Selfdiagnostics SARS CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography)

ID: SABP0001

Instructions for use – READ BEFORE USE

INTENDED USE

This product is used for the qualitative detection of IgM and IgG antibodies to SARS-CoV-2 in human serum, plasma, whole blood, or fingertip blood *in vitro*. This product is only a supplementary detection indicator for suspected cases with a negative detection of SARS-CoV-2 nucleic acid or used in conjunction with nucleic acid detection in the diagnosis of suspected cases. It cannot be used as a basis for diagnosis and exclusion of COVID-19 and is not suitable for general population screening. It is for use in medical institutions only. A positive test result needs further confirmation. A negative test result cannot rule out the possibility of infection.

TEST PRINCIPLE

This product is based on colloidal gold immune technology, spraying SARS-CoV-2 recombinant antigen labeled with colloidal gold and chicken IgY on the gold pad; two detection lines (G-line and M-line) and a control line (C-line) are coated on the nitrocellulose membrane. The M-line is coated with mouse anti-human IgM monoclonal antibody, which is used to detect IgM antibody to SARS-CoV-2. The G-line is coated with mouse anti-human IgG monoclonal antibody for detecting the IgG antibody to SARS-CoV-2. The C-line is coated with rabbit anti-chicken IgY. When testing, an appropriate amount of sample is added to the sample well of the test card. The sample will move forward along the test card under capillary action. If the sample contains the IgM antibody to SARS-CoV-2, the antibody binds to the colloidal gold-labeled SARS-CoV-2 recombinant antigen. The immune complex will form a complex with the coated mouse anti-human IgM monoclonal antibody at the M-line, showing a purple-red M-line, suggesting that the test is positive for IgM antibody to SARS-CoV-2. If the sample contains the IgG antibody to SARS-CoV-2, the antibody binds to the colloidal gold-labeled SARS-CoV-2 recombinant antigen, and the immune complex will form a complex with the coated mouse anti-human IgG monoclonal antibody at the G-line, showing a purple-red G-line. This suggests that the test is positive for IgG antibody to SARS-CoV-2. If the test G-line and M-line are not colored, a negative result is displayed. The test card also contains a control C-line. The purple-red control C-line should appear regardless of whether a test line appears. If the control C-line does not appear, the test result is invalid, and the sample needs to be tested again.

STORAGE AND VALIDITY

Store the test kit at 2-30°C. Valid period of 6 months. The test card should be used within 20 minutes once the foil pouch was opened. Do not use the test after the expiry date shown on the label.

PACKAGE SPECIFICATION:

25 tests/pack.

MATERIAL PROVIDED:

1. **Test card:** The test card consists of a plastic card and a test strip. The test strip consists of a nitrocellulose membrane (the detection area is coated with mouse anti-human IgM antibody and mouse anti-human IgG antibody, and the quality control area is coated with rabbit anti-chicken IgY antibody), gold pad (sprayed with colloidal gold-labeled SARS-CoV-2 recombinant antigen and chicken IgY antibody), sample pad, absorbent paper, and PVC board.

2. **Sample diluent:** Buffer solution (pH 6.5-8.0) containing phosphate corresponds to the kit's specifications.

3. **Capillary pipette:** corresponded to the specifications of the kit.

4. **Pasteur pipette:** corresponded to the specifications of the kit.

Table 1: Content of package specification.

Package	25 tests/pack
Test cards	25
Sample diluent	4 ml/bottle | 1 bottle
Capillary pipette	≥ 25 pcs | 1 bag
Pasteur pipette	≥ 25 pcs | 1 bag

Note: The components in different batches of kits cannot be used interchangeably. Abbreviation: pcs – pieces.

ADDITIONAL MATERIAL REQUIRED:

1. Equipment for blood sampling (e.g., lancet for fingertip blood, butterfly cannula and tubes, alcohol pad)
2. Centrifuge (for serum or plasma specimen only)
3. Timer

SAMPLE REQUIREMENT

1. For serum, heparin, and sodium citrate anticoagulated plasma, EDTA anticoagulated whole blood samples and fingertip blood are required.

2. The samples should be shaken up and down 5-10 times immediately after collection and should not be shaken with too much force.

