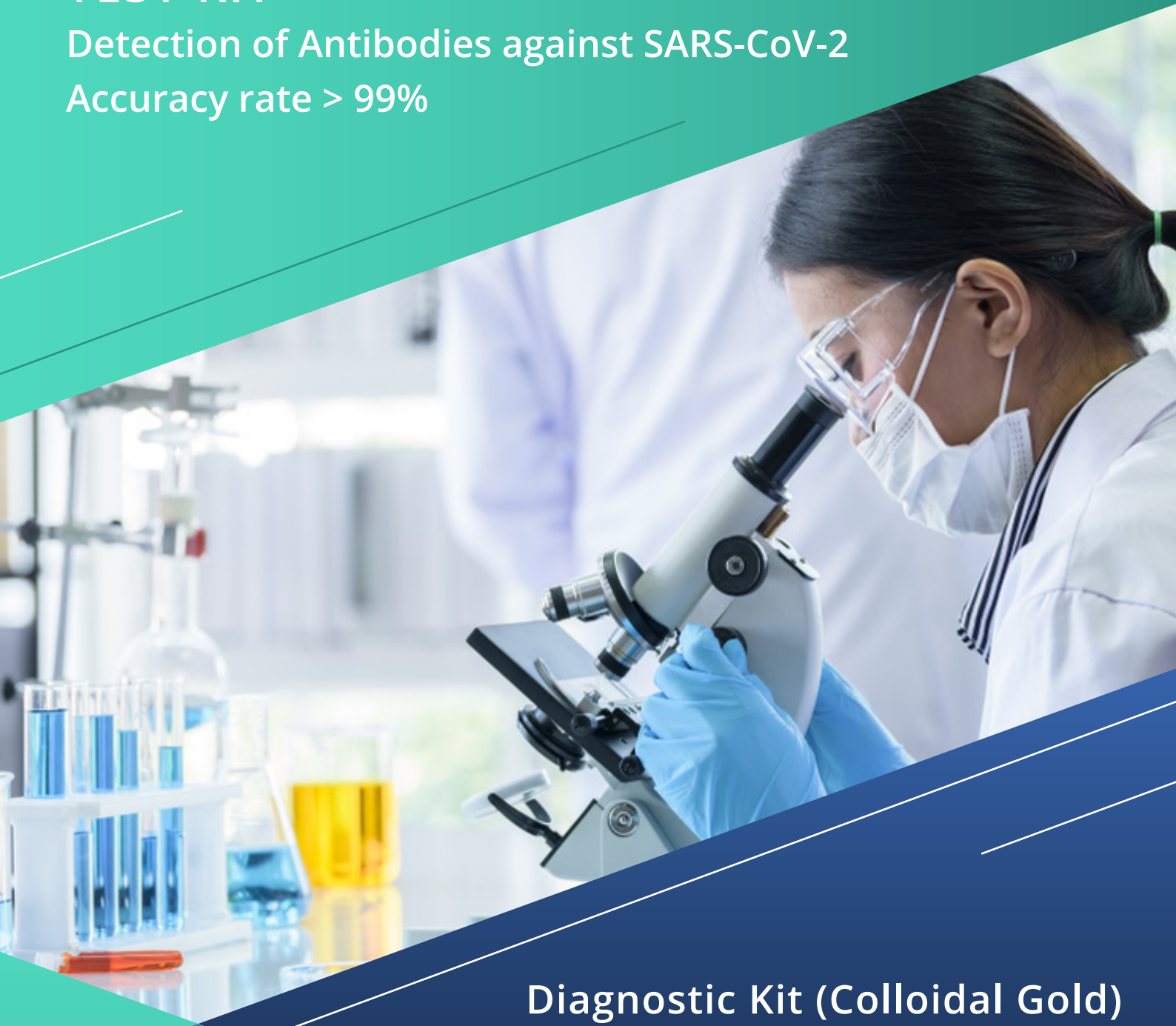
# TEST KIT

## Detection of Antibodies against SARS-CoV-2

## Accuracy rate > 99%



## Diagnostic Kit (Colloidal Gold) for IgG and IgM Antibodies against SARS-CoV-2

CE MHRA ISO13485:2016

# Diagnostic Kit (Colloidal Gold) for IgG and IgM Antibodies against SARS-CoV-2

Very high accuracy

Fast, easy and safe to use

No equipment requirement

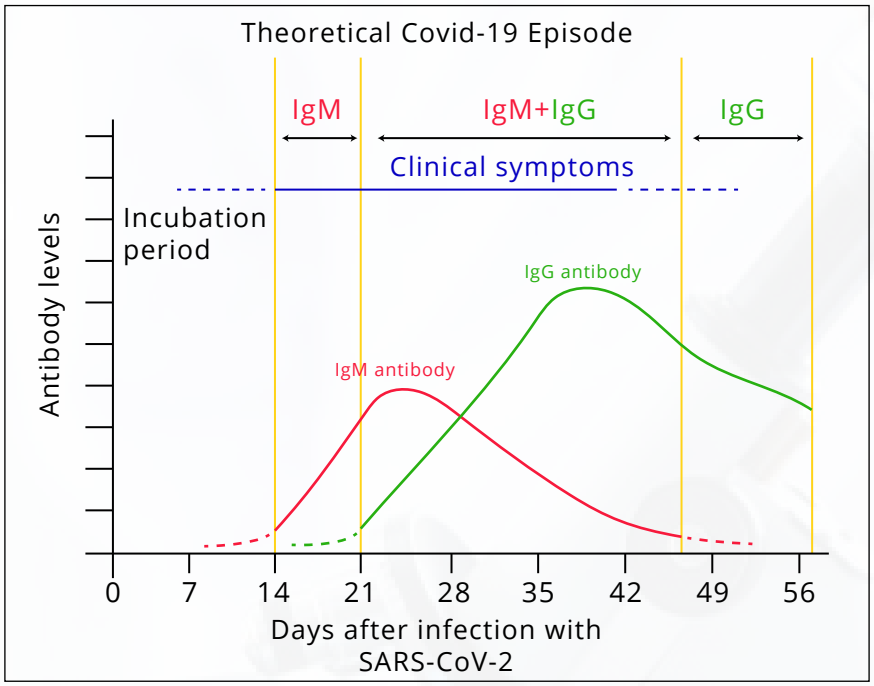
Can monitor all phases of covid-19

High sensitivity

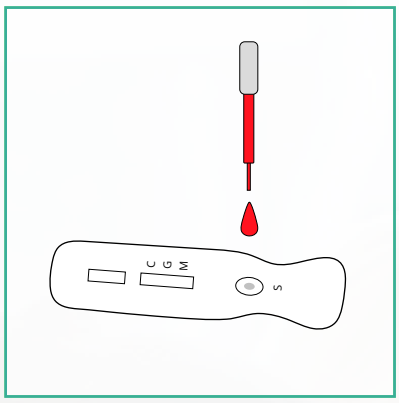
## IMMUNE DEFENSE: IgM & IgG ANTIBODIES

Immunoglobulin M (IgM), which is found mainly in the blood and lymph fluid, is the first antibody to be made by the body to fight a new infection (the acute phase). IgM can be tested and detected very early after infection and disappears within 1 to 2 months after the infection (see the graph below).

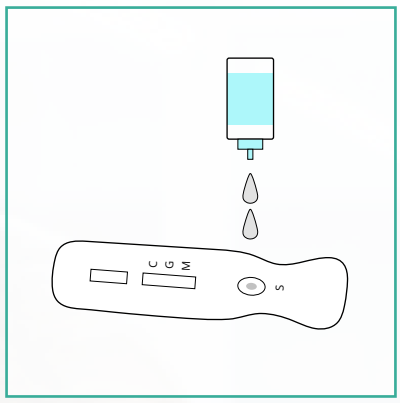
Immunoglobulin G (IgG), the most abundant type of antibody, is found in all body fluids and protects against for example bacterial and viral infections. IgG is the antibody being produced from the middle -, and through the infection period all the way into the late stage infection (see the graph below). It is also this immunoglobulin-type which will be synthesized as a response to a new infection with SARS-CoV-2 and try to destroy the infection process. Therefore, a positive result for IgG indicates that the patient is either recovering or has had a previous infection.



