Vaperon™ SARS-CoV-2 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold Immunochromatography)

CE IVD Cat.No.: COVNA-503

INTENDED USE

Vaperon™ SARS-CoV-2 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold Immunochromatography) is an immunochromatographic membrane assay that uses the immuno-capture method to direct detection of total neutralizing antibodies that block receptor-binding domain (RBD) to novel coronavirus (SARS-CoV-2) from human serum/plasma/whole blood specimens. Vaperon™ SARS-CoV-2 Neutralizing Antibody Rapid Detection Kit is intended for identifying individuals with adaptive immune response to SARS-CoV-2, indicating recent or prior infection or vaccination. Performance of the test is should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified to perform moderate or high complexity tests.

At this time, it is unknown for how long antibodies persist following infection and if the presence of neutralizing antibodies confers protective immunity. The sensitivity of the Vaperon™ SARS-CoV-2 Neutralizing Antibody Rapid Detection Kit early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary. **For *in vitro* diagnostic use only.**

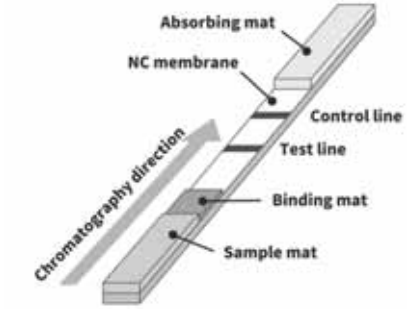
SUMMARY

Novel coronavirus pneumonia (Coronavirus disease 19, COVID-19) is an infectious disease caused by SARS-CoV-2 infection. On February 11, 2020 the International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.

SARS-CoV-2 has several structural proteins including spike (S), envelope (E), membrane (M) and nucleocapsid (N). The spike protein (S) contains a receptor-binding domain (RBD), which is responsible for recognizing the cell surface receptor, angiotensin converting enzyme-2 (ACE2). It is found that the RBD of the SARS-CoV-2 S protein strongly interacts with the human ACE2 receptor leading to endocytosis into the host cells of the deep lung and viral replication.

Immune cells secrete antibodies when immune response initiated and subpopulation of the antibodies that can block cellular infiltration and viral replication are called neutralizing antibodies. It is unknown how long it takes for neutralizing antibodies to be produced, and if they are always produced after SARS-CoV-2 infection. Vaperon™ SARS-CoV-2 Neutralizing Antibody Rapid Detection Kit is specific to SARS-CoV-2 neutralizing antibodies.

PRINCIPLES OF THE TEST



Vaperon™ SARS-CoV-2 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold Immunochromatography) is a lateral flow immunoassay that uses the immune-capture method to detect the SARS-CoV-2 neutralizing antibodies from serum/plasma/whole blood specimens. Anti-human antibody and a control antibody are immobilized onto a membrane support as two distinct lines and combined with other materials to construct a test strip.

If SARS-CoV-2 neutralizing antibodies that block RBD is present, it will migrate on membrane, reach to test area and caught by anti-human antibody to form a complex result in a visible red ribbon on Test line (T line). If the quality control line (C line) does not appear, it means that the test result is invalid. This sample needs to be tested again.

MATERIAL PROVIDED

- Test Cassettes (20×)
- Assay Diluent [5ml/bottle] (1×)
- Alcohol Prep Pad (20×)
- Sterile Disposable Lancet (20×)
- Blood Transfer Pipette (20×)
- Instruction for Use (1×)

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer/Watch
- Personal protective equipment, such as protective gloves, medical mask, goggles and lab coat
- Appropriate biohazard waste container and disinfectants

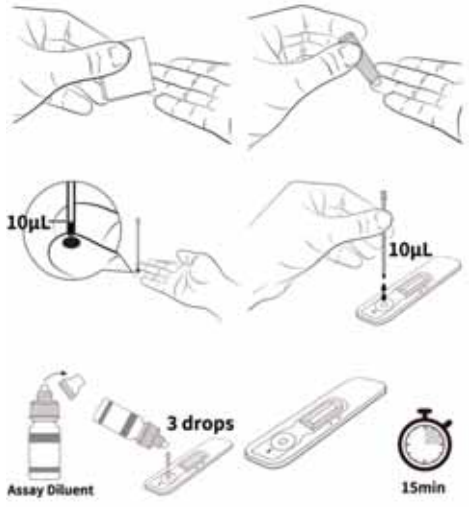
WARNINGS AND PRECAUTIONS

1.For *in vitro* diagnostic use.
2.To avoid erroneous results, specimens must be processed as indicated in the TEST PROCEDURES section.
3.This test has been used only for the presence of total neutralizing antibodies against SARS-CoV-2, not for any other viruses or pathogens.
4.Do not touch the reaction area of test strip.
5.Do not use test kit beyond the expiration date.
6.Do not use the kit if the pouch is punctured or sealed not well.
7.Performance of the test should be applied by professionally trained staff working in certified laboratories or clinics.
8.The test result should be interpreted by the physician along with clinical findings and other laboratory test results.
9. Dispose of cassette and items in contact with samples as medical waste after use.
10.Do not freeze the cassette or any other material.

STORAGE AND STABILITY

The kit is stored at 2 ~ 30 °C in sealed, preserve avoid light. The validity period is now at 18 months, can be extended if new stability data are available.
Reagents and devices must be used at room temperature (15–30 °C).
The unsealed cassette is valid for 1 hour. It is recommended to use the testing kit immediately after opening, especially the test environment humidity is more than 60%. The expiration date is printed on the package.

