet your specific needs such as training, experimental technical guidance, troubleshooting and so on.

Genobio is a wholly-owned subsidiary of Era Biology Group

EC Declaration of Conformity

Manufacturer:

Name: Genobio Pharmaceutical Co., Ltd.

Address: 2-1, 2, 3-101, No.2 Zone, Binlv Industrial Park, Binhai Tourism Area, Binhai New Area, Tianjin 300480, P. R. China

Tel+86 (022) 60978665

Email: marketing@era-bio.com

Whose Authorized Representative:

Name: Lotus NL B.V.

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

E-mail: peter@lotusnl.com

We, the manufacturer, here with declare that the product(s)

Product Name	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) (Saliva/Swab)	**Model/Specification**	VSLFA-01/1 test/kit VSLFA-20/20 tests/kit
Intended Use	The SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) (Saliva/Swab) is a colloidal gold method intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens in saliva, nasopharyngeal swab and oropharyngeal swab from individuals who are suspected of SARS-CoV-2 infection by their healthcare provider. The SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) (Saliva/Swab) is intended for use by trained clinical laboratory personnel specifically instructed and trained in vitro diagnostic procedures.		
Classification	Others		

Conformity Assessment Route: IVDD98/79/EC Annex III.

Applicable Standards:

ISO 13485:2016
ISO 14971:2019
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 18113-3:2011
EN 13641:2002
ISO 15223-1:2016
EN 13612:2002
ISO 23640:2015
EN 62366-1:2015

CE

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We agree to develop,implement and maintain a documented post-production monitoring process.

Name of General Manager	Danrong Zang
Signature	Danrong Zang
Date	April 30, 2021
Place	Tianjin, China
Seal (Manufacturer)	

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen via:
medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20212403

Bijlagen
-

Uw aanvraag
30 april 2021

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 10 mei 2021
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 30 april 2021 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Genobio Pharmaceutical Co., Ltd. met Europees gemachtigde Lotus NL B.V. onderstaand product als in-vitro diagnosticum op de Europese markt te brengen.

Het product staat geregistreerd als in-vitro diagnosticum onder nummer:

SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) (Saliva/Swab) (geen merknaam) (NL-CA002-2021-58665)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermeld product verzoek ik u dit nummer te vermelden. Aan dit nummer kunnen geen verdere rechten ontleend worden, het dient alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

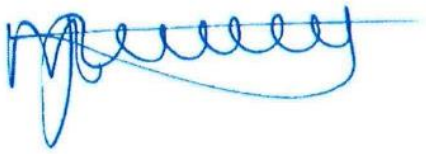
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Genobio Pharmaceutical Co., Ltd. de CE-conformiteitsmarkering heeft aangebracht op het desbetreffende product alvorens het in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat het in-vitro diagnosticum voldoet aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

Virusee® SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)
Instruction for Use

only for in vitro diagnostic and professional use

Please read this IFU carefully before use!

[Name]

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

[Model/Specifications]

VSLFA-01/1 test/kit, VSLFA-20/20 tests/kit

[Intended Use]

The SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) is a colloidal gold method intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens in saliva, nasopharyngeal swab and oropharyngeal swab from individuals who are suspected of SARS-CoV-2 infection by their healthcare provider.

Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results do not rule out of SARS-CoV-2 infection and should not be used as the sole basis for treatment patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

The SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) is intended for use by trained clinical laboratory personnel specifically instructed and trained in vitro diagnostic procedures.

For in vitro diagnostic use only. For professional use only.

[Summary]

The novel coronaviruses (SARS-CoV-2) belong to the β-genus. COVID-19 is an acute respiratory infections disease. People are generally susceptible. Currently, the patients infected by the novel coronaviruses are the main source of infection, asymptomatic infected people can also be one. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

[Principle]

SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) adopts a colloidal gold method based on the principle of the double antibody-sandwich technique. It is designed to detect nucleocapsid protein antigen from the SARS-CoV-2 in saliva, nasopharyngeal swab and oropharyngeal swab, from patients who are suspected of SARS-CoV-2 infection.

