BETTER AG

Top quality at manufacturer prices

COVID-19 quick test for professional use

With integrated buffer solution

4 in 1

Lollipop / Anterio-nasal / Nasopharyngeal / Oropharyngeal

ID No.: 2109

Listed for EU-wide acceptance in the "EU-common list" of the European Commission - Directorate General for Health and Food Safety Common List of COVID-19 Antigen Rapid Tests

The result is visible after 15-20 minutes.

Sensitivity	96.77%
Specificity	100%
Result after	15 - 20 Minutes
Packing	25 pcs per box

Shenzhen Lvshiyuan Biotechnology Co.,Ltd

Green Spring®SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)
Instructions for Use

REF GF102B1L Rev. 7.1	English

Rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigen. For professional use.

INTENDED USE

The Green Spring® SARS-CoV-2 Antigen Rapid Test is intended for the rapid qualitative detection of SARS-CoV-2 nucleocapsid protein antigen in human saliva, nasal, nasopharyngeal or oropharyngeal swab samples. The results are used for the detection of SARS-CoV-2 antigen. The antigen is generally detectable in upper respiratory tract samples during the acute phase of infections. Positive results do not exclude bacterial infection or co-infection with other viruses. The pathogen detected may not be the sole cause of the disease.
Negative results should be treated as suspected cases and confirmed with a molecular assay. Negative results should be considered in the context of a patient's recent exposures, history and presence of clinical signs and symptoms consistent with COVID-19. The test should only be performed by trained medical personnel.

SUMMARY

The novel coronaviruses belong to a ß-genus. COVID-19 is an acute respiratory infectious disease. Humans are generally susceptible to it. Currently, patients infected with the novel coronavirus are the main source of infection; asymptomatically infected people may also be a source of infection. The main manifestations include fever, fatigue and a dry cough. A stuffy or runny nose, sore throat, muscle aches and diarrhoea occur in a few cases.

TEST PRINCIPLE

The Green Spring® SARS-CoV-2 Antigen Rapid Test is a qualitative, membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein antigen. The test line area is coated with SARS-CoV-2 antibody. The sample reacts with the SARS-CoV-2 antibody in the test line area. If the sample contains SARS-CoV-2 antigen, a coloured line appears in the test line area as a relevant result. As a procedural control, a coloured line appears in the control line area, indicating that the correct volume of sample has been applied and membrane wetting has proceeded correctly.

STORAGE AND STABILITY

Store the tests in the sealed foil pouch at room temperature or refrigerated (2 - 30 ℃). The test is stable until the expiry date printed on it. The test cassettes must be stored in the sealed foil pouch until use. Do not freeze. Do not use after the expiry date. Protect from sun, moisture and heat.

MATERIALS SUPPLIED

- Test cassettes (25 pieces)
- Sampling swabs: 25 pieces
- Extraction tubes with buffer: 25 pieces disposable reaction tubes with 0.5 ml extraction buffer each and 25 pieces nozzle cap
- Package leaflet: 1 instruction leaflet
- Workstation: 1 piece
- Desiccant: 1 package

PRECAUTIONS

1. Read the package leaflet carefully before performing the test. Failure to follow the instructions in the package leaflet may result in inaccurate test results.
2. For professional in vitro diagnostic use only. Do not use after the expiry date.
3. Do not eat, drink or smoke for 10 minutes before and during sample collection.
4. Do not use the test if the packaging or test components are damaged.
5. All samples must be considered potentially infectious. Observe established precautions against microbiological hazards throughout the collection, handling, storage and disposal of patient samples and used test components.
6. Wear protective clothing such as lab coats, disposable gloves and eye protection while testing samples.
7. Wash your hands thoroughly after performing the test.
8. Viral transport media (VTM) may affect the test result: Extracted samples for PCR testing cannot be used for testing.
9. All used test components should be disposed of according to local regulations.
10. Humidity and temperature may adversely affect the results.

PREPARATION

Use only the materials supplied with the respective set. Test the samples immediately.

Use the test kit only at room temperature (15 to 30 ℃). The test kit is intended only for swab samples that are collected and tested directly (i.e. swabs that have NOT been placed in transport media). This kit is NOT intended for testing liquid samples such as wash or aspirate samples or swabs in transport media, as results may be affected by over-dilution.

1. Tear off the foil pouch, take out the test cassette and place it on a clean and flat surface.
2. Freshly collected samples should be processed within 1 hour.
3. Label the respective test cassette for each test or control.
4. Place the labelled extraction tubes in a rack in the designated area of the workspace.

COLLECTING THE SAMPLE

Correct sample collection is the most important step. Select one of the four methods and then proceed with the test procedure.

1) Saliva (lollipop)
Be aware that false results may occur if the saliva is not collected properly.

1. Place an extraction tube in the cardboard workstation.

2. Press the tip of your tongue against the lower root of your jaw. Cough deeply. Make the sound of "kuuua" to gather the saliva.
3. Place the swab on the tongue for at least 10 seconds, rotating it 3 times or more to fully absorb the saliva.

2) Anterio-nasal swab (nose in front).
Make sure to collect enough nasal secretions with the swab. It is advisable to blow your nose first.

1. Place an extraction tube in the cardboard workstation.
2. Carefully insert the swab into the patient's nostril. The tip of the swab should be inserted up to 2.5 cm deep from the edge of the nostril.
3. Swab along the mucosa in the nostril to ensure that both mucus and cells are collected.
4. Take the swab out of the nostril while gently rotating it between your fingers.

3) Nasopharyngeal swab (nose-throat).

1. Place an extraction tube in the cardboard workstation.
2. Tilt the patient's head slightly backwards. Hold the swab like a pen and insert it through the nostril parallel to the palate.
3. While inserting, gently rub and roll the swab. As soon as you feel the throat resistance, stop and let the swab absorb secretion.
4. Slowly and carefully move the swab outwards while gently rotating it between your fingers.

4) Oropharyngeal swab (throat).

1. Place an extraction tube in the cardboard workstation.
2. Let the patient open the mouth wide and make "Ah" sounds, which will expose the pharyngeal tonsils on both sides.
3. Hold the swab tightly and wipe back and forth on the pharyngeal tonsils on both sides at least three times per side with moderate force. Do not touch the palate, tongue, teeth or gums.
4. Remove the swab while gently rotating it between your fingers.

For best results, the nasopharyngeal (nose-throat) method is recommended.

PERFORMING THE TEST

After collecting the sample, perform the test as follows:

1. Tear off the sealing of the extraction tube.
2. Insert the swab sample into the extraction tube and dip it up and down in the liquid. Rotate the swab several times during this process.
3. While removing the swab squeeze the sides of the tube to extract the remaining liquid our of the swab.
   Place the dropper tip firmly on the extraction tube and mix the liquid thoroughly .
4. Dispense 3 drops (approximately 100uL) into the sample well of the test cassette via the dropper tip.
5. Interpret the test results after 15 minutes. Do not interpret the results after 20 minutes.

INTERPRETING THE TEST RESULT

POSITIVE: Two lines appear. One coloured line appears in the control line area (C) and another coloured line appears in the test line area (T). A positive result in the test area indicates the detection of SARS-CoV-2 antigen in the sample. A positive result does not exclude infection with other pathogens.

NEGATIVE: A coloured line appears in the control area (C). No coloured line appears in the test line area (T). A negative result does not exclude viral infection with SARS-CoV-2 and should be confirmed by molecular diagnostic methods if COVID-19 is suspected.

INVALID: The control line does not appear. Insufficient sample volume or incorrect handling are the most likely reasons causing the control line not to appear. Check the procedure and repeat the test with a new test cassette. If the problem persists, stop using the test kit immediately and contact your dealer.

QUALITY CONTROL

The control area (C) acts as an internal procedure control. A coloured line appears when the procedure or sample volume has been applied correctly. Control standards are not provided with this test. As good laboratory practice, it is recommended to perform positive and negative controls periodically to verify test performance.

LIMITATIONS

This test is intended for the qualitative detection of SARS-CoV-2 virus antigen only. The exact concentration of SARS-CoV-2 viral antigen cannot be determined by this test.

Test results are for clinical reference only and should not be the sole basis for clinical diagnosis and treatment. Clinical management of patients should be considered in combination with their symptoms, physical signs, patient history, other laboratory tests, therapeutic responses and epidemiological information.

Proper sampling is crucial. Failure to follow the procedure can lead to incorrect test results. Improper collection, storage or even freezing and thawing of the sample can lead to inaccurate test results.

A false-negative test result may occur if the viral antigen level in a sample is below the detection limit of the test or if the sample was not collected or transported properly; therefore, a negative test result does not exclude the possibility of SARS-CoV-2 infection.

A positive result does not exclude co-infection with other pathogens.

Monoclonal antibodies may not detect SARS-CoV-2 viruses with slightly altered amino acid levels in the region of the target epitope, or may detect them with less sensitivity.

The amount of antigen in a sample may decrease with increasing disease duration. Samples collected after day 5 of illness are more likely to be negative compared to an RTPCR test.

The tests target the nucleocapsid proteins. Performance is not affected by mutations in the spike protein. Mutations in the nucleocapsid protein are not excluded in the future.

CHARACTERISTICS OF PERFORMANCE

The clinical performance of *the Green Spring® SARS-CoV-2 Antigen Rapid Test* was determined in prospective, randomised, single-blind studies. A total of 365 nasopharyngeal samples from symptomatic and asymptomatic patients were collected within 5 days of the onset of initial symptoms. The performance of the kit was compared with the results of a commercially available molecular test. The PCR comparisons use a nasopharyngeal swab.

Table 1: Clinical study nasopharyngeal (nose-throat)

Green Spring SARS-COV-2 Antigen Rapid Test	**PCR-Comparison**		**Total**
	Positive	**Negative**	
Positive	150	0	150
Negative	5	210	215
Total	155	210	365
Sensitivity	**96,77%** (95%KI: 92,24-98,81%)		
Specificity	**100,00%** (95%KI: 97,76-100%)		
Accuracy	**98,63%** (95%KI: 96,89-100%)		

PPA(Ct≤ 37): 96,77% (150/155), (95%KI: 92,24-98,81%)
NPA(Ct≤ 37): 100,00% (210/210), (95%KI: 97,76-100%)

For the anterior nasal swab method, a total of 298 anterior nasal samples were collected from symptomatic and asymptomatic patients within 5 days of the onset of the first symptoms. The performance of

the kit was compared with the results of a commercially available molecular test. The PCR comparisons use a nasopharyngeal swab.

