SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold)

Instructions for Use

For in vitro Diagnostic Use Only

Manufactured for ThermoGenesis Corp. by
Jiangsu Superbio Biomedical (Nanjing) Co., Ltd.

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2 Symbol Legend

3 Intended Use

The SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) is intended for *in vitro* qualitative detection of IgM and IgG antibodies in human serum, plasma or whole blood from individuals suspected of COVID-19 by their healthcare point of care provider.

This test is only provided for use by clinical laboratories or to health care workers for point of care testing, and *not* for at home testing.

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. The diagnosis should be confirmed in combination with clinical symptoms or other conventional testing methods.

4 Summary and Explanation of the Test

A novel coronavirus (enveloped RNA virus) designated as “SARS-CoV-2” has been detected in Wuhan City, Hubei Province, China.\(^1\) During this time, the World Health Organization (WHO) has declared this disease “Coronavirus Disease 2019” (COVID-19) as a pandemic and cases have been detected internationally. Currently, there are seven coronavirus species known to cause human disease. Four viruses (229E, OC43, NL63, and HKU1) are prevalent and typically cause common cold symptoms in immunocompetent individuals while the remaining three other strains - severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV) and SARS-CoV-2 are zoonotic in origin and have been linked to sometimes fatal illness.\(^2\) In addition, SARS-CoV-2 has shown the ability to spread rapidly, leading to significant impacts on healthcare systems and causing societal disruption. In efforts to combat the COVID-19 outbreak, rapid detection of cases is necessary. IgG and IgM antibodies to SARS-CoV-2 can be detected 2-3 weeks after exposure. IgG will remain positive, however the antibody level drops overtime. The COVID-19 IgG/IgM test is an immunological diagnostic test based on the colloidal gold-immunochromatography assay. This method is rapid and convenient to use and requires few equipment.
5 Test Principle

This kit adopts colloidal gold-immunochromatography assay (GICA).

The test card contains:

1. Colloidal gold-labeled antigen and quality control antibody complex.
2. Nitrocellulose membranes immobilized with two test lines (M line and G line) and one quality control line (C line).

When 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 an IgM/IgG antibody of SARS-CoV-2, the antibody will bind to the colloidal gold-labeled SARS-CoV-2 antigen, and the immune complex will be captured by the monoclonal anti-human IgM antibody or monoclonal IgG antibody immobilized on the nitrocellulose membrane to form a purple/red M line or G line, showing that the sample is positive for IgM or IgG antibody.

6 Kit Reagents and Components

One kit contains 20 tests.

Materials Provided:

<table>
<thead>
<tr>
<th>Component Name</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterile Peripheral Blood Collector</td>
<td>1/Test</td>
</tr>
<tr>
<td>Disposable Plastic Dropper</td>
<td>2/Test</td>
</tr>
<tr>
<td>Sample Diluent*</td>
<td>1/Test</td>
</tr>
<tr>
<td>Cotton Alcohol Swabs</td>
<td>2/Test</td>
</tr>
<tr>
<td>Desiccant</td>
<td>1/Test</td>
</tr>
<tr>
<td>Disposable Test Card</td>
<td>1/Test</td>
</tr>
</tbody>
</table>

*Active Ingredients (% by weight): Sodium phosphate, dibasic, dodecahydrate (0.006%); sodium phosphate, monobasic, dihydrate (0.001%); sodium chloride (0.009%); polyethylene glycol sorbitan monolaurate (0.001%); purified water (0.9%).
Materials Not Provided:

- PPE such as gloves, masks, lab coats, and eye protection
- Biohazard Waste Container
- Tube holder

7 Warnings and Precautions

1. For emergency and use by medical or health professionals only at designated point of care facilities.
2. Read the package insert in its entirety prior to performing the test. Failure to follow the package insert instructions may result in an invalid test result.
3. Wear appropriate protective clothing when handling and processing specimens.
4. Wash hands thoroughly after handling specimen.
5. Handle specimens as if they contain infectious agents in accordance to standardized procedures, and OSHA standards on blood-borne pathogens.¹
6. Do not use it if the tube/pouch is damaged or broken.
7. Test is for single use only. Do not re-use under any circumstances.
8. Humidity and temperature can adversely affect results.
9. Follow storage recommendations listed on the product labels. Storage and handling outside of these conditions may adversely affect product.
10. Do not use product after indicated expiration date.
11. Dispose of all samples and used test components in appropriately approved and labeled biohazard waste containers.

8 Shelf Life and Storage

1. The original packaging should be stored in a dry place at 4-30°C and protected from light.
2. The shelf life of the test kit is 6 months from date of manufacture. Refer to the product labels for stated expiration date.
3. After opening the inner package, the test card will become invalid due to moisture absorption, please use it within 1 hour.

9 Sample Collection and Preparation

This test can be performed using either human serum, plasma or whole blood samples, including peripheral blood, plasma prepared from clinically used anticoagulants (EDTA, heparin, sodium citrate), etc. Fresh whole blood samples can be collected using components provided with the test and should be tested immediately. Please see diagram in Test Procedure section on the next page.
10 Test Procedure

The test card can show results in 3 minutes, and the whole process takes about 8 minutes.