During testing, the specimen migrates upward under capillary action. The SARS-CoV-2 antigens, if present in the specimen, will bind to the anti- SARS-CoV-2 nucleocapsid protein monoclonal antibody-colloidal gold complex formed immune complex，the immune complex is then captured on the membrane by the pre-coated SARS-CoV-2 nucleocapsid protein monoclonal antibody coated on the T-line., and a visible colored line will show up in the test line region indicating a positive result. In the absence of SARS-CoV-2 antigens, no colored line will form in the test line region, which indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

[Components]

Model/Specifications	Main components	VSLFA-01 1 test/kit	VSLFA-20 20 tests/kit
SARS-CoV-2 Antigen Detection Cassette	Coating the anti- SARS-CoV-2 nucleocapsid protein monoclonal antibody -colloidal gold complex and chicken IgY antibody-colloidal gold complex on the colloidal gold pad. The test line (T) is coated with anti-SARS-CoV-2 nucleocapsid protein monoclonal antibody, and the control line (C) is coated with goat anti-chicken IgY antibody.	1	20
Sterilized Swab	-	1	20
Saliva Collection Device	-	1	20
Extraction Tube with Extraction Reagent	Phosphate buffer solution	300μL×1	300μL×20
Dropper Tip	-	1	20
Package Insert	-	1	1

Note: Components in different batch kits are not interchangeable.

Materials Required but Not Provided: Timer

[Storage Conditions and Validity]

Store at 2-30℃ in a dry and cool place, valid for 18 months.

The SARS-CoV-2 Antigen Detection Cassette should be used within 1h after taken out from aluminum foil bag.

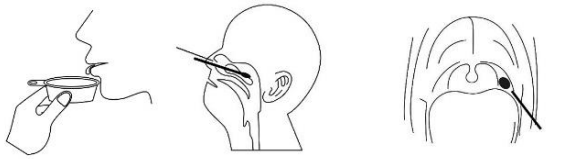
[Warnings and Precautions]

- For in vitro diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use this product as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status of COVID-19.
- Do not use after the expiration date.
- Please read all the information in this leaflet before performing the test.
- The test cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cassette should be discarded according to federal, state and local regulations.

[Specimen requirements]

Specimens obtained early during symptom onset will contain the highest viral titers; specimens obtained after five days of symptoms are more likely to produce negative results when compared to an RT-PCR assay. Inadequate specimen collection, improper specimen handling and/or transport may yield a falsely negative result. Therefore, training in specimen collection is highly recommended due to the importance of specimen quality for generating accurate test results.

Sample Collection



Saliva Sample　Nasopharyngeal Swab Sample　Oropharyngeal Swab Sample

Saliva Sample

Spit 1- 1.5 mL of CLEAR saliva into the saliva collection device. The device must not touch the mouth, and foam does not count to the saliva sample. Do not eat, drink (even water), smoke, vape, chew gum, or tobacco or take medication for at least 30 minutes before your sample collection.

Nasopharyngeal Swab Sample

Insert the swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the tip is saturated with fluid from the first collection. If a deviated nasal septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

Oropharyngeal Swab Sample

Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.

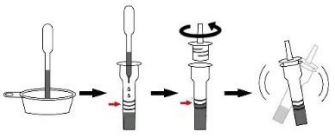
Sample Transport and Storage

Freshly collected specimens should be put into the Extraction Tube with Extraction Reagent as soon as possible, and testing should be performed within one hour.

[Specimen Preparation]

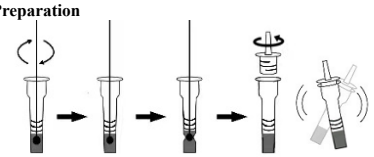
Insert the Extraction Tube into the pre-set hole on the package for fixed placement.

Saliva Sample Preparation



1. Take the saliva sample with a dropper, avoid generating foam in it.
2. Add 8-10 drops (about 300μL) of saliva into the extraction tube to the second mark.
3. Tighten the cap firmly onto the extraction tube.
4. Mix well by swirling the extraction tube at least 20 times.

Swab Sample Preparation



1. Insert the swab sample into the extraction tube which contains extraction reagent.

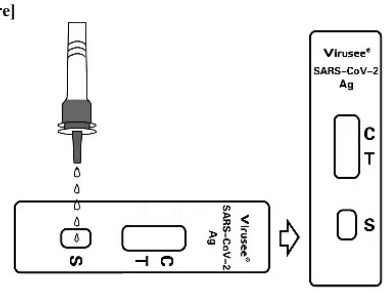
Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.

2. Leave the swab in the extraction tube stand for one minute.

3. Squeeze the sides of the tube to make the liquid immerse the swab. Remove the swab, the extracted solution will be used as test specimen.

