MD COVID-19 IgG/IgM Rapid test

Rapid test for the detection of COVID-19 antibodies in human blood, serum, or plasma

MEDICAL DIAGNOSTECH

Product Code: MDCOVID19
Version: 210317

Intended Use

The MD Corona Virus COVID-19 device is a rapid visual immunoassay for the qualitative detection of COVID-19 also known as SARS-CoV-2 (Severe Acute Respiratory Syndrome Corona Virus). It is intended for professional use to accurately diagnose COVID-19 in human whole blood, serum, or plasma.

COVID-19 (Corona Virus Disease of 2019) formally referred to as the 2019 novel Corona Virus, produces symptoms such as fever, respiratory complications, cough and in more severe cases, pneumonia.

The presence of the virus itself causes the immune system to produce antibodies, which can be detected by the MD COVID-19 IgG/IgM rapid test kit.

Principle of the Test

The MD COVID-19 IgG/IgM rapid test detects COVID-19 through visual interpretation of colour development on the membrane. Capture antibodies (Human anti-IgG and Human anti-IgM) are immobilized on the nitrocellulose membrane. The red blood cells are held back by the blood filtration pad releasing serum which bind selectively to these antibodies as the serum is wicked up the strip. The colloidal gold signal reagent is coated with specific COVID-19 antigens which bind with the antibody-antigen complexes formed on the membrane producing a red line.
Presence of coloured bands at the test line region indicate a positive result, while their absence indicates a negative result. The presence of an upper red line (the procedural control line) demonstrates the test has been performed correctly.

Reagents and material provided in the kit

Units	Components
25	Single pouched test cassettes with desiccant
25	Disposable blood collection devices (10 µL)
25	Sterile Wipes
25	Lancets
1	Reaction Buffer 5 mL
1	Instructions for use

Timer required but not provided.

Storage conditions and shelf life

The following indications must be followed to ensure accurate test performance:

1. Store kits at room temperature between 4 and 40°C.
2. Store in a dry place, humidity can affect test performance.
3. The test devices must remain pouched until usage.
4. The kits have a shelf-life of 24 months after manufacturing.
5. The expiration date printed on the kits and pouches must be verified prior to use.
6. Kits must not undergo freezing conditions.

Precautions and warnings

1. For in vitro diagnostic use only.
2. All tests are for single use; do not re-use.
3. Follow the test procedure as closely as possible for the most accurate results.
4. Do not open the sealed pouch, unless ready to conduct the assay.
5. Verify the expiration date, do not use expired tests.
6. Do not mix reagents and components of different lots.
7. Do not use the test if pouch is damaged or seal is broken.
8. Do not eat, drink or smoke while handling specimens and test devices.
9. Wear protective gloves and eye protection while handling specimens.
10. Respect standard procedures to dispose specimens and potentially contaminated material, in biohazard container.
11. MD COVID-19 IgG/IgM rapid test or device does not present any risk to the user if used as recommended.
12. Not to be used in the diagnosis of an acute infection.

Specimen collection and storage

Collection by venipuncture

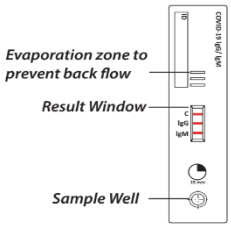
1. Collect the whole blood into the collection tube (containing EDTA, citrate, or heparin) by venipuncture.
2. If specimens are not immediately tested, they should be refrigerated at 2 - 8°C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use. Using the specimen in the long-term keeping more than three days can cause non-specific reactions.
3. When stored at 2 - 8°C, the whole blood sample should be used within three days.

Collection using a lancet

1. Clean area to be lanced with an alcohol swab.
2. Squeeze the end of the fingertip and pierce with a sterile lancet.
3. Wipe away the first drop of blood with sterile gauze or cotton.
4. Take a sample pipette provided, and while gently squeezing the tube, immerse the open end in the blood drop and then gently release the pressure to draw blood into the sample pipette up to the second line (10 µL).

Test Procedure

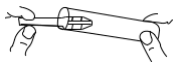
Prior to use, allow the test in the foil bag to reach room temperature.



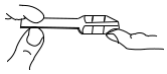
Open the foil bag to be used, only prior to conducting the test, exposing the cassette.

Select the finger for puncture, usually the side of the third or fourth finger.
Clean with antiseptic and allow to air dry.

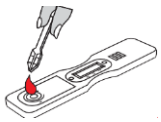
Puncture the finger with a sterile lancet. Blood will well to the surface, redo procedure on another finger if necessary.



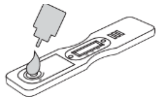
Touch the collection device supplied to the blood spot and allow the blood to fill up to the second (10 µL) line.



Step 1
Transfer blood/serum/plasma to the test cassette by gently touching the nozzle to the sample well.



Step 2
Place 5 drops of the reaction buffer into the sample well.



Step 3
Allow the reaction to proceed for 15 minutes.
Read the result and dispose of the cassette.

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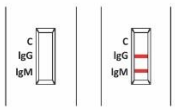
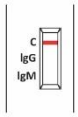
Interpretation of results

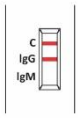
Invalid:
Either no lines are observable or either test line without a control line. Improper test procedure was carried out or reagents have deteriorated. Re-test.



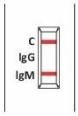
Negative:
The control line is present but not either test line, demonstrating the test was performed correctly however, COVID-19 antibodies were not detected.



IgG Positive:
The middle (IgG) and top (control; C) lines are evident.



IgM Positive:
The bottom (IgM) and top (control) lines are evident.



Symbol

IVD	For in-vitro diagnostic use only		For single use only
	Content		Expiry date
LOT	Lot number		Storage temperature

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NOTE:

Both IgG and IgM lines may be present indicating the presence of both IgG and IgM antibodies against COVID-19.

Limitations of the test

1. The MD COVID-19 IgG/IgM rapid test is for professional in vitro diagnostic use. It is intended to be used for the qualitative detection of COVID-19 specific antibodies.
2. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods are recommended. A negative result does not at any time rule out the existence of COVID-19 antibodies in blood, as the antibodies may be absent or below the minimum detection level of the test.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. Definitive clinical diagnosis should not be made until the physician has evaluated the result in combination with other clinical and laboratory findings.

Internal quality control

The MD COVID-19 IgG/IgM test includes a control line that is used as a procedural control. It should always appear confirming that the test procedure has been performed accurately.