Green Spring 4in1 SARS-CoV-2 Antigen Rapid Test

- German BfArM Listing: AT1188/21
- EU Common List, Device ID: 2109
- Evaluated by German Paul-Ehrlich-Institute
- Sensitivity 96.77%
- Specificity 100.00%
- 4 in 1 = Nose, Deep Nose, Throat & Lolli
- Prefilled tubes

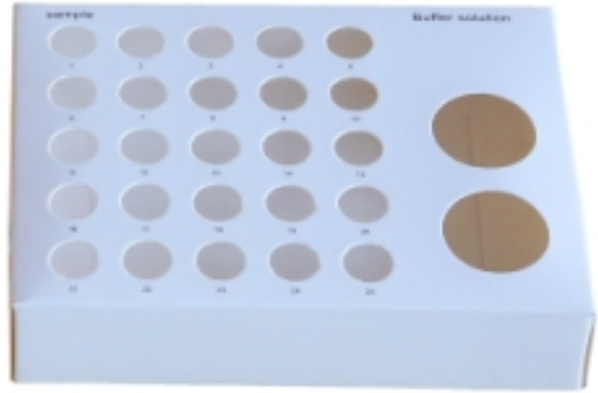
Easy-to-use, efficient rapid test with very good sensitivity and specificity. Has shown very good sensitivity in the PEI test even at lower viral loads.


25T/box
SARS-CoV-2 Antigen Rapid Test Kit
(Colloidal Gold)
Shenzhen Lvshiyuan Biotechnology Co.,Ltd.
CE
SARS-CoV-2 Antigen Rapid Test Kit
(Colloidal Gold)
Shenzhen Lvshiyuan Biotechnology Co.,Ltd.
CE


Shenzhen Lvshiyuan Biotechnology Co.,Ltd.
SARS-CoV-2 Antigen Rapid Test Kit
(Colloidal Gold)
Instruction for use
Shenzhen Lvshiyuan Biotechnology Co.,Ltd.


CE
SARS-CoV-2 Antigen Rapid Test Kit
(Colloidal Gold)
For In Vitro Diagnostic Use Only


合格证
Product Qualified Certificate
Product Name:
SARS-CoV-2 Antigen Rapid Test Kit
Technical Standard: Q/LSY002-2020
Valid Date: 12 months
Production Date: Printed on the outer packaging
Production Batch: Printed on the outer packaging
Manufacturer: Shenzhen Lvshiyuan Biotechnology Co.,Ltd.
Address: 101,201,301, D Building , No. 2, Industrial Avenue, Bantin Village, Buxin Community, Dapeng Subdistrict Office, Dapeng New District, Shenzhen,China.
Tel: 0755-28439000 0755-28438788


Sample
Buffer solution

SARS-CoV-2 Antigen Rapid Test Kit
(Colloidal Gold)
For In Vitro Diagnostic Use Only
Green Spring
CE
25T/box
Shenzhen Lvshiyuan Biotechnology Co.,Ltd
合格证
Product Qualified Certificate

January 07, 2022

The Statement on detection of mutant viruses

We, Shenzhen Lvshiyuan Biotechnology Co., Ltd., as the manufacturer, hereby declare that Greensprings SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) can detect the following SARS-CoV-2 Virus variants which is listed as 'variants of concern (VOC)'& 'variants of interest (VOI)' by the World Health Organization. VOC refers to the large number and wide range of cases caused worldwide, and data confirms its transmission ability, strong toxicity, or reduced effectiveness of vaccines and clinical treatments. VOI refers to a confirmed case of community transmission, or has been found in multiple countries, but has not yet formed a large-scale infection.

WHO Categories	WHO Label	Pango Lineage	Date of Designation
Variants Of Concern (VOC)	Alpha	B.1.1.7	September, 2020
	Beta	B.1.351	May 2020
	Gamma	P.1	November 2020
	Delta	B.1.617.2	October 2020
	Omicron	B.1.1.529	November 2021
Variants Of Interest (VOI)	Epsilon	B.1.427	February, 2021
		B.1.429	June 2021
	Eta	B.1.525	February 2021
	Iota	B.1.526	February 2021
	Kappa	B.1.617.1	May, 2021
	N/A	B.1.617.3	May, 2021
	Zeta	P.2	February 2021
	Mu	B.1.621, B.1.621.1	September, 2021
	IHU	B.1.640.2	September, 2021

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.

