SARS-CoV-2 Neutralizing Antibody
Rapid Test Cassette
Package Insert

Cat: COVB-602 **Specimens:** Serum, plasma, whole blood, fingertip whole blood

Version:01 **Effective Date:**03.2021

For professional *invitro* diagnostic use only.

INTENDED USE

This product is used for in vitro qualitative detection of SARS-CoV-2 neutralizing antibodies in human serum, plasma, whole blood and fingertip whole blood samples.
This product is a disposable diagnostic aid, the test results are for clinical reference only and should not be used as the only basis for Clinical diagnosis and treatment. It is only suitable for professional in vitro diagnosis, not for personal use.

Package Specifications

1 test/kit，25 tests/ kit, 50 tests/ kit, 100 tests/ kit

PRINCIPLE

The cassette by immune chromatography test, the sample will be under the capillary action to move forward along the test strip. Spraying colloidal gold-labeled SARS-CoV-2 recombinant RBD antigen and chicken IgY antibody on the gold pad. The T line is coated with the SARS-CoV-2 recombinant S protein, and the C line is Coated with goat anti-chicken IgY antibody. If the sample contains a SARS- CoV-2 anti-RBD neutralizing antibody, then the antibody combines with the colloidal gold-labeled SARS-CoV-2 recombinant RBD antigen to form an immune complex, which diffuses forward along the nitrocellulose membrane under capillary action and will be captured by the SARS-CoV-2 recombinant S protein precoated on the nitrocellulose membrane T line. The more SARS-CoV-2 anti-RBD neutralizing antibodies in the sample, the more complexes accumulate on the detection line, the intensity of the color is positively correlated with the titer of the SARS-CoV-2 anti-RBD neutralizing antibodies in the sample.

Main Components

1. Test card: The test card is Composed of a plastic card and a test strip; the test strip is made of nitrocellulose membrane (the T line in the detection area is coated with the SARS-CoV-2 recombinant S protein, and the C line in the quality Control area is coated with goat anti-chicken IgY antibody), gold pad (colloidal gold-labeled SARS-CoV-2 recombinant RBD antigen, colloidal gold-labeled chicken IgY antibody), sample pad, absorbent paper and PVC bottom plate
2. Pasteur pipette
3. Sample diluents
4. Blood collection needle
5. Alcohol cotton sheet

Package Specifications	1test/kit	25tests/kit	50 test/kit	100 test/kit
Pasteur pipette	≥1pcs*1pack	≥25pcs*1pack	≥25pcs*2pack	≥25pcs*4pack
Sample diluents	1pcs*1pack	1pcs*1pack	1pcs*2pack	1pcs*4pack
Blood collection needle	≥1pcs*1pack	≥25pcs*1pack	≥25pcs*2pack	≥25pcs*4pack
Alcohol cotton sheet	≥1pcs*1pack	≥25pcs*1pack	≥25pcs*2pack	≥25pcs*4pack
/	Refer to the package			

Note: The components in different batches of kits cannot be interchanged

PRECAUTIONS

1. Equilibrate the test card to room temperature (more than 30min) before testing.
2. The test should be performed strictly in accordance with the instructions.
3. Read the displayed result within 15-20 minutes, and the results read after 20 minutes is invalid.
4. Do not use repeated freeze-thaw, highly hemolyzed and lipemia samples.
5. The test samples should be regarded as infectious agents, and they must be operated in accordance with the infectious disease laboratory operation rules and pay attention to biological safety.
6. This product is a single-use in vitro diagnostic reagent. Do not reuse it. It is only used for in vitro diagnostics. Do not use expired products.
7. Do not use the kit with obvious damage and test card with damaged package.
8. Do not take the desiccant in the aluminum foil bag.
9. The test results of this kit are only used as diagnostic aids. If the test results are inconsistent with the clinical evaluation, further inspection and confirmation are required.
10. The test should be performed strictly in accordance with the detection procedures. Correct operation ensures correct results.

Storage Conditions and Validity Period

This product is valid for 18 months when stored at 2°C-30°C and should be used within 20 minutes once the foil bag is opened. See the label for production date and expiration date.

