CE IVD

reOpenTest

SARS-CoV-2

Neutralizing Antibody Rapid Test

(Whole Blood/Serum/Plasma)

About the test

Introduction

The Coronavirus disease (COVID-19), also known as the SARS-CoV-2 virus, is an acute respiratory infectious disease. The SARS-CoV-2 is a β-coronavirus, which is an enveloped non-segmented positive-sense RNA virus. It is the cause of coronavirus disease 2019 (COVID-19), which is contagious in humans. Infection with the SARS-CoV-2 initiates an immune response, which includes the production of antibodies in the blood. The secreted antibodies provide protection against future infections from viruses, because they remain in the circulatory system for months to years after infection and will bind quickly and strongly to the pathogen to block cellular infiltration and replication. These antibodies are named neutralizing antibodies. The SARS-CoV-2 neutralizing antibodies are protective antibody produced by the human body after inoculation with novel coronavirus vaccine or infection with novel coronavirus.

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 for professional use only and is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, monitor the presence of SARS-CoV-2 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 SARS-CoV-2 neutralizing antibodies are produced in human body after infection with novel coronavirus. The SARS-CoV-2 Neutralizing Antibody Rapid Test should not be used to diagnose acute SARS-CoV-2 infection.

Principle of The Test

The reOpenTest SARS-CoV-2 Neutralizing Antibody Rapid Test is based on colloidal gold immunochromatography and uses double-antigen sandwich assay to detect SARS-CoV-2 neutralizing antibodies against coronavirus in blood/serum/plasma 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 SARS-CoV-2 neutralizing antibodies were detected by the specific recognition of neutralizing antibodies by the recombinant novel coronavirus S-RBD antigen. The T line of the reOpenTest SARS-CoV-2 Neutralizing Antibody Rapid Test 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 SARS-CoV-2 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 - SARS-CoV-2 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 with colorimetric cards, the semi-quantitative detection of SARS-CoV-2 neutralizing antibodies against novel coronavirus in blood samples can be realized.

Materials Provided

- 1 Test device with desiccant and 30μl pipette in individual foil pouch
- 1 Buffer （80ul）
- 1 Alcohol Pad
- 1 Instruction for use
- 1 Colorimetric Card

Materials Required but not Provided

- Clock, Timer or Stopwatch

Storage and Stability

- Store the test kit at temperature, 2°C to 30°C (36°F to 86°F), out of direct sunlight. When stored in refrigerator, all kit components must be brought to room temperature (15-30℃) for a minimum of 30 minutes prior to performing the test. Do not open the sealed pouch before components come to room temperature.
- Shelf-Life is 23 months, Kit contents are stable until the expiration date printed on the outer box and poil pouch. ***DO NOT FREEZE***.

Warnings and Precautions

1. For in vitro diagnostic use only.
2. These instructions must be strictly followed by a trained healthcare professional to achieve accurate results.
3. All users have to read the instruction prior to performing a test.
4. The test device should remain in the sealed pouch until instructed.
5. Do not open the foil pouch until instructed. Do not use the aluminum foil bag if it is damaged.
6. Do not store the test kit in direct sunlight.
7. Do not use kit past its expiration date.
8. Do not reuse the sterilized lancets for specimen collection
9. Do not interchange or mix components from different kit lots.
10. Do not mix buffer of different lots or those for other products.
11. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials (i.e. swab, extraction tube, test device) in a biohazard container as if they were infectious waste and dispose according to applicable local regulations.
12. The test cassette must be used within 1 hour after opening. Test devices that have been outside of the sealed pouch for more than 1 hour should be discarded.
13. The buffer contains <0.1% ProClin 300 as preservative, may be toxic if ingested. When disposed of through a sink, or comes in contact with the skin or eyes, flush with a large volume of water.

Quality Control

Internal Quality Control

The reOpenTest SARS-CoV-2 Neutralizing Antibody Rapid Test contains a built-in internal procedural control in the test device. A red-colored line appearing in the control region “C” is designed as an internal procedural control. The appearance of the procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained. If the procedural control line does not develop in 20 minutes, the test result is considered invalid and retesting with a new device is recommended. If the internal procedural control line is still absent in the retest, please contact the manufacturer or distributor.

External Control

External Negative and Positive Controls are not supplied with this test 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 Nab External Control Kit can be purchased separately. Please contact reOpenTest or your distributor for information on purchasing these controls. When testing with External Negative and Positive Controls, the following criteria should be met.

1. Negative references compliance rate: Use the External Negative Control for testing, and the negative references should be detected at least 24/24 (-/-).
2. Positive references compliance rate: Use the External Positive Control for testing, and the positive references should be detected at least 5/5 (+/+).

Test Procedure (Please follow the figure on reverse)

Preparation

1. Allow the test kit and its components to reach room temperature (15℃-30℃) prior to testing for 30 minutes.
2. Look at the expiration date (EXP) of the kit box or foil pouch. If the expiration date has passed, use another kit.
3. Ensure foil pouch is intact. Do not use the test if there is visible damage to the foil pouch.
4. Tear the sealed foil pouch along the incision and take the test device flat on a clean, dry surface. Make sure the test kit has all components.

