Tribioscience

SARS-CoV-2 Neutralizing Antibody Rapid Test Kit (Colloidal gold)

Fast, Sensitive and Simple Method for Nab Detection

COVID 19 NAb Test Kit (Colloidal Gold Method)

Catalog / Composition	TBS3241-05	TBS3241-20
1.Test kit	5 pieces	20 pieces
2.Safety Lancet	5 pieces	20 pieces
3.Buffer tube	5 Pieces	20
4.Instruction for Use	1 piece	1 piece

Intended Use

This kit is intended to use for detection of neutralizing antibody against COVID-19. It is helpful to monitor protective immunity and evaluate the efficacy of vaccines after mass vaccination.

Suitable Specimen types

1. Suitable for specimen of human serum, plasma or whole blood. It is recommended to use fresh specimen for testing.
2. The specimen of serum and plasma can be stored at 2-30 ºC for 7 days, or stored at -20ºC for 3 months.
3. Whole blood specimens should be used as soon as possible after collection, and storage is not recommended.
4. Specimen must be restored to room temperature (10ºC-30 ºC) before testing. The frozen specimen should be completely thawed, rewarmed, and mixed before use.
5. Avoid specimen being freeze-thawed more than five times.

Kit Size: 5Tests (TBS3241-05) or 20Tests/kit (TBS3241-20)

Kit Contents

Materials provided

Test Card, Sample Diluent Buffer, Safety Lancet for fingertip blood collection

Storage conditions and shelf life

The test card and sample diluent buffer should be stored at 4ºC -30ºC valid for 24 months. Test cards should be used as soon as possible within 1 hour after the foil pouch open. The bottle of sample diluent should be capped immediately after use and stored at 4ºC-30ºC, please use it within the validity period.

Procedure

Allow the test card, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening. Remove the test card from the sealed pouch and use it as soon as possible.

2. Place the test card on a clean and level surface.

3. Specimen Collection and Preparation:

For Fingertip Blood Specimen Collection (Figure 1):

3A: Wipe to clean the puncture site on the fingertip with Alcohol pad.

3B: Remove the cap from Safety Lancet, Push the lancet firmly against the puncture site.

3C: Use the Dropper to draw the blood from puncture site.

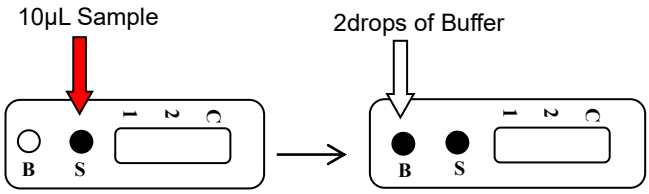
Figure 1.

3D: Transfer 10 μL of whole blood to the specimen well (S) of the test card, then add 2 drops of Sample Diluent Buffer into the buffer well (B) of the test card (Figure2).

3E: start the timer: Read results at 20 minutes.

For Serum or Plasma Specimens: Using the micropipette. and transfer 10 μL serum/plasma to the specimen well of the test card, then add 2 drops of buffer, and start the timer (Figure 2). Wait for the colored line(s) to appear, Read results at 20 minutes.

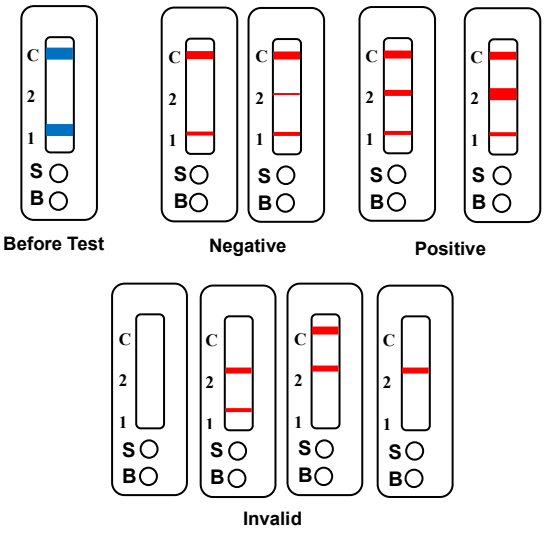
Figure 2



Result interpretation

The result interpretation as below (Figure3):

Figure 3



Result Interpretation Details

Intensity of line	Result	Test Result Interpretation
C>1>2 or no line in region (2)	Negative	Neutralizing antibodies for SARS-CoV-2 are not detected The signal inhibition: Less than 30%
C>2>1	Positive	Neutralizing antibodies for SARS-CoV-2 are detected. The Signal inhibition is between 30-50%
2>C>1	Positive	Neutralizing antibodies for SARS-CoV-2 are detected. The signal inhibition is > 50%
No line in C or 1region	Invalid	No line appeared in reference region at C or 1. It means that e test is failure, and need to retest.

Quality Control

Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal positive 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.

