SARS-CoV-2 Spike Protein Test Kit Ref.: COVG-010
Qualitative Determination of Coronavirus Spike protein 25 tests
Only for *in vitro* use in clinical laboratory
Store at 2-30ºC

SARS-CoV-2

CE

INTRODUCTION

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.

PRINCIPLE OF THE METHOD

The novel Coronavirus ((SARS-CoV-2) Spike Protein in population throat swab and nose swab samples is qualitatively detected by colloidal gold method. After blending population throat swabs and nose swabs, the novel Coronavirus (SARS-CoV-2) Spike Protein in the sample to be tested is combined with the novel coronavirus (SARS-CoV-2) antibody labeled with colloidal gold on the binding pad to form SARS-CoV-2 Spike Protein-SARS-CoV-2 antibody-colloidal gold complex. Due to chromatography, the SARS-CoV-2 Spike Protein-SARS-CoV-2 antibody-colloidal gold complex diffuses along the nitrocellulose's membrane. Within the detection line area, the SARS-CoV-2 Spike Protein-antibody complex binds to the antibody enclosed within the detection line area, showing a purple-red band. Colloidal gold labeled SARS-CoV-2 antibody diffused to the quality control line (C) region and is captured by sheep anti-mouse IgG to form red bands. When the reaction is over, the results can be judged by visual observation.

COMPONENTS

Component	Quantity	Description
Test card	25 card tests	Each test card is mainly composed of a plastic shell and a test strip. The main part of the test strip is coated with SARS-CoV-2 antibody, combined with SARS-CoV-2 antibody coated with colloidal gold, and other components include polyester film, blood filter film and absorbent paper.
Sample treatment solution	1 vial	Normal saline solution 10 mL per tube
IFU	1 copy	
Sterile Nasal Swabs	25 units	
Extraction tubes + droppers	25 units	

ADDITIONAL EQUIPMENT (NOT PROVIDED)

- Timer

NOTES

Various components of different batch of reagents cannot be used interchangeably to avoid wrong results.

STORAGE AND STABILITY

Test kit store at 2-30℃ in dry place and protect from light.
Test kit is valid for 12 months.

SAMPLES

1. Sample collection

Oropharyngeal swab collection method:

1. Tip the patient's head slightly.
2. Instruct the patent to open mouth as wide as possibly to reveal the pharyngeal tonsils on either side.
3. Wipe the base of patient's tongue with swab.
4. Slightly rub the pharyngeal tonsils back and forth on both sides of the collected subjects at least 3 times.
5. Rub the posterior pharyngeal wall up and down at least 3 times.
6. Test the sample as soon as possible

Nasopharyngeal swab collection method:

1. Tip the patient's head back and collect sample from the nostril that has more mucus (head should be inclined from vertical for proper specimen collection).
2. Insert the swab through the nostril entry and then slowly move along the bottom of the nasal cavity (Move gently to avoid traumatic bleeding).
3. When the tip of the swab reaches the posterior wall of the nasopharyngeal cavity, gently rotate it several times. (Collect as much secretion as possible)
4. To prevent reflex coughing, stop for one minute.
5. Slowly remove the swab.
6. Test the sample as soon as possible

2. Sample treatment

2.1. Swab samples:

1. Add 300μL sample treatment solution to the extraction tubes and dip the swab into the sample treatment solution to make the sample treatment solution fully permeate the swab.
2. Rotate and squeeze the swab 10 times, then remove the swab and load the dropper for sample testing.

2.2. CDC Media/Viral Transport Media:

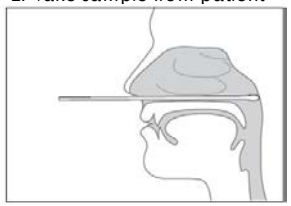
1. Mix the specimen received in viral transport media by shaking the tubes in circles for 5 seconds, then add 100μL sample treatment solution to the extraction tubes
2. Fill a calibrated micropipette with 100μL of patient sample from the viral transport media. Then empty the contents of the micropipette into the extraction tubes and load the dropper for sample testing.

