



COVID-19 Antigen Rapid Test Kit (Colloidal Gold)

Instructions for Use with Saliva Swab Specimen

For self-testing/home use/private use

【INTENDED USE】

This test kit is used for in vitro qualitative detection of SARS-CoV-2 antigens in human saliva swab samples. It is intended for rapid detection of suspected COVID-19 cases within the first 7 days of symptom onset.

A positive test result indicates that the sample contains SARS-CoV-2 antigen. A negative test result does not rule out the possibility of infection.

This test kit is for self-testing by lay person in a non-laboratory setting (such as user's home or certain non-traditional sites such as airports, offices, schools, stadiums, etc.). The test results of this test kit are for preliminary screening and clinical reference only. It is recommended to conduct a comprehensive analysis of the condition based on the user's clinical manifestations and other laboratory tests.

【TEST PRINCIPLE】

This kit uses immunochromatography for qualitative detection of SARS-CoV-2 nucleocapsid protein antigens present in saliva swab specimen. The specimen will move forward along the test card under capillary action. If the specimen contains a novel corona virus antigen, the antigen will bind to the colloidal gold-labeled new corona virus monoclonal antibody. The immune complex will be captured by corona virus monoclonal antibodies which are membrane fixed, form the fuchsia line, display will be corona virus antigen positive, if the line does not show color, the negative result will be displayed. The test card also contains a quality control line C, which shall appear fuchsia regardless of whether there is a detection line.

【MATERIALS PROVIDED】

| Components | Specification | | |
|--|---------------|---------------|---------------|
| | 1 Test/Kit | 5 Tests/Kit | 25 Tests/Kit |
| | CG01Ag-01S-ST | CG01Ag-05S-ST | CG01Ag-25S-ST |
| Test card | 1 | 5 | 25 |
| Saliva swab | 1 | 5 | 25 |
| Extraction tube with extraction solution | 1 | 5 | 25 |
| Instructions for use | 1 | 1 | 1 |
| Tube rack | 1(packaging) | 1 | 1 |

【PERFORMANCE CHARACTERISTICS】

Clinical performance

| Method | PCR Comparator (nasopharyngeal swab specimen) | Total |
|--------|--|-------|
|--------|--|-------|

| COVID-19 Antigen Rapid Test Kit (Colloidal Gold) (saliva specimen) | Results | Positive | Negative | |
|--|----------|----------|----------|-----|
| | Positive | 196 | 0 | 196 |
| | Negative | 7 | 474 | 481 |
| | Total | 203 | 474 | 677 |
| Sensitivity(true positive rate): 96.55% (95% CI, 93.05% ~98.32%) | | | | |
| Specificity(true negative rate): >99% (95% CI, 99.20% ~100.00%) | | | | |
| Accuracy(true positive and negative rate): 98.97% (95% CI, 97.88% ~99.50%) | | | | |

Limit of Detection: 5×10^2 TCID₅₀/mL

【CROSS-REACTIVITY】

To evaluate the cross reactivity, the following panel of common organisms were tested with COVID-19 antigen rapid test Kit (Colloidal Gold). Each of samples was tested in triplicate and no cross-reactivity was found.

| Potential Cross-Reactant | Test Concentration | Potential Cross-Reactant | Test Concentration |
|----------------------------------|--|--------------------------|--|
| Adenovirus | 1.0×10^5 TCID ₅₀ /mL | EBV | 1.0×10^5 TCID ₅₀ /mL |
| Human metapneumovirus (hMPV) | 1.0×10^5 TCID ₅₀ /mL | CMV | 1.0×10^5 TCID ₅₀ /mL |
| Mycobacterium tuberculosis | 1.0×10^6 cells/mL | Bordetella pertussis | 1.0×10^6 cells/mL |
| Enterovirus/Coxsackievirus B4 | 1.0×10^5 TCID ₅₀ /mL | Chlamydia pneumoniae | 1.0×10^6 PFU/mL |
| Human coronavirus OC43 | 1.0×10^5 TCID ₅₀ /mL | Haemophilus influenzae | 1.0×10^6 cells/mL |
| Human coronavirus 229E | 1.0×10^5 TCID ₅₀ /mL | Legionella pneumophila | 1.0×10^6 cells/mL |
| Human coronavirus NL63 | 1.0×10^5 TCID ₅₀ /mL | Mycoplasma pneumoniae | 1.0×10^6 U/mL |
| Human parainfluenza virus1 | 1.0×10^5 TCID ₅₀ /mL | Streptococcus pneumoniae | 1.0×10^6 cells/mL |
| Human parainfluenza virus2 | 1.0×10^5 TCID ₅₀ /mL | Influenza A | 1.0×10^5 TCID ₅₀ /mL |
| Human parainfluenza virus3 | 1.0×10^5 TCID ₅₀ /mL | Rhinovirus | 1.0×10^5 PFU/mL |
| Human parainfluenza virus4 | 1.0×10^5 TCID ₅₀ /mL | Staphylococcus aureus | 1.0×10^6 org/mL |
| Streptococcus pyogenes (group A) | 1.0×10^6 cells/mL | Influenza B | 1.0×10^5 TCID ₅₀ /mL |
| Staphylococcus epidermidis | 1.0×10^6 org/mL | E. coli | 1.0×10^7 cells/mL |
| Respiratory Syncytial Virus A | 1.0×10^5 PFU/mL | Candida albicans | 1.0×10^6 cells/mL |