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 Eta 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 as listed in the table above.

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

Shenzhen Lvshiyuan Biotechnology Co.,Ltd.

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

Obelis EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER — Obelis — SINCE 1998

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 I Registered Office Address: Bd Brand Whitlock 30, B – 1200 Brussels - Belgium
T: + 32 (0) 2 732 5954 I F: + 32 (0) 2 732 6003 I Email: mail@obelis.net I Website: www.obelis.net

V3 – ID: 00454716 – 22/02/2019

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. ELKAYAM
C.E.O

Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

Corporate Contact Information

COMPANY NAME: Shenzhen Lvshiyuan Biotechnology Co., Ltd.
COMPANY ADDRESS: 101, 201, 301, D Building, No. 2 Industrial Avenue, Buxin Village, Buxin Community Dapeng Subdistrict Office, Dapeng New District, Shenzhen 518120 China
COMPANY PHONE: +86 755 28438788
COMPANY FAX: +86 755 28938800
COMPANY EMAIL: sales@lsybt.com
RESPONSIBLE PERSON'S name: Jiang Yongqing
Position: Vice General Manager
SIGNATURE :
Date : 2020/11/09
Stamp

European Authorized Representative:
Registered Address:
Obelis s.a.
Bd. Général Wahis 53
B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
Fax: 32.2.732.60.03
E-mail: mail@obelis.net
Representative: Mr. Gideon ELKAYAM (CEO)

Shenzhen Lvshiyuan Biotechnology Co.,Ltd

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

REF GF102B1 Rev. 7	English

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

INTENDED USE

The Green Spring® SARS-CoV-2 Antigen Rapid Test Kit is for the rapid qualitative detection of SARS-CoV-2 nucleocapsid protein antigen in human saliva, nasal, nasopharyngeal or oropharyngeal swab specimens. The results are used for the detection of SARS-CoV-2 antigens. The antigen is generally detectable in upper respiratory tract specimens during the acute phase of infections. Positive results do not rule out bacterial infection or co-infection with other viruses. The pathogen detected may not be the sole cause of the disease.
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. Suspected cases should be confirmed with a molecular assay. For professional use only.

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 novel coronavirus are the main source of infection; asymptomatic infected people may also be a source of infection. The main manifestations include fever, fatigue, and dry cough. A stuffy or runny nose, sore throat, muscle aches, and diarrhea 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 nucleocapsid protein antigens of SARS-CoV-2. The test line region is coated with a SARS-CoV-2 antibody. The sample reacts with the SARS-CoV-2 antibody in the test line region. If the specimen contains SARS-CoV-2 antigens, a colored line appears in the test line region (T) as a result. As a procedural control, a colored line appears in the control line region (C) indicating that the correct volume of sample has been added and membrane wicking has occurred correctly.

STORAGE AND STABILITY

Store the tests in the sealed foil pouch at room temperature or refrigerated (2 - 30 °C). The test is stable until the expiry date. The test cassettes should be kept in the sealed foil pouch until use. Do not freeze. Do not use after expiration date. Keep away from sun, moisture and heat.

MATERIALS SUPPLIED

- Test cassette with a pack of desiccant: 25 pieces
- Sterile swab: 25 pieces
- Extraction tube with buffer and nozzle cap: 25 pieces disposable extraction tubes with 0.5 ml extraction buffer each
- Tube rack: 1 piece
- Package insert: 1 instruction manual

WARNINGS AND PRECAUTIONS

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

PREPARATION

Only use the materials supplied with the set. Test the specimens immediately.

Let the test kit equilibrate to room temperature (15 to 30 °C). The test kit is intended only for swab specimens 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 specimens such as wash or aspiration samples or swabs in transport media, as results may be affected by over-dilution.

