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SARS-CoV-2 RBD Protein IgG Detection Kit (Colloidal Gold-Based) (Version 2.1)

[PRODUCT NAME]

SARS-CoV-2 RBD Protein IgG Detection Kit (Colloidal Gold-Based)

[SPECIFICATION]

1 test/kit, 5 tests/kit, 20 tests/kit.

[SUMMARY AND EXPLANATION]

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2, or 2019-nCoV) is the key pathogen triggering COVID-19, and this virus is a positive-sense single strand RNA virus in the family Coronaviridae. Main symptoms of COVID-19 include fever, cough and breathing difficulty, and the disease generally has an incubation period of 2-14 days. The window period of individual cases may be up to 24 days, but there is a period of about one week from infection to the appearance of symptoms in most cases. This virus encodes 4 main types of structural protein, including spike (S) protein, envelope (E) protein, membrane (M) protein and nucleocapsid (N) protein. The S protein contains a receptor binding domain (RBD), and 2019-nCoV attaches to the cell through the interaction of the RBD with angiotensin converting enzyme 2 (ACE2), a surface receptor of the host's airway epithelial target cells. In a respiratory tract, ACE2 is widely distributed on the epithelial cell surface of the pulmonary alveoli, trachea and bronchi. 2019-nCoV identifies and bonds with ACE2 receptors, then enters into the host's cells through membrane fusion, triggering an infection.

[INTENDED USE]

This product is intended for the in vitro qualitative detection of RBD (SARS-CoV-2 RBD Spike Receptor-Binding Domain) IgG antibody in human serum, plasma and whole blood specimens. It can be used to clinically assess the level of SARS-CoV-2 RBD IgG antibody in the human.
For in vitro diagnostic use only, for professional use only.

[TESTING PRINCIPLE]

The capture method is adopted for this product for the test using solid phase immunochromatography. The specimen to be tested (serum/plasma/whole blood) diffuses upward by capillary force at the sampling end, and when passing by the marker pad, the RBD IgG antibody in the specimen is combined with the recombinant SARS-CoV-2 RBD protein colloidal gold conjugates to form an immune complex of colloidal gold labeled RBD protein-RBD IgG antibody to be tested. The complex continues to spread with the specimen to reach the nitrocellulose membrane and is intercepted by T-line (test line) coated with mouse anti-human IgG antibody to form an immune complex of colloidal gold labeled RBD protein-antibody to be tested-coating mouse anti-human IgG antibody is formed, forming a red T-line. The remaining colloidal gold conjugates continue to ascend and are combined with C-line (quality control line), indicating completion of the reaction. The detected color of T-line is proportional to the effective activity of RBD receptors.

[MAIN COMPONENTS]

Component name	Main components
Test Cassette	Aluminum foil bag, desiccant, test strip, and plastic card. The test strip is composed of absorbent paper, nitrocellulose membrane, sample pad, cushion pad, colloidal gold marker pad, and PVC board. The T-line (test line) of nitrocellulose membrane is coated with about 1.0 mg/mL mouse anti-SARS-CoV-2 monoclonal antibody, the C-line (quality control line) is coated with about 1.0 mg/mL internal reference protein C, and the marker pad contains about 40 OD SARS-CoV-2 RBD protein colloidal gold conjugates.
Specimen diluent	Casein-containing HEPES buffer solution (0.1 M), 5 mL/bottle , 200 μL/bottle.
Dropper	According to different specification, 1dropper/pack, 5 droppers/pack, 20 droppers/pack
Quantitative pipette (optional)	1 / pack, 5 / pack, 20 / pack.
Lancet (optional)	1 / pack, 5 / pack, 20 / pack.
Alcohol cotton sheet (optional)	1 / pack, 5 / pack, 20 / pack.

Note: The components of different batches are not interchangeable.

[STORAGE CONDITION AND VALIDITY PERIOD]

This kit should be stored at 4-30℃ and its period of validity is temporarily defined to be 18 months.
Once the package of the Detection card is opened (4-30℃, humidity <65%), it must be used within 1 hour. The period of validity of specimen diluent is 28 days after opening.
Production date and expiration date: See the label.