DETECTION METHOD

Before testing, the user must read the operating instructions completely, and restore the testing kit and samples to room temperature (20-25℃) before using.
Tears open the foil bag, take out the test card, and use it as soon as possible within 1 hour.

PROCEDURE

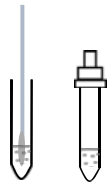
1. Take sample from patient



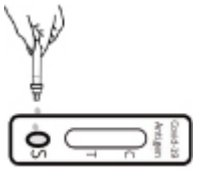
2. Add 300 μL sample treatment solution to the tube

3. Squeeze the tube and rotate the swab 10 times

4. Remove the swab and load the dropper lid



5. Add 2 drops (About 50 μL) of sample to the sample hole, then wait for 15 minutes of reaction at room temperature.



The test card is kept at room temperature for 15 minutes to observe the test results, but the observation results over 20 minutes are invalid. NOTE: The experiment should be done at 20~25℃.

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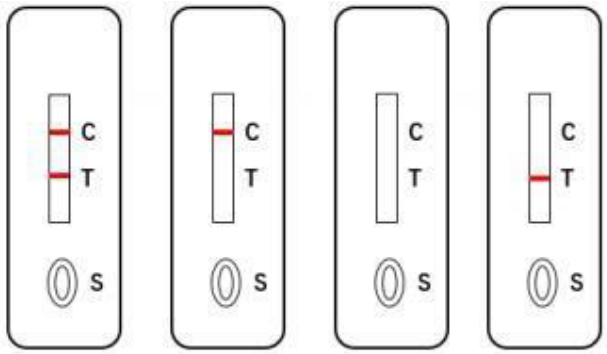
INTERPRETATION OF RESULTS

Positive: Two red strips, both the detection line (T line) and the quality control line (C line) display color.

Negative: A red strip, only quality control line (C line) display color.

Invalid: The position of the quality control line (Line C) in the observation window does not show any color rendering, indicating that the test is invalid, so the sample should be re-sampled for testing.



POSITIVE **NEGATIVE** **INVALID**

INTERPRETATION OF RESULTS

1. This kit is a qualitative test and is only used for in vitro auxiliary diagnosis.
2. With the limit from the method of Spike Protein detection reagent, the minimum detection limit (sensitivity analysis) is generally lower than the nucleic acid reagent. So, the researcher should pay attention to the possible cases of false negative. Researcher should also look at symptoms of patients. Further tests, including nucleic acid tests are recommended for suspected negative results to assist in judgment.
3. Unreasonable sampling, transportation, handling, and low virus content in samples may lead to false negatives.
4. The test results of this reagent are for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The final diagnosis of the disease should be based on a comprehensive assessment of all clinical situations and laboratory results after making.

INDEX OF CHARACTERISTICS

1. Positive reference coincidence rate: the positive reference coincidence rate of the enterprise should be 100%.

2. Negative reference product conformity rate: the negative reference product conformity rate of the enterprise should be 100%.

3. Limit of detection (LoD): The LoD is determined using limiting dilutions of inactivated SARS- CoV-2 in two separate methods. The inactivated virus is spiked into the extraction buffer processed with a negative nasopharyngeal swab sample or into a negative VTM sample to have a concentration of TCID50 of 3.6x105/mL. Each sample is serially 10-fold diluted and by testing in triplicate, a tentative LoD showing 100% (3/3) positive rate is determined for each. For confirmation LoD study, 4 concentrations below the lowest concentration of the pre-test are tested in 20 replicates and a concentration showing over 95% (19/20) are positive, determined as the LoD of the SARS-CoV-2 Spike Protein Test Kit. This was: 39 TCID50/mL

4. Cross-reactivity: Virus/bacteria listed below are confirmed not to have cross-reactivity with SARS-CoV-2 Spike Protein Test Kit.

