



## OnSite COVID-19 IgG/IgM Rapid Test

With cases of coronavirus COVID-19 disease rising at an unprecedented rate, CTK has taken their proven strength in developing infectious disease diagnostics and in collaboration with its partners in China, has proudly launched two diagnostic tests for this virus, both a real-time PCR based nucleic acid detection kit and a serological rapid screening test, for the International market.

The virus (SARS-CoV-2) causing the COVID-19 disease is a new pathogen that can lead to severe acute respiratory syndrome (SARS).

Unlike other infectious disease outbreaks seen so far, the SARS-CoV-2 has proven to spread faster and affect a wider range of population, stretching to every continent, infecting over 115,000 people and causing over 4,200 deaths during the last 3 months alone.

It is vital to diagnose affected patients as quickly as possible for early containment and treatment.

The **World Health Organization** (WHO) has officially declared that COVID-19 is now a pandemic.

WHO declared in the Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19) as following: Development of rapid and accurate point-of-care tests which perform well in field settings are especially useful if the test can be incorporated into presently commercially available multiplex respiratory virus panels.

This would markedly improve early detection and isolation of infected patients and by extension, identification of contacts

Rapid IgM and IgG antibody testing are also important ways to facilitate early diagnosis.



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## OnSite COVID-19 IgG/IgM Rapid Test

The OnSite COVID-19 IgG/IgM Rapid Test is a single use lateral flow immunoassay rapid test intended for qualitative detection and differentiation of anti-SARS-CoV-2 IgG and IgM antibodies in human serum and plasma or whole blood containing EDTA, heparin or citrate anti-coagulants.

The OnSite COVID-19 IgG/IgM Rapid Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.

For prescription use only. For in vitro diagnostic use only.

Currently, the laboratory method for detecting SARS-CoV-2 infection is RT-PCR. However, this method requires sophisticated equipment and highly trained laboratory technicians. Moreover, viral load decreases rapidly 9 or 10 days after onset of symptoms.

During the acute phase of infection, the titer of IgM to SARS-CoV-2 rises rapidly and peaks around 2-3 weeks after the infection. SARS-CoV-2 specific IgG antibodies appear shortly after IgM and persist for months.

It is unknown if SARS-CoV-2 infection leads to lifetime immunity or if a 2<sup>nd</sup> infection is possible.

Nevertheless, the SARS-CoV-2 specific antibodies are useful markers for immune response and epidemiologic survey.

- Finger prick specimen allows testing at point-of-care, saving crucial time
- Results in 15 minutes allow doctors to take immediate action 97.1 % sensitivity, 97.8% specificity (vs. PCR-confirmed specimens)
- Complementary to PCR by detecting immune response
- Compatible with CTK Rapid Test Reader (RTR-1)

