CE IVD

FRENOVO

COVID-19 IgG/IgM Rapid Test Kit

Instructions For Use

PRODUCT NAME

COVID-19 IgG/IgM Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

The kit is a rapid chromatographic immunoassay for the qualitative of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum or plasma as an aid in the diagnosis of primary and secondary COVID-19 infections.

The novel corona viruses belong to the β genus.COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

The kit is a rapid test that utilizes a combination of COVID-19 antigen coated colored particles for the detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum, or plasma.

The kit is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 antibodies in whole blood, serum, or plasma. This test consists of two test lines, an IgG line and an IgM line. In the IgG line, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with SARS-CoV-2 antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region. If the specimen contains IgG antibodies to SARS-Cov-2,a colored line will appear in IgG test line region. In the IgM line, anti-human IgM is coated in IgM test line region. During testing, the specimen reacts with anti-human IgM. IgM antibodies to SARS-CoV 2, if present in the specimen, reacts with the anti-human IgM and the SARS-CoV-2 antigen-coated particles in the test cassette, and this complex is captured by the anti-human IgM, forming a colored line in IgM test line region.

Therefore, if the specimen contains IgG antibodies to SARS-CoV-2, a colored line will appear in IgG test line region. If the specimen contains IgM antibodies to SARS-CoV-2, a colored line will appear in IgM test line region. If the specimen does not contain antibodies to SARS-CoV-2, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS PROVIDED

Each kit contains:

1. Test Devices: 20 pieces test devices individually pouched.
2. Wash Buffer Solution: 2.0 ml in dropper bottle.
3. Droppers: 20 pieces droppers of 25 ul
4. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing
- Centrifuge(for plasma only)
- Micropipette
- Lancets(for fingertip whole blood only)

WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kitis for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. The kit rapid test is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The kit is intended for in vitro diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke,eat,drink,apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121℃ for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of extraction Solution, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate dropper and device for each specimen tested.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix wash buffer solution/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 10 minutes incubation time following the addition of specimen and wash buffer solution. Do not read results beyond 15 minutes.

STORAGE INSTRUCTIONS

1. The kit should be stored between 2-30°C and the shelf life is 24 months.
2. The Kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the wash buffer solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

SAMPLE COLLECTION AND PREPARATION

1. Applicable samples： Whole Blood/Serum/Plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear nonhemolysis specimens.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
4. Serum and plasma specimens may be stored at 2~8℃ for up to 7 days, for long term storage, serum/plasma 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.
5. Do not freeze whole blood specimens.
6. Whole blood collected by finger stick should be tested immediately.
7. 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.
8. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
9. EDTA K2,Heparin sodium,Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

QUALITY CONTROL

An internal procedural control is included in the test. a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

TEST PROCEDURE

Allow the test device, specimen, extraction solution to equilibrate to room temperature (15-30°C) prior to testing.

1 Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface.

2 **For Serum or Plasma Specimens**

To use a dropper: Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (one drop/approximately 25ul), then add 2 drops of buffer(approximately 60ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

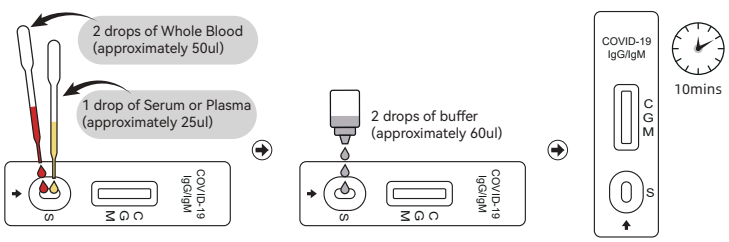
To use a micro-pipette: Pipette and dispense 25ul of specimen to the sample well of the test cassette, then add 2 drops of buffer(approximately 60ul) to the sample well and start the timer.

For Whole Blood Specimens

To use a dropper: Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (two drops/approximately 50ul), then add 2 drops of buffer(approximately 60ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

To use a micropipette: Pipette and dispense 50ul of specimen to the sample well of the test cassette, then add 2 drops of buffer(approximately 60ul) to the sample well and start the timer.

3 Wait for the colored line(s)to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

IgG and IgM POSITIVE: Three lines appear. One colored line should be in the control line region(C), and two colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match. the result is positive for IgG&IgM antibodies and is indicative of secondary COVID-19 infection.

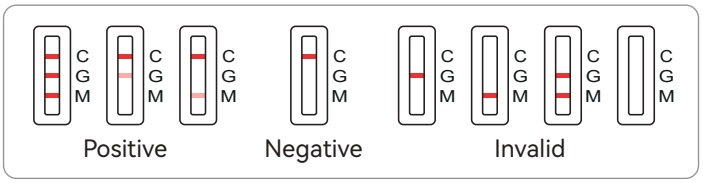
IgG POSITIVE: Two lines appear. One colored line should be in the control line region(C), and a colored line appears in IgG test line region. The result is positive for CovID-19 virus specific-IgG and is probably indicative of secondary COVID-19 infection.

