Verify DIAGNOSTICS

COVID-19 ECOTEST
ANTIBODY RAPID TEST

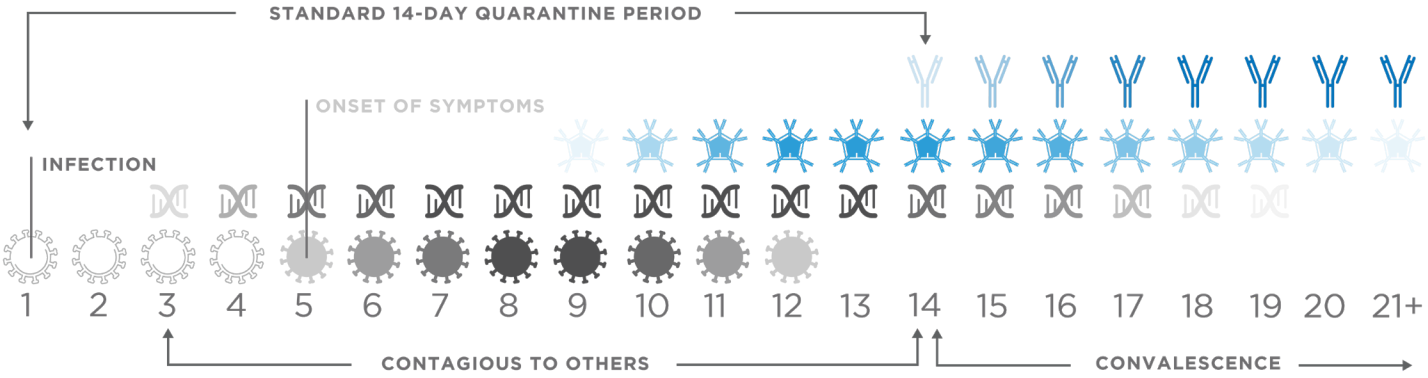
Detect the presence of SARS-CoV-2 IgM and IgG antibodies instantly from a whole blood sample collected from a minimally-invasive fingerstick blood collection process.

The COVID-19 Antibody Rapid test will detect antibodies **5 to 7 days** after symptoms first appear.

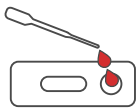
HEALTH CANADA AUTHORIZED

CLIA WAIVED

IgM/IgG DETECTABLE TEST WINDOW



3 EASY STEPS

1.  Draw blood with lancet
2.  Pipette blood sample on device
3.  Add buffer and read results

AUTHORIZED USE

CANADA

The authorized use of this test in Canada is limited to trained healthcare professionals.

This test shall not be used for self-testing or distributed or sold for home use.

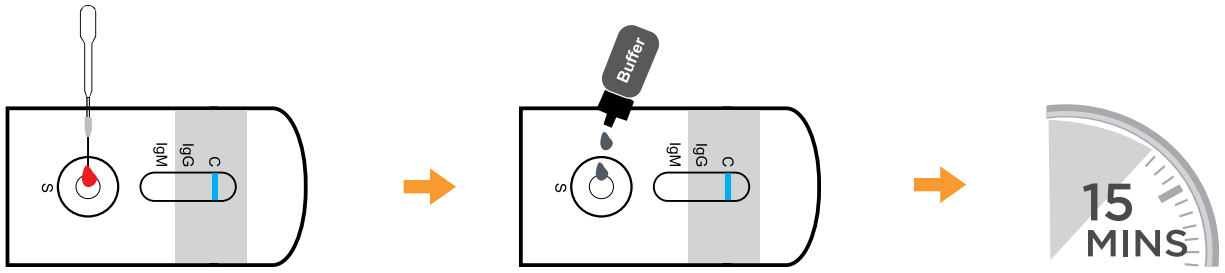
UNITED STATES

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.

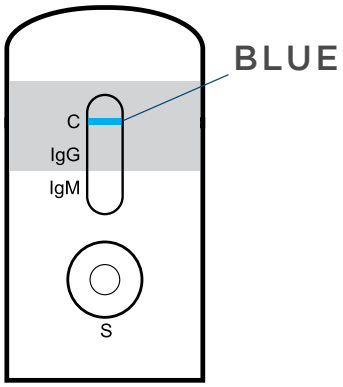
This test is also authorized for use with fingerstick whole blood specimens only at the Point-of-care (POC) in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

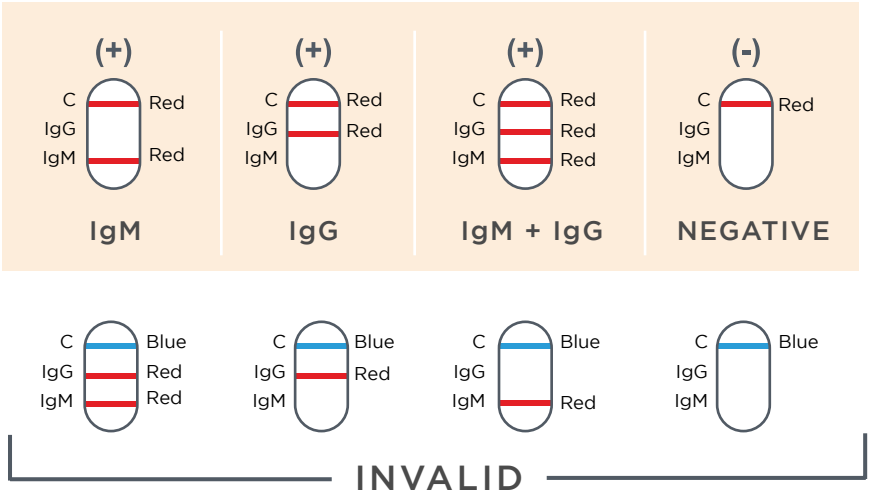
TEST PROCEDURE & READING RESULTS

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



READING 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.

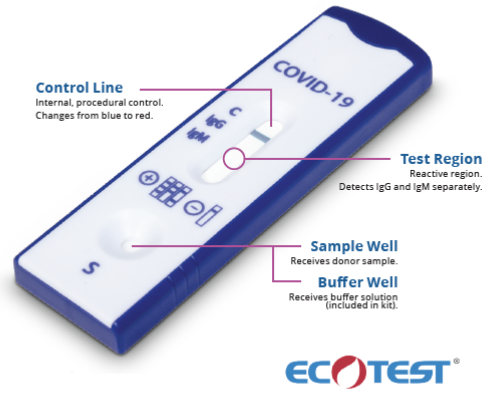
IgG and IgM POSITIVE

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.



ECOTEST®

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		Convalescent samples	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

TEST OUTCOMES

SARS-CoV-2 ANTIGEN (Ag) AND IgM/IgG ANTIBODY TEST RESULTS AND CLINICAL SIGNIFICANCE

TEST RESULTS			SIGNIFICANCE
Ag	IgM Ab	IgG Ab	
+	−	−	Patient may be in the initial stage 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 a late or recurrent stage of infection.
−	+	−	Patient may be in the acute phase of SARS-CoV-2 infection.
−	−	+	Patient may have been infected with SARS-CoV-2 in the past.
−	+	+	Patient has recently been infected with SARS-CoV-2 and is in the recovery stage.

Verify DIAGNOSTICS

Results only experience can deliver.

1-866-446-2953 VERIFYDIAGNOSTICS.COM

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