COVID-19 IgG/IgM Rapid Test Kit

Package: 40T/kit
Catalogue No: UNCOV-40

INTENDED USE

COVID-19 IgG/IgM Rapid Test (Whole Blood/ Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum or plasma as an aid in the diagnosis of primary and secondary COVID-19 infections.

SUMMARY

COVID-19(Corona Virus Disease) is an infectious disease caused by the most recently discovered coronavirus. The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some people become infected but don't develop any symptoms and don't feel unwell. People can catch COVID-19 from others who carry the virus. The disease can spread from person to person through small droplets from the nose or mouth when a person with COVID-19 coughs or exhales. The incubation period for COVID-19 generally ranges from 1-14 days.

TEST PRINCIPLE

COVID-19 IgG/IgM Rapid Test (Whole Blood/ Serum/ Plasma) is a qualitative membrane-based immunoassay for the detection of COVID-19 antibodies in whole blood, serum, or plasma. This test consists of two test lines, an IgG line and an IgM line, which is pre-coated with two mouse anti-human monoclonal antibodies separately.

During testing, the specimen reacts with COVID-19 antigen-coated on conjugated pad. As the complex continues to travel up the strip, the anti-COVID-19 IgM antibodies are bound on the IgM line, and the anti-COVID-19 IgG antibodies are bound on the IgG line. The control (C) line appears when sample has flowed through the strip. The presence of anti- COVID-19 IgM and/or IgG will be indicated by a visible test line in the IgM and IgG region.

To serve as a procedural control, the control line should always appear if the test procedure is performed properly and the reagents are working as intended.

REAGENTS

- **Test Cassette:** 40T/Kit.
- **Buffer:** 7 mL.
- **Dropper:** 40 pieces/Bag.
- Desiccant.

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Centrifuge (for plasma only)
- Micropipette
- Timer
- Lancets (for finger prick whole blood only)

PRECAUTIONS

1. For medical professional use only.
2. Do not eat, drink or smoke in the area where specimens or kits are handled.
3. Handle all specimens cautiously 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.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. The used tests, specimens and potentially contaminated should be discarded according to the local regulation.
6. Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30℃). The test cassette is stable before the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use after the expiration date.

SPECIMEN COLLECTION AND PREPARATION

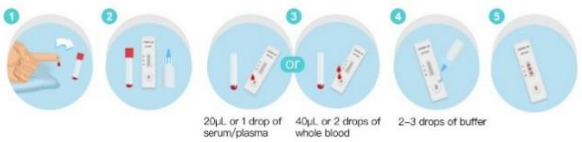
COVID-19 IgG/IgM Rapid Test can be performed using whole blood, serum, or plasma.

- **To collect finger prick whole blood specimens.**
  Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger. Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  Rub the hand gently from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- **Separate serum or plasma from blood** as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Test should be performed immediately after specimen collection.
- Serum and plasma specimens may be stored at 2-8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃. Whole blood collected by venipuncture should be stored at 2-8℃ if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingertip should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

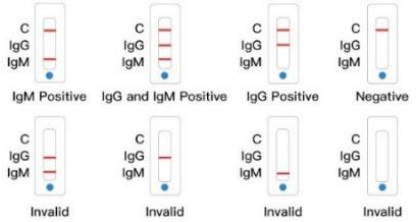
TEST PROCEDURE

Keep the test cassette, specimen, buffer to room temperature (15-30℃) prior to testing.

- Bring the pouch to room temperature before opening. Take the test cassette from the sealed pouch and use it within one hour.
- Place the test cassette on a clean and flat surface.
- **For Serum or Plasma Specimens:** add 1 drop/20 µL sample into sample well using the dropper/ micropipette, then add 1 drop/40 µL of buffer and start the timer. Avoid trapping air bubbles in the specimen well.
- **For Whole Blood Specimens:** add 2 drop/40 µL sample into sample well using the dropper/micropipette, then add 3 drop/100 µL of buffer and start the timer. Avoid trapping air bubbles in the specimen well.
- Wait for the colored line(s) to appear. The test result should be read at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS



NOTE: This figure is only used as a reference for judging results.