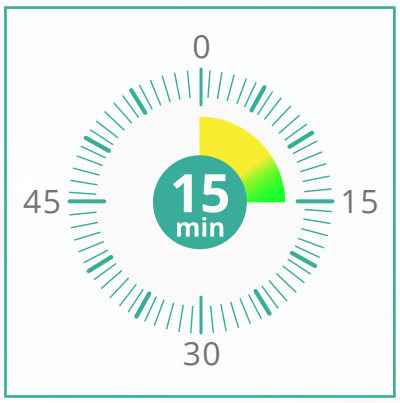

## TEST METOD




Add 20uL ( 1 drop)
Specimen into the “S” well

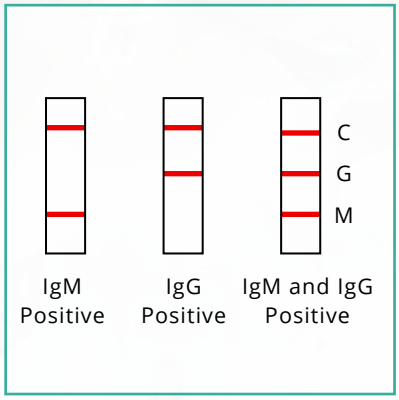


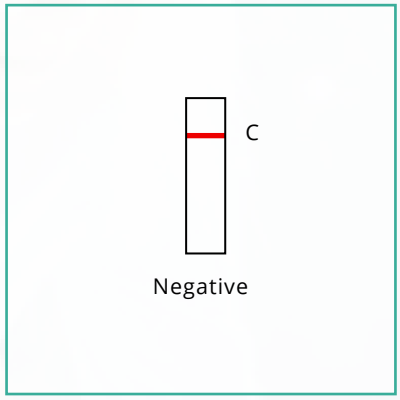

Add 2 drops sample
diluent into the “S” well

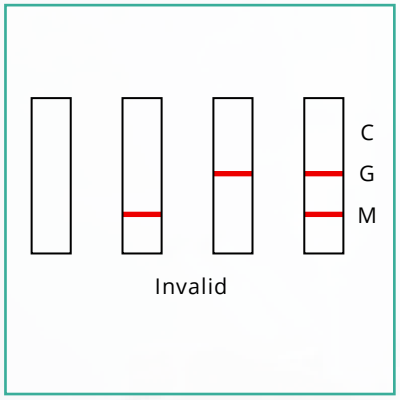



Report the results
in 10-15 minutes.

## RESULT INTERPRETATION




## CLINICAL STUDY

### Comparative analyses of clinical diagnostic

#### I Clinical diagnostic study

- The comparison of the detection by the test-kit of IgG and/or IgM antibodies against SARS-CoV-2 compared with the clinical diagnostic results is shown in the following table:

| | | Clinical diagnosis results | | Total |
|---|---|---|---|---|
| | | Confirmed diagnosis | Negative | |
| Test kit results | Positive (+) | 186 | 8 | 194 |
| | Negative (-) | 16 | 372 | 388 |
| Total number | | 202 | 380 | 582 |

Sensitivity: 92.08%; (95%CI : 87.52%~95.07%)
Specificity: 97.89%; (95%CI : 95.90%~98.93%)
Total clinical rate: 95.88%. (95%CI : 93.94%~97.21%)

## II Nucleic acid tests

- The comparison of the detection by the test-kit of IgG and/or IgM antibodies against SARS-CoV-2 compared with the nucleic acid test results is shown in the following table:

| | | Nucleic acid test results | | Total |
|---|---|---|---|---|
| | | Positive (+) | Negative (-) | |
| Test kit results | Positive (+) | 116 | 78 | 194 |
| | Negative (-) | 10 | 378 | 388 |
| Total number | | 126 | 456 | 582 |

Positive coincidence rate: 92.06%; (95%CI : 86.01%~95.63%)
Negative coincidence rate: 82.89%; (95%CI : 79.17%~86.07%)
Total rate: 84.88%. (95%CI : 81.74%~87.56%)

## III Accuracy

The word “exclusion” is normally used for a patient who cannot participate in the analyses (too old, wrong sex; complications with other diseases, taking medicine etc.). What we mean in our text is that the patient is negative for SARS-CoC-2 and therefore we should use the word “negative”.

