COVID-19 IgM/IgG test kit

【Product Name】
COVID-19 IgM/IgG test kit (Colloidal Gold)

【Specifications】
25 Tests/Box, 50 Tests/Box

【Intended Use】
This kit is used for the qualitative determination of COVID-19 IgM/IgG antibodies in human serum, plasma and venous whole blood samples in vitro. As an auxiliary diagnosis of COVID-19 infection.

【Detection principle】
This kit uses colloidal gold immunochromatography. Testing COVID-19 IgG antibody and COVID-19 IgM antibody in human serum, plasma and whole blood samples. The blood samples diluted containing COVID-19 IgG antibody and/or COVID-19 IgM antibody chromatography to colloidal gold binding pad, recombinant with colloidal gold marked COVID-19 antigen antibody, forming colloidal gold - antigen complex, chromatography to test area, combining to precoated anti-human IgG antibody and/or anti-human IgM antibody respectively, forming complexes in the test area and presenting red precipitation line. Unbound rabbit IgG colloidal gold bond chromatography to quality control line (C) combined with precoated sheep anti-rabbit IgG antibody presented a red precipitation line.

If the samples do not contain COVID-19 IgG antibody and/or COVID-19 IgM antibody, there is no corresponding red precipitation line existed in the test area. A red precipitation line appears on the quality control line (C) no matter if there is COVID-19 IgG antibody and/or COVID-19 IgM antibody in the sample or not.

【Components】

<table>
<thead>
<tr>
<th>Components</th>
<th>Specification / quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>25 Tests/kit</td>
</tr>
<tr>
<td>Test card</td>
<td></td>
</tr>
<tr>
<td>Anti-human IgG antibody, Anti-human IgM antibody, Nitrocellulosic membrane coated with sheep anti-rabbit IgG antibody</td>
<td>1 test/bag</td>
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<tr>
<td>Colloidal gold labeled novel COVID-19 recombinant antigen and rabbit IgG antibody binding pad</td>
<td>25 bags/kit</td>
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<tr>
<td>Absorbent paper</td>
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<tr>
<td>Sample diluent (pH8.0 Tris-HCl)</td>
<td>1 bottle/kit (5ml)</td>
</tr>
</tbody>
</table>

Do not mix use the Components from different lot number

【Storage and Stability】
1. Store at 2~30℃ for 18 months in a cool place, no direct sunlight and no freeze preservation. The test card and sample diluent should be used up in 1 hour after opening the package (opening temperature 10~30℃, humidity 25%~95%).
2. The date of production and the term of use are labeled.

【Specimen collection and preparation】
1. This kit is suitable for serum, (EDTA anticoagulation, heparin anticoagulation, sodium citrate anticoagulant 1:9) plasma and venous whole blood samples. Fresh samples are recommended.
2. Sample collection: Referring to the "national clinical laboratory operation regulations" venous blood collection. If it cannot be tested in time, the sample can be stored in refrigerator at 2~8℃. The separated serum and plasma samples should be stored at 2~8℃ within 7 days, and -20℃ for more than 7 days. -20℃ can be preserved for 3 months. Samples can be frozen and melted...
Whole blood samples cannot be stored at 2~8℃ for more than 7 days. Restore to room temperature before test.

**[Test Procedure]**

1. Restore the test card to room temperature, tear off the seal of the aluminum foil bag, remove the test card from the aluminum foil bag and lay it flat on the operating table.
2. 10 μl of serum/plasma / 15 μl of whole blood samples to be measured should be absorbed with a proper range pipper and added to the sample hole. Then two drops of diluent (about 80 μl) should be added to the sample hole of the test card. Avoid producing obvious bubbles when absorbing and adding samples.
3. The timer keeps time and the results are interpreted in 10 minutes.

**[Interpretation of Results]**

1. Positive result:
   a. Positive result of COVID-19 IgG: red precipitation line appeared in both quality control area C and test area (test line T1), while no red precipitation line appeared in test area (test line T2).
   b. Positive result of COVID-19 IgM: red precipitation line appeared in both quality control area C and test area (test line T1), while no red precipitation line appeared in test area (test line T2).
   c. Double positive result of COVID-19 IgG/IgM: red precipitation line appeared in both quality control area C and test area (test line T1 and T2)
2. Negative result:
   Red precipitation line appeared in quality control area C, while no red precipitation line appeared in test area (test line T1/T2).
3. Invalid result:
   No precipitation line appeared in quality control area C.

The test results are interpreted as following graphs:

**[Limitations of Procedure]**

1. This reagent is only for the in vitro detection of plasma and of human serum, plasma and venous whole blood samples.
2. Operation must be strictly operated according to the operation rules and careful operate to get the correct result. Any modification to the operation procedure may affect the result.
3. Unreasonable sample collection, transfer and processing, and low concentration of the measured substance in the sample may lead to false negative results.
4. The test results of this kit cannot be used as the only standard for clinical diagnosis, which should be combined with other test results and clinical manifestations to make a judgment.
5. Limited by the sensitivity of the analysis, negative results cannot completely exclude the possibility of infection with COVID-19.
If the test results are negative while clinical symptoms exist, it is recommended to use other clinical methods for testing.

6. This reagent is a colloidal gold detection reagent, which is only used for the initial screening and cannot be used as a diagnostic result.

**[Performance Characteristics]**

1. Negative coincidence rate: the reference for testing negative enterprises (N1-N10), 10 copies shall be negative.
2. Positive coincidence rate: the reference for positive enterprises (P1-P10), P1-P4 should be IgM positive and IgG positive, P5-P7 should be IgM positive and IgG negative, P8-P10 should be IgM negative and IgG positive.
3. Minimum test limitation: test the enterprise sensitivity reference S1~S4(diluted by the enterprise sensitivity reference S in accordance with 1:32, 1:64, 1:128, and 1:512). It is required that S1 and S2 should be positive for IgM and IgG, while S3 and S4 should be negative.
4. Batch repeatability: use the same batch kits to test negative enterprise repetitive reference products C1 and repetitive positive reference C2 (IgM and IgG are all positive) respectively. Each sample was tested 5 times in parallel, where C1 test results should be negative and C line color is consistent, and C2 test results should be IgM positive and IgG positive with consistent color display.
5. Inter-batch repeatability: three consecutive batch number kits were used to test the enterprise's repeatable negative reference C1 and repeatable positive reference C2 (both IgM and IgG were positive), and each sample was tested 5 times in parallel, and the C2 test results were all positive IgM and positive IgG.

**[Warnings and Precautions]**

1. This kit is for in vitro diagnosis only. Please do not use expired products.
2. Do not swallow the reagent or contact with the skin, eyes and mucous membranes. Once contact, the pollution part should be flushed with water.
3. After the test card is taken out of the aluminum foil bag, the experiment should be carried out as soon as possible to avoid being placed in the air for too long, resulting in damp.
4. Protective measures should be taken during the collection, disposal, storage, mixing and determination of samples, and all clinical samples, used reagents and waste should be treated as infectious after the test.

**[Reference]**


**[Essential Information]**

Registrant / manufacturer: Xiamen AmonMed Biotechnology Co., Ltd.
Registered address: Unit 503, 120 Xinyuan Road, Haicang District, Xiamen, Fujian China.
Tel: 0592-6081739
Name of after-sales service unit: Xiamen AmonMed Biotechnology Co., Ltd.
Tel: 0592-6081739
Production address: Unit 1203, 120 Xinyuan Road, Haicang District, Xiamen, Fujian China.
Production license number: The production permit of Fujian food drug supervision equipment No. is 20180411