For Prescription Use and Non-Lab Settings Use.

For In Vitro Diagnostic Use Only

reOpenTest

COVID-19 Antigen Rapid Test

(Colloidal Gold)

202211

LOT 202011002

REF COVG10C

Contains:

1 Test Cassette
1 Reagent Tube / Nozzle Cap / Reagent Solution
1 Nasopharyngeal Swab
1 Package Insert

Distributor LOGO here

CE-Mark

IVD In vitro diagnostic medical

Read instructions for use

REF Catalogue number

LOT Batch code

Use by

Manufacturer

EC REP Authorized Representative in the European Community / European Union

Contains sufficient for <n> tests

Do not re-use

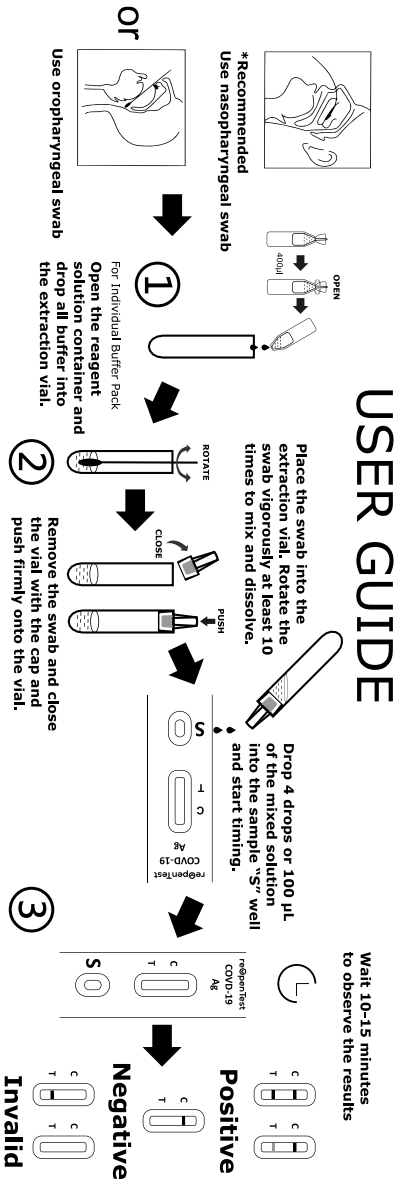
Do not use if package is damaged

Keep away from sunlight

Keep dry
Keep away from raineep dry

Temperature limit

Caution



INTENT OF USE

The reOpenTest COVID-19 Antigen Rapid Test is a lateral flow immunoassay intended to detect N-protein antigen from the SARS-CoV-2 virus that causes COVID-19 in Nasopharyngeal/Oropharyngeal swab, or saliva from individuals age 2 years and older symptomatic individuals who are suspected of COVID-19 by a healthcare provider, or individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection.

Persons who test positive with the reOpenTest COVID-19 Antigen Rapid Test should seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or co-infection with other viruses. Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

All test results shall be reported to healthcare providers and relevant public health authorities in accordance with local, state, and nation requirements.

The reOpenTest COVID-19 Antigen Rapid Test is intended for professional-use or, as applicable for a professionally trained user testing another person in a non-laboratory setting and, as applicable for healthcare provider testing of another person in laboratories certified to perform moderate or high complexity tests and as applicable, Point of Care (POC) testing at patient care settings.

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. Please note that if applicable, an in-silico analysis against available reference protein sequences for different strains of the target pathogen is requested as part of the cross-reactivity evaluation (Section J).

REAGENTS AND MATERIALS SUPPLIED

MATERIALS	COVG10C	COVG10X
Test Cassette * Individual foil pack	1	25
Extraction Via with Cap * With 400µL reagent solution	1	25
Swab	1	25
Package Insert	1	1

MATERIALS NOT SUPPLIED IN KIT

- Timer or watch or smart mobile phone

Note: External Negative and Positive Controls are not supplied with this kit. However, external positive and negative controls should be tested in accordance with good laboratory practice to confirm the test procedure and to verify proper test performance. Additional testing may be required according to guidelines or local, state, and/or nation regulations or accrediting organizations. The SARS-COV-2 Ag External Control Kit can be purchased separately. Please contact reOpenTest or your distributor for information on purchasing these controls.

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 COVID-19 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 COVID-19 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 COVID-19 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

- If you are testing for other people, 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.
- Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product. For the most current hazard information, see the product Safety Data Sheet. Safety Data Sheets are available at www.reopentest.com/ifu or contact your local representative.
- 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

- The applicable sample types of this test reagent: upper respiratory tract specimens (including pharyngeal swabs, nasal swabs, nasopharyngeal extracts); lower respiratory tract specimens (including respiratory tract extracts, bronchial lavage fluid, alveolar lavage Fluid and lung tissue biopsy specimens, deep cough sputum, saliva*); tissue culture and other samples. **Note: THE NASOPHARYNGEAL SWABBING IS RECOMMENDED, if use other specimens, sensitivity would be lower, especially saliva.**
- 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.
- For non-Lab settings use please follow the guide in *http://www.reopentest.com/guide* or scan QR below.

TEST PROCEDURE

(Please refer to the guide illustration of page 1/2)

Specimen extraction

1. Open the reagent solution container and drop all buffer into the extraction vial to prepare.
2. Place the swab into the extraction vial. Rotate the swab vigorously at least 10 times to mix and dissolve.
3. Remove the swab and close the vial with the cap and push firmly onto the vial.

Detection operations

4. Before testing, the unopened reagents should be placed at room temperature to make the temperature of the reagents reach equilibrium.
5. Tear the aluminum foil bag along the incision and take the reagent kit flat on a clean table. Directly drop 4 drops (approximately 100 µL) of the mixed solution into the sample "**S**" well and start timing.
6. 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).

