

APPROVED FDA EUA

Rapid Results in  
**15 Minutes**

# COVID-19

## IgM/IgG Antibody Rapid Test

The **most accurate** test on the market, backed by **clinical data\***





### COVID-19 FACTS

- COVID-19 (SARS-CoV-2) is mainly transported through respiratory droplets
- Symptoms of COVID-19 may appear 2-14 days after exposure and can range from mild to severe and may even result in death
- Symptoms mainly include fever, cough and shortness of breath

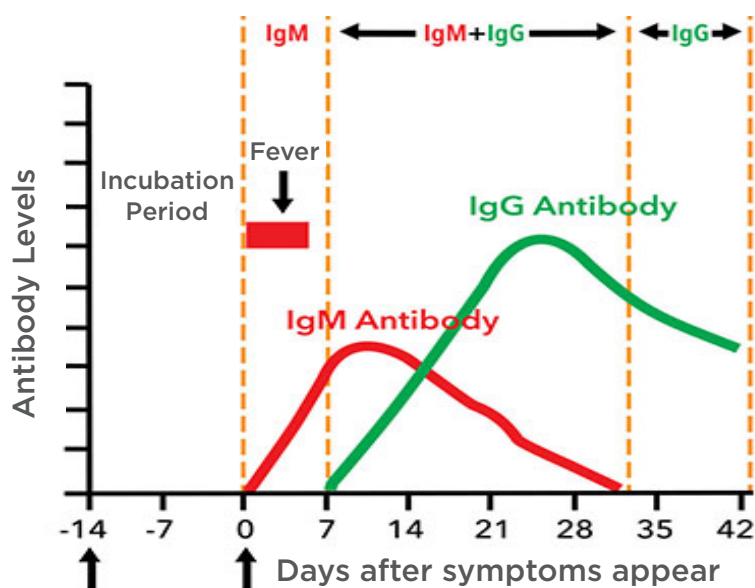
### QUICKLY SCREEN → QUARANTINE

- The test is designed to be administered by professional personnel. **Not for individual use at home**
- The COVID-19 Antibody Rapid test will detect antibodies 5 to 7 days after symptoms first appear
- The test will show clear results in 15 minutes, unlike a PCR test, which can take hours
- The COVID-19 Antibody Rapid Test is cost effective, at approx. 5% of the cost of a PCR test

### 4 Easy Steps

- 1** CLEAN THE FINGER 
- 2** PIERCE TOP OF FINGER WITH LANCET 
- 3** PIPETTE BLOOD SAMPLE ON DEVICE 
- 4** ADD BUFFER AND READ RESULTS 

### IgM/IgG Detectable Test Window



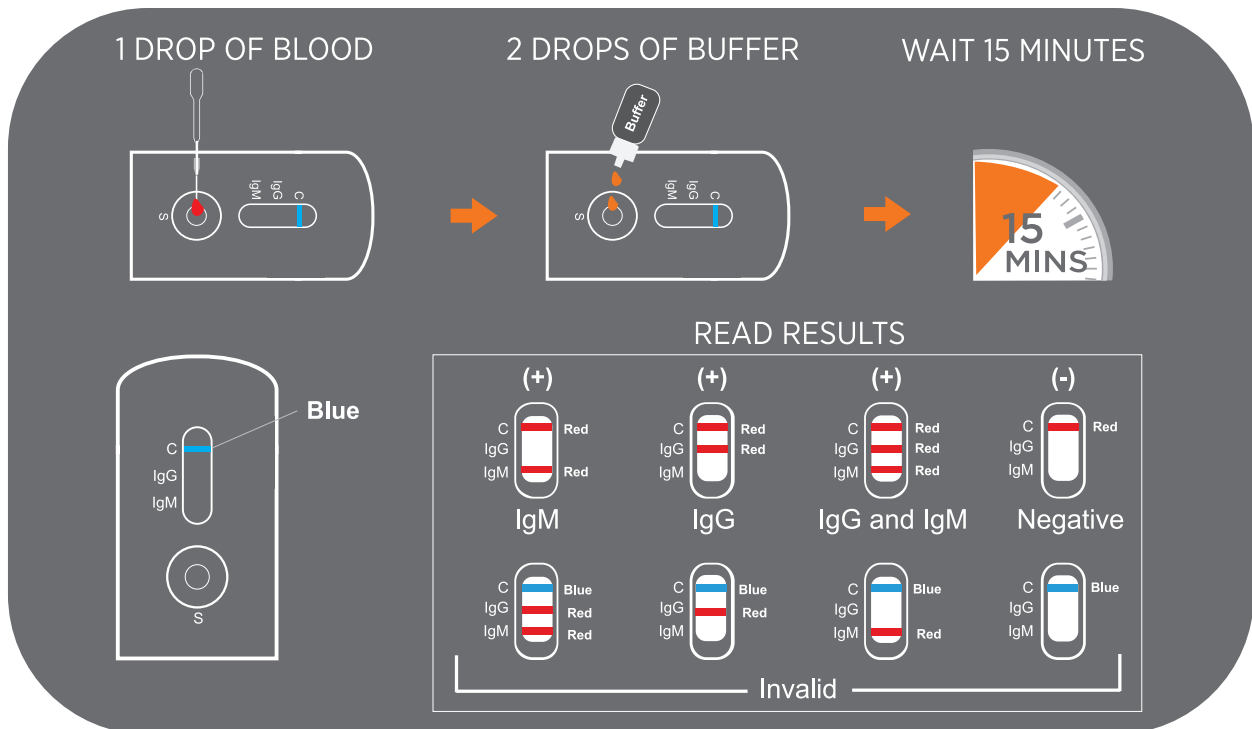
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# COVID-19

