For Prescription Use and Non-Lab Settings Use.

For In Vitro Diagnostic Use Only

reOpenTest

SARS-CoV-2
Neutralizing Antibody Rapid Test

(Whole Blood/Serum/Plasma)

LOT

REF COVN200

CONTAINS:

- 25 Test Cassettes
- 25 Droppers (30ul) and 25 Plastic Droppers(25ul)
- 25 Buffer（400ul）
- 25 Alcohol Pads
- 1 Package Insert
- 1 Color Index

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 raineep dry
Use by	Temperature limit
Manufacturer	Caution

EC REP Authorized Representative in the European Community / European Union

INTENT OF USE

The reOpenTest SARS-CoV-2 Neutralizing Antibody Rapid Test is an immunochromatographic assay kit for the qualitative detection of SARS-CoV-2 Neutralization antibody in blood/serum/plasma from human. It is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. The novel coronavirus neutralizing antibodies are protective antibody produced by the human body after inoculation with novel coronavirus vaccine or infection with novel coronavirus. The kit is used to monitor the presence of neutralizing antibodies in subjects vaccinated with the novel coronavirus vaccine or in people infected with the novel coronavirus, it can be used to evaluate the immune effect after vaccination or whether neutralizing antibodies are produced in human body after infection with novel coronavirus. The COVID-19 Neutralization Antibody Detection Kit should not be used to diagnose acute SARS-CoV-2 infection.

SUMMARY AND EXPLAINATION

For the reOpenTest SARS-CoV-2 Neutralizing Antibody Rapid Test, neutralization antibody in the specimens are allowed to react with the anti SRBD protein-coupled gold conjugate followed by reaction with anti-ACE2 receptor protein immobilized in the test line. When the sample contains neutralization antibody, a visible line appears in the test region on the membrane. The solution continues to migrate to encounter a control reagent that binds a control conjugate, thereby producing another band in the control region. The reOpenTest SARS-CoV-2 Neutralizing Antibody Rapid Test is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of neutralization antibody in human whole blood, serum or plasma. This test provides only a preliminary test result. Therefore, any reactive specimen with the reOpenTest SARS-CoV-2 Neutralizing Antibody Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

PRINCIPLE OF THE TEST

The reOpenTest SARS-CoV-2 Neutralizating Antibody Rapid Test is based on colloidal gold immunochromatography and uses double-antigen sandwich assay to detect novel neutralizing antibodies against coronavirus in blood samples. Neutralizing antibodies is an immunoglobulin that targets the receptor-binding domain (S-RBD) of novel coronaviruss protein, including IgM antibody, IgG antibody and IgA antibody. The neutralizing antibodies were detected by the specific recognition of neutralizing antibodies by the recombinant novel coronavirus S-RBD antigen. The T line of the novel coronavirus neutralizing antibody test cassette was coated with recombinant novel coronavirus S-RBD antigen, and the C line was coated with sheep anti-S-RBD multi-antibody. During detection, the samples were dripped into the sample well, and the neutralizing antibodies of the novel coronavirus was combined with the recombinant S-RBD antigen of the novel coronavirus labeled with colloidal gold, a solid phase the recombinant S-RBD antigen of the novel coronavirus - novel coronavirus neutralizing antibodies - labelled the recombinant S-RBD antigen of the novel coronavirus - colloidal gold complex at the T line position, solid-phase sheep anti-S-RBD multiantibody - the recombinant S-RBD antigen of the novel coronavirus-colloidal gold complex was formed at the C line. After detection, combined withcolorimetric cards, the semi-quantitative detection of neutralizing antibodies against novel coronavirus in blood samples can be realized.

REAGENTS AND MATERIALS SUPPLIED

- 25 Test Cassettes
- 25 Droppers (30ul) and 25 Plastic Droppers(25ul)
- 25 Buffers（400ul）
- 25 Alcohol Pads
- 1 Package Insert
- 1 Color Index

