ENGINEERED AND DESIGNED IN CANADA

Fact Sheet

COVID-19 Antibody IgG/IgM Rapid Test Device

Rapid™ Response COVID-19 Antibody IgG/IgM Rapid Test

RESULTS AFTER 15 MINS | **SAMPLE TYPE: WHOLE BLOOD, SERUM, PLASMA** | **SPECIFICITY 100%**

COV-13C25 CE IVD

Health Canada APPROVED

Background

The Rapid Response™ COVID-19 IgG/IgM Rapid Test Device is an in vitro immunoassay for the direct and qualitative detection of anti-SARS-CoV-2 IgM and anti-SARS-CoV-2 IgG in human whole blood (including venous whole blood and capillary whole blood), serum, or plasma.

The test is for use by trained laboratory or healthcare professionals. This assay is not intended for home testing (or self-testing).

The Rapid Response™ COVID-19 IgG/IgM Rapid Test Device detects anti-SARS-CoV-2 IgG/IgM antibody through visual interpretation of color development.

Target Customers

Essential Businesses: Production and manufacturing sites, logistics, customer facing employees, residential delivery, public transport employees, private hire companies, border control facilities.
Health Care: Residential care homes, visiting nurses, physical and occupational health, therapists, GP practices.
Education: Colleges, universities, private and public schools, boarding schools, school support staff.
Hospitality and Recreation: Service and bar staff, hotel staff and guests, airline and airport staff, sports teams.

Performance

Sensitivity:	IgG/IgM 94.6%
Specificity	IgG 100%, IgM 98.1%
Quantity	25 Tests/Kit
Storage:	2-30°C

Materials provided:

- Individually packed test devices
- Disposable pipettes
- Buffer
- Package insert

Materials required but not provided:

- Clock, timer, or stopwatch
- Specimen collection container
- Lancet
- Alcohol prep pad

ONLY INTENDED FOR USE BY TRAINED PERSONNEL SPECIFICALLY INSTRUCTED AND TRAINED IN THE TECHNIQUES OF *IN VITRO* DIAGNOSTIC PROCEDURES

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Procedure

Allow the test device, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Label the test with patient or control identification.

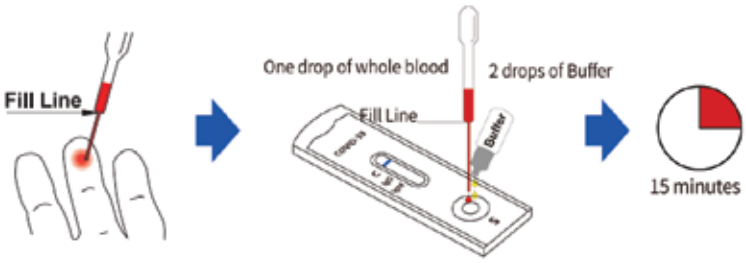
For Fingerstick Blood

a) Clean the puncture site with the alcohol prep pad
b) Carefully remove the cap from the safety lancet. Push the safety lancet firmly against the puncture site until it pricks the finger.
c) Using the provided disposable pipette, draw the specimen above the fill line (avoid the specimen entering the bubble of disposable pipette) and transfer one drop of the specimen into the specimen well of the test device, then add 2 drops of buffer and start the timer.

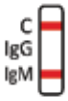
Note: There should be a blue line in the control region (next to "C"), discard the device if there is no blue line.

3. Add the specimens
4. Wait for the blue line change to red line, read results at 15 minutes.

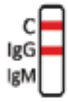
Note: Specimens can also be applied using a micropipette.



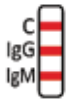
Results for COVID-19 IgG/IgM Test



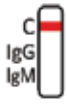
IgM Positive: *The colored line in the control region (C) changes from blue to red, and a colored line appears in the IgM test region. The result is positive for COVID-19 virus specific-IgM antibodies.



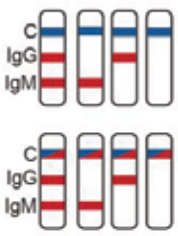
IgG Positive: *The colored line in the control region (C) changes from blue to red, and a colored line appears in the IgG test region. The result is positive for COVID-19 virus specific-IgG antibodies.



IgM and IgG Positive: *The colored line in the control region (C) changes from blue to red, and two colored lines should appear in IgG and IgM test regions. The color intensities of the lines do not have to match. The result is positive for IgM and IgG antibodies.



Negative: The colored line in the control region (C) changes from blue to red. No line appears in IgM or IgG test regions.



Invalid: Control line (C) is still completely or partially blue and fails to completely change from blue to red. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

For more information please refer to product insert

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