For Rapid Detection of SARS-CoV-2

For In Vitro Diagnostic Use Only

reOpenTest

SARS-CoV-2 Antigen Rapid Test

(Colloidal Gold)

INTENT OF USE

This SARS-CoV-2 Antigen Rapid Test is used for the qualitative detection of SARS-COV-2 infection. The entire detection process takes only 5-8 minutes, and the operation is simple and sensitive. No instrument required. It can be used for the screening of early infected patients and asymptomatic patients. This method is an effective supplement for nucleic acid detection.

SUMMARY AND EXPLAINATION

The novel coronaviruses belong to the β genus. SARS-CoV-2, also known as the COVID-19 virus, 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 TEST

The detection of SARS-COV-2 adopts the principle of double antibody sandwich method and colloidal gold immunochromatography to qualitatively detect SARS-COV-2 antibodies in human Nasal swabs, pharyngeal swabs, sputum, bronchoalveolar lavage fluid, etc., with two highly specific and highly sensitive SARS-COV-2 N antigen monoclonal antibodies, wherein monoclonal antibody I is a capture antibody, fixed in the detection area on the NC membrane, monoclonal antibody II is a colloidal gold-labeled antibody, sprayed on the binding pad, and the NC membrane quality control area C is coated with rabbit anti-mouse IgG antibody. The double antibody sandwich method is used in the detection area, and the antigen-antibody reaction is used in the quality control area, combined with colloidal gold immunochromatography technology to detect the SARS-COV-2 in the human body. During detection, the sample is chromatographed under the capillary effect. If the tested sample contains SARS-COV-2, the gold-labeled SARS-COV-2 N antigen monoclonal antibody I combines with SARS-COV-2 to form a complex, and combines with the anti-human IgG antibody fixed at the detection line during the chromatography process, which will form the "Au-antibody I-N antigen antibody II" sandwich, so that a purple band appears in the detection area (T); Otherwise, no magenta bands appear in the detection area (T). Regardless of whether there is a SARS-COV-2 antibody in the sample, the complex will continue to be chromatographed up to the control area (C), and a purple band appears when reacting with the rabbit anti-mouse IgG antibody. The purple-red band presented in the control area (C) is a standard for judging whether the chromatographic process is normal, and also serves as an internal control standard for reagents.

REAGENTS AND MATERIALS SUPPLIED

20-Test Kit:

- Individually Packaged Test cassettes (20)
- Reagent Tubes (20)
- Reagent Solution (1): Ampoules with salt solution
- Droppers (20)
- Sterile Nasal Swabs (20)
- Package Insert (1)

MATERIALS NOT SUPPLIED IN KIT*

- Timer or watch
- UV Light Device

WARNINGS AND PRECAUTIONS

1. Please read the instruction manual carefully before use. It requires professionally trained inspectors to operate, and strictly follow the kit instructions for test operations.
2. Inspectors who need professional training should be operated in safety-protected laboratories and wear protective equipment.
3. This product is a one-time use in vitro diagnostic product, please use it within the validity period.
4. Do not use the aluminum foil bag if it is damaged. Please use it as soon as possible after opening the aluminum foil bag.
5. Temperature has a greater influence on the test results.
6. It indicates an error if no line appears in the quality control area (C) and test area (T). Please retest.
7. If the test result is negative and there are clinical symptoms, it may be recommended to use other clinical methods for testing. Negative results cannot rule out the possibility of infection with new coronavirus.
8. The high temperature of the experimental environment should be avoided. The test kit which was stored at low temperature needs to be restored to room temperature before opening to prevent moisture absorption.
9. It is recommended to use fresh samples, do not use repeatedly freeze-thaw samples.
10. Please use the swab and sample extraction solution provided in this kit when sampling. Do not mix test cassettes and sample extraction solutions from different batches.
11. If the virus sampling solution is used to treat the specimen, then it can be directly detected without using sample extraction solution.
12. The laboratory requires bio-safety level II or operation in a bio-safety cabinet.
13. Pay attention to safety measures during operation, such as wearing protective clothes and gloves. Used swabs, test cassettes, extraction tubes, etc. should be decontaminated before disposal. High-pressure steam disinfection is recommended.
14. Keep clean, contaminants should be treated as a potential source of infection, the operation should be carried out in accordance with laboratory safety management regulations. Waste disposal shall be carried out in accordance with the WS / T249-2005 "Principles for Waste Disposal in Clinical Laboratories".
15. There is desiccant inside the aluminum foil bag. **DO NOT EAT**.

KIT STORAGE AND STABILITY

Store the kit at room temperature, 4°C to 30°C (40°F to 86°F), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box. **DO NOT FREEZE**.

