COVID-19 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold)

【Product Name】

COVID-19 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold)

【Specification】

One test/package; One test/kit; 5 tests/kit;10 tests/kit; 20 tests/kit; 25 tests/kit; 30 tests/kit; 40 tests/kit; 50 tests/kit.

【Intended Use】

The COVID-19 neutralizing antibody rapid detection kit is used for in vitro detection of neutralizing antibody of COVID-19 in serum, plasma and whole blood sample taken from individuals COVID-19 vaccine injected.

The detection of neutralizing antibody can be used to evaluate immune reaction, immunological effect and defensive capability of COVID-19 vaccine injected population. Also, the test can provide valuable evidence of vaccines effect to their producer.

【Principle】

The kit adopts immunochromatography and the test card contains: 1) Colloidal gold-labeled COVID-19 RBD recombinant protein (Colloidal gold-RBD) and chicken IgY antibody; 2) The test line (T-line) and a quality control line (C-line) are fixed on the nitrocellulose membrane. The T-line is fixed with RBD recombinant protein and the C-line is fixed with rabbit anti-chicken IgY antibody.

When an appropriate amount of sample is added to the sample hole of the test card, it moves forward along the test card under the action of chromatography. If the sample contains a neutralizing antibody, the neutralizing antibody will combine with the colloidal gold-labeled COVID-19 RBD recombinant protein to form an immune complex which will be captured by the RBD recombinant protein immobilized on the nitrocellulose membrane. It will appear a red line on the T line indicates that the sample is positive.If there is no color line appears on the T line indicates that the sample is negative.The test card also contains a quality control line(C line).Regardless of whether there is a test line appears,there is a red line appears on the quality control line.If the quality control line does not appear,it indicates that the test result is invalid and the sample needs another test card to perform the test again.

【Main Components】

The product consists of test card, Instructions for use,Sample diluent, Alcohol Pad, Blood lancet, Dropper. And in each test card bag, it includes one COVID-19 antigen detection card and one package of desiccant.

Blood lancet

Alcohol Pad

Dropper

Instructions for use

Test card

Sample diluent

【Storage Conditions and Shelf Life】

Store in a dry place at 2-30℃, stable for 18 months at required condition.

Once exposed to air, test cassette should be used as fast as possible (within 1 hour).

After each use, sample diluent should be well-sealed in bottle and safely store at cool and dark place. Sample diluent is stable for 18 months at required condition.

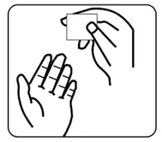
Production and expiration date is printed on label with kit.

【Sample Requirements】

1. The applicable sample types for this test card are serum/ plasma/ whole blood.
2. The sediment and suspended matter in the sample may affect the test result and should be removed by centrifugation.
3. The severely hemolyzed, lipemic or turbid samples cannot be used for testing.
4. The plasma samples can use heparin sodium or EDTA anticoagulant. After the sample is collected, the test must be completed within the same day. If the test cannot be completed on the same day, please save as follows: The serum and plasma samples can be stored at 2-8℃ for 7 days and at -20℃ for 24 days, the test results will not be affected.
5. The samples and reagents must be fully balanced to room temperature (15-30℃) before testing. The frozen samples should be completely thawed, rewarmed and evenly mixed before use. Avoid repeated freezing and thawing.

【Test Procedure】

1

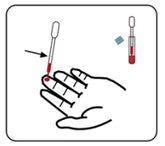


Open the alcohol pad bag and wipe the fingertips of blood collection.

2

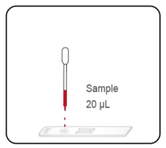
Open the blood lancet and press the blood collection needle.

3



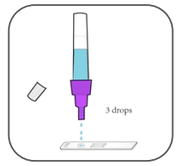
a) Use a dropper to draw fingertip blood to the mark. b) If the sample(serum / plasma / whole blood) has be collected use the blood tube, a dropper can be used to directly draw sample to the mark from the blood tube.

4



Add all the sample into the sample hole of the card.

5



Drop 3 drops of the sample diluent into the sample hole of the card and start timing.

6

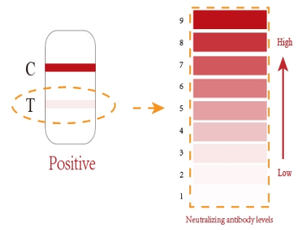
Strictly control to observe the test card within 15 minutes after the start of the test to determine the result.

【Interpretation of Test Results】

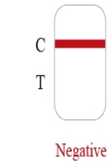
Result interpretation:

Positive (+): There appear red stripes in both quality control area (C) and test area (T).

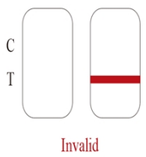
The darker the color of the T-line, the higher the level of the neutralizing antibody; The lighter the color of the T-line, the lower the level of the COVID-19 neutralizing antibody.