[SPECIMEN REQUIREMENTS]

1. The applicable specimen types of this test cassette are serum, plasma and whole blood.
2. Sediments and suspended matters in the specimens may possibly affect the test results and shall be centrifugally removed at 3000 g×10 min.
3. Specimens with serious hemolysis, lipaemia or that are turbid cannot be used.
4. Heparin sodium or EDTA anticoagulant can be used for plasma specimens. After collection, specimens shall be tested within the same day. If the test cannot be performed on the same day, specimens shall be preserved as follows: serum/plasma specimens can be stored for 7 days at 2-8℃ and stored for 6 months at -20℃, without affecting the test results.
5. Specimens must be restored to room temperature (18℃-28℃) before testing. Freeze-preserved specimens should be completely melted, reheated and mixed thoroughly before use. The specimen can only be re-thawed once, and do not freeze and thaw them repeatedly.
6.When collecting blood from your finger with a lancet and an alcohol cotton sheet, remove the first drop of whole blood and use the second drop of whole blood for testing.

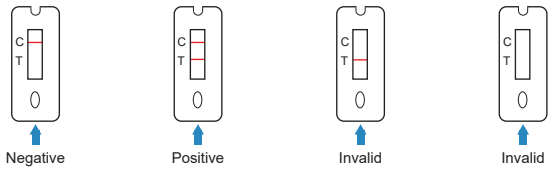
[TESTING METHOD]

Please read the Instructions carefully before operation.

1. The test cassette shall be brought to the room temperature before use. The test shall be conducted at room temperature.
2. Take out the test cassette from the aluminum foil bag and place it on a horizontal and dry plane.
3. Using the dropper provided, add 1 drop (about 20 μL) of the serum, plasma and whole blood to the specimen addition port; when testing fingertip whole blood, using the quantitative pipette to add 20 μL to the specimen addition port. Then add 3 drops of dilution buffer (about 60 μL) to the specimen; Begin timing.
4. Be sure to observe the test cassette 15 minutes after the test starts and determine the results. The results observed after 20 minutes are invalid.

[EXPLANATION OF INSPECTION RESULT]

1. Due to factors such as differences in methodology or antibody specificity, the test results of reagents provided by different manufacturers may vary. Therefore, the test results cannot be compared directly, lest wrong medical interpretation would be caused. In a series of monitoring activities, if reagent types are changed, additional continuous detections shall be conducted and such detection results shall be compared with the detection results using original reagents in parallel to re-determine the baseline value.
2. The test results are determined as follows:



1) Negative result: Only a red quality control line (C-line) is visible.
2) Positive result: Two clear red lines are visible, one is quality control line (C-line), and the other is T test line.
3) Invalid result: There is no red line or there is only T test line, but no quality control line (C-line), suggesting that the item has a test error or the test result is invalid, and the item should be retested.

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[LIMITATIONS OF TESTING METHOD]

1. The test results of this product are for clinical reference and should not serve as the only basis. Actual diagnosis shall be considered in conjunction with other test methods like euvirus and pseudovirus experiments.
2. The test accuracy is affected by the specimen collection process, and improper specimen collection and storage process will affect the test results. High temperature and direct sunlight must be avoided.
3. This reagent can be used to carry out qualitative detection only for the SARS-CoV-2 RBD IgG antibodies in specimens, and is not intended for quantitative measurement.
4. Specimens with cross contamination, microbial contamination, serious hemolysis or that are turbid might lead to incorrect test results, and best efforts should be made to avoid using such specimens.

[PERFORMANCE INDICATORS]

1.Limit of Detection (LoD): When enterprise LoD references are used for detection, S1-S4 detection results shall be positive for SARS-CoV-2 RBD IgG antibody, and there are no requirements for S5-S6.
2.Coincidence rate of negative references: When enterprise negative references are used for detection, NC01-NC25 detection results shall be negative for SARS-CoV-2 RBD IgG antibody, and the coincidence rate shall be 100%.
3.Coincidence rate of positive references: When enterprise positive references are used for detection, PC01-PC10 detection results shall be positive for SARS-CoV-2 RBD IgG antibody, and the coincidence rate shall be 100%.
4. Precision:
Within-batch variation: When enterprise repeatability references are used for detection, CV1 and CV2 detection results shall be positive for SARS-CoV-2 RBD IgG antibody, with consistent color rendering.
Batch-to-batch variation: When enterprise repeatability references are used for detection, CV1 and CV2 detection results among the kits in three different batches shall be positive for SARS-CoV-2 RBD IgG antibody, with consistent color rendering.
5. Analytical specificity:
5.1 Cross reaction: The cross-reactivity of the product is evaluated by performing various common cross-reactions on positive samples of pathogenic microorganisms. These cross-reactions are likely to cause the same and similar symptoms in clinical practice. This product does not cross-react with positive samples of the following microorganisms:

