SARS-CoV-2 Antigen Rapid Test

(Colloidal Gold Method)

Instructions for Use

CE

IVD

For in vitro diagnostic use only
Store at 2°C -30°C

CONTENT

1. INTENDED USE

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease caused by SARS-CoV-2. 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 genome of coronavirus encodes spike protein, envelope protein, membrane protein and nucleocapsid. In the process of viral assembly, N protein binds to viral RNA and leads to the formation of spiral nucleocapsid. N protein is a highly immunogenic phosphoprotein, which is related to viral genome replication and cell signaling. Because of the conserved sequence of N protein, detection of SARS-CoV-2 N protein is of great clinical significance.

This rapid kit is used for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigen (hereinafter referred to as SARS-CoV-2 N-antigen) in anterior nasal swab samples.

2. TEST PRINCIPLE

This rapid kit is based on the Colloidal Gold Method to detect SARS-CoV-2 N-antigen.

The SARS-CoV-2 N-antigen in the sample forms a complex with the antibody labeled with colloidal gold. This complex migrates along the membrane and reaches the test region (T-line) on which a second antibody against the SARS-CoV-2 N-antigen is applied. Unbound colloidal gold migrate along the membrane to the control region (C-line) and are bound by the control region antibody. If both the T-line and the C-line are red, the test result is SARS-CoV-2 N-antigen positive; if only the C-line is red and no T-line becomes visible, the test result is SARS-CoV-2 N-antigen negative. If no C-line becomes visible, the test result is invalid and the sample must be retested with a new test cassette.

3. KIT COMPONENTS

Note: This kit comes in packs of 5 or 25 tests. The number of items in the kit supplied will depend on which pack is purchased.

5 Test-Kit:

- 5 Test Cassettes
- 1 Instructions for Use
- 5 Swabs
- 1 Extraction Buffer (2 mL)
- 5 Extraction Vials with Caps
- 1 tube rack

25 Test-Kit:

- 25 Test Cassettes
- 1 Instructions for Use
- 25 Swabs
- 2 Extraction Buffer (2 mL)
- 25 Extraction

- 1 tube rack

4. WARNINGS AND PRECAUTIONS

4.1. Samples should be considered as potentially infectious. Operators should wear protective clothing, masks, gloves and are advised to take other appropriate safety precautions to avoid or reduce the risk of infection.

4.2. This test should be performed at 18-30°C. The test and samples must be brought to room temperature before testing.

4.3. Follow the Instructions for Use carefully. The accuracy of the assay results cannot be guaranteed if there is any deviation from the instructions for Use.

4.4. Operators and users must handle the potentially contaminated materials safely according to local requirements.

4.5. Use a new clean disposable pipette/extraction vial for each sample to avoid cross contamination.

4.6. Although the test kit uses detergents in the extraction buffer which neutralize SARS-CoV-2, operators should dispose of all samples and materials as if they were infectious waste in a biohazard waste container. Users can dispose the components in the house-hold waste in accordance with local guidelines and should inform themselves on local regulations on garbage disposal.

4.7. Once the test cassette is removed from the pouch, perform the test as soon as possible to avoid being humidified. The test cassette is sensitive to humidity as well as to heat.

4.8. Do not use the test cassette if the pouch is damaged or if the seal is broken.

4.9. The test cassette cannot be reused.

5. STORAGE CONDITIONS AND SHELF LIFE

The test can be stored at 2 °C to 30 °C for 15 months from the date of manufacture.

The test cassette inside the foil bag shall be used within 1 hour after opening.

6. APPLICABLE INSTRUMENT

None.

7. SAMPLE REQUIREMENTS

7.1. Applicable to Anterior-Nasal swab samples.

7.2. It is recommended that the samples are tested at the time of sample collection.

7.3. If not tested immediately, swab samples should be stored in a dry and clean tube tightly sealed.

7.4. The swabs can be stored at 2-8 °C for 24 hours.

8. MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

9. COLLECTION OF NASAL SWAB SAMPLES

9.1. The test can be performed according to the standard nasal swab collection procedure.

9.2. Nasal sample collection:

(1) Remove the Swab from the pouch and hold with the handle only. Do not touch the swab tip.

(2) Gently insert the swab up to 1/2 to 3/4 of an inch (1 to 2 cm) into the nostril of the patient. Roll the swab around the inside wall of nostril at least 4 times.

