COVID 19 Neutralization Antibody Test Kit (Colloidal Gold Method)
Instructions for Use

[Packaging specification]

Test cassette (single test packaging): 5 tests/box; 20 tests/box.

[Intended use]

This product is used for qualitative detection of Covid-19 neutralizing antibody (NAb) in human serum, plasma and whole blood samples in vitro.

[Test principle]

This product is tested by colloid gold competitive inhibition method. Recombinant human receptor protein (HACE2) was used to coat nitrocellulose membrane and recombinant novel Coronavirus surface receptor-binding domain (RBD) protein was used to label colloidal gold. In vitro qualitative detection of novel Coronavirus antibody was performed.

When the test, drop the sample into the reagent sampling well. In the sample, the Novel Coronavirus antibody and the test line were coated with hACE2 to compete for binding to colloidal gold labeled RBD protein. When the concentration of the Novel Coronavirus antibody in the sample exceeded the detection limit, the colloidal gold-labeled antigen combined with the antibody in the sample to form the antibody-antigen-colloidal gold complex. During chromatography, the antigen labeled with colloidal gold binds to the Novel Coronavirus antibody so that part of it cannot bind to the receptor in the test line. Conversely, when the concentration of Novel Coronavirus antibody in the sample is lower than the detection limit concentration or the sample does not contain Novel Coronavirus antibody, the colloidal gold labeled antigen partially or completely binds to the receptor in the test line, and the color depth of the test line is inversely proportional to the concentration of Novel Coronavirus antibody in the sample.

[Kit Content]

COVID 19 NAb Test Kit (Colloidal Gold Method)

Catalog / Composition	TBS3241-05	TBS3241-20
1.Test kit	5 pieces	20 pieces
2.Blood sampling needle	5 pieces	20 pieces
3.Buffer tube	5 bottles (150ul/bottle)	20 bottles (150ul/bottle)
4.Instruction for Use	1 piece	1 piece

[Material Required but Not Provided]

- Timer
- Alcohol sterilized cotton tablets
- Hand-held colloidal gold quantitative detector

[Storage conditions and shelf life]

The original packaging should be stored in a dark and dry place at 2 ℃~30 ℃ and should not be frozen. The shelf life of the product is 24 months.

The reagent should be used as soon as possible within 1 hour after the aluminum foil bag is opened.

Date of production: see the product label.

Date of expiration: see the product label.

[Sample requirements]

1. Samples with severe hemolysis, lipidemia or turbidity should not be used.
2. After sample collection, the test must be completed within the same day. If the test cannot be completed on the same day, please keep the serum / plasma sample as follows: it can be stored for 7 days at 2 ℃ ~ 8 ℃, and it can be stored for 6 months at - 20 ℃ or below. Avoid heating to inactivate the sample.

3. Samples must be fully recovered to room temperature (15 ℃ ~ 30 ℃) before testing. The frozen samples should be thawed completely, rewarming and mixed evenly before use. The samples can only be thawed once.

Fig.1 Diagram of adding serum, plasma, and whole blood with pipette.

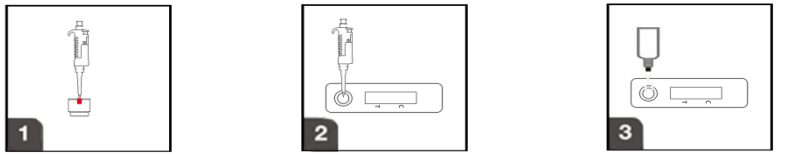
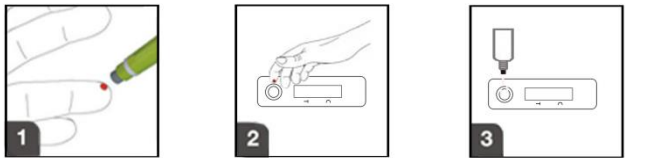


Fig. 2 Terminal blood test diagram



[Test procedure]

1. Read the instruction completely before testing.
2. Unpack the package, take out the test card and use it within one hour as soon as possible.
3. Draw the serum, plasma and whole blood samples with a dropper, add 1 drop (about 30 μL) vertically into the sampling hole, then add 2 drops (about 60 μL) of buffer, and start timing at the same time.
4. After 10 minutes, the test results were detected by the matching Fast Reader for colloidal gold quantitative detection (TBS3242). The test results were invalid after 15 minutes.