Table 2: clinical study anterior-nasal (nose-front)

Green Spring SARS-COV2 Antigen Rapid Test	**PCR-Comparison**		**Total**
	Positive	**Negative**	
Positive	154	0	154
Negative	6	138	144
Total	160	138	298
Sensitivity	**96,25%** (95%KI: 91,65-98,47%)		
Specificity	**100,00%** (95%KI: 96,62-100%)		
Accuracy	**97,99%** (95%KI: 96,97-100%)		

PPA(Ct≤ 37): 96,25% (154/160), (95%KI: 91,65-98,47%)
NPA(Ct≤ 37): 100,00% (138/138), (95%KI: 96,62-100%)

For the saliva swab method, a total of 298 saliva samples from symptomatic and asymptomatic patients were collected within 5 days of the onset of the first symptoms. The performance of the kit was compared with the results of a commercially available molecular test. The PCR comparisons use a nasopharyngeal swab.

Table 3: clinical study saliva (lollipop)

Greenspring SARS-COV2 Antigen Rapid Test	**PCR-Comparison**		**Total**
	Positive	**Negative**	
Positive	147	0	147
Negative	13	138	151
Total	160	138	298
Sensitivity	**91,88%** (95%KI: 86,22-95,43%)		
Specificity	**100,00%** (95%KI: 96,62-100%)		
Accuracy	**95,64%** (95%KI: 93,32-97,96%)		

PPA(Ct≤ 37): 91,88% (147/160), (95%KI: 86,22-95,43%)
NPA(Ct≤ 37): 100,00% (138/138), (95%KI: 96,62-100%)

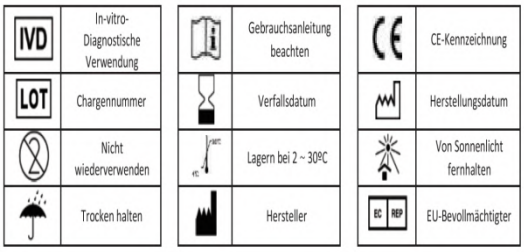
CROSS-REACTIVITY

Potential cross-reactant	**Concentration**	**Cross-reactivity (Yes/No)**
Influenza A	1.6 x 10^5 $TCID_{50}$/mL	No
Influenza B	1.6 x $10^5$$TCID_{50}$/mL	No
Human coronavirus HKU1	1.6 x 10^5 $TCID_{50}$/mL	No
Human coronavirus OC43	1.6 x 10^5 $TCID_{50}$/mL	No
Haemophilus influenzae	2.2x 10^5 $TCID_{50}$/mL	No
MERS-coronavirus	2.1 x 10^5 $TCID_{50}$/mL	No
SARS-coronavirus	3.2 x 10^5 PFU/mL	Yes
Adenovirus C1	1.5 x 10^5 $TCID_{50}$/mL	No
Adenovirus 71	1.5 x 10^5 $TCID_{50}$/mL	No
Candida albicans	4.2 x 10^5 CFU/mL	No
Respiratory syncytial virus	5.1 x 10^5 $TCID_{50}$/mL	No
Enterovirus	5.4 x 10^5 $TCID_{50}$/mL	No
Malaria	2.2 x 10^6 CFU/mL	No
Dengue	1.2 x 10^5 $TCID_{50}$/mL	No
Human coronavirus NL63	1.7x 10^5 $TCID_{50}$/mL	No
Human coronavirus 229E	2.2 x 10^5 $TCID_{50}$/mL	No
Streptococcus pneumoniae	1.1 x 10^6CFU/mL	No
Pneumocystis jirovecii (PJP)	1.0 x 10^5 $TCID_{50}$/mL	No
Legionella pneumophila	1.4 x 10^6 CFU/mL	No
Chlamydia pneumoniae	1.1 x 10^6 IFU/mL	No
HumanMetapneumovirus(hMPV)	1.1 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 1	1.0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 2	1.0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 3	3.5 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 4	1.4 x 10^5 $TCID_{50}$/mL	No
Rhinovirus	1.3 x 10^5 PFU/mL	No
Mycoplasma pneumoniae	1.8 x 10^6 CFU/mL	No
Bordetella pertussis	1.5 x 10^6 CFU/mL	No
Mycobacterium tuberculosis	1.0 x 10^6 CFU/mL	No
Concentrated human nasal contents (representative of normal respiratory microbial flora)	100%	No
Streptococcus pyogenes	1.0 x 10^6 CFU/mL	No

INTERFERENCE

SARS-CoV-2 antigen nasal swab samples were mixed with one of the following substances to specific concentrations and tested in multiple replicates. No false-positives or false-negatives were found:

Substance	Concen-tration	Substance	Concen-tration
Whole Blood	5%	Naso GEL(Nei Med)	6%v/v
Fluticasone Propionate	4%v/v	Mucin	0.54%
CVS Nasal Drops(Phenylephrine)	17%v/v	Ricola(Menthol)	1.6mg/mL
Tamiflu (Oseltamivir Phosphate)	6mg/ml	Afrin (Oxymetazoline)	14%v/v
Sucrets (Dyclonin/Menthol)	1.4 mg/mL	CVC Nasal Spray(Cromolyn)	16%v/v
Chloraseptic (Menthol/Benzocaine)	1.8 mg/mL	Nasal Gel (Oxymetazoline)	9%v/v
Homeopathic(Alkalol)	1:10dilution	Mupirocin	12 mg/mL
Ore Throat Phenol Spray	16%v/v	Fisherman's Friend	1.3mg/mL
Tobramycin	5 μg/mL	Zicam	4%v/v



In-vitro diagnostic use	Read the instruction before using	CE marking
Batch number	Expiry date	Date of manufacture
Do not re-use it	Store at 2℃ -30℃	Keep away from sunlight
Keep dry	Manufacturer	EU authorised representative

LIMIT OF DETECTION (ANALYTICAL SENSITIVITY)

The limit of detection (LOD) for the *Green Spring® SARS-CoV-2 Antigen Rapid Test* is 4 x 10^2 $TCID_{50}$/mL. The LOD for Green Spring® SARS-CoV-2 Antigen Rapid Test Kit was determined using limiting dilution of a gamma irradiation inactivated virus sample. The sample was provided at a concentration of 1.3 ×10^6 $TCID_{50}$/mL.

HIGH-DOSE HOOK EFFECT

The LOD study tested the highest concentration of the sample ($TCID_{50}$ of 1.3 x 10^6 $TCID_{50}$/mL). No hook effect was observed.

FURTHER PRODUCT INFORMATION

Manufacturer: Shenzhen Lvshiyuan Biotechnology Co., Ltd

101,201,301, D Building, No.2 Industrial Avenue, Buxin Village, Buxin Community, Dapeng Subdistrict Office, Dapeng New District, Shenzhen, 518120 China

EU representative: Obelis s.a.

Bd General Wahis 53, 1030 Brussels Belgium

Importer: Better AG
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6300 Zug, Switzerland
Tel: + 353 1 513 7511
Email: info@OdemShop.com
Shop: www.OdemShop.com

深圳市绿诗源生物技术有限公司
Green Spring Shenzhen Lvshiyuan Biotechnology Co.,ltd.

Authorization

It is hereby certified and declared that the company:

Our Shenzhen Lvshiyuan Biotechnology Co.,Ltd. is a legally established and

-manufacturing(COVID- 19(2019-nCoV) Coronavirus IgG/IgM Rapid Test Kit、

SARS-CoV-2 Antigen Rapid Test Kit 、ARS-CoV-2 Neutralizing Antibody Rapid Test Kit)

based enterprise Its main place of business is located in 101,201,301,D Building,

"Better AG" located in General-Guisan-Str. 8, 6300 Zug, Switzerland Is authorized to import, sell, distribute the "Green spring" branded goods in Europe, Asia and Africa.

We hereby confirm the authenticity of the antigene tests sold by this distributor.

The authorization period is from May 24,2021 to May 23.2025

Authorized company name (seal):

Date: May 24,2021

深圳市绿诗源生物技术有限公司
Shenzhen Lvshiyuan Biotechnology Co., Ltd
Add: D Building, National Biological Industrial Park of Marinelife, No.2 Binhai Road, Dapeng, Shenzhen, 518120, China.

The Statement on detection of mutant viruses

WHO held an emergency meeting on 26 November 2021 to discuss the recently discovered mutant strain of the novel coronavirus B.1.1.529. After the meeting, WHO issued a statement, has designated B.1.1.529 as a "Variant of Concern" , named Omicron.

The B.1.1.529 variant was first reported to WHO from South Africa on 24 November 2021 and the first sample infected with the mutant strain was collected on 9 November,the WHO said in a statement .This variant has a large number of mutations, some of which are concerning

Preliminary studies suggest that this variant causes an increased risk of reinfection in humans compared to other "concerns" variants. The number of cases of this variant appears to be increasing in almost all provinces in South Africa.

Since the outbreak of the SARS-CoV-2 virus, it has been reliably reported that there have been at least hundreds of mutations in the gene sequence, all of which have resulted in the virus being more infectious and more pathogenic. The most famous strains include Alpha, which first appeared in Kent, England, Beta in South Africa, Gamma in Brazil, Delta in India and Mu which was first discovered in Colombia and officially named by the WHO on August 30. And Omicron, recently discovered in South Africa. Among them, Omicron variant virus has recently invaded many countries and regions around the world with its strong infectivity and pathogenicity.

The new coronavirus (SARS-CoV-2 or 2019-nCoV) is a non-segmented forward RNA virus. This is the cause of the new type of coronavirus pneumonia (COVID-19), which is highly contagious in humans. The SARS-CoV-2 virus has several structural proteins, including spikes (S), envelope (E), membrane (M) and nucleocapsid (N).

The SARS-CoV-2 virus has the characteristics of strong nucleocapsid (N) protein stability. The mutant virus strains that have been found worldwide are derived from the SARS-CoV-2 20B/GR evolutionary strain (lineage B.1.1.7), including many mutation, the mutation location is the spike (S) protein of the new coronavirus, which is the location where the SARS-CoV-2 virus uses to bind to the cell's ACE2 receptor.

深圳市绿诗源生物技术有限公司
Shenzhen Lvshiyuan Biotechnology Co., Ltd
Add: D Building, National Biological Industrial Park of Marinelife, No.2 Binhai Road, Dapeng, Shenzhen, 518120, China.

The SARS-CoV-2 Antigen Rapid Test Kit produced by Shenzhen Lvshiyuan Biotechnology Co., Ltd. is used for in vitro qualitative detection of SARS-CoV-2 virus nucleocapsid (N) protein in human nasopharyngeal , oropharyngeal , anterior -nasal or saliva samples.

