For Prescription Use and Non-Lab Settings Use.

For In Vitro Diagnostic Use Only

CE IVD No test component to be used inside the body except the Swab as directed.

reOpenTest

COVID-19 Antigen Rapid Test

INSTRUCTION FOR USER

FOR HEALTHCARE PROFESSIONALS

www.reopentest.com/ifu | service@reopentest.com

CE Mark	Contains sufficient for <n> tests
IVD In vitro diagnostic medical	Do not re-use
Read instructions for use	Do not use if package is damaged
REF Catalogue number	Keep away from sunlight
LOT Batch code	Keep Dry Keep away from rain
Use by	Temperature limit
Manufacturer	Caution
EC REP Authorized Representative in the European Community / European Union	

Version: EN2103F200260

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, nasal swab 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 medically 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	COVG10S	COVG10C	COVG10X
Tests Cassettes *Individual foil pouch	25	1	5
Extraction Vials & Caps	25	1	5
Extraction Reagents *Ampoules with salt solution	25 (400µL)	1 (400µL)	5 (400µL)
Swabs	25	1	5
Package Inserts	1	2	2

MATERIALS NOT SUPPLIED IN KIT

- Timer or watch

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. **DO NOT open the foil pouch until instructed**.
- Temperature have 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

- 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, if not please follow "specimen collection and preparation" section.
- The contents of this kit are to be used for the qualitative detection of COVID-19 Antigens from 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 been evaluated for use in patients with signs and symptoms of respiratory infection only, 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 vials, 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

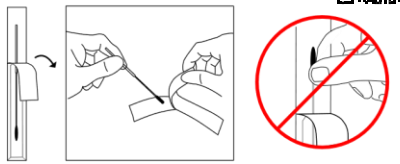
Store the kit at temperature, 2°C to 30°C (36°F to 86°F), out of direct sunlight. Shelf-Life is 23 months, Kit contents are stable until the expiration date printed on the outer box. ***DO NOT FREEZE.***

TEST PROCEDURE

(Please refer to the guide illustration)

Specimen collection and preparation

- Use the swab included in the kit.
- The applicable sample types of this test reagent: upper respiratory tract specimens (including pharyngeal swabs, nasal swabs, nasopharyngeal extracts).
- After the sample is collected, the test must be completed within one hour. 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.
- Nasopharyngeal/Nasal swab sampling please see illustration shown as below or follow the guide in ***http://www.reopentest.com/guide*** or scan the QR code:



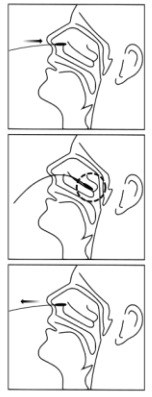
Nasopharyngeal Swabbing

Tilt patient's head back about 70°.

Insert the swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient.

Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions.

Slowly remove swab while rotating it.entlely rub and roll the swab. Leave swab in place for several seconds to absorb secretions.

