A Rapid IgM-IgG Combined Antibody Test Kit for SARS-CoV-2 (ICA)

INFECTIOUS DISEASE

Instructions For Use

Product Name | A Rapid IgM-IgG Combined Antibody Test Kit for SARS-CoV-2(ICA)

Product Types And Specifications | Type: I/II Test cassette:1pc/bag Kit:20pcs/box,50pcs/box,100pcs/box

Intended Use |

The Medomics Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2 is a lateral flow immunoassay intended for the qualitative, differential detection of IgG and IgM antibodies to SARS-CoV-2 in human serum, plasma, or whole blood samples (capillary or venous) including samples prepared by commonly-used anticoagulants (K2EDTA, NaCitrate, Li-Heparin) from individuals with current or prior SARS-CoV-2 infection. The Medomics Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2 is intended for use as an aid in identifying patients with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The Medomics Rapid IgM-IgG Combined Antibody Test for SARS- CoV-2 should not be used to diagnose acute SARS-CoV-2 infection.

Results are for the detection of SARS CoV-2 antibodies. IgM and IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Patients may have detectable virus present for several weeks following seroconversion.

The sensitivity of Medomics Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2 early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for Medomics Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2 may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a second, different IgG or IgM assay.

Summary |

The SARS-CoV-2 belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by SARS-CoV-2 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.

Test Principle |

Medomics Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2 is immunochromatography based. The test strip contains (1) colloidal gold-labeled recombinant SARS-CoV-2 antigen, (2) two detection lines (G and M lines) and one quality control C line fixed on a nitrocellulose membrane. M line is fixed with monoclonal anti-human IgM antibody for detecting the SARS-CoV-2 IgM antibody. G line is fixed with monoclonal anti-human IgG antibody for detecting the SARS-CoV-2 IgG antibody. The quality control antibody is fixed on the C line.

When an appropriate amount of test sample is added to the sample well of the test cassette, the sample will move forward along the test strip via capillary action. If the sample contains IgM antibody, the antibody will bind to the colloidal gold- labeled SARS-CoV-2 antigen.

The antibody/antigen complex will be captured by the anti-human IgM antibody immobilized on the membrane, forming a red M line and indicating a positive result for the IgM antibody.

If the sample contains IgG antibodies, the antibody will bind to the colloidal gold-labeled SARS-CoV-2 antigen and the antibody/antigen complex will be captured by the antibody immobilized on the membrane, forming a red G line and indicating a positive result for the IgG antibody.

If neither antibody is present, a negative result is displayed. The test strip also contains a quality control C line. Regardless of what antibodies are present the C line should appear to indicate that the sample has been transported properly through the membrane. If the C line does not appear it indicates that the test result is invalid and a new, unopened test cassette is required to repeat the test.

Contents of the Kit |

One test kit contains:

Type I: 20 Test Cassettes | 1 Buffer Solution | 1 Package Insert

Type II: 20 Test Cassettes | 20 Individual Buffer Solution | 1 Package Insert

One test cassette contains:

- A test strip in a plastic cassette
- Dried reagents with stabilizers
- Colloidal gold-labeled novel coronoavirus antigen
- Anti-mouse IgG polyclonal antibody
- Anti-human IgG monoclonal antibody
- Anti-human IgM monoclonal antibody

Materials not provided but required:

Sampling Devices | Alcohol Pads | Personal protective equipment | Timer

Warnings and Precautions |

- This test kit is used for in vitro diagnostics only.
- This test kit should only be used by trained healthcare professionals.
- This test kit should be used within 1 hour after opening the package, and samples from transport media will reduce sensitivity. The test cassette should not be used if being wet or polluted.
- Proper protection should be taken during testing to avoid splashing when adding sample.
- Dispose of all used or damaged test cassettes, buffer solution bottle or other kit components as biohazardous materials.
- Handle specimens in accordance to the OSHA Standard on Bloodborne Pathogens.
- Wash hands thoroughly after handling specimens.
- Do not use test cassette, buffer solution, or any other kit components if the pouch is damaged or the seal is broken.
- Do not use samples containing lipids, hemolysis, or turbidity which can affect results.
- Not for use with heat inactivated or other inactivated human specimen (blood, serum, plasma).
- This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.
- Test results should be read between 10 and 20 minutes after a specimen is applied to the sample well. Results read after 20 minutes may give erroneous results
- Do not use test cassette, buffer solution, or any kit component beyond the indicated expiration date.
- Bring all reagents to room temperature (2°C-30°C) before use.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus.
- Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

Storage Instructions |

The test kit should be stored away from direct sunlight at 2°C to 30°C with a shelf-life of 24 months. Do not freeze.

