SARS-CoV-2 Neutralizing Antibody Rapid Test (Colloidal Gold Immunochromatography)
Catalog Number 41A260

(Please read this instruction manual before use.)

INTENDED USE

This kit can be used for the qualitative measurement of SARS-CoV-2 neutralizing antibodies in human serum, plasma and whole blood.

SUMMARY

The SARS-CoV-2 virus is a new type of coronavirus of the genus β, encoding four major structural proteins: spike (S), envelope (E), membrane (M) and nucleocapsid (N). The neutralizing antibodies can target the S1 subunit of S protein and bind to the S1 receptor binding domain (RBD), thereby blocking the interaction between S1RBD of the virus and angiotensin-converting enzyme 2 (ACE2) on the surface of human cells, alleviate the threat from SARS-CoV-2. The detection of neutralizing antibodies can be used to monitor the immune response of vaccinated people or people infected by SARS-CoV-2.

ASSAY PRINCIPLE

This assay is based on the specific antibody-antigen reaction with colloidal gold immunochromatography. Colloidal gold particles conjugated with recombinant SARS-CoV-2 S1RBD is pre-coated on the conjugation pad together with colloidal gold conjugated goat anti-chicken IgY as the control particles. The detection line (T) on the strip is coated with recombinant SARS-CoV-2 S1RBD, and the control line is coated with chicken IgY.
During testing, neutralizing antibodies present in the samples bind to the S1RBD conjugated colloidal gold particles. The complex migrates upward by the capillary effect and is captured by the S1RBD immobilized on the membrane forming the test line (T). Meanwhile, the colloidal gold labeled with goat anti-chicken IgY is captured by chicken IgY forming the control line (C). The result is visible within 15~20 minutes.

REAGENTS AND MATERIALS

Components	1 test/kit	25 tests/kit
SARS-CoV-2 neutralizing antibody test strip	1	25
Assay buffer	0.1ml/tube	2 ml/tube
Quantitative pipette	1	25
Instruction for use	1	1

OTHER MATERIALS REQUIRED, BUT NOT PROVIDED

Timer, Lancets and Alcohol pad

PRECAUTIONS

-All reagents are for *in vitro* diagnostics use only.
-All reagents should be equilibrated to room temperature before use.
- Avoid touching nitrocellulose membrane with your fingers.
-Strips are sensitive to temperature and humidity. The reaction temperature should be at 15 °C ~30 °C and the humidity should be below 70%.
-Handle all specimens as if they contain infectious agents. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are tested.
-Ensure an appropriate amount of samples is used for assessment.
-The quality of expired reagents cannot be guaranteed or if reagents are not stored under required conditions as indicated in the manual.
- Do not use the strip if the pouch is damaged or the seal is broken.
-The used reagents should be discarded according to local regulations.

STORAGE

- The kit needs to be stored at 4 °C ~30 °C and in a dry environment.
- Avoiding freezing strips and buffer.
- The test strip is stable until the expiry date only if it has not been opened and kept in the sealed aluminum pouch.
- The sample diluent is valid for 30 days after opening the bottle.
- Do not open the sealed pouch until use. Once opened, the strip should be used within 1 hour.

SPECIMEN COLLECTION AND STORAGE

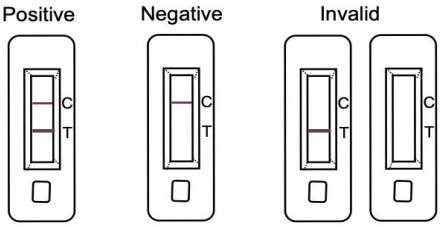
1. For serum/plasma/whole blood
a. EDTA, heparin or sodium citrate anticoagulation is recommended.
b. The serum/plasma can be stored at 2~8°C for 7 days if it can not be tested in time. For long time storage, serum/plasma samples should be stored below -15°C.
c. Whole blood samples should not be frozen and can be stored at 2~8°C for 3 days.
2. For fingertip whole blood
The fingertip whole blood sample should be tested immediately.

