HUIAN 惠安
Biosci Technology

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

INTENDED USE

The SARS-CoV-2 Antigen Test is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) and nasal (NS) swab, and saliva specimens directly from individuals and is aid in rapid diagnosis of patients with suspected SARS-CoV-2 infection.

FEATURES

- Carefully selected special monoclonal antibody to the nucleocapsid protein antigen from SARS-CoV-2;
- Various specimen applied: Nasopharyngeal (NP) swab, Nasal (NS) swab and Saliva;
- Easy run, easy to interpretation by naked eyes;
- Test result will be present within 15minutes.

PERFORMANCES

- LoD: 1.5×10^2 $TCID_{50}$ for virus lysate, 10pg/mL for recombinant Nucleocapsid protein antigen.
- Compared with NAT method, the specimens with the Ct range between 30-35 will be detectable.
- No cross reactions with various bacteria, viruses and fungi normally available in respiratory track.
- Positive Agreement (95% CI): 30/31 96.8% (83.3% - 99.9%)
- Negative Agreement (95% CI): 80/80 100.0% (95.5% - 100%).

ORDER INFOMATION

Product Name	Type	Cat.No.	Specification	Components		
				Pak. Qty	Sample Tube	Swab
SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	Finished product	REF203-001	1T/Kit	1 T/Bag	0.5ml/vial	1
		REF203-020	20T/Kit	1 T/Bag × 20	0.5ml/vial × 20	20x1
Uncut sheet For SARS-CoV-2 Antigen Test	MP	IP271060	300 × 60mm	20 pcs/Bag	Matched	Customized
		IP271080	300 × 80mm	20 pcs/Bag		
Test Cassette	MP	IP272003	Customized	100 T/Bag		

SHENZHEN HUIAN BIOSCI TECHNOLOGY CO., LTD.
Address: 3f/4f Blk3, hangcheng Hedong Industrial Park, xixiang Baoan District, Shenzhen, guangdong, P.R.China
TEL: +86-755-26433456 FAX: +86-755-26405778
Website: www.huiantech.com Email: info@huiantech.com

CE IVD

Instruction for Use

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

INTENDED USE

The SARS-CoV-2 Antigen Test Kit is a gold immuno-chromatographic assay (GICA) that is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) swab, nasal (NS) swab, and saliva specimens directly from individuals who are suspected of COVID-19 by their healthcare provider.

The SARS-CoV-2 Antigen Test Kit does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

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

The SARS-CoV-2 Antigen Test Kit is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings.

GENERAL INFORMATION

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases. The median incubation time is estimated to be 5.1 days with symptoms expected to be present within 12 days of infection. The symptoms of COVID-19 are similar to other viral respiratory diseases and include fever, cough and shortness of breath.

PRINCIPLE OF THE TEST

The SARS-CoV-2 Antigen Test Kit is a rapid lateral flow immuno-chromatographic sandwich assay to directly detect nucleocapsid protein of SARS-CoV-2 in nasopharyngeal swab, nasal swab and saliva specimens and diagnosis of SARS-CoV-2 infection.

The patient sample is placed in the Sample Tube, during which time the virus particles in the sample are disrupted, exposing internal viral nucleoproteins. After disruption, the sample is added into the Test Cassette sample well. And the sample migrates through a test strip, if the SARS-CoV-2 virus antigen is present, a red color line will be showed on the T line. If SARS-CoV-2 viral antigen is absent, there is not a red line will be showed on the T line, however, a red line will be always showed on the C line indicating that the reaction system is properly happened.

REAGENTS AND MATERIALS PROVIDED

Item	Component	Specification/Qty.	
1	Test Cassette individually foil pouched with a desiccant	REF 203-001	REF 203-020
		1	20
2	Sample Tube, with 0.5 ml sample buffer.	1	20
3	Single packaged nasal swab	1	20
4	Instruction for use	1	1

Materials needed but not provided：

Timer or watch.

Nylon flocked nasopharyngeal swab.

Vortex

1.0-mL Calibrated Micropipette with pipette tips

PRECAUTIONS

1. For in vitro diagnostic use only.

2. Please read this manual carefully prior to using this test kit. And follow the testing procedures strictly described in the manual, otherwise it will lead to incorrect results.

3. Do not use expired reagents.

4. Do not re-use the test kit.

5. All throat swab samples, used reagents, test cards, and other materials used during testing are considered to be infectious, and personal protection should be done during the experiment.

6. Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples. Wear suitable protective clothing and eye/face protection when handling the contents of this kit.

7. Sample handling and waste disposal must comply with relevant regulations. Wash hands thoroughly after handling.

8. Avoid using visually bloody or overly viscous samples for testing.

8. Do not use components from different batch lots.

9. The sample tube contains a salt solution. If the solution contacts the skin or eye, flush with copious amounts of water.