Sample Requirements |

- Suitable for human serum, plasma, or whole blood samples (capillary or venous) including samples prepared by commonly-used anticoagulants (K2EDTA, NaCitrate, Li- Heparin).
- Fresh samples should be collected and tested without inactivation.
- Not for use with heat inactivated or other inactivated human specimen (blood, serum, plasma).
- Serum and plasma samples can be stored at 2°C -8°C for 5 days. If long-term storage of serum or plasma samples is required, store at -20°C and avoid repeated freeze/thaw cycles.
- Anticoagulated whole blood samples can be stored at 2°C-8°C for 5 days.
- Before testing, samples stored in refrigerated or frozen storage should be slowly returned to room temperature and stirred. When particulates are clearly visible in the sample the precipitate should be removed by centrifugation before testing.

Test procedure |

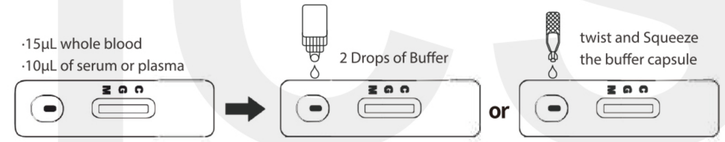
Do not open pouch until ready to use. Prep necessary materials: Test Cassette | Buffer Solution | Sampling Devices | Timer | Any necessary personal protecitve equipment

1 | Obtain a specimen using standard laboratory or provider protocols. Using appropriate sampling device, obtain 15µL of fingerstick or venous whole blood specimen, or 10µL of serum or plasma using appropriate titration device.
- For intravenous sampling follow standard laboratory protocols.

2 | Dispense the specimen into the Test Cassette sample well.
- Ensure that the entire sample is dispensed into the sample well.

3 | Remove colored cap of the Buffer Solution bottle and dispense 2 drops into the Test Cassette sample well , or twist to open the buffer capsule and squeeze all buffer into sample well.
- Remove any air bubbles in the dropper.
- Test on a level surface at room temperature.

4 | Allow test to run for 10 minutes. Read the results by viewing the detection window.
- Test results that have run over 20 minutes are invalid.

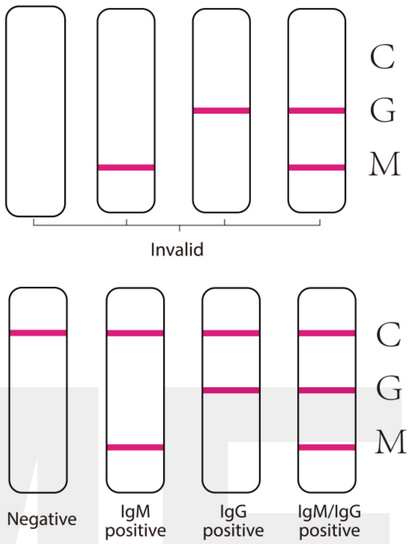


Test Method Limitations |

- This product can only be used to detect the IgG and IgM antibodies of the SARS-CoV-2 in human whole blood (capillary or venous), serum, or plasma. It cannot be used with other body fluids or secretions.
- Proper sample collection is critical for optimum test performance. Failure to follow the collection and sampling requirements may give inaccurate results.
- This product is only for qualitative testing and the intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Negative results may be caused by low concentration of the SARS-CoV-2 gG/IgM antibody in the sample and therefore cannot completely rule out the possibility of infection.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. Results should be used in combination with clinical observations and other testing methods.
- Test results can be affected by temperature and humidity.
- A negative or non-reactive result can occur if the virus has undergone minor amino acid mutation(s) in the epitoperecognized by the antibody detected by the test.
- This test should not be used for screening of donated blood.

Display of Results/Expected Values

A total of three detection lines are possible, with the control C line appearing when sample has flowed through the cassette.



1 | Invalid Result: If the quality control C line does not appear, then the test result is invalid and sample must be retested with a new cassette.

2 | Negative Result: If only the quality control C line appears and the detection G and M lines are not visible, then no SARS-CoV-2 antibody has been detected and the result is negative.

3 | Positive Result, M only: If both the quality control C line and the detection M line appear, then the SARS-CoV-2 IgM antibody has been detected and the result is positive for the IgM antibody.

4 | Positive Result, G only: If both the quality control C line and the detection G line appear, then the SARS-CoV-2 IgG antibody has been detected and the result is positive for the IgG antibody.

5 | Positive Result, G and M: If the quality control C line and both detection G and M lines appear, then the SARS-CoV-2 IgG and IgM antibodies have been detected and the result is positive for both the IgG and IgM antibodies.

