APPROVED FDA EUA

COVID-19

IgM/IgG Antibody Rapid Test

Rapid Results in **15 Minutes**

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

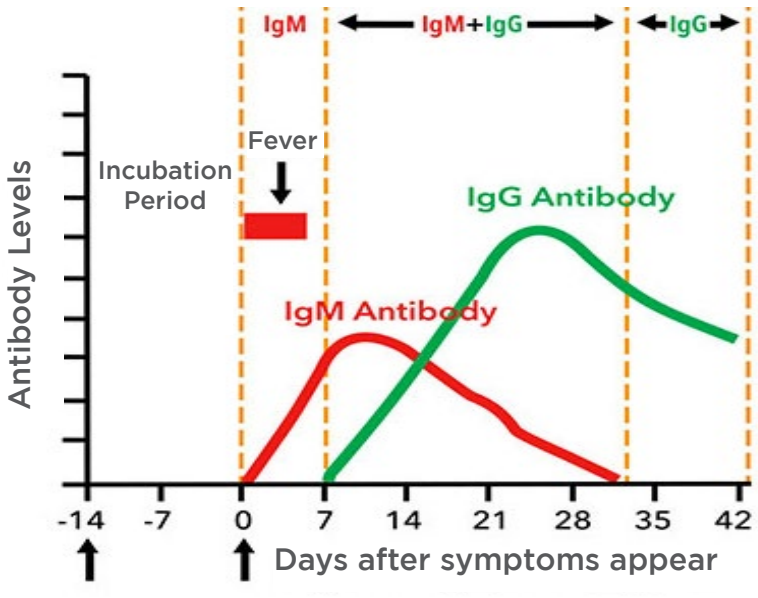
QUICKLY SCREEN → QUARANTINE

- 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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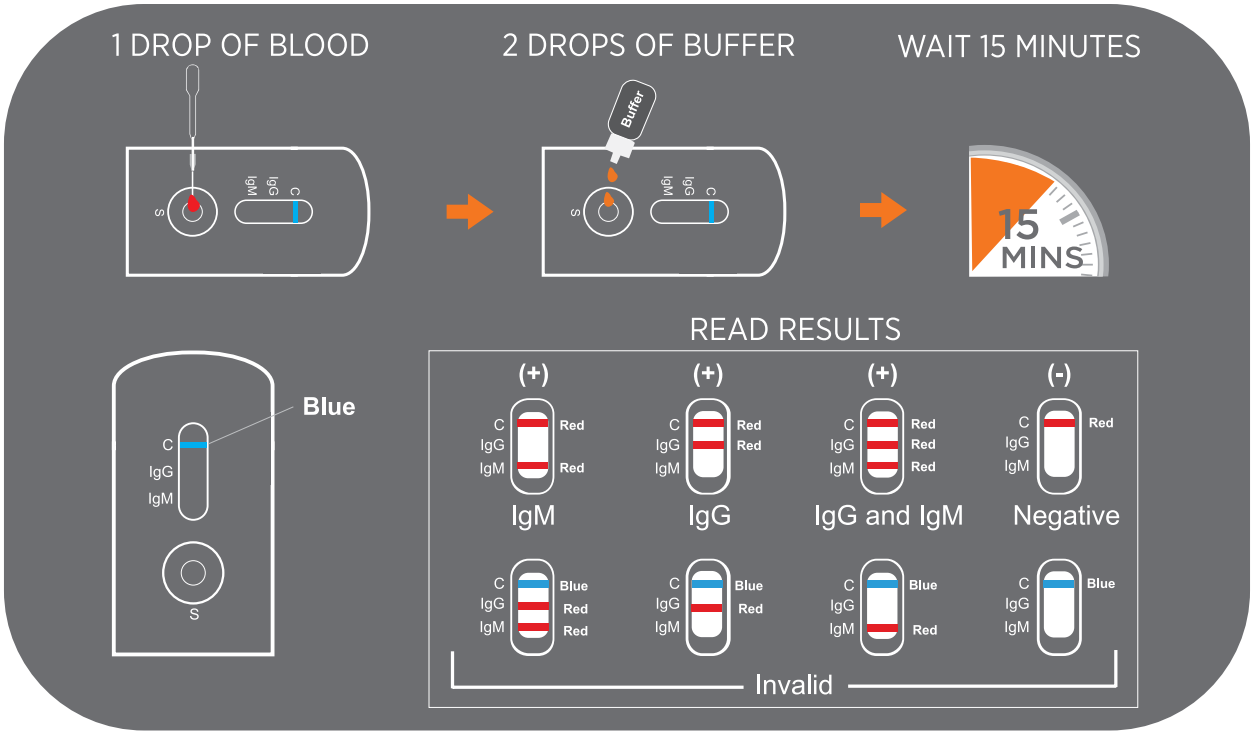
COVID-19
IgM/IgG Antibody Rapid Test

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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Assay Clinical Study Results

Method			PT-PCR		Subtotal
			Positive	Negative	
COVID-19 IgG/IgM Rapid Test Cassette	Positive	IgG+/IgM+	78	0	78
		IgG-/IgM+	0	0	1
		IgG+/IgM-	9	2	11
	Negative	IgG-/IgM-	3	98	101
Subtotal			90	101	191

IgG

Positive Percent agreement (PPA): 96.7% (87/90) (95%CI: 90.7% 98.9%)
Negative Percent agreement (NPA): 98.0% (99/101) (95%CI: 93.1%~99.5%)

IgM

Positive Percent agreement (PPA): 86.7% (78/90) (95%CI: 78.1%~92.2%)
Negative Percent agreement (NPA): 99.0% (100/101) (95%CI: 94.6%~99.8%)

Overall (either IgG+ or IgM+)

Positive Percent agreement (PPA): 96.7% (87/90) (95%CI: 90.7% 98.9%)
Negative Percent agreement (NPA): 97.0% (98/101) (95%CI: 91.6% 99.0%)

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

Measure	Estimate	Confidence Interval
IgM Sensitivity	100% (30/30)	(88.7%; 100%)
IgG Sensitivity	96.7% (29/30)	(83.3%; 99.4%)
(IgM+ or IgG+; Total) Sensitivity (PPA)	100% (30/30)	(88.7%; 100%)
(IgM-/IgG-; Total) Specificity (NPA)	97.5% (78/80)	(91.3%; 99.3%)
Cross-reactivity with HIV+	0% (0/10) not detected	