

WELLMEDPRO



SARS-CoV-2

**IgM/IgG Antibody
Rapid Test Kit
(Immunochromatography)**

www.coronarapid-test.com

CONTACT



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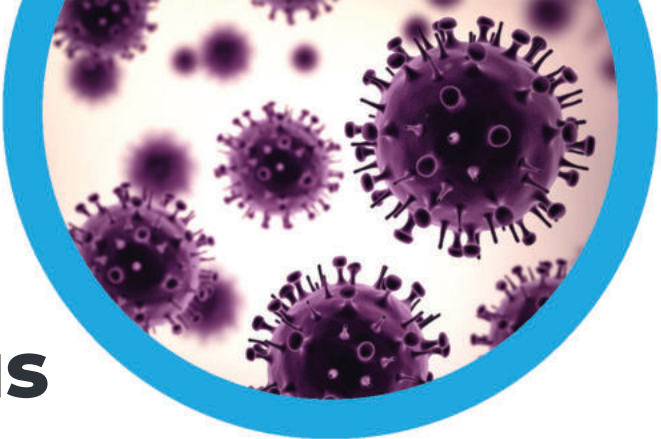
(+86) 0755-82830455



www.coronarapid-test.com



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Novel Coronavirus (COVID-19) Test

SPECIFICATION

- Sample Volume:
10µl
- Fast Reaction:
15 minutes
- No Cross Reaction:
Separated IgM/IgG strip



Intended Use

Used for the qualitative detection of the antibody IgM/IgG to novel Coronavirus (COVID-19) in human serum/plasma, whole blood.

Storage

Store as packaged in the sealed pouch at 4-30°C , avoid hot and sunshine, dryplace, sample.

*NOTE: The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decision.

Covid-19 & Test Knowledge



COVID-19

Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus.

Most people infected with the COVID-19 virus will experience mild to moderate respiratory illness and recover without requiring special treatment. Older people, and those with underlying medical problems like cardiovascular disease, diabetes, chronic respiratory disease, and cancer are more likely to develop serious illness.

*Source: https://www.who.int/health-topics/coronavirus#tab-tab_1



KIT CONTAIN

• **Materials provided:**

- 25 Test cassettes
- 25 Droppers
- 1 Buffer Solution Bottle
- Package insert

• **Materials required but not provided:**

- Specimen collection containers
- Centrifuge (for plasma only)
- Micropipette
- Timer
- Lancets (for fingerstick whole blood only)



TEST METHOD INFO

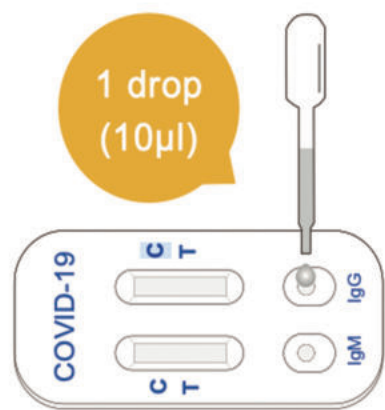
This kit is an immunochromatographic assay, using capture method for rapid, qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) IgM/IgG antibody in human serum, plasma or whole blood sample.

TEST PROCEDURE AND READ RESULT for serum/plasma



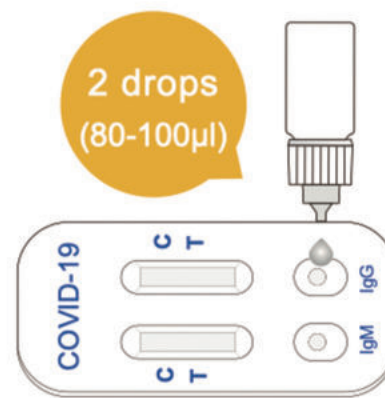
01

Add one (1) full drop of serum or plasma (10µl) vertically into the samples



02

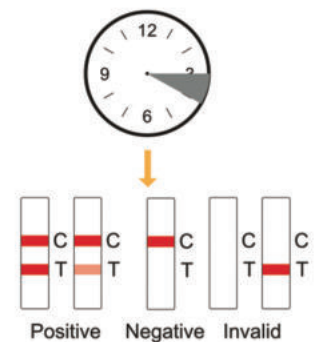
Add two (2) drops (80-100µl) of sample buffer into the samples