4. Tighten the cap firmly onto the extraction tube. Mix well by swirling the tube at least 6 times.

[Test Procedure]



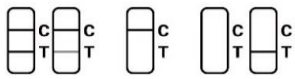
Balance the test device and specimens to room temperature (15-30℃ or 59-86°F) prior to testing.

1. Remove the test cassette from the aluminum foil bag.

2. Reverse the specimen extraction tube, holding the specimen extraction tube up right, transfer 5 drops to the specimen well(S) of the test cassette, then start the timer. See illustration below.

3. Wait for colored lines to appear. Interpret the test results at 15 minutes. Do not read results after 20 minutes.

[Interpretation of results]



Positive Negative Invalid

Positive: Two lines appear. One colored line should be in the control region (C), and another apparent colored line adjacent should be in the test line (T). Positive for presence of SARS-CoV-2 nucleocapsid protein antigen with patient history and other diagnostic information is necessary to determine infection status Positive results do not rule bacterial infection or co -infection with other viruses. The agent detected may not be the definite cause of disease.

Negative: One colored line appears in the control region (C). No line appears in the test line (T). Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including symptoms consistent with COVID-19, or in those who have been in contact with virus. It is recommended that these results be confirmed by a molecular testing method, if necessary, for patient management.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test cassette. If the problem persists, discontinue using the lot immediately and contact your local distributor.

[Quality Control]

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standard are not supplied with the kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

[Limitations of Detection Method]

The SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) is limited to provide a qualitative detection. The intensity of the test line does not necessarily correlate to the concentration of antigen of specimens.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis of patient management decisions.

A physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.

A negative result can occur if the quantity of antigens for the SARS-CoV-2 virus present in the specimen is below the detection threshold of assay, or the virus has undergone minor amino acid mutation(s) in the target epitope region recognized by the monoclonal antibodies utilized in the test.

Proper specimen collection is critical, and failure to follow the procedure may give inaccurate results, improper specimen storage or repeated freezing and thawing of specimens can lead to inaccurate results.

[Performance Characteristics]

Limit of Detection (Analytical sensitivity)

The Limit of Detection (LoD) of the SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) is $5\times10^{2.50}TCID_{50}$/mL (cultured SARS-CoV-2 virus).

Cross Reactivity (Analytical specificity)

Cross reactivity with following Virus or Bacteria culture with certain concentration has been studied. The results were found negative when tested with the SARS-CoV-2 Antigen Rapid Test (Colloidal Gold):

Virus/Bacteria	Concentration	Results
Influenza A (H1N1)	1×10^6 PFU/mL	-
Influenza A (H3N2)	1×10^6 PFU/mL	-
Influenza B (Yamagata)	1×10^6 PFU/mL	-
Influenza B (Victoria)	1×10^6 PFU/mL	-
Adenovirus	1×10^6 PFU/mL	-
Human metapneumovirus	1×10^6 PFU/mL	-
Parainfluenza virus	1×10^6 PFU/mL	-
Respiratory syncytial virus	1×10^6 PFU/mL	-
Streptococcus pyogenes	1×10^6 CFU/mL	-
Candida albicans	1×10^6 CFU/mL	-
Mycoplasma pneumoniae	1×10^6 CFU/mL	-
Chlamydia pneumoniae	1×10^6 CFU/mL	-
Legionella pneumophila	1×10^6 CFU/mL	-
Human coronavirus 229E	1×10^6 PFU/mL	-
Human coronavirus OC43	1×10^6 PFU/mL	-
Human coronavirus NL63	1×10^6 PFU/mL	-
Human coronavirus HKU1	1×10^6 PFU/mL	-

Clinical Performance

To estimate the clinical performance between the SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) and the PCR comparator, 1020 samples were collected from patients who were suspected of COVID-19.