It can be seen that the mutation sites of mutated virus strains including Omicron strain have no effect on the detection rate of the kits produced by our company. The kit is suitable for assay of the SARS-CoV-2 variant virus called 'Omicron '.

Shenzhen Lvshiyuan Biotechnology .Co., Ltd.

Chief Director :Mr Jiang Date：28th November .2021

Tel: +86-755-28438788 Fax: +86-755-28938800

SHENZHEN LVSHIYUAN BIOTECHNOLOGY CO.,LTD 深圳市绿诗源生物技术有限公司

ISO 13485 认证证书 ISO 13485 certification

SGS

Certificate CN20/42084

The management system of

Shenzhen Lvshiyuan Biotechnology Co., Ltd.

101, 201, 301, Building D, No. 2, Industrial Avenue, Buxin Village, Buxin Community, Dapeng Subdistrict Office, Dapeng New District, Shenzhen, Guangdong, 518120, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, Manufacture and Distribution of Dry Fluorescent Immunoassay Instrument and In Vitro Diagnostic Test Kits (ELISA, Colloidal Gold) for SARS-CoV-2, Influenza A and Influenza B.

This certificate is valid from 2 March 2021 until 13 June 2023 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 26 May 2023
Issue 2. Certified since 14 June 2020

Authorised by

SYSTEM CERTIFICATION ISO 13485 SGS

UKAS MANAGEMENT SYSTEMS 0005

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HC SGS 13485 2016 0118

Page 1 of 1

ISO9001 认证证书 ISO9001 certification

GUARDIAN INDEPENDENT CERTIFICATION

CERTIFICATE OF REGISTRATION

The Quality Management Systems of

Shenzhen Lvshiyuan Biotechnology Co., Ltd

Unified Social Credit Code:914403007576264357

Registration address:101, 201, 301, D Building, No.2 Industrial Avenue, Buxin Village, Buxin Community, Dapeng Subdistrict Office, Dapeng New District, Shenzhen
Production address:D Building, National Biological Industrial Park Of Marinelife, Binhai No.2 Road, Dapeng, Shenzhen

has been assessed by GIC and complying with

GB/T19001-2016/ISO9001:2015

For the following activities

Research and development, production and service of food safety testing kits, animal disease diagnostic kits and test cards

Date of Issue: **13 February 2019** Date of Expiry: **12 February 2022**

Date of Initial Certification: **13 February 2019**

Certificate No.: J19Q2GZ8012523R0M

Scan for certificate status

The granting of this certificate does not mean that the certificate holder can avoid any legal obligation. If the products or activities covered in the scope of certification require administrative license, the certificate shall be only valid within the scope of administrative licensing. The registered organization shall be subject to regular annual supervision by GIC, and the continual validity of the certificate is base upon conformity of audit. Please scan two-dimension code at lift to find the certificate information. This certificate can be queried at Certification and Accreditation Administration of the People's Republic of China official website (www. cnca.gov.cn) & GIC website (www. gicg.com.cn)

GIC WeChat public number

Signature: Helen

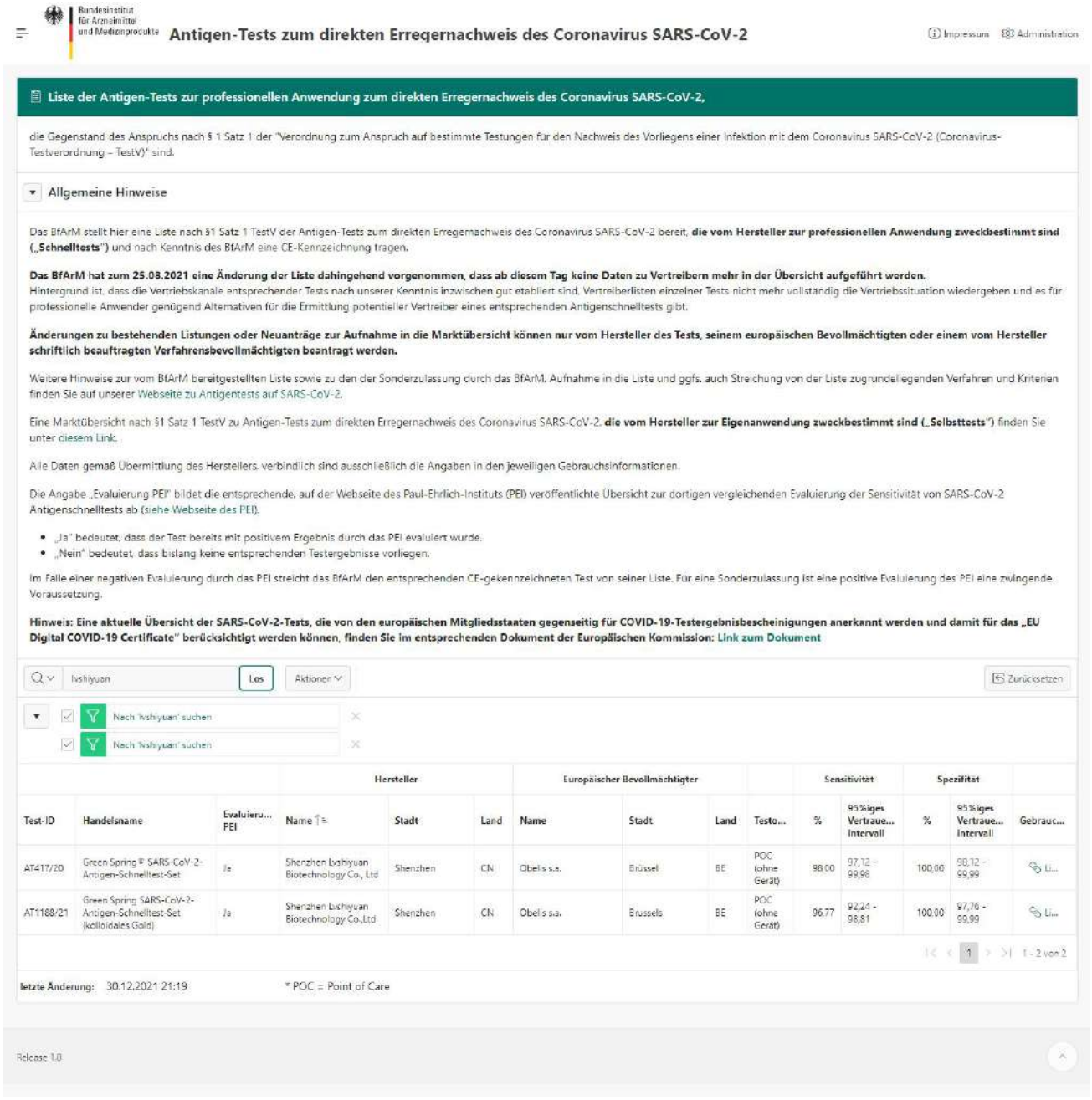
Guardian Independent Certification Ltd
Registered in England
Sovereign House 212-224 Shaftesbury Avenue London England WC2H 8HQ
Accredited by Member of IAF MLA
JAS-ANZ registration no. 535105061L, www.jas-anz.org/register

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

JAS-ANZ

德国 BfArM 批准抗原检测用于专业检测

Germany BfArM Approval of antigen tests for professional testing



Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2

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).

- „Ja" bedeutet, dass der Test bereits mit positivem Ergebnis durch das PEI evaluiert wurde.
- „Nein" bedeutet, dass bislang keine entsprechenden Testergebnisse vorliegen.

Im Falle einer negativen Evaluierung durch das PEI streicht das BfArM den entsprechenden CE-gekennzeichneten Test von seiner Liste. Für eine Sonderzulassung ist eine positive Evaluierung des PEI eine zwingende Voraussetzung.

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

Ivshiyuan | Los | Aktionen | Zurücksetzen

Nach 'Ivshiyuan' suchen

Nach 'Ivshiyuan' suchen

			Hersteller			Europäischer Bevollmächtigter				Sensitivität		Spezifität		
Test-ID	Handelsname	Evaluieru... PEI	Name	Stadt	Land	Name	Stadt	Land	Testo...	%	95%iges Vertraue... intervall	%	95%iges Vertraue... intervall	Gebrauc...
AT417/20	Green Spring® SARS-CoV-2-Antigen-Schnelltest-Set	Ja	Shenzhen Ivshiyuan Biotechnology Co., Ltd	Shenzhen	CN	Obelis s.a.	Brüssel	BE	POC (ohne Gerät)	98,00	97,12 - 99,98	100,00	98,12 - 99,99	Li...
AT1188/21	Green Spring SARS-CoV-2-Antigen-Schnelltest-Set (kolloidales Gold)	Ja	Shenzhen Ivshiyuan Biotechnology Co.,Ltd	Shenzhen	CN	Obelis s.a.	Brussels	BE	POC (ohne Gerät)	96,77	92,24 - 98,81	100,00	97,76 - 99,99	Li...

