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**Instruction For Use: COVID-19 IgG/IgM Rapid Test Kit**

Catalogue No.: G-COVID-19 IgG/IgM-0102

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**Instruction manual: COVID-19 IgG/IgM Rapid Test Kit**

**1. Product name：** COVID-19 IgG/IgM Rapid Test Kit

**2. Intended Use**

COVID-19 IgG/IgM Rapid Test Kit is intended for the qualitative detection of IgM and IgG antibodies against SARS-CoV-2 in human serum, plasma or whole blood from those with clinical suspicion of SARS-CoV-2 infection. **For *in vitro diagnostic* use.**

**3. Summary**

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

Polymerase Chain Reaction (PCR)-based assays have been developed and widely used for the





| EN 15223-1:2016 | MEDICAL DEVICES SYMBOL |
|---|---|
| | Storage temperature limitation |
| LOT /LOT | Batch code |
| /MFG | Date of manufacture |
| /E1XP | Use-by date |
| | Consult operating instructions |
| IVD | *In vitro* diagnostic device |
| | Manufactured by |
| REF | Catalogue number |
| Σ | Number of determination |
| EC REP | Authorized representative in the European Community |
| | Keep dry |
| | Cannot be reused |
| | Damaged package cannot be used |
| | Warning, please refer to the instruction in the annex |
| | Biological risks |





detection of suspicious patients of COVID-19. But the sensitivity for detection of SARS-CoV-2 infection can be low, as reported previously the sensitivity of only 30%~50% in certain COVID-19 studies, at least for certain PCR-based assays.

The antibody-based tests can identify those who were not known to be infected either because they never developed symptoms, or they had symptoms but failed in the diagnosis. IgM antibodies become detectable in 3-7 days after the infection and reach peak levels after 10-14 days. These IgM antibodies persist but diminish over the next 12 weeks until the antibodies are no longer clinically detectable. IgG antibodies, on the other hand, are produced 7-14 days after infections, and the concentrations will increase rapidly, then tend to stabilize or decline gradually.

**4. Principle**

This product employs the immune colloidal gold immunochromatography technique to detect specific IgG and/or IgM antibodies against SARS-CoV-2. SARS-CoV-2 antigen conjugated colloidal gold particles are coated in the reagent binding pad. Anti-human IgM is coated at IgM test line (M), anti-human IgG is coated at IgG test line (G), and anti-mouse IgG is coated at the control line





(C). During the testing, if specific IgM (sIgM) and/or IgG (sIgG) antibodies to SARS-CoV-2 are present in the test specimen (S), such sIgM or sIgG will bind to the antigen labeled with the colloidal gold, forming an immune complex. These immune complexes then migrate upward on the membrane chromatographically by capillary action, and be captured either by the anti-human IgM coated in the M test line (M) forming a colored M line or by the anti-human IgG coated at the G test line (G) forming a colored G line. The free colloidal gold markers or immune complexes continue moving forward and specifically combine to the anti-mouse IgG coated at the control line (C) forming a colored C line. If the specimen does not contain sIgM and sIgG to SARS-CoV-2, no colored test lines (M and G) will appear, only C line will appear colored.

**5. Kit Presentation**

**5.1 Materials Supplied**

**Test cassettes:** 20/25/40 test cassettes containing a membrane coated respectively with SARS-CoV-2 antigen conjugated colloidal gold, anti-human IgM, anti-human IgG, and anti-mouse IgG.

**Dropper:** 20/25/40 pcs.

**Buffer:** 4mL×1 bottle for 20 pcs/box; 4mL×1 bottle for 25 pcs/box; 4mL×2 bottles for 40 pcs/box.





7.4 Exercise protective measures such as wearing laboratory coats, disposable gloves and eye protection wares when handling specimens.

7.5 Treat all material wastes as if they were infectious and dispose of such in accordance with local regulations.

7.6 Liquid solutions in this kit contain 0.02% bromonitrodioxane, these solutions should be handled with care and disposed in accordance with local regulations.

7.7 Do not use the kit beyond the expiration date.

7.8 The test cassette is sealed in a protective foil pouch. Do not use it if the pouch is damaged or open. Use the test cassette as soon as it is taken out from the pouch. NEVER touch the reaction area of test cassette.

7.9 NEVER use any damaged cassettes. Do not mix components from different kits.

7.10 Use the disposable dropper and cassette provided for each specimen tested.

7.11 NEVER re-use the test cassette.

7.12 Information accompanying the result should be confirmed before issuing the test report. Incorrect information will lead to the patient being reported with an incorrect result.