SPECIMEN COLLECTION AND PREPARTION

1. The test sample should be serum, plasma (anticoagulated with heparin or EDTA), whole blood (anticoagulated with EDTA) or fingertip whole blood.
2. The test should be carried out soon after the clinical samples are collected. If the samples cannot be detected within 4 hours, the sample should be stored at 2°C-8°C, where whole blood for no more than 2 days, serum/plasma for no more than 7 days. Pay attention to return to room temperature before testing.
3. Samples with severe lipemia, hemolysis, and microbial contamination cannot be used for the detection of this product; turbid samples will affect the results of this product.

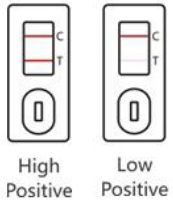
DIRECTIONS FOR USE

1. Please read this instruction carefully before use. Please return all reagents to room temperature before the test. The test should be performed at room temperature.
2. Preparation
   Before testing, equilibrate the kit at room temperature for 30 minutes.
3. Sampling and testing
   Pipette 20μl (about 2 drops) serum/plasma or 30μL (about 3 drops) whole blood/fingertip whole blood sample into the sample hole of the test card (Note: can use a pipette or a matching drawing dropper to sample.),and then immediately add 30μL (about 1 drop) sample diluent to the sample hole to start timing;
   Read the displayed result within 15-20 minutes, and the results read after 20 minutes is invalid.

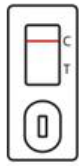
INTERPRETATION OF RESULTS

Positive result:

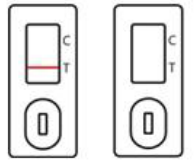
If there are color bands on the test line (T) and quality control line (C), the result is positive, as shown in the Figure:



Negative result:
If only the quality control line C develops color and the test line (T) does not develop color， the result is negative, as shown in the Figure :



Invalid result:
If no color band appears on the quality control line (C), and it is judged as an invalid result regardless of whether the detection line (T) shows color band or not, as the picture shows below:



QUALITY CONTROL

1. A procedural control is included in the test. A colored line appearing in the control region(C) is considered an internal procedural control. It confirms adequate membrane wicking.
2. Control standards are not supplied with this cassette; 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.

LIMITATIONS OF THE TEST

1. This kit is only for the detection of human serum, plasma, whole blood, and fingertip whole blood samples.
2. The hemoglobin, triglycerides and bilirubin in the sample will interfere with

the test results, and the maximum allowable concentrations are 5.0g/L, 10.0g/L and 0.2g/L respectively. Samples that exceed the interference concentration and heavily contaminated samples may cause false results.

3. The test results may be wrong due to technical issues, operational errors and other sample factors.
4. For patients with impaired immune function or receiving immunosuppressive therapy, such as human immunodeficiency virus (HIV) infected patients or patients receiving immunosuppressive therapy after organ transplantation, the reference value of serological testing is limited and may lead to wrong medical interpretations.

Product Performance Index

Clinical verification

The listed product is used as similar product for comparison, and the results are as follows

		Similar Product		
		Positive(case)	Negative(case)	Total(case)
Sejoy	Positive(case)	117	2	119
	Negative(case)	6	212	218
	Total(case)	123	214	337

Relative Sensitivity :95.12%(95%CI*:89.68%-98.19%)
Relative Specificity:99.2%(95%CI*:96.66%-99.89%)
Total coincidence rate: 97.63%(95%CI*:95.38%-98.97%)

Minimum detection limit

Test the enterprise reference products for the minimum detection limit of SARS-CoV-2 neutralizing antibody, test results of SI and S2 should be positive, test result of S3 should be positive or negative.

Precision

Three consecutive batches of reagents were tested for precision. Different batches of reagents were used to test the same negative sample 10 times in succession, and the results were all negative. Different batches of reagents were used to test the same positive sample 10 times in succession, and the results were all positive.

Index of Symbols

	Consult instructions for use		Tests per kit		Authorized Representative
	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalogue number

Hangzhou Sejoy Electronics& Instruments Co., Ltd.
Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City 311100 Zhejiang China
Website: www.sejoy.com

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany