3 Analytical specificity

1) Cross Reactivity

Cross reactivity with the following organisms has been studied. Samples positive for the following organisms were found negative when tested with the SARS-CoV-2 Antigen Test.

No.	Type	Pathogens	Concentration
1	Virus	Respiratory syncytial virus Type A	6.4×10^7 PFU/mL
2		Respiratory syncytial virus Type B	2.8×10^6 PFU/mL
3		Novel influenza A H1N1 virus (2009)	1×10^6 PFU/mL
4		Seasonal influenza A H1N1 virus	1×10^5 PFU/mL
5		Influenza A H3N2 virus	1×10^6 PFU/mL
6		Influenza A H5N1 virus	1×10^6 PFU/mL
7		Influenza B Yamagata	1×10^5 PFU/mL
8		Influenza B Victoria	1×10^6 PFU/mL
9		Rhinovirus	1×10^6 PFU/mL
10		Adenovirus 3	5×10^7 PFU/mL
11		Adenovirus 7	2×10^6 PFU/mL
12		EV-A71	1×10^5 PFU/mL
13		Mumps virus	1×10^5 PFU/mL
14		Human coronavirus 229E	1×10^5 PFU/mL
15		Human coronavirus OC43	1×10^5 PFU/mL
16		Human coronavirus NL63	1×10^6 PFU/mL
17		Human coronavirus HKU1	1×10^6 PFU/mL
18		Parainfluenza virus 1	7.3×10^6 PFU/mL
19		Parainfluenza virus 2	1×10^6 PFU/mL
20		Parainfluenza virus 3	5.8×10^6 PFU/mL
21		Parainfluenza virus 4	2.6×10^6 PFU/mL
22	Bacteria	Haemophilus influenzae	5.2×10^6 CFU/mL
23		Streptococcus pyogenes	3.6×10^6 CFU/mL
24		Mycobacterium tuberculosis	1×10^5 CFU/mL
25		Streptococcus pneumoniae	2×10^6 CFU/mL
26		Candida albicans	1×10^7 CFU/mL
27		Bordetella pertussis	1×10^6 CFU/mL
28		Staphylococcus aureus	3×10^7 CFU/mL
29		Legionella pneumophila	1×10^4 CFU/mL
30	Mycoplasma	Mycoplasma pneumoniae	1.2×10^6 CFU/mL
31	Chlamydia	Chlamydia pneumoniae	2.3×10^6 IFU/mL

2) Interfering Substance

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the SARS-CoV-2 Antigen Test at the concentrations listed below and were found not to affect test performance.

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No.	Pathogens	Concentration
1	Human blood (EDTA anticoagulated)	20% (v/v)
2	Mucin	5 mg/mL
3	Pooled human nasal wash	N/A
4	0.9% sodium chloride	20% (v/v)
5	Oseltamivir phosphate	5 mg/mL
6	Ribavirin	5 mg/mL
7	Levofloxacin	5 mg/mL

No.	Pathogens	Concentration
8	Azithromycin	5 mg/mL
9	Meropenem	5 mg/mL
10	Tobramycin	5 mg/mL
11	Phenylephrine	5 mg/mL
12	Oxymetazoline	5 mg/mL
13	A natural soothing ALKALOL	5 mg/mL
14	Beclomethasone	5 mg/mL
15	Hexadecadrol	5 mg/mL

4 Hook Effect

1. There was no hook effect of SARS-CoV-2 Antigen Test at the detection of nasopharyngeal swab samples.
2. No hign does hook effect was observed up to 0.5mg/ml SARS-CoV-2 nucleocapsid protein solution.

Symbols meaning

	IDo not use if package is damaged		Consult instructions for use
CE	CE symbol	EC REP	Authorized representative in the European Community
	Do not re-use	Σ	Tests per kit
REF	Catalogue number	LOT	Batch code
	Manufacturer	STERILE R	Sterilized using irradiation
	Temperature limit(2-30℃)		USE- by date

Manufacturer and EU Representative

Manufacturer: Wuxi Techstar Technology Co.,Ltd
Address: Meiyu Road No.117 Workshop No.2,Meicun Road Street, Xinwu District, Wuxi City, Jiangsu Province, PRC
Tel: +86-510-6851 8058
Website: http://www.tech-star.cn/
E-mail: techstar@tech-star.cn

EC REP **SUNGO Europe B.V.**
ADD: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Contact: SUNGO Secretary
Tel/Fax: +31（0）2021 11106

Version: A/1
Issue date: 2021.03.10

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SARS-CoV-2 Antigen Test

(Colloidal Gold)

techstar CE

[Intend Use]

The product is used for the detection of N protein antigen from SARS-CoV-2 in nasal or saliva form individuals who are suspected of COVID-19. Antigen detection is generally used for the detection of samples in the acute infection period, that is, within 7 days of the onset of symptoms in suspected patients.

The antigen test provides individuals with the option to self-collect and test their nasal or saliva sample. The antigen test can not be used for the diagnosis of COVID-19 alone, but should be combined with nucleic acid test, imaging and other diagnostic information, medical history, contact history to determine the infection status.

[Principle]

SARS-CoV-2 Antigen in human nasal or saliva was determined by colloid gold immunochromatography.

The test card is composed of the following parts: namely sample pad, conjugate pad, nitrocellulose membrane, and absorbing pad. The conjugate pad contains the colloidal gold labeled monoclonal antibody against the nucleocapsid protein of SARS-CoV-2; the nitrocellulose membrane contains the secondary antibody for nucleocapsid protein of SARS-CoV-2 (Test line,T) and goat anti-mouse IgG antibody (Control line,C). When the sample is added into the sample well, conjugates absorbed in the conjugate pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen is present in the sample, the complex of the anti-SARS-CoV-2 conjugate and the SARS-CoV-2 will be captured by the specific anti-SARS-CoV-2 monoclonal antibodies coated on the test region, a red line will appear on the test region (Test line, T), indicating a positive result. If SARS-CoV-2 antigen is absent in the sample, complex cannot be formed in the test region, and no red line appears on the test region (Test line, T), indicating negative result.

No matter whether the samples contain antigens or not, the colloidal gold labeled monoclonal antibody will be captured by the goat anti-mouse IgG antibody in the quality control region (Control line, C), a red line will always appear in the quality control region (Control line, C).

[Constitute]

Cat. No.	SC6h1-01	SC6h3-01	SC6h4-01
Test card	1	1	1
Single extraction reagent	1	1	1
Extraction tube (with dropper)	1	1	1
Nasal swab	1	/	1
Plastic round container	/	1	1
Straw	/	1	1

[Storage conditions and Expiration period]

1.This product is expected to be stored at 2℃~30℃ or 38-83℉.
2.Avoid exposure to sunlight.
3.The test card must be used within one hour if opened.
4.The lot number and expiration date are printed on the packing box.

[How to use]

Please read the instruction carefully before testing. Sample, test reagent and other test material shall be balanced to room temperature, and the test shall be carried out at room temperature.

1 Sample collection

A. Nasal swabs sample collection

1. Using the sterile swab provided in the kit, carefully insert the swab into one nostril of the patient. The swab tip should be inserted up to 2-4 cm until resistance is met.
2. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.
3. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.
4. Withdraw the swab from the nasal cavity. The specimen is now ready for preparation using the extraction reagent provided in the kit. (see Figure 1)

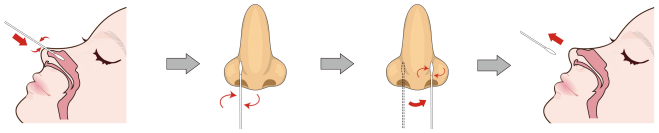

Figure 1

B.Saliva sample collection

1. Rinse your mouth with water 30minutes before sampling, and do not eat, smoke, drink alcohol or drinks after rinsing.
2. Place the tip of tongue against the upper or lower tooth root to enrich saliva, and spit saliva into a plastic container gently until the liquid saliva fills the bottom of the container(no bubbles). (see Figure 2)