3. Serum, plasma, whole blood, or fingertip blood samples can be stored at 2-8 °C for seven days; serum and plasma samples can be stored frozen at -20 °C for three months. It should be returned to room temperature before the test. The test should be conducted as soon as possible within 8 hours after the sample is collected. If the samples cannot be processed promptly, they should be stored at 2-8 °C. Avoid repeated freezing and thawing.

4. Samples with severe lipemia, hemolysis, and microbial contamination cannot be used for the detection by this product; Turbid samples impact the determination of results of this product. The use of heat-inactivated samples is not recommended.

PRECAUTIONS

1. Equilibrate the sample diluent and test card to room temperature (more than 30 minutes) before testing.

2. The test should be strictly performed as per the instructions.

3. The result must be read at 15 minutes, and any result after 18 minutes is invalid.

4. Do not repeatedly freeze and then thaw highly hemolyzed and lipemia samples.

5. The test samples should be regarded as infectious agents. They must be operated following the infectious disease laboratory operation rules and adhere to all biological safety precautions.

6. This product is a single-use in vitro diagnostic reagent. Do not reuse it. It is only used for in vitro diagnostics. Do not use reagents or kits beyond the stated expiry date.

7. Do not use a kit with any obvious damage or a damaged test card in the package.

8. There is desiccant in the aluminum foil bag, this must not be taken orally.

9. There may be bleeding or slight hemolysis during the product's use, which is normal and does not affect the outcome of the result.

Caution: After the test is completed, the used test cards, sample diluents, straws, etc. should be treated as biomedical waste. Users should take precautions to ensure their safety and that of others.

DETECTION PROCEDURE

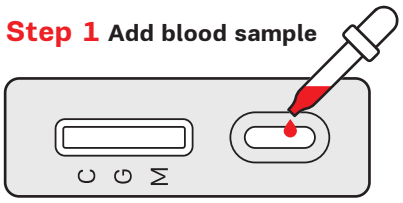
1. If the reagent is removed from the refrigerator, it needs to be equilibrated to room temperature before testing. The test should be performed at room temperature.

2. Open the aluminum foil bag of the test card, take out the test card and place it horizontally on the table.

3. Pipette about 10 μL of serum/plasma to the first scale of the capillary pipette (or 1 drop with a Pasteur pipette), or pipette about 20 μL of whole blood/fingertip blood to the second scale of the capillary pipette (Or 2 drops with a Pasteur pipette) into the sample hole, and then also pipette 60 μL of buffer (2 drops with the Drip bottle) into the sample hole of the test card.

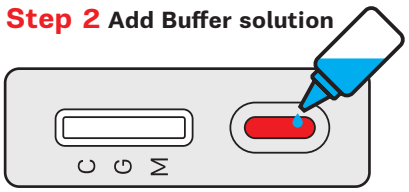
4. Read the result **within 15 minutes**. Any results read after 18 minutes are invalid.

Step 1 Add blood sample



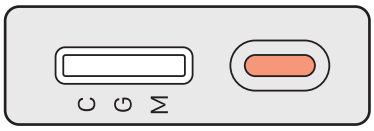
serum/plasma (10μL with the Capillary pipette or 1 drop with the Pasteur pipette) whole blood/fingertip blood (20μL with the Capillary pipette or 2 drops with the Pasteur pipette)

Step 2 Add Buffer solution



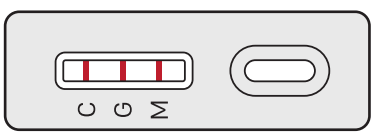
buffer (2 drops with the Drip bottle)

Step 3 Incubation reaction



Wait for 15 minutes

Step 4 Read the result



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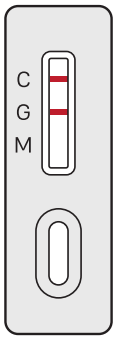
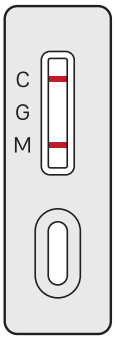
INTERPRETATION OF RESULTS

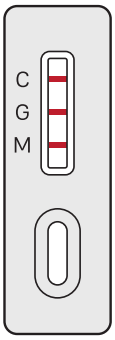
1. Positive results: Both the test line (M) and the control line (C) show color bands, indicating that the test is positive for IgM antibody to SARS-CoV-2. Both the test line (G) and the control line (C) show color bands, indicating that the test is positive for the IgG antibody to SARS-CoV-2. The test line (M), (G) and control line (C) all show color bands, indicating that the test is positive for IgM and IgG antibodies to SARS-CoV-2. As shown in the figure below.



