Hotgen

Stock Code 688068.SH

Novel Coronavirus (SARS-CoV-2) Neutralizing Antibodies Test (Colloidal Gold)

FDA Submission Number: EUA203138

ISO CE

Product Features

S-RBD based on S protein was used as diagnostic antigen

S-RBD is the main epitope for neutralizing antibody production.
S-RBD protein detection is more suitable for vaccine effect evaluation.

Cover all detection targets(IgA, IgM,IgG, etc.) of S-RBD.

Some of the raw materials used in serological detection reagents are S protein, S-RBD protein and N protein; S-RBD protein detection is more suitable for vaccine effect evaluation.

Double Antigen Sandwich Method

The double antigen sandwich method is an ideal alternative to evaluate the neutralization antibody level.

Semi-quantitative detection

Equipped with colorimetric card, can get the range of neutralizing antibody titer.
No need instrument, get results in 15 minutes.

Intended use

It is used to evaluate the vaccine effect,determine whether there are neutralizing antibodies in infected patients.

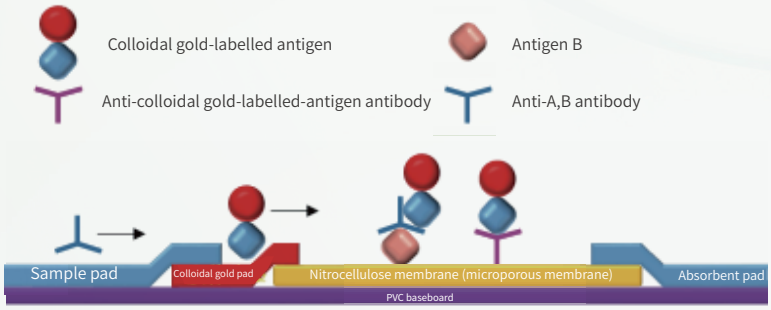
The main neutralizing epitope of SARS-CoV-2—S-RBD

The neutralizing antibody of SARS-CoV-2 is mainly against the receptor binding domain (S-RBD) of S protein, which provides theoretical basis for vaccine development.

At present, the high neutralizing active antibodies screened are targeted at the S-RBD region.

Some of the raw materials used in serological detection reagents are S protein, S-RBD protein and N protein; S-RBD protein detection is more suitable for vaccine effect evaluation.

Novel Coronavirus (SARS-CoV-2) Neutralizing Antibodies Test (Colloidal Gold)

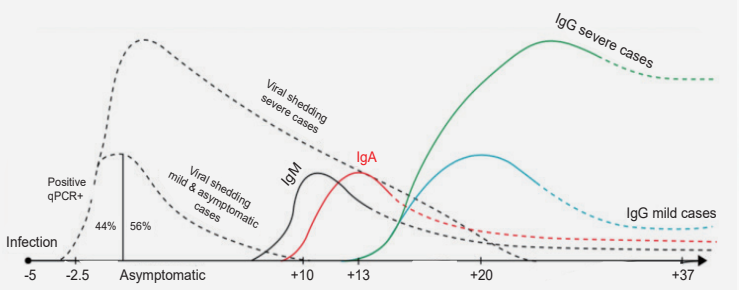


Double antigen sandwich method (detecting antibodies)

The double-antigen sandwich method makes the detection more specific;

Simultaneous detection of total antibody (IgA, IgM, IgG, etc.) of S-RBD.

IgA, IgM and IgG three kinds of antibody responses after infection of Novel Coronavirus (SARS-CoV-2)



① On the basis of the traditional IgM / IgG antibody index, increasing the detection of IgA antibody which can effectively improve the sensitivity of antibody diagnosis.

② IgA level in serum was positively correlated with disease severity.

③ S-RBD based on S protein as a diagnostic antigen has higher detection Sensitivity and specificity.

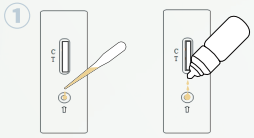
S-RBD protein detection is more suitable for vaccine effect evaluation.

Comparison of most detection of SARS-CoV-2 antibody

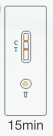
Test Antibody	Coating antigen	Test method
SARS-CoV-2 IgM antibody	S-RBD protein	Capture method
SARS-CoV-2 IgG antibody	N protein	Indirect method
SARS-CoV-2 antibody(IgA, IgM, IgG, etc.)	S-RBD protein	Double-antigen Sandwich Method

Test Procedure

Serum and plasma samples or Venous whole blood samples

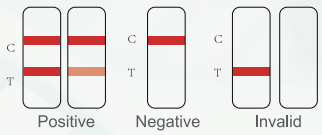


Take sample of 25μL Venous whole blood samples or 20ul Serum and plasma samples (1 drop with a dropper), add it into the sample well of the test cassette, and add 80μL(approximately 3 drops) of sample diluent. And then use a cotton swab to stop the bleeding.



Read result after incubate for 15 minutes at room temperature. Result got after 30 miunutes is invalid

Interpretation of result



Clinical Performance

Clinical performance of Novel Coronavirus (SARS-CoV-2) Neutralizing Antibodies Test (Colloidal Gold) was determined by testing 339 positive and 869 negative specimens for SARS-CoV-2 neutralizing antibody to have a sensitivity of 98.5%(95%CI: 96.59%～99.52%%) and specificity of 99.3% (95%CI:98.50%～99.75%).

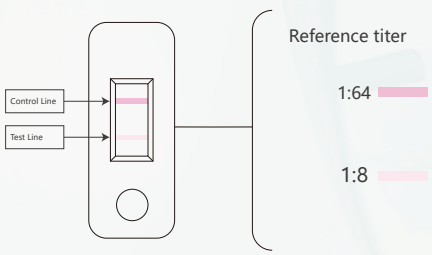
The coincidence rate of the venous whole blood samples test results

Assessment system	Reference system		
	Positive(+)	Negative(-)	Total
Positive(+)	334	6	340
Negative(-)	5	863	868
Total	339	869	1208

Sensitivity:98.53%; specifity: 99.31%; Accuracy :99.09%

The correlation between neutralizing antibody titer and detection results.

Assessment system	Neutralizing Antibody Titer			
	＜1：4	1：4-1:64	＞1:64	Total
-	863	6	0	869
+	5	177	157	339
Total	868	183	157	1208



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Product information

Product name	Stock Code	Test samples	Specifications	Storage conditions
Novel Coronavirus (SARS-CoV-2) Neutralizing Antibodies Test (Colloidal Gold)	16101040	Peripheral whole blood, Venous whole blood, Serum, plasma	40T/Kit,20T/Kit 5T/Kit,1T/Kit	4-30℃

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