Negative (-): There is only one red stripe in the quality control area (C), and without red stripe in test area (T).



Invalid: No red line displays in the quality control area (C). This indicates that the incorrect operation or the test card has deteriorated or damaged. Repeat the test with a new kit. If the problem persists, stop using this lot kit immediately and contact local supplier.



【Limitations of Test】

1. The results of the kit are only for clinical reference, and should not be used as the sole basis for clinical diagnosis and treatment. The final diagnosis result should be made by the doctor after comprehensively combining the various test indicators and clinical symptoms. It is recommended to retest the suspicious samples at intervals.
2. The accuracy of the test is affected by the sample collection process. Improper sample collection and storage process will affect the test results. Avoid high temperature and direct sunlight.
3. The kit only provides qualitative detection for the COVID-19 neutralizing antibody in the sample and cannot be quantitatively detected.
4. Due to the limitations of the test reagent methodology, the low-level COVID-19 neutralizing antibody results cannot rule out the possibility that there is no COVID-19 neutralizing antibody. It is recommended to combine the new coronavirus vaccine injection history or the new coronavirus infection history and other comprehensive judgments.

【Product Performance Index】

1. Analysis specificity：

1.1 Cross reaction: The kit has no cross-react with human coronaviruses HKU1, OC43, 229E, H1N1 influenza virus, seasonal H1N1 influenza virus, H3N2, H5N1, H7N9, influenza B Yamagata, Victoria, respiratory syncytial virus, parainfluenza virus, rhinovirus A, B, Group C, Adenovirus 1, 2, 3, 4, 5, 7, 55, Coxsackie virus (Enterovirus B group), Enterovirus 71 (Enterovirus A group), Enterovirus 68 (EV-D68) (Enterovirus group D), Epstein-Barr virus, measles virus, human cytomegalovirus, rotavirus, norovirus, mumps virus, varicella-zoster virus, Mycoplasma pneumoniae, Chlamydia pneumoniae IgG antibody and IgM antibody-positive samples.

1.2 Interfering substances: The results are not affected by allergic symptoms (histamine hydrochloride), alleviating drugs and antiviral drugs (a-interferon, zanamivir, ribavirin, oseltamivir, peramivir, lopinavir and Tonavir, Arbidol) antibiotics (levofloxacin, azithromycin, cebutriaxone, meropenem), systemic antibacterial drugs (tobramycin), nasal spray (oxymetazoline) nasal skin steroid drugs (Budesonide, mometasone, fluticasone) interference.

2. Hook effect:Within the titers of clinically positive samples of the COVID-19 neutralizing antibody, the results of the kit did not show a hook effect.

3. Heparin sodium and EDTA anticoagulant have no effect on the detection of this kit.

4.Clinical Performance

A total of 252 samples were collected, including 102 positive samples and 150 negative samples. After comparing the test results of this product, the comparison results are summarized in the table below:

Assessment reagent	ELISA		Total
	Positive(+)	Negative(-)	
Positive(+)	97	2	99
Negative(-)	5	148	153
Total	102	150	252
Diagnostic Sensitivity, 95% CI	95.10%(89.03%-97.89%)		
Diagnostic pecificity, 95% CI	98.67%(95.27%-99.63%)		
Overall coincidence rate, 95% CI	97.22%(94.38%-98.65%)		

【Precautions】

1. Please read this instruction carefully before testing. If medical staff do not follow the instructions, they will get inaccurate results.
2. Sample should be tested in a laboratory with certain conditions and all samples and materials in the testing process should be handled in accordance with the operating specifications of the infectious disease laboratory.
3. Beware of the product getting humidity and do not open the aluminum foil bag before it is ready for testing. If the aluminum foil bag is damaged or the test card is damp, it cannot be used.
4. Please use the kit within the shelf life.
5. Before use, all reagents and samples should be balanced at the room temperature (15-30℃).
6. Do not replace the components in the kit with the components in other kits.
7. The interpretation of inspection methods and results must be carried out in strict accordance with the IFU.
8. The samples and the materials used for testing should be treated as biohazardous waste.

【Approval Date and Revision Date of The Instruction for Use】

Approval Date: 05/06/2021
Revision Date: 05/06/2021
Date of Issue: 05/06/2021

【Index of CE Symbols】

IVD	The product is used in vitro, please don't swallow it.		Please don't reuse it
	Validity		Please read the instruction book carefully before using
	Warning, please refer to the instruction in the annex		Manufacturer
2℃ 30℃	Temperature scope within which the product is reserved	LOT	Batch number
EC REP	European union authorization representative		Keep dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	Date of manufacture		Biological risks
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

【Basic Information】

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