Summary data as bellow:

		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	204	6	210
	Negative	8	802	810
Total		212	808	1020

Positive coincidence rate =96.23% (204/212); (95%CI: 92.43-98.23%)

Negative coincidence rate =99.26% (802/808); (95%CI: 98.31-99.70%)

[Symbols Instructions]

CE	CE MARK		KEEP DRY
	CAUTION		BIOLOGICAL RISKS
	CONSULT INSTRUCTIONS FOR USE	LOT	BATCH CODE
	DO NOT REUSE	IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE
	TEMPERATURE LIMITATION		DATE OF MANUFACTURE
	MANUFACTURER	Σ	SUFFICIENT FOR
	KEEP AWAY FROM SUNLIGHT		USE BY
EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		

[Preparation and Revision Date]

2021.12.02

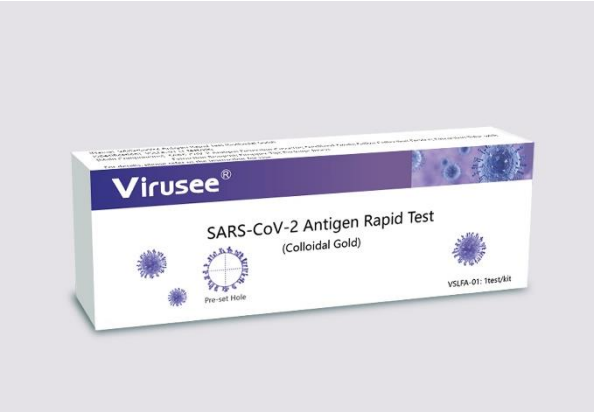
[Basic information]

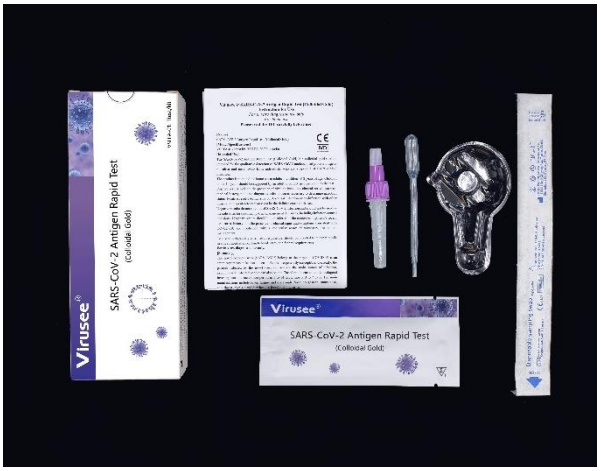
Genobio Pharmaceutical Co., Ltd.
Address: 2-1, 2, 3-101, No.2 Zone, Binlv Industrial Park, Binhai Tourism Area, Binhai New Area, Tianjin 300480, P. R. China
Telephone: +86 (022) 60978665
Fax: +86(022) 60978661-802
Email: marketing@era-bio.com

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

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

Product Photos





Packing Information

产品名称（Product Name）	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)
规格（Specifications）	1 test/kit
包装尺寸 Package Size）	160*60*20 mm
单位（Unit）	盒 kit

Label Information

外包装标签：见包装盒

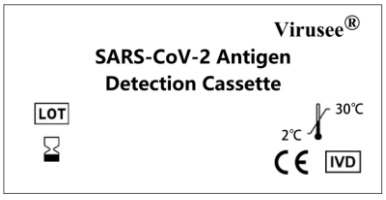
Label of outer box: See the package design

检测卡标签

Label of test cassette

尺寸：50*25 毫米

Size: 50*25 mm



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

Clinical Trial Summary Report

Clinical trial sponsor	Genobio Pharmaceutical Co., Ltd.
Clinical trial name	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)
Purpose	In order to evaluate the application value of our product- Virusee® SARS-CoV-2 Antigen Rapid Test (Colloidal Gold), carrying out clinical trial in hospital and investigate the sensitivity and specificity of the kit.
Specimen collection	1. According to the clinical collection guidelines for laboratory test samples to collect samples. 2. Avoid contamination during the collection, transportation, and storage.
Experimental reagent information	Experimental reagent Company: Genobio Pharmaceutical Co., Ltd. Product Name: SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) Specification: VSLFA-01, VSLFA-20 Method: Lateral Flow Assay Validity: 1 year
Clinical procedure	Detect the sample with VSLFA-01/VSLFA-20, the detection results are compared with the clinical RT-PCR results. **Saliva Sample Preparation** 1. Take the saliva sample with a dropper, avoid generating foam in it. 2. Add 3 drops of saliva into the extraction tube. 3. Tighten the cap firmly onto the extraction tube. 4. Mix well by swirling the extraction tube at least 6 times. **Swab Sample Preparation** 1. Insert the swab sample into the extraction tube which contains extraction reagent. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube. 2. Leave the swab in the extraction tube stand for one minute. 3. Squeeze the sides of the tube to make the liquid immerse the swab. Remove the swab, the extracted solution will be used as test specimen. 4. Tighten the cap firmly onto the extraction tube. Mix well by swirling the tube at least 6 times. **[Test Procedure]** Balance the test device and specimens to room temperature (15-30℃ or 59-86°F) prior to testing. 1. Remove the test cassette from the aluminum foil bag. 2. Reverse the specimen extraction tube, holding the specimen extraction tube up right, transfer 3 drops to the specimen well(S) of the test cassette, then start the timer. See illustration below. 3. Wait for colored lines to appear. Interpret the test results at 15 minutes. Do not read results after 20 minutes.
Result interpretation	The presence of two lines (line T and line C), regardless of the intensity of the test line, indicates a positive result. If the control line (line C) does not appear, the result is invalid and the test should be repeated.
Quality control	The control line (line C) is internal quality control. The test result is invalid if there is no control line.
Evaluation method	Compare the experimental reagent's results with clinical results, calculate