Human coronavirus 229E (1x105 PFU/mL),Human coronavirus OC43 (1x105 PFU/mL),Human coronavirus NL63 (9.87x103 PFU/mL), MERS (7930 PFU/mL), Adenovirus (e.g. C1 Ad. 71)(1x105 PFU/mL), Human Metapneumovirus (hMPV)(1x105 PFU/mL),Parainfluenza virus Type 1(1x105 PFU/mL), Parainfluenza virus Type 2 (1x105 PFU/mL), Parainfluenza virus Type 3 (1x105 PFU/mL), Parainfluenza virus Type 4a (1x105 PFU/mL), Influenza A H3N2 (Wisconsin/67/05)(8.82x104 PFU/mL), Influenza A H1N1(1x105 PFU/mL), Influenza B (3.24x104 PFU/mL), Enterovirus (1x105 PFU/mL), Respiratory syncytial virus (1x105 PFU/mL), Rhinovirus (3.95x105 PFU/mL), Haemophilus influenzae (1x106 CFU/mL), Streptococcus pneumoniae (1x106 CFU/mL), Streptococcus pyogenes (1x106 CFU/mL), Candida albicans (1x106 CFU/mL), Pooled human nasal wash (15% v/v),Bordetella pertussis (1x106 CFU/mL), Mycoplasma pneumoniae(1x106 CFU/mL), Chlamydia pneumoniae (1x106 CFU/mL), Legionella pneumophila (1x106 CFU/mL), Mycobacterium tuberculosis(1x106 CFU/mL), Pneumocystis jirovecii (1x106 CFU/mL), Pseudomonas Aeruginosa (1x106 CFU/mL), Staphylococcus Epidermidis (1x106 CFU/mL), Streptococcus Salivarius (1x106 CFU/mL)

5. Interference: Substances listed below are confirmed not to have interference response with SARS-CoV-2 Spike Protein Test Kit.

Benzocaine (150 mg/dL), Blood (human)(5%), Mucin (5 mg/mL), Naso GEL (NeilMed)(5%), CVS Nasal Drops(phenylephrine)(15%), Afrin (Oxymetazoline) (15%), CVS Nasal Spray (Cromolyn) (15%), Zicam Cold Remedy (5%), Homeopathic (Alkalol)(10%), Sore Throat Phenol Spray (15%), Tobramycin (3.3mg/dL), Mupirocin (0.15mg/dL), Fluticasone (0.000126mg/dL), Tamiflu (Oseltamivir phosphate) (500mg/dL), Budenoside (0.00063 mg/dL), Biotin (0.35mg/dL), Methanol (150mg/dL), Acetylsalicylic Acid (3mg/dL), Diphenhydramine (0.0774mg/dL), Dextromethorphan (0.00156mg/dL), Dexamethasone (1.2 mg/dL), Mucinex (5%).

6. Clinical accuracy: The clinical performance of the SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay) was evaluated compared to RT-PCR positive cases. Positive percent agreement is 88.24 % and negative percent agreement is 100.00% in theSARS-CoV-2 Spike Protein Test Kit.

7. Repeatability reference products of the enterprise were tested, repeated for 10 times, and the positive coincidence rate was 100%.

ATTENTION

1. The kit is only used for in vitro diagnosis; it cannot be used repeatedly. Kits should be treated as infectious materials.
2. During the time of interpretation, no matter the shade of the color band, it can be found to be positive if two lines appear on the quality control area and the detection area, respectively.
3. Please ensure that an appropriate amount of sample is used for testing, too much or too little of sample amount will cause the result deviation.
4. The result should be read in 15 minutes. Please do not read the result after 30 minutes.

		RT-PCR		PPA(%)	NPA(%)
		Pos	Neg		
SARS-CoV-2 Spike Protein Test Kit	Pos	45	0	88.24% (95%CI:76.13% ~95.56%)	100% (95%CI:98.78% ~100%)
	Neg	6	300		
	Total	51	300		

	Do not re-use		Temperature limit
IVD	*In vitro* diagnostic medical device		Consult instructions for use
Σ	Contains sufficient for *<n>* tests		Keep dry
	Keep away from sunlight	EC REP	Authorized representative in the European Community
	Manufacturer		Caution
	Biological risks	CE	CE marking