

COVID-19 IgG/IgM Rapid Test

- 10 Minutes for Results
- Whole Blood, Serum or Plasma
- 100% Combined Sensitivity and 94% Combined Specificity to PCR
- CE marked

Coronaviruses (CoVs) belong to the subfamily *Orthocoronavirinae* in the family *Coronaviridae* and the order *Nidovirales*. Recently, a novel CoV, SARS-CoV-2, has been identified as the etiological agent responsible for the outbreak in Wuhan, China.

Symptoms of infection:

- Low-grade fever
- Shortness of breath
- Cough



Serology Tests

Serology tests look for the presence of antibodies which are specific proteins made in response to infections. The antibodies detected by this test indicate that a person has had an immune response to SARS-CoV-2, whether symptoms developed from infection or the infection was asymptomatic.⁽¹⁾

A serology test used as an adjunct to PCR testing will allow for health ministries and hospitals to monitor seroprevalence and potentially identify suspected, confirmed, or probable exposures.



Studies

Studies have shown that the current strategy for the detection of viral RNA in oral swabs used for COVID-19 diagnosis is not ideal. The virus may be present in anal swabs or blood of patients when oral swab detection is negative. In contrast, studies found anti-viral antibodies in nearly all patients, indicating that serology should be considered as part of COVID-19 epidemiology.⁽²⁾

1. CDC Tests for COVID-19, Centers for Disease Control and Prevention, Accessed 26 FEB 2020 www.cdc.gov/coronavirus/2019-ncov/about/testing.html

2. Emerging Microbes & Infections 2020, VOL. 9 Molecular and serological investigation of 2019-nCoV infected patients



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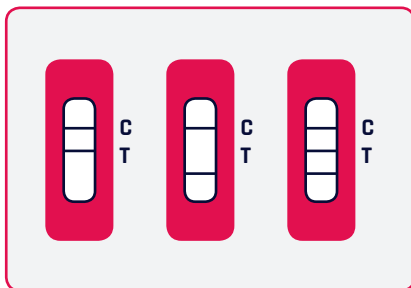
The Biomerica COVID-19 IgG/IgM Rapid Test is a qualitative rapid immunoassay for the detection of IgG and IgM antibodies to SARS-CoV-2 in whole blood, serum or plasma specimens. The specimen reacts with SARS-CoV-2 coupled gold conjugate and then reacts with anti-human IgM and/or anti-human IgG in the test line region if the specimen contains antibodies directed to SARS-CoV-2.



The Test

'T' ZONE

Lines appearing in the test 'T' zone represent the presence of IgG, IgM or both IgG & IgM antibodies to SARS-CoV-2 in specimens.



Positive



Negative

Performance

SENSITIVITY AND SPECIFICITY

The Biomerica COVID-19 IgG/IgM Rapid Test was compared with a commercial PCR test. The results show that the test has high combined sensitivity and specificity:

IgG and/or IgM Result:	PCR	
	Positive	Negative
Biomerica COVID-19 IgG/IgM Rapid Test Positive	20	3
Negative	0	47

Combined Sensitivity instead of Relative Sensitivity:
100% (95%CI*: 83.16% to 100.00%)

Combined Specificity instead of Relative Specificity:
94.0% (95%CI*: 83.45% to 98.75%)

Accuracy:
96.0% (95%CI*: 87.98% to 99.11%)

*Confidence Interval

