Instruction for Novel Coronavirus（2019-nCoV）IgG/IgM Test Kit (Colloidal gold)

1. Product Name

Generic name: Novel Coronavirus（2019-nCoV）IgG/IgM Test Kit (Colloidal gold)

Trade name: 2019-nCoV IgG/IgM

2. Package

Specification 1: 25T/kit REF: 52026069

Specification 2: 50T/kit REF: 52027072

3. Intended Use & Indication

For in vitro qualitatively detecting novel coronavirus (2019-nCoV) IgG and IgM in human serum, plasma or whole blood. of suspected cases of novel coronavirus infection in pneumonia, patients with suspected clustering cases, and other cases that need to be identified

4. Test Principle

When the test sample is added to the sample port on the test card, 2019-nCoV IgM,IgG in the sample combines with antibody coated on a glass fiber and coupled with colloidal gold to form colloidal gold - antibody - 2019-nCoV IgM complexes and colloidal gold - antibody - 2019-nCoV IgG complexes.This immune complex reaches to the test area (T) along the nitrocellulose membrane and combines with the pre-coated novel coronavirus antigen, If the sample contains the novel coronavirus IgM,,IgG. Visible bands (detection lines) are formed in detection area 1 (T1) and detection area 2 (T2), respectively. , and the result will be positive. The remaining rabbit IgG colloidal gold antibodies will be chromatographed to the pre-coated goat anti-rabbit IgG.,forming a visible band (quality control line) in the quality control area(C) If the sample does not contain the novel coronavirus IgM or IgG, no detection line appears, only the quality control line appears.

5. Main Components& Additional required equipment

The test kit consists of test card, Sample diluent and the instruction.

Component	Content	
Kit Size (# of Tests)	25	50
Test Card (#)	25	50
Sample diluent	2.5mL	2×2.5 mL

(1) The test card consists of the card housing and test strip. Test strip contains a sample pad, glass fiber (coated with colloidal gold -rat anti-human IgM conjugates, colloidal gold -rat anti-human IgG conjugates colloidal gold -rabbit IgG conjugates), nitrocellulose (NC) membrane (test area (T) is coated with novel coronavirus antigen, quality control area (C) is coated with goat anti-rabbit IgG , absorbent paper and PVC plate.

(2) Sample diluent: the main component is phosphate buffer (PBS).

6. Accessories Required But Not Provided

(1) Pipettes and pipette tips: 100 μL.

(2) Timer.

7. Special storage &Transport conditions

(1) The test kit can be stored at 2-30℃, aluminum foil bag in a sealed state is valid for 12 months , once opened, it is valid for 1 hour when the temperature is 2-35℃, the humidity is less than 65%. Make sure to use the product immediately after opening the packing bags when humidity is higher than 65%. The opening period of sample solution is 1 month. And the production date is shown in the outer packing box.

(2) Transport at 2-30℃.

8. Sample Requirements

(1) The optimal sample is fresh non-hemolyzed serum, plasma or whole blood. Recommended to use venous blood, results of other body fluids and samples may not be accurate.

(2) Complete the sample test within 24h at room temperature after the sample is collected. Keep serum and plasma refrigerated at 2-8℃ for not more than 7 days and frozen below -18℃ for not more than 1 month. Whole blood sample should not be frozen, store it at 2-8℃ for not more than 7 days.

(3) Bring the samples to room temperature before the test. Frozen samples need to be melted completely, re-warmed and mixed before use, avoid repeated freezing and thawing.

(4) Human serum or plasma is recommended to be used for testing. EDTA is recommended to be used as the anti-coagulant

9. Test Method

Carefully read the reagent instruction before using the test kit and strictly operate according to the instruction to ensure reliable results. Bring all reagents to room temperature (18-25℃) before use.

(1)Prepare

(a) Remove the test sample and required reagents from storage conditions and equilibrate to room temperature.

b) Remove the test card from the packaging bag and lay it flat on a dry surface.