【INTERFERENCES】

The following substances have been tested and no interference was found with the COVID-19 Antigen Rapid Test Kit (Colloidal Gold):

| | | |
|--|-----------------------|-------------------------------|
| Zincum gluconium (i.e. Zicam):5% w/v | Cromolyn:15% v/v | Whole Blood:1% v/v |
| Benzocaine, Menthol:0.15% w/v | Alkalol:10% v/v | Phenylephrine:15% v/v |
| Galphimia glauca, Sabadilla:20% v/v | Oxymetazoline:15% v/v | Tobramycin:0.0004% w/v |
| Sodium Chloride (i.e. NeilMed):5% v/v | Fluconazole:5% w/v | Fluticasone Propionate:5% v/v |
| Tamiflu (Oseltamivir Phosphate):0.5% w/v | Phenol:15% v/v | Mupirocin:0.25% w/v |
| | | Mucin:2% w/v |

【WARNINGS AND PRECAUTIONS】

1. Children under 18 years of age should be assisted by an adult.
2. Read the Instructions for Use (this leaflet) carefully before use.
3. Do not re-use. Do not drink any liquid in the test kit.
4. Do not use the test kit beyond the expiry date.

5. Do not use the test kit if any of the kit components are missing, broken, or unsealed.
6. Store the test kit at 2-30°C. Do not freeze.
7. Handle all specimens as potentially infectious.
8. The specimens should be tested immediately after collection.
9. Inadequate or inappropriate specimen collection, storage, and transport may yield inaccurate test results.
10. Correct specimen collection is a quite important step during the testing procedures. Make sure to collect enough specimens with the saliva swab.
11. The test should be used at room temperature (8-30 °C). If the test has been stored in a cool area (less than 8°C), leave it at normal room temperature for 30 minutes before using.
12. Use the saliva swab provided in the test kit to ensure optimal performance of the test.
13. Apply the drops of test specimen only to the specimen well (S) on the test card.
14. Too many or too few drops of extracted specimen may result in invalid or incorrect test result.
15. The specimen collection procedures may be uncomfortable. Do not insert the saliva swab too much deeper, please stop the test if you feel strong resistance or pain.
16. Keep the test kit and kit components out of the reach of children and pets before and after use.

【LIMITATIONS】

1. The components of this test kit are to be used exclusively for the qualitative detection of SARS-CoV-2 antigen in saliva swab specimens. Other specimen types may lead to incorrect results and must not be used.
2. The test kit is used for rapid detection of suspected COVID-19 cases within the first 7 days of symptom onset, so asymptomatic individuals may get a false-negative test result.
3. Failure to follow the instructions for test procedures and interpretation of test results may adversely affect test performance and/or produce invalid results.
4. A negative test result may occur if the specimen was collected or extracted improperly. A negative test result does not eliminate the possibility of SARS-CoV-2 infection and should be confirmed by a molecular assay.
5. Improper storage, collection, or even freezing and thawing of the specimen can lead to inaccurate test results.
6. Positive test results do not rule out co-infections with other pathogens.
7. If the viral load of the specimen is below the detection limit of the test, the test may produce a negative result.
8. Test results must be evaluated in conjunction with other clinical data available to the physician laboratory test results.
9. The amount of antigen in a sample may decrease as the duration of illness develops. Specimens collected after 5-7 days of symptom onset of illness are more likely to be tested negative compared to a molecular assay.