(3) Repeat swab step for the other nostril with the same swab to ensure adequate sample is collecte

9.3. It is recommended that the sample is tested at the time of sample collection.

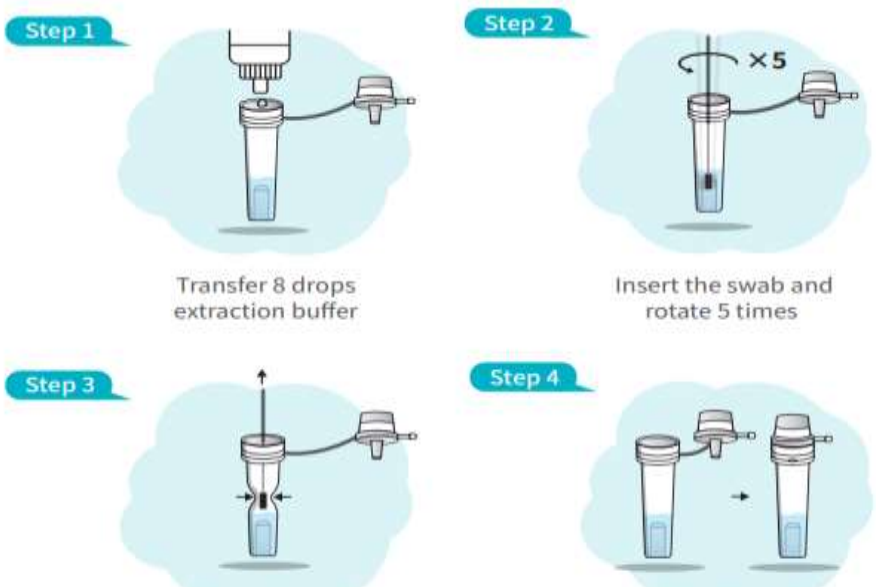
10. TEST PROCEDURE FOR NASAL SWAB SAMPLES

Step 1: Transfer 8 drops of extraction buffer to the extraction vial. The kit includes a convenient tube rack: 5 test-kit, use the perforations of box holding the extraction tubes: 25 test-kit use the perforations of the box holding the swabs.

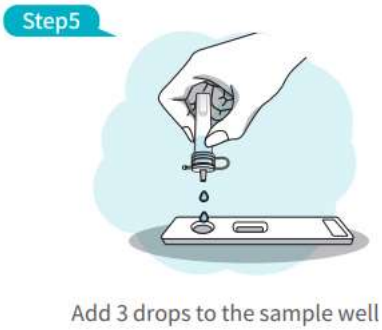
Step 2: Insert the swab into the extraction vial. Rotate the swab 5 times and squeeze the sides of the extraction vial to mix the sample in the buffer.

Step 3: Remove the swab while squeezing the sides of the extraction vial to extract the liquid from the swab as much as possible. Discard the swab.

Step 4: Place the filter cap on the extraction tube and press firmly so that the cap sits tightly in the extraction vial.



Step 5: Place the test cassette on a flat surface. Apply 3 drops of extracted sample to the sample well of the test cassette. Dispense the sample at 90-degree angle to avoid bubbles.



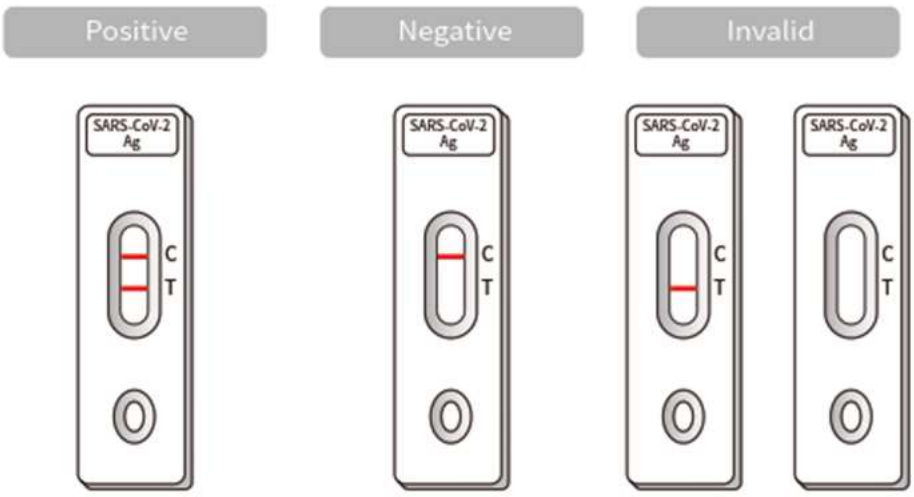
Step 6: After 15 minutes of development time, observe the result window for the result. Dispose of all materials in the intended disposal for infectious material in the laboratory or in the household trash in accordance with local guidelines.

