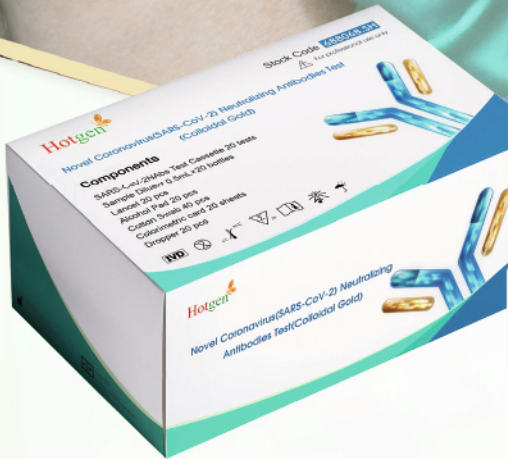


Hotgen 

Stock Code **688068.SH**

 **BCEE** linea Medica



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

 **BCEE** linea Medica  
[www.checkmylife.it](http://www.checkmylife.it)

FDA Submission Number: EUA203138

 **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.



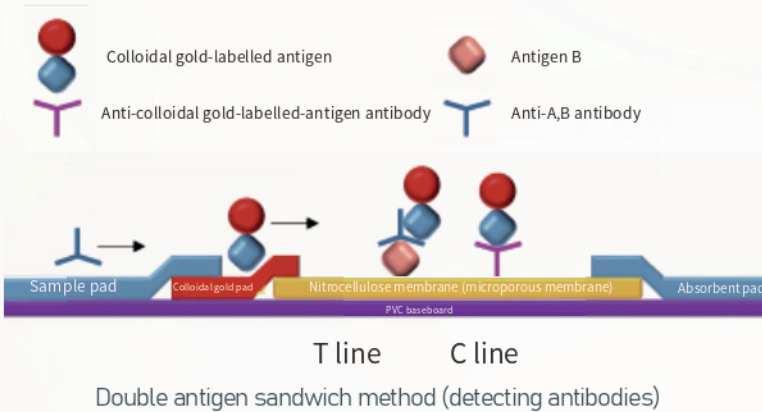
## The main neutralizing epitope of SARS-CoV-2—S-RBD

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.

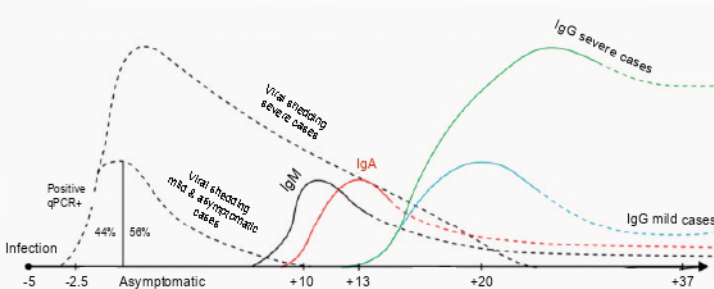
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The double-antigen sandwich method makes the detection more specific;  
Simultaneous detection of total antibody (IgA, IgM, IgG, etc.) of S-RBD.

## 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.

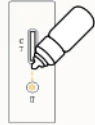
## S-RBD protein detection is more suitable for vaccine effect evaluation.

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

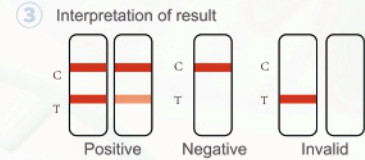
### Serum and plasma samples or Venous whole blood samples



Take sample of 25 $\mu$ L Venous whole blood samples or 20 $\mu$ L Serum and plasma samples (1 drop with a dropper), add it into the sample well of the test cassette, and add 80 $\mu$ L (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 minutes is invalid



## 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

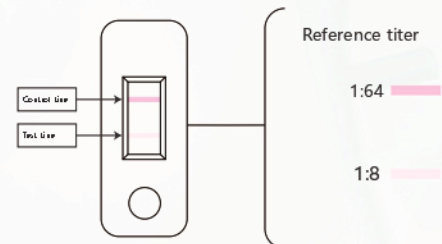
| Assessment system | Reference system |              |       |
|-------------------|------------------|--------------|-------|
|                   | Positive (+)     | Negative (-) | Total |
| Positive(+)       | 334              | 6            | 340   |
| Negative(-)       | 5                | 863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

**Sensitivity:98.53%; specificity: 99.31%; Accuracy :99.09%**

The correlation between neutralizing antibody titer and detection results.

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

**Sensitivity:98.53%; specificity: 99.31%; Accuracy :99.09%**



## 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<br>5T/Kit,1T/Kit | 4-30C              |

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