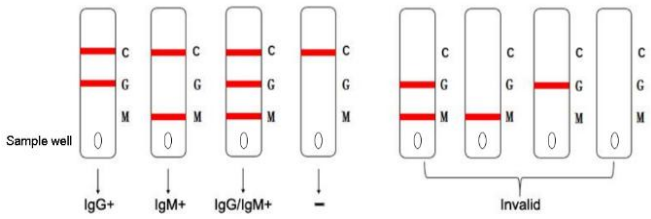
(2)Sampling:

(a)Serum / plasma samples: Take 10 μL of serum or plasma samples and add them to the sample well , and vertically add 4 drops (about 100 μL) of sample diluent.

(b)Whole blood samples: Take 20 μL of whole blood samples and add them to the sample well , and add 4 drops (about 100 μL) of sample diluent solution vertically.

(c) After adding the sample, the positive sample can be detected within 15 minutes. It is confirmed by the experiment that the reaction time (calculated after adding the sample) exceeding 15 minutes will affect the observation of the test results. Therefore, it is recommended that the final test results be recorded and recorded within 15 minutes.

10. Explanation for Test Results



(1) Positive Result, G only: If both the quality control line (C) and the detection line G appears, then the novel coronavirus IgG antibody has been detected and the result is positive for the IgG antibody.

(2) Positive Result, M only : If both the quality control line (C) and the detection line M appears, then the novel coronavirus IgM antibody has been detected and the result is positive for the IgM antibody.

(3) Positive Result, G and M: If the quality control line (C) and both detection lines G and M appear, then the novel coronavirus IgG and IgM antibodies have been detected and the result is positive for both the IgG and IgM antibodies.

(4) Negative Result: If only the quality control line (C) appears and the detection lines G and M are not visible, then no novel coronavirus antibody has been detected and the result is negative.

(5) Invalid result: No quality control line (C) appears, indicating that the test is invalid, and the sample needs to be tested again.

11. Limitations

(1) This test kit is for in vitro diagnostic use only.and the results cannot be used as a basis for diagnosis. Comprehensive judgment should be made in combination with clinical symptoms, epidemiological conditions and further clinical data.

(2) A negative test result does not exclude the possibility of novel coronavirus infection.

(3).This product can only qualitatively detect the novel coronavirus IgM, IgG antibody in the sample, and cannot determine the concentration of the antibody in the sample.

(4) Diagnosis and treatment can not only rely on this test result, taking into account the clinical history and other laboratory test results.

(5) For medical professional use only.

12.Performance characteristic

(1) Limit of detection

Use the detection limit reference materials of the enterprise to test, L1 result is negative, L2 result can be positive or negative, L3 result should be positive.

(2) Positive coincidence rate

The test was performed with positive reference materials of the enterprise, and the coincidence rate (+/+) of 10 enterprise reference materials was 10/10.

(3) Negative coincidence rate

The test was conducted with negative reference materials of the enterprise, and the coincidence rate (-/-) of 20 enterprise reference materials was 20/20.

(4) Precision

Negative precision reference material of the enterprise P1, critical positive precision reference material of the enterprise P2, and medium-strong positive precision reference material of the enterprise P3 were measured 10 times in parallel. P1 results were negative, P2 results were positive, and P3 results were positive.

(5) Clinical performance

In order to test the detection Positive Percent Agreement and Negative Percent Agreement, blood samples were collected from multiple Chinese hospital and CDC laboratories. The testing results were summarized in the table below:

Results in serum and plasma:

			Comparator		Subtotal
			Pos	Neg	
Novel Coronavirus (2019-nCoV) IgG/IgM Test Kit (Colloidal gold)	Pos	IgG+/IgM+	137	0	137
		IgG-/IgM+	6	5	11
		IgG+/IgM-	19	5	24
	Neg	IgG-/IgM-	16	206	222
Subtotal			178	216	394