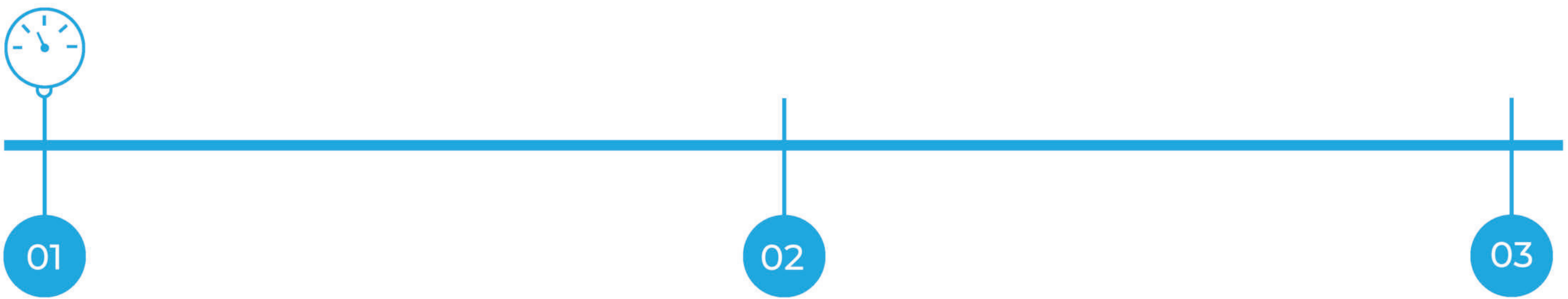
03

Read results within 15~20 minutes, the result is invalid over 20 minutes.

Within 15~20 minutes



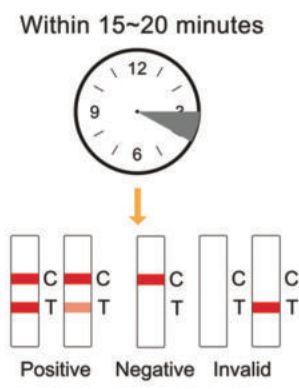
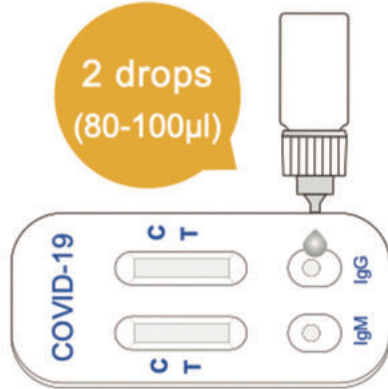
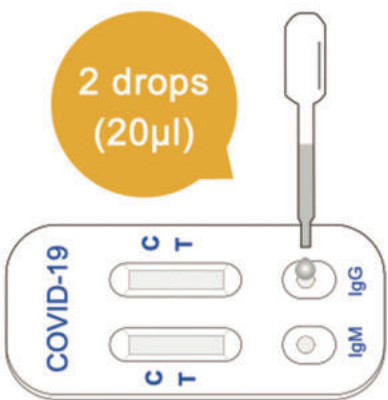
TEST PROCEDURE AND READ RESULT for whole blood



Add two (2) full drops of whole blood (20µl) vertically into the samples

Add two (2) drops (80-100µl) of sample buffer into the samples

Read results within 15~20 minutes, the result is invalid over 20 minutes.





Efficacy Test

Antibody Rapid Test	COVID-19 IgM	COVID-19 IgG
Positive Coincident Rate	82%	93%
Negative Coincident Rate	96%	97.5%
Total Coincident Rate	92.8%	96.5%

*Note: Results compared to Molecular testing.

Precautions and Secure Use

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.

Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.
- Humidity and temperature can adversely affect results
- Reagents should be used as soon as possible after opened. This reagent cannot be reused for disposable.
- The test device should remain in the sealed pouches until use. If sealing problem happens, do not test. Don't use after the expiration date.
- Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 12 months.
- DO NOT FREEZE.
- Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze thaw.
- Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity≤60%, Temp: 20°C-30°C). Please use immediately when the humidity>60%.

Certificates & Declarations



o MSDS Certificate: Certificate required for air shipment.

o Certificate for Safe Transport of Air Cargo:
IVD diagnostic reagent. According to IATA DGR Special Provision A122, it is classified as Not Restricted, as per Special Provision A122.

o Comparative Test Report conclusion:
SARS-CoV-2 IgM Ab rapid test and PCR test positive coincidence rate of 82%, negative coincidence rate of 96%, total coincidence rate of 92.8%. SARS-CoV-2 IgG Ab rapid test and PCR test positive coincidence rate of 93%, negative coincidence rate of 97.5%, total coincidence rate of 96.5%.



o Declaration of Conformity can be provided upon request

o EUROPEAN REPRESENTATIVE: MedNet GmbH, Borkstrasse 10, 48163 Muenster, Germany