****Note**: The color intensity in the test region will vary depending on the amount of SARS-CoV-2 nucleocapsid protein antigen present in the sample. Any faint colored line(s) in the test region(s) should be considered as positive.*

- ***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 COVID-19 Antigen Rapid Test is designed for the primary test of COVID-19 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

- ***Clinical sensitivity, specificity and accuracy***

To evaluate diagnostic performance, COVID-19 positive samples from 48 people and COVID-19 negative samples from 100 people were introduced into this study.

Table 1: The COVID-10 Antigen Test compared to PCR

Method		PCR		Total Results
	Results	Positive	Negative	
reOpenTest	Positive	46	1	47
	Negative	2	99	101
Total Result		48	100	148

Sensitivity = 95.8% (95% CI = 89.17% to 94.39%)
Specificity = 99.0% (95% CI = 91.21% to 97.68%)
Accuracy = 97.9% (95% CI = 92.1% to 98.6%)

- ***Detection limit***

LOD studies determine the lowest detectable concentration of SARS-CoV-2 at which around 95% of all (genuinely positive) replicates test positive. Heat-inactivated SARS-CoV-2 virus with an initial concentration of $1.15x10^7 TCID_{50}$/ml (tissue culture infection dose of 50%) was transferred to negative samples and serially diluted. Each dilution was tested in triplicate with the reOpenTest COVID-19 Antigen Rapid Test. The detection limit of the coronavirus antigen rapid test is $5.75x10^2 TCID_{50}$/ml.

Table 2: Results of the limit of detection study

Concentration ($TCID_{50}$/ml)	Number Positive / overall	Positive accordance
$5.75x10^2$	200/200	100%

- ***Hook effect***

In the investigation with heat-inactivated SARSCoV-2 virus, no Hook effect was found up to a concentration of $4.6x10^5 TCID_{50}$/ml.

- ***Cross reactivity***

The following organisms were examined for cross-reactivity. Samples that tested positive for the following organisms were found negative when tested with the reOpenTest COVID-19 Antigen Rapid Test:

Potential Cross-Reactant	Concentration
Respiratory Syncytial Virus Type A	$5,5 \times 10^7$ PFU/ml
Respiratory Syncytial Virus Type B	$2,8 \times 10^5$ $TCID_{50}$/ml
Novel Influenza AH1N1 Virus 2019	1×10^6 PFU/ml
Seasonal influenza A H1N1	1×10^5 PFU/ml
Influenza A H3N2	1×10^6 PFU/ml
Influenza A H5N1	1×10^6 PFU/ml
Influenza B Yamagata	1×10^5 PFU/ml
Influenza B Victoria	1×10^6 PFU/ml
Rhinovirus	1×10^6 PFU/ml
Adenovirus 3	$5 \times 10^{7.5}$ $TCID_{50}$/ml
Adenovirus 7	$2,8 \times 10^6$ $TCID_{50}$/ml
EV-A71	1×10^5 PFU/ml
Mycobacterium tuberculosis	1×10^3 Bacteria/ml
Mumps virus	1×10^5 PFU/ml
Human coronavirus 229E	1×10^5 PFU/ml
Human coronavirus OC43	1×10^5 PFU/ml
Human coronavirus NL63	1×10^6 PFU/ml
Human coronavirus HKU1	1×10^6 PFU/m
Parainfluenza virus 1	$7,3 \times 10^6$ PFU/m
Parainfluenza virus 2	1×10^6 PFU/ml
Parainfluenza virus 3	$5,8 \times 10^6$ PFU/ml
Parainfluenza virus 4	$2,6 \times 10^6$ PFU /ml
Haemophilus influenzae	$5,2 \times 10^6$ CFU/ml
Streptococcus pyogenes	$3,6 \times 10^6$ CFU/ml
Streptococcus pneumoniae	$4,2 \times 10^6$ CFU/ml
Candida albicans	1×10^7 CFU/ml
Bordetella pertussis	1×10^4 Bacteria/ml
Mycoplasma pneumoniae	$1,2 \times 10^6$ CFU/ml
Chlamydia pneumoniae	$2,3 \times 10^6$ IFU/ml
Influenza B Victoria	1×10^6 PFU/ml
Legionella pneumophila	1×10^4 Bacteria/ml
Influenza A H3N2	1×10^6 PFU/ml
Influenza A H5N1	1×10^6 PFU/ml
Influenza B Yamagata	1×10^5 PFU/ml
Influenza B Victoria	1×10^6 PFU/ml
Rhinovirus	1×10^6 PFU/ml

- ***Interfering Substances***

The following substances, which occur naturally in respiratory samples or which can be artificially introduced into the nasal cavity or the nasopharynx, were examined with the coronavirus antigen rapid cassette test in the concentrations listed below and classified as not impairing performance.

Substance	Concentration
Human blood (EDTA)	20% (v/v)
Mucin	5 mg/ml
Oseltamivir phosphate	5 mg/ml
Ribavirin	5 mg/ml
Levofloxacin	5 mg/ml
Azithromycin	5 mg/ml
Meropenem	5 mg/ml
Tobramycin	2 mg/ml
Phenylephrine	20% (v/v)
Oxymetazoline	20% (v/v)
0.9% sodium chloride	20% (v/v)
A natural, calming ALKALOL	20% (v/v)
Beclomethasone	20% (v/v)
Hexadecadrol	20% (v/v)
Flunisolide	20% (v/v)
Triamcinolone	20% (v/v)
Budesonide	20% (v/v)
Mometason	20% (v/v)
Fluticasone propionate	20% (v/v)
Fluticasone	20% (v/v)

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
3. E-mail: sales@reopentest.com

CUSTOMER SERVICE

Contact your local representative
or find country-specific contact information with
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