The “test reagent” is the liquid in the second bottle in the test. It is correct that this reagent is important for the test; but it is the result of the analysis with the entire test kit (bound antibodies to the device etc.) that is responsible for the detection. Therefore, a much better phrase is “Test kit results”

- Accuracy rate (test performed on patients at Jinyintan Hospital, China)
  Positive sample rate: 100% (160 of 160 samples)
  Negative sample rate 98.7% (159 of 160 samples)

## IV Detection time

- Comparison of the first positive detection point detected by the test-kit of IgG and/or IgM antibodies against SARS-CoV-2 compared with the nucleic acid test. The comparison is based on continuous sample collection from the same patients at different time points.
  The comparison is shown in the following table:

| Test kit results | Number of cases | Percentage |
|---|---|---|
| Earlier than the nucleic acid test results | 3 | 15% |
| Same as the nucleic acid test results | 14 | 70% |
| Later than the nucleic acid test results | 3 | 15% |

The comparisons above show that there were no statistical significantly differences between the test-kit and the clinical diagnostic results.

# Diagnostic Kit (Colloidal Gold) for IgG and IgM Antibodies against SARS-CoV-2


- Kit Size: 16*14.5*8cm
- 25 tests / kit
- Kit weight: 272g
- 30 kits in a box
- Box Size: 455mm*345mm*435mm
- Box weight: 9.33kg

Very high accuracy

Fast, easy and safe to use

No equipment requirement

Can monitor all phases of covid-19

High sensitivity

# Diagnostic Kit (Colloidal Gold) for IgG and IgM Antibodies against SARS-CoV-2

## Package Insert
## (For *in vitro* diagnostic use only.)

| | |
|---|---|
| **Catalog No:** | 51211211 (version: 01) |
| **Required Test Specimen:** | Whole Blood/Serum/Plasma |
| **Effective Date:** | 2020-02 |

## INTENDED USE

The Diagnostic Kit (Colloidal Gold-based) for IgG and/or IgM antibodies against SARS-COV-2 is a rapid and very sensitive immunoassay for the qualitative detection of antibodies IgG and IgM against SARS-COV-2 virus in whole blood, serum and plasma.

## SUMMARY

Coronaviruses (CoVs) belong to the Nidovirales,Coronaviridae and Coronavirus A large class of viruses and are found widely in nature. Coronavirus is a RNA-virus, where the 5 'end of the RNA of this viral group has a methylated cap structure, and the 3' end of the RNA has a poly (A) tail. The genome is 27-32kb long. It is the largest known RNA virus with the largest genome, which can code for approx. 28 proteins.

Coronaviruses are divided into three genera: α, β and γ. α andβ are pathogenic to mammals, and γ mainly leads to infections of the birds. CoV was also demonstrated to be transmitted mainly through direct contact with secretions or through aerosols and droplets, and it has also been shown to be transmitted via the fecal-oral route.

Coronaviruses are associated with a variety of diseases in humans and animals, causing diseases of the respiratory, digestive and nervous systems in humans and animals. So far, seven human coronavirus (HCoV) viruses have caused respiratory diseases in humans: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and SARS-COV-2.

Globally, 10% to 30% of the upper respiratory tract infections are caused by the four classes of coronavirus: HCoV-229E, HCoV-OC43, HCoV-NL63 and HCoV-HKU1.

SARS-COV-2 was found in more cases of viral pneumonia in Wuhan, China in December 2019. It is a kind of a novel type of CoV and has not been found in humans before. SARS-COV-2 belongs to the β coronavirus , which is enveloped, and the particles are round or elliptic, often pleomorphic, with a diameter of 60~140nm, and its genetic characteristics are significantly different from those of SARSr-CoV and MERSr-CoV.