1 - 2 von 2

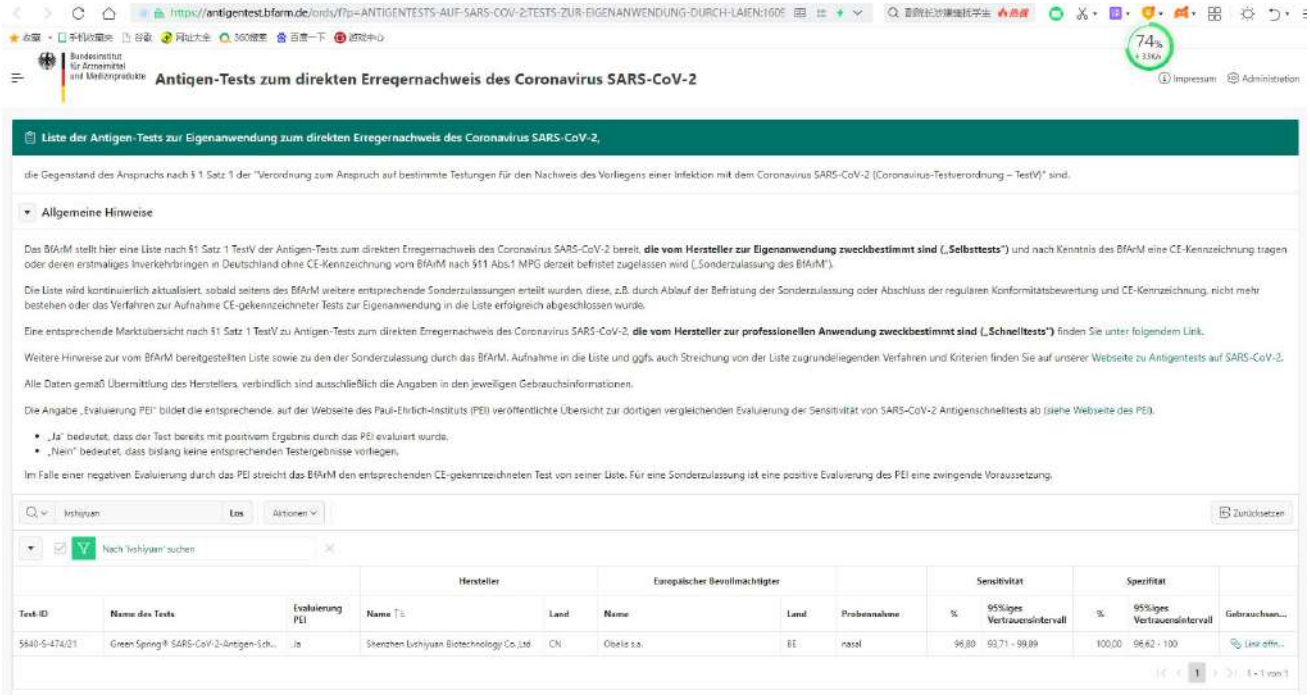
letzte Änderung: 30.12.2021 21:19

* POC = Point of Care

Release 1.0

德国 BfArM 批准用于自检的抗原检测

Germany BfArM Approval of antigen tests for self-testing



PEI 认证证书 Paul-Ehrlich-Institut certification

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

12.02.2021

Comparative evaluation of the sensitivities of SARS-CoV-2 antigen rapid tests

Aim

Comparison of different antigen rapid tests with using identical sample material

Material

Pools from nasopharyngeal and oropharyngeal swabs.

Dry swabs were included in PBS; moist swabs were already included in the transport media of various compositions. Pools are random mixtures obtained from up to 10 samples of comparable CT values diluted 1:10 in negative samples in PBS. The CT values of a pool were determined by means of different PCR assays, and the putative number of RNA copies calculated with the aid of the INSTAND standards. In the case of the PCRs used, a CT value of 25 corresponds to around 10^6 RNA copies/mL. 18 samples each were analysed with CT<25, 23 samples with CT between 25 and 30, and 9 samples with CT>30. The replication of the virus in cell culture was determined as a possible correlate for infectiousness as another characteristic of the samples.

Method

The pools were aliquoted, frozen, shipped, and thawed for evaluation of the tests. For each test, 50 µL of the pool were analysed using the components of the test provided, e.g. swabs. Laboratories participating in the comparative evaluation included the Robert Koch-Institut, the Paul-Ehrlich-Institut, the reference laboratory for coronaviruses (Charité), and the Institute for Microbiology of the German Army (Bundeswehr).

Summary

This comparative evaluation of a large number of SARS-CoV-2 rapid antigen tests (point of care tests; POCT) of different designs and manufacturers with the same sample set allows an overview of the current state of art regarding sensitivity. The results do not allow any conclusions regarding specificity of the tests.

Those POCTs which have up to now been included in the evaluation and have been assessed as reflecting the current state of the art are listed in the table below. Other tests, which were assessed as not reflecting the state of the art were deleted from the list of the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). This comparative evaluation is constantly continued, and the table is amended accordingly.

You should be aware that this comparative evaluation can only cover a random sample of the SARS-CoV-2 rapid antigen tests listed by the BfArM, thus eligible for refunding, and that many other products could not (yet) be taken into account, despite the interests on the part of the manufacturers/distributors.

Contact

Email: sarscov2ivd@pei

Last updated: 12.02.2021

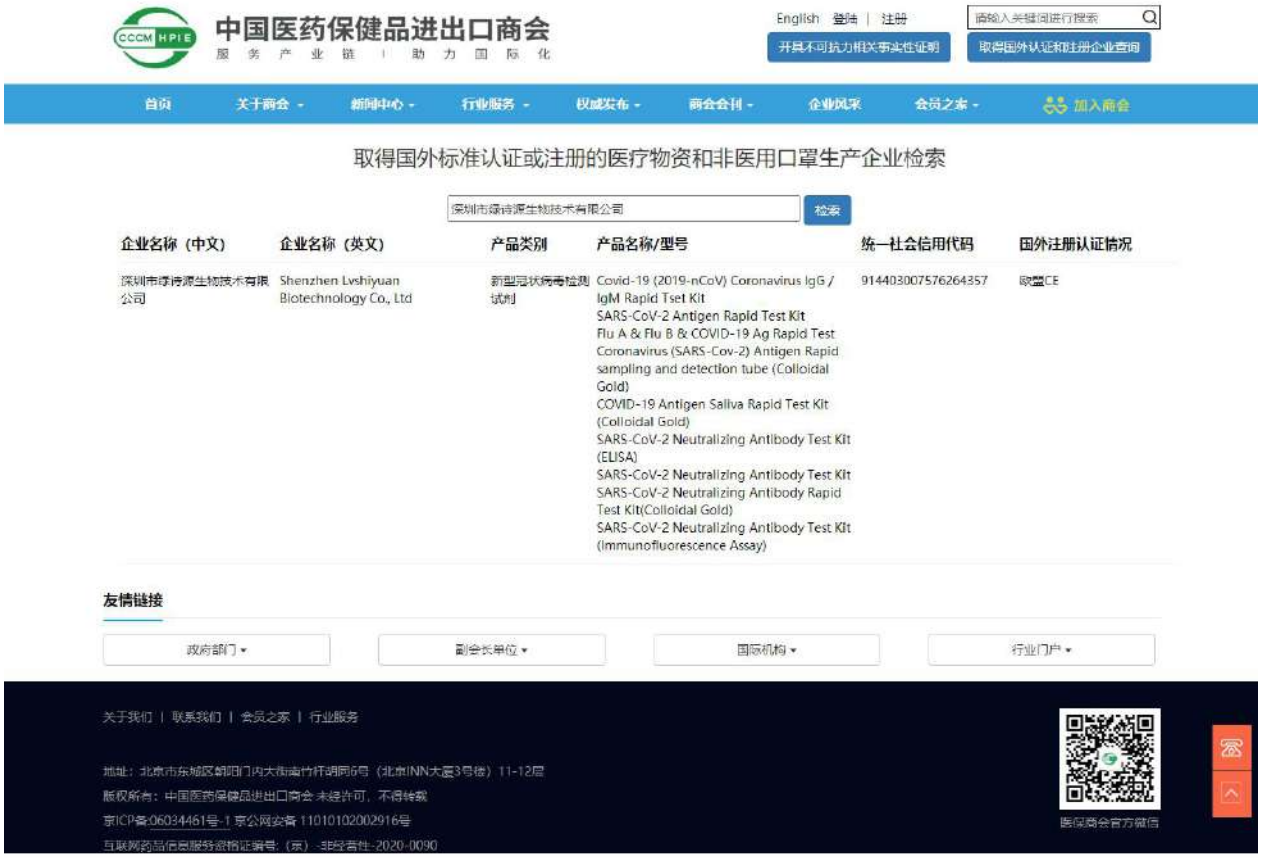
Overview of SARS-CoV-2 Antigen Rapid Tests Assessed as Reflecting the Current State of the Art

Name of Test	Manufacturer (Distributor)
Panbio™COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)	Abbott Rapid Diagnostics Jena GmbH
RIDA®QUICK SARS-CoV-2 Antigen	R-Biopharm AG
SARS-CoV-2 Rapid Antigen Test	SD BIOSENSOR (Roche Diagnostics GmbH)
NADAL® COVID-19 Ag Schnelltest	nal von minden gmbh
STANDARD™ F COVID-19 Ag FIA	SD BIOSENSOR
STANDARD™ Q COVID-19 Ag Test	SD BIOSENSOR
BIOSYNEX COVID-19 Ag BSS	BIOSYNEX SWISS SA
MEDsan® SARS-CoV-2 Antigen Rapid Test	MEDsan GmbH
TestNOW® - COVID-19 Antigen	Affimedix
NowCheck® COVID-19 Ag Test	BIONOTE
Coronavirus Ag Rapid Test Cassette (Swab)	Zhejiang Orient Gene Biotech Co.,Ltd
Sofia SARS Antigen FIA	Quidel Corporation
COVID-19 Ag Test Kit	Guangdong Wesail Biotech Co., Ltd.
CLINITEST® Rapid COVID-19 Antigen Test	Siemens Healthineers
ESPLINE® SARS-CoV-2	Fujirebio Inc. (Mast Diagnostica GmbH)
BD Veritor™ System for Rapid Detection of SARS-CoV-2	Becton Dickinson
GenBody COVID-19 Ag	IVC Pragen Healthcare
LumiraDx SARS-CoV-2 Ag Test	LumiraDX
Exdia COVID-19-Ag-Test	Precision Biosensor Inc. (Axon Lab AG)
SARS-CoV-2 Ag Rapid Test (FIA)	Wantai (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.)
SARS-CoV-2 Antigen Schnelltest	Xiamen Boson Biotech Co., Ltd (Medicovid-AG; technomed GmbH; Löwe Medizintechnik)
COVID-19 Antigen Schnelltest (Colloidal Gold)	Joinstar Biomedical Technology Co., Ltd (CIV care impuls Vertrieb)
mö-screen Corona Antigen Test	Mölab GmbH
Rapid SARS-CoV-2 Antigen Test Card	MP Biomedicals Germany GmbH
Lyher Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	Hangzhou Laihe Biotech Co., Ltd. (Lissner Qi GmbH)
AMP Rapid Test SARS-CoV-2 Ag	Ameda Labordiagnostik GmbH
Clungene COVID-19 Antigen Rapid Test	Hangzhou Clongene Biotech Co., Ltd.
GensureTM COVID-19 Antigen Rapid Test Kit	GenSure Biotech Inc.
SARS-CoV-2 Antigen Rapid Test Kit	Beijing Lepu Medical Technology Co., Ltd
Hightop SARS-CoV-2 (Covid-19) Antigen Rapid Test	Qingdao Hightop Biotech Co., Ltd.
Rapid Covid-19 Antigen Test (Colloidal Gold)	Anbio (Xiamen) Biotechnology Co., Ltd

