Hotgen

CE

Novel Coronavirus (SARS-CoV-2) Neutralizing Antibodies Test (Colloidal Gold)

Instructions for Use

PRODUCT NAME

Novel Coronavirus (SARS-CoV-2) Neutralizing Antibodies Test (Colloidal Gold)

SPECIFICATIONS

Specifications	Catalog Number
1T/kit	HGCG16100101
5T/kit	HGCG16100105
20T/kit	HGCG16100120
40T/kit	HGCG16100140

INTENDED USE

This kit is used for in-vitro semi-quantitative determination of novel coronavirus neutralizing antibodies in human serum, plasma,venous whole blood or peripheral whole blood.

The novel coronavirus neutralizing antibodies are protective antibody produced by the human body after inoculation with novel coronavirus vaccine or infection with novel coronavirus. The kit is used to monitor the presence of 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 neutralizing antibodies are produced in human body after infection with novel coronavirus.

For professional use only.

PRINCIPLE OF THE ASSAY

This kit is based on colloidal gold immunochromatography and uses double-antigen sandwich assay to detect novel neutralizing antibodies against coronavirus in blood 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 neutralizing antibodies were detected by the specific recognition of neutralizing antibodies by the recombinant novel coronavirus S-RBD antigen.

The T line of the novel coronavirus neutralizing antibody test cassette 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 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 - novel coronavirus 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 neutralizing antibodies against novel coronavirus in blood samples can be realized.

COMPONENTS

1.SARS-CoV-2 NAbs Test Cassette; 2.Sample Diluent; 3.Lancet; 4.Alcohol Pad; 5.Cotton Swab; 6.Instruction Manual; 7.Colorimetric Card; 8.Dropper.

STORAGE AND VALIDITY

1. The kit should be stored at 4~ 30°C, the validity is set for 18 months.
2. See manufacturing date and expiration date on label.

SPECIMEN REQUIREMENTS

Suitable for serum,plasma, venous whole blood or peripheral whole blood.

Serum and plasma samples should not be stored for more than 1 week at 2~8℃. If the detection cannot be performed within 1 week after blood collection, the samples should be sealed and stored below -20℃ for less than 2 months. Repeated freeze-thaw should be avoided, the freeze-thaw cycles should not exceed 5 times. The thawed frozen samples should be fully equilibrated to room temperature before being used for testing; venous whole blood should be tested within 8 hours after collection, and peripheral whole blood should be tested immediately after collection; severe hemolytic and lipemia samples shouldn't be used for testing.

TEST PROCEDURE

1. Place the test cassette, sample diluent and test sample for 15~30 minutes, and equilibrate to room temperature (10~30℃).
2. Open the aluminum foil pouch of the test cassette, and place the test cassette on a flat surface.
3. Write sample ID on the plastic case of the test cassette.
4. Peripheral whole blood samples:

1) Tear off the disposable alcohol pad, wipe your finger, and dry naturally.
2) Using the lancet, pull out the lid of the lancet, press it on the finger that has been disinfected, and puncture the finger with the lancet.
3) Squeeze out the first drop of whole blood and wipe it off with a cotton swab.
4) Squeeze out the second drop of whole blood, and use a dropper to draw the whole blood above the mark.
5) Take 25μL sample (1 drop), add it into the sample well of the test cassette, and add 80μL(approximately 3 drops) of sample diluent. And then use a cotton swab to stop the bleeding.
6) Incubate for 15 minutes at room temperature. Result got after 30minutes is invalid.

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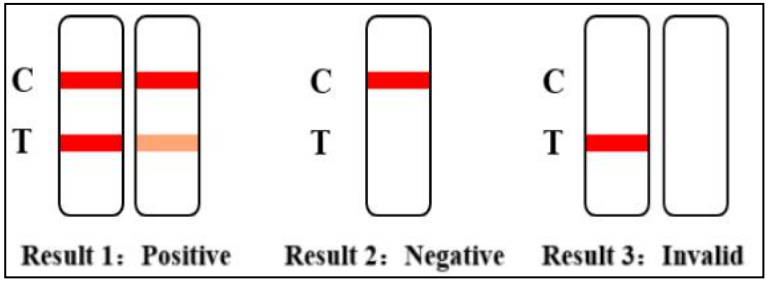
5. Serum and plasma samples: Take 20μL sample(1 drop with a dropper), add it into the sample well of the test cassette, and add 80μL sample diluent (approximately 2~3 drops with a dropper). Incubate at 10~30℃ for 15 minutes. Result got after 30 minutes is invalid.
6. Venous whole blood and peripheral whole blood samples: Take 25μL sample (1 drop with a dropper), add it into the sample well of the test cassette, and add 80 μL sample diluent (approximately 2~3 drops with a dropper). Incubate at 10~30℃ for 15 minutes. Result got after 30 minutes is invalid.

