



## **COVID-19 IgM/IgG Rapid Test Kit (Colloidal Gold)**

### **Simple, portable and fast: Screening for COVID-19 in ten minutes!**

The Test Kit is suitable for the qualitative detection of COVID-19 IgM/IgG antibodies in human serum, plasma and whole blood samples. It can be used for the rapid screening of carriers of the COVID-19 virus who are symptomatic or asymptomatic.

### **Product Features of COVID-19 IgM/IgG Rapid Test Kit (Colloidal Gold)**

- Portable: No additional equipment or instruments required
- Flexible: Can be applied with fingertip blood, serum, plasma or whole blood samples
- Simple: Easy to use with basic steps.
- Quick: Within ten minutes clarity on results with high accuracy.
- Ready to be marketed: CE-IVD marked under Directive 98/79/EC

### **Detecting Principles**

The COVID-19 IgG/IgM test kit (Whole Blood/Serum/Plasma) is a lateral flow immunochromatographic assay. The burgundy coloured conjugate pad contains recombinant COVID-19 antigens conjugated with colloidal gold (COVID-19 conjugates) and rabbit IgG-gold conjugates.

When a specimen - followed by sample diluent - is added to the sample well, IgM and/or IgG antibodies - if present - will bind to COVID-19 conjugates to form an antigen antibody complex. This complex migrates through the nitrocellulose membrane by capillary action.

When the complex meets the line of the corresponding immobilized antibody (anti-human IgM and/or anti-human IgG), it is trapped to form a burgundy coloured band, which indicates a positive test result.

The absence of a coloured band in the test region indicates a negative test result. The test contains an internal control (C band) which should give a burgundy coloured band for the immunocomplex goat anti-rabbit IgG/rabbit IgG-gold conjugate, regardless of the colour development on any of the test bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

### **Directions for Use**

1. Bring the test card to room temperature prior to testing. Remove the test card from the sealed aluminium foil pouch and use it as soon as possible. Place the test card on a clean and level surface.



2. Venous blood collection: Add 10  $\mu$ l of serum/plasma/15  $\mu$ l of whole blood sample to the sample well, and then add two drops of diluent (about 80  $\mu$ l) to the sample well. Avoid air bubbles.
3. Fingertip blood collection: Lancets used to collect fingertip blood. Transfer 1 drop of whole blood (about 15  $\mu$ l) to the sample well, and then add two drops of diluent (about 80  $\mu$ l) to the sample well. Avoid air bubbles.
4. The results can be interpreted in 10 minutes. Results measured after 20 minutes are invalid and should be discarded.

### **Test Results**

- IgM/IgG positive indicates recent infection with SRAS-COV-2 and positive blood test for double antibody.
- IgM positive indicates recent infection with SRAS-COV-2, IgM has appeared in the blood.
- IgG positive indicates that SRAS-COV-2 has been infected, IgM has disappeared.
- Negative result indicates neither antibody is present.

### **Clinical Trial Results**

A total of 227 subject samples were tested in this clinical trial. The test results shall be summarized as the following: The examination results of 227 clinical stool samples showed that the total reagent (IgM + IgG) sensitivity was 93.13%, the total IgM sensitivity was 78.43%, the total IgG sensitivity was 84.31%.

Conclusion: The measurement results of the COVID-19 IgM/IgG Test Kit (Colloidal Gold) of AmonMed Biotechnology Co., Ltd. and the results of the "Pneumonia Diagnosis and Treatment Scheme for Printing and Distribution of New Coronavirus Infection" issued by the General Office of the National Health and Health Commission (PRC) are highly consistent. Given that, they are equivalent to the clinical confirmed diagnosis standards.

### **Application Fields**

- Clinical COVID-19 detection and screening
- COVID-19 detection at Immigration Border
- Self-testing at home
- Screening at schools, universities and companies before reopening