⚠Please read the instruction carefully before beginning.

Specimen collection and storage

- The reOpenTest SARS-CoV-2 Neutralizing Antibody Rapid Test can be performed using either whole blood, serum or plasma.
- Blood sample is obtained by fingerstick using safety lancet and collected using pipette.
- 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

Safety lancet to Procedure from Fingerstick

5. Use the Alcohol Pad to clean the puncture site on finger. ⚠Allow to dry. Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
6. Twist off the tab of the lancet to break the seal and discard the cap. Please do not directly pull off the protective cap.
7. Perform the puncture. Position the safety lancet firmly against the puncture site as illustrated. Hold lancet between fingers. To activate, press safety lancet firmly against the puncture site.
8. Discard used safety lancet into a sharps container according to your facility's established procedures. Squeeze gently going along finger capillaries up to the puncture site to produce a blood drop on the fingertip

Procedure for Collecting Blood Specimen Using pipette

9. Hold the tube horizontally, press gently the pipette to let the air out, and then touch the tip of the pipette to the blood sample and release the pressure from pipette. Pipette will draw the sample to the air vent, please wait until the tip is completely filled with blood and then stop.

Detection operations

10. Hold the **30 μL** pipette vertically and transfer the whole blood (about 30 μL) to the **"S"** well of the test device, then unscrew the lid of a buffer pack to open, add all its buffer (approximately 80 μL) to the **"S"** well immediately. ⚠Caution: Avoid making bubble when dropping.
11. Wait for the colored line(s) to appear. The result should be read after 15-20 minutes. Positive results may be visible as soon as 2 minutes. ⚠ **DO NOT use the result after 30 minutes**.

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).
  ⚠*Caution: The T line can be very faint. Any pink/gray line visible here indicates a positive result when the result is valid.*

  Compare the T-line color with the colorimetric card, the semi-quantitative detection of SARS-CoV-2 neutralizing antibodies against novel coronavirus in blood samples can be realized accordingly. **(Please refer to the figure on reverse page)**
- ***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.

Performance Characteristics

For Plasma samples

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

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

Sensitivity of 98.82% (95% CI : 97.01% ~ 99.68%)
Specificity of 99.17% (95% CI :98.50% ~ 99.75%)

For Plasma samples

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

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

Sensitivity of 98.82% (95% CI: 97.01% ~ 99.68%)
Specificity of 99.17% (95% CI :98.50% ~ 99.75%)

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 & Reproducibility

Repeatability & Reproducibility of reOpenTest SARS-CoV-2 Neutralizing Antibody Rapid Test was established using in-house reference panels containing negative specimens and a range of positive specimens. There were no differences observed within-run, between-run, between-lots, between-sites, and between-days.

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.
- 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 reOpenTest SARS-CoV-2 Neutralizing Antibody Rapid Test is known to cross-react with SARS-CoV-1 neutralizing antibodies.
- This test should not be used for blood donor screening.

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Version: EN2021E15U200260

REF COVN20C

EN

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Version: EN2021E15U200260

reOpenTest

CE IVD

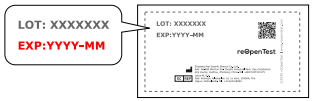
SARS-CoV-2
Neutralizing Antibody Rapid Test

In vitro diagnostic rapid test for qualitative detection of SARS-CoV-2 neutralizing antibodies

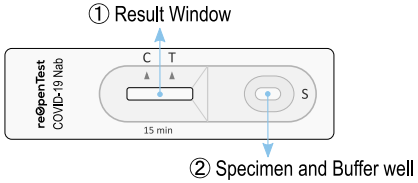
Preparation

1. **Allow the test kit and its components to reach room temperature (15°C-30°C)** prior to testing for 30 minutes.

2. **Look at the expiration date (EXP) of the kit box or foil pouch. If the expiration date has passed, use another kit.**

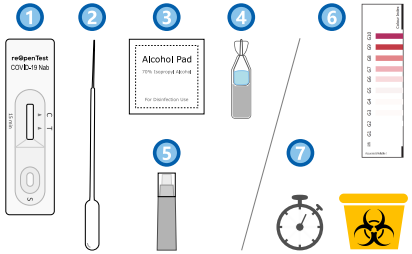


3. **Ensure foil pouch is intact. Do not use the test if there is visible damage to the foil pouch. Open foil pouch and look for the following ① to ②, and take the test device flat on a clean, dry surface:**



4. **Find the following components:**

① Test device (with desiccant in individual foil pouch)
② Pipette (sealed in test device foil pouch)
③ Alcohol Pad
④ Buffer (80μl individual pack)
⑤ Safety Lancet ⑥ Colormetric Card

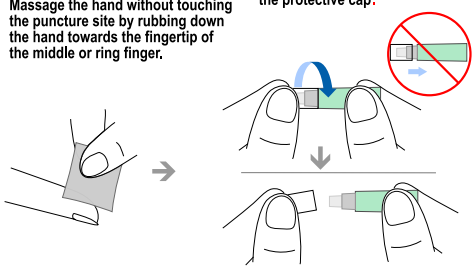


⑦ timer or watch is required but not provided.