<table>
<tr><td></td><td>the sensitivity and specificity.
<table>
<tr><td colspan="2" rowspan="2"></td><td colspan="2">Clinical result</td><td rowspan="2">Total</td></tr>
<tr><td>Positive</td><td>Negative</td></tr>
<tr><td rowspan="2">Virusee®</td><td>Positive</td><td>a</td><td>b</td><td>a + b</td></tr>
<tr><td>Negative</td><td>c</td><td>d</td><td>c + d</td></tr>
<tr><td colspan="2">Total</td><td>a + c</td><td>b + d</td><td>a+b+c+d</td></tr>
</table>
(1) Sensitivity: a/(a+c)*100%
(2) Specificity: d/(b+d)*100%
Where:
a—The result of clinical is positive and the result of Virusee® is also positive;
b—The result of clinical results is negative while the result of Virusee® is positive;
c—The result of clinical results is positive while the result of Virusee® is negative;
d—The result of clinical results is negative and the result of Virusee® is also negative.</td></tr>
<tr><td>Evaluation results</td><td>SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)
<table>
<tr><td colspan="2" rowspan="2"></td><td colspan="2">RT-PCR</td><td rowspan="2">Total</td></tr>
<tr><td>Positive</td><td>Negative</td></tr>
<tr><td rowspan="2">SARS-CoV-2 Antigen</td><td>Positive</td><td>204</td><td>6</td><td>210</td></tr>
<tr><td>Negative</td><td>8</td><td>802</td><td>810</td></tr>
<tr><td colspan="2">Total</td><td>212</td><td>808</td><td>1020</td></tr>
</table>
Positive coincidence rate =96.23% (204/212); (95%CI: 92.43-98.23%)
Negative coincidence rate =99.26% (802/808); (95%CI: 98.31-99.70%)</td></tr>
<tr><td>Conclusion</td><td>Compare the experimental reagent’s results with clinical RT-PCR results, the sensitivity and specificity were calculated. The sensitivity and specificity for SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) are 96.23%, 99.26% respectively.</td></tr>
</table>

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

Functional parameters test report

Company Name:	Genobio Pharmaceutical Co., Ltd.
Company Address:	2-1,2,3-101, No.2 Zone, Binlv Industrial Park, Binhai Tourism Area, Binhai New Area, Tianjin 300480, P. R. China
Product:	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)
Model:	VSLFA-01: 1 test/kit VSLFA-20: 20 tests/kit
Accessories:	
Standard:	EN 13612:2002
Result:	The results show that the indexes, such as appearance, the width of the dipstick, migration velocity of liquid, analysis sensitivity, analysis specificity, reproducibility , variation inter batches, diagnose sensitivity, diagnose specificity have reached the design requirements. The product meets the needs of clinical practice.

Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus

Impressum Administration

Liste der Antigen-Tests zur professionellen Anwendung zum direkten Erregernachweis des Coronavirus SARS-CoV-2,

die Gegenstand des Anspruchs nach § 1 Satz 1 der "Verordnung zum Anspruch auf bestimmte Testungen für den Nachweis des Vorliegens einer Infektion mit dem Coronavirus SARS-CoV-2 (Coronavirus-Testverordnung – TestV)" sind.

