

# COVID-19 Rapid Antibody Test Device

The COVID-19 antibody rapid test device is a lateral flow in-vitro immunoassay to detect the presence of SARS-CoV-2 IgM and IgG antibodies instantly from a whole blood, serum, plasma and fingerstick whole blood. This kit\* is intended for professional use in both laboratory and Point of Care (POC) settings.



## Advantages

- ✓ Rapid results within 15 minutes
- ✓ Simple 2- step procedure
- ✓ Identifies individuals with adaptive immune response to SARS-CoV2
- ✓ FDA EUA-approved, CLIA - waived

## Contents

The following components are needed for testing and are included in the kit

- ✓ 20 pcs test cassettes
- ✓ 20 pcs disposable pipettes
- ✓ 20 pcs alcohol prep pads
- ✓ 20 pcs sterile lancets and buffer bottles
- ✓ Positive and Negative control controls are available upon request

## Specifications

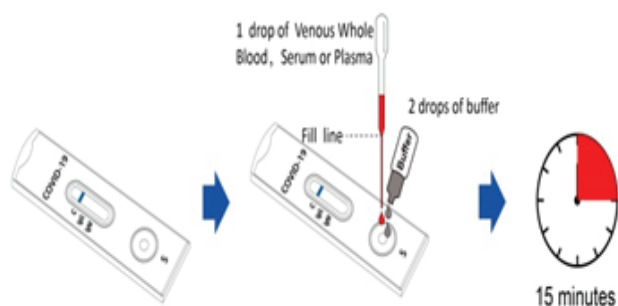
Kit size:20 tests/kit\*

Storage:2-30 °C

Shelf life:18 months

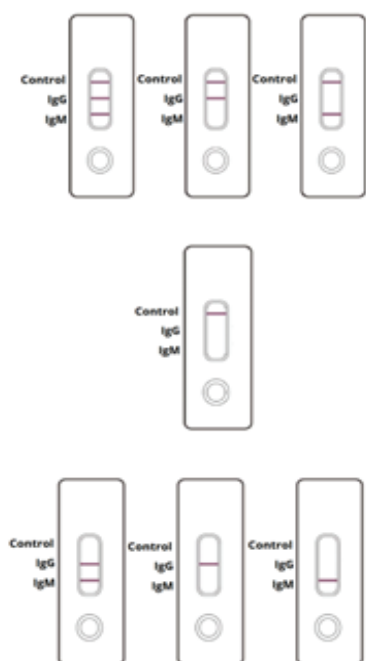
\*The test is for professional use only

## Test Procedure



1. Bring the pouch to room temperature before opening. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface.  
Note: There should be a blue line in the control region (next to "C"), discard the device if there is no blue line.
3. Label the test with patient or control

## Interpretation of Results



IgG and IgM POSITIVE (left): Both the test lines and the quality control line are colored in the COVID-19 IgM/IgG Antibody Test Cassette.

IgG POSITIVE (middle): Two lines appear on the COVID-19 IgM/IgG Antibody Test Cassette. One colored line appears in the control line region, and another colored line appears in the IgG test line region. The result is positive for SARS-CoV-2 specific-IgG antibodies.

IgM POSITIVE (right): Two lines appear on the COVID-19 IgM/IgG Antibody Test Cassette. One colored line appears in the control line region, and another colored line appears in the IgM test line region. The result is positive for SARS-CoV-2 specific-IgM antibodies.

NEGATIVE: One colored line appears in the control region. No apparent colored line appears in the IgG or IgM test region.

INVALID: Control line fails to appear. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette.

## Independent Clinical Agreement Validation

COVID-19 IgG/IgM Rapid		Comparative Methods		
Test Device		Positive (IgM/IgG) +	Negative (IgM/IgG) -	Total
Positive	IgM+, IgG-	27	0	27
	IgM+, IgG+	3	1	4
	IgM-, IgG-	0	0	0
Negative	IgM+, IgG-	0	69	79
Total (n=110)		30	70	110