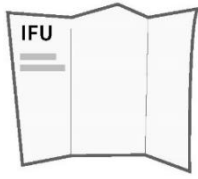
【STORAGE AND SHELF LIFE】

1. The test kit should be stored at 2-30°C, and the shelf life is 18 months.
2. After the aluminum foil pouch is unsealed, it is recommended to use the test card within 1 hour at room temperature.
3. The extraction solution is recommended to be used within 1 hour after opening at room temperature.

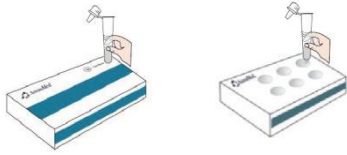
【PREPARATION BEFORE TEST PROCEDURES】

1. Make sure all kit components are equilibrated to room temperature on the flat and clean surface.
2. Make sure the kit components are complete without any missing or damaged after opening.
3. Make sure to check the kit expiry date before testing.
4. Make sure to wash or sanitize your hands, and make sure they are dry before starting.
5. Make sure to prepare the following materials required but not provided in the kit.
 - Timer (watch)
 - Waste container

【OPERATION OF TEST PROCEDURES】



1. Take out the Instructions for Use and read it carefully.



2. Take out the tube rack and assemble it. Gently press one tube rack well and place the extraction tube into the tube rack.

Note: For specification of 1 Test/Kit, tube rack is on the kit packaging.



3. Peel off the foil seal from the top of extraction tube, being sure to keep the extraction tube upright.

Caution: Safely peel off the foil seal away from your eyes and face. Do not splash the liquid.



4. Find the saliva swab in the sealed wrapper. Identify the fabric, soft tip of the saliva swab. Peel off the swab packaging and gently take out the saliva swab.

Caution: Never touch the fabric, soft tip of the saliva swab with your fingers to avoid pollution.

5. Specimen Collection

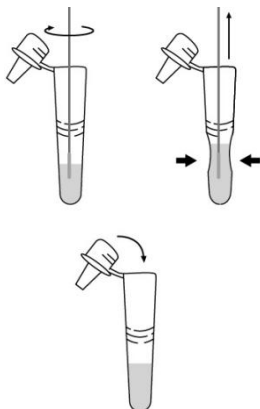
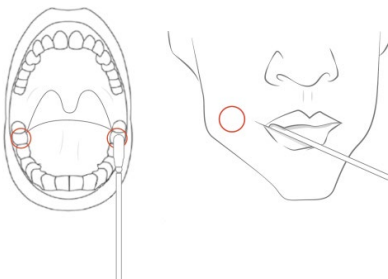
Do not eat or drink anything, such as gum, tobacco, liquor, etc. 30 minutes prior to sampling.

5.1 Insert the saliva swab by one hand into the mouth cavity.

5.2 Place the saliva swab tip between upper and lower molar teeth, then gently immobilize the swab tip with upper and lower molar teeth for no less than 10 seconds and meanwhile close the mouth for complete saliva absorption in the depths of the mouth.

5.3 After saliva collection, gently take out the swab.

NOTE: False negative results may occur if the saliva specimen is not collected properly.

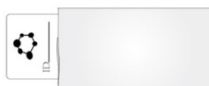


6. Specimen Handling

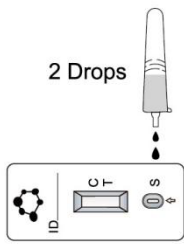
6.1 Insert the saliva swab into extraction tube. Stir the saliva swab more than 5 times. Leave saliva swab in extraction tube for about 1 minute.

6.2 Squeeze the swab against the inner wall of extraction tube to release the liquid as much as possible when you remove the swab. Dispose of the test swab with normal household waste in accordance with applicable local regulations.

7. Press the cap onto the extraction tube tightly.



8. Unseal the foil pouch and take out the test card. Place the card on the flat surface.



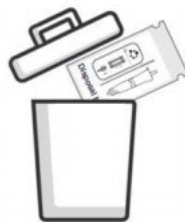
9. Apply 2 drops of extracted specimens to the specimen well of the test card, and then start timing.