10. Sample collection and handling procedures require specific training and guidance.

STORAGE AND STABILITY

1. The test device is sensitive to humidity as well as to heat.

2. Store kit components at 2-30°C, out of direct sunlight. Kit components are stable until the expiration date printed on the outer box.

3. After unsealing the aluminum foil bag, the test cassette should be used as soon as possible within **Two hours**.

4. Do not freeze.

SPECIMEN COLLECTION AND PREPARATION

Test specimens immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) ***https://www.cdc.gov/coronavirus/2019- nCoV/lab/guidelines-clinical-specimens.html.***

1. Nasal swab:

To collect a nasal swab sample, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, rotate the swab against the wall of the nostril into the patient's nostril to the nasal palate, and then slowly remove it while wiping.

2. Nasopharyngeal swab:

To collect a nasopharyngeal swab sample, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab several times then remove it from the nasopharynx.

3. Saliva

Collect the saliva specimen 1-2 ml using a clean collecting cup, then take 1ml saliva sample into the sample tube.

SAMPLE TRANSPORT AND STORAGE

Samples should be tested as soon as possible after collection. The nasal or nasopharyngeal swabs are stable for up to 24 hrs at room temperature or 2- 8°C.

If the samples are needed for transporting with CDC media / viral transport medium (VTM), minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity. Nasal or nasopharyngeal swabs in CDC media or in VTM are stable for up to 72 hrs at 2- 8°C.

TEST PROCEDURE

Please read the instructions for use carefully before testing, and complete the test in strict accordance with the directions of the manual, otherwise reliable results cannot be guaranteed.

- Open the aluminum foil bag, put the test cassette on a clean, horizontal bench.
- Bring the samples to room temperature prior to assay in case of the samples were stored at 2- 8°C.

Swab Test Procedure (Nasal/Nasopharyngeal):

1. Place the swab into the sample tube that has been pre-filled with 0.5 ml sample buffer, rotate the swab for about 10 seconds, and press the swab applicator against the tube wall to release the antigen in the swab.

2. Roll the swab applicator against the inside of the sample tube as you remove it. Dispose of the used swab in a biohazard waste following the local government regulations.

3. Install the dropper cap onto the sample tube, add two drops of the extraction solution into the sample well and start the timer.

Saliva Test Procedure:

1. Transfer 0.5ml saliva specimen into the sample tube, vortex to extract the viral antigen in the specimen.

2. Install the dropper cap onto the sample tube, add two drops of the extraction solution into the sample well and start the timer.

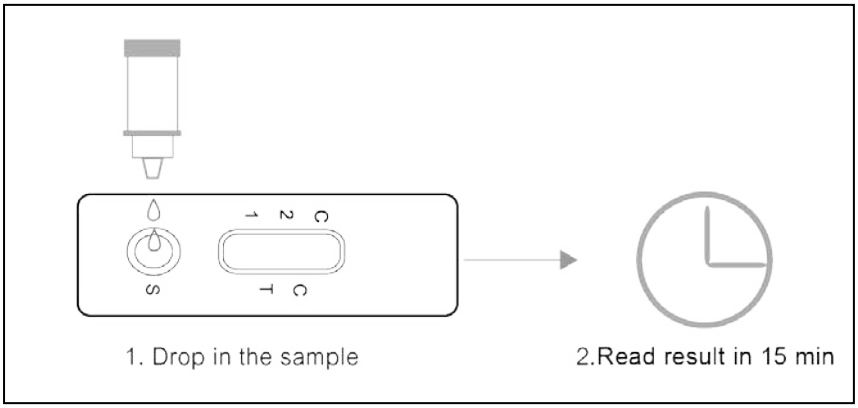
CDC Media/ Viral Transport Media Test Procedure:

1. Vortexing the sample tube containing the specimen in CDC media / VTM for a short time (about 5-10 seconds).

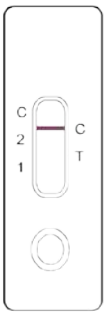
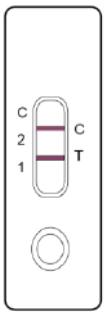
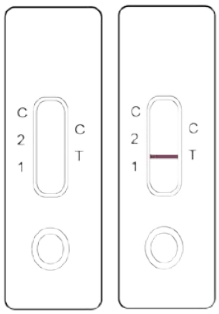
2. Take 60-80 μL of patient sample from the sample tube containing the specimen.

3. Adding the specimen into the test cassette sample well and start the timer.

- Read the results within 15 minutes, and the results after 15 minutes are invalid.



INTERPRETATION OF TEST RESULTS

Negative result	Positive result	Invalid result
		

1. Positive: A red line appears on the test line (T) and the control line (C).

NOTE: A positive result does not rule out co-infections with other pathogens.