The clinical manifestations are fever, fatigue and other systemic symptoms, accompanied by dry cough, dyspnea, etc. It can rapidly develop into severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multi-organ failure, severe acid-base metabolic disorder – all life-threatening diseases. SARS-COV-2 transmission has been identified primarily through respiratory droplets (sneezing, coughing, etc.) and contact transmission (nostril picking, eye rubbing, etc.). The virus is sensitive to ultraviolet light and heat, and can be effectively inactivated at 56°C for 30 minutes or lipid solvents such as ethyl ether, 75% ethanol, chlorine-containing disinfectant, peroxyacetic acid and chloroform.

## PRINCIPLE

The Diagnostic Kit for IgG and IgM Antibodies against SARS-CoV-2 is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 antibodies in whole blood, serum, or plasma. This test consists of two components, an IgG component and an IgM component. The test line region is coated with antibodies against human IgM (**Ab(IgM$_{human}$)**) and human IgG (**Ab(IgG$_{human}$)**), respectively. During testing, the specimen (whole blood, serum or plasma) reacts with SARS-CoV-2 antigen-coated particles (**Ag(SARS-CoV-2)-Particle**) in the test strip.

If the specimen contains antibodies against SARS-CoV-2 (Ab(IgM$_{human}$(SARS-CoV-2)) and/or Ab(IgG$_{human}$(SARS-CoV-2))) they will react with the **Ag(SARS-CoV-2)-Particles** and form the complexes:

Ab(IgM$_{human}$(SARS-CoV-2))=**Ag(SARS-CoV-2)**

and/or

Ab(IgG$_{human}$(SARS-CoV-2))=**Ag(SARS-CoV-2)**

The mixture will then migrate upward on the membrane due to chromatographically, capillary action and reacts with the bound **Ab(IgM$_{human}$)** and Ab(IgG$_{human}$) in the test line region. The complexes in the specimen will then bind to the bound **Ab(IgM$_{human}$)** and Ab(IgG$_{human}$), respectively.
The following complexes will be formed:

**Ab(IgM$_{human}$)**=Ab(IgM$_{human}$(SARS-CoV-2)=**Ag(SARS-CoV-2)-Particles** **(Line M)**

and/or

Ab(IgG$_{human}$)=Ab(IgG$_{human}$(SARS-CoV-2)=**Ag(SARS-CoV-2)-Particles** **(Line G)**

It is important to remember that a patient can easily be positive in both Lines M and G, respectively, if the patient is more or less in the middle of the infection episode with SARS-CoV-2. Later the IgM-response will fade out and the IgG-response will increase in intensity.

## KIT COMPONENTS

| | |
|---|---|
| • Individually packed test devices | 25 tests/kit |
| • Sample diluents | 1 vail/kit |
| • Disposable pipettes | 25 /kit |
| • Package insert | 1 copy/kit |

## MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen collection containers
• Timer
• Centrifuge (if necessary – whole blood can be used for the test)

## REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied.
The kit can be stored at room temperature (2°C -30°C, **do not freeze!**) for 12 months from the date of manufacture.
If stored at 2°C-8°C, **please notice that the test device is brought to room temperature before use.**
It must be used within 1 hour after opening the sealed aluminum foil bag (in room temperature; humidity < 80%)
The test device is stable until the expiration date printed on the sealed aluminum foil bag.

## SPECIMEN COLLECTION AND STORAGE

**Consider any materials of human origin as infectious and handle them using standard biosafety procedures.**

**• Whole Blood:**
Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in a Vacutainer®) by veno-puncture.

• **Plasma:**
Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veno-puncture.
Separate the plasma by centrifugation.
Carefully withdraw the plasma into new pre-labeled tube.

• **Serum:**
Collect blood specimen into a red top collection tube (containing no anticoagulants in a Vacutainer®) by veno-puncture.
Allow the blood to clot.
Separate the serum by centrifugation.
Carefully withdraw the serum into a new pre-labeled tube.

The specimens should be tested as soon as possible after collecting.
Store specimens at 2°C-8°C if not tested immediately – can be stored up to 5 days.
The specimens should be frozen at -20°C or lower for longer storage and avoid multiple freeze-thaw cycles.
Prior to testing, bring frozen specimens to room temperature slowly and mix gently.
Specimens containing visible precipitate - by gently shaking the vial with the specimen - should be clarified by centrifugation before testing.
Do not use samples showing gross lipemia, gross hemolysis or turbidity in order to avoid interference in result interpretation.