1. Tear off the foil pouch, remove 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 or control for each test.
4. Place the labeled extraction tubes in a rack in the designated area of the work area.

SPECIMEN COLLECTION

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

1) Saliva (Lolly-Test)
Be aware that incorrect results may occur if the saliva is not collected properly.

1. Place an extraction tube in the cardboard tube rack.
2. Press the tip of the tongue against the lower root of the jaw. Cough deeply. Make the sound of "kuuua" to concentrate the saliva.
3. Place the swab on the tongue for at least 10 seconds, rotate it 3 times or more to fully absorb the saliva.

2) Anterior-nasal swab

Be sure to collect sufficient nasal secretions with the swab. It is recommended to blow your nose first.

1. Place an extraction tube in the cardboard tube rack.
2. Carefully insert the swab into the patient's nostril. The swab tip 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. Remove the swab from the nostril while gently rotating it between your fingers.

3) Nasopharyngeal swab

1. Place an extraction tube in the cardboard tube rack.
2. Tilt the patient's head slightly backward. 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. Once you feel pharyngeal resistance, stop and allow the swab to absorb secretions.
4. Slowly and gently remove the swab outward while gently rotating it between your fingers.

4) Oropharyngeal swab

1. Place an extraction tube in the cardboard tube rack.
2. Ask the patients open their mouth wide and make "Ah" sounds, exposing the pharyngeal tonsils on both sides.
3. Hold the swab firmly 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 method is recommended.

TEST PROCEDURE

After taking the sample, perform the test as follows:

1. Tear off the seal of extraction buffer tube.
2. Insert the swab into the tube and dip the swab up and down in the liquid for at least 10 seconds. Then, hold the swab against the bottom of the tube and rotate it 3 turns, making sure that no contents splash out of the tube.
3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
4. Place the dropper tip firmly on the extraction buffer tube and mix the liquid thoroughly.
5. Dispense 3 drops (approximately 100μL) into the sample well of the test cassette via the dropper tip.
6. Interpret the test results after 15 minutes. Do not interpret the results after 20 minutes.

INTERPRETATION OF THE TEST RESULT

POSITIVE: Two lines appear. One colored line appears in the control line region (C) and another colored line appears in the test line region (T). A positive result in the test region indicates the detection of SARS-CoV-2 antigens in the specimen but does not rule out infection with other pathogens.

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

INVALID: Control line does not appear. Insufficient sample volume or incorrect handling are the most likely reasons for the control line not appearing. 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 distributor.

QUALITY CONTROL

The control region (C) serves as an internal procedure control. A colored 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 that positive and negative controls be performed periodically to verify test performance.

LIMITATIONS

- This test is for the qualitative detection of SARS-CoV-2 Virus antigens only. The exact concentration of SARS-CoV-2 virus antigens 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 epidemiologic information.
- Proper specimen collection is critical. Failure to follow the procedure can lead to inaccurate test results. Improper collection, storage, or even freezing and thawing of the specimen can lead to inaccurate test results.
- A false-negative test result may occur if the viral antigen level in a specimen is below the detection limit of the test or if the specimen was not collected or transported properly; therefore, a negative test result does not rule out the possibility of SARS-CoV-2 infection.
- A positive result does not rule out 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 RT-PCR test.
- The test target is the nucleocapsid proteins. Performance is not affected by mutations in the spike protein. Mutations in the nucleocapsid protein are not excluded in the future.

CLINICAL PERFORMANCE

The clinical performance of the Green Spring® SARS-CoV-2 Antigen Rapid Test was determined in prospective, randomized, single-blind studies. A total of 365 nasopharyngeal specimens 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)

Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	**PCR-Comparator**		**Total**
	Positive	**Negative**	
Positive	150	0	150

Negative	5	210	215
Total	155	210	365
Sensitivity	**96,77%** (95%CI: 92,24-98,81%)		
Specificity	**100,00%** (95%CI: 97,76-100%)		
Accuracy	**98,63%** (95%CI: 96,89-100%)		

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

For the anterior nasal swab method, a total of 298 anterior nasal specimens 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 assay. The PCR comparisons use a nasopharyngeal swab.

