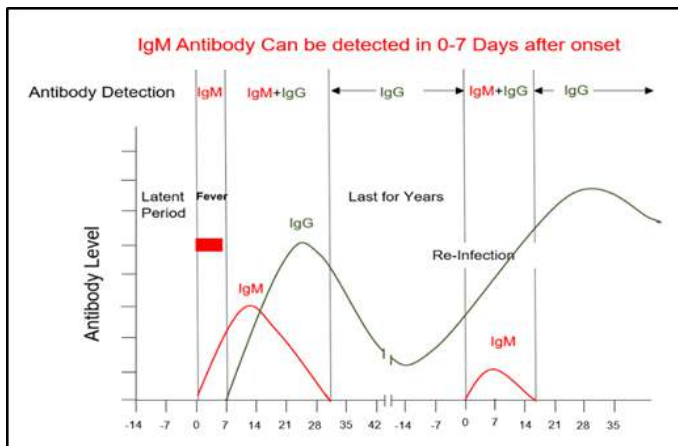
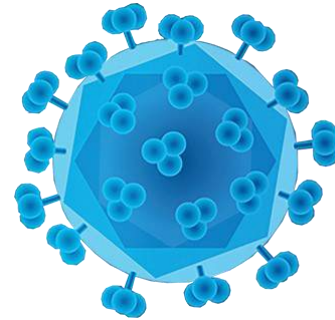


## COVID-19 IgG/IgM Rapid Test (Colloidal Gold)

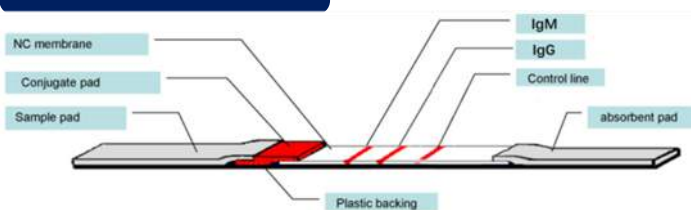
COVID-19 comprehensive screening and monitoring

Coronaviruses belong to a large family of potentially harmful RNA viruses. In humans, they are known to be involved mainly in respiratory infections ranging from the common colds to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The recently discovered coronavirus, SARS-CoV-2, causes coronavirus disease COVID-19, a significant global health problem.



**IgM antibodies** provide the first line defense mechanism during viral infections, followed by the adaptive, high affinity, **IgG antibodies**. IgG antibodies are also important for the long term immunity and for immunological memory. Testing for COVID-19 **IgM** and **IgG** antibodies is an effective method for the rapid diagnosis of COVID-19 infection. Detection of COVID-19 **IgM** antibodies indicates a recent exposure to COVID-19, whereas detection of COVID-19 **IgG** antibodies indicates a later stage of the infection.

