

COVID-19

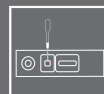
IgM/IgG Antibody Rapid Test

In the continued effort to deliver high quality on-site testing technologies, SBL has secured the first COVID-19 IgM/IgG Antibody Rapid Test to be licensed by Health Canada (Class III). This on-site rapid test detects antibodies produced when infected by the COVID-19 virus (Corona Virus Disease), caused by 2019-nCoV (SARS-CoV-2).

The COVID-19 Rapid Test compliments existing nucleic acid / antigen detection (nasopharyngeal swab, sputum or alveolar lavage fluid specimen). These nucleic acid / antigen swab tests, which detects the virus, are currently not available due to government demand. The COVID-19 Rapid Test detects at the onset of symptoms, once a patient begins producing antibodies to fight the virus. For workplace and non-public applications, this qualitative screen can immensely assist in the assessment of individuals potentially showing flu, cold, or COVID-19 symptoms.

4 EASY STEPS

- 1 CLEAN THE FINGER**
- 2 PIERCE TOP OF FINGER WITH WITH LANCET**
- 3 PIPETTE BLOOD SAMPLE ON DEVICE**
- 4 ADD BUFFER AND READ RESULTS**



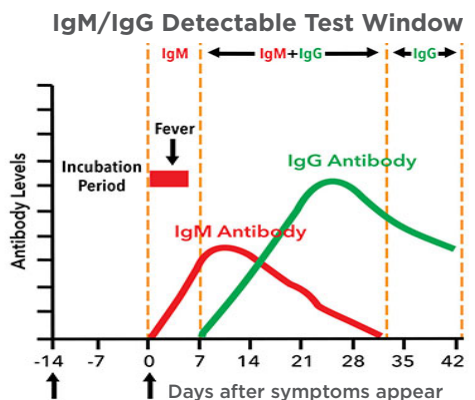
QUICKLY SCREEN → QUARANTINE

- 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
- The test is easy to administer and can be performed by health personnel with no specific medical training

HOW IT WORKS

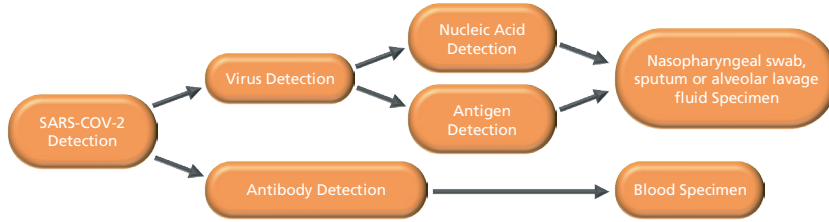
The COVID-19 Rapid Test is a simple point-of-care lateral flow immunoassay detecting IgM and IgG antibodies simultaneously against the COVID-19 virus in human blood within 15 minutes detecting patients at different infection stages. It does not detect the COVID-19 virus itself, but the antibodies produced to fight the virus.

It is widely accepted that IgM provides the first line of defense during viral infections, followed by the generation of adaptive, high affinity IgG responses for long-term immunity and immunological memory. Therefore, testing of COVID-19 IgM and IgG antibodies is an effective method for the rapid diagnosis of COVID-19 infection. Furthermore, detection of COVID-19 IgM antibodies tends to indicate a recent exposure to COVID-19, whereas detection of COVID-19 IgG antibodies indicates a later stage of infection. Thus, this combined antibody test could also provide information on the stage of infection.



DIAGNOSIS OF COVID-19

At different stages of COVID-19 disease progression, the efficiency of nucleic acid and antibody detection is not the same. The two are used in synergy to complement each other, improve diagnosis and monitor disease progression.



Analytes	COVID-19	
	IgG	IgM
Relative Sensitivity	98.8%	93.7%
Relative Specificity	98.7%	99.1%
Overall Agreement	98.7%	97.7%

ALL-INCLUSIVE KIT

Each box of COVID-19 rapid test kits contains everything you need to administer 20 tests, where you need them.

The full kit includes:

- 1) Pipettes
- 2) Test Devices
- 3) Alcohol Pads
- 4) Lancets
- 5) Buffer solution



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 "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-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.