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

Note Changes Highlighted

Cat. No.

IM4101079: 10 Tests
IM4102079: 20 Tests
IM4103079: 100 Tests

Intended use

For in vitro diagnostic use in the qualitative determination of IgM and IgG antibodies to SARS-CoV-2 virus in human serum and plasma specimens. It is intended for use only in individuals with clinical signs and symptoms consistent with SARS-CoV-2 infection as a supplementary detection indicator in conjunction with nucleic acid detection. It cannot be used as the sole basis for the confirmation or exclusion of novel coronavirus-infected pneumonia. And it is for medical institutions use only.

Summary

Coronavirus is a single-stranded positive-strand RNA virus. Its genetic material is the largest among all RNA viruses, and it is divided into four genera: α, β, γ, and δ. SARS-CoV-2 is a novel coronavirus that was first discovered in Wuhan virus pneumonia cases in 2019, and was named by the World Health Organization on January 12, 2020. It belongs to the genus β and is listed as class VII coronavirus, which can cause viral pneumonia that is mainly manifested in respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death.

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 will first bind to the colloidal gold-labeled coronavirus recombinant antigen on the colloidal gold. The IgG anti-viral antibody-antigen-colloid gold complex will move in the mobile phase during the lateral flow chromatographic process, and captured by the anti-human IgG antibody immobilized on the detection line G. The accumulation of colloid gold containing IgG antibody-antigen-colloid gold complex at the detection line G will form 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. By the same principle, the immuno-complex complex formed by the IgM anti-viral antibody and the colloidal gold-labeled antigen will be captured by the mouse anti-human IgM monoclonal antibody at the detection line M. This reaction will form a neat red band M. The presence or absence of the red band is the interpretive criteria for the presence of IgM anti-viral antibodies. The colloidal gold-labeled avidin continues to move forward and reacts with biotin 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 card: Nitrocellulose membrane coated with mouse anti-human IgG monoclonal antibody, mouse anti-human IgM monoclonal antibody and biotin, conjugate pad coated with colloidal gold complex of novel coronavirus recombinant antigen and avidin, sample pad, absorbent paper, etc.
Diluent: NaCl, NP40.
Dropper.
Components from different lots cannot be mixed or interchanged.

Precautions and warnings

- For in vitro diagnostic use.
- The diluent provided in the kit should be used for the test. The test result using the non-matched 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. The left-over product in an open bag cannot be stored for later use.
- 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 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 tested for all types, and manufacturers of blood collection tubes that may be used. 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. The samples can be stored for 7 days under the conditions of 2°C - 8°C. Serum or plasma samples can be stored for 3 months at -20°C, and repeated freeze-thaw cycles should not exceed 3.
- 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.
- Bilirubin≤1200μmol/L, hemoglobin≤2 g/L, and triglyceride≤17.6mmol/L in the sample have no significant effect on the interpretive results of this reagent.

Assay procedure

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

- Tear off the seal of aluminum foil bag and carefully take out the test card.
- Take 10μL of sample into the diluent-containing test tube and blend well for 5s~10s.
- Add 2~3 drops of blended sample vertically and slowly to the sample well of the test card, and leave it at ambient temperature.
- Observe the result within 10~15 minutes, and the interpretive result is invalid after 15 minutes

Result Interpretation

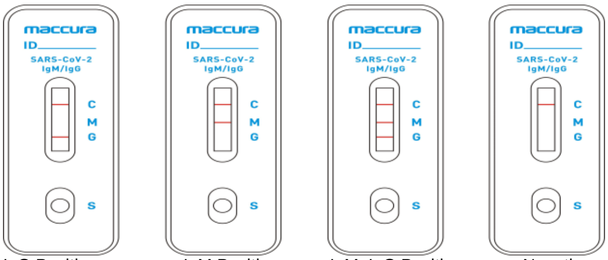
- Positive (+):

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.

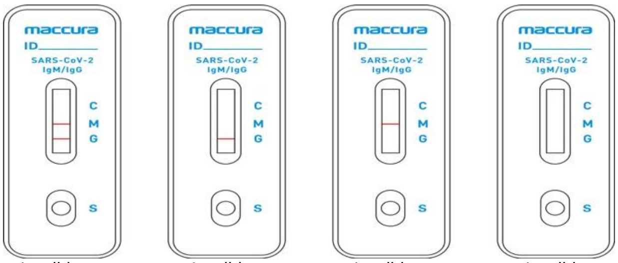
Both the quality control line (line C) and the detection line (line M) developed color, indicating that a novel coronavirus IgM antibody was detected in the sample.

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.



IgG Positive | IgM Positive | IgM, IgG Positive | Negative



Invalid | Invalid | Invalid | Invalid

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 novel coronavirus IgG antibodies and IgM antibodies in human serum, plasma 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.

Performance characteristics

1. Limit of detection (LOD)

Detection of 3 SARS-CoV-2-IgG enterprise LOD reference products, L1 is positive, L2 can be positive or negative, and L3 is negative.
Detection of 3 SARS-CoV-2-IgM enterprise LOD reference products, L1 is positive, L2 can be positive or negative, and L3 is negative.

2. Positive coincidence rate

Detection of 5 SARS-CoV-2-IgM/IgG enterprise positive reference products, IgG antibodies in P1, P2, and P3 are positive, IgM antibodies in P4 and P5 are positive, and the positive coincidence rate≥5/5.

3. Negative coincidence rate

Detection of 20 SARS-CoV-2-IgM/IgG enterprise negative reference products, the coincidence rate of IgG antibody≥20/20, and the coincidence rate of IgM antibody negative reference products≥18/20.

4. Repeatability

Detection of 1 SARS-CoV-2-IgM/IgG enterprise repeatability reference product in parallel for 10 times. The IgM antibody/IgG antibody is positive and consistent in color development.

5. Cross-reactivity

This product has no 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, Anti-human cytomegalovirus, rotavirus, norovirus, mumps virus, and varicella-zoster virus antibodies.

6. Interference

Drugs commonly used in the treatment of pathogen infections, such as alpha-interferon, zanamivir, ribavirin, oseltamivir, paramivir, lopinavir, ritonavir, abidol, levofloxacin, azithromycin, ceftriaxone, meropenem, tobramycin, etc. have no significant effect on the determination of this product.

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. Xu Weiwen. Evaluation of analytical performance of commonly used technical indicators for the development of in vitro diagnostic reagents [J]. Journal of Molecular Diagnosis and Therapy, 2010, 2 (2): 140-144.
2. Zhang Zhuoran. Clinical Microbiology and Microbiological Examination (3rd ed.), People's Medical Publishing House, 2006: 415-419.

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Maccura Biotechnology Co., Ltd.
16#, Baichuan Road, Hi-tech Zone, 611731
Chengdu, PEOPLE'S REPUBLIC OF CHINA
Tel : +86 28 8782 6777
Fax: +86 28 8782 5783
E-mail: maccura@maccura.com

EC REP Shanghai International Holding Corp.GmbH(Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

www.maccura.com

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
	CONSULT INSTRUCTIONS FOR USE
LOT	BATCH CODE
REF	CATALOG NUMBER
	USE BY
	DATE OF MANUFACTURE
	MANUFACTURER
Σ	SUFFICIENT FOR <N> TESTS