ALCOPRO
DRUG & ALCOHOL TESTING PRODUCTS

COVID-19
IgM/IgG ANTIBODY RAPID TEST

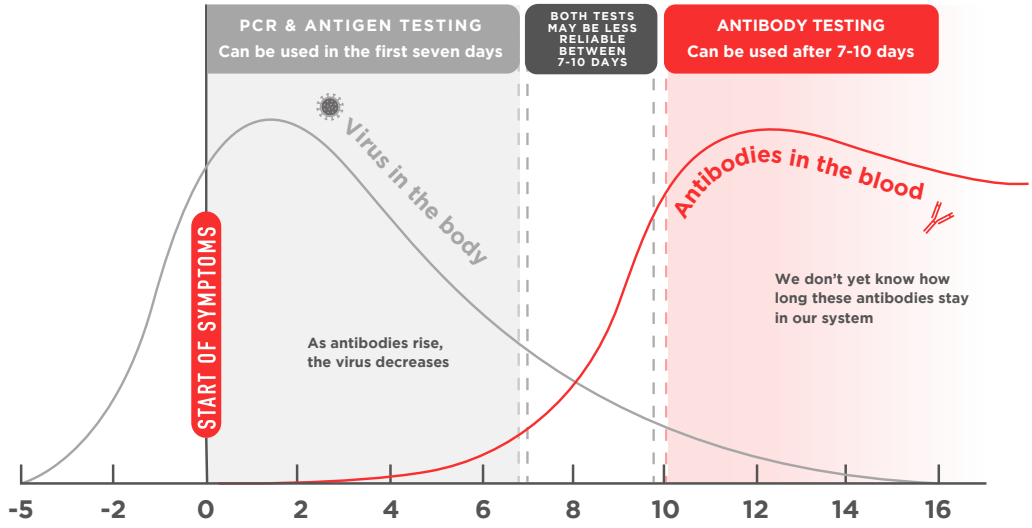
FDA & EUA AUTHORIZED
CLIA WAIVED

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.

IgM/IgG DETECTABLE TEST WINDOW



AUTHORIZED LABORATORIES:

Use of this test with all authorized specimen types is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests.

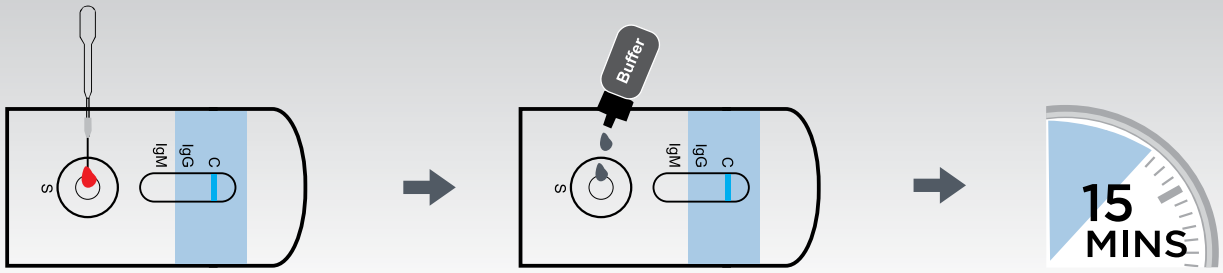
This test is also authorized for use with fingerstick whole blood specimens only at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

4 EASY STEPS

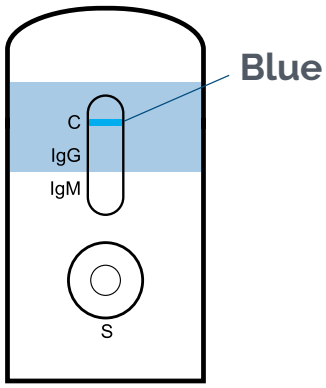
1. Clean the site
2. Draw blood
3. Pipette blood sample on device
4. Add buffer and read results

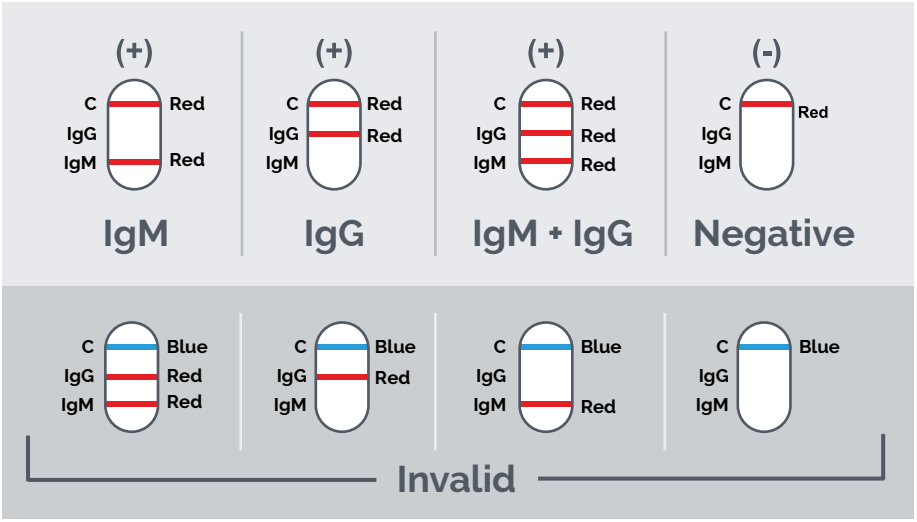
TEST PROCEDURE & READING RESULTS

1 DROP OF BLOOD → 2 DROPS OF BUFFER → WAIT 15 MINUTES



READ 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.

ASSURETECH

ECOTEST®

KIT CONTAINS:

- 20 - In Vitro Diagnostic Devices (IVDD)
- 20 - 10 uL pipettes (for whole blood)
- 20 - Alcohol wipes
- 20 - One-time-use safety lancets (automatic, spring loaded, with retractable blade)
- 1 - Bottle of buffer
- 1 - Product insert

FOR IgM DETECTION

METHOD		PCR +	PCR -	Total
COVID-19 IgG/IgM 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		PCR +	PCR -	Total
COVID-19 IgG/IgM 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

CLINICAL DATA

SARS-COV-2 ANTIGEN AND IGM/IGG ANTIBODY TEST RESULTS AND CLINICAL SIGNIFICANCE

TEST RESULTS			SIGNIFICANCE
PCR (Ag)	IgM Ab	IgG Ab	
+	−	−	Patient may be in the “window 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-COVD-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-COVD-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-COVD-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.

AlcoPro
800.227.9890 | alcopro.com