SARS-CoV-2 Antibody Assay Kit（ELISA）

【Product Name】

SARS-CoV-2 Antibody Assay Kit (ELISA)

Catalog Number: XG100H2

Package Size: 48T

【Intended use】

The SARS-CoV-2 antibody assay Kit (ELISA) is used for the qualitative determination of novel coronavirus (SARS-CoV-2) antibodies in human blood samples (plasma, serum) in vitro.

It is suitable for the rapid screening of SARS-CoV-2 virus antibodies for patients, employees, students and residents in medical institutions at all levels, which can realize rapid and accurate serological test.

For in vitro research use only

【Principle】

Briefly, flat-bottom 96-well plates are coated with S1 protein of SARS-CoV-2 that captures SARS-CoV-2 antibodies in the sample. A quick wash removes any unbound materials. Captured SARS-CoV-2 antibodies are detected by Goat Anti-Human IgG(H+L) pAb conjugated with horse radish peroxidase (HRP). After wash, the chromogenic substrate 3, 3´, 5, 5´-tetramethylbenzidine (TMB) is added. The amount of SARS-CoV-2 antibodies is proportional to the color density generated in the coupled oxidation-reduction reaction.

【Kit components】

Size	Regents	Quantity
48T	S1 protein coated plate	12 wells × 8 strips
	Negative control	1 vial
	100X Enzyme-conjugated pAb	1 vial
	Enzyme dilution buffer	1 vial
	Sample dilution buffer	1 vial
	20X Wash buffer	1 vial
	Stop buffer	1 vial
	Substrate solution A	1 vial
	Substrate solution B	1 vial
	Medium positive control	1 vial
	Weak positive control	1 vial
	Sealing films	2 pieces

【Storage conditions】

1. The components of the kit remain stable through the expiration date indicated on the label if stored at 2-8℃, do not freeze and avoid light.

2. After opening, please keep it sealed for further use in three months.

【Materials Required】

1.Water: freshly distilled or deionized.

2.Disposable gloves, timer and appropriate waste containers.

3.Dispensing system and/or pipette (single or multichannel), disposable pipette tips.

4.Microplate shaker with temperature and speed control.

5.Microwell plate washer.

6.Vortex.

7.Microwell plate reader, single wavelength of measuring absorbance at 450nm or dual wavelength at 450nm and 620nm or 630nm (correction wavelength).

【Sample requirements】

1.Sample type

The kit is applicable for human plasma and serum.

2.Sample collection and processing

Plasma/serum collection: Serum/plasma samples isolated after blood collection are stored at 2-8°C for less than one week. If the measurement cannot be performed within 1 week after blood collection, the plasma/serum sample should be sealed and placed below -20°C for no more than 1 month, and avoid repeated freeze-thaw cycles.

【Protocol】

1. Before using, pre-warm all the reagents to room temperature (18~30℃) for 30 minutes.

2. Buffer preparation:

Washing buffer: dilute the 20X Wash Buffer with water by 20-fold and mix well.

Enzyme solution: Dilute 100X Enzyme-conjugated pAb with Enzyme Dilution buffer by 100-fold and mix well.

3. Dilute samples with Sample Dilution Buffer by 20-fold, mix well. Transfer 100μL of diluted samples, negative control and positive control into their respective wells in the ELISA plate (It is recommended that all samples and controls be assayed in duplicates). Incubate at 37℃, 200 rpm for 60 minutes with constant shaking.

4. Remove samples from wells and wash all wells 3 times with Washing Buffer (250μL/well). Remove residual solution by taping against paper pat (optimal).

5. Add 100μL of Enzyme Solution (diluted Enzyme-conjugated pAb) to each well. (Careful not to touch or scratch the surface of the wells). Incubate plate at 37℃, 200rpm for 60 minutes with constant shaking.

6. Remove samples from wells and wash all wells 3 times with prepared Washing Buffer (250μL/well). Remove residual solution by taping against paper pat (optimal).

7. Add 50μL each of Substrate Solution A and Substrate Solution B into each well. Mix thoroughly with shaking. Incubate at room temperature for 5-10 minutes and avoid light.

8. Stop the reaction by adding 50μL of Stop solution into each well,

mix well.

9. Record the absorbance at 450nm (with correction wavelength or not) on a plate reader within 30 minutes after adding the Stop Solution.

【Data Analysis】

1. Calculate the mean value (AVG1) and standard deviation (SD) of Negative control, and use the value of AVG1 + 3xSD as the negative cut-off point (N-Cut); calculate the mean value (AVG2) of Weak positive control, use AVG2 as the positive cut-off point (P-Cut).

2. If the absorbance value of the sample is greater than or equal to the positive cut-off point (P-Cut), the result of the sample is positive, indicating that the sample has detected antibodies that recognize the SARS-CoV-2; if the absorbance value of the sample is less than the negative cut-off point (N-Cut), the result of the sample is negative, it means that no antibody that recognizes the SARS-CoV-2 is detected in the sample; if the absorbance value of the sample is less than the positive critical point value (P-Cut) and greater than or equal to the negative critical point value (N-Cut), the result of the sample falls into a gray area and needs further experimental confirmation.

3.This result is for reference only, and the diagnosis result of the patient needs to be judged in conjunction with the clinical diagnosis.

【Limitations of the method】

1. Results beyond the measurement range of the kit are unreliable.

2. Severe hemolysis, chyle, and bilirubin samples can cause abnormal test results.

【Caution】

1.This reagent is intended for in vitro diagnostic use only.

2.Please read the instruction carefully prior to use.

3.Reagents of different batches and varieties must not be mixed.

4.Please store and use reagents reasonably in strict accordance with the instructions.

5.Avoid direct sunlight.

6.Testing must comply with the requirements of the Biosafety Code and strictly prevent cross-infection.

7.All samples, washing liquids and various wastes should be treated as potentially hazardous substances.

8.It is also strongly suggested that the whole assay is performed by the same operator from the beginning to the end.

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