15-20 min

10. Read the test results in 15-20 minutes, and test results after 20 minutes may not be accurate.

【WASTE DISPOSAL AFTER TEST PROCEDURES】

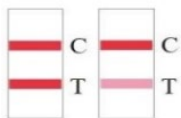


1. Place the used test card, extraction tube and saliva swab in a disposal bag and seal the disposal bag.

2. Dispose all used devices and other components into normal household waste container in compliance with the applicable local regulations.

3. Wash or sanitize your hands again.

【INTERPRETATION OF TEST RESULT】



Positive

Positive:

If both the control line (C) and the test line (T) appear within 15-20 minutes, the result is positive.

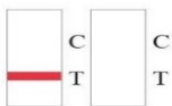
Caution: No matter how faint the colored band is in the test line(T), the result should be considered as positive.



Negative

Negative:

If there is only a control line (C) and test line (T) is colorless within 15-20 minutes, the test result is negative.



Invalid

Invalid:

If the control line (C) is not observed within 15-20 minutes, the test is invalid. And the test shall be conducted again with a new test card.

【FREQUENTLY ASKED QUESTIONS (FAQ)】

1. When can/should I test myself?

You can have a test on yourself whether you have symptoms or not. Please note that the test result is a snapshot that is valid for this point in time. Tests should therefore be repeated according to local regulations.

2. What should I pay attention to in order to have the optimal test result?

Always follow the instructions for use correctly. Perform the test immediately after collecting the sample. Apply two drops from the extraction tube into the specimen well of the test card. Too many or too few drops can lead to an incorrect or invalid test result.

3. The test strip is very discolored. What may be the reasons?

The reason for a clearly visible discoloration of the test strip is that too many drops has been dispensed from the extraction tube into the specimen well of test card. The indicator strip can only hold a limited amount of liquid. If the control line (C) does not appear or the test strip is very discolored, please retest by using a new test card according to the instructions for use.

4. I have taken the test, but the control line (C) doesn't appear. What should I do?

According to the instructions for use, this test result is invalid. Please retest by using a new test card.

5. I am not sure about reading test result. What should I do?

Read the instructions for use again, and if this doesn't help, please contact the nearest health facility recommended by your local authorities for help.

6. If my test result is positive, what should I do?

There is possibility of hospitalization, complications and even death after infection with SARS-CoV-19. You should immediately contact the nearest health facility recommended by your local authorities.


7. If my test result is negative, what should I do?

If you test result is negative by the test, you also need to obey the local regulations. If you experience symptoms such as fever, headaches, migraines, loss of sense of smell and taste, contact the nearest health facility recommended by your local authorities.





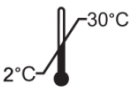




8. Will this test hurt?

No, the saliva swab is not sharp and it should not hurt. Sometimes the saliva swab can make slightly uncomfortable or tickly. If you feel pain, please stop the test and ask for help from a healthcare provider.

【ACCESSORY】

| Accessory | Manufacturer | EC-Representative | CE-Mark |
|-------------|--|---|---|
| Saliva Swab | Shenzhen Kangdaan Biological Technology Co. Ltd. 3rd floor, Building A2, Shunheda factory, Liuxiangdong industrial zone, Xilli street, Nanshan district, Shenzhen, China. | Share Info Consultant Service LLC Repräsentanzbüro Heerdter Lohweg 83 40549 Düsseldorf, Deutschland |  0197 acc. 93/42/EEC |

【EXPLANATION FOR SYMBOLS】

| | | | | | |
|---|------------------|---|-----------------|---|--------------------------|
|  | Expiry date |  | Batch Number |  | See Instructions for use |
|  | Test (s) per kit |  | Store at 2-30°C |  | Catalogue Number |
|  | Manufacturer |  | CE Mark |  | Do not reuse |

| | | | |
|---|----------------------------|---|------------------------------------|
| <div style="border: 1px solid black; padding: 2px; display: inline-block;">IVD</div> | In Vitro diagnostic use | <div style="border: 1px solid black; padding: 2px; display: inline-block;"> <div style="border: 1px solid black; padding: 2px; display: inline-block;">EC</div> <div style="border: 1px solid black; padding: 2px; display: inline-block;">REP</div> </div> | European Authorized Representative |
|---|----------------------------|---|------------------------------------|

【ISSUE DATE AND VERSION NO.】

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