Limitations

1. This product is only for human whole blood, serum and plasma.
2. The test results of this kit are only for reference and should not be used as the sole basis for clinical diagnosis and treatment.
3. Sample collection and sample processing have a great impact on the detection of pathogens, and a negative test result does not exclude the possibility of containing antibody.
4. In early stage of vaccination, test result may be negative due to no or low titer of pathogen-specific antibody.
5. Analysis of the likelihood of false-negative results.
(i) Some unknown components shield the antibody determinant from binding to the labeled protein.
(ii) Unstable specimen storage: The analyte in the specimen is degraded over time temperature and cannot be recognized.
(iii) Antibody has not yet been produced.
7. Be cautious in analyzing test results of people who have received blood transfusion or other blood products treatment in recent months.
8. Excessive specimen loading can cause false positive results. Some non-specific components in the blood have similar antigenic determinants to capture gold-labeled proteins, which will lead to false positives.

Performance Index

1. Sensitivity and Specificity

This reagent	Microneutralization Assay (MNA)		Total
	Positive	Negative	
Positive	106	1	107
Negative	2	61	63
Total	108	62	170
Relative sensitivity	98.11%(95%CI:93.35%-99.77%)		
Relative specificity	98.39%(95%CI:91.34%-99.96%)		

2. Cross Reactivity
The kit has been tested for anti- Coronavirus (HKU1, OC43, NL63, 229E); anti- MERS Coronavirus; anti- Influenza A virus (2009H1N1, seasonal H1N1, H3N2, H5N1, H7N9); Influenza B virus (Yamagata, Victoria); anti- Respiratory syncytial virus, anti- Rhinovirus (group A, B, C); anti- Respiratory adenovirus (type 1~5, 7, 55); anti-Enterovirus (group A, B, C, D); anti-Epstein-barrvirus capsid antigen; anti-Measles virus; anti-Mumps virus; anti-Parainfluenza virus; anti-Mycoplasma pneumonia positive specimens, anti-Chlamydia pneumonia positive specimens, the result showed no cross-reactivity.
3. Repeatability and reproducibility
Repeatability: Repeated testing was conducted for repeatability references for 10 times. The test results were consistent with the known results of the references and were uniform in color.
Reproducibility: Negative sample, weak positive samples and strong positive samples were tested for 5 consecutive days. The results showed that the reproducibility was good among different operators, intra-batch/inter-batch, intra-day/ inter-day.
4. Interference Test
1) Normal human serum/plasma/whole blood specimen test: 20 negative serum, 20 negative plasma and 20 negative whole blood specimens were collected for testing, all of which were negative.
2) Endogenous interfering substance: Hemoglobin (≤2g/L), Triglyceride(≤37mmol/L), Bilirubin(≤342μmol/L), Rheumatoid Factor(≤100IU/mL), HAMA(≤200ng/mL), Antinuclear antibody(≤150RU/ml), Antimitochondrial antibody(150RU/ml), Total IgG(≤30mg/mL), Total IgM(≤2mg/mL) in blood specimens would not interfere test results of this kit.
3) Drug interfering substance: The tests spiked with following drugs were not affected:
Alpha-Interferon, Zanamivir, Ribavirin, Oseltamivir, Peramivir, Lopinavir, Ritonavir, Abidor, Levofloxacin, Azithromycin, Ceftriaxone, Meropenem, Tobramycin.
4) Anticoagulant test: 160mg/mL sodium citrate,10mg/mL Disodium EDTA, 0.5mg/mL Heparin sodium would not affect test results.
5. Hook effect
This kit doesn't have hook effect.
6.The results of serum, plasma and whole blood samples from the same person were consistent.

Precautions

1. For professional in vitro diagnostics use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
3. Use the sample diluent provided with this reagent for sampling, and do not mix use different batches of test cards and sample diluent.
4. Use fresh specimens for testing, do not recommended to use repeated freeze-thaw specimens. If there is obvious hemolysis or blood clot in the specimen, it will interfere with the test and cause false results, do not use.
5. Operate at room temperature. Test cards kept at low temperature should be restored to room temperature before opening to avoid moisture absorption.
6. Do not use reagent kits with obvious damage or test cards with damaged or expired packaging.
7. There is desiccant in the aluminum foil pouch and must not be taken orally.
8. Improper sample collection or processing may result in false-negative results.
9. The final diagnosis should be made by a physician after combining the various test parameters and clinical symptoms.
10. If you have any questions or suggestions on the use of this kit, please contact the manufacturer.

Symbols meaning

CE	CE Symbol	IVD	In vitro diagnostic medical device
	No secondary use		Reference instructions
REF	Reference Number	LOT	Lot Number
	Use By	Σ	Number of Tests
	Temperature Limitation		Damaged packing, do not use
	Manufacturer Name Address	EC REP	Name and Address of European Union Representative

Research Use only.