# fluorecare® SARS-CoV-2 Antigen Test Kit CE

## PRODUCT NAME

Common Name: **SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)**

Product Code: **MF-68**

## PACKING

1 Test/box, 5 Tests/box

## INTENDED USE

The fluorecare® SARS-CoV-2 Antigen Test Kit is applicable to the qualitative detection novel Coronavirus (SARS-CoV-2) Antigen in population nasal swab and nasopharyngeal swab 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) Antigen in population nasal swab or nasopharyngeal swab samples is qualitatively detected by the colloidal gold method. After blending population nasal swabs, the novel Coronavirus (SARS-CoV-2) Antigen 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 Antigen-SARS-CoV-2 antibody-colloidal gold complex. Due to chromatography, the SARS-CoV-2 Antigen-SARS-CoV-2 antibody-colloidal gold complex diffuses along the nitrocellulose's membrane. Within the detection line area, the SARS-CoV-2 Antigen-antibody complex binds to the antibody enclosed within the detection line area, showing a purple-red band. Colloidal gold-labelled 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 |
|---|---|---|---|
| | 1 Test/box | 5 Tests/box | |
| Test Card (including the desiccant) | 1 cassette | 5 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 and absorbent paper. |
| Instruction of use | 1 copy | 1 copy | / |
| SOP | 1 copy | 1 copy | / |
| Sterile nasal swabs | 1 piece | 5 pieces | (Optional) |
| Sterile Nasopharyngeal swab | 1 piece | 5 pieces | (Optional) |
| Prefilled Sample treatment tube | 1 piece | 5 pieces | Normal saline solution 0.5 mL per tube. |

**NOTE**: Accessories required but not provided:

- Timer

The test card and prefilled samples treatment tube supplied are compatible for this test and should not be exchanged for use with other components from different test batches or brands to avoid inaccurate results.

## STORAGE CONDITION AND EXPIRY DATE

Test kit store at 2-30℃ in dry place and protect from light.

Test kit is valid for 12 months.

## REQUIREMENTS OF SPECIMENS

**1. Sample collection**

**Nasal swabs collection method:**

1. Wash or disinfect your hands, ensuring they are dry before testing
2. Carefully remove the sterile nasal swab from the packaging, ensuring you do not touch the end of the cotton swab
3. Gently insert the cotton swab end of the nasal swab into the left nostril to a depth of 2.5 cm (1 inch)
4. Rotate the nasal swab 5 times against the walls (mucous membrane) of the left nostril to ensure adequate sampling
5. Remove the nasal swab and insert it into the right nostril to a depth of 2.5cm (1 inch)
6. Rotate the nasal swab 5 times against the walls (mucous membrane) of the right nostril to ensure adequate sampling
7. Ensure you use the same nasal swab for both nostrils to ensure adequate sampling

**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**

**Swab samples:**

1. Take the prefilled sample treatment tube and open its cap, taking care not to spill any of the solution
2. Place the swab sample in the treatment tube but positioning the cotton swab end in the solution
3. Rotate the swab 10 times in the treatment tube before breaking the swab at the swab node to leave the lower half of the swab in the treatment tube
4. Put the dropper lid back onto the treatment tube, squeeze the swab in the treatment tube 10 times
5. Then wait for 5 minutes of reaction between the swab sample and the treatment solution before proceeding with the next stage of the test

## DETECTION METHOD

1. If required, wash or disinfect your hands again, ensuring they are dry before continuing with the test

2. Read the standard operating instructions carefully. If required, view the user video via the provided QR code

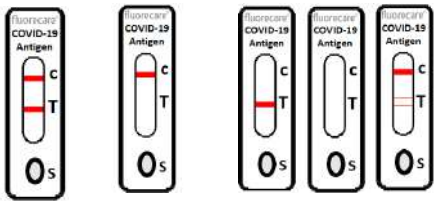
3. The test card and sample must be used at room temperature (20-25 °C)

4. Tear open the foil bag, take out the test card and place it on a flat surface for the duration of the test. Do not touch the sample hole or result areas of the test card. Ensure the test is conducted as soon as possible and within 1 hour of removing the test card from the foil bag

5. Once the 5 minute sample reaction time is completed, open the lid of the dropper on the sample tube. Vertically drop 2 drops (approximately 60mL) of the sample solution into the sample hole of the test card

6. The test card must remain on a flat surface at room temperature for 15 minutes, following which you can observe the test results. Please note that test results after 20 min should be considered invalid.