TEST PROCEDURES

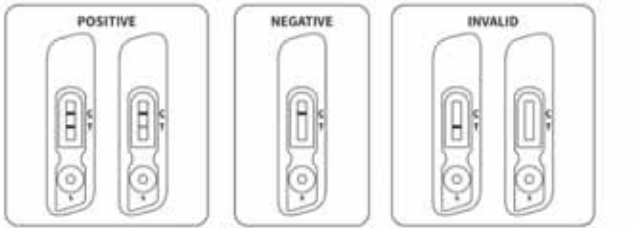


Before the test, carefully read the Instruction For Use and strictly follow it. If test with serum/plasma, please skip to step 4 directly.

1. Unpack the cassette aluminum foil bag, take out the cassette and lay it on the flat platform.
2. Disinfect the fingertip to be tested with alcohol prep pad.
3. Pierce with lancet provided and squeeze the fingertip until blood drop appears. Keep squeezing and transfer adequate blood into indicant line of pipette.
4. Transfer fresh blood specimen or prepared serum/plasma specimen (10μL) into middle of sample well.
5. Twist off the cap of the assay diluent, dispense 3 drops of the solution (70-80μL) vertically into the cassette sample well (S sign).
6. Placed the cassette at room temperature for 15 minutes then read the test result.

Warning: Results must be interpreted in 20 minutes after completing the testing procedure.

INTERPRETATION OF RESULT



1.Positive: Two red ribbon, the test line (T line) and the quality control line (C line) are colored.
2. Negative: One red ribbon, just quality control line (C line) is colored;
3. Invalid: No color appears in the position of the quality control line (C line) in the observation window, indicating that this test is invalid and should be resampled for testing.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C line) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATION

1. The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 neutralizing antibodies.
2. Test results must be evaluated in conjunction with other clinical data available to the physicians.
3. Failure to follow the TEST PROCEDURES may adversely affect test performance and / or invalidate the test result.
4. The test may have lower sensitivity for total neutralizing antibodies detection in individuals prior to 10 days since SARS-CoV-2 vaccination which lead a negative result.
5. Individuals infected with SARS-CoV-2 develop binding antibodies to the virus, not all of them develop neutralizing antibodies to SARS-CoV-2.
6. Positive test results do not rule out co-infections with other pathogens.
7. Performance has only been established with the specimen types listed in the INTENDED USE. Both venous whole blood and fingertip whole blood is applicable.
8. Positive result may not indicate previous SARS-CoV-2 infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
9. According to what is currently understood, the content of neutralizing antibodies in the human body may drop to an undetectable level several months after vaccination. The best time to test for neutralizing antibodies within 2 months of the last vaccination.
10. Results from this test should not be used to diagnose or to exclude acute SARS-COV-2 infection or to inform infection status.
11.Not for the screening of donated blood.

PERFORMANCE CHARACTERISTICS

150 individuals were selected for clinical trial. All individuals are SARS-CoV-2 virus non-infected and tested by an Emergency Use Authorization (EUA) -authorized medical device: cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit produced by GenScript and Vaperon™SARS-CoV-2 Neutralizing Antibody Rapid Detection Kit. The first test results are as follows:

First neutralizing antibodies test for 150 individuals		
Result	GenScript	AtlasLink
Positive	0	0
Negative	150	150

30 individuals were selected for double-blind experiment and received treatment with coronaVac vaccine which produced by Sinovac. All individuals did second neutralizing antibodies test 10 days after the clinical trial. Calculated the specificity and sensitivity, results are as follows:

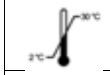
Second neutralizing antibodies test for 150 individuals				
Vaccination individuals		Test result	GenScript	AtlasLink
Accepted	30	Positive	29	29
Unaccepted	120	Negative	121	121
Total	150	Total	150	150

Diagnostic Sensitivity:
29/29×100%=100% 95%CI(88.3%~100%)
Diagnostic Specificity:
121/121×100%=100% 95%CI(96.9%~100%)
Overall Agreement:
(29+121)/150×100%=100% 95%CI(97.5%~100%)

REFERENCE

1. Rui Shi, Chao Shan, Xiaomin Duan, *et al*. A human neutralizing antibody targets the receptor-binding site of SARS-CoV-*2.Nature* **584**,120-124(2020).
2. C.O. Barnes, C.A Jette, M.E. Abernathy, *et al*. SARS-CoV-2 neutralizing antibody structures inform therapeutic strategies. *Nature*,1-6 (2020).
3. Li K., Huang B., Wu, M, et al. Dynamic changes in anti-SARS-CoV-2 antibodies during SARS-CoV-2 infection and recovery from COVID-19. *Nat Commun.*11, 6044 (2020).
4. Yj Zhang, G Zeng, Hx Pan. et al. Safety, tolerability, and immunogenicity of an inactivated SARS-CoV-2 vaccine in healthy adults aged 18-59 years: a randomised, double-blind, placebo-controlled, phase 1/2 clinical trial. *Lancet Infect Dis* .2020 Nov 17,30843-4.

INDEX OF SYMBOLS

	Attention, see instructions for use
	For In-Vitro Diagnostic Use only
	Authorized Representative
	Use-by date
	Lot Number
	Catalogue Number
	Store between 2 – 30 centigrade
	Contains sufficient for <n> tests
	Do Not use if package is damaged

	Do Not Reuse
CE	CE Mark!

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