## ASSAY PROCEDURE

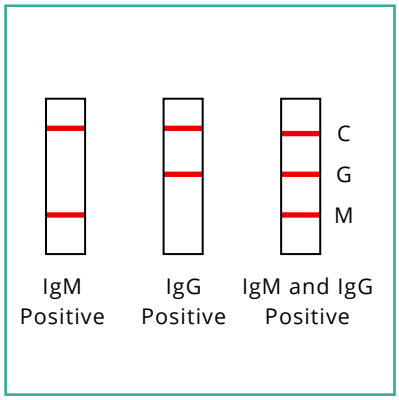
**Read the package insert carefully and thoroughly before testing!**
Bring the specimen and test components to room temperature
Mix the specimen well prior to testing – especially if it has been frozen
Visual inspection method:

Step 1: Place the test device on a clean, flat surface.
Step 2: Fill the capillary tube and transfer approximately 20 µL (or 1 drop) of serum, plasma or whole blood specimen to the specimen well of the test device
Step 3: Add 2 drops of Sample Diluent (about 40 - 80 µL) immediately into the sample well to assist the antibody reaction with the particles
Step 4: The test results should be read in 10-15 minutes

**Note: Results read after 15 minutes are invalid**

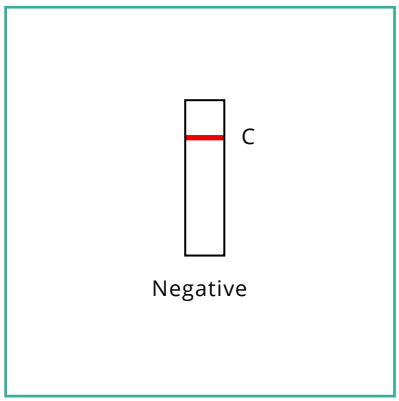
## INTERPRETATION OF RESULTS WARNINGS AND PRECAUTIONS

**NOTE: Only tests with a clear colored line in the control test line region C (C) are valid**



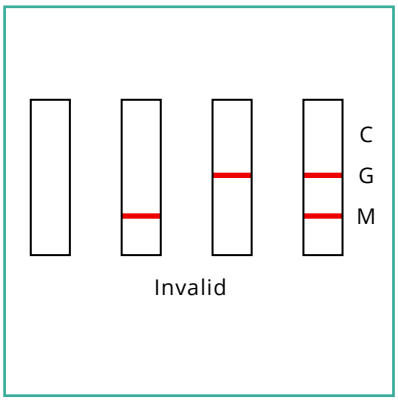

• **Positive:**
At least a colored line appears in the test line region G (G: the test person expresses Ab(IgG$_{human}$(SARS-CoV-2))) or in the test line region M (M: the test person expresses Ab(IgM$_{human}$(SARS-CoV-2)).
If both a colored line appears in the test line region G and region M it indicates that the test person expresses **both** Ab(IgM$_{human}$(SARS-CoV-2) and Ab(IgG$_{human}$(SARS-CoV-2))

**NOTE: The intensity of the color in the test line region(s) (G and M) will vary depending on the concentration of SARS-CoV-2 antibodies in the specimen. Therefore, any shade of color in the test line region(s) (G and M) should be considered positive.**




- **Negative:**

No line appears in test line regions G and M (G and M).




- **Invalid:**

Control line fails to appear.
Insufficient specimen volume or incorrect procedure for the test are the most likely reasons for control line failure.
Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## WARNINGS AND PRECAUTIONS