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- **IgM POSITIVE: Two lines appear.**
  Colored lines should be in the control line region (C) and IgM test line region. No line appears in IgG test line region.
- **IgG and IgM POSITIVE: Three lines appear.**
  Colored lines should be in the control line region(C), IgG line test region and IgM test line region. The color intensities of the lines do not have to match.
- **IgG POSITIVE: Two lines appear.**
  Colored lines should be in the control line region(C) and IgG test line region. No line appears in IgM test line region.
  NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of COVID-19 antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s) should be considered positive.
- **NEGATIVE: One colored line should be in the control line region (C). No line appears in IgG and IgM test line region(s).**
- **INVALID: Control line fails to appear.**
  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 cassette. If the problem persists, discontinue using the test kit and contact your local distributor.

PERFORMANCE

1. **Positive reference of product compliance rate:** should be 5/5.
2. **Negative reference of product compliance rate:** should be 10/10.
3. **Minimum detection limit:** The reference product S1 should be negative, S2A, S2B and S3 should be positive.
4. **Repeatability:** Three reference products (S2A, S2B and S3) are tested. Each test is repeated 10 times and should be positive.
5. **Specificity analysis:**

5.1 Cross-reaction:

This product does not have cross reaction with antibody positive specimens against parainfluenza virus, influenza A virus, influenza B virus, Chlamydia pneumoniae, Mycoplasma pneumoniae, adenovirus, respiratory syncytial virus, hepatitis B surface, type C Hepatitis virus, Treponema pallidum, human immunodeficiency virus, EB virus, measles virus, cytomegalovirus, enterovirus 71, mumps virus, HKU1 virus, OC43 virus, NL63 virus, 229E virus and chicken pox-zoster virus.

5.2 Interfering substances:

1) When the bilirubin concentration is ≤250 μmol/L, the hemoglobin content is ≤9 g/L, the triglyceride content is ≤15 mmol/L, the rheumatoid factor content is ≤80IU/mL, and the antinuclear antibody (ANA) titer is ≤ 1: 240, anti-mitochondrial antibody (AMA) ≤80U/mL, mouse IgG content ≤1000μg/mL, will not interfere with the detection results of this product.
2) Histamine hydrochloride, alpha-interferon, zanamivir, ribavirin, oseltamivir, peramivir, lopinavir, ritonavir, abidol, levofloxacin, azithromycin, Ceftriaxone, meropenem, and tobramycin, they will have no effect on the test results of product.

6. **Hook effect:** Within the titer range of clinically positive specimens of the new coronavirus antibody, the test result of this product does not show a hook effect.
7. The test results of this product are not affected by the disrupted new coronavirus-specific IgM antibodies.
8. The minimum detection limit and repeatability of 12 copies of 2019-nCoV clinical positive serum specimens were studied, and the results met the requirements.
9. **Clinical performance:** The in vitro diagnostic reagents are compared with the clinical diagnostic criteria of 2019-nCoV to verify the clinical performance of this product. The enrolled cases were suspected cases of 2019-nCoV infection, a total of 1585 cases, including 421 confirmed cases and 1164 excluded cases. The test results show that the product has a **clinical sensitivity of 98.81% (95% CI: 97.25%, 99.61%)** and **specificity of 98.02% (95% CI: 97.05%, 98.74%)**. In addition, 203 subjects received homologous serum/plasma and whole blood specimens (125 of which were positive and 78 were negative) for comparative tests. The results show that **the consistency rate of the whole blood is 96.85% (95% CI: 95.87% to 97.60%)**, based on the serum/plasma test results.

LIMITATIONS

1. COVID-19 Rapid Test is for in vitro diagnostic use only. The test should be performed using serum, plasma or whole blood specimens only. Neither the quantitative value nor the rate of increase in COVID-19 antibody concentration can be determined by this qualitative test.
2. COVID-19 Rapid Test will only indicate the presence of COVID-19 antibodies in the specimen and should not be used as the sole criteria for the diagnosis of COVID-19 infection.
3. In the early onset of fever, anti-COVID-19 IgM concentrations may be below detectable levels.
4. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
5. Results from immunosuppressed patients should be interpreted with caution.
6. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
7. If the test result is negative and clinical symptoms persist additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of COVID-19 infection.

BASIC INFORMATION

GLOSSARY OF SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device	30℃ 2℃	Temperature limitation
	Manufacturer	EC REP	Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instructions for use
LOT	Batch code	CE	Meet the requirements of EC Directive 98/79/EC

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