IgG positive

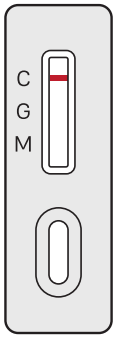


IgM positive



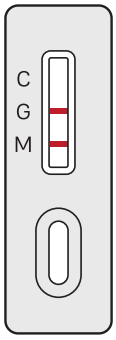
IgG and IgM positive

2. Negative results: If only the control line C develops color, and neither the G nor M detection lines develop color, no IgM/IgG antibody to SARS-CoV-2 is detected, and the result is negative. As shown in the figure below.

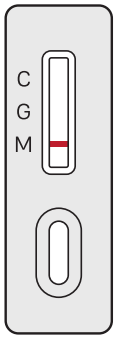


negative

3. Invalid results: No band appears on the control line (C), and whether the detection line (G) and/or (M) shows a band it is judged as an invalid result. As shown in the figure below.



Invalid



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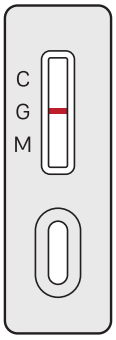

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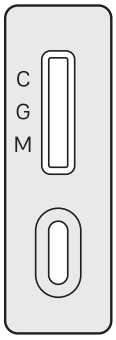

Invalid

LIMITATIONS OF THE TEST

1. The kit is only for the detection by using human serum, plasma, whole blood, or fingertip blood samples.

2. The test results may be wrong due to technical reasons, operational errors, and other sample factors.

3. In the early stage of infection, if the virus-specific IgM antibody is not produced or the titer is very low, it will lead to negative results. If a virus infection is suspected, the patient should be reminded to check again within 7-14 days. During the reexamination of the patient, the second sample and the backup first sample should be tested separately under the same conditions simultaneously. If the test result is positive after reexamination, then antibody concentration was possibly very low in the first sample examined.

4. The test results of this product are only for clinical reference and should not be used as the sole basis for clinical diagnosis and/or treatment. The clinical management of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests, treatment response, epidemiology and other patient-related information.

5. Patients with an impaired immune function or are receiving immunosuppressive therapy, including those infected with human immunodeficiency virus (HIV) or receiving immunosuppressive therapy after organ transplantation, will likely have a limited reference value for serological IgM antibody detection, that may lead to a wrong medical interpretation.

6. Those who have accepted blood transfusions or have been treated with other blood products in recent months should be cautious in analyzing their positive test results.

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PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The Selfdiagnostics SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography) was evaluated with 200 clinically confirmed SARS-CoV2-positive samples, and 100 clinically excluded samples resulting in the following performance:

Table 2: Clinical confirmed samples – Serum – Sensitivity

Item	Positive	Negative	Total	Sensitivity	95% CI*
Days of infection < 7days					
IgM Antibody	**47**	**13**	**60**	**78.33%**	**66.38%-86.88%**
IgG Antibody	**38**	**22**	**60**	**63.33%**	**50.68%-74.38%**
Days of infection 7 – 14 days					
IgM Antibody	**67**	**13**	**80**	**83.75%**	**74.16%-90.25%**
IgG Antibody	**69**	**11**	**80**	**86.25%**	**77.03%-92.15%**
Days of infection > 14 days					
IgM Antibody	**9**	**51**	**60**	**15.00%**	**8.10-26.11%**
IgG Antibody	**58**	**2**	**60**	**96.67%**	**88.64%-99.08%**
Total clinically confirmed cases					
IgM or IgG	**176**	**24**	**200**	**88.00%**	**82.77%-91.80%**

* 95 % Confidence interval

Table 3: Clinical excluded samples – Serum – Specificity

Item	Positive	Negative	Total	Specificity	95% CI
IgM or IgG	**1**	**99**	**100**	**99.00%**	**94.55%-99.82%**

Results of Consistency Analysis with Serum and Plasma:

50 serum and plasma samples (30 clinically confirmed and 20 clinically excluded samples) have been analyzed with the Selfdiagnostics SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography) in direct comparison. Comparing the results of serum and plasma, the positive coincidence rate of IgM was 100%, the negative coincidence rate was 100%, the positive coincidence rate of IgG was 100%, and the negative coincidence rate was 100%; the kappa value was 1.00. Thus, the consistency between the serum and plasma is perfect.