INTERPRETATION OF RESULT

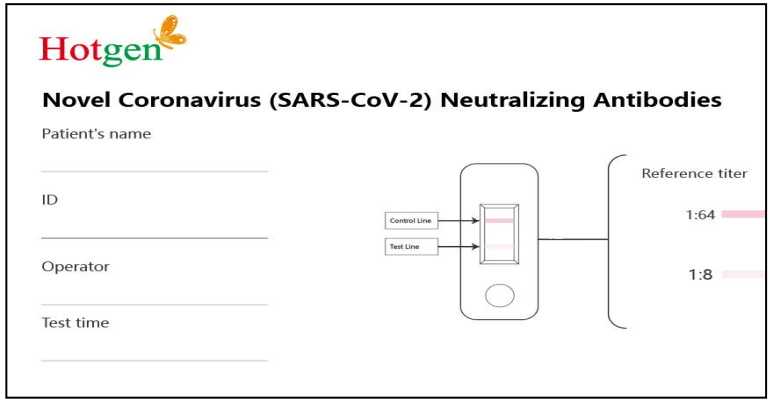
Positive: Two color bands appear in the observation window, that is, a red or magenta line appears at the position of the quality control line (C line) and the detection line (T line) (as shown in result 1), which indicates the test result of novel coronavirus neutralizing antibodies in the sample was positive.

Negative: A red or magenta line appears at the position of the quality control line (C line) in the observation window, and no line appears at the position of the test line (T line) (as shown in the result 2), indicating the test results of the novel coronavirus neutralizing antibodies in the sample were negative or the concentration was below the limit of detection of the kit.

Invalid: No line appears in the position of the quality control line (line C) in the observation window (as shown in result 3), which indicates that the test is invalid, should collect sample again and retest.



The results were interpreted using a colorimetric card as follows:



1) Color band < 1:8 color band: neutralizing antibodies titer less than 1:8, or neutralizing antibodies titer lower than the detection limit of this kit.
2) Color band between 1:8 color band and 1:64 color band: neutralizing antibodies titer between 1:8-1:64.
3) Color band > 1:64 color band: neutralizing antibodies titer more than 1:64.

LIMITATIONS

1. This kit is semi-quantitative test and cannot quantify the concentration of the novel coronavirus neutralizing antibodies.
2. The test results of this kit can only be used to determine the production of neutralizing antibodies, and can be used to evaluate the immune effect of vaccination or the evaluation of the presence of neutralizing antibodies in human body after infection with novel coronavirus, however, it is not applicable to the evaluation of protective ability after vaccination or after infection with novel coronavirus.
3. The test results of samples are related to the quality of sample collection, processing, transportation and storage. Any errors may cause inaccurate test results. If cross-contamination is not controlled during sample processing, false positive results may occur.

PERFORMANCE CHARACTERISTICS

When testing with enterprise references, the following criteria should be met.

1. Negative references compliance rate: Use the enterprise negative references for testing, and the negative references should be detected at least 24/24 (-/-).
2. Positive references compliance rate: Use the enterprise positive references for testing, and the positive references should be detected at least 5/5 (+/+).
3. Minimum detection limit: Use enterprise sensitivity references for testing, and the sensitivity references should be detected at least 1/3 (+/+).

4. Repeatability: Use enterprise precision references for testing, and the test results should be consistent.

5. Limit of Detection (LoD):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).

6. Analytical specificity:

6.1 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.

6.2 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.

7.Hook effect: There was no hook effect in the detection of clinical positive samples of novel coronavirus neutralizing antibodies (titer not higher than 1:1024).

8.Clinical performance:

The clinical trial of this product was compared with the virus neutralization test(VNT). The sample types were serum,plasma,venous whole blood or peripheral whole blood.

8.1 Serum samples

Clinical performance of Novel Coronavirus (SARS-CoV-2) Neutralizing Antibodies Test (Colloidal Gold) was determined by testing 339 positive and 869 negative specimens for SARS-CoV-2 neutralizing antibody to have a sensitivity of 98.53% (95% CI: 96.59%～99.52%) and specificity of 99.31% (95% CI : 98.50%～99.75%).