**8. Specimen Collection and Storage**





8.1 Handle all specimens of blood, plasma and serum with extreme cautions and follow the guidelines from your local authorities. Treat these specimens as they were infectious agents.

8.2 For optimal performance of the kit, please use fresh plasma, serum or whole blood specimens (clear, non-hemolyzed, non-lipemic, non-icteric). If repeated testing is required, a minimum specimen volume of 50 μL is recommended.

8.3 Specimen storage:

- DO NOT freeze the whole blood specimens. The whole blood samples should be tested within 7 days, if stored at 2-8 ℃.
- Serum or plasma specimens should be stored at 2-8℃ if testing will take place within 7 days; or stored below -20℃ for longer than 7 days.
- DO NOT use a frost-free freezer since it may allow the specimens to go through freeze-thaw cycles.
- Specimens that are improperly stored and/or subjected to multiple freeze-thaw cycles may yield erroneous results.

8.4 Consult New Coronavirus Pneumonia Prevention and Control Program (Fifth Edition) for more recommendations on handling and processing blood specimens.





**Note: Always use all reagents and components of the kit from the same lot number in order to avoid erroneous results.**

**5.2 Materials Required But Not Provided**

(1) Timer
(2) Specimen collection container
(3) Micropipette and tips (optional)
(4) Centrifuge (for plasma or serum)
(5) Lancets (for fingerstick whole blood tests only)

**6. Storage and Stability**

The shelf life of the kit is 24 months, when stored at 2-30℃ and protected from light.

Do not freeze.

In general, the test cassettes should be used within 1 hour after the foil bag is opened. If the temperature is above 30℃ and/or the humidity of the environment is higher than 60%, the kit shall be used as soon as the foil bag opens.

Please see the labels of the kit for the manufacturing date and expiry date.

**7. Precautions**

7.1 This test is designed for *in vitro* diagnostic use only.

7.2 For professional use only.

7.3 Material should not be pipetted by mouth.

## 9. Quality Control

A built-in procedural control in the cassette ensures that the test has been performed correctly; a pink/red colored line should always appear at the control line (C). It confirms sufficient specimen volume and correct technical procedures. If the C line does not appear after 15 minutes, it is an invalid test; discard the test cassette and perform the test again.

Control antibody standards are not supplied with this kit; however, it is recommended that the positive and negative control antibodies should be run with each new lot number or as required by your laboratory QA standard operating procedures. If such control results do not read as expected, repeat the test. Contact your local technical support if the QC results continue to be invalid.

## 10. Test Procedures

### 10.1 Preparation

a. Transfer the specimens for testing and the required reagents from the storage and balance to room temperature (15-30 ℃) prior to testing.

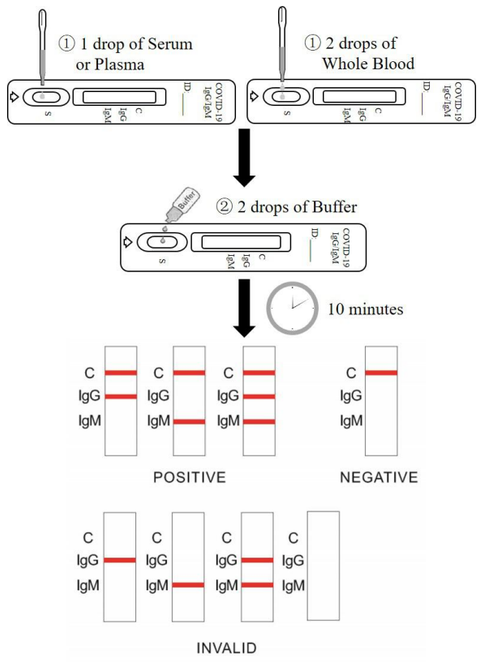
b. Remove the test cassette from the sealed pouch and use it within one hour.

c. Place the test cassette on a clean and flat surface.





d. Read the test result after 10 minutes. Do not interpret the result after 20 minutes.








### 10.2 Testing

a. Add specimen

**Serum/Plasma:** The volume of 1 drop of the specimen dripping from the supplied dropper is approximately 10 μL. Add vertically 1 drop or 10 μL of serum or plasma to specimen well (S), then add 2 drops (approx. 100 μL) of buffer to the specimen well (S) and start the timer. Avoid trapping air bubbles in the specimen well.

**Whole blood:** The volume of 1 drop of the specimen dripping from the supplied dropper is approximately 10 μL. Add vertically 2 drops or 20 μL of whole blood to specimen well (S), then add 2 drops (approx. 100 μL) of buffer to the specimen well (S) and start the timer. Avoid trapping air bubbles in the specimen well.