[Result interpretation]

Antibody qualified： The testing result of Fast Reader displays **qualified**: indicating that the neutralizing antibody has reached the protective titer.

Antibody unqualified： The testing result of the Fast Reader displays **unqualified:** indicated that no neutralizing antibody was produced, or the amount of neutralizing antibody could not reach the protective titer.

Invalid： The test result of the Fast Reader displays **invalid**: indicating that the operation process is incorrect, or the test strip is invalid (please retest or contact the local service provider).

[Limitations of test methods]

1. The test results of this reagent are suspicious samples near the reference value. It is recommended to re measure and dynamically observe.
2. Due to methodological or immune specificity and other reasons, using reagents from different manufacturers to test the same sample may get different test results. Therefore, the test results of different reagents should not be directly compared with each other, so as not to cause wrong medical interpretation. It is suggested that the laboratory should indicate the characteristics of the reagents used in the test report.
3. The test results of this product are only for clinical reference and should not be used as the only basis for diagnosis.
4. Samples with cross contamination, microbial contamination, severe hemolysis or turbidity may cause incorrect test results, so avoid using such samples as far as possible.

[Product performance index]

1. Repeatability: 12 samples from the same source were tested continuously, and the results were consistent.
2. The cut-off value of 1812 normal blood samples was determined to be < 0.2 inhibition rate by enzyme-linked immunosorbent assay compared with the 99th

percentile method.

[Precautions]

1. Read the instructions carefully before operation and carry out the test operation in strict accordance with the instructions of the kit.
2. The test card should be used once within the shelf life.
3. Restore the test card and samples to room temperature before use.
4. Do not touch the white film in the center of the test card.
5. Droppers should not be mixed to avoid cross contamination.
6. Avoid direct sunlight and direct blowing of electric fan.
7. Do not use tap water, purified water or distilled water as negative control.
8. Pay attention to ensure the freshness of samples and avoid failure or pollution caused by deterioration. appear antibody:qualified The results should be packaged in bottles according to the legal procedures for the diagnosis method.
9. Please contact the supplier for any problems during the test。

[Symbol]

	Consult instructions for use		Contains sufficient for <n> tests		In vitro diagnostic medical device
	Caution		Use by date		Do not reuse
	Temperature limitation		Batch code		Catalogue number
	Keep away from sunlight		Keep dry		Date of manufacture
	Manufacturer		Prescription only		Do not use if package is damaged
	Biological risks		Fragile, handle with care		This way up

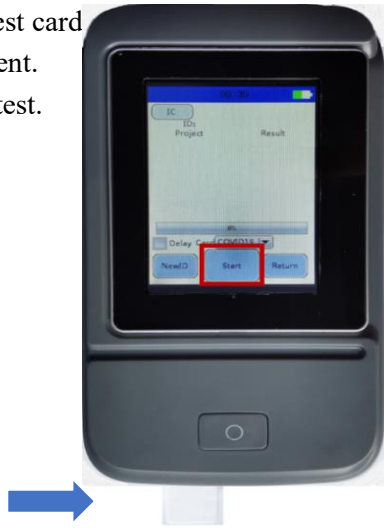
Operation steps of Fast Reader for colloidal gold quantitative detector

1. Turn on the power switch of the device (as shown in the figure).

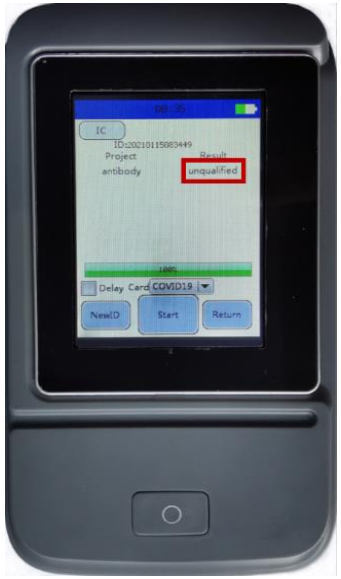
2. Click test to enter the next step.

3. Select the type of test card (COVID 19) at the bottom of the screen.

4. 10 minutes after sample addition, insert the test card into the card hole at the bottom left of the instrument. As shown in the figure, and click start to start the test.



5. At the end of the test, the test results will be displayed at the top of the screen, as shown in the figure below.



6. After all the samples are tested, turn off the machine and store them in a clean, cool, and dry place (in case of power loss during the test, please plug in the 110-220 V power supply).