11. INTERPRETATION OF RESULTS

11.1 If a visible band appears in the detection area(T) and the control region (C) at same time, the test is SARS-CoV-2-N-protein positive, there is an acute possibility of COVID-19 infection. Please consult a physician or your local health authorities and follow up with a confirmatory test with PCR. Please also follow the instructions of the locally applicable regulation for self-isolation.

If a band becomes visible in the control region(C), and no visible band in the detection area(T), the test is SARS-CoV-2-N-proteinis negative. Please continue to obey local regulations on contact and protective measures. A negative result may not rule out an infection. In case of suspected infection, repeat the test after 1 to 2 day as the SARS-CoV-2 virus may not be detected in all phases of an infection.

If there is no visible band in the control region(C), regardless of whether there is a band visible to in the detection area(T), the test result is invalid. This may have been a result to faulty test procedure. Please repeat the test. Following a second invalid result, please contact a physician or a COVID-19 test center.



11.2. Due to the complex structure of bioactive substances in samples and the difference of antigen antibody specificity, the possibility of false positive results cannot be completely ruled out when using this kit. If the test results are inconsistent with the clinical indications, other appropriate test methods should be used for confirmation.

11.3. The test results of this kit are only used as the basis of auxiliary diagnosis. Clinical diagnosis should be combined with clinical symptoms and other diagnostic methods.

12. LIMITATIONS

12.1. The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage or repeated freezing and thawing of the sample may affect the test result.

12.2. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.

12.3. The performance of SARS-CoV-2 Antigen Rapid Test was evaluated using the procedures provided in the product insert only. Modifications to these procedures may alter the performance of the test.

12.4. False negative results may occur if swabs are stored in their paper sheath after Specimen collection.

12.5. Positive test results do not rule out co-infections with other pathogens.

12.6. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.

12.7. Swab sample after heat inactivation may affect the accuracy of the detection and may lead to erroneous results.

13. PERFORMANCE CHARACTERISTICS

13.1. Limit of Detection

13.1.1 Method

The SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method) limit of detection (LoD) for SARS-CoV-2 was determined by evaluating different concentrations of heat inactivated viruses and recombinant N protein, respectively. Natural nasal swab specimens were collected from healthy donors and confirmed negative for PCR test and were eluted in PBS. Swab elutes were combined and mixed thoroughly to create a negative clinical matrix pool to be used as the diluent. Inactivated SARS-CoV-2 virus and recombinant N protein were diluted in this natural nasal swab matrix pool to generate virus and recombinant N protein dilutions, respectively, for testing. Contrived nasal swab samples were prepared by adding 50µL of each virus dilution onto the sterile swab. The nasal swab samples were tested according to the test procedure in the Instructions for

Use.

13.1.2 LoD Screening

(1) LoD Screening of Recombinant N protein

The recombinant N protein was added to the natural nasal swab matrix pool to obtain samples with concentrations of 200 pg/mL, 100 pg/mL, 50 pg/mL, 25 pg/mL and 10 pg/mL. Each sample was tested five times. The lowest concentration demonstrating 5 of 5 positives was chosen for LoD. Based on this testing, the concentration chosen was of 50 pg/mL.

Test Concentration (pg/mL)	Test Cycles	Test Result
200	5	5/5 Positive
100	5	5/5 Positive
50	5	5/5 Positive
25	5	1/5 Positive
10	5	0/5 Positive

(2) LoD Screening of SARS-CoV-2 virus

The SARS-CoV-2 virus (IVCAS 6.7512) was propagated and titrated in Vero E6 cell lines (ATCC CRL-1586). SARS-CoV-2 stock solution (2.0×10^4 $TCID_{50}$/mL) (IVCAS 6.7512) that had been inactivated at 56℃ for 30 minutes was diluted to 2000 $TCID_{50}$/mL, 1000 $TCID_{50}$/mL, 200 $TCID_{50}$/mL, 100 $TCID_{50}$/ mL and 50 $TCID_{50}$/mL nasal swab samples extracts. Each sample was tested five times. The lowest concentration demonstrating 5 of 5 positives was chosen for LoD. Based on this testing, the concentration chosen was of 200 $TCID_{50}$/mL.

