Safe and reliable new method for laboratory diagnosis of coronavirus. Therefore, it is of great clinical significance to establish a simple, fast and reliable new method for laboratory diagnosis of coronavirus.

PRINCIPLE

This kit is based on the principle of colloidal gold technology. After an appropriate amount of sample is added to the detection well, the sample moves under the action of the capillary. The new coronavirus IgG / IgM antibody in the sample will combine with the colloidal gold-labeled new coronavirus antigen to form a colloidal gold-antigen-antibody complex. The immune complex product is then chromatographed along the nitrocellulose membrane to the detection area (M), combined with the pre-coated monoclonal anti-human IgM to form a purple M line, showing that the new coronavirus IgM is positive. The immune complex continuously is chromatographed to the detection area (G) and combined with pre-coated anti-human IgG to form a purple G-line, showing a new coronavirus IgG positive.

The quality control antibody-labeled colloidal gold particles are chromatographed to the quality control area (C) and combined with the pre-coated anti-quality control antibody to form a purple C line, indicating that the test is effective. If the QC line does not appear, the test result is invalid.

STORAGE AND STABILITY

The cassette is stable for 18 months (while sealed in an aluminum foil pouch) if stored at 2-30°C. The kit is effective in 1 hour after moving from aluminum foil pouch. The date of manufacture is detailed in the label.

SAMPLE REQUIREMENTS

- Clinical fresh non-hemolized serum, plasma or whole blood (EDTA anticoagulation) samples.
- After sampling, the sample should be tested within 24h at room temperature. The sample should be stored for no more than 5 days in cold condition of 2-8°C and should be stored for no more than one month in cryopreservation condition of -18°C. The whole blood sample should be stored for no more than five days at 2-8°C if it can’t be tested within two hours after sampling.
- The sample needs to be restored to room temperature before testing. Cryopreserved samples need to be completely melted, rewarmed, mixed evenly before use, avoid freezing and thawing repeatedly.

TEST PROCEDURE

1. Please read the manual of the kit before operation.
2. If the sample is stored refrigerated or frozen, please allow the sample to fully melt at room temperature (20-30 °C), and mix the sample upside down before use.
3. Before starting the test, remove the test strip from the aluminum foil bag, lay it flat on the table, and mark the sample number.
4. Use a sample gun or a dropper to draw 10ul of the sample to be tested (serum, plasma or whole blood sample) into the sample well on the test card. Immediately add 2 drops (70-90ul) of the sample dilution solution to the sample well, and avoid significant bubbles during operation.
5. Count and read the results within 15 minutes at room temperature. Please strictly control the reaction time and read the result within 15 minutes.
The test results are divided into three cases: negative, positive or invalid. The specific interpretation methods are as follows:

<table>
<thead>
<tr>
<th>M line</th>
<th>G line</th>
<th>C line</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>No color</td>
<td>No color</td>
<td>Color rendering</td>
<td>Negative, no new coronavirus antibodies detected</td>
</tr>
<tr>
<td>Color rendering</td>
<td>No color</td>
<td>Color rendering</td>
<td>Positive, new coronavirus IgM antibody detected, no new coronavirus IgG antibody detected</td>
</tr>
<tr>
<td>No color</td>
<td>Color rendering</td>
<td>Color rendering</td>
<td>Positive, new coronavirus IgG antibody detected, new coronavirus IgM antibody not detected</td>
</tr>
<tr>
<td>Color rendering</td>
<td>Color rendering</td>
<td>Color rendering</td>
<td>Positive, Simultaneous detection of novel coronavirus IgM and IgG antibodies</td>
</tr>
<tr>
<td>Color rendering</td>
<td>No color</td>
<td>No color</td>
<td>Invalid test, need to re-measure</td>
</tr>
<tr>
<td>No color</td>
<td>Color rendering</td>
<td>No color</td>
<td>Invalid test, need to re-measure</td>
</tr>
<tr>
<td>Color rendering</td>
<td>Color rendering</td>
<td>No color</td>
<td>Invalid test, need to re-measure</td>
</tr>
</tbody>
</table>

**LIMITATIONS OF THE TEST**

1. This reagent is a qualitative test and cannot be used for quantitative determination of antibody content.
2. This reagent is used for the detection of human whole blood, serum or plasma samples. It cannot be used for the detection of saliva, urine or other body fluids.
3. The test results of this product are for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms / signs, medical history, other laboratory tests, treatment response, and epidemiology.
4. 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 10-20 days and take a second sample, which should be the same as the first sample. Simultaneously test under conditions to determine if there is a seroconversion or a virus-specific IgG or IgM antibody titer that is significantly higher in the first infection.
5. The interpretation of positive results should be further determined in conjunction with clinical symptoms and other etiological methods (nucleic acid and sequencing).
6. Negative results indicate that no new coronavirus IgM / IgG antibodies have been detected, but if the new coronavirus IgM / IgG antibody content in the sample is below the minimum detection limit of the kit, negative results may also be obtained.

The following shall appear in the test report with the result:
- This test has not been reviewed by the FDA.
- 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.
- 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.
- Not for the screening of donated blood

**PRODUCT PERFORMANCE**

- Appearance: The appearance of the reagent should be neat and tidy, and the text symbol should be clearly marked. There is no leakage. The test strip is intact.
- The positive rate, precision, and minimum detection limit of this product meet the requirements of quality standards, and the product quality is stable during the validity period. Hepatitis B virus surface antigen antibody, Hepatitis C virus antibody, Hepatitis E virus IgM antibody, Hepatitis A virus IgM antibody, Syphilis antibody, HIV antibody, Rheumatoid factor, Antinuclear antibody, Coxsackie virus A16 IgM antibodies, adenovirus IgM antibodies, respiratory syncytial virus IgM antibodies, influenza A virus antibodies, EV71 virus IgM antibodies, Mycoplasma pneumoniae IgM antibodies, anti mitochondrial antibody (AMA) positive samples, and high-concentration non-specific IgG (serum total IgG) will not cause interference with this product.

**NOTES**

- This product is for in vitro diagnostic use only.
- The operation steps cannot be omitted or simplified.
- The positive samples detected by this kit need to be confirmed by other methods.

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- Disinfect or treat all samples and reagents as potential sources of contamination in accordance with local regulations.

**INDEX OF SYMBOLS**

- **IVD**: In Vitro Diagnostic Use
- **U**: Use By
- **T**: Temperature Limitation
- **lot**: Batch Code
- **M**: Manufacturing Data

For technical assistance, please contact:

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