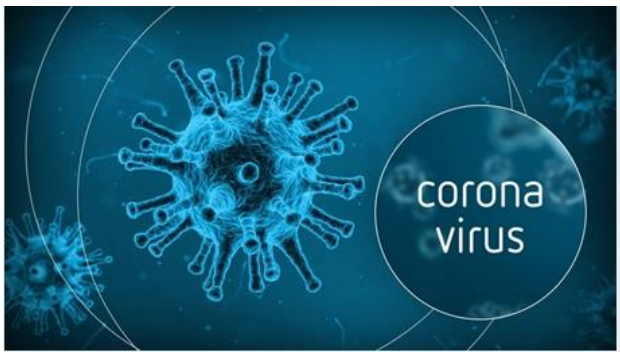
# FAQs

***COVID-19(Corona Virus Disease) is an infectious disease caused by the most recently discovered coronavirus. This highly contagious new virus and disease were unknown before the outbreak began in Wuhan, China which spread all over the world very quickly. COVID-19 IgG/IgM Rapid Test (Whole Blood/ Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative of IgG and IgM antibodies to COVID-19 in human whole blood, serum or plasma as an aid in the diagnosis of primary and secondary COVID-19 infections.***




**How is COVID-19 Rapid Test Composed?**
The test strip consists of a sample pad and a chromatographic membrane (the detection area is coated with a mouse anti-human **IgM** monoclonal antibody and a mouse anti-human **IgG** monoclonal antibody and goat anti-mouse IgG antibody), colloidal gold binding pad (coated with colloidal gold-labeled recombinant novel coronavirus (COVID-19) antigen and mouse lgG antibody), liner and absorbent pad.

**What Influences the testing results?**
Please make sure the kit is recovered into room temperature and perform the kit under the room temperature (15℃~30℃). The results will be affected by high or low temperature.

**What are sample requirements?**
Serum and plasma specimens may be stored at 2-8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃. Whole blood collected by venipuncture should be stored at 2-8℃ if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingertip should be tested immediately.

**How is the clinical performance?**
Clinical performance: The in vitro diagnostic reagents used in the test are compared with the clinical diagnostic criteria of new coronavirus pneumonia to verify the clinical performance of this product. The enrolled cases were suspected cases of new coronavirus infection, a total of 1585 cases, including 421 confirmed cases and 1164 excluded cases. A comparative study was performed using in vitro diagnostic reagents for testing and the clinical diagnostic criteria of new coronavirus pneumonia. The test results show that the product has a clinical **sensitivity of 98.81%** (95% CI: 97.25%, 99.61%) and **specificity of 98.02%** (95% CI: 97.05%, 98.74%) 98.74%). In addition, 203 subjects received homologous serum/plasma and whole blood specimens (125 of which were positive and 78 were negative) for comparative tests. The results show that the product is based on the serum/plasma test results, and the consistency rate of the whole blood test results is 96.85% (95% CI: 95.87% to 97.60%) 97.60%). **After preliminary evaluation, it is basically confirmed that the clinical performance of the product can meet the emergency needs of the epidemic.**
Please see also the **Performance Evaluation Studies for COVID-19 IgM/IgG Rapid Test CE-IVD.**

**What are the alternatives?**
The COVID-19 IgM/IgG Rapid Test can be used to screen patients suspected of having been affected by the novel coronavirus. However, results of test should not be the only basis for diagnosis. Results should be used in combination with clinical observations and other testing methods such as nucleic acid PCR test.

**Which antigens are used?**
The antigens used in this kit are Spike protein and Nucleocapsid protein.

**Are there any cross reactions known?**
This product **does not have cross reaction** with positive specimens of parainfluenza virus antibody, influenza A virus antibody, influenza B virus antibody, Chlamydia pneu moniae antibody, Mycoplasma pneumoniae antibody, adenovirus antibody, respiratory syncytial virus antibody, hepatitis B surface antibody, type C Hepatitis virus antibody, T reponema pallidum antibody, human immunodeficiency virus antibody, EB virus antibo dy, measles virus antibody, cytomegalovirus antibody, enterovirus 71 antibody, mump s virus antibody, HKU1 virus antibody, OC43 virus antibody, NL63 virus antibody, 229E virus antibody, chicken pox-zoster virus. We have not tested SARS1 and MERS and MERS antibody with this kit.

**What is the exact product identification?**
Coronavirus-19 (COVID-19)
Antibody (IgM/IgG) Rapid Test Kit (Colloidal gold immunochromatography).

**What is the product designation?**
Immunochromatographic Test Kits for in vitro diagnostics.

**What is the risk class as medical device?**
Else.

**What is the service life, expiration date?**
Expiration date is 18 months.

**What is the behavior with different anticoagulants?**
EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the a nticoagulant for sample collection.

**Which statistical test was used for consistency evaluation?**
This is a qualitative product and Kappa test was used for consistency evaluation.

**How is the stability tested?**
We have conducted accelerated stability research according to relevant domestic indust ry standards.
By accelerating stability study, the properties of the reagents (in this case Lot Number: Lot Number: 20200226, 20200228, 20200302) were maintained after accelerated for 2 1 days at 37℃. Please see also the **Research Data of Stability.**