NOTE: the test should be conducted 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.

After the observation, the kit including the sample processing tube is put back into the bag and thrown into the trash can.

*If your test result is positive, please follow the local protocols for your territory, ensuring that you isolate yourself to minimise the spread of infection to others

## LIMITATION OF METHODOLOGY

1. This kit is a qualitative test and is only used for in vitro auxiliary diagnosis.

2. Failure to comply with test procedures may affect the test results.

3. When the antigen content in the sample is lower than the minimum detection limit, false negative test results may occur. Further tests, including nucleic acid tests are recommended for suspected negative results to assist in judgment.

4. False negative test results may occur when samples are wrongly collected.

5. Negative test results do not rule out the presence of coronaviruses in the sample at any time because they may be present below the minimum detection limit

6. Unreasonable sampling, transportation, handling, and low virus content in samples may lead to false negatives.

7. 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 treatment buffer processed with a negative nasopharyngeal swab sample or into a negative VTM sample to have a concentration of $TCID_{50}$ of 5.6 x $10^5$/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 Antigen Test Kit. This was: 49 $TCID_{50}$/mL.

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

Human coronavirus 229E (1 x $10^5$ PFU/mL),Human coronavirus OC43 (1 x $10^5$ PFU/mL), Human coronavirus NL63 (9.87 x $10^3$ PFU/mL), MERS (7930 PFU/mL), Adenovirus (e.g. C1 Ad. 71)(1 x $10^5$ PFU/mL), Human Metapneumovirus (hMPV) (1 x $10^5$ PFU/mL), Parainfluenza virus Type 1 (1 x $10^5$ PFU/mL), Parainfluenza virus Type 2 (1 x $10^5$ PFU/mL), Parainfluenza virus Type 3 (1 x $10^5$ PFU/mL), Parainfluenza virus Type 4a(1 x $10^5$ PFU/mL), Influenza A H3N2 (Wisconsin/67/05) (8.82 x $10^4$ PFU/mL), Influenza A H1N1(1 x $10^5$ PFU/mL), Influenza B (3.24 x $10^4$ PFU/mL), Enterovirus (1 x $10^5$ PFU/mL), Respiratory syncytial virus (1 x $10^5$ PFU/mL),Rhinovirus (3.95 x $10^5$ PFU/mL), Haemophilus influenza (1 x $10^6$ CFU/mL),Streptococcus pneumoniae (1 x $10^6$ CFU/mL), Streptococcus pyogenes (1 x $10^6$ CFU/mL), Candida albicans(1 x $10^6$ CFU/mL), Pooled human nasal wash (15% v/v),Bordetella pertussis (1 x $10^6$ CFU/mL), Mycoplasma pneumoniae (1 x $10^6$ CFU/mL), Chlamydia pneumoniae (1 x $10^6$ CFU/mL), Legionella pneumophila (1 x $10^6$ CFU/mL), Mycobacterium tuberculosis (1 x $10^6$ CFU/mL), Pneumocystis jirovecii (1 x $10^6$ CFU/mL), Pseudomonas Aeruginosa (1 x $10^6$ CFU/mL), Staphylococcus Epidermidis(1 x $10^6$ CFU/mL), Streptococcus sputumrius (1 x $10^6$ CFU/mL).

5. Interference

Substances listed below are confirmed not to have interference response with SARS-CoV-2 Antigen 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 (0.000126 mg/dL),Tamiflu (Oseltamivir phosphate) (500mg/dL), Budenoside (0.00063 mg/dL), Biotin (0.35mg/dL),Methanol(150mg/dL),Acetylsalicylic Acid(3mg/dL), Diphenhy-dramine (0.0774mg/dL),Dextromethorphan (0.00156mg/dL), Dexamethasone (1.2 mg/dL), Mucinex(5%).