## IgM/IgG Antibody Rapid Test

### TEST PROCEDURE & READING RESULTS



### INTERPRETATION OF RESULTS

#### NEGATIVE

The coloured line in the control line region (C) changes from blue to red. No line appears in the test line regions M or G.

**The result is Negative.**

#### IgM POSITIVE

The coloured line in the control line region (C) changes from blue to red, and a coloured line appears in test line region M.

**The result is anti-COVID-19 IgM Positive.**

#### IgG POSITIVE

The coloured line in the control line region (C) changes from blue to red, and a coloured line appears in test line region G.

**The result is anti-COVID-19 IgG Positive.**

#### IgG and IgM POSITIVE

The coloured line in the control line region (C) changes from blue to red, and two coloured lines appear in test line regions M and G.

**The result is anti-COVID-19 IgM and IgG Positive.**

#### INVALID

Control line is still completely or partially blue, and fails to completely change from blue to red. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.

Review the procedure and repeat the test with a new cassette. If the problem persists, discontinue using the kit immediately and contact your distributor.

# CLINICAL DATA

## SARS-CoV-2 Antigen and IgM/IgG Antibody Test Results and Clinical Significance

Test Results			Significance
PCR (Ag Test)	IgM Ab	IgG Ab	
+	-	-	Patient may be in the "incubation period" of SARS-CoV-2 infection.
+	+	-	Patient may be in the early stages of infection, and the body's immune response first produced the antibody IgM, but no IgG was produced or the IgG content did not reach the detection limit of the diagnostic reagent.
+	-	+	Patient may be in late or recurrent stage of infection.
+	+	+	Patient is in the active phase of infection, but the human body has developed some immunity to SARS-CoV-2 (the persistent antibody IgG has been produced).
-	+	-	Patient may be in the acute phase of SARS-CoV-2 infection. At this time, nucleic acid test results need to be considered (PCR may be false negative).
-	-	+	Patient may have been infected with SARS-CoV-2 in the past, but the patient has recovered or the virus in the body has been cleared.
-	+	+	Patient has recently been infected with SARS-CoV-2 and is in the recovery stage, or the nucleic acid test result is false negative and the patient is in the active infection stage.

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### Clinical Summary of COVID-19 IgM/IgG

#### For IgM Detection:

Method		PCR+	PCR-	Total
COVID-19 IgM/IgG Rapid Test	IgM+	74	2	76
	IgM-	5	225	230
Total		79	227	306

Relative Sensitivity: 93.7% (86.0% - 97.3%)\*  
 Relative Specificity: 99.1% (96.8% - 99.8%)\*  
 Overall Agreement: 97.7% (95.4% - 98.9%)\*  
 \*95% Confidence Interval

#### For IgG Detection:

Method		Convalescent Samples	PCR-	Total
COVID-19 IgM/IgG Rapid Test	IgG+	82	3	85
	IgG-	1	224	225
Total		83	227	310

Relative Sensitivity: 98.8% (93.5% - 99.8%)\*  
 Relative Specificity: 98.7% (96.2% - 99.5%)\*  
 Overall agreement: 98.7% (96.7%-99.5%)\*  
 \*95% Confidence Interval

### Conclusion

For IgM detection, 79 specimens collected from symptomatic patients were tested. Compared to PCR testing results, the sensitivity for IgM detection was 74/79=93.7%.

For IgG detection, 83 convalescent patients were tested. The sensitivity for IgG detection was 82/83=98.8%.

To evaluate the assay specificity, 227 specimens from healthy individuals were tested. The specificity for IgM detection was 225/227=99.1%, and the specificity for IgG detection was 224/227=98.7%.

\*Based on relative sensitivity and relative specificity of the test in clinical trials