Severe Acute Respiratory Syndrome Coronavirus 2(SARS-CoV-2) IgM/IgG Antibody Assay Kit by Colloidal Gold Method

Note Changes Highlighted

Cat. No.

EIM4101080: Cassette: 10 Tests
EIM4102080: Cassette: 20 Tests
EIM4103080: Strip: 50 Tests×2

Intended use

For in vitro diagnostic use in the qualitative determination of IgM and IgG antibodies to SARS-CoV-2 virus in human serum, plasma and whole blood specimens. It is intended for use only as a supplementary detection indicator in conjunction with nucleic acid detection in individuals with clinical signs and symptoms consistent with SARS-CoV-2 infection. It cannot be used as the sole basis for the confirmation or exclusion of COVID-19. And it is for medical institutions use only. A positive test result needs further confirmation. A negative test result cannot rule out the possibility of infection.

Summary

This product is limited to clinical use and emergency reserves during the outbreak of COVID-19 since December 2019, and cannot be used as a routine in vitro diagnostic reagent in clinical practice. The test results of this kit are for clinical reference only. It is recommended to combine the patient's clinical manifestations and other laboratory tests to conduct a comprehensive analysis of the condition.
Carrying out laboratory tests for SARS-CoV-2 should comply with the requirements of the local regulations and guidelines, etc., and the biosecurity should be well considered
SARS-CoV-2 is a positive-sense single-stranded RNA virus, belonging to genus Betacoronavirus which can cause acute pneumonia in humans. The incubation period for human infection with new coronavirus is 1-14 days, mostly 3-7 days. The virus is transmitted mainly through respiratory droplets and close contact, patients infected with the SARS-CoV-2 may be asymptomatic or develop symptoms such as fever, cough, fatigue, or gradually develop severe symptoms such as dyspnea. After infection, human body will develop an immune response against the virus and produce antibodies. IgM antibodies are produced faster (5~7 days) and gradually disappear after a few weeks or months, IgG antibodies are produced later (10~14 days), with higher affinity, and can last for many years or even survive.

Test principle

SARS-CoV-2 IgM/IgG Antibody Assay uses the principle of lateral flow immunochromatography. The IgG antibody or IgM antibody against the SARS-CoV-2 virus in the sample first binds to the colloidal gold-labeled coronavirus recombinant antigen on the colloidal gold. The immuno-complex formed by the IgM anti-viral antibody and the colloidal gold-labeled antigen is then captured by the mouse anti-human IgM monoclonal antibody at the detection line M. This reaction will form a neat red band at the position M. The presence or absence of the red band is the interpretive criteria for the presence of IgM anti-viral antibodies. By the same principle, the IgG anti-viral antibody-antigen-colloid gold complexes move in the mobile phase during the lateral flow chromatographic process, and are captured by the anti-human IgG antibody immobilized on the detection line G. The accumulation of colloid gold containing IgG antibody-antigen-colloid gold complexes at the detection line G forms a neat red band. The presence or absence of the red band is the interpretive criteria for the presence of SARS-CoV-2 IgG antibodies in the sample. The colloidal gold-labeled Chiken IgY continues to move forward and reacts with sheep anti-chicken IgY polyclonal antibody on the quality control line C, where a neat red band C is the indication that the detection reaction system is effective.

Reagents components

Test strip: Nitrocellulose membrane coated with mouse anti-human IgG monoclonal antibody, mouse anti-human IgM monoclonal antibody and sheep anti-chicken IgY polyclonal antibody, conjugate pad coated with colloidal gold complex of novel coronavirus recombinant antigen and Chiken IgY, sample pad, absorbent paper, etc.
Diluent: NaCl, NP40.
Dropper (Optional)

Components from different lots cannot be used interchangeably.