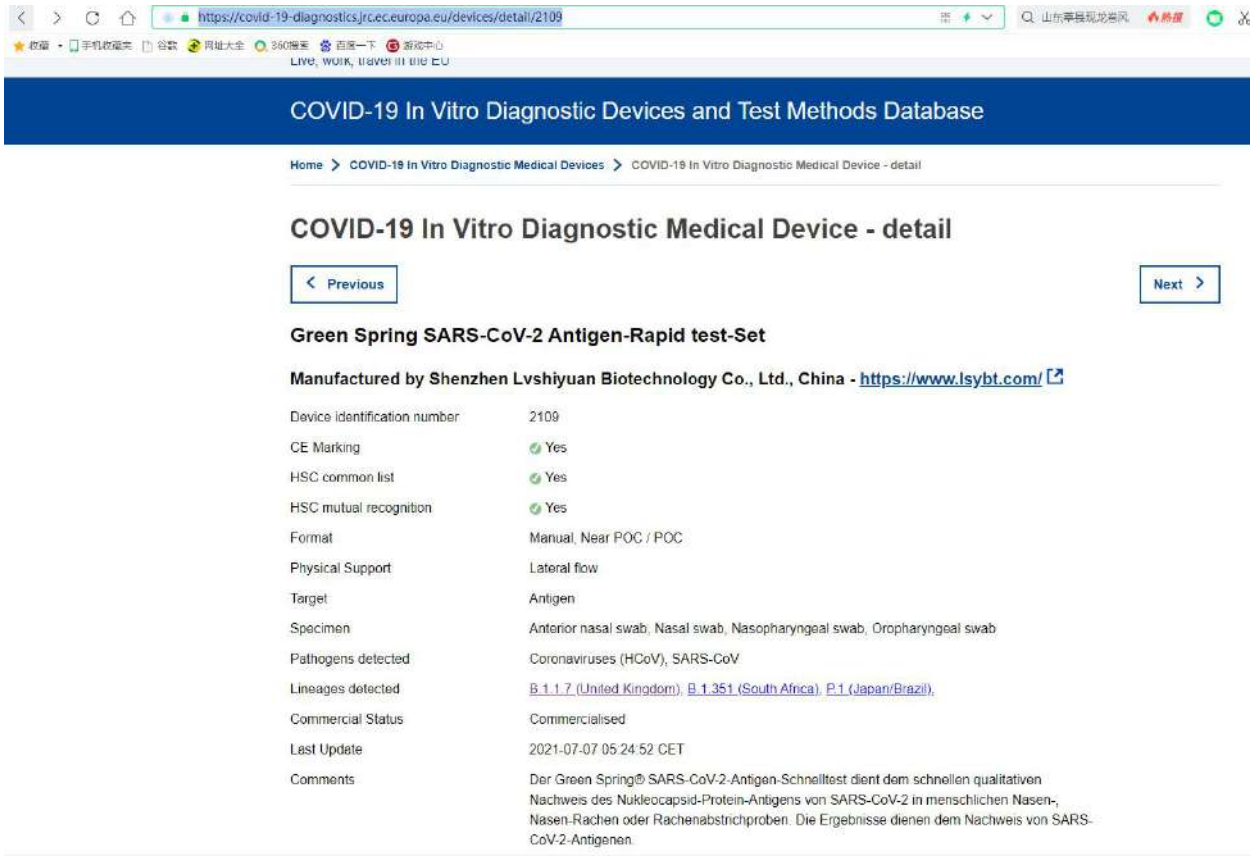
Name of Test	Manufacturer (Distributor)
Safecare COVID-19 Ag Rapid Test Kit (Swab)	Safecare Biotech Hangzhou Co., Ltd.
QuickProfile Covid-19 Antigen Test Card	LumiQuick Diagnostics, Inc.
Covid 19 Antigen Schnelltest	BioRepair GmbH
Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	Shenzhen Lvshiyuan Biotechnology Co., Ltd.
CAT Antigen Covid Rapid Test	Oncosem Onkolojik Sistemler San. Ve Tic. A.S.
ScheBo SARS-CoV-2 Quick Antigen	ScheBo Biotech AG
Nova Test SARS-CoV-2 Antigen Rapid Test Kit	Atlas Link Technology Co., Ltd.
Toda Coronadiag Ag	Toda Pharma
Humasis COVID-19 Ag Test	Humasis Co., Ltd.
Beijing Hotgen Biotech Co., Ltd.	Neuartiges Coronavirus (2019-nCoV)-Antigentest (Kolloidales Gold); Novel Coronavirus 2019-nCoV Antigen Test (Colloidal gold)
Xiamen AmonMed Biotechnology Co.,Ltd.	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)
Canea COVID-19 Antigen Schnelltest	Core Technology Co., Ltd.
fluorecare COVID-19 SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)	Shenzhen Microprofit Biotech Co., Ltd
Tetsealabs® Rapid Test Kit COVID-19 Antigen Test Cassette	Hangzhou Testsea Biotechnology Co., Ltd
Lysun COVID-19 Antigen Rapid Test Device (Colloidal Gold)	Hangzhou Lysun Biotechnology Co., Ltd.

取得国外标准认证截图

Obtained screenshots of foreign standard certification



欧盟通用和互认清单 On the EU common list & Mutual Recognition list



https://covid-19-diagnostics.jrc.ec.europa.eu/devices/detail/2109

COVID-19 In Vitro Diagnostic Devices and Test Methods Database

Home > COVID-19 In Vitro Diagnostic Medical Devices > COVID-19 In Vitro Diagnostic Medical Device - detail

COVID-19 In Vitro Diagnostic Medical Device - detail

< Previous Next >

Green Spring SARS-CoV-2 Antigen-Rapid test-Set

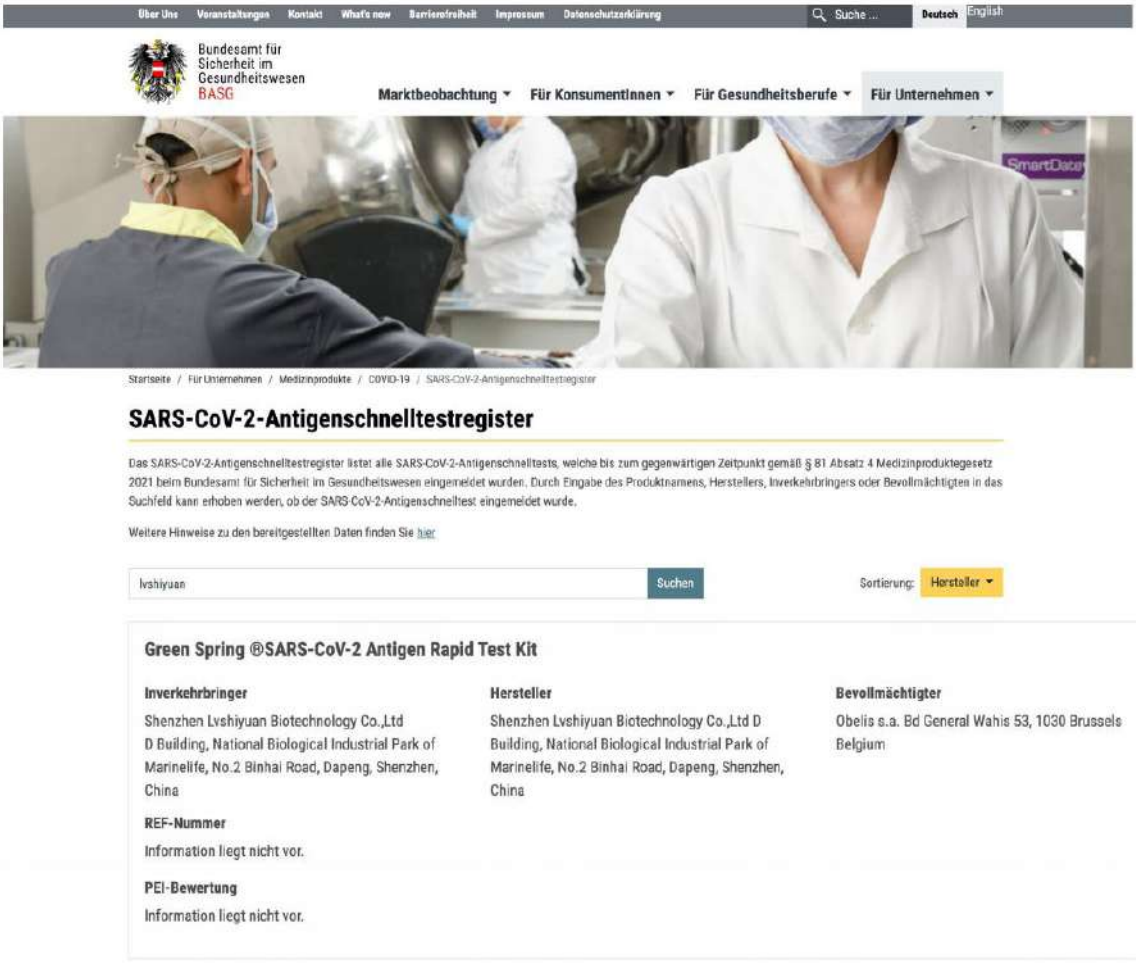
Manufactured by Shenzhen Lvshiyuan Biotechnology Co., Ltd., China - https://www.lsybt.com/

Device identification number	2109
CE Marking	Yes
HSC common list	Yes
HSC mutual recognition	Yes
Format	Manual, Near POC / POC
Physical Support	Lateral flow
Target	Antigen
Specimen	Anterior nasal swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal swab
Pathogens detected	Coronaviruses (HCoV), SARS-CoV
Lineages detected	B.1.1.7 (United Kingdom), B.1.351 (South Africa), P.1 (Japan/Brazil)
Commercial Status	Commercialised
Last Update	2021-07-07 05:24:52 CET
Comments	Der Green Spring® SARS-CoV-2-Antigen-Schnelltest dient dem schnellen qualitativen Nachweis des Nukleocapsid-Protein-Antigens von SARS-CoV-2 in menschlichen Nasen-, Nasen-Rachen oder Rachenabstrichproben. Die Ergebnisse dienen dem Nachweis von SARS-CoV-2-Antigenen.