1. Open the packaging box, take out the inner package and let it equilibrate to room temperature.
2. Remove the test card from sealed pouch and use within 1 hour after opening.
3. Place the test card on a clean and level surface.

11 Test Quality Control

1. The test card includes an internal procedural control. This control confirms that sufficient specimen volume and technique have been applied.
2. Control standards are not provided with this kit.
3. It is recommended to follow good laboratory practice including adding positive and negative controls in order to verify proper test performance.

12 Interpretation of Results

NEGATIVE:

If only the quality control line C appears, and the test lines M and G are not purple/red, it indicates that no antibody is detected, and the result is negative. Due to the limitation of detection sensitivity, negative results may be caused by antibody concentrations lower than the analytical sensitivity of the product.
POSITIVE:

**IgM positive:**
If both the quality control line C and the test line M appear purple/red, it indicates that the IgM antibody is detected, and the result is positive for IgM antibody.

**IgG positive:**
If both the quality control line C and the test line G appear purple/red, it indicates that the IgG antibody is detected, and the result is positive for IgG antibody.

**IgM and IgG positive:**
If the quality control line C and the test lines M and G all appear purple/red, it indicates that the IgM and IgG antibodies are detected, and the result is positive for both IgM and IgG antibodies.

INVALID TEST RESULT:

If the quality control line C is not displayed, the test result is invalid regardless of whether there is a purple/red test line, and it should be tested again.

- Repeat the test using remaining sample (100uL or 5 drops) or new sample, if results are not clear.
- If the test repeated fail to produce a result, discontinue using the kit and contact ThermoGenesis Corp. by email at customerservice@thermogenesis.com.

13 Performance Characteristics

The sensitivity, specificity and accuracy of SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) have passed the performance verification test of Nanjing Institute of Biomaterials and Medical Devices (Southeast University). Test results and conclusion are as follows:
Test results:
Through the test results of using SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) to test on SARS-CoV-2 virus nucleic acid positive blood samples and negative blood samples, and blank diluent, it can be seen:

<table>
<thead>
<tr>
<th>Sample Property</th>
<th>IgM Single Line</th>
<th>IgG Single Line</th>
<th>IgM/IgG Double Line</th>
<th>Invalid</th>
<th>Negative</th>
<th>Coincidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>2</td>
<td>2</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Negative</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>48</td>
<td>95.8%</td>
</tr>
<tr>
<td>Diluent</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>50</td>
<td>100%</td>
</tr>
</tbody>
</table>

- The sensitivity of the reagent began to fail to detect IgG-positive strip after the S13HC antibody protein was diluted to 80 times (concentration: 71.4ng/mL)
- The detection accuracy of the reagent for positive samples was 100%, and the accuracy for negative samples was 95.8%.
- The test results of reagent on diluent were all negative, and the coincidence rate was 100%.

Conclusion:
The sensitivity, specificity and accuracy of SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) are very high. SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) is applicable to the detection and scientific research of SARS-CoV-2 virus antibodies in blood.

Clinical Performance
A total of 392 samples were tested which included plasma, serum, and whole blood.

<table>
<thead>
<tr>
<th>Conclusion</th>
<th>Colloidal Gold</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Kit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>67</td>
<td>7</td>
</tr>
<tr>
<td>Negative</td>
<td>4</td>
<td>314</td>
</tr>
<tr>
<td>Total</td>
<td>71</td>
<td>321</td>
</tr>
</tbody>
</table>

- Positive coincident rate: $67/71 \times 100\% = 94.37\%$
- Negative coincident rate: $314/321 \times 100\% = 97.82\%$
- Total coincident rate: $(67+314)/(71+321) = 97.19\%$
- Kappa value is 0.9816.

In addition, this study included a comparative analysis of serum, plasma, and whole blood in which the results demonstrated the following:

- The results of serum, plasma and whole blood tests were positive in 20 positive samples.
- The results of serum, plasma and whole blood tests were negative in 30 negative samples.
Cross Reactivity
A total of 150 cases, 30 each of Influenza A, Influenza B, Adenovirus, Mycoplasma, Pneumonia and Respiratory Syncytial Virus IgM antibody positive serum samples were selected for cross-reactivity/Analytical specificity test.

The results were all negative for cross reactivity to Influenza A, Influenza B, Adenovirus, Mycoplasma, Pneumonia and Respiratory Syncytial Virus IgM antibody.

14 Limitations

1. This product is for qualitative assessment only. This test has not been reviewed by the FDA.
2. This test is only provided for use by clinical laboratories or to health care workers for point of care testing, and not for at home testing.
3. 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. The diagnosis should be confirmed in combination with clinical symptoms or other conventional testing methods.
4. 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.
5. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
7. It takes a period of time for the antibody to be produced in the human body. It is recommended to retest 5-7 days after the first test.
8. Within the United States and its territories, all positive results are required to be reported to appropriate public health authorities.

15 References