IgM POSITIVE: Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for COVID-19 virus specific-IgM antibodies and is indicative of primary COVID-19 infection.

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 test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



LIMITATIONS

1. The kit is for in vitro diagnostic use only. The test should be used for the detection of COVID-19 antibodies in 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. The kit 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.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity
Clinical study was performed to compare the results obtained by The kitand PCR. The results indicated that The kithas a high sensitivity and specificity as summarized below:

Saliva samples		PCR				Total Results
	Results	IgG Positive IgM Negative	IgG Negative IgM Positive	IgG Positive IgM Positive	IgG Negative IgM Negative	
COVID-19 IgG/IgM Rapid test	IgG Positive IgM Negative	18	0	6	9	33
	IgG Negative IgM Positive	0	10	0	15	25
	IgG Positive IgM Positive	0	0	205	0	205
	IgG Negative IgM Negative	4	3	1	287	295
Total Results		22	13	212	311	558

IgG Results:
Clinical sensitivity =(18+6+205)/(22+212)=97.86 % (95%CI* 95.08% to 99.30%)
Clinical specificity = (10+3+15+287)/(13+311)=97.22 % (95%CI* 94.79% to 98.72%)
Accuracy: (18+6+205+10+3+15+287)/ (22+212+13+311) =97.49% (95%CI* 95.83% to 98.62%)

IgM Results:
Clinical sensitivity =(10+205)/(13+212)=95.56 % (95%CI* 91.98% to 97.88%)
Clinical specificity = (18+4+9+287)/(22+311)=95.49 % (95%CI* 92.68% to 97.46%)
Accuracy: (10+205+18+4+9+287)/ (22+212+13+311) =95.52% (95%CI* 93.46% to 97.08%)

Interference Substances
The following potential interfering substances have been tested using The kitand no interference was observed:

Substance	Tested Concentration
HAMA	positive sample
Rheumatoid factor	100 IU/mL
Antinuclear antibody (ANA)	103.748 IU/mL
Anti-mitochondrial antibody(AMA)	80 U/mL
Bilirubin	0.3 mg/mL
Hemoglobin	8 mg/mL
Triglycerides	5mg/mL
α-interferon	2 ng/mL
Zanamivir	142 ng/mL
Ritonavir	53 μg/mL
Tramadol	12 μg/mL
Azithromycin	4 μg/mL
Azithromycin	156 μg/mL
Meropenem	10 mg/mL
Levofloxacin	2 mg/mL
Oseltamivir	1275 ng/mL
Mupirocin	10 mg/mL
Benzocaine	1.7 mg/mL
Tobramycin	4 μg/mL
Peramivir	18 μg/mL
Epinephrine	546 pmol/L
Menthol	1.7 mg/mL
Ribavirin	5.4 μg/mL
Lopinavir	2 mg/L

Cross Reaction
Cross-reactivity of The kit was evaluated using serum samples containing antibodies to other pathogens, which has no effect on the negative and positive test results, and there is no cross-reaction.

IgM potential cross-reactant	IgG potential cross-reactant
Influenza A virus (H1N1, H3N2)	Influenza A virus (H1N1, H3N2)
Influenza B virus (Yamagata IgM,Victoria IgM)	Influenza B virus (Yamagata IgG, Victoria IgG)
Endemic human coronavirus (OC43, 229E)	Endemic human coronavirus (OC43, 229E)
CMV IgM	CMV IgG
Rubella IgM	Rubella IgG
Toxo IgM	Toxo IgG
HSV IgM	HSV IgG
Coxsackie virus group B IgM	Coxsackie virus group B IgG
Epstein-Barr virus IgM	Epstein-Barr virus IgG
Enterovirus 71 IgM	Enterovirus 71 IgG
Coxsackie virus type A16 IgM	Coxsackie virus type A16 IgG
Varicella zoster virus IgM	Varicella zoster virus IgG
Mumps Virus IgM	Mumps Virus IgG
Respiratory syncytial virus IgM	Respiratory syncytial virus IgG
Adenovirus IgM	Adenovirus IgG
Chlamydia pneumoniae IgM	Chlamydia pneumoniae IgG
Mycoplasma pneumoniae IgM	Mycoplasma pneumoniae IgG
Measles virus IgM	Measles virus IgG

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2°C 30°C	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	Biological risks	CE	CE mark

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INSTRUCTION APPROVAL AND REVISION DATE

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