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CAT. NO.: VC012103

SARS-CoV-2 IgM/IgG Antibody Rapid Test

(Immunochromatography)

CE IVD

FOR PROFESSIONAL USE ONLY

PRODUCT NAME

SARS-CoV-2 IgM/IgG Antibody Rapid Test

(Immunochromatography)

INTENDED USE

The kit is used to detect the IgM and IgG antibodies to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in human serum, plasma or whole blood sample qualitatively. It is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2 .

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.

TEST PRINCIPLE

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.

When the sample contains the SARS-CoV-2 IgM antibody, it forms a complex with the gold label antigen (SARS-CoV-2 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 T2 line to form a complex and develop color (T2 line), which is a positive result. When the sample does not contain the SARS-CoV-2 IgM antibody, no complex can be formed at the T2 line, and no red band appears, which is a negative result.

When the sample contains the SARS-CoV-2 IgG antibody, it forms a complex with the gold label antigen (SARS-CoV-2 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 T1 line to form a complex and develop color (T1 line), which is a positive result. When the sample does not contain the SARS-CoV-2 IgG antibody, no complex can be formed at the T line, and no red band appears, which is a negative result.

Regardless of whether the SARS-CoV-2 IgM and/or IgG antibody is contained in the sample, the gold label quality control antibody will bind with the coated antibody at the C line to form a complex and develop color (C line).

MAIN COMPONENTS

The test cassette

Sample dilution: composed of 20 mM phosphate buffer solution (PBS)

STORAGE AND EXPIRY

Store as packaged in the sealed pouch at 4-30℃, 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℃-30℃). Please use immediately when the humidity＞60%.

SAMPLE REQUIREMENT

1. The reagent can be used for the serum, plasma and whole blood samples.

2. A serum / plasma / whole blood sample must be collected in a clean and dry container. EDTA, sodium citrate, heparin can be used as anticoagulants in plasma / whole blood samples. Detect immediately after collecting blood.

3.Serum and plasma samples may be stored at 2-8℃ for 3 days prior to assay. If testing is delayed more than 3 days, the sample should be frozen (-20℃ or colder). Repeat freeze and thaw for no more than 3 times. Whole blood samples with anticoagulant can be stored at 2-8℃ for 3 days, and should not be frozen; whole blood samples without anticoagulant should be used immediately (if the sample has agglutination, it can be detected by serum) .

TEST METHODS

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20℃-30℃) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity≤60%, Temp: 20℃-30℃). Please use immediately when the humidity＞60%.

For Serum/Plasma

1. Remove the test device from the sealed pouch, place it on a clean and level surface with the sample well up.

2. Add 10μl of serum or plasma vertically into the sample well .

3. Add two (2) drops (80-100μl) of sample buffer into the sample well .

4. Observe the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.

For Whole Blood

1. Remove the test cassette from the sealed pouch, place it on a clean and level surface with the sample well up.

2. Add 20μl of whole blood vertically into the sample well .

3. Add two (2) drops (80-100μl) of sample buffer into the sample well .

4. Observe the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.

INTERPRETATION OF RESULTS

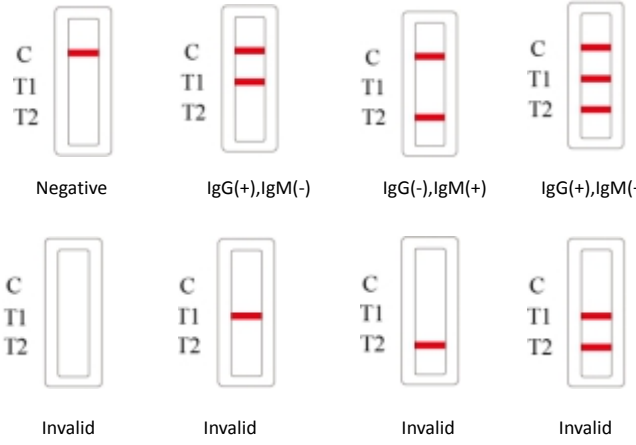
POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the T1 test region (T1),indicating the IgG positive.

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the T2 test region (T2),indicating the IgM positive.

POSITIVE: Three distinct red lines appear. One line should be in the control region (C) ,the T1 test region (T1) and the T2 test region (T2), indicating the IgG and IgM positive.

NEGATIVE: One red line appears in the control region(C). No red or pink line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.



LIMITATIONS

1. This reagent is designed for the qualitative screening test. Concentration of SARS-CoV-2 IgM/IgG antibody cannot be determined by this qualitative test. The depth of the T-line color is not necessarily related to the concentration of the antibody in the sample.

2. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment

should only be made by a physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

1. Sensitivity and Specificity

SARS-CoV-2 IgM

SARS-CoV-2 IgM Ab	PCR Test		Total
Rapid Test	Positive	Negative	
Positive	246	40	286
Negative	54	960	1014
Total	300	1000	1300

Analysis of coincidence rate of SARS-CoV-2 IgM Ab rapid test and PCR Test in serum samples:

Positive coincidence rate=246 / (246+54) × 100% = 82%,

Negative coincidence rate=960 / (40+960) × 100% = 96%,

Total coincidence rate=(246+960) / (246+54+40+960) × 100% = 92.8%.

SARS-CoV-2 IgG

SARS-CoV-2 IgG Ab	PCR Test		Total
Rapid Test	Positive	Negative	
Positive	279	25	304
Negative	21	975	996
Total	300	1000	1300

Analysis of coincidence rate of SARS-CoV-2 IgG Ab rapid test and PCR Test in serum samples:

Positive coincidence rate=279 / (279+21) × 100% = 93%,

Negative coincidence rate=975 / (25+975) × 100% = 97.5%,

Total coincidence rate=(279+975) / (279+21+25+975) × 100% = 96.5%.

2. Cross-reactivity

Specimens which tested positive with following various agents from patients were investigated with SARS-CoV-2 IgM/IgG Ab Rapid Test. The results showed no cross reactivity.

SARS-CoV-2 IgM	**SARS-CoV-2 IgG**
Mycoplasma pneumoniae IgM Ab	Mycoplasma pneumoniae IgG Ab
Influenza A IgM Ab	Parainfluenza IgG Ab
Influenza B IgM Ab	Respiratory Syncytial virus IgG Ab
Parainfluenza IgM Ab	Adenovirus IgG Ab
Respiratory Syncytial virus IgM Ab	Chlamydia pneumoniae IgG Ab
Adenovirus IgM Ab	-
Chlamydia pneumoniae IgM Ab	-

3. Interferences

The test result of SARS-CoV-2 IgM/IgG Ab Rapid Test do not be interfered with the substance at the following concentration:

Substance	**Concentration**
Hemoglobin	⩽ 10g/L
Triglyceride	⩽ 6mmol/L
Bilirubin	⩽ 1000μmol/L
No interference from rheumatoid factors, antinuclear antibodies and antimitochondrial antibodies.	

ATTENTIONS

1. For IN VITRO diagnostic use only.

2. Reagents should be used as soon as possible after opened. This reagent cannot be reused for disposable.

3. 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.

4.All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.

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INSTRUCTIONS OF SYMBOL

	Consult instruction for use		Keep dry
	Store between	LOT	Batch number
	For single use	IVD	In vitro diagnostic medical device
	Manufacturer		Date of manufacture
	Expire date	Σ	Contains sufficient for <n> tests
EC REP	European representative	CE	CE Mark

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