2. Negative:

Only the control line (C) appears, and no red line appears on the test line (T).

NOTE: A negative result does not exclude infection.

3. Invalid:

There is no red line at the position of the control line (C). Regardless of whether the TEST line (T) is displayed, it is an invalid result and the sample should be tested again.

PERFORMANCES

LoD:

The LoD of the test kit is 10 pg/ml for detection with recombinant SARS-CoV-2 nucleocapsid protein and is 1.5×10^2 $TCID_{50}$ with inactive viral culture.

The Negative Percent Agreement (NPA):

The NPA of the test kit should be 20/20 (-/-) using an internal negative reference panel.

The Positive Percent Agreement (PPA):

The PPA of the test kit should be 8/8 (+/+) using an internal positive reference panel.

Repeatability:

The repeatability of the test kit should be tested using same batch number, and all of the test results should be positive, and the T lines have even intensities.

ANALYTICAL PERFORMANCE

Limit of Detection (LoD)

The limit of detection (LoD) of SARS-CoV-2 Antigen Test Kit was determined by evaluating different concentrations of inactivated SARS-CoV-2 virus from viral cell culture and of recombinant nucleocapsid protein (rNp). Tested nasal swab samples were prepared by absorbing 20 ul of each virus or rNp dilution onto the swab. The swab samples were tested according to the test procedure.

The LoD was determined as the lowest virus concentration that was detected ≥ 95% of the time (i.e.,

concentration at which at least 19 out of 20 replicates tested positive).

The LoD of the test kit in nasal swab was confirmed as 1.5 x 10^2 $TCID_{50}$/swab and 10 ng/ml of rNp.

LoD Test Results

Concentration	Number Positive/Total	Detected Percentage (%)
1.5 x 10^2 $TCID_{50}$/Swab	20/20	100%
10 pg/ml	19/20	95%

High Dose Hook Effect

No high dose hook effect was observed when tested with up to a concentration of 1.0x 10^5 $TCID_{50}$/ml of inactivated SARS-CoV-2 virus with the test kit.

Cross Reactivity

Cross reactivity of SARS-CoV-2 Antigen Test Kit was evaluated by testing normal respiratory track pathogenic microorganisms (bacteria, viruses, yeast) and a pooled human nasal wash that may be present in the nasal cavity. Each of the bacteria, viruses, and yeast were tested in duplicate in the absence or presence of heat inactivated SARS-CoV-2 virus (1.5 x 10^2 $TCID_{50}$/swab). No cross-reactivity or interference came out of these tests when tested at the concentration listed below.

Potential Cross-Reactant		Test Concentration
Virus	Respiratory Syncytial Virus A	1.0 x 10^5 PFU/mL
	Measles Virus	1.0 x 10^5 TCID50/mL
	Mumps Virus	1.0 x 10^5 TCID50/mL
	Adenovirus Type 3	1.0 x 10^5 TCID50/mL
	Parainfluenza Type 2	1.0 x 10^5 TCID50/mL
	Partial Pulmonary Virus	1.0 x 10^5 TCID50/mL
	Human coronavirus OC43	1.0 x 10^5 TCID50/mL
	Human coronavirus 229E	1.0 x 10^5 TCID50/mL
	Influenza B (Victoria Strain)	1.0 x 10^5 TCID50/mL
	Influenza B (Y Strain)	1.0 x 10^5 TCID50/mL
	Influenza A (H1N1,2009)	1.0 x 10^5 TCID50/mL
	Influenza A (H3N2)	1.0 x 10^5 TCID50/mL
	Avian Influenza Virus H7N9	1.0 x 10^5 TCID50/mL
	Avian Influenza Virus H5N1	1.0 x 10^5 TCID50/mL
	Epstein Barr Virus	1.0 x 10^5 TCID50/mL
	Enterovirus CA16	1.0 x 10^5 TCID50/mL
	Rhinovirus	1.0 x 10^5 PFU/mL

Bacteria	*Staphylococcus aureus*	1.0 x 10^6 CFU/mL
	Streptococcus pneumoniae	1.0 x 10^6 CFU/mL
	Mycoplasma pneumoniae	1.0 x 10^6 IFU/mL
	Parapertussis	1.0 x 10^6 cells/mL
	Chlamydia pneumoniae	1.0 x 10^6 IFU/mL
	Pooled human nasal wash	N/A
Yeast	*Candida albicans*	1.0 x 10^6 cells/mL

CLINICAL PERFORMANCES

The clinical performance characteristics of SARS-CoV-2 Antigen Test Kit was evaluated with 31 nasal swabs collected from individual symptomatic patients who were suspected of COVID-19 and 80 nasal swabs collected from persons who were no contact risk for COVI . An CE marked real-time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2 was used as the comparator method for this study.

