

PRODUCT NAME

Common Name: SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)
Product Name: fluorecare®

PACKING

25 Tests/box

INTENDED USE

The fluorecare® SARS-CoV-2 Spike Protein Test Kit is applicable to the qualitative detection novel Coronavirus (SARS-CoV-2) Spike Protein in population Oropharyngeal swabs or Nasopharyngeal swabs samples *in vitro*.

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

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.

MAJOR COMPONENTS

Components	Quantity	Major Components
Test Card (including the desiccant)	25 Cassettes	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 absorbent and absorbent paper.
Sample treatment solution	1 tube	Normal saline solution 10mL per tube.
Instruction of use	1 Copy	/
Sterile nasal swabs	25 Pieces	/
Extraction tubes	25 Pieces	/
Droppers lid	25 Pieces	/

NOTE: Accessories required but not provided:

- Timer;
- For samples from Viral Transport Media, we will need plastic transfer

pipette (Or reusable sample collector) to collect the sample and transfer to the extraction tube.

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

STORAGE CONDITION AND EXPIRY DATE

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

REQUIREMENTS OF SPECIMENS

1. Sample collection

Oropharyngeal swab collection method:

1. Tip the patient's head slightly.
2. Instruct the patient 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:

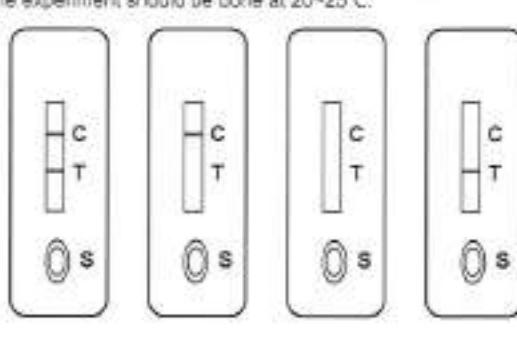
1. Add 300 μ L sample treatment solution to the extraction tube and dip the swab into the sample treatment solution. (The sample treatment solution should fully permeate the swab)
2. Rotate and squeeze the swab 10 times, then remove the swab and load the dropper for sample testing

2.2 CDC Media/Viral Transport Media:

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

DETECTION METHOD

1. Before testing, read the operating instructions carefully, and restore the testing kit and samples to room temperature (20-25 °C) before using.
 2. Tear open the foil bag, take out the test card, and use it as soon as possible within 1 hour.
 3. Vertically drop 1 drop (about 60 μ L) of the treated sample solution into the sample hole of the test card.
 4. The test card is kept at room temperature for 15 minutes to observe the test results, but the observation results over 20 minutes were invalid.
- NOTE: The experiment should be done at 20-25°C.



Positive

Negative

Invalid

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, quality control line (C line) 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.

LIMITATION OF METHODOLOGY

- This kit is a qualitative test and is only used for in vitro auxiliary diagnosis.
- 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.
- Unreasonable sampling, transportation, handling, and low virus content in samples may lead to false negatives.
- 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

- Positive reference coincidence rate: the positive reference coincidence rate of the enterprise should be 100%.
- Negative reference product conformity rate: the negative reference product conformity rate of the enterprise should be 100%.
- Minimum detection limit: the reference products (L1-L5) of the enterprise shall be positive, while (L6-L8) shall be negative. 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 3.6×10^3 PFU/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 Fluorecare® SARS-CoV-2 Spike Protein Test Kit. This was: 39 TCID₅₀/mL.
- Cross-reactivity: Virus/bacteria listed below are confirmed not to have cross-reactivity with SARS-CoV-2 Spike Protein Test Kit.

Human coronavirus 229E (1×10^5 PFU/mL), Human coronavirus OC43 (1×10^5 PFU/mL), Human coronavirus NL63 (9.87×10^3 PFU/mL), MERS (7930 PFU/mL), Adenovirus (e.g. C1 Ad. 71) (1×10^5 PFU/mL), Human Metapneumovirus (hMPV) (1×10^5 PFU/mL), Parainfluenza virus Type 1 (1×10^5 PFU/mL), Parainfluenza virus Type 2 (1×10^5 PFU/mL), Parainfluenza virus Type 3 (1×10^5 PFU/mL), Parainfluenza virus Type 4a (1×10^5 PFU/mL), Influenza A H3N2 (Wisconsin/87/05) (8.82×10^4 PFU/mL), Influenza A H1N1 (1×10^5 PFU/mL), Influenza B (3.24×10^4 PFU/mL), Enterovirus (1×10^5 PFU/mL), Respiratory syncytial virus (1×10^5 PFU/mL), Rhinovirus (3.95×10^5 PFU/mL), Haemophilus influenza (1×10^6 CFU/mL), Streptococcus pneumoniae (1×10^6 CFU/mL), Streptococcus pyogenes (1×10^6 CFU/mL), Candida albicans (1×10^6 CFU/mL), Pooled human nasal wash (15% v/v), Bordetella pertussis (1×10^6 CFU/mL), Mycoplasma pneumoniae (1×10^6 CFU/mL), Chlamydia pneumoniae (1×10^6 CFU/mL), Legionella pneumophila (1×10^6 CFU/mL), Mycobacterium tuberculosis (1×10^6 CFU/mL), Pneumocystis jirovecii (1×10^6 CFU/mL), Pseudomonas aeruginosa (1×10^6 CFU/mL), Staphylococcus epidermidis (1×10^6 CFU/mL), Streptococcus salivarius (1×10^6 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 (Alkaloi) (10%), Sore Throat Phenol Spray (15%), Tobramycin (3.3 mg/dL), Mupirocin (0.15 mg/dL), Fluticasone (0.000126 mg/dL), Tamiflu (Oseltamivir phosphate) (500 mg/dL), Budenoside (0.00063 mg/dL), Biotin (0.35 mg/dL), Methanol (150 mg/dL), Acetylsalicylic Acid (3 mg/dL), Diphenhydramine (0.0774 mg/dL), Dextromethorphan (0.00156 mg/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 the SARS-CoV-2 Spike Protein Test Kit.

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

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

ATTENTION

- The kit is only used for in vitro diagnosis; it cannot be used repeatedly. Kits should be treated as infectious materials.
- During the time of interpretation, no matter the shade of the color band, it can be found to be positive as long as two lines appear on the quality control area and the detection area, respectively.
- 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.
- The final result should be read in 15 minutes. Please do not read the result after 20 minutes.

INTERPRETATION OF ICONS

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

GENERAL INFORMATION

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