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

The reOpenTest SARS-CoV-2 Antigen Rapid Test is a lateral flow immunoassay intended for the rapid and qualitative detection of N-protein antigen from SARS-CoV-2 in swab specimen from individuals who are suspected of COVID-19 by their healthcare provider. Testing is as applicable, Point of Care (POC) testing.

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

25-Test Kit:

- Individually Packaged Test cassettes (25)
- Reagent Tubes (25)
- Reagent Solution (2): Ampoules with salt solution
- Droppers (25)
- Sterile Nasal Swabs (25)
- Package Insert (1)

MATERIALS NOT SUPPLIED IN KIT*

- Timer or watch

WARNINGS AND PRECAUTIONS

Section I

- Please read the instruction manual carefully before use. It requires professionally trained inspectors to operate, and strictly follow the kit instructions for test operations.
- This product is a one-time use in vitro diagnostic product, please use it within the validity period.
- Do not use the aluminum foil bag if it is damaged. Please use it as soon as possible after opening the aluminum foil bag.
- Temperature has a greater influence on the test results. 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.

Section II

- Clinical performance was evaluated with frozen samples, and test performance may be different with fresh samples. Do not use repeatedly freeze-thaw samples. Specimen stability recommendations are based upon stability data from influenza testing and performance may be different with SARS-CoV-2. Users should test specimens as quickly as possible after specimen collection, and within one hour after specimen collection.
- The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from nasal swab specimens only
- 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.
- It indicates an error if no line appears in the quality control area (C) and test area (T). Please retest.
- This device has been evaluated for use with human specimen material only.

Section III

- The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals.
- Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false positive results during periods of little/no SARS-CoV-2 activity when disease prevalence is low. False negative test results are more likely when prevalence of disease caused by SARS-CoV-2 is high.
- Sensitivity of the test after the first five days of the onset of symptoms has been demonstrated to decrease as compared to a RT-PCR SARS-CoV-2 assay.
- Results from the SARS-CoV-2 Antigen Rapid Test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
- A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection.
- Negative test result should be treated as presumptive and confirmed with an approved molecular assay, if necessary, for clinical management, including infection control. If the test result is negative and there are clinical symptoms, it is recommended to use other clinical methods for testing.
- The validity of the SARS-CoV-2 Antigen Rapid Test has not been proven for identification/confirmation of tissue culture isolates and should not be used in this capacity.
- Negative test results are not intended to rule in other non-SARS-CoV-2 viral or bacterial infections.
- Monoclonal antibodies may fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.

Section IV

- Inspectors who need professional training should be operated in safety-protected laboratories. The laboratory requires bio-safety level II or operation in a bio-safety cabinet.
- 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.
- 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".
- There is desiccant inside the aluminum foil bag. **DO NOT EAT**.

KIT STORAGE AND STABILITY

Store the kit at room temperature, 2°C to 30°C (36°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.

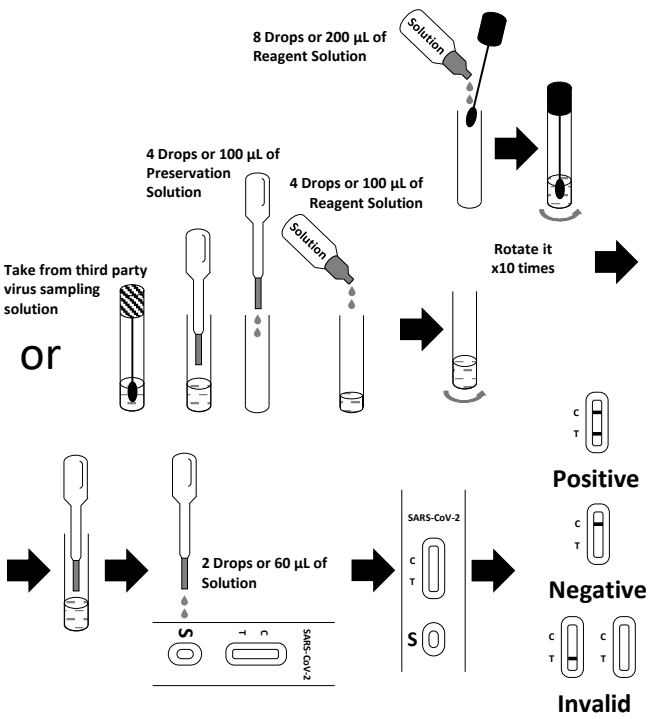
TEST PROCEDURE

Specimen extraction

- 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.
- **If the virus sampling solution is used to treat the specimen**, take out 100 μL of the sampling 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.

Detection operations

- Before testing, the unopened reagents should be placed at room temperature to make the temperature of the reagents reach equilibrium.
- 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 mixed solution into the sample well and start timing.
- Observe the results showed within 10-20 minutes, and the results shown 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

The reOpenTest SARS-CoV-2 Antigen Rapid Test is designed for the primary test of SARS-CoV-2 antigen and only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing

PERFORMANCE CHARACTERISTICS

1. Analytical sensitivity/cross-reactivity

- Detection limit (LoD): 2.87 x 10^3 $TCID_{50}$/mL (heat-inactivated culture fluid).
- Cross-reactivity: There was cross-reactivity of SARS-CoV-1. However, there were no cross-reactivities of MERS-coronavirus, Human coronavirus (NL63), Human coronavirus (229E), Human coronavirus (OC43), Human Adenovirus type 1, Human Adenovirus type 3, Human Adenovirus type 8, Human Adenovirus type 18, Human Adenovirus type 23, Human Adenovirus type 7, Human Adenovirus type 5, Human Adenovirus type 11, Human Parainfluenza virus type 1, Human Parainfluenza virus type 2, Human Parainfluenza virus type 3, Human Parainfluenza virus type 4, Human Rhinovirus type 1, Human Rhinovirus type 14, Human Rhinovirus type 42, Human Metapneumovirus, Respiratory syncytial virus-A, Respiratory syncytial virus-B.

2.Interference

- Not interfered for Whole blood, Mouth wash, Phenylephrine, Acetylsalicylic acid, Beclomethasone, Benzocaine, Flunisolide, Guaiacol glyceryl ether, Menthol, Oxymetazoline, Tobramycin, Zanamivir, Oseltamivir phosphate, mucous.

3.Clinical evaluation

- For the evaluation of diagnostic performance, COVID-19 positive samples form 30 individuals and COVID-19 negative samples from 100 individuals were introduced in this study.

Method		PCR		Total Results
	Results	Positive	Negative	
reOpenTest	Positive	27	2	29
	Negative	3	98	101
Total Result		30	98	130

Sensitivity = 90.0% (95% CI = 73.47% to 97.89%)
Specificity = 98.0% (95% CI = 92.96% to 99.76%)

REFERENCE

- Templeton, K.E., Scheltinga, S.A., et al. (2004). Rapid and sensitive method using multiplex real-time 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.
- 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.

reOpenTest

ORDERING

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

CUSTOMER SERVICE

Contact your local representative
or find country-specific contact information with
E-mail: service@reopentest.com

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
Σ	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