MATERIALS NOT SUPPLIED IN KIT

- Clock, Timer or Stopwatch

WARNINGS AND PRECAUTIONS

For in vitro diagnostic use only. 2.The test device should remain in the sealed pouch until use. 3.Do not use kit past its expiration date. 4.The buffer contains a solution with a preservative (0.1% Proclin300). If solution comes in contact with the skin or eyes, flush with ample volumes of water. 5.Do not interchange or mix components from different kit lots. 6.This kit is for in vitro diagnostic use only. Please read this instruction carefully before experiment. 7.The collection, storage, and testing of specimens should be carried out in strict compliance with the "Technical Guidelines for Laboratory Testing of Novel Coronavirus Pneumonia (Second Edition)" and "Guidelines for Biosafety of Novel Coronavirus Laboratories (Second Edition)". 8.Storage of remaining specimens after detection and various waste disposal, should strictly abide by "Guidelines for Biosafety of Novel Coronavirus Laboratories (Second Edition)" and "Guidelines for Biosafety Protection of Novel Coronavirus Pneumonia Clinical Laboratory Testing (Trial Version 1)) "; it is recommended to refer to the above guidelines for the waste or remaining samples generated during the test. Firstly soak in ether, 75% ethanol, chlorine-containing disinfectant, peracetic acid, and chloroform to inactivate the virus, and then refer to the above guidelines for handling infectious materials. 9. The test cassette must be used within 30 minutes after opening, and the unused test cassette must be sealed and dryly stored. 10. Operation should be strictly performed according to the instruction, and different batches should not be mixed use.

KIT STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C).
- Do not freeze any of the test kit components.
- Do not use test device and reagents after expiration date.
- Test devices that have been outside of the sealed pouch for more than 1 hour should be discarded.

QUALITY CONTROL

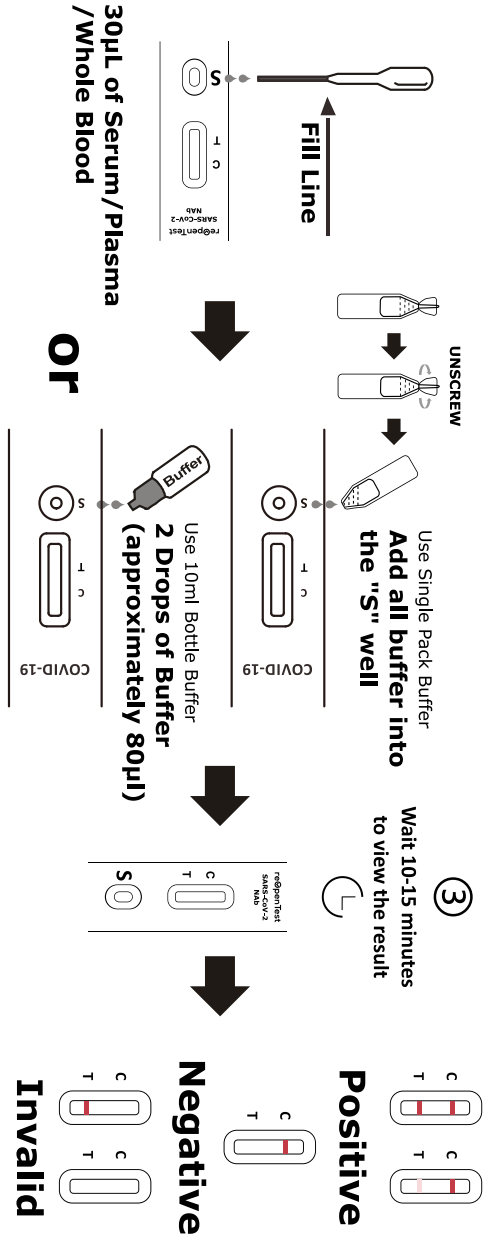
A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance

TEST PROCEDURE

(Please refer to the guide illustration)

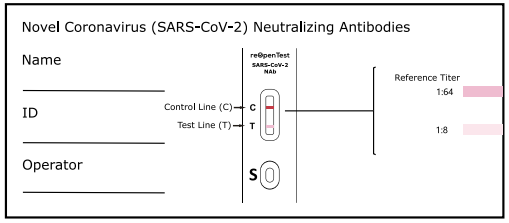
Specimen collection

1. The reOpenTest SARS-CoV-2 Neutralizing Antibody Rapid Test can be performed using either whole blood, serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.



Detection operations

1. Place all specimens, test devices, and assay solution at room temperature prior to testing (15~30min).
2. Place the device on a flat surface.
3. **For Serum or Plasma Specimens:**
   With a **25 μL** plastic dropper provided: Draw serum/plasma specimen to exceed the specimen line as showed in the following image and then transfer drawn serum/plasma specimen into the **"S"** well. Then add 2 drops (about 80 μL) of sample buffer to the **"S"** well immediately. Avoid air bubbles.
   For Whole Blood Specimen: Hold the **30 μL** plastic dropper vertically and transfer 1 drop of whole blood (about 30 μL) to the **"S"** well of the test device, then add 2 drops (about 80 μL) of sample buffer to the **"S"** well immediately. Avoid air bubbles.
4. Wait for the colored line(s) to appear. After 2 minutes, if the red colour has not moved across the test window or if blood is still present in the **"S"** well, add 1 additional drop of the sample buffer to the **"S"** well.
5. The result should be read in 10 minutes. Positive results may be visible as soon as 2 minutes. Do not interpret the result after 15 minutes.



