[Performance Characteristics]

1. Limit of detection (LOD)
   Detection of 3 commercial COVID-19-IgM/IgG LOD reference materials. L1 is positive, L2 can be positive or negative, and L3 is negative.
2. True positive rate
   Detection of 5 commercial COVID-19 IgM/IgG positive reference materials, and the true positive rate was ≥5/5.
3. True negative rate
   Detection of 20 commercial COVID-19-IgM/IgG negative reference materials, the true negative rates of IgG and IgM antibodies were both ≥20/20.
4. Repeatability
   Detection of 1 commercial COVID-19-IgM/IgG positive reference material for 10 times. Both IgM and IgG antibodies showed 100% consistency in positive results.
5. Analytical specificity
   ①The negative detection rate of sample B1 containing 5mg/mL hemoglobin was 100%.
   ②The negative detection rate of sample B2 containing 10mg/mL triglyceride was 100%.
   ③The negative detection rate of sample B3 containing 0.2mg/mL bilirubin was 100%.

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SYMBOL	DESCRIPTION
	Manufacturer
EC REP	Authorized representative in the European Community
IVD	*In Vitro* Diagnostic Medical Device
LOT	Batch Code
	Use-by date
	Temperature Limitation
CE	CE Mark
REF	Catalogue number
	Biological risks
	Do not re-use
	Contains Sufficient for <n> Tests
	Date of manufacture
	Keep Away From Sunlight
	Consult instructions for use
	Keep Dry

Coronavirus COVID-19 IgM/IgG Test Kit

(For Medical Professional Use Only)

[Version No] 0002

[Issued Date] 2020-11-10

[Packaging Specifications]

1 test/kit, 20 tests/kit.

[Intended Use]

The Coronavirus COVID-19 IgM/IgG Test Kit is used for the qualitative detection of COVID-19 IgM and IgG antibodies in human serum, plasma or whole blood samples, and is designed for preliminary screening tests for patients with suspected COVID-19 infection.

[Summary and Explanation]

The novel coronaviruses 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.

[Principle]

This kit is based on the principle of lateral flow colloidal gold immunoassay and uses capture method to detect the COVID-19 IgM and IgG antibodies in the sample. When the sample contains the COVID-19 IgM antibody, it forms a complex with the gold labeled antigen (COVID-19 recombinant antigen). The complex moves forward under the action of chromatography and combines with the coated antibody (Mouse anti-human IgM monoclonal antibody) at the T1(M) band and develop color, which is a positive result. When the sample contains the COVID-19 IgG antibody, it forms a complex with the gold labeled antigen (COVID-19 recombinant antigen). The complex moves forward under the action of chromatography and combines with the coated antibody (Mouse anti-human IgG monoclonal antibody) at the T2(G) band and develop color, which is a positive result. When the sample does not contain the COVID-19 IgM or IgG antibody, no complex can be formed at the T1(M) or T2(G) band, and no red band appears, which is a negative result. Regardless of whether the samples contains COVID-19 IgM or IgG antibody, the gold labeled quality control antigen will bind to the coated antibody at the C band and develop color.

[Supplied Kit Components]

Component	1 test/kit		20 tests/kit	
	Quantity	Specification	Quantity	Specification
Test Cassette	1	Individual package	20	Individual package
Sampling pipette	1	-----	21	21 tubes per bag
Diluent	1	120μL per dropper	1	2mL per bottle
Product Insert	1 Copy	-----	1 Copy	-----
Lancets	1	-----	-----	-----
Alcohol pad	1	-----	-----	-----

Note: Timer is needed but not provided. Lancets are needed but not provided in 20 tests/kit package. Various components of different batches of reagents can not be used interchangeably in order to avoid false results.

[Warnings and Precautions]

1. This kit is for *in vitro* diagnostic use.
2. This kit is for medical professional use only.
3. Do not use cassettes which are damaged, or have an unclear label or expired.
4. Samples with invalid results must be retested.
5. The cassette is for one time use only. Used cassettes and samples should be treated as potential bio-hazardous materials.
6. Do not eat the desiccant in the foil pouch.
7. Do not reuse the used test cassette and pipette.

[Kit Storage and Product Shelf Life]

Store at room temperature (2 -30°C or 35.6-86°F) in a dry shady place. Avoid direct sunlight.
18 months of shelf life (production date to expiration date).

[Specimen Requirements]

1. Only serum or heparinized /EDTA-treated plasma/whole blood can be tested.
2. Samples should be collected in an approved blood collection device. Contaminated samples should not be used.
3. Samples are recommended to be tested immediately after being collected. Extensively hemolytic samples should not to be used.
4. Stability of plasma/serum:

Storage temperature	Shelf time
≤-20°C	1 month
2~8°C	24 hours
15~25°C	8 hours

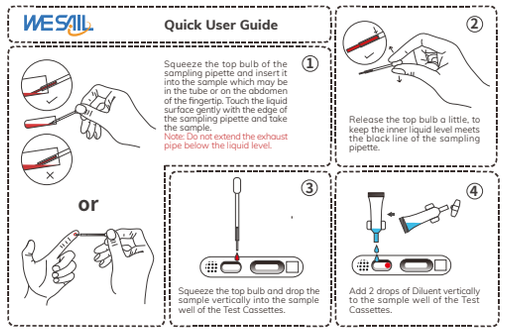
5. Whole blood samples should be tested within 4 hours at room temperature (15-25°C) or 24 hours at 2-8°C after collection, without any freeze/thaw cycle.
6. Sample should be stored tightly capped at room temperature (15-25°C) for no longer than 8 hours.
7. If the assay will not be completed within 4 hours, the sample should be stored at 2-8°C.
8. If the assay will not be completed within 8 hours, samples should be frozen at -20°C.
9. Frozen samples should be warmed up to room temperature (15-25°C) before use.
10. Samples with extensive hemolysis or lipemia or high levels of bilirubin are not allowed to be used.
11. Specimens are allowed to Freeze only once. Specimens must be mixed thoroughly after thawing, by LOW speed vortex or gently inverting, then centrifuged at ≥10,000g for at least 5 minutes to remove particulate matter prior to testing and ensure consistency in the results.

[Test Procedure]

Caution: Please read the product insert of the kit carefully.

Quick User Guide (1 test/kit)

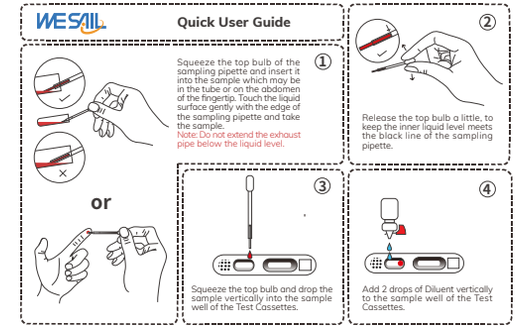
1. Equilibrate stored samples to room temperature prior to use.
2. Take out a Wesail Coronavirus COVID-19 IgM/IgG Test Kit cassette from the foil pouch. Take one drop (about 10μL) of serum, plasma or whole blood sample with sampling pipette and add it to the sample well.
3. Break the front end of the dropper, then add 2 drops (about 60μL) of Diluent vertically to the sample well.
4. Observe the result within 6 minutes. Please do not read the result after 6 minutes.



Quick User Guide (1 test/kit)

Quick User Guide (20 tests/kit)

1. Equilibrate stored samples to room temperature prior to use.
2. Take out a Wesail Coronavirus COVID-19 IgM/IgG Test Kit cassette from the foil pouch. Take one drop (about 10μL) of serum, plasma or whole blood sample with sampling pipette and add it to the sample well, then add 2 drops (about 60μL) of Diluent vertically to the sample well.
3. Observe the result within 6 minutes. Please do not read the result after 6 minutes.



Quick User Guide(20 tests/kit)

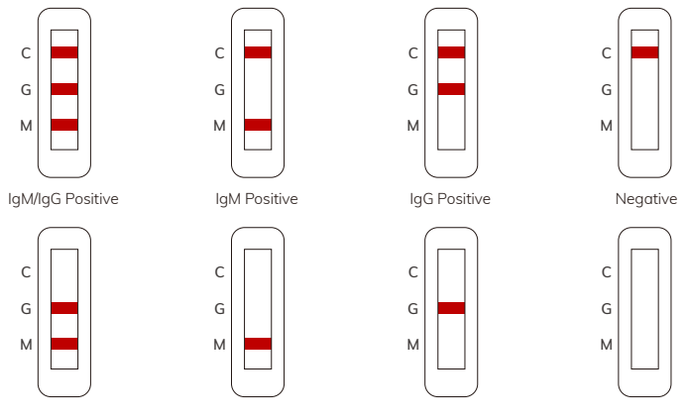
Caution: Keep the WESAIL Coronavirus COVID-19 IgM/IgG Test Kit cassette in sealed foil pouch prior to use. The cassette should be used within 30 minutes once the foil pouch is opened. If the temperature is higher than 30°C or under conditions of high humidity, it should be used immediately after the foil pouch is opened.

[Disposal]

Disposal of bio-hazardous materials should follow the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with all federal, state, and local regulations.

[Result Interpretation]

Positive: colored bands appear at both test band (M/G) and control band (C).
Negative: colored band appear at control band (C) only.
Invalid: no visible colored band appears at control band. The test procedures may not be followed correctly, or the cassette is deteriorated. It is recommended to retest the specimen.
Note: The color intensity of the test bands (M and G) may vary according to the concentration of antibodies in the sample. The lower the concentration, the weaker the intensity. The determination of a positive result should be based on the presence of the test bands (M and G) and control band (C), regardless of whether the test bands (M and G) are weaker than the control band (C).



[Limitations of the Procedure]

1. The test results of this product are for diagnostic aid only and cannot be used as the sole basis for confirming or excluding diagnosis. To achieve diagnostic purposes, the results should always be assessed in combination with clinical examination, medical history, and other laboratory data.
2. This product is only used for the qualitative detection of novel coronavirus IgG antibodies and IgM antibodies in human serum, plasma samples, but not for quantitative detection.
3. This product is only for the initial screening test. The disease diagnosis should be made in conjunction with clinical observations, patient history, epidemiological information, and other laboratory evidence.
4. Subject to the limitations of the assay methodology, the questionable results should be verified with other test methodology.