Preparation

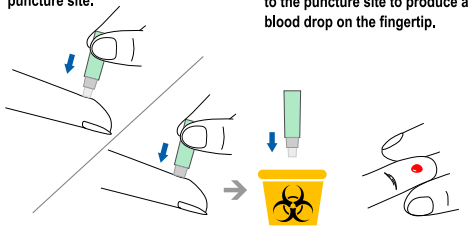
5. **Use the Alcohol Pad to clean the puncture site on finger.**
⚠**Allow to dry.**
Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.

6. **Twist off the tab of the lancet to break the seal and discard the cap. Please do not directly pull off the protective cap.**

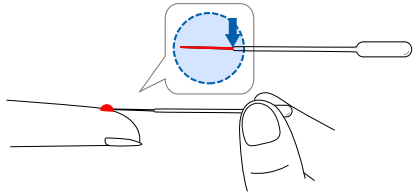


7. **Perform the puncture. Position the safety lancet firmly against the puncture site as illustrated. Hold lancet between fingers. To activate, press safety lancet firmly against the puncture site.**

8. **Discard used safety lancet into a sharps container according to your facility's established procedures. Squeeze gently going along finger capillaries up to the puncture site to produce a blood drop on the fingertip.**

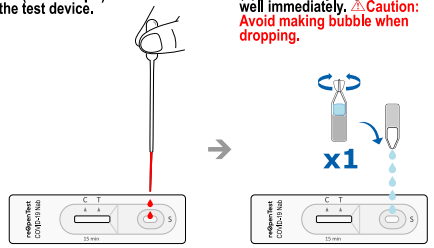


9. **Hold the tube horizontally, press gently the pipette to let the air out, and then touch the tip of the pipette to the blood sample and release the pressure from pipette. Pipette will draw the sample to the air vent,**
⚠**please wait until the tip is completely filled with blood and then stop**

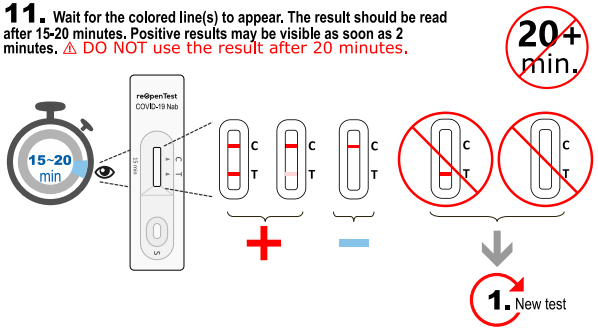


10. **Hold the 30 μL dropper vertically and transfer the whole blood (about 30 μL) to the "S" well of the test device.**

then unscrew the lid of a buffer pack to open, add all its buffer (approximately 80 μL) to the "S" well immediately. ⚠**Caution: Avoid making bubble when dropping.**



11. **Wait for the colored line(s) to appear. The result should be read after 15-20 minutes. Positive results may be visible as soon as 2 minutes.** ⚠ **DO NOT use the result after 20 minutes.**

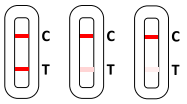


Disposal

After test is completed, place the test unit in plastic disposal bag and dispose all test kit materials in trash.

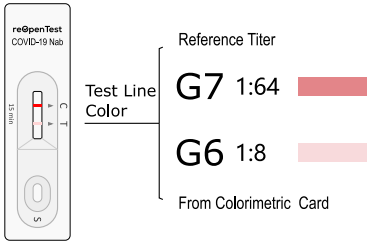
Read Results

Corona Positive (+): **Two red lines appear. One is in the test area (T) and the other is in the quality control area(C).**
⚠Caution: The T line can be very faint. Any pink/gray line visible here indicates a positive result when the result is valid.

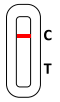


It is very likely patient has produced certain protective neutralizing antibodies after inoculation with novel coronavirus vaccine or infection with novel coronavirus.

Compare the T-line color with the colorimetric card, the semi-quantitative detection of neutralizing antibodies against novel coronavirus in blood samples can be realized accordingly as below:

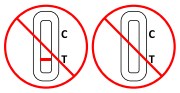


Negative (-): **Only a red line appears in the quality control area (C), and no line appears in the test area (T).**



A negative result means the coronavirus neutralizing antibodies were not found in the sample. The patient who took this test, his/her body has not yet produced enough protective neutralizing antibodies after inoculation with novel coronavirus vaccine or infection with novel coronavirus.

Invalid: No red line displays in the quality control area (C). This means something with the test did not work properly. If the test result is invalid, it will need to retest with **a new test** or consult a healthcare professional.



Symbols Reference

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

REF COVN20C

reOpenTest

Date Issued: 2021-05-12
Version: EN2021E15U200260

ORDER / SERVICE
1. Contact reOpenTest's distributors or
2. Visit reOpenTest website: http://www.reopentest.com
3. E-mail: service@reopentest.com

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