Instructions of COVID-19 IgM/IgG Test Kit (Colloidal Gold)

【Product Name】
COVID-19 IgM/IgG Test Kit (Colloidal Gold)

【Specifications】
25 tests/kit, 50 tests/kit

【Intended Use】
This kit is suitable for the qualitative detection of COVID-19 IgM/IgG antibodies in human serum, plasma and whole blood samples. It can be used for rapid screening of carriers of the COVID-19 virus that are symptomatic or asymptomatic.

【Detection Principle】
The COVID-19 IgG/IgM test kit (Whole Blood/Serum/Plasma) is a lateral flow immunochromatographic assay. The burgundy colored conjugate pad contains colloidal gold conjugated to recombinant COVID-19 antigens conjugated with colloid gold (COVID-19 conjugates) and rabbit IgG-gold conjugates. When a specimen followed by sample diluent is added to the sample well, IgM and/or IgG antibodies if present, will bind to COVID-19 conjugates making antigen antibodies complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the corresponding immobilized antibody (anti-human IgM and/or anti-human IgG), the complex is trapped forming a burgundy colored band which confirm a reactive test result. Absence of a colored band in the test region indicates a non-reactive test result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

【Components】
The components of the test kit are test cards and sample diluent. The test card is mainly composed of mouse anti-human IgM antibody, mouse anti-human IgG antibody and goat anti-rabbit IgG antibody fixed on the nitrocellulose membrane, and colloidal gold-labeled COVID-19 recombinant antigen and rabbit IgG antibody fixed on glass fiber conjugate pad.

<table>
<thead>
<tr>
<th>Components</th>
<th>Specification / Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Card</td>
<td></td>
</tr>
<tr>
<td>Mouse anti-human IgM antibody, mouse anti-human IgG antibody and goat anti-rabbit IgG antibody fixed on the nitrocellulose membrane</td>
<td>1 test/bag</td>
</tr>
<tr>
<td>Colloidal gold-labeled COVID-19 recombinant antigen and rabbit IgG antibody fixed on glass fiber conjugate pad</td>
<td>25 bags/kit</td>
</tr>
<tr>
<td>Absorbent Paper</td>
<td></td>
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<tr>
<td>Sample Diluent (pH8.0 Tris-Hcl)</td>
<td>1 bottle/kit (5ml)</td>
</tr>
</tbody>
</table>

Note: The components in different batches cannot be used interchangeably.

【Storage and Expiry date】
1. Keep test kits in a cool and dry place at 2 ~ 30 ºC. Do not freeze. The Kits are valid for 18 months. The test card and sample diluent should be used up in 1 hour after opening the package (opening temperature 10 ~ 30ºC, humidity 25% ~ 95%).
2. The date of production and the term of use are labeled.
【Sample Requirement】

1. This kit is suitable for serum, (EDTA anticoagulation, heparin anticoagulation, sodium citrate anticoagulant 1:9) plasma, venous whole blood and fingertip blood samples. Fresh samples are recommended.

2. Sample collection: The whole blood/fingertip blood collected from the vein must be sterile, separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens. The separated serum and plasma samples can be stored at 2 ~ 8 °C within 7 days if not run immediately. If long-term storage is required, please store at – 20 °C for periods less than 3 months. Samples can be frozen and thawed for 3 times. Whole blood samples can be stored at 2 ~ 8 °C within 7 days. Bring samples to room temperature prior to testing.

【Test Assay】

1. Bring the test card to room temperature prior to testing. Remove the test card from the sealed foil pouch and use it as soon as possible. Place the test card on a clean and level surface.

2. Venous blood collection: Add 10 µl of serum/plasma/15 µl of whole blood sample to the sample well, and then add two drops of diluent (about 80 µl) to the sample well. Avoid air bubbles.

3. Fingertip blood collection: Lancets used to collect fingertip blood. Transfer 1 drop of whole blood (about 15 µl) to the sample well, and then add two drops of diluent (about 80 µl) to the sample well. Avoid air bubbles.

