SARS-Cov-2 Neutralizing Antibody Assay Kit by Immunofluorescence Chromatography Method

Cat. No.:

Cat. No.:	Specification	Test card (strip)	Tips (piece)
T3801W	5 Tests	5	5
T3802W	25 Tests	25	25
T3803W	50 Tests	50	50
T3804W	100 Tests	100	100
T3805W	200 Tests	200	200

Intended use

For in vitro qualitative determination of SARS-Cov-2 neutralizing antibody in human whole blood (heparin anticoagulation recommended), serum, and plasma (heparin anticoagulation recommended).

Test principle

Based on the principle of Immunofluorescence analysis, SARS-CoV-2 Neutralizing Antibody Assay Kit by Immunofluorescence Chromatography Method was used to immobilized ACE-2 protein (T line) and goat anti-chicken IgY Antibody (C line) using nitrocellulose membrane (NC) as solid phase carrier. Fluorescent microspheres were conjugated to recombinant SARS-CoV-2 S-RBD antigen in the fluorescent labeling pad.

When the buffer solution was added to the sample well, the S-RBD-labeled fluorescent microspheres in the labeling pad were pushed to bind to the corresponding immobilized ACE-2 protein on the NC membrane, and the fluorescent signal could be detected at the marking position. If there is a neutralizing antibody in the sample, it will bind to the labeled S-RBD antigen when passing through the labeling pad. The neutralizing antibody can prevent the binding of S-RBD to ACE-2, resulting in a decrease in the signal value, and the T-line signal value is negatively correlated with the neutralizing antibody content.

Reagents components

The reagent consists of test cards, tips, and instructions. Wherein:

Test card: It consists of reagent strip and plastic box. The main ingredients on the reagent strip are: nitrocellulose membrane, absorbent paper, PVC board and other test strip support; the reagent strip is coated with ACE-2 protein(each reagent strip contains 0.11 μg to 1.12 μg) and goat anti-chicken IgY Antibody (each reagent strip contains 0.20 μg to 1.50 μg) and recombinant S-RBD antigen (each reagent strip contains 0.11 μg to 1.12 μg) and fluorescent microspheres (each reagent strip contains 2 μg to 10 μg)

The determination system can be traced to the measurement procedure selected by the manufacturer;

The ingredients in the kits of different batches cannot be interchanged or mixed.

Storage and stability

The test card is valid for 15 months at 2 ℃ to 30 ℃. Transport and storage should be carried out at 2 ℃ to 30 ℃.

Applicable instrument

- Immunofluorescent Analyzer (Auto-HFIAS 1000) produced by Sichuan Xincheng Biological Co., Ltd.
- Immunofluorescent Analyzer (IFP-3000) produced by Sichuan Xincheng Biological Co., Ltd.
- Immunofluorescent Analyzer (AFS-1000) produced by Guangzhou Labsim Biotech Co., Ltd.
- Immunofluorescent Analyzer (IFP-2000) produced by Sichuan Xincheng Biological Co., Ltd.

Specimen collection and preparation

1. Human whole blood (heparin

anticoagulation recommended), serum, or plasma (heparin anticoagulation recommended) sample.
2. Test the sample as soon as possible after it is collected. If it cannot be measured in time, it should be transported and stored as required.
3. The samples should be transported and stored at 2℃ to 8℃. Whole blood samples can be stored for 7 days at 2℃ to 8℃, and serum/plasma samples can be stored for 3 days at 2℃ to 8℃. Stable at -20 ℃ for 7 days. Refrigerated samples must be left to recover to 20 ℃ to 28 ℃ before testing , multiple freeze-thaw cycle should be avoided. The sample should be measured during the stable period, otherwise the sample must be collected again.
4. The test result may be affected by severe jaundice, hemolysis, and lipemia samples.

Assay procedure

Please read the instruction manual of the applicable instrument and this manual carefully before use. The reagent should be returned to room temperature before testing, and the testing process should also be performed at room temperature.
1. Testing steps
1.1 Open the kit and insert the test card into the instrument interface.
1.2 Use the Capillarity Tube to aspirate the sample, insert it into the diluent, Mix well and drop three drops of liquid into the test card sample hole. After 8 minutes, place the test card into the instrument and click "Test".
1.3 Select the appropriate sample detection mode for testing on the instrument operation screen.
1.4 After the test is completed, remove the test card from the instrument and process it in accordance with the regulations.
2. Interpretation
Interpret the test result in accordance with the interpretation criteria of qualitative result in the manual.

Result interpretation

Inhibition rate	result	state	Clinical significance
≤20%	negative	No neutralizing antibody were detected in the sample	Weak ability to resist virus infection
20%~50%	positive	Low concentration neutralizing antibody were detected in the sample	It has certain antiviral infection ability
50%~100%	positive	Medium and high concentration neutralizing antibody	The ability to resist virus infection is strong

Limitation

1. Inhibition rate > 20% indicates that there may be neutralizing antibodies in the sample, which cannot rule out the false positive caused by inhibitory peptides or small molecule inhibitors.

2. The negative result indicates that the amount of neutralizing antibody detectable is below the detection limit, and the negative result does not exclude the possibility that there is no neutralizing antibody in the body.

3. Use fresh samples whenever possible. Freeze-thaw samples contain particles that block the nitrocellulose membrane, which may impede the flow of the reagent and lead to biased results.

Performance characteristics

1. Negative coincidence rate
Test 10 enterprise negative reference materials, the results should all be negative.
2. Positive coincidence rate
Test 10 enterprise positive reference materials, the results should all be positive.
3. Repeatability

Test for 10 times repeatedly with the same enterprise negative reference material, the results should be negative. Test for 10 times repeatedly with the same enterprise positive reference material, the results should be positive.

4. Limit of Detection (LoD)

The enterprise Limit of Detection (LoD) reference S1 should be negative, S2 and S3 should be positive.

Precautions and warnings

1. This product is for in vitro diagnostic and professional use only.
2. This reagent contains animal-derived ingredients and its biosafety complies with regulations, but it is still handled as a potentially dangerous substance.
3. The reagent contains chemical ingredients. Avoid accidental ingestion or contact with the skin and mucous membranes. If the reagent is splashed into the eyes, rinse immediately with plenty of water and consult a doctor if necessary.
4. Samples and waste liquids generated after testing shall be treated as infectious agents. All used packaging materials shall be treated in accordance with relevant regulations.
5. Never insert a test card whose surface is wet with other liquids into the detector, otherwise the instrument may be contaminated or damaged.
6. See the packaging label for the production date and expiration date.

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Manufacturer: Sichuan Xincheng Biological Co.,LTD
Registered Address: No. 101, Tianxin Road, Hi-tech Zone, Chengdu, Sichuan, China
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Attachment: Symbols for use in the labelling of medical devices

IVD :In vitro diagnostic medical device


:Do not re-use


:Keep away from sunlight


:Keep dry


:Consult instructions for use

LOT :Batch code

REF :Catalogue number


:Use-by date


:Date of manufacture


:Temperature limit


:Manufacturer

EC REP :Authorized representative in the European Community

Our commitment: In order to obtain reliable clinical laboratory analysis results, we pay attention to all important factors, including reagents, instruments, calibration, quality control and laboratory capabilities.
As for the bad analysis results, we, as a reagent manufacturer, promise to the distributors and clinical laboratories and assume our corresponding responsibilities. Thank you for purchasing and using Xincheng Bio prod.