Allgemeine Hinweise

Das BfArM stellt hier eine Liste nach §1 Satz 1 TestV der Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2 bereit, **die vom Hersteller zur professionellen Anwendung zweckbestimmt sind („Schnelltests")** und nach Kenntnis des BfArM eine CE-Kennzeichnung tragen.

Das BfArM hat zum 25.08.2021 eine Änderung der Liste dahingehend vorgenommen, dass ab diesem Tag keine Daten zu Vertreibern mehr in der Übersicht aufgeführt werden.
Hintergrund ist, dass die Vertriebskanäle entsprechender Tests nach unserer Kenntnis inzwischen gut etabliert sind, Vertreiberlisten einzelner Tests nicht mehr vollständig die Vertriebssituation wiedergeben und es für professionelle Anwender genügend Alternativen für die Ermittlung potentieller Vertreiber eines entsprechenden Antigenschnelltests gibt.

Änderungen zu bestehenden Listungen oder Neuanträge zur Aufnahme in die Marktübersicht können nur vom Hersteller des Tests, seinem europäischen Bevollmächtigten oder einem vom Hersteller schriftlich beauftragten Verfahrensbevollmächtigten beantragt werden.

Weitere Hinweise zur vom BfArM bereitgestellten Liste sowie zu den der Sonderzulassung durch das BfArM, Aufnahme in die Liste und ggfs. auch Streichung von der Liste zugrundeliegenden Verfahren und Kriterien finden Sie auf unserer Webseite zu Antigentests auf SARS-CoV-2.

Eine Marktübersicht nach §1 Satz 1 TestV zu Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2, **die vom Hersteller zur Eigenanwendung zweckbestimmt sind („Selbsttests")** finden Sie unter diesem Link.

Alle Daten gemäß Übermittlung des Herstellers, verbindlich sind ausschließlich die Angaben in den jeweiligen Gebrauchsinformationen.

Die Angabe „Evaluierung PEI" bildet die entsprechende, auf der Webseite des Paul-Ehrlich-Instituts (PEI) veröffentlichte Übersicht zur dortigen vergleichenden Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests ab (siehe Webseite des PEI).

Hinweis: Eine aktuelle Übersicht der SARS-CoV-2-Tests, die von den europäischen Mitgliedsstaaten gegenseitig für COVID-19-Testergebnisbescheinigungen anerkannt werden und damit für das „EU Digital COVID-19 Certificate" berücksichtigt werden können, finden Sie im entsprechenden Dokument der Europäischen Kommission: Link zum Dokument

genobio | Los | Aktionen

Nach 'genobio' suchen

			Hersteller			Europäischer Bevollmächtigter			
Test-ID	Handelsname	Evaluieru... PEI	Name	Stadt	Land	Name	Stadt	Land	Testo...
AT1100/21	Virusee® SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) (Speichel/Abstrich)	Ja	Genobio Pharmaceutical Co., Ltd.	Tianjin	CN	Lotus NL B.V.	The Hague	NL	POC (ohne Gerät)

letzte Änderung: 20.12.2021 18:26

* POC = Point of Care

Release 1.0

EU health preparedness:

A common list of COVID-19 rapid antigen tests; A common standardised set of data to be included in COVID-19 test result certificates; and A common list of COVID-19 laboratory based antigenic assays

Agreed by the Health Security Committee

Common list of COVID-19 rapid antigen tests (Annex I)

Agreed by the Health Security Committee on 17 February 2021.

First update: 10 May 2021; Second update: 16 June 2021; Third update: 7 July 2021; Fourth update: 14 July 2021; Fifth update: 23 July 2021; Sixth update: 20 October 2021; Seventh update: 10 November 2021; Eight update: 8 December 2021.

Common standardised data set to be included in COVID-19 test result certificates (Annex II)

Agreed by the Health Security Committee on 17 February 2021.