6. Clinical Accuracy NASOPHARYNGEAL SAMPLES

Test method: RT-PCR positive nasopharyngeal samples within 7 days after symptoms were tested and the positive coincidence rate of the kit was compared. Number of test samples: 668 samples, including 368 RT-PCR positive samples; 300 RT-PCR negative samples; 342 SARS-CoV-2 Antigen Test Kit positive results; 26 SARS-CoV-2 Antigen Test Kit negative results.

Samples: In total, 668 test samples are included for the unit and all test samples included are tested.

6.1.Statistics on test results and those of the product tested are as follows:

| Method | | RT-PCR | | Total Results |
|---|---|---|---|---|
| SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) | Results | Positive | Negative | |
| | Positive | 342 | 0 | 342 |
| | Negative | 26 | 300 | 326 |
| Total Results | | 368 | 300 | 668 |

6.2 PCR Cycle Threshold (CT) analysis of PPA

| Cycle Threshold (CT) | # of RT-PCR positive | fluorecare® SARS-CoV-2 Antigen Test (Colloidal Gold Chromatographic Immunoassay) | | |
|---|---|---|---|---|
| | | # of positive results | PPA | NPA |
| <20 | 39 | 39 | 100.00% | 100% |
| <25 | 112 | 111 | 99.11% | |
| <30 | 217 | 214 | 98.62% | |
| <35 | 297 | 292 | 98,32% | |

**Clinical sensitivity at Ct<30** = 214/217 **= 98,62%**
**Clinical specificity** = 300/300 **= 100%**

The **nasopharyngeal swab** result of fluorecare® SARS-CoV-2 Antigen Test (Colloidal Gold Chromatographic Immunoassay): clinical sensitivity was 98.62% (Ct <30) and the clinical specificity was 100%

7. Clinical Accuracy – NASAL SWAB SAMPLES

Test method: RT-PCR positive Nasal swab samples within 7 days after symptoms were tested and the positive coincidence rate of the kit was compared. Number of test samples: 424 samples, including 124 RT-PCR positive samples; 300 RT-PCR negative samples; 117 SARS-CoV-2 Antigen Test Kit positive results; 26 SARS-CoV-2 Antigen Test Kit negative results.

Samples: In total, 424 test samples are included for the unit and all test samples included are tested.

7.1.Statistics on test results and those of the product tested are as follows:

| Method | | RT-PCR | | Total Results |
|---|---|---|---|---|
| SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) | Results | Positive | Negative | |
| | Positive | 117 | 0 | 117 |
| | Negative | 7 | 300 | 307 |
| Total Results | | 124 | 300 | 424 |

7.2 PCR Cycle Threshold (CT) analysis of PPA

| Cycle Threshold (CT) | # of RT-PCR positive | fluorecare® SARS-CoV-2 Spike Protein Test (Colloidal Gold Chromatographic Immunoassay) | | |
|---|---|---|---|---|
| | | # of positive results | PPA | NPA |
| <20 | 44 | 44 | 100.00% | 100% |
| <25 | 82 | 82 | 100.00% | |
| <30 | 107 | 107 | 100.00% | |
| <35 | 123 | 117 | 95,12% | |

**Clinical sensitivity at Ct<30** =107/107 **= 100%**
**Clinical specificity** = 300/300 **= 100%**

The **nasal swab** result of fluorecare® SARS-CoV-2 Antigen Test (Colloidal Gold Chromatographic Immunoassay): clinical sensitivity was 100% (Ct <30) and the clinical specificity was 100%

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

9.The fluorecare® SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) tests for SARS-CoV-2 nucleocapsid protein.The mutants of SARS-CoV-2 N501Y and E484K can be identified by the fluorecare® SARS-CoV-2 Antigen Test Kit.

## ATTENTION

1. The test is only used for in vitro diagnosis; it cannot be used more than once. Used tests 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 as long as 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, The sample volume, too much or too little, may cause a deviation in the result.

4. 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 |
| 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 |
| REF | Catalogue number | LOT | Batch code |
| | Date of manufacture | | Use-by date |

## GENERAL INFORMATION

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