比利时白名单 Whitelist of Belgium

DiaClear Biotech (Hangzhou)	SARS-COV-2 Nucleocapsid (N) Antigen Rapid Test Cassette	95.1	99.3	NP swab	-	No
LumiQuick Diagnostics	QuickProfile COVID-19 Antigen Test Strip	94.0	99.0	NP swab	1927	Yes
MEDsan	SARS-CoV-2 Antigen Rapid Test	92.5	99.8	Nasal swab/OP swab	1180	Yes
MP Biomedicals	Rapid SARS-CoV-2 Antigen Test Card	96.4	99.0	NP swab/OP swab	1481	Yes
Multi-G	Covid19CHECK-GEN	82.6	99.2	NP swab/OP swab	-	No
	COVID19CHECK-NAS (COVID-19 antigen rapid test cassette)	96.1	99.2	Nasal swab	-	No
	COVID19CHECK-SAL (Sars-Cov-2 Antigen Rapid Test)	96.8 (Ct≤33)	99.1	Saliva	-	No
Mylab Discovery Solutions Pvt	PathoCatch COVID-19 Antigen Lateral Flow Test Device	82.0	100.0	Nasal swab	-	No
nal von minden	NADAL COVID-19 Ag Rapid Test	97.8	99.9	NP swab/OP swab	1182	Yes
Nanjing Vazyme Medical Technology	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)	97.6	99.3	Nasal swab/OP swab	1849	No
NanoEntek	FREND COVID-19 Ag	94.7	100.0	NP swab	1470	Yes
Nantong Diagnosis Biotechnology	Covid-19 Antigen Saliva Test Kit (Colloidal Gold) (Cassette)	98.1	99.3	Saliva	1817	No
	Covid-19 Antigen Test Kit (Colloidal Gold)	98.8/98.8	100.0	NP swab/OP swab	-	No
New Gene (Hangzhou) Bioengeneering	Covid-19 Antigen Detection Kit	97.3/95.7/96.1	99/99/99.1	Nasal swab/OP swab/Sputum	1501	Yes
ONCOSEM Onkolojik Sistemler San. ve Tic. A.S.	2019-nCoV Antigen Rapid Test Kit	97.6	99.3	NP swab	-	No
Ortho-Clinical Diagnostics	VITROS SARS-CoV-2 Antigen test	97.8	99.2	NP swab	1800	Lab test
PCL	PCL COVID19 Ag Gold	80.8 (Ct<30)/91.7	99.5/100	Saliva/NP swab	1758	No
Prestige Diagnostics	2019-nCoV Antigen Device	90.9	99.1	NP swab	1702	No
PRIMA Lab	PRIMACOVID COVID-19 Antigen Rapid Test	96.4/92.9	99.2/100	NP swab/Nasal swab	1787	No
Qingdao Hightop Biotech	SARS-CoV-2 Antigen Rapid Test (Immunochromatography)	92.7/95.0/96.0	99.8/99.8/99.8	Nasal swab/NP swab/OP swab	1341	Yes
Quidel	Sofia SARS Antigen FIA	96.7	100.0	NP swab/Nasal swab	1097	Yes
	Sofia 2 Flu + SARS Antigen FIA	95.2	100.0	NP swab/Nasal swab	-	No
Roche Diagnostics	Elecsys SARS-CoV-2 Antigen	94.5	99.9	NP swab/OP swab	2158	Lab test
SD Biosensor (distributed by Roche)	SARS-CoV-2 Rapid Antigen Test	96.5	99.7	NP swab	1604	Yes
Shenzhen Hulan Biosci Technology	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	94.6	99.1	Nasal swab	-	No
Shenzhen Landwind Biotechnology	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	95.7	99.2	Nasal swab	-	No
Shenzhen Lvshiyuan Biotechnology	Green Spring SARS-CoV-2-Antigen-Rapid Test Kit (Colloidal Gold)	96.8/98	100.0	Nasal swab/NP swab	2109	Yes
Shenzhen Microprofit Biotech	Fluorecare SARS-CoV-2 Test Kit	98.6/100	100.0	NP swab/Nasal swab	-	No
	Fluorecare SARS-CoV-2 Spike Protein Test Kit	98.8	100.0	NP swab	1709	No
Shenzhen Ultra Diagnostics Biotech	SARS-CoV-2 Antigen Test kit (SC0201 + SC0202)	92/100/96	100.0	NP swab/OP swab/Saliva	-	No
	SARS-CoV-2 Antigen Test kit (SC0203 + SC0204)	92/96.7/97.2	100/99/99	NP swab/OP swab/Sputum	-	No
Shenzhen YHLO Biotech Co	GLINE-2019-nCoV Ag	96.6/97.4	99.3/99.3	NP swab/Nasal swab	1347	No
Sunscreen	COVID-19 Coronavirus Rapid Antigen Test Cassette	93.3	100.0	NP swab/OP swab	1478	No
Todapharma	TODA Coronadiag Ag	96.6	100.0	NP swab/OP swab	1466	Yes
Ulti med Products	COVID-19 Antigen Test (Nasopharyngeal Swab)	96.4	99.2	NP swab	1488	No
	COVID-19 and Influenza A+B Antigen Combo Rapid Test (Nasopharyngeal Swab)	96.4	99.2	NP swab	1931	No
Van Oostveen Medical	Coronavirus Ag Rapid Test Cassette (Swab)	96.7	99.2	NP swab	1931	No
VivaChek Biotech	VivaDiag Pro SARS-CoV-2 Ag Rapid Test	96.1/96.1/97.0	100.0	NP swab/OP swab/Nasal swab	2103	Yes
	VivaDiag SARS-CoV-2 Ag Rapid Test	95.0	100.0	NP swab/OP swab/Nasal swab	2102	No
	VivaDiag SARS-CoV-2 Ag Saliva Rapid Test	96.3	100.0	Saliva	1999	No

奥地利白名单 Whitelist of Austria



意大利白名单 Whitelist of Italy

瑞士白名单 Whitelist of Switzerland

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Eidgenössisches Departement des Innern EDI
Bundesamt für Gesundheit BAG
Taskforce BAG Covid-19 AG Testung

Listen der validierten SARS-CoV-2-Schnelltests zur Fachanwendung[1]
Listes des tests rapides validés pour le SARS-CoV-2 pour usage professionnel
Liste dei test rapidi validati per il SARS-CoV-2 per uso professionale

25.10.2021

Die Schnelltests sind ausschliesslich für **bestimmte Probematerialien** validiert und nur dementsprechend anzuwenden. In der Schweiz dürfen **keine** Antigen-Schnelltests mit **Speichel** als Probematerial ausserhalb von Laboratorien eingesetzt werden. Informationen bezüglich des Einsatzes der Schnelltests finden Sie auf der BAG-Webseite Covid-19 Testung. — Webseite Covid-19 Testung

Les tests rapides sont validés exclusivement pour **certains types de prélèvements** et ne doivent ainsi être utilisés que pour ceux-ci. En Suisse, **aucun** test antigénique rapide utilisant la **salive** comme matériel de prélèvement ne peut être utilisé en dehors des laboratoires. Des informations sur l'emploi prévu des tests rapides sont disponibles sur le site web de l'OFSP Tests COVID-19. — Site internet Tests COVID-19

I testi rapidi sono validati solo per **certi tipi di campioni** e possono essere utilizzati solo per questo scopo. In Svizzera, **nessun** test antigenico rapido che utilizza la **saliva** come materiale di campionamento può essere utilizzato al di fuori dei laboratori. Le informazioni su come utilizzare i test rapidi sono disponibili sul sito internet dell'UFSP «Test COVID-19». — Sito web Test COVID-19

Validierte SARS-CoV-2-Schnelltests
Tests rapides SARS-CoV-2 validés
Test rapidi SARS-CoV-2 validati

