Anti-SARS-CoV-2 Neutralization Antibody Test Kit

(Immunofluorescence Assay)

Product name: Anti-SARS-CoV-2 Neutralization Antibody Test Kit (Immunofluorescence Assay)

Catalogue No: CP04006-25

Packing specification: 25T/kit

INTENDED USE

Anti-SARS-CoV-2 Neutralization Antibody Test Kit is a rapid chromatographic immunoassay for semi-quantitative detection of neutralization antibodies to SARS-CoV-2 in human serum or plasma.

SUMMARY

Neutralizing antibody is the most important marker of possible immunity. Anti-SARS-CoV-2 Neutralization Antibody Test Kit is used to detect neutralizing antibodies in serum and plasma, determine whether the body has obtained immunity after vaccine injection, whether the individual that recovered from clinical treatment has potential immunity, and the lifetime of neutralizing antibodies in human body. Coronaviruses encode four major structural proteins, spike (S), membrane (M), envelop (E), and nucleocapsid (N), notably, S protein contains a receptor-binding domain (RBD) which is one of the vital immunodominant epitopes and has a superior capacity to induce neutralizing antibodies. It is proved that RBD of SARS-CoV-2 is responsible for recognizing and interacting with the cell surface receptor, angiotensin-converting enzyme-2 (ACE2). In the respiratory tract, ACE2 is widely expressed on the cell surface of alveoli, trachea, bronchi, macrophages, etc. Following the binding of the RBD to the receptor ACE2, SARS-CoV-2 enters target cells, where the fusion of the virus envelops the endosome membranes and leads to the release of the viral nucleocapsid into the cytosol of the infected cell. Neutralizing antibodies are secreted by B lymphocytes and can bind to virus SP(RBD), which can prevent pathogenic microorganisms from attaching to the receptor ACE2, avoid virus infection.

TEST PRINCIPLE

The Anti-SARS-CoV-2 Neutralizing Antibody Test Kit (Serum/Plasma) is a semi-quantitative membrane-based immunoassay for the detection of SARS-CoV-2 neutralizing antibodies in serum or plasma. the sample is dropped into the sample well, and chromatography is performed under the capillary effect. The SARS-CoV-2 neutralizing antibodies in the sample combined with the fluorescence labeled SARS-CoV-2 SP (RBD), then spread to the test area, ACE2 coated on T line is competitively bound to SP (RBD) with neutralizing antibody in the sample, the more neutralizing antibodies in the sample, the weaker signal of T-line showed. The quality control area (C line) is coated with the mouse anti-chicken IgY, and the fluorescence labeled chicken IgY is captured to form a complex and aggregate in the C line. If the C line does not show signal, it indicates that the result is invalid, and this sample needs to be tested again.

INSTRUMENT TYPE

FLUORESCENT IMMUNOANALYZER (AFS-1000)

REAGENTS

- Test Cassette: 25T/Kit.
- Buffer: 0.9mL/vial, 25vials.
- Desiccant
- Dropper
- ID card

STORAGE AND STABILITY

The kit can be stored at 2-30℃ for 18 months. Do not use after the expiration date.

SAMPLE COLLECTION AND PREPARATION

Anti-SARS-CoV-2 Neutralization Antibody Test Kit can be performed using serum and plasma.

- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed samples.
- Test should be performed immediately after sample collection.
- Serum and plasma samples may be stored at 2-8℃ for up to 3 days. For long-term storage, samples should be kept below -20℃
- Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. samples should not be frozen and thawed repeatedly.

PRECAUTIONS

- For medical professional use only.
- Do not reuse.
- Handle all samples cautiously as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the process and properly handle samples in accordance with standard procedures.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
- The used tests, samples and potentially contaminated should be discarded according to the local regulation.
- Unreasonable sampling, transportation and handling, or low virus content in the sample will lead to false negative results. Humidity and temperature can adversely affect results.
- Each laboratory should build its own reference range.

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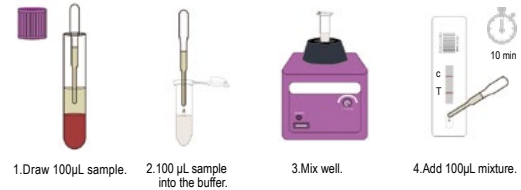

1.Draw 100μL sample. 2.100 μL sample into the buffer. 3.Mix well. 4.Add 100μL mixture.

5.Insert ID card. 6.Choose sample type. 7.Test.