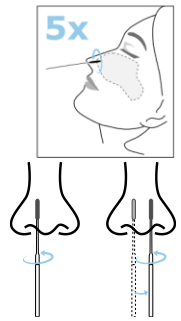


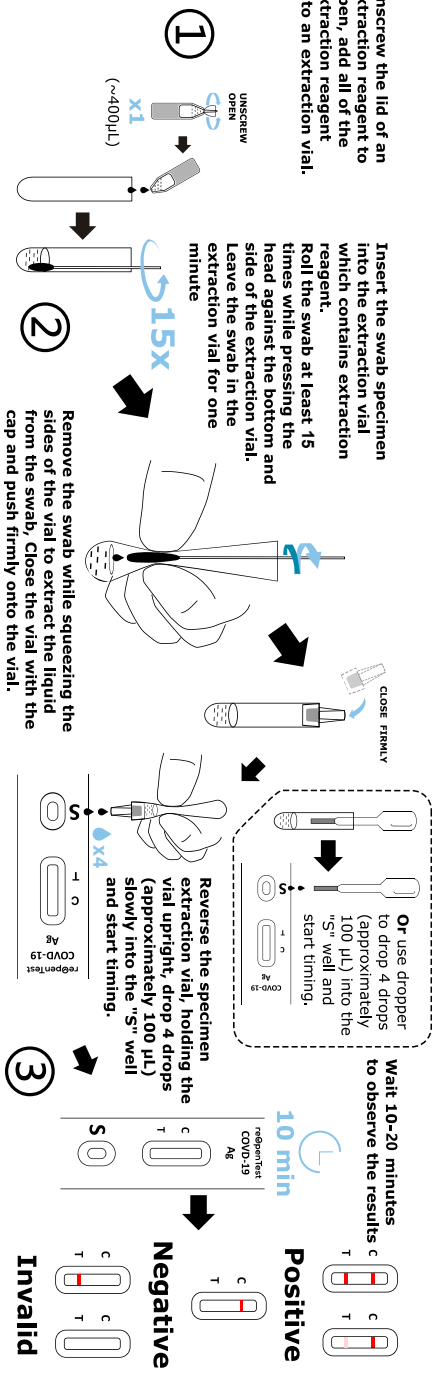
Nasal Swabbing

Gently insert swab tip (usually 15mm to 25mm) until it is fully inside your nostril and you meet resistance;

Rub swab tip around inside of nose cavity at least 5 times or more for 15 seconds to make sure collect a good sample;

Remove swab and repeat in another nostril;





Specimen extraction

1. Unscrew the lid of an extraction reagent to open, add all of the extraction reagent (approximately 400 μL) into an extraction vial.
2. Insert the swab specimen into the extraction vial which contains extraction reagent. Roll the swab at least 10 times while pressing the head against the bottom and side of the extraction vial to make the sample dissolve in the extraction reagent as much as possible.
3. Leave the swab in the extraction vial for one minute.

Detection operations

4. **Before testing, the unopened reagents and specimens should be placed at room temperature (15~30°C) to make the temperature of the reagents reach equilibrium.**
5. Tear the sealed foil pouch along the incision and take the test kit flat on a clean and dry table.
6. Remove the swab while squeezing the sides of the vial to extract the liquid from the swab, Close the vial with the cap and push firmly onto the vial.
7. Reverse the specimen extraction vial, holding the vial upright, drop **4 drops** (approximately 100 μL) slowly into the **"S"** well and start timing.
8. Observe the results showed within **10-20 minutes**, and the results shown after 30 minutes have no clinical significance for quantitative testing.

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 unless your local government regulation exemption allows.

PERFORMANCE CHARACTERISTICS

- *Nasal swabbing performance*

To evaluate nasal swabbing specimen's diagnostic performance, COVID-19 positive samples from 161 people and COVID-19 negative samples from 230 people were introduced into this study.

Table 1: The COVID-19 Antigen Test compared to PCR

Method		PCR		Total Results
	Results	Positive	Negative	
reOpenTest	Positive	157	2	159
	Negative	4	228	232
Total Result		161	230	391

Sensitivity = 97.52% (95% CI = 93.76% to 99.32%)
Specificity = 99.13% (95% CI = 96.89% to 99.89%)
Accuracy = 98.47% (95% CI = 96.69% to 99.43%)

- *Nasopharyngeal swabbing performance*

To evaluate nasopharyngeal swabbing diagnostic performance, COVID-19 positive samples from 161 people and COVID-19 negative samples from 230 people were introduced into this study.

Table 1: The COVID-19 Antigen Test compared to PCR

Method		PCR		Total Results
	Results	Positive	Negative	
reOpenTest	Positive	158	2	160
	Negative	3	228	231
Total Result		161	230	391

Sensitivity = 98.14% (95% CI = 94.65% to 99.61%)
Specificity = 99.13% (95% CI = 96.89% to 99.89%)
Accuracy = 98.72% (95% CI = 97.04% to 99.58%)

- *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	1×10^5 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.

Version: EN2103F200260
Last revision: March 2021

reOpenTest

REF **COVG10C / COVG10S / COVG10X**

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
E-mail: service@reopentest.com

Zhejiang Anji Saianfu Biotech Co., Ltd.
Add: 2nd Floor, No 3 Factory, No 489 WenYun Road, TangPu Industrial Park, Dipu Subdistrict, Anji County, HuZhou City, ZheJiang Province, China.
Tel: +8657187763175 Web: www.reopentest.com

EC REP **Lotus NL B.V.**
Add: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Tel: +31644168999