		VNT		
		Positive	Negative	Total
Novel Coronavirus (SARS-CoV-2) Neutralizing Antibodies Test (Colloidal Gold)	Positive	334	6	340
	Negative	5	863	868
	Total	339	869	1208
		Sensitivity	Specificity	Overall Peccentage Agreement
		98.53% [96.59%～99.52%]	99.31% [98.50%～99.75%]	99.09% [98.38%～99.54%]

8.2 Plasma samples

Clinical performance of Novel Coronavirus (SARS-CoV-2) Neutralizing Antibodies Test (Colloidal Gold) was determined by testing 339 positive and 869 negative specimens for SARS-CoV-2 neutralizing antibody to have a sensitivity of 98.82% (95% CI : 97.01%～99.68%)and specificity of 99.31% (95% CI :98.50%～99.75%).

		VNT		
		Positive	Negative	Total
Novel Coronavirus (SARS-CoV-2) Neutralizing Antibodies Test (Colloidal Gold)	Positive	335	6	341
	Negative	4	863	867
	Total	339	869	1208
		Sensitivity	Specificity	Overall Peccentage Agreement
		98.82% [97.01%～99.68%]	99.31% [98.50%～99.75%]	99.17% [98.48%～99.60%]

8.3 Venous whole blood samples

Clinical performance of Novel Coronavirus (SARS-CoV-2) Neutralizing Antibodies Test (Colloidal Gold) was determined by testing 339 positive and 869 negative specimens for SARS-CoV-2 neutralizing antibody to have a sensitivity of 98.23% (95% CI : 96.19%～99.35%)and specificity of 99.19% (95% CI : 98.35%～99.68%).

		VNT		
		Positive	Negative	Total
Novel Coronavirus (SARS-CoV-2) Neutralizing Antibodies Test (Colloidal Gold)	Positive	333	7	340
	Negative	6	862	868
	Total	339	869	1208
		Sensitivity	Specificity	Overall Peccentage Agreement
		98.23% [96.19%～99.35%]	99.19% [98.35%～99.68%]	98.92% [98.17%～99.43%]

8.4 Peripheral whole blood samples

Clinical performance of Novel Coronavirus (SARS-CoV-2) Neutralizing Antibodies Test (Colloidal Gold) was determined by testing 339 positive and 869 negative specimens for SARS-CoV-2 neutralizing antibody to have a sensitivity of 97.94% (95% CI :95.79%～99.17%)and specificity of 99.19% (95% CI : 98.35%～99.68%).

		VNT		
		Positive	Negative	Total
Novel Coronavirus (SARS-CoV-2) Neutralizing Antibodies Test (Colloidal Gold)	Positive	332	7	339
	Negative	7	862	869
	Total	339	869	1208
		Sensitivity	Specificity	Overall Peccentage Agreement
		97.94% [95.79%～99.17%]	99.19% [98.35%～99.68%]	98.84% [98.06%～99.36%]

PRECAUTIONS

1. This kit is for *in vitro diagnostic use* only. Please read this instruction carefully before experiment.
2. The collection, storage, and testing of specimens should be carried out in strict compliance with the "Technical Guidelines for Laboratory Testing of Novel Coronavirus Pneumonia (Second Edition)" and "Guidelines for Biosafety of Novel Coronavirus Laboratories (Second Edition)".
3. Storage of remaining specimens after detection and various waste disposal, should strictly abide by "Guidelines for Biosafety of Novel Coronavirus Laboratories (Second Edition)" and "Guidelines for Biosafety Protection of Novel Coronavirus Pneumonia Clinical Laboratory Testing (Trial Version 1)) "; it is recommended to refer to the above guidelines for the waste or remaining samples generated during the test. Firstly soak in ether, 75% ethanol, chlorine-containing disinfectant, peracetic acid, and chloroform to inactivate the virus, and then refer to the above guidelines for handling infectious materials.
4. The test cassette must be used within 30 minutes after opening, and the unused test cassette must be sealed and dryly stored.
5. Operation should be strictly performed according to the instruction, and different batches should not be mixed use.

EXPLANATION FOR IDENTIFICATION

	Use by date	LOT	Batch		Consult Instruction for use
Σ	Content Sufficient For <n> Tests	4℃ 30℃	Temperature limitation (4℃~30℃)	REF	Catalog Number
	Manufacturing date		Caution		Do not reuse
CE	CE Marking – IVDD 98/79/EC	EC REP	Authorized representative in the European Community		Manufacturer
IVD	For In Vitro Diagnostic Use		Keep away from sunlinght		Keep dry

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IVD

APPROVAL DATE AND REVISION DATE OF THE INSTRUCTION

Approved on Oct., 2020;

Verision number:V. 2020-10.02[Eng.]