Interpretation of results

When testing with enterprise references, the following criteria should be met.

- Negative references compliance rate: Use the enterprise negative references for testing, and the negative references should be detected at least 24/24 (-/-).
- Positive references compliance rate: Use the enterprise positive references for testing, and the positive references should be detected at least 5/5 (+/+).
- Minimum detection limit: Use enterprise sensitivity references for testing, and the sensitivity references should be detected at least 1/3 (+/+).

PERFORMANCE CHARACTERISTICS

- *For Plasma samples*

The clinical performance of SARS-CoV-2 Neutralizing Antibodies Test was determined by testing 339 positive and 369 negative specimens for SARS-CoV-2 neutralizing antibody to have:

Snsitivity of 98.82% (95% I : 97.01%～99.68%)
Secificity of 99.17% (95% CI :98.50%～99.75%)

Method		VNT		Total Results
	Results	Positive	Negative	
reOpenTest	Positive	335	3	338
	Negative	4	366	370
Total Result		339	369	708

- *For Plasma samples*

The clinical performance of SARS-CoV-2 Neutralizing Antibodies Test was determined by testing 339 positive and 869 negative specimens for SARS-CoV-2 neutralizing antibody to have:

Snsitivity of 98.82% (95% I : 97.01%～99.68%)
Secificity of 99.17% (95% CI :98.50%～99.75%)

Method		VNT		Total Results
	Results	Positive	Negative	
reOpenTest	Positive	333	7	340
	Negative	6	862	868
Total Result		339	869	1208

DETECTION LIMIT(LoD) STUDY RESULT

The determination study of the minimum detection limit proved that the test result meeting the positive detection rate of more than 95% was 0.250(Corresponding OD value).

CROSS REACTIVITY

The kit has no cross reactivity with Human Coronavirus (229E,OC43,HKU1,NL63), SARS, MERS, Adenovirus(1,2,3,4,5,7,55), Human Metapneumovirus (hMPV), Parainfluenza virus(1,2,3,4), Influenza A virus(H1N1, H3N2, H5N1,H7N9),Influenza B virus(Yamagata,Victoria),Haemophilus influenzae, Rhinovirus(A,B,C), Respiratory syncytial virus, Epstein-Barr virus, Human Immunodeficiency virus(HIV), Plasmodium falciparum, Plasmodium ovale, Dengue virus(1, 2, 3, 4), Enterovirus(A, B, C, D), Chlamydia pneumoniae, Legionella pneumophila, Mycobacterium tuberculosis, Streptococcus pneumoniae, Bordetella pertussis, Mycoplasma pneumoniae.

INTERFERENCE ANALYSIS

The kit has no interference with Bilirubin Unconjugated, Bilirubin Conjugated, Lipids (triglycerides), Hemoglobin, Rheumatoid factor, HAMA, Human Serum Albumin, Antinuclear antibody, Antimitochondrial antibody, Cholesterol, e. coli.

REPEATABILITY

Use enterprise precision references for testing, and the test results should be consistent.

LIMITATIONS

This test is designed for qualitative detection of SARS-CoV-2 neutralizing antibodies.

- Negative results do not rule out SARS-COV-2 infection, particularly those who have been in contact with the virus. Direct testing with a molecular diagnostic should be performed to evaluate for acute SARS-CoV-2 infection in symptomatic individuals.
- Positive results may be due to current or past infection with non-SARS-COV-2 corona virus strains, such as HKU1, NL63, OC43, or 229E.
- Results from this test should not be used to diagnose or to exclude acute SARS-COV-2 infection or to inform infection status.
- 4.A positive result may not indicate previous SARS-CoV-2 infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
- It is unknown at this time if the presence of antibodies to SARSCoV-2 confers immunity to reinfection.
- The Neutralization Antibody Detection Kit is known to cross-react with SARS-CoV-1 neutralizing antibodies.
- This test should not be used for blood donor screening.

reOpenTest

REF COVN200

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 | www.reopentest.com

EC REP
Brand-New Trading GmbH
Add: Mondseestraße 28/6, 5310 Tiefgraben, Österreich, Austria. Tel: +436763500180