Positive Percent Agreement: 162/178, 91.01% (85.81%～94.77%)
Negative Percent Agreement: 206/216, 95.37% (91.65%～97.76%)
Overall Percent Agreement: 368/394, 93.40% (90.48%～95.64%)
IgM Positive Percent Agreement: 143/178, 80.34% (73.73%～85.91%)
IgG Positive Percent Agreement: 156/178, 87.64% (81.89%～92.09%)

Results in whole blood:

			Comparator		Subtotal
			Pos	Neg	
Novel Coronavirus (2019-nCoV) IgG/IgM Test Kit (Colloidal gold)	Pos	IgG+/IgM+	41	0	41
		IgG-/IgM+	2	1	3
		IgG+/IgM-	6	2	8
	Neg	IgG-/IgM-	5	53	58
Subtotal			54	56	110

Positive Percent Agreement: 49/54, 90.74% (79.70%～96.92%)
Negative Percent Agreement: 53/56, 94.64% (85.13%～98.88%)
Overall Percent Agreement: 102/110, 92.73% (86.17%～96.81%)
IgM Positive Percent Agreement: 43/54, 79.63% (66.47%～89.37%)
IgG Positive Percent Agreement: 47/54, 87.04% (75.10%～94.63%)

13. Internal quality control

Each test card has a built-in control. A red colored line at the control line can be considered an internal positive procedural control. The control line will appear if the procedure has been correctly performed. If the control line does not appear, the test is invalid and new test must be performed. If the problem persists, the use of this batch of products should be stopped immediately, please contact your local vendor for technical support.

14. Interfering substance

(1) Hemoglobin, bilirubin, cholesterol, triglycerides, HAMA antibody and rheumatoid factor in samples can interfere with the test results, the maximum allowable concentrations of hemoglobin is 5 g/L, bilirubin is 2 mg/mL, cholesterol is 15 mg/mL, triglycerides is 30 mg/mL, HAMA antibody is 40 ng/mL, rheumatoid factor is 525 IU/mL.

(2) This product does not cross react with influenza A virus, influenza B virus, respiratory syncytial virus, parainfluenza virus, Mycoplasma pneumoniae and Chlamydia pneumoniae positive samples.

15. Precautions

(1) Once opened, use the test cards as soon as possible, which may cause moisture. Do not re-use the test cards.

(2) Do not use expired products. Reagents should not be used if the product packaging bag is damaged or the sample diluent is leaking.

(3) Components in test kit of different batches cannot be used interchangeably.

(4) For substances containing sources of infection or suspected of containing sources of infection, there should be proper bio-safety assurance procedures. Pay attention to the following matters:

a) Wearing protective clothing, protection glasses, and wear gloves when handling sample, operational process and disinfecting test cards and consumables after using.

b) Disinfect spilled sample or reagent with disinfectant.

c) Disinfect or handle potential contamination sources of all samples or reagents in accordance with local regulations.

d) Disposal of the device after use is according to local regulations.

16. Explanation of graphic symbol

	Consult Instructions for use		Temperature Limitation
LOT	Lot No.		Expiry Date
IVD	In Vitro Diagnostic Reagent	CE	CONFORMITE EUROPEENNE
	Production Date		Biohazard
	Manufacturer		Volume
Σ	Contains sufficient for < n>tests		Keep away from sunlight
	Do not re-use		Keep dry
EC REP	Authorized representative in the European community	REF	Catalogue number

17. Reference

(1) Heshui Shi, Xiaoyu Han, et al. Clinical features and imaging manifestations of pneumonia infected with novel coronavirus (2019-nCoV) [J] Journal of Clinical Radiology ISSN 1001-9324, CN 42-1187 / R.

(2) Miaomiao Ma, Xiaoling Shen, et al. Research progress on serological detection methods of Middle East Respiratory Syndrome Coronavirus [J] Chinese Journal of Virology, 2018, 8 (2): 156-161.

(3) Baoxing Fan , Jingfen Sun et al. Changes in IgM and IgG antibody levels of coronary disease in patients with SARS in Beijing area [J] Chinese Journal of Nosocomiology, 2005, 15 (3): 241-243.

18. Help Information

If you need help please contact after-sales

19. Manufacturer

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