Hersteller, Antigen Schnelltest Fabricant, Tests rapides antigéniques Azienda, Test antigenici rapidi	Test/Kit/Code for electronic declaration[3]	Combi-test[1]	JRC ID	Grace period until[4]
AAZ-LMB, COVID-VIRO	26		1835	
Abbott Rapid Diagnostics, Panbio Covid-19 Ag Rapid Test	2		1232	
Abisteq GmbH, Cora Genitest-19			2374	
AccuBioTech Co,Ltd, Accu-Tell SARS-CoV-2 Ag Cassette			2579	
Acon Biotech (Hangzhou) Co., Ltd, Flowflex SARS-CoV-2 Antigen Rapid Test			1457	
ACON Laboratories, Inc, Flowflex SARS-CoV-2 Antigen rapid test			1468	
AESKU.DIAGNOSTICS GmbH & Co. KG, AESKU.RAPID SARS-CoV-2			2108	
Affirmedix, Inc., TestNOW® - COVID-19 Antigen Test			2130	
AMEDA Labordiagnostik GmbH, AMP Rapid Test SARS-CoV-2 Ag	19		1304	
Anbio (Xiamen) Biotechnology Co., Ltd, Rapid COVID-19 Antigen Test(Colloidal Gold)			1822	
Anhui Deep Blue Medical Technology Co., Ltd, COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) - Nasal Swab			1835	
Anhui Deep Blue Medical Technology Co., Ltd, COVID-19 (SARS-CoV-2) Antigen Test Kit(Colloidal Gold)			1736	
Anhui Formisser Biosci Co., Ltd., New Coronavirus (COVID-19) Antigen Rapid Test			2089	
ArcDia International Ltd, mariPOC SARS-CoV-2			768	
ArcDia International Oy Ltd, mariPOC Quick Flu+		X	2079	
ArcDia International Oy Ltd, mariPOC Respi+		X	2078	
Artron Laboratories Inc, Artron COVID-19 Antigen Test			1618	
Asan Pharmaceutical CO., LTD, Asan Easy Test COVID-19 Ag			1654	
Assure Tech. (Hangzhou) Co., Ltd, ECOTEST COVID-19 Antigen Rapid Test Device			770	
Assure Tech. (Hangzhou) Co., Ltd., ECOTEST COVID-19 Antigen Rapid Test Device			2350	
Atlas Link Technology Co., Ltd., NOVA Test® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)	22		2010	
AVALUN SAS, Kemard® SARS-COV2 Antigen Rapid Test			1800	
AXIOM Gesellschaft für Diagnostica und Biochemica mbH, COVID-19 Antigen Rapid Test			2101	
Azuni Biotech Inc, COVID-19 Antigen Rapid Test Device			1906	
Becton Dickinson, BD Veritor™ System for Rapid Detection of SARS CoV 2			1065	
Beijing Hotgen Biotech Co., Ltd, Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)			1870	
Beijing Jiewofu Bioengineering Technology Co., Ltd., Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit			2072	
Beijing Lepu Medical Technology Co., Ltd, SARS-CoV-2 Antigen Rapid Test Kit			1331	
Beijing O&D Biotech Co., Ltd., COVID-19 Antigen Rapid Test			2494	
Beijing Wantai Biological Pharmacy Enterprise Co., Ltd, WANTAI SARS-CoV-2 Ag Rapid Test (Colloidal Gold)			1486	
Beijing Wantai Biological Pharmacy Enterprise Co., Ltd, Wantai SARS-CoV-2 Ag Rapid Test (FIA)			1484	15.12.2021
BioGnost Ltd, CovKinnot AG Test Device 1x20			2031	
BIOHIT HealthCare (Hefei) Co., Ltd, SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence Immunochromatography)			2247	
BioMaxima SA, SARS-CoV-2 Ag Rapid Test			1286	
Biomerica, Inc., Biomerica COVID-19 Antigen Rapid Test (nasopharyngeal swab)			2035	
Biondia, Inc, NowCheck COVID-19 Ag Test			1939	
Bio-Rad Laboratories / Zhejiang Orient Gene Biotech, Coronavirus Ag Rapid Test Cassette (Swab)	11		2242	
BIOSYNEX S.A., BIOSYNEX COVID-19 Ag BSS	17		1223	
BIOSYNEX S.A., BIOSYNEX COVID-19 Ag+ BSS	18		1494	
BIOTEKE CORPORATION (WUXI) CO., LTD, SARS-CoV-2 Antigen Test Kit (colloidal gold method)			2057	
Biotical Health S.L.U., biotical SARS-CoV-2 Ag Card			2013	
Bodltech Med Inc, AFIAS COVID-19 Ag			1989	
BTNX Inc, Rapid Response COVID-19 Antigen Rapid Test			1236	
CerTest Biotec, CerTest SARS-CoV-2 Card test			1173	
Chil Tıbbi Malzeme Sanayi ve Ticaret Limited Şirketi, CHIL COVID-19 Antigen Rapid Test (Nasopharyngeal / Oropharyngeal Swab-Cassette)			1691	
Chongqing M&D Biotechnology Co. Ltd, 2019-nCoV Antigen Test Kit			2150	
Core Technology Co., Ltd, Coretests COVID-19 Ag Test			1919	
CTK Biotech, Inc, OnSite COVID-19 Ag Rapid Test			1581	
DDS DIAGNOSTIC, Test Rapid Covid-19 Antigen (tampon nazofaringian)			1225	
DIALAB GmbH, DIAQUICK COVID-19 Ag Cassette			1375	
DiaSorin S.p.A, LIAISON® SARS-CoV-2 Ag			1900	
DNA Diagnostic, COVID-19 Antigen Detection Kit			2242	
Dräger Safety AG & Co. KGaA, Dräger Antigen Test SARS-CoV-2			2273	
Dynamiker Biotechnology (Tianjin) Co., Ltd, Dynamiker SARS-CoV-2 Ag Rapid Test			2533	
Edinburgh Genetics Limited, AcivXpress+ COVID-19 Antigen Complete Testing Kit			1243	
Eurobio Scientific, EBS SARS-CoV-2 Ag Rapid Test	25		1739	
Fujirebio, ESPLINE SARS-CoV-2			2147	
GA Generic Assays GmbH, GA CoV-2 Antigen Rapid Test			1895	
GenBody, Inc, Genbody COVID-19 Ag Test			1244	15.12.2021
Genrui Biotech Inc, SARS-CoV-2 Antigen Test Kit (Colloidal Gold)			2012	
GenSure Biotech Inc, GenSure COVID-19 Antigen Rapid Kit			1253	
Getein Biotech, Inc, SARS-CoV-2 Antigen (Colloidal Gold)			1820	
Getein Biotech, Inc., One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)			2183	
Goldsite Diagnostics Inc, SARS-CoV-2 Antigen Kit (Colloidal Gold)			1197	
Green Cross Medical Science Corp., GENEDIA W COVID-19 Ag			1144	
Guangdong Hecin Scientific, Inc., 2019-nCoV Antigen Test Kit (colloidal gold method)			1747	
Guangdong Longsee Biomedical Co., Ltd, COVID-19 Ag Rapid Test Kit (Immuno-Chromatography)			1216	
Guangdong Wesail Biotech Co., Ltd, COVID-19 Ag Test Kit			1300	
Guangzhou Decheng Biotechnology Co., LTD, V-CHEK 2019-nCoV Ag Rapid Test Kit (Immunochromatography)			1324	
Guangzhou Wondfo Biotech Co., Ltd, Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	23		1437	
Hangzhou AllTest Biotech Co., Ltd, COVID-19 Antigen Rapid Test	10		1257	
Hangzhou Clongene Biotech Co., Ltd, COVID-19 Antigen Rapid Test Cassette			1610	
Hangzhou Clongene Biotech Co., Ltd, Covid-19 Antigen Rapid Test Kit	20		1263	
Hangzhou Clongene Biotech Co., Ltd, COVID-19&Influenza A+B Antigen Combo Rapid Test		X	1305	
Hangzhou Immuno Biotech Co.,Ltd, immunobio SARS-CoV-2 Antigen ANTERIOR NASAL Rapid Test Kit (minimal invasive)			1844	
Hangzhou Immuno Biotech Co.,Ltd, SARS-CoV-2 Antigen Rapid Test			2317	
Hangzhou Laihe Biotech Co., Ltd, LYHER Novel Coronavirus (COVID-19) Antigen Test Kit(Colloidal Gold)			1216	
HANGZHOU LYSUN BIOTECHNOLOGY CO., LTD, COVID-19 Antigen Rapid Test Device (Colloidal Gold)	7		2139	
Hangzhou Testsea Biotechnology Co., Ltd, COVID-19 Antigen Test Cassette			1392	
Healgen Scientific, Coronavirus Ag Rapid Test Cassette			1767	
Hoyotek Biomedical Co.,Ltd, Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)			1929	
Hubei Jinjian Biology Co., Ltd, SARS-CoV-2 Antigen Test Kit			1759	
Humasis, Humasis COVID-19 Ag Test			1203	
Innova Medical Group, Inc., Innova SARS CoV-2 Antigen Rapid Qualitative Test			1801	
Innovation Biotech (Beijing) Co.,ltd, Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)			2278	
InTec PRODUCTS, INC., Rapid SARS-CoV-2 Antigen Test (nasopharyngeal specimen)			2419	
Jiangsu Biopertedus Technologies Co., Ltd., Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit			2107	
Jiangsu Diagnostics Biotechnology Co.,Ltd., COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)			1928	
Jiangsu Medomics medical technology Co.,Ltd., SARS-CoV-2 antigen Test Kit (LFIA)			2006	
Jiangsu Well Biotech Co., Ltd., COVID-19 Ag Rapid Test Device			2144	
Joinstar Biomedical Technology Co., Ltd, COVID-19 Rapid Antigen Test (Colloidal Gold)			1333	
JOYSBIO (Tianjin) Biotechnology Co., Ltd, SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)			1754	
Labnovation Technologies Inc, SARS-CoV-2 Antigen Rapid Test Kit			1266	
Lumigenex (Suzhou) Co., Ltd, PocRedi5SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)			2128	
LumiQuick Diagnostics Inc, QuickProfile COVID-19 Antigen Test			1267	
LumiraDX, LumiraDx SARS-CoV-2 Ag Test	9		1268	
MEDsan GmbH, MEDsan SARS-CoV-2 Antigen Rapid Test	6		1180	
Merlin Biomedical (Xiamen) Co., Ltd., SARS-CoV-2 Antigen Rapid Test Cassette			2029	
MEXACARE GmbH, MEXACARE COVID-19 Antigen Rapid Test			1775	
mdi, ab, md-screen Corona Antigen Test			1100	
MP Biomedicals, Rapid SARS-CoV-2 Antigen Test Card	15		1481	
Nal von minden GmbH, NADAL COVID-19 Ag +Influenza A/B Test		X	2104	
Nal von minden GmbH, NADAL COVID-19 Ag Test	33		1162	
NanoEntek, FREND COVID-19 Ag	34		1420	
NanoRegro AG, NanoRegro SARS-CoV-2 Antigen Rapid Test			2200	
NESAPOR EUROPA SL, MARESKIT			2241	
New Gene (Hangzhou) Bioengineering Co., Ltd, COVID-19 Antigen Detection Kit	30		1501	
Novatech, SARS CoV-2 Antigen Rapid Test			1762	
Orcosem Onkoloji Sitoloji San. ve Tic. A.S., CAT			1199	
PCL Inc, PCL COVID19 Ag Rapid FIA			308	
PCL Inc, PCL COVID19 Ag Gold			2243	
PerGrande BioTech Development Co., Ltd., SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic Assay)			2116	
Precision Biosensor, Inc, Exdia COVID-19 Ag	13		1271	
Prognosis Biotech, Rapid Test Ag 2019-nCov			1495	
Qingdao Hightop Biotech Co., Ltd, SARS-CoV-2 Antigen Rapid Test (Immunothromatography)			1341	
Quidel Corporation, Sofia SARS Antigen FIA	21		1097	
Rapid Pathogen Screening, Inc., LIAISON® Quick Detect Covid Ag Assay			2200	
Roche (SD BIOSENSOR), SARS-CoV-2 Rapid Antigen Test	1		1804	
Roche (SD BIOSENSOR), SARS-CoV-2 Rapid Antigen Test Nasal			2228	
ROCHE Diagnostics, Elecsys® SARS-CoV-2 Antigen			2156	
Safecare Biotech (Hangzhou) Co.,Ltd, COVID-19 Antigen Rapid Test Kit (Swab)			1489	
Safecare Biotech (Hangzhou) Co.,Ltd, Multi-Respiratory Virus Antigen Test Kit(Swab) (Influenza A+B/ COVID-19)		X	1490	
Schwito Biotech AG, Schwito SARS CoV2 Quick Antigen			1201	
SD BIOSENSOR Inc, STANDARD F COVID-19 Ag FIA	24		344	
SD BIOSENSOR Inc, STANDARD Q COVID-19 Ag Test			345	
SD BIOSENSOR Inc, STANDARD Q COVID-19 Ag Test Nasal			2052	
SGA Medikal, V-Chek SARS-CoV-2 Ag Rapid Test Kit (Colloidal Gold)			1319	
SGA Medikal, V-Chek SARS-CoV-2 Rapid Ag Test (colloidal gold)			1357	
Shenzhen Dymind Biotechnology Co., Ltd, Sars-CoV-2 antigen test kit (colloidal gold)			2415	
Shenzhen Huian Bioscl Technology Co., Ltd., SARS-CoV-2 Antigen Test Kit (Colloidal Gold)			2414	
Shenzhen Kesheslth Biotechnology Co., Ltd, SARS-CoV-2 Antigen Test Kit (GICA)			1613	
Shenzhen Lvshiyuan Biotechnology Co., Ltd., Green Spring SARS-CoV-2 Antigen-Rapid test-Set			2109	
Shenzhen Microprofit Biotech Co., Ltd, SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)			1967	
Shenzhen Microprofit Biotech Co., Ltd, SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)			1178	

英国注册证书 Registration Certificate of UK

Medicines & Healthcare products Regulatory Agency

MHRA

Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

PureUKCA Ltd
59
St. Martin's Lane
Middlesex
London
WC2N 4JS
England, United Kingdom

09 September 2021

Dear **Avril Huang**

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **09 September 2021** has been reviewed:

Application reference: **2021090901215399**

Manufacturer organisation: **Shenzhen Lvshiyuan Biotechnology Co.,Ltd.**
Address:
D Building, No.2 Industrial Avenue, Buxin Village, Buxin Community, Dapeng Subdistrict Office, Dapeng New District, Shenzhen, 518120 China
Shenzhen
518120
China

Manufacturer registration status: **Registered**

Device(s):

GMDN term	Status	Comment
SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	

Please note this letter does not represent any form of accreditation, certification or approval by the UK Competent Authority.