SPECIMEN COLLECTION AND PREPARATION

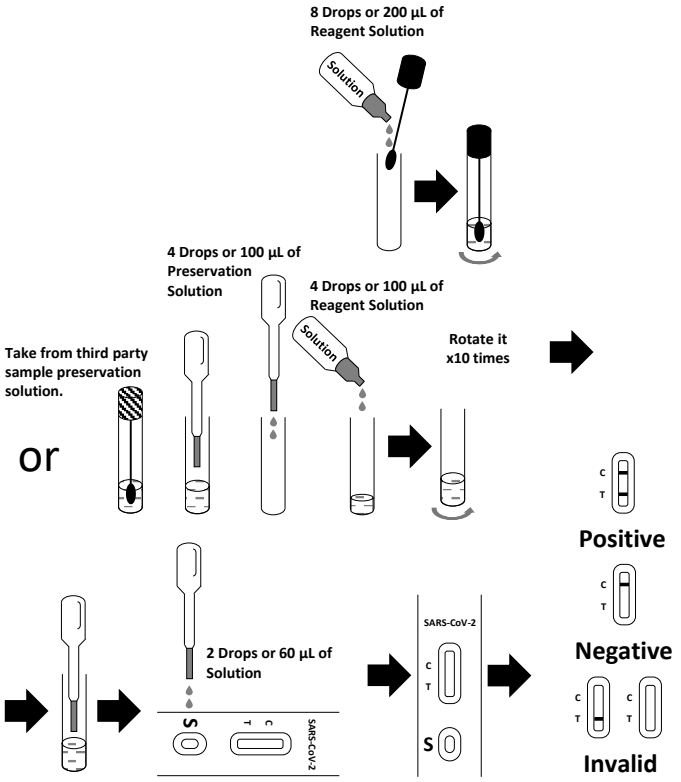
1. The applicable sample types of this test reagent: upper respiratory tract specimens (including pharyngeal swabs, nasal swabs, nasopharyngeal extracts, deep cough sputum); lower respiratory tract specimens (including respiratory tract extracts, bronchial lavage fluid, alveolar lavage Fluid and lung tissue biopsy specimens); tissue culture and other samples.
2. For the specific method of sample collection, please refer to the book "Microbiological Specimen Collection Manual".
3. After the sample is collected, the test must be completed on the same day. Otherwise, save according to the following scheme: Store at 2-8 ° C for no more than 24 hours; Store at -20 ° C or less than 3 months; Store at -70 ° C for a long time, but avoid repeated freeze-thaw cycles.

TEST PROCEDURE

1. Specimen extraction:

1.1. Put the swab into the empty sampling tube, drop 8 drops (approximately 200 μL) of the reagent solution into the sampling tube, and rotate it about 10 times to make the sample dissolve in the solution as much as possible.

1.2. **If sample is stored in third party sample preservation solution**, take out 100 μL of the sample preservation solution to the empty sampling tube, and add 100 μL of the reagent solution into it, then rotate it about 10 times to make the sample dissolve in the solution as much as possible.



2. Detection operations:

2.1. Before testing, the unopened reagents should be placed at room temperature to make the temperature of the reagents reach equilibrium.

2.2. Tear the aluminum foil bag along the incision and take the reagent kit flat on a clean table. Specimens such as pharyngeal swabs or nasal swabs: Directly drop 2 drops (approximately 60 μL) of the solution of the collected pharyngeal swabs or nasal swabs directly into the sample hole and start timing.

2.3. Observe the results showed within 10-20 minutes, and the results showed after 30 minutes have no clinical significance.

INTERPRETATION OF RESULTS

Positive (+): Two red lines appear. One is in the test area (T) and the other is in the quality control area (C).

Negative (-): Only a red line appears in the quality control area (C), and no line appears in the test area (T).

Invalid: No red line displays in the quality control area (C). This indicates that the incorrect operation or the test cassette has deteriorated or damaged.

LIMITATIONS

■ Physical performance

1.1 Appearance

1) The test kit and its components should be complete;

2) The packaging bag should be sealed well, with no breakage and with clear label;

3) The material is firmly attached, and the strip width is suitable for the cassette.

1.2 Film strip width: ⩾ 3.0mm.

1.3 Liquid migration velocity: The liquid moving speed should not be less than 10 mm/min.

■ Accuracy and repeatability

Repeat the test 10 times with negative quality control solution (0 ng/mL) and 10 ng/mL, 20 ng/mL, and 40 ng/mL COVID-2019-NP recombinant antigen control solutions. Positive quality control solution must not show negative results, and negative quality control solution cannot have positive results.

■ Inter-batch difference

Testing 10ng/mL, 40ng/mL samples 10 times for each by using three batches test kits. 10 ng/mL samples should be shown weakly positive results, and no positive or strongly positive results should appear. 40 ng/mL samples should be shown strongly positive results, and no positive or weakly positive results should appear. Negative results should be negative.

■ HOOK effect

Test the 100 ng/mL COVID-2019-NP recombinant antigen sample, the result should be strongly positive.

■ Specificity

Test the 100 ng/mL canine coronavirus, feline coronavirus, and porcine coronavirus positive samples, the result should be negative.

PERFORMANCE CHARACTERISTICS

Please refer to updated clinical research reports published on website: http://www.reopentest.com/reports

REFERENCE

1. Templeton, K.E., Scheltinga, S.A., et al. (2004). Rapid and sensitive method using multiplex realtime PCR for diagnosis of infections by influenza A and influenza B viruses, respiratory syncytial virus, and parainfluenza viruses 1, 2, 3 and 4 [J]. Journal of clinical microbiology 42(4): 1564-1569.

2. Smith, A.B., Mock, V., et al. (2003). Rapid detection of influenza A and B viruses in clinical specimens by Light Cycler real time RT-PCR [J]. Journal of Clinical Virology 28(1): 51-58.

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ORDERING

1. Contact reOpenTest's distributors or
2. Visit reOpenTest website: http://www.reopentest.com

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Joinstar Biomedical Technology Co.,Ltd.
Address: NO.519, XingGuo RD., Yuhang Economic and Technological Development Zone, Hangzhou, Zhejiang-311188, China.

CMC Medical Devices& Drugs S.L.
Address: C/ Horacio Lengo N º18, CP 29006, Málaga, Spain.

ISO 15223 Symbols

CE	This product fulfils the requirements of the Directive 98/79/EC on in vitro diagnostic medical device
	Read instructions for use
	Use by
	Do not re-use
	Do not use if package is damaged
	Temperature limit
	Keep away from sunlight
	Contains sufficient for <n> tests
EC REP	Authorized Representative in the European Community / European Union
LOT	Batch code
REF	Catalog number
IVD	In vitro diagnostic medical
SN	Serial number
	Biological risks
	Manufacturer
	Date of manufacture
	Caution