Table 2: clinical study (anterior-nasal)

Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	**PCR-Comparator**		**Total**
	Positive	**Negative**	
Positive	154	0	154
Negative	6	138	144
Total	160	138	298
Sensitivity	**96,25%** (95%CI: 91,65-98,47%)		
Specificity	**100,00%** (95%CI: 96,62-100%)		
Accuracy	**97,99%** (95%CI: 96,97-100%)		

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

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

Table 3: clinical study (Saliva)

Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	**PCR-Comparator**		**Total**
	Positive	**Negative**	
Positive	147	0	147
Negative	13	138	151
Total	160	138	298
Sensitivity	**91,88%** (95%CI: 86,22-95,43%)		
Specificity	**100,00%** (95%CI: 96,62-100%)		
Accuracy	**95,64%** (95%CI: 93,32-97,96%)		

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

CROSS–REACTIVITY

No cross-reactivity with potentially cross-reactive agents was observed, other than SARS coronavirus.

Potential cross reactant	**Concentration**	**Cross-reactivity (Yes/No)**
Influenza A	1.6 x 10^5 TCID50/mL	No
Influenza B	1.6 x 10^5TCID50/mL	No
Human coronavirus HKU1	1.6 x 10^5 TCID50/mL	No
Human coronavirus OC43	1.6 x 10^5 TCID50/mL	No
Haemophilus influenzae	2.2x 10^5 TCID50/mL	No
MERS-coronavirus	2.1 x 10^5 TCID50/mL	No
SARS-coronavirus	3.2 x 10^5 PFU/mL	Yes
Adenovirus C1	1.5 x 10^5 TCID50/mL	No
Adenovirus 71	1.5 x 10^5 TCID50/mL	No
Candida albicans	4.2 x 10^5 CFU/mL	No
Respiratory syncytial virus	5.1 x 10^5 TCID50/mL	No
Enterovirus	5.4 x 10^5 TCID50/mL	No
Malaria	2.2 x 10^6 CFU/mL	No
Dengue	1.2 x 10^5 TCID50/mL	No
Human coronavirus NL63	1.7x 10^5 TCID50/mL	No
Human coronavirus 229E	2.2 x 10^5 TCID50/mL	No
Streptococcus pneumoniae	1.1 x 10^6CFU/mL	No
Pneumocystis jirovecii (PJP)	1.0 x 10^5 TCID50/mL	No
Legionella pneumophila	1.4 x 10^6 CFU/mL	No
Chlamydia pneumoniae	1.1 x 10^6 IFU/mL	No
Human Metapneumovirus(hMPV)	1.1 x 10^5 TCID50/mL	No
Parainfluenza virus 1	1.0 x 10^5 TCID50/mL	No
Parainfluenza virus 2	1.0 x 10^5 TCID50/mL	No
Parainfluenza virus 3	3.5 x 10^5 TCID50/mL	No
Parainfluenza virus 4	1.4 x 10^5 TCID50/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
Konzentrierte menschliche Naseninhalte repräsentativ für normale respiratorische mikrobielle Flora	100%	No
Streptococcus pyogenes	1.0 x 10^6 CFU/mL	No

INTERFERENCE

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

Substance	**Concentration**	**Substance**	**Concentration**
Whole Blood	5%	Naso GEL(Nei Med)	6%v/v
Fluticasone	4%v/v	Mucin	0.54%

Propionate			
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

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 TCID50/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 ($TCID_{50}$ von 1,3 x 10^6 $TCID_{50}$/mL). No Hook-effect was detected.

FURTHER PRODUCT INFORMATION

Manufacturer: Shenzhen Lvshiyuan Biotechnology Co., Ltd

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EU authorized representative: Obelis s.a.

Bd Général Wahis 53, 1030 Brussels Belgium

SYMBOL DESCRIPTION

IVD	In Vitro Diagnostic Use		Instruction for Use	CE	CE Mark
LOT	Batch Number		Expiry Date		Manufacturing Date
	Do not reuse	2° 30°	Store between 2～30℃		Keep away from Sunlight
	Keep Dry		Manufacturer	EC REP	EU Authorized Representative