Results of Consistency Analysis with Serum and Whole blood:

50 serum and plasma samples (30 clinically confirmed and 20 clinically excluded samples) have been directly analyzed in comparison with the Selfdiagnostics SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography. Comparing the results of the serum and whole blood, the positive coincidence rate of IgM was 95.83%, the negative coincidence rate was 96.15%, the positive coincidence rate of IgG was 96.3%, and the negative coincidence rate was 100%; the kappa value for IgM was 0.9199, the kappa value for IgG was 0.9599. Thus, the consistency between serum and whole blood is perfect.

Results of Consistency Analysis with Plasma and Fingertip blood:

46 plasma and fingertip blood samples (18 clinically confirmed and 28 clinically excluded samples) have been directly analyzed in comparison with the Selfdiagnostics SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography). Comparing the results of the plasma and fingertip blood, the positive coincidence rate of IgM was 100%, the negative coincidence rate was 100%, the positive coincidence rate of IgG was 100%, and the negative coincidence rate was 100%; the kappa value was 1.00. Thus, the consistency between plasma and fingertip blood is perfect.

Cross-reactivity

The Selfdiagnostics SARS-CoV2 IgM/IgG Antibody Assay Kit has been tested for endemic human coronavirus antibodies (HKU1, OC43, NL63 and 229E), new type A H1N1 influenza virus (2009) antibody, seasonal H1N1 influenza virus antibody, H3N2 antibody, H5N1 antibody, H7N9 antibody, Influenza B Yamagata antibody, Victoria antibody, RSV antibody, Rhinovirus A, B, C antibody, Adenovirus 1, 2, 3, 4, 5, 7, 55 antibodies, Enterovirus A, B, C, D antibodies, EBV antibodies, Measles virus antibodies, human cytomegalovirus antibodies, Rotavirus antibodies, Norovirus antibodies, Mumps virus antibodies, VZV antibodies, Mycoplasma pneumoniae antibodies. The sample matrix applied was human serum. The results showed no cross-reactivity.

Interference

In the table below, potentially interfering compounds have been tested at recommended concentrations using the Selfdiagnostics SARS-CoV2 IgM/IgG Antibody Assay Kit. The sample matrix applied was human serum.

Table 4: Potentially interfering compounds tested

Compound	Concentration	Compound	Concentration
bilirubin	0.5 g/L	lopinavir	40.0 mg/L
hemoglobin	10.0 g/L	levofloxacin	200.0 mg/L
triglycerides	15.0 mmoL/L	azithromycin	5.0 µg /mL
α-interferon	200.0 mg/L	tobramycin	4.0 mg/L
zanamivir	30.0 mg/L	anti-mitochondrial antibody	80.0U/mL
ribavirin	30.0 mg/L	ritonavir	200.0 mg/mL
oseltamivir	30.0 mg/L	phenylephrine	10.0 mg/L
ceftriaxone	80.0 mg/L	oxymetazoline	10.0 µg/L
meropenem	200.0 mg/L	NaCl (preservative	10.0 g/L
Abidor	30.0 mg/L	Beclomethasone	300.0 µg/L
rheumatoid factor	200.0 IU/mL	hexadecadrol	80.0 µg/L
anti-nuclear antibody	Titer ≤ 1:240	flunisolide	40.0 ng/mL
mucoprotein antibody	1.0 g/L	triamcinolone acetonide	24.0 ng/mL
HAMA	1000.0 µg/mL	budesonide	5.0 mg/L
total IgG	40.0 g/L	Mometasone	0.25 ng/L
total IgM	3.0 g/L	fluticasone	0.3 ng/mL
paramivir	200.0 mg/L		

The results showed that no interference was observed with any of the tested compounds at the stated concentration in table 4.

INDEX OF SYMBOLS

CE	CE mark	2 °C 30 °C	Store at 2 °C to 30°C
	Consult instruction for use		Do not reuse
	Keep away from direct sunlight		Do not use if the package is damaged
	Keep dry	LOT	Batch code
	Manufacturer	REF	Catalog number
	Date of manufacture	Σ 25	Contains sufficient for <25> tests
IVD	*In vitro* diagnostic medical device		Use by date
	Caution		

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