Precautions and warnings

- For in vitro diagnostic use only.
- The diluent provided in the kit should be used for the test. The test result using the other diluent is invalid.
- Avoid freezing samples, all samples must be allowed to reach ambient temperature before starting the assay.
- After the aluminum foil bag is open, the product should be used within 1 hour. The test procedure should be completed as soon as possible especially in high temperature and high humidity environment.
- The product in an open aluminum foil bag is considered to be used, and this product is for one-time use only.
- After opening the upper cover of the container and taking out the strip, the container should be capped immediately to avoid the extended exposure of the remaining strips in the container to the humid environment which may affect the test result.
- Do not use samples that have been left for too long, or with bacteria growth, or have odors, since microbial contamination can cause non-specific test results.
- Due to the difference in the concentrations of antibodies in the positive samples, the red bands of the detection lines (line G/line M) can develop into different shades of color. At the specified observation time, regardless of the color of the band, even a very weak band should be interpreted as a positive result.
- After the test is completed, the tested samples and tested strip cards should be treated as the infectious waste. Pay attention to the biological safety of the operation. Desiccants in aluminum foil bags cannot be taken orally.
- This product requires proper visual inspection in a well-lit room, please do not interpret the results in a dim light environment. Practitioner with color blindness and color weakness may give incorrect test results.
- This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled in accordance with applicable laws. All materials contaminated with patient specimens should be inactivated by validated procedures (autoclaving or chemical treatment) in accordance with applicable regulations.

Storage and stability

The product is stable until the expiration dates stated on the box and aluminum foil bag labels, when sealed and stored at 4°C ~30°C and protected from direct sunlight. Avoid freezing.

Specimen collection and preparation

- Collect serum, EDTA or heparin anticoagulated plasma, or anticoagulated whole blood according to the standard operation procedure of the sample collection tube manufacturer. Blood collection tubes produced by different manufacturers have different raw materials and additives, which may lead to different results. This product has not been validated for blood collection tubes of different types, or different manufacturers. Each laboratory should determine the suitability of the blood collection tubes and serum isolation products it uses.
- Transport and store the samples under low temperature conditions. Serum or plasma samples can be stored for 7 days at 2°C~8°C, or 2 months at -20°C, and repeated freeze-thaw cycles should not exceed 3. Note that the whole blood samples can only be stored for 3 days at 2°C~8°C.
- At ambient temperature (10°C~30°C), equilibrate the samples stored at low temperature for at least 30 minutes before use.
- When using serum or plasma samples, if there is turbidity or visible flocculent fibrin, centrifuge the samples at 3000 rpm for 3 minutes, and use the supernatant.
- The samples should be free of severe lipemia, hemolysis, jaundice, or microbial contamination.

Assay procedure

Please read this manual carefully before use. Please follow the procedures below.

- Card:

◆ Tear off the seal of aluminum foil bag and carefully take out the test card.
◆ Transfer 10μL of serum or plasma, or 20μL whole blood into the sample well of the test card. If using a 10μL plastic dropper, add 1 drop of serum or plasma, or 2 drops of whole blood.
◆ Add 2 drops of diluent, and leave it at ambient temperature.
◆ Observe the result within 10~15 minutes, and the interpretive result is invalid after 15 minutes.

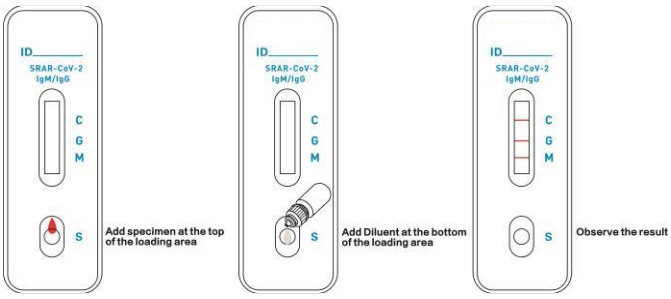


Figure 1 Schematic diagram of card type test procedure

- Strip:

◆ Open the container, carefully take out the test strip and lay it flat on the record card.
◆ Transfer 10μL of serum or plasma, or 20μL whole blood into the loading area of the test strip. If using a 10μL plastic dropper, add 1 drop of serum or plasma, or 2 drops of whole blood.
◆ Add 2 drops of diluent, and leave it at ambient temperature.
◆ Observe the result within 10~15 minutes, and the interpretive result is invalid after 15 minutes.