1. The assay procedure and the test result interpretation must be followed closely according to the insert when testing for the presence of antibodies against SARS-CoV-2 in whole blood, serum or plasma from individual persons.
Failure to follow the described procedure may give inaccurate results.
2. The sample should be tested in the laboratory with certain safety conditions. All samples and materials in the testing process shall be handled in accordance with the laboratory practice for infectious diseases.
3. Be careful to prevent the product from getting wet, and do not open the sealed aluminum bag before it is ready for testing; If the aluminum foil bag is damaged or the test device is damp, it must not be used.
4. Please use the test kit within the validity period.
5. Do not use samples which are cloudy for testing.
6. Do not dilute the sample for testing - otherwise inaccurate results may be obtained.
7. The kit shall be stored in strict accordance with the conditions specified in this manual. Please do not store the kit under freezing conditions.
8. The interpretation of the inspection methods and results shall be strictly in accordance with this manual.
9. This kit is limited to **qualitative** detection of SARS-CoV-2 antibodies in human whole blood, serum and plasma. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
10. The kit will produce negative results under the following conditions:
    - The titer of the SARS-CoV-2 antibody in the specimen is below the minimum detection limit of the kit
    - The SARS-CoV-2 antibody is not present at the time of specimen collection.
11. Specimen containing higher titers of heterophobic antibodies or rheumatoid factors may affect the expected results

## LIMITATION

1. The test kit for SARS-CoV-2 IgG and IgM human antibodies is for *in vitro* diagnostic use only. The test kit should be used for the detection of SARS-CoV-2 antibodies in whole Blood, serum or plasma specimens only.
2. The results obtained with this test kit should only be interpreted in conjunction with other diagnostic procedures and clinical findings.
3. The test kit for SARS-CoV-2 IgG and IgM human antibodies cannot be used to differentiate if the infection is of primary - or secondary nature. No information of nCoV-19 serotypes can be provided with this test kit.
4. If the test kit result is negative and the clinical symptoms persist, additional testing using other clinical methods is strongly recommended.
5. A negative or non-reactive test result does not preclude the possibility of exposure to or infection with SARS-CoV-2 virus at any time.
6. Serological IgM antibody testing is of limited reference value in patients with impaired immune function or receiving immunosuppressive therapy.
7. Positive test results of people who have recently received blood transfusion or other blood products should be carefully analyzed.
7. All components in the test kit have been tested in the same batch. It is not recommended to mix with reagents from different batches.
8. If the symptoms for a coronavirus infection persist, while the result from the test kit for SARS-CoV-2 IgG and IgM human antibodies is negative or show a non-reactive result, it is recommended to re-sample the patient few days later or test with an alternative test device.

## REFERENCES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2. Masters PS and Perlman S: “Coronaviridae”. In: “Fields virology”; 6th ed.; 2013: p. 825-58. Eds.: Lippincott Williams & Wilkins. Publisher: Philadelphia.
3. Su S, Wong G, Shi W, et al.: “Epidemiology, genetic recombination, and pathogenesis of coronaviruses”. Trends Microbiol.: 2016; vol. 24; p. 490-502.
4. Cui J, Li F and Shi ZL: “Origin and evolution of pathogenic coronaviruses”. Nat. Rev. Microbiol.: 2019; vol. 17; p. 181-192.
5. Wong G, Liu W, et al.: ”MERS, SARS, and Ebola: the role of super-spreaders in infectious disease”. Cell Host Microbe: 2015; vol. 18; p. 398-401.
6. Wuhan Municipal Health Commission: “Report of clustering pneumonia of unknown etiology in Wuhan City”. 2019 (http://wjw.wuhan.gov.cn/front/web/showDetail/2019123108989. opens in a new window).


## SYMBOLS

**Key to symbols used:**

| | |
|---|---|
| IVD In Vitro Diagnostic Medical Device | Manufacturer |
| Store at 2-30 °C | Expiration Date |
| Do Not Reuse | CAUTION |
| Consult Instructions For Use | EU Authorised Representative |

CE


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# I About the Manufacturer

- The manufacturer is a high-tech medical bio-tech enterprise based in Xiamen, China, which devotes itself to the field of fast diagnostic reagents and integrates innovative research and development into their products.

## QUALIFICATION AND TECHNOLOGY PLATFORM

- Individually packed test devices
- Medical Device Manufacturing Enterprise License
- ISO 9001 & ISO 13485 certified
- GMP CFDA approval
- 25 diagnostic Kits CFDA approved
- 15 patents have been authorized
- Immune chromatography technology
- Molecule diagnostic technology
- Cooperation with Institute of semiconductors, Chinese Academy of Sciences for Microfluidic technology