An update to Annex II was agreed by the HSC on 19 March 2021

Common list of COVID-19 laboratory based antigenic assays (Annex III)

Agreed by the Health Security Committee on 20 October 2021

Genobio Pharmaceutical Co., Ltd.	Virusee® SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)	2642	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.2%	OP: sensitivity: 97.14%, specificity: 99.28% NP: sensitivity: 97.22%, specificity: 99.23%	DE[2]	Nucleo-capsid protein	Oropharyngeal swab; Nasopharyngeal swab	8 December 2021

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2181818-1

Organization: Genobio Pharmaceutical Co., Ltd.
2-1,2,3-101,No.2 Zone, Binlv Industrial Park, Binhai Tourism Area,
Binhai New Area, 300480 Tianjin, P.R. China

Scope: Design and Development, Manufacture and Distribution of In-vitro Diagnostic Analyzers; In-Vitro Diagnostic Test Kits used in the Microbial Detection Testing, Infectious Diseases Testing for Clinical Laboratory Use and Disposable Vacuum Blood Collection Tubes

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 16806550 005

Effective date: 2021-01-20

Expiry date: 2022-12-26

Issue date: 2021-01-20

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

1 / 1

P.05 Medical Devices - Audit
Certification Department

TÜVRheinland
Precisely Right.

Sebastiano Pane
Email : medical-products@de.tuv.com

March 20, 2020

Genobio Pharmaceutical Co., Ltd
2-1,2,3-101,No.2 Zone, Binlv Industrial Park,
Binhai Tourism Area,Binhai New Area,
Tianjin,300480
China

Re: Successful certification
Requirement: ISO 13485: 2016 under MDSAP
Certificate number: MD 60067623 1140043638-30

Dear Madam or Sir,

Thank you for your patience and kind support during the certification process. Please find enclosed the certificate stating compliance to the above-mentioned requirement.

As certification holder / MDSAP participant, your organization is subject to the following guideline: General Conditions for Promoting Certification and Using Certification Body/Auditing Organization Trade Marks and Accreditation Marks, found on the TÜV Rheinland website: https://www.tuv.com/en/usa/legal_disclaimer/imprint.html#tab4.

Please do not hesitate to contact us if you have any further questions or concerns.

Best regards,

Dipl-. S. Pane
Certification officer
P.05 Medical Devices - Audit

TUV Rheinland
of North America, Inc.

12 Commerce Road
Newtown, CT 06470
USA

Toll Free TUV-RHEINLAND
Tel 203-426-0888
Fax 203-426-4009
Web www.tuv.com
Mail info@us.tuv.com

Member of the
TÜV Rheinland Group

Certificate

TÜVRheinland®

Certificate No.:	MD 60067623 1140043638-30
Manufacturer:	Genobio Pharmaceutical Co., Ltd 2-1,2,3-101,No.2 Zone, Binlv Industrial Park, Binhai Tourism Area,Binhai New Area,Tianjin,300480,China
D-U-N-S No.:	55-442-1736
Certification criteria	ISO 13485:2016 Canada Medical Devices Regulations – Part 1 – SOR 98/282

Scope: Design and Development, Manufacture and Distribution of In-Vitro Diagnostic Test Kits used in the Microbial Detection Testing for Clinical Laboratory Use

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	50168597 002
Issue Date:	2020-03-20
Effective Date:	2020-03-20
Expiry Date:	2022-01-17

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl-Ing. S. Pane
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified by calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

인정번호(No.) : KCL-DBAA-10273

체외진단의료기기 제조 및 품질관리 기준 적합인정서 (Certificate of GMP)

■ 업소명/허가번호 (Company name of Applicant / License No.)

(주)다이아제닉스/체외 제 2020 호
Diagenex

■ 업소 소재지 (Company address of Applicant)

서울특별시 강남구 헌릉로569길 29 , 베이팜하우스1동 2층, 3층 301호(세곡동)
2Fl, 3Fl #301, 29, Heolleung-ro 569-gil, Gangnam-gu, Seoul, Republic of Korea

■ 제조소명 (Name of Manufacturer)

제 조 자 : Genobio Pharmaceutical Co., Ltd

■ 제조소 소재지 (Address of Manufacturer)

제 조 자 : 2-1, 2, 3-101, No.2 Zone, Binlv Industrial Park, Binhai Tourism Area, Binhai New Area, Tianjin, 300480, China

■ 품목군 (Category)

면역 검사기기(Devices for Clinical Immunology)

체외진단의료기기 제조 및 품질관리기준에 적합함을 인정합니다.
(We hereby certify that the above manufacturer complies with Korea Good Manufacturing Practices of In-Vitro Diagnostic Devices for the product group listed above)

발행일자(Date of Issue) : 2021. 01. 20
유효기간(Date of Expiration) : 2024. 01. 19

서울지방식품의약품안전청장
SEOUL REGIONAL FOOD AND DRUG ADMINISTRATION

(재)한국건설생활환경시험연구원장
Korea Conformity Laboratories