Figure 2

2 Sample extraction

A.Nasal swabs sample extraction

1. Open the package of single extraction reagent and pour it into the extraction tube (with dropper) provided in the kit.
2. Insert the swab into the tube, rotating 10 times, hold still for 1 minute .
3. Thoroughly squeeze the swab head several times from the outside to immerse the swab, remove the swab.
4. Cover the dropper onto the reagent tube. (see Figure 3)

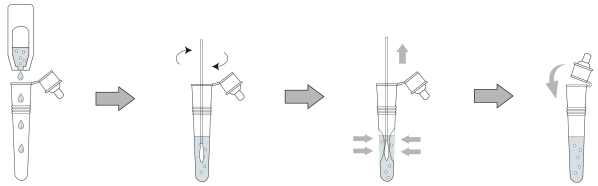

Figure 3

B.Saliva sample extraction

1. Open the package of single extraction reagent and squeeze the bottle to make all extraction reagent into the extraction tube.
2. The collected saliva was sucked to the straw, and 7 drops (about 200μl) was dripped into the solution of the sample extraction tube. Squeeze the extraction tube by hand to blend the liquid.
3. Cover the dropper and wait for inspection. (see Figure 4)

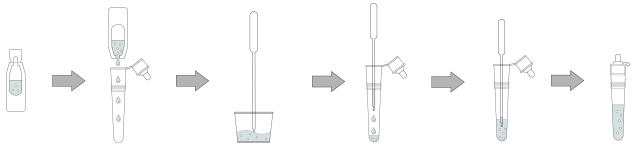

Figure 4

3 Sample testing

1. Open the package and take out the test card,lay it flat.
2. Add 3 drops (about 80μl) swab eluate into the sample well of the test card.
3. Lay it flat, the result will be read at 10-15min, and will be invalid after 20 minutes.(see Figure 5)

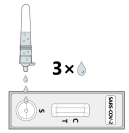

Figure 5

[Determination of test results]

Positive: Two red lines. One red reaction line in the test area (T) and one red reaction line in the control area (C).
Negative: A red line. A red reaction line occurs only in control area (C).
Invalid: When no red line appears in the control area (C), the test is invalid. It is recommended to re-test with a new test card, especially pay attention to whether the sample amount is enough.(see Figure 6)

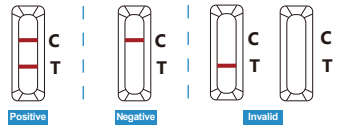

Figure 6

[Precautions]

1. This product is disposable in vitro diagnostic reagent, do not reuse.
2. The product must be used within the validity period.
3. After adding the sample, the test card is always in the horizontal state.
4. The depth of color does not affect the result.
5. Avoid testing in an excessively high temperature environment: the test card stored below room temperature should be restored to room temperature before opening the aluminum foil bag to avoid moisture absorption.
6. It is recommended to use fresh samples instead of repeated freeze-thaw samples.
7. Please use the extraction reagent provided with this reagent to handle the sample. Do not mix different batches of test card and extraction reagent.
8. If the initial screening is positive, please contact your local public health authority.
9. The used swab, test card and extract should be disposed of properly.
10. Do not contact the extraction reagent directly with skin.
11.Do not suck extraction reagent with your mouth.
12.Carefully read this Instructions before starting the procedure.

[Performance Characteristics]

1 Clinical performance

A total of 228 fresh nasal swab samples were detected by RT-PCR assays, which includes 100 positive samples (Ct value≤30) and 128 negative samples. The SARS-CoV-2 Antigen Test results were compared to RT-PCR assays for SARS-CoV-2 in nasal swab samples.

Overall study results are shown in the table below.

Method		PCR		Total Results
	Results	Positive	Negative	
SARS-CoV-2 Antigen Test	Positive	89	2	91
	Negative	11	126	137
Total		100	128	228

Relative Sensitivity: 89.00% (95% CI*: 81.17% to 94.38%)
Relative Specificity: 98.44% (95% CI*: 94.47% to 99.81%)
Accuracy: 94.30% (95%CI*: 90.45% to 96.93%)

* Confidence Intervals

2 Limit of Detection (LOD)

The Limit of Detection of the SARS-CoV-2 Antigen Test is about 1ng/ml SARS-CoV-2 nucleocapsid protein solution.