4. The results can be interpreted in 10 minutes. Results measured after 20 minutes are invalid and should be discarded.

【Result Interpretation】

1. Positive result:
   a. Positive result of COVID-19 IgG: Both the test line (G) and the quality control line (C) are colored. The test line (M) does not develop color.
   b. Positive result of COVID-19 IgM: Both the test line (M) and the quality control line (C) are colored. The test line (G) does not develop color.
   c. Double positive result of COVID-19 IgG/IgM: Both the test line (G and M) and the quality control line (C) are colored.

2. Negative result:
   Both the test line (G and M) does not develop color, but the quality control line (C) is colored.

3. Invalid result:
   There is no colored control line (C) band. The results are invalid regardless of whether a red band appears on the test line (G and M); additional testing is required.

Representative schematic of possible lateral flow device results as follows:
【Limitations of Test Assay】

1. This reagent is only for the in-vitro detection of human serum, plasma and venous whole blood samples.
2. Optimal assay performance requires strict adherence to the assay procedure described in this insert sheet. Deviations may lead to aberrant results.
3. Unreasonable way of sample collection, transfer and processing, and sample with low concentration may lead to wrong results.
4. This product test results are for reference only and should not be the sole basis for diagnosis and treatment. Use of this kit should be combined with clinical symptoms and should be confirmed by other conventional detection methods.
5. This test kit is a kind of colloidal gold detection reagent, which is only used for the initial screening and cannot be used as a diagnostic result.

【Performance Indicators】

1. Confirmation of Positive Reference Samples: 10 negative reference samples (N1-N10) and products were tested, and the results should find all samples as negative. Results found 10 of 10 samples to show a negative result.
2. Confirmation of Positive Reference Samples: 10 individual positive references samples (P1-P10) were tested, and the result should identify all as positive samples. Results found P1-P4 to be IgM positive and IgG positive, P5-P7 to be IgM positive and IgG negative, P8-P10 to be IgM negative and IgG positive.
3. Minimum Detection Limit: 4 samples (S1-S4) (diluted by the enterprise sensitivity reference S in accordance with 1:32, 1:64, 1:256 and 1:512) were tested, whereby S1, S2 should be IgM positive and IgG positive, while S3, S4 should be negative. Results confirmed S1, S2 as IgM positive and IgG positive, while S3, S4 as negative.
4. Repeatability: 2 reference samples (C1, C2) and products were tested, negative repetitive reference samples C1 and positive repetitive reference samples C2 were tested 5 times in parallel, results confirmed C1 as negative and C line color is consistent, and C2 to be IgM positive and IgG positive with consistent color display.

【Precaution】

1. This kit is for in-vitro diagnosis only. Do not use expired or damaged products.
2. Take care to prevent the possibility of virus infection when collecting samples. Wear disposable gloves, masks, etc., and wash your hands afterwards.

3. The test should be used within 1 hour after opening. If the ambient temperature is higher than 30 °C, or the test environment is humid, the Detection Cassette should be used immediately.

4. This test card is designed for a single, one-time use. After use, the test card and samples should be regarded as medical waste with risk of biological infection and properly disposed of in accordance with relevant national regulations.

【Reference】


【Essential Information】

Registrant/manufacturer: Xiamen AmonMed Biotechnology Co., Ltd.
Registered address: 120 Xinyuan Road, Haicang District, Xiamen, China.
Tel: +86-592-6519307

Name of after-sales service unit: Xiamen AmonMed Biotechnology Co., Ltd.
Tel: +86-592-6519307

Production address: 120 Xinyuan Road, Haicang District, Xiamen, China.
Production license number: The production permit of Fujian food drug supervision equipment No. is 20180411

【Medical Device Registration Number/Product Technical Requirement No.】

【Date of Approval and Revision of Instructions】