TEST PROCEDURE

Preparation of the test:
Equilibrate kit components in unopened packaging to room temperature (15-30 °C) before starting the test.

Assay procedure:
1. Take the strip out of the packaging bag and place it on the table.
2. Add the sample:
   For serum/plasma/whole blood samples:
   Transfer 60 µL serum or plasma sample to the sample hole (S) on the test strip using a quantitative pipette.
   For fingertip whole blood samples:
   a. Clean the puncture site with the alcohol pad.
   b. Puncture the fingertip with a safety lancet.
   c. Transfer 60 µL fingertip whole blood to the sample hole (S) on the test strip using a quantitative pipette.
3. Remove the vial cap and add 1 drop of the assay buffer to the sample hole.
4. Read the test results within 15~20 minutes. Do not read the results after 25 minutes.

INTERPRETATION OF TEST RESULT



✧ **Positive result:**
The presence of two lines as the control line (C) and the test line (T) in the result window. A positive result indicates that the neutralizing antibodies are detected in the sample.

✧ **Negative result:**
The presence of a single line as the control line (C) in the result window. A negative result indicates that the neutralizing antibodies are not detected in the sample.

✧ **Invalid result:**
If the control line (C) is not visible within the result window after performing the test, the result is invalid. In this case, you should read the instructions carefully and retest the sample.
Note: The test line could be faint. Any line, even if faint, should be interpreted as a line. Do not compare the color intensity of each line to another.

LIMITATIONS OF TEST

- This kit is a qualitative test, and the test results are only for clinical reference, which should not be used as the only basis for clinical diagnosis and treatment.
- The test results of sample are related to the quality of sample collection, processing, transportation and storage, and any error may lead to the inaccuracy of the test results.
- Hemolytic samples may cause false positive result. Please avoid using hemolytic samples for this test.

ASSAY PERFORMANCE

Sensitivity and specificity:
The SARS-CoV-2 Neutralizing Antibody Rapid Test has been evaluated with samples obtained from 89 vaccinated people at 14-16 days after their second injection and 220 non-vaccinated people. The comparator method Plaque Reduction Neutralization Test (PRNT) using virus (strain HCoV-19/USA/WAI/2020; BEI Resources, Manassas, VA) was used in this trial.

SARS-CoV-2 Neutralizing Antibody Rapid Test (Colloidal Gold Immunochromatography)	$PRNT_{50}$		
	Positive	Negative	Total
Positive	86	6	92
Negative	3	214	217
Total	89	220	309
Positive agreement: 86/89 96.63% (95%CI: 91.13%-99.05%)			
Negative agreement: 214/220 97.27% (95%CI: 95.54%-99.47%)			

Limit of detection:
The detection limit was 15 IU/ml, determined by WHO International Standard for anti-SARS-CoV-2 immunoglobulin, NIBSC code:20/136).

Cross-reactivity:
There was no cross-reactivity with sample obtained from below disease status.

Conditions	Conditions
Anti-influenza A IgG	Anti-HBV IgM
Anti-influenza A IgM	ANA
Anti-influenza B IgG	Anti-HIV
Anti-influenza B IgM	Anti-respiratory syncytial virus IgG
Anti-Haemophilus influenzas IgG	Anti-respiratory syncytial virus IgM
Anti-Haemophilus influenzas IgM	Anti-229E
Anti-HCV IgG	Anti-NL63
Anti-HCV IgM	Anti-OC43
Anti-HBV IgG	Anti-HKU1

Interfering substances:
No interfering was noted with substance listed in the table at the indicated concentration.

Substance	Concentration
Triglyceride	40 mmol/L
Hemoglobin	2 g/L
Bilirubin	350 μmol/L

SYMBOLS

	Manufacturer	CE	EC Declaration of Conformity
	Expiry date		Consult Instruction
LOT	Lot number		Store
REF	Catalog number		Caution
IVD	In Vitro Diagnostic Device	EC REP	Name and Address of EU REP