Human coronaviruses HKU1	Influenza B Viruses (Yamagata and Victoria)	Adenovirus type1,2,3,4,5,7,55
Human coronaviruses OC43	Respiratory Syncytial Virus	Coxsackie Virus (enterovirus group B)
Human coronaviruses 229E	Parainfluenza Virus	Enterovirus type 71 (enterovirus group A)
Human coronaviruses NL63	Rhinoviruses A, B and C	Enterovirus type 68 (EV-D68) (enterovirus group D)
Human Immunodeficiency virus (HIV)	Measles Virus	Myocoplasima Pneumonia
Influenza A Virus(H1N1,H3N2,H5N1, H7N9)	EB virus	-

5.2 Interfering substances: Interference verification is carried out for the product according to the maximum plasma concentration of common clinical therapeutic drugs in the following table under normal usage and dosages, and the product showcases good anti-interference performance.

Interfering substances	concentration	Interfering substances	concentration
Bilirubin	0.2 g/L	Oseltamivir	75 mg/L
Triglyceride	10 g/L	Levofloxacin	0.1 g/L
Hemoglobin	5g/L	Ceftriaxone	0.043 mg/mL
Rheumatoid Factor	500 IU/mL	Zanamivir	5 mg/L
Anti-nuclear antibody	1:240	α-interferon	200 IU
Anti-mitochondrial antibody	1:160	Ribavirin	40 mg/L
HAMA	20 ng/mL	Peramivir	0.2 g/L
Total IgG	50 mg/L	Lopinavir	600 mg/L
Total IgM	5 mg/L	Ritonavir	150 mg/L
Arbidol	40 mg/L	Histamine hydrochloride	0.5 mg/L
Azithromycin	100 mg/L	Phenylephrine	0.5%
Meropenem	200 mg/L	Oxymetazoline	0.2 mg/L
Tobramycin	20 mg/L	Sodium chloride	0.9%
Beclomethasone	0.05 mg/L	Dexamethasone	0.1 mg/L
Flunisolide	500 ug/L	Triamcinolone acetonide	0.5%
Budesonide	400 ug/L	Mometasone	400 ug/L
Fluticasone	0.05%	-	-

6. Hook effect: the hook effect will occur if the antibody level in a specimen exceeds at the concentration levels that exceed the lowest limit of detection of RBD IgG antibodies of this product by more than 1280 times.
7. Neither heparin sodium or EDTA anticoagulant has any effect on the detection results using this product.
8. For precision test conducted by different experimenters at different times using this kit, the results meet the performance requirements of this product.

[PRECAUTIONS]

1. This product is only for in vitro diagnosis.
2. Only operators who have received professional training can perform test operations strictly according to the instructions for the kit after reading through the instructions carefully.
3. All specimens and used kits shall be deemed potentially infectious, and shall be discarded or otherwise disposed of in accordance with the provisions of local governments and related countries.
4. The reagents shall be used within their period of validity. Remaining reagents shall be put away in time and stored under the conditions required by the Instructions.

[BASIC INFORMATION]

Manufacturer: Nanjing Vazyme Medical Technology Co., Ltd.
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EC REP

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[APPROVAL AND REVISION DATE OF THE INSTRUCTIONS]

May 8, 2021

[SYMBOLS]

EC REP	Authorized representative in the European Community
IVD	*In vitro* diagnostic medical device
4°C 30°C	Temperature limit 4 ~ 30℃
	Date of manufacture
Σ	Contains sufficient for <*n*> tests

REF	Catalogue number
LOT	Batch Code
	Do not re-use
	Do not use if package damaged

	Manufacturer
	Use-by date
	Consult instructions for use
CE	CE Mark

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IVD CE

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