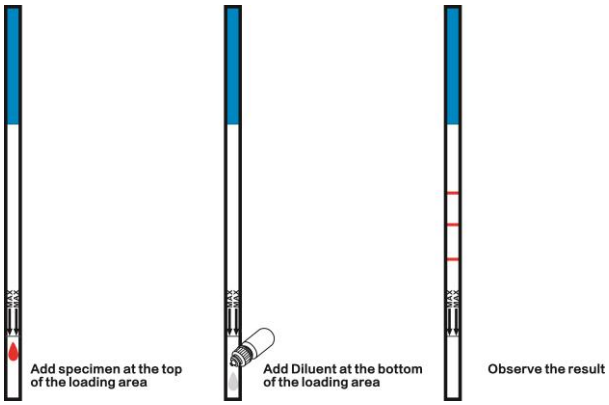


Figure 2 Schematic diagram of strip type test procedure

Result Interpretation

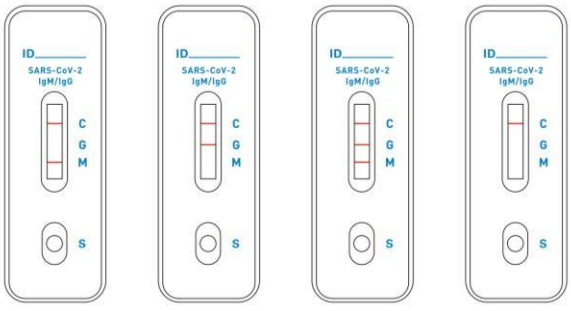
- Positive (+):

Both the quality control line (line C) and the detection line (line G) developed color, indicating that a novel coronavirus IgG antibody was detected in the sample.

Both the quality control line (line C) and the detection line (line M) developed color, indicating that a novel coronavirus IgM antibody was detected in the sample.

The quality control line (line C), detection lines (line G) and (line M) all developed color, indicating that both the novel coronavirus IgG antibody and the novel coronavirus IgM antibody were detected in the sample.

- Negative (-): Only the quality control line (line C) developed color.
- Invalid: The quality control line (line C) did not develop color, indicating that the test strip has failed due to deterioration or incorrect operation. Retest is recommended.



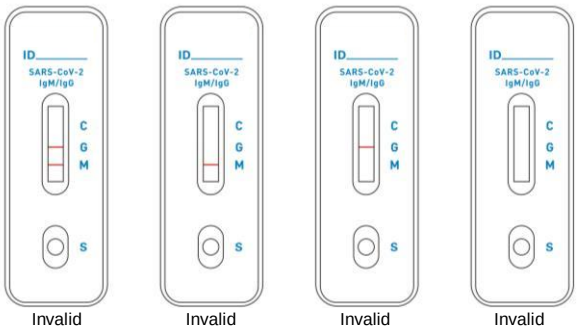


Figure 3 Schematic diagram of card type test result determination

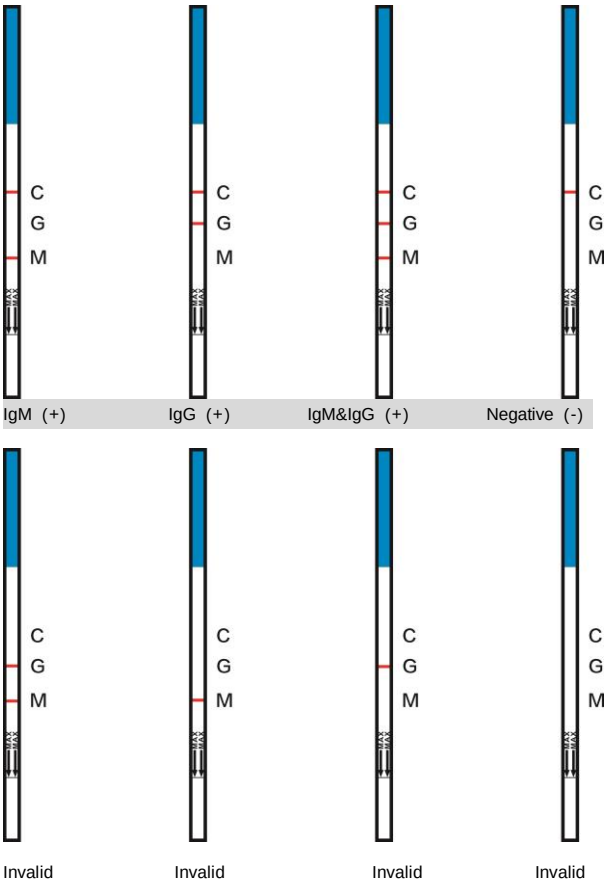


Figure 4 Schematic diagram of strip type test result determination

Limitation

- 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.
- This product is only for the qualitative detection of SARS-CoV-2 IgG antibodies and IgM antibodies in human serum, plasma, or whole blood samples but not for quantitative detection.
- 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.
- Subject to the limitations of the assay methodology, the questionable results should be verified with other test methodology.
- Due to the limited number of verification of endemic human coronavirus (HKU1, 0C43, NL63 and 229E) patient samples, the test could have cross-reactive false positive results.

