

REF COV-13C25

COVID-19 IgG / IgM

Rapid Test Device

(Whole Blood / Serum / Plasma)

Point of Care for Fingerstick Blood Sample

Authorized by Health Canada (Interim Authorization #313076)



The **Rapid Response® COVID-19 IgG/IgM Rapid Test Device** is the first of its kind in Canada and is currently authorized by Health Canada (Interim Order #313076) for **Point-Of-Care Use** with fingerstick blood sample. The test device can rapidly & qualitatively test for the presence of anti-SARS-CoV-2 IgM and anti-SARS-CoV-2 IgG antibodies in human whole blood, serum, or plasma samples.

✓ Easy to Use:

Bring all testing materials and specimens to room temperature (18-30°C) before use.

1. Add 1 drop (10µL) of whole blood or 5µL of serum/plasma to sample well.
2. Add 2 drops of the included buffer solution.
3. See results in **15 minutes**.

*Please follow the product insert for specimen collection and test procedure.

🎯 PCR Validated Samples

Clinical Study Results Using Fingerstick Blood Samples

*≥15 Days from Symptom Onset:

IgG Sensitivity - 100%

Combined Sensitivity and Specificity Data:

IgG Sensitivity - 90.5%

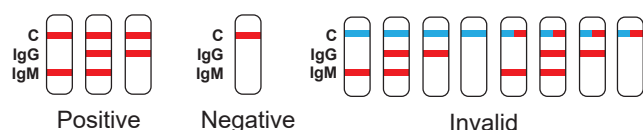
IgM Sensitivity - 88.1%

IgG Specificity - 100%

IgM Specificity - 100%

*IgG antibodies become detectable 1-3 weeks after infection.

📊 Interpretation of Test Results



📦 Kit Contents

- 25 Test Devices
- Disposable Pipettes
- Buffer
- Product Insert

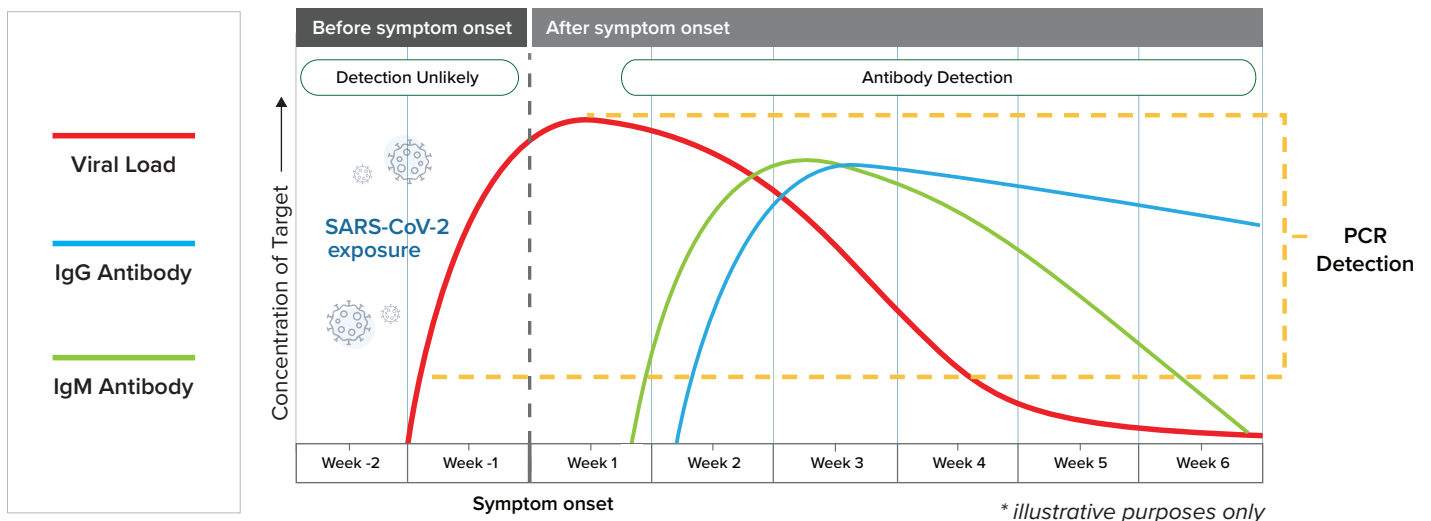
Coronavirus disease 2019 (COVID-19) is a respiratory illness that can spread from person to person. The virus is transmitted mainly via respiratory droplets that people sneeze, cough, or exhale. The incubation period for COVID-19 is currently estimated at between 2 and 14 days. The main tests that aid in the diagnoses include Molecular Tests (RT-PCR) and Antigen Tests that help identify active infection in patients and Antibody Tests (IgG/IgM) which are specific to detecting antibodies indicating prior infection.

Molecular VS Rapid Response® COVID-19 IgG / IgM Rapid Test Device

	Molecular Testing (RT-PCR)	Rapid Response® COVID-19 Antibody Test
Assay Target	Viral Nucleic Acids/RNA/Genes	Anti-SARS-CoV-2 (IgG/IgM) Antibodies
Time to Results	> 6 hours	15 minutes
Specimen	Throat, Nasopharyngeal Fluid	Whole blood, Serum, Plasma
Test Capacity	Limited Throughput	High Turnover
Characteristics	<ul style="list-style-type: none"> - Detects active infection in patients - Testing requires equipment primarily housed in laboratory settings - Does not identify prior infections 	<ul style="list-style-type: none"> - Detects prior infection or immune response - Rapid results can be easily interpreted - Does not require specialized laboratory equipment

SARS-CoV-2 Testing Timeline

The chart below gives a representation of SARS-CoV-2 Infection and the onset of antibodies in an infected individual.



Ordering Information

Product Code	Product Name	Contents
COV-13C25	Covid-19 IgG/IgM Rapid Test Device	25 Tests / Kit