

# SARS-CoV-2 Antibody Assay Kit (ELISA)

## 【Product Name】

SARS-CoV-2 Antibody Assay Kit (ELISA)

Catalog Number: XG100H2

Package Size: 96T

## 【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	Reagents	Quantity
96T	S1 protein coated plate	12 wells × 8 strips
	Negative control	1 vial
	100X Enzyme-conjugated pAb	1 vial
	Calf serum	1 vial
	20X Wash buffer	1 vial
	Substrate solution A	1 vial
	Substrate solution B	1 vial
	Positive control	1 vial

### 【Storage conditions】

1. The components of the kit remain stable through the expiration date indicated on the label if stored at 2-8°C, 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. Microwell plate washer.

5. 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°C) for 30 minutes.
2. Buffer preparation:  
Washing buffer: dilute the 20X Wash Buffer with water by 20-fold and mix well.  
Dilution buffer: transfer 5 ml of Calf serum to 20 ml of PBS, mix well.  
Enzyme solution: Dilute 100X Enzyme-conjugated pAb with Dilution buffer by 100-fold and mix well.
3. Dilute samples with 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 room temperature for 30 minutes with taping every 5 mins. or using a temperature controlled micorplate shaker.
4. Wash the plate 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 at room temperature for 15 minutes with taping every 5 mins or using a temperature controlled micorplate shaker.
6. Wash the plate 3 times with 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 taping. Incubate at room temperature for 5-10 minutes at dark.
8. Stop the reaction by adding 50µL of 0.1 M H<sub>2</sub>SO<sub>4</sub> into each well, mix well.
9. Record the absorbance at 450nm (with correction wavelength or not) on a plate reader within 30 minutes

### 【Data Analysis】

1. Calculate the mean value (AVG1) of Negative control, and time the lot-specific converting factor (CF) as the negative cut-off point (N-Cut); This lot's CF is **1.75**
2. Calculate the mean value (AVG2) of positive control, use AVG2 as the positive cut-off point (P-Cut).

3. 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 antibodies that recognize the SARS-CoV-2;
4. 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 in the sample;
5. 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.

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 may 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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In order to obtain better service, please have the lot number of the kit ready when you contact us (found on the outside of the box).