Test Concentration ($TCID_{50}$/mL)	Test Cycles	Test Result
20000	5	5/5 Positive
2000	5	5/5 Positive
1000	5	5/5 Positive
200	5	5/5 Positive
100	5	1/5 Positive
50	5	0/5 Positive

13.1.3 LoD Confirmation

(1) LoD Confirmation of Recombinant N protein

The nasal swab sample extract concentration of 50 pg/mL was tested twenty times to confirm. Twenty (20) of twenty (20) results were positive. Based on this testing, the LoD was confirmed to be 50 pg/mL.

(2) LoD Confirmation of SARS-CoV-2 virus

The nasal swab sample extract concentration of 200 $TCID_{50}$/mL was tested twenty times to confirm. Twenty (20) of twenty (20) results were positive. Based on this testing,

the LoD was confirmed to be 200 $TCID_{50}$/mL.

13.2. **Cross-reactivity Studies**

Cross-reactivity of SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method) was evaluated by testing a panel of high prevalence respiratory pathogens that could potentially cross-react with SARS-CoV-2 Antigen Rapid Test Kit in a negative sample. Each organism and virus were tested in triplicate. Results do not show any cross reactivity with the below listed microbial substances:

Microbial Substance	Test Concentration	Cross-reactivity (Yes/No)
Escherichia coli	1.0×10^6 CFU/mL	No
Hepatitis C Virus (HCV)	1.12×10^5 pfu/mL	No
Hepatitis B Virus (HBV)	1.54×10^5 pfu/mL	No
Influenza B	$0.7\times10^{6.67}$ pfu/mL	No
Influenza A	$1.05\times10^{5.67}$ pfu/mL	No
Herpes Simplex Virus-1 (HSV-1)	1.12×10^5 pfu/mL	No
Herpes Simplex Virus-2 (HSV-2)	1.47×10^5 pfu/mL	No
Human Immunodeficiency Virus – 1 (HIV-1)	2.24×10^5 pfu/mL	No
Enterovirus	2.52×10^5 pfu/mL	No
Staphylococcus epidermidis	1.0×10^6 CFU/mL	No
Legionella pneumophila	3.5×10^6 CFU/mL	No
Chlamydia pneumoniae	1.7×10^6 CFU/mL	No
Mycoplasma pneumoniae	1.5×10^6 CFU/mL	No
Parainfluenza virus	1.26×10^5 pfu/mL	No
Respiratory syncytial virus	1.47×10^5 pfu/mL	No
Adenovirus	1.19×10^5 pfu/mL	No
Cytomegalovirus (CMV)	1.4×10^5 pfu/mL	No
Epstein-Barr Virus (EBV)	1.33×10^5 pfu/mL	No
Varicella Zoster Virus (VZV)	1.05×10^5 pfu/mL	No
Parvovirus B19	1.05×10^5 pfu/mL	No
Streptococcus pneumoniae	1.0×10^6 CFU/mL	No
Streptococcus pyogenes	1.6×10^6 CFU/mL	No
Staphylococcus aureus	1.2×10^6 CFU/mL	No
Human coronavirus 229E	1.26×10^5 pfu/mL	No
Human coronavirus OC43	1.05×10^5 pfu/mL	No
Human coronavirus (NL63)	1.47×10^5 pfu/mL	No
MERS	1.61×10^5 pfu/mL	No

13.3. **Interference Studies**

13.3.1. Endogenous Interference Substances Studies

Endogenous Interference of SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method) was evaluated by testing a panel of high prevalence respiratory pathogens that could potentially endogenous interference-react with SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method) in a negative and a 3x LoD sample. Each organism and virus were tested in triplicate. The endogenous interference substances listed below do not interfere with the test results of the SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method):

Interfering Substance	**Concentration**	**Endogenous Interference (Yes/No)**
Whole Blood	4%	No
Menthol	1.5 mg/mL	No
Naso GEL (NeilMed)	5% v/v	No
CVS Nasal Drops (Phenylephrine)	15% v/v	No
Afrin (Oxymetazoline)	15% v/v	No
CVS Nasal Spray (Cromolyn)	15% v/v	No
Zicam	5% v/v	No
Sore Throat Phenol Spray	15% v/v	No
Tobramycin	4 µg/mL	No
Fluticasone Propionate	5% v/v	No
Mucin	2% w/v	No
Homeopathic (Alkalol)	10% v/v	No
Mupirocin	10 mg/mL	No
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No