Internal Quality Control Procedure

Each Test Cassette has a built-in control. A red colored line in the detection window at the Control line can be considered an internal positive procedural control. The Control line will appear if the test procedure has been correctly performed. If the Control line does not appear, the test is invalid and a new test must be performed. If the problem persists, please contact your local vendor or Medomics for technical support.

Performance Characteristics

Clinical Agreement Validation Study | The Medomics Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2 was validated using clinical samples.The test was validated against a panel of previously frozen samples consisting of one hundred and twenty-one (121) SARS-CoV-2 antibody-positive and one hundred and ten(110) antibody-negative plasma sample. The antibody-positive samples were collected from clinically confirmed SARS-CoV-2 infected patients confirmed with BioSciences chemiluminescent IgM and IgG assay (magnetic particles) which was approved by The National Medical Products Administration (NMPA).Within the 121 positive samples,there were 74 samples with both IgM and IgG antibodies present,34 samples were tested IgG only positive, 13 samples were tested IgM only positive. All 110 negative specimen tested by Medomics Rapid IgM-IgG Combined Antibody Test, there was 1 sample was tested IgG antibody positive.

Testing was performed using one lot of the Medomics Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2. Confidence intervals for SARS-CoV-2 displayed a combined sensitivity of 100% and a combined specificity of 99.09%.

Table 1: Summary Results

Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2	Clinical Diagnosis				
	Clinical Diagnosis			Antibody Positive	
	IgM+	IgM+	IgM-	Negative	Total
	IgG+	IgG-	IgG+		
IgM+,IgG+	74				74
IgM+,IgG-	1	12			13
IgM-,IgG+			34	1	35
IgM-,IgG-				109	109
Total	75	12	34	110	231

Table 2: Summary Statistics

Measure	Estimate	95% Confidence Interval
IgM Sensitivity	100%(87/87)	94.73%-100%
IgM Specificity	100%(110/110)	95.79%-100%
IgG Sensitivity	99.08%(108/109)	94.99%-99.98%
IgG Specificity	99.09%(109/110)	95.04%-99.98%
Combined Sensitivity	100%(121/121)	97.00%-100%
Combined Specificity	99.09%(109/110)	95.04%-99.98%

Table 3: Clinical Sensitivity by Days After Onset of Symptoms

Days	Samples	IgM+	IgG+
1-5	42	7(16.7%)	6(14.3%)
6-10	43	15(34.9%)	17(39.5%)
11-15	47	42(89.4%)	40(85.1%)
16-20	32	28(87.5%)	30(93.8%)
≥ 20	51	45(88.2%)	51(100.0%)

Cross reactivity

Cross-reactivity of the Medomics Rapid IgM-IgG Combined Antibody Test was evaluated using specimens containing the antibodies and virus listed below.the results showed no cross reactivity with the following:

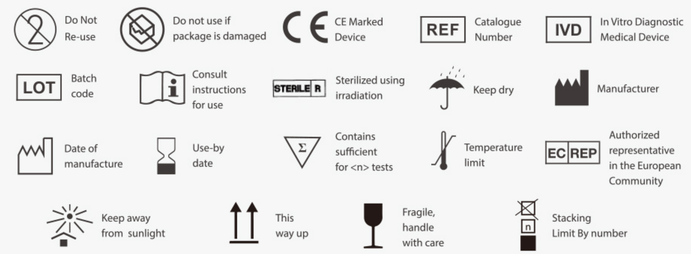
Endemic human coronavirus	**H1N1**	**H3N2**
H7N9	**Influenza B**	**Rhinovirus/Enterovirus**
Adenovirus	**Respiratory tract syncytial virus**	**Human metapneumonia virus**
Hepatitis B	**Hepatitis C**	**HIV**
Haemophilus influenza	**Antinuclear antibody**	**Parainfluenza Virus 3**

Interference

The test results of Medomics Rapid IgM-IgG Combined Antibody Test are not interfered with the substance at the following concentration.

Substannce	Concentration
RF	300 IU/mL
HAMA	200 ng/mL
Hemoglobin	5mg/mL
Triglyceride	20 mM
Bilirubin	27 μmol/L
Serum albumin	180 g/L
Human IgG	90 g/L
Human IgM	4 g/L
Plasma cholesterol	2.5 g/L

The test results of Medomics Rapid IgM-IgG Combined Antibody Test are not interfered with these drugs:Heparin, EDTA, phenylephrine, oxymetazoline, sodium chloride, beclomethasone, dexamethasone, flunisolide, triamcinolone acetonide, budesonide, mometasone, fluticasone, histamine hydrochloride, a-interferon, zanamivir, ribavirin, oseltamivir, peramivir, lopinavir, ritonavir, arbidol and tobramycin.



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