If you stop placing devices on the market or if you are not complying with the Regulations, you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market UKCA or CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:

1. **company/organisation information e.g. name and address**
2. **additional devices (GMDN code or term)**

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/ discontinuation of a device (GMDN) or product from your registration record, change of contact person, telephone number and/or email address, for which payment of our statutory fee does not apply.

Please note that the name and address of manufacturer, UK Responsible Person or Authorised Representative (Northern Ireland only) and devices that have been registered will be published on our Public Access Registration Database (PARD).

The account number for your company/organisation is **0000018481.**

Yours sincerely,

Ngozi Onyeukwu
Device registrations service
Devices division
MHRA

荷兰注册证 Registration Certificate in Netherlands

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Kingsmead Service B.V.
T.a.v. de heer Jeff
Zonnehof 36
2632 BE Nootdorp

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-20216547

Bijlagen
-

Uw aanvraag
1 november 2021

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

Datum: 18 november 2021
Betreft: aanmelding In-vitro diagnostica

Geachte heer Jeff,

Op 1 november 2021 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Shenzhen Lvshiyuan Biotechnology Co.,Ltd met Europees gemachtigde Kingsmead Service 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 Kit (Colloidal Gold)
(geen merknaam) (NL-CA002-2021-62947)

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, Shenzhen Lvshiyuan Biotechnology Co.,Ltd de CE-conformiteitsmarkering heeft aangebracht op het desbetreffende product alvorens het in een EU-lidstaat in de handel te brengen. Zodoende garandeert Kingsmead Service 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)

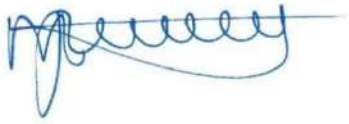
Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van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

Let op:
de notificatie van uw 'IVD Algemeen' product vervalt per 26 mei 2022.
Valt uw IVD product onder een hogere risicoklasse (lijst A, B of zelftesten)? Dan mag uw product tot en met uiterlijk 25 mei 2025 op de markt blijven als IVD product.

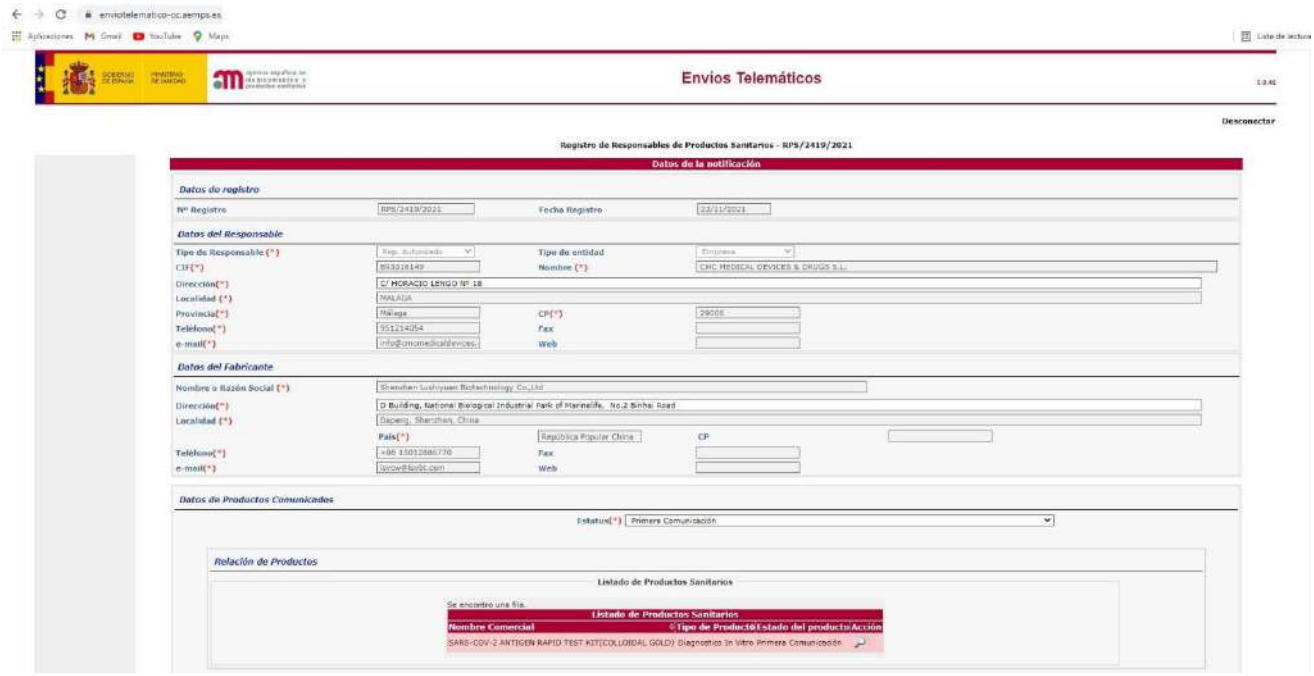
De Staatssecretaris van Volksgezondheid, Welzijn en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

西班牙注册证 Spanish Registration Certificate



泰国白名单 Whitelist of Thailand

รายชื่อชุดตรวจสำหรับ COVID-19 ประเภท Rapid Test แบบตรวจหา Antigen
รูปแบบการใช้โดยบุคลากรทางการแพทย์เท่านั้น (Professional Use Only)
ที่ได้รับการอนุญาตให้ผลิต/นำเข้า จากสำนักงานคณะกรรมการอาหารและยา
ข้อมูล ณ วันที่ 16 ธันวาคม 2564

ลำดับที่	ชื่อผลิตภัณฑ์	ชื่อผู้นำเข้า	ชื่อผู้ผลิต	วันที่ได้รับอนุญาต (วัน/เดือน/ปี)	เลขที่ใบรับรองประเมินเทคโนโลยี
130	Virusee ® SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) รหัสสินค้า VSLFA-01, VSLFA-20	บริษัท สรรพสิริ เทรดดิ้ง จำกัด	Genobio Pharmaceutical Co., Ltd. China	9/12/2564	T 6400558
131	Servere Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based) รหัสสินค้า C8602CA	บริษัท ซาจุน จำกัด	Nanjing Vazyme Medical Technology Co., Ltd. China	9/12/2564	T 6400559
132	BD Kit for Rapid Detection of SARS-CoV-2 รหัสสินค้า 256091, 256113, 256114	บริษัท ซิลลิค ฟาร์มา จำกัด	BD Rapid Diagnostics (Suzhou) Co., Ltd. China	9/12/2564	T 6400561
133	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	บริษัท แฮปปี้ วิชั่นส์ จำกัด	Shenzhen Lvshiyuan Biotechnology Co., Ltd. China	13/12/2564	T 6400562

Order No.: OG 0117-2020
Ref No.: BS 0171-2020

Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN/ EDMS Code	Class
1	GF102B1	SARS-CoV-2 Antigen Rapid Test Kit	SARS-CoV-2 (COVID-19) Antigen Rapid Test Kit (Colloidal Gold)	SARS-CoV-2 (Covid-19) Antigen Rapid Test Kit is used to quanlitatively detect antigen of the novel coronavirus in nasal swab.	15.04.80.19	Others

Obelis s.a.

G. ERKAYAM
C.E.O.

Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles

CE 认证 CE certification

Obelis EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER Obelis SINCE 1988

CERTIFICATE OF IVD NOTIFICATION

Ref. No.: BS 0171-2020

Order No.: OG 0117-2020

BELGIUM

Date: 19/11/2020

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: SHENZHEN LVSHIYUAN BIOTECHNOLOGY CO., LTD.

ADDRESS: 101, 201, 301, D BUILDING, NO. 2 INDUSTRIAL AVENUE, BUXIN VILLAGE, BUXIN COMMUNITY, DAPENG SUBDISTRICT OFFICE, DAPENG NEW DISTRICT, SHENZHEN, 518120, CHINA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 18/11/2020 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (1 PAGE, 1 DEVICE)

As of the 19/11/2020, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

Mr. G. Elkayam CEO

Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

* This is not a CE mark and is only provided as a template for informational purposes.

** This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

Registered Address: Bd. Général Wahis 53 - 1030 Brussels | Registered Office Address: Bd Brand Whitlock 30, B – 1200 Brussels - Belgium

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

Company Name: Shenzhen Lvshiyuan Biotechnology Co., Ltd.
Address: 101, 201, 301, D Building, No. 2 Industrial Avenue, Buxin Village, Buxin Community, Dapeng Subdistrict Office, Dapeng New District, Shenzhen 518120 China

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

List of Products:

1. SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

- **ISO 9001: 2015**

Corporate Contact Information

COMPANY NAME: Shenzhen Lvshiyuan Biotechnology Co., Ltd.
COMPANY ADDRESS: 101, 201, 301, D Building, No. 2 Industrial Avenue, Buxin Village,
RESPONSIBLE PERSON'S name: Jiang Yongqing
Position: Vice General Manager
SIGNATURE : Yongqing Jiang
Date : 2020/11/09
Stamp

深圳市绿诗源生物技术有限公司
Shenzhen Lvshiyuan Biotechnology Co., Ltd

依据联合国 GHS 制度第八修订版编/According to UN GHS (the 8th revised edition)

材料安全数据表
Material Safety Data Sheet

产品名称：	新型冠状病毒抗原检测试剂盒（胶体金法）
Product Name：	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

编制/Written by：Linda (Linda)　审核/Inspected by：Jose (Jose)　批准/Approved by：Grady (Grady)

ZHONGKE SERVICES OF TESTING (SHENZHEN) CO., LTD. 中科检测认证服务（深圳）有限公司 检测专用章 TESTING SERVICES NO.L1979

发布：中科检测认证服务（深圳）有限公司

ISSUED BY: ZHONGKE SERVICES OF TESTING (SHENZHEN) CO., LTD.

2022 年 01 月 印制 Jan. 2022 Print

编制日期：2022 年 01 月 05 日
Compilation Date: Jan. 05, 2022

修订日期：2022 年 01 月 05 日
Revision Date: Jan. 05, 2022