

# COVID-19 IMMUNITY TESTS

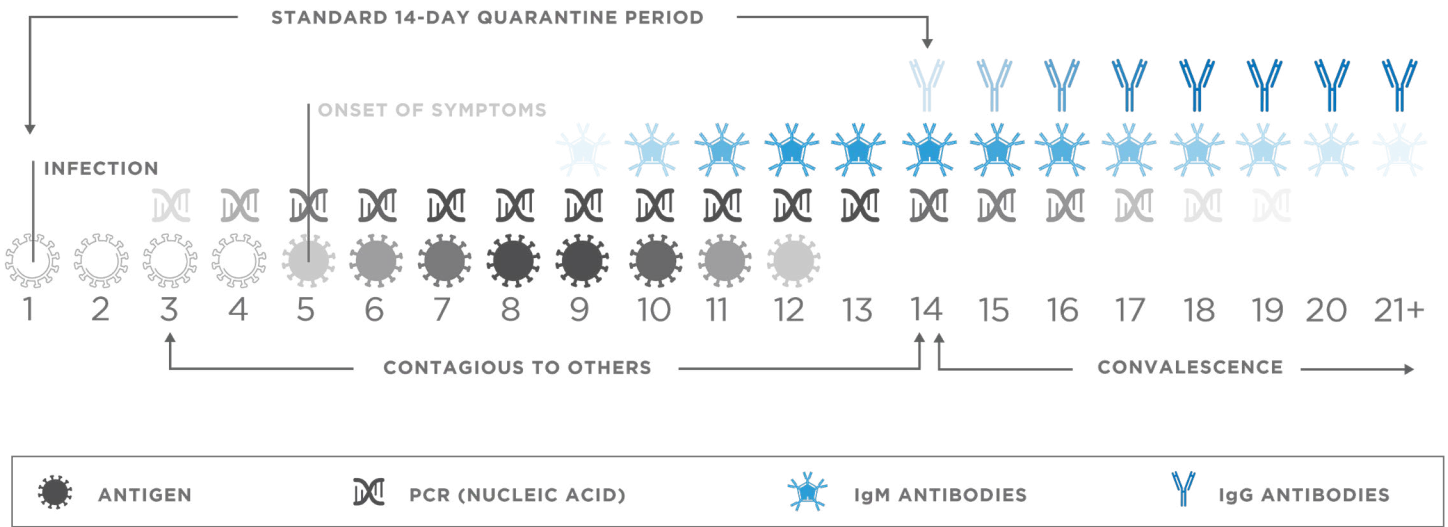
COVID-19 Antibody tests can help a person determine if they had a past infection and/or determine if antibodies are present in their system.

Simply put, this Canadian-made test makes it easy to tell if you have immunity against COVID-19.


**HEALTH CANADA AUTHORIZED**

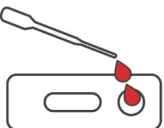


## Detectable Test Window for Antibodies



## 3 Easy Steps

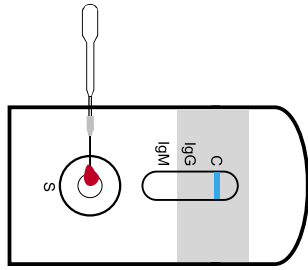
**1**  **DRAW BLOOD WITH LANCET**

**2**  **PIPETTE BLOOD SAMPLE ON DEVICE**

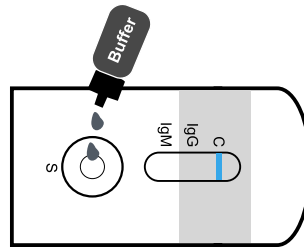
**3**  **ADD BUFFER AND READ RESULTS**

# Test Procedure & Reading Results

1 DROP OF BLOOD



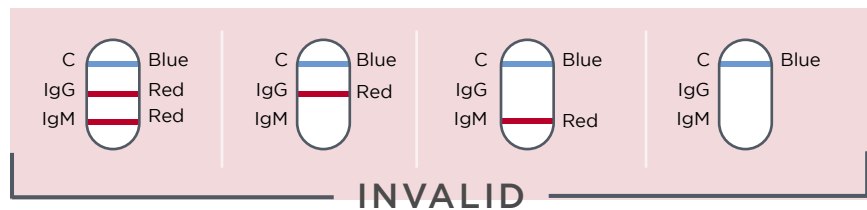
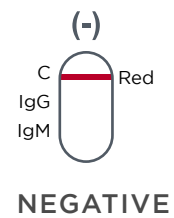
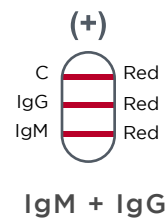
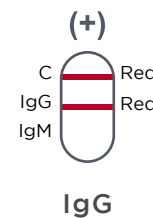
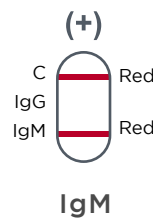
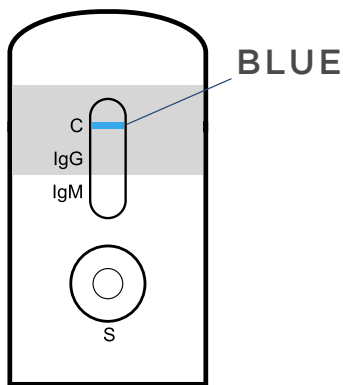
2 DROPS OF BUFFER



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.

### 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.



ALCOHOL WIPES

LANCET

CAPILLARY TUBE

TEST CASSETTE

BUFFER SOLUTION

**IgM Results of Testing COVID-19 Antibody Test**

	POSITIVE	NEGATIVE	TOTAL
POSITIVE	100	6	106
NEGATIVE	6	158	164
TOTAL	106	164	270

Diagnostic Sensitivity:  $100/(100+6) \times 100\% = 94.33\%$

Diagnostic Specificity:  $158/(158+6) \times 100\% = 96.34\%$

Overall Agreement:  $(100+158)/270 \times 100\% = 95.56\%$

**IgG Results of Testing COVID-19 Antibody Test**

	POSITIVE	NEGATIVE	TOTAL
POSITIVE	69	12	81
NEGATIVE	3	186	189
TOTAL	72	198	270

Diagnostic Sensitivity:  $69/(69+12) \times 100\% = 85.19\%$

Diagnostic Specificity:  $186/(186+3) \times 100\% = 98.41\%$

Overall Agreement:  $(69+186)/270 \times 100\% = 94.44\%$

## 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.