Performance characteristics

1. Sensitivity

Detection of national sensitivity reference materials, the results meet the requirements.
Detection of manufacturer's sensitivity reference materials, the results are as follows:
IgM antibody: L1 is positive, L2 can be positive or negative, and L3 is negative.
IgG antibody: L1 is positive, L2 can be positive or negative, and L3 is negative.

2. Negative coincidence rate

Detection of national negative reference materials, the results meet the requirements.

Detection of manufacturer's negative reference materials, the results are as follows:
IgM antibody: Negative coincidence rate (-/-) is no less than 24/25.

IgG antibody: Negative coincidence rate (-/-) is no less than 24/25.

3. Positive coincidence rate
Detection of national positive reference materials, the results meet the requirements.
Detection of manufacturer's positive reference materials, the results are as follows:
IgM antibody: Positive coincidence rate (+/+) is 5/5.

IgG antibody: Negative coincidence rate (+/+) is no less than 9/10.

4. Repeatability

Detection of national repeatability reference materials, the results meet the requirements.
Detection of manufacturer's repeatability reference material in parallel for 10 times. The IgM antibody and IgG antibody are positive and consistent in color.

5. Cross-reactivity

This product has no observed cross-reaction with endemic human coronavirus (HKU1, 0C43, NL63 and 229E), H1N1, H3N2, H5N1, H7N9, influenza B, respiratory syncytial virus, rhinovirus, adenovirus, enterovirus, EB virus, measles virus, human cytomegalovirus, rotavirus, norovirus, mumps virus, varicella-zoster virus and mycoplasma pneumonia antibodies.

6. Interference

The bilirubin (1200μmol/L), hemoglobin (2g/L), triglycerides (17.6mmol/L), α-interferon (40ng/mL), Zanamivir (0.25μg/mL), Ribavirin (6.6μg/mL), Oseltamivir (15μg/mL), Paramivir (150μg/mL), Lopinavir (30μg/mL), Ritonavir (3μg/mL), Abidol (2.1μg/mL), Levofloxacin (9μg/mL), Azithromycin (15μg/mL), Ceftriaxone sodium (1.5g/mL), Meropenem (150μg/mL) , Tobramycin (12mg/L), histamine hydrochloride (200ng/mL), rheumatoid factor (2000IU/mL), total IgG (22.668mg/mL), total IgM (6mg/mL), HAMA (771.484ng/mL), anti-mitochondrial antibody (200AU/mL), anti-nucleosome antibody (200AU/mL) in the specimens and high concentration SARS-CoV-2-specific IgG antibody positive specimens have no significant effect on this assay.

7. Hook effect

This reagent has no obvious hook effect on high-concentration specificity IgM antibodies and IgG antibodies.

Vigilance

If any serious incident has occurred in relation to this product, please contact the manufacturer and report to the local competent authority.

Bibliography

1. COVID-19 diagnosis and treatment plan. National Health Office Medical Letter (2020) No. 145, 2020.2.19.
2. SARS-CoV-2 Laboratory Biosafety Guide. National Health Office Science and Education Letter (2020) No. 70, 2020.1.23
3. COVID-19 Laboratory Testing Technology Guide. National Health Office Letter of Disease Control, 2020.1.22.

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	CONSULT INSTRUCTIONS FOR USE
LOT	BATCH CODE
REF	CATALOG NUMBER
	USE BY
	DATE OF MANUFACTURE
	MANUFACTURER
Σ	SUFFICIENT FOR <N> TESTS
EC REP	AUTHORIZED REPRESENTATITVE IN THE EUROPEAN COMMUNITY

Symbols for use in the labeling

Symbols	Definition
	PROTECT FROM SUNLIGHT
	STORAGE TEMPERATURE LIMITATION
IVD	IN VITRO DIAGNOSTIC USE
	UPWARD
	DISPOSE IN TRASH AFTER USE
	RECYCLABLE MATERIAL