SARS-CoV-2 Antigen Test Kit Performance against the NAT Method

SARS-CoV-2 Antigen Test Kit	**Comparator Method (NTA)**		
	Positive	**Negative**	**Total**
Positive	30	0	30
Negative	1	80	81
Total	31	80	111
Positive Agreement (95% CI): 30/31	96.8% (83.3% - 99.9%)		
Negative Agreement (95% CI): 80/80	100.0% (95.5% - 100%)		

The data below is for understanding information refer to NAT cycle threshold (Ct):

The performance of SARS-CoV-2 Antigen Test Kit with positive results stratified by the NAT method Ct counts were assessed to more understand the correlation of assay performance to the NAT Ct value, estimating the viral amount present in the clinical sample. As showed in the following table, the positive agreement of the SARS-CoV-2 Antigen Test Kit is higher with samples of a Ct count <33.

Performance against the NTA Method – by Ct Counts

SARS-CoV-2 Antigen Test Kit	NAT Method (Ct)	
	POS (Ct < 33)	POS (Ct ≥ 33)
Positive	23	7
Negative	0	1
Total	23	8
Positive Agreement (95% CI)	100.0 (88.1, 100.0)	87.5 (47.4, 99.7)

Endogenous Interfering Substances

The following interfering substances, that may be introduced into the nasal cavity or nasopharynx, were evaluated with the SARS-CoV-2 Antigen Test Kit at the concentrations listed below and were no affect to the performance of the test kit.

Substance	Active Ingredient	Concentration
Endogenous	Whole Blood	1.2 % v/v
	Mucin	2.0 % w/v
Nasal Drops	Sodium Chloride	5% v/v
Nasal Spray	Fluticasone Propionate	0.3 ng/mL
	Gluconic Acid Zinc	5 % w/v
	Fluconazole	5 % w/v
	Oxymetazoline	12 % v/v
	Cromolyn	15 % v/v
Sore Throat Phenol Spray	Phenol	15 % v/v
Throat Lozenge	Benzocaine, Menthol	0.15% w/v
Anti-viral Drug	Tamiflu (Oseltamivir Phosphate)	1.3 mg/mL
	Ribavirin	12.9 mg/mL
Antibacterial, Systemic	Tobramycin	4.0 ug/mL

LIMITATIONS

1. This test is for in vitro diagnostic use only.
2. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
3. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
4. Test results must be evaluated in conjunction with other clinical data available to the physician.
5. This test cannot distinguish between asymptomatic carriers and infected persons of the SARS-CoV-2.
6. A false negative result may be obtained if the concentration of the viral antigen in the nasopharyngeal and nasal swab is below the sensitivity.
7. Negative results should be treated as presumptive and confirmed with an approved molecular assay.
8. Clinical performance was evaluated with frozen samples, and performance may be different with fresh samples.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on DVST Kit are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2016.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Instructions for use		Batch code
	Temperature limitation		*In vitro* diagnostic medical device
	CE Symbol		Authorized representative in the European Community
	Catalogue number		Do not use if package is damaged

CONTACT

Manufacturer: Shenzhen Huian Biosci Technology Co., Ltd.
Address: 3F/4F BLK3,Hangcheng Hedong Industrial Park, Xixiang, Baoan District, Shenzhen, Guangdong, P.R.China
Contact Number: +86 755 26433456 **Website:** www.huiantech.com

EC Representative
SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

CE

DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer:	SHENZHEN HUIAN BIOSCI TECHNOLOGY CO., LTD.
Address:	3F/4F BLK3,HANGCHENG HEDONG INDUSTRIAL PARK, XIXIANG, BAOAN DISTRICT, SHENZHEN, GUANGDONG, P.R.CHINA
EC Representative:	SUNGO Europe B.V.
Address:	Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name:	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)
Specification:	REF 203-001: 1T/Kit, REF 203-020: 20T/Kit
Classification:	Others (IVDD)
Conformity Assessment Procedure:	Annex III of In Vitro Diagnostic Directive (98/79/EC)

We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2012 EN ISO 18113-2:2011

EN ISO 18113-1:2011

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Signature:

Name/ Position: Gao Xiang / GM

Sungo global service

Authorized Signature (S)

Date: 2020.09.18

Place: Shenzhen / China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Shenzhen Huian Biosci Technology Co.,Ltd.
Address:3F/4F, BLK3, Hangcheng Hedong Industrial Park,
Baoan District, Shenzhen,Guangdong, P.R.CHINA.
Tel: +86-755-2643 3456 E-mail: info@huiantech.com
EC REP
SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands.
REF 203-020
Sampling Tube
10 Tube/Bag
LOT:200401 EXP:20210413
Specimen Collection Swab
Number: 20
LOT:20200518
MFG:20200518
EXP:20230517
SARS-CoV-2 Antigen Test Cassette