**b.** Wait for the colored line(s) to appear. The test result should be read in 10 minutes. Do not interpret the result after 20 minutes.

### 10.3 Summary of the test procedures:

a. Set the reagents and specimen to room temperature (15-30°C) when needed.

b. Add 1 drop (~10 μL) of serum/plasma or 2 drops (~20 μL) of whole blood to the specimen (S) well.

c. Add 2 drops (~100 μL) of buffer to the S well and start the timer.





## 11. Interpretation of the Results

**IgG POSITIVE*:** Two lines appear: one colored line at the control line (C), and the other colored line appears at the IgG test line (G). This result indicates the presence of IgG antibodies against SARS-CoV-2 in the specimen.

**IgM POSITIVE*:** Two lines appear: one colored line at the control line (C), and the other colored line appears at the IgM test line (M). This result indicates the presence of IgM antibodies against SARS-CoV-2 in the specimen.

**IgG and IgM POSITIVE*:** Three lines appear: one colored line at the control line (C), the second colored line at the IgG test line (G), and the third at IgM test line (M). This result indicates the presence of both IgG and IgM antibodies against SARS-CoV-2 in the specimen.

***NOTE:** The intensity of the color at the test lines may vary from different specimens, depending on the antibodies against SARS-CoV-2 present in the specimens. Any shades of color at the test lines should be considered positive readings.

**NEGATIVE:** One colored line appears at the control (C). No apparent colored line appears at the IgG test line (G) nor at the IgM test line (M).





**INVALID:** Control line (C) fails to appear. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for the control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## 12. Limitation of Test Methods

12.1 This product is only used for testing of individual serum, plasma or whole blood samples.

12.2 A negative result does not rule out the possibility of SARS-CoV-2 infection. A negative result may occur for some patients in their early phase of infection/ symptoms. Repeat the test on subsequent days to demonstrate seroconversion. Please be noted that specific IgM antibodies may be below the detectable levels at the onset of infection.

12.3 An IgG and/or IgM positive result alone does not provide a diagnosis of active SARS-CoV-2 infection. In general, IgM antibodies can last up to 3 months, and IgG antibodies can last 1 year or longer no matter the patients are cured or not. Further testing for SARS-CoV-2 RNA in highly





kit is 98.43% (188/191), the specificity is determined to be 98.73% (78/79), and the total coincidence rate is 98.52% (266/270).

13.2 Cross-reactivity: this kit has been tested for FluA-IgG/IgM, FluB-IgG/IgM, PIV-IgG/IgM,RSV-IgG/IgM,CPn-IgG/IgM,MP-IgG /IgM,CMV-IgG/IgM,ADV-IgG/IgM,SV1-IgG/IgM, SV2-IgG/IgM,MuV-IgG/IgM,RV-IgG/IgM,MV-IgG /IgM,VZV-IgG/IgM,EB-VCA-IgG/IgM,RhV-IgG/Ig M,EV71-IgG/IgM,NV-IgG/IgM,CVB-IgG/IgM,AN A-IgG/IgM,AMA-IgG/IgM and HAMA positive specimens. The results showed no cross-reactivity, but it is not ruled out that high concentration of positive samples will interfere with the analysis.

13.3 Interfering Substances: the following potentially interfering substances were added to SARS-CoV-2 negative and positive specimens.

Total IgG: 8mg/mL Total IgM: 0.8mg/mL Hemoglobin: 10g/L

Triglyceride: 31mg/ml Total bilirubin: 0.4mg/mL RF: 9mg/mL

None of the substances at the concentration tested





recommended to determine the patient's infectious status.

12.4 The test results of this kit are for clinical references only and shall not be taken as the sole basis for clinical diagnosis and treatment. The clinical management of patients shall be considered in combination with their symptoms, signs, medical history, other laboratory tests (especially pathogen detection), treatment responses, epidemiology and other information.

12.5 Serological antibody testing is of limited reference value in patients with impaired immune function or receiving immunosuppressive therapy.

12.6 IgM positive result occurs not only in primary infections but also in secondary infections.

12.7 The target detection object of this kit are IgM/IgG antibodies of SARS-CoV-2, which does not directly reflect the presence of SARS-CoV-2 virus in the specimen.

## 13. Performance Characteristics

13.1 Samples and excluded samples of COVID-19 patients diagnosed by testing, the sensitivity of the





interfered in the assay.

## 14. Manufacturer information

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## 15.Instruction Approval and Revision Date

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