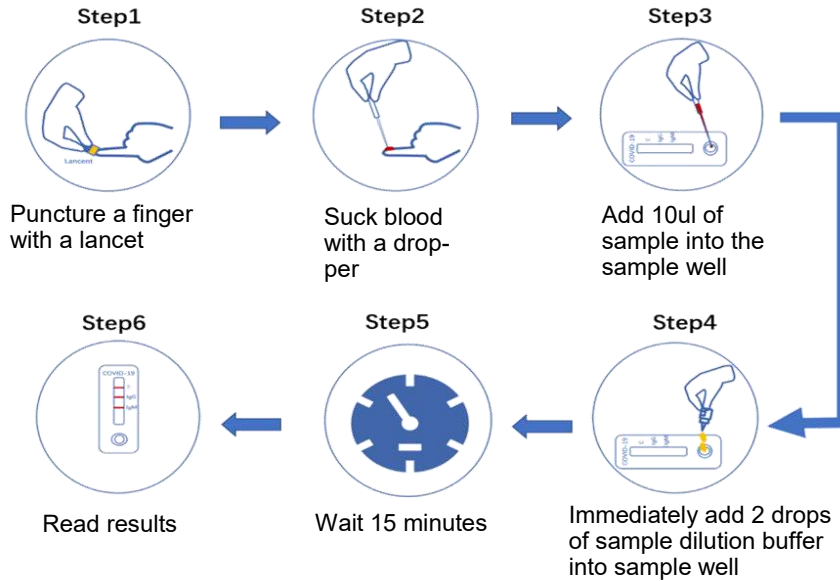
### Principle of the Test



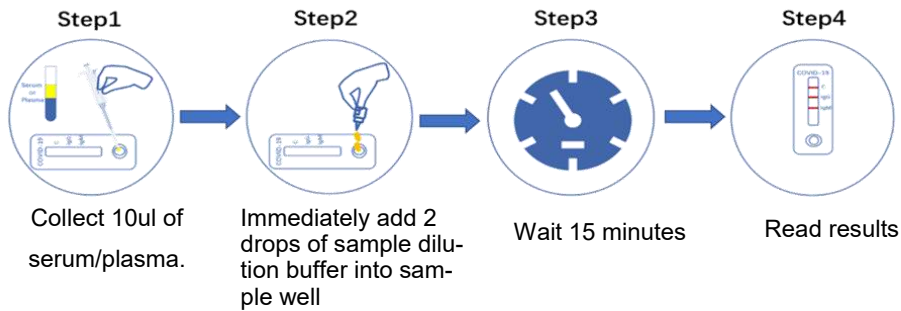
Rapid Test Results	Compared with RT PCR Results		
	positive	negative	Total
IgG/IgM positive	246	5	251
IgG/IgM negative	35	314	349
Total	281	319	600

POSITIVE RESULT	
Visible C and G lines indicate presence of Covid-19 IgG	
Visible C and M lines indicate presence of Covid-19 IgM	
Visible C, G and M lines indicate presence of Covid-19 IgG and IgM	
NEGATIVE RESULT	
Only C line visible indicates negative result	

## Finger-prick/Whole Blood Testing Procedure



## Serum/Plasma Testing Procedure



## Rapid Test vs. RT PCR Test - Comparison

Parameter	Rapid Test	RT PCR Test
Test Duration	15 minutes	3-4 hours
Operation Method	Portable, easy to perform and stable test	Complex test requiring specialized equipment
Convenience	Doesn't require sophisticated set up. Testing can be performed at designated locations, small labs, clinics, or patient's bedsides. No special equipment required	Requires complex and highly specialized equipment and trained personnel. More suitable for larger labs, hospitals

## COVID-19 IgG/IgM Rapid Test Results Interpretation and Clinical Significance

Test Results			
PCR	IgM	IgG	
+	-	-	Patients may be in the asymptomatic phase of the SARS-COV-2 infection.
+	+	-	Patient may be in the early stages of infection. Body's immune system already produced the IgM antibodies, but no IgG antibodies. Alternatively, the IgG antibodies did not reach the test's detection limit.
+	-	+	Patients may be in late or in recurrent stage of the infection.
+	+	+	Patient is in the active phase of infection; the human body has developed some immunity to SARS-COV-2 (presence of the IgG antibody).
-	+	-	Patient may be in the acute phase of SARS-COV-2 infection. RT PCR test should be reevaluated (PCR may be false negative).
-	-	+	Patient may have been infected with SARS-COV-2 in the past, but recovered. The individual should be virus free.
-	+	+	Patient has been recently infected with SARS-COV-2 and is in the recovery phase. Or the RT PCR test results are false negative and the patient is in the active phase of the infection.

### Advantages of the Rapid Test

Early Disease  
Detection

Positive IgM indicates early phase of infection

All Stages of Disease

Covers early, mid and late phases of disease

Efficiency

2 Tests in one cassette Results in 15minutes

Safety

Easy to perform, low chances for errors

## Recommended Target Groups

### High Risk Individuals

Obvious clinical symptoms but negative RT PCR test

### Confirmed Cases

Monitoring the progression of the disease and convalescence

### Close Contacts

Family members of confirmed or suspected patients, recent close contacts

### Susceptible Individuals

Elderly, children, immunosuppressed and chronically ill individuals

## Package Specification

### Catalog Number

CoV19-001

### Package Size

1 Test/kit 20 Tests/kit

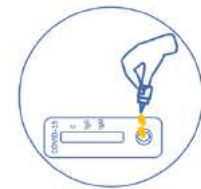
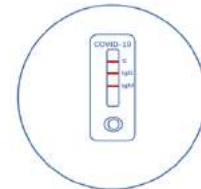
### Content of the Kit

Test cassette -Sample Dilution Buffer-Capillary Sampler

Introduction For Use

Required but not provided:

Lancet | Alcohol wipes | Gloves | Timer



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