13.3.2. Microbial Interference Studies

Microbial Interference of SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method) was evaluated by testing a panel of high prevalence respiratory pathogens that could potentially microbial interference-react with SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method) in a 3 x LoD sample. Each organism and virus were tested in triplicate. The following pathogens had no influence on the test results on SARS-CoV-2 antigen positive samples in the tested concentration:

Microbial Interfering Substance	**Test Concentration**	**Interference (Yes/No)**
Escherichia coli	1.0×10^{6} CFU/mL	No
Hepatitis C Virus (HCV)	1.12×10^{5} pfu/mL	No
Hepatitis B Virus (HBV)	1.54×10^{5} pfu/mL	No
Influenza B	$0.7\times10^{6.67}$ pfu/mL	No
Influenza A	$1.05\times10^{5.67}$ pfu/mL	No
Herpes Simplex Virus-1 (HSV-1)	1.12×10^{5} pfu/mL	No
Herpes Simplex Virus-2 (HSV-2)	1.47×10^{5} pfu/mL	No

Human Immunodeficiency Virus – 1 (HIV-1)	2.24×10^5 pfu/mL	No
Enterovirus	2.52×10^5 pfu/mL	No
Staphylococcus epidermidis	1.0×10^6 CFU/mL	No
Legionella pneumophila	3.5×10^6 CFU/mL	No
Chlamydia pneumoniae	1.7×10^6 CFU/mL	No
Mycoplasma pneumoniae	1.5×10^6 CFU/mL	No
Parainfluenza virus	1.26×10^5 pfu/mL	No
Respiratory syncytial virus	1.47×10^5 pfu/mL	No
Adenovirus	1.19×10^5 pfu/mL	No
HAMA	1.4×10^5 pfu/mL	No
Cytomegalovirus (CMV)	1.33×10^5 pfu/mL	No
Epstein-Barr Virus (EBV)	1.05×10^5 pfu/mL	No
Varicella Zoster Virus (VZV)	1.05×10^5 pfu/mL	No
Parvovirus B19	1.0×10^6 CFU/mL	No
Streptococcus pneumoniae	1.6×10^6 CFU/mL	No
Streptococcus pyogenes	1.2×10^6 CFU/mL	No
Staphylococcus aureus	1.26×10^5 pfu/mL	No
Human coronavirus 229E	1.05×10^5 pfu/mL	No
Human coronavirus OC43	1.47×10^5 pfu/mL	No
Human coronavirus (NL63)	1.61×10^5 pfu/mL	No
MERS	1.0×10^6 CFU/mL	No

13.4. **Hook Effect**

No high dose Hook effect was observed when tested with a concentration of $2.0x10^6$ $TCID_{50}$/mL of heat inactivated SARS-CoV-2 virus.

13.5. **Clinical Evaluation**

The sensitivity of the test was determined with 129 PCR confirmed positive nasal swab samples. The specificity was determined with 196 PCR confirmed negative swab samples. The sensitivity and specificity of the test was compared to a commercial PCR test. A sensitivity of 96.12% and a specificity of 99.49% were determined for the SARS-CoV-2 Antigen Rapid Test.

		PCR results	
		Positive	**Negative**
SARS-CoV-2 Antigen Rapid Test	Positive	124	1
	Negative	5	195
	Total	129	196

Sensitivity	96.1% (95CI: 91.19%~98.73%)
Specificity	99.5% (95CI: 97.19%~99.99%)

14.PROCEDURAL NOTES

14.1. Read the Instructions for Use carefully before performing the test.

14.2. Testing needs to be performed under proper testing conditions.

14.3. Protect the test cassette from moisture.

14.4. All reagents and samples should reach room temperature before use.

14.5. Do not use turbid or contaminated samples.

15. EXPLANATION OF THE SYMBOLS USED

	In vitro diagnostic medical device
	Catalogue Number
	Batch Code
	Manufacturer
	Date of Manufacture
	Use by date
	Do Not Use if Package is Damaged
	Consult Instructions for Use
	Temperature Limit at 2°C~30°C.
	Sufficient content for 5 or 25 Cassettes (Tests)
	Do Not Re-use
	Caution
	Keep Dry

16.GENERAL INFORMATION

Applicant/ Manufacturer

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