* Micropipette is recommended

TEST PROCEDURE

- Bring the pouch to room temperature before opening. Take the cassette from the sealed pouch and use it within ONE hour.
- Place the cassette on a clean and flat surface.
- Add 100 μL of serum or plasma sample into the buffer, mix well, then add 100 μL of mixture into the sample hole and start the timer. Avoid trapping air bubbles into the sample well.
- Take out the ID card and confirm that the ID card matches the batch number of the detection card.
- Turn on the instrument, enter the detection interface and read the ID card. Check whether the test items and reagent information are consistent with the reagent used.
- Mode: according to the sample types, choose the matching sample type option on the AFS-1000 immunofluorescent analyzer, please refer to the operation manual of the supporting instrument for details.
- Interpretation: immediately insert the detection card into the slot of the applicable instrument at the time of 10 minutes, and click "instant Test" for quantitative interpretation results.

NOTE: It is recommended to use serum or plasma as the priority sample types for testing.

INTERPRETATION OF RESULTS

- Immunofluorescent analyzer is used to analyze the test card and provide quantitative test results.
- The detection range of this kit is 0.1-15. When the sample content exceeds the detection limit, calf serum or negative sample could be used to do gradient dilution. The maximum dilution ratio is 5-fold each time.
- COI (cut-off index) = $\frac{2.722}{\text{Value}_{\text{T line}}}$

  If result≤1.0, it means that the signal value of T line is greater than cut-off value, indicating negative.

  If result>1.0, it means that the signal value of T line is less than cut-off value, indicating positive.

PERFORMANCE

1. **Compliance rate:** Result by negative reference should be 0.5-1, result by positive reference should be 1.5-2.
2. **Repeatability:** ≤15%.
3. **Specificity analysis:** There is no cross-reaction with antibody/antigen positive sera samples from patients with other human coronaviruses (HCoV-HKU1, HCoV-OC43, HCoV-NL63, HCoV-229E), or non-coronaviruses, including influenza A virus (H1N1, H3N2, H5N1, H7N9), influenza B virus (yamagata lineages, victoria lineages), respiratory syncytial virus, rhinovirus, adenovirus, enterovirus, epstein-Barr virus, measles virus, human cytomegalovirus, rotavirus, norovirus, mumps virus, herpes zoster virus, or mycoplasma pneumoniae.
4. **Cut-off:** The serum/plasma of 464 healthy people is statistically analyzed, The Cut-off value of "T line" is 2.722 (Non-parametric percentile method (CLSI C28-A3)).
5. **Hook effect:** There is no hook effect within the titer range of positive samples.
6. **Clinical performance:** 626 clinical samples (111 positive cases and 515 negative cases) showed the sensitivity is 98.198% (95%CI: 93.643%, 99.781%) and specificity is 98.252% (95%CI: 96.709%, 99.198%).

CP04006-25	Plaque-reduction neutralization test		Total
	Positive	Negative	
Positive	109	9	118
Negative	2	506	508
Total	111	515	626
Sensitivity		98.198% (93.643%,99.781%)	
Specificity		98.252% (96.709%,99.198%)	
Positive Predictive Value (PPV)		92.373% (86.366%,95.860%)	
Negative Predictive Value (NPV)		99.606% (98.463%,99.900%)	

Statistics of 111 positive samples (compared with plaque-reduction neutralization test)

Titer (PNT50)	POS By PNT	POS By UNscience	Coincidence rate	CP04006-25 COI		
				Min	Max	Median
<4	14	12	85.71%	0.9	1.6	1.2
4-24	32	32	100%	1.1	2.0	1.4
24-48	22	22	100%	1.5	3.9	2.8
48-96	21	21	100%	1.9	9.9	6.9
>96	22	22	100%	4.5	14.9	8.9

Diagnostic analysis of neutralizing antibodies in different populations:

Characteristic	Total	POS By PNT	POS By UNscience	CP04006-25 COI		
				Min	Max	Median
Heathy	490	0	9	0.5	1.5	0.7
Convalescent	15	6	6	0.6	1.4	0.9
Infestor	21	5	4	0.7	1.6	0.9
Vaccination	100	100	99	1.0	14.9	2.9

LIMITATIONS

1. FOR PROFESSIONAL USE ONLY. The presence of binding antibodies does not guarantee the presence of neutralizing antibodies, and the levels can not be consistent.
2. The half-life of binding antibody and neutralizing antibody is different, and the decline rate may be different.
3. Anti-SARS-CoV-2 Neutralization Antibody Test Kit is for in vitro diagnostic use only. The test should be performed using serum or plasma samples only.
4. Anti-SARS-CoV-2 Neutralization Antibody Test Kit will only indicate the presence of SARS-CoV-2 neutralization antibodies in the sample and should not be used as the sole basis, and should be combined with other test methods, as live virus and pseudovirus neutralizing antibodies assay.
5. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician. Each laboratory should build its own reference range.

BASIC INFORMATION

GLOSSARY OF SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device	2℃ 30℃	Temperature limitation
	Manufacturer	EC REP	Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instructions for use
LOT	Batch code	CE	Meet the requirements of EC Directive 98/79/EC

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Version: A1.0 Date Adopted: 2020-12-01