NOTIFICATION FOR COVID-19 ANTIBODY TESTS
1. This test has not been reviewed by the FDA.
2. 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.
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.
4. 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.
5. Not for the screening of donated blood.
6. This kit is only for in vitro diagnosis and is not intended for at home testing.

PRECAUTIONS AND WARNINGS
1. This test kit is intended to be used by suitably qualified healthcare practitioners only. Read the instructions carefully before use and conduct the test strictly in accordance with the kit instructions.
2. In order to reduce the risk of transmission, use appropriate PPE when collecting and handling specimens per the current CDC guidance for COVID-19 infection control precautions.
3. Samples and controls should always be treated as if infectious and biohazardous in accordance with safe laboratory procedures.
4. Follow the necessary precautions when handling specimens. Use personal protective equipment (PPE) consistent with current guidelines for the handling of potentially infectious samples.
5. Dispose of waste in compliance with local, state, and federal regulations.
6. Safety Data Sheets are available upon request.
7. Laboratories and health care facilities are required to report all positive results to the appropriate public health authorities.
8. Do not use if the product is expired or damaged.
9. Only use the diluent in the kit package. Other diluents may result in poor performance of the product.
10. Cassettes are intended to be for single use. Do not reuse.
11. After opening the inner packaging and specimen dilution, follow the storage instructions as outlined in this IFU.
12. Proper specimen collection, storage, and transport are critical to the performance of this test. Inadequacy can result in a false result.
13. Retest if any results are invalid (control line is not visible).

REFERENCES

CONTACT
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DATE OF APPROVAL AND MODIFICATION OF INSTRUCTION
April 1st, 2020

DATE OF MANUFACTURE AND EXPIRATION
See packaging.

Symbols

Rapid detection within 10 min.
No testing equipments required.
**PRODUCT NAME**
2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based).

**CatalOG nuMber & SIZe**
C0603C: 50 tests / kit.

**uNtENDED INTENTS**
This product is intended for the detection of 2019-Novel Coronavirus (2019-nCoV). It is an in vitro diagnostic test for the qualitative detection of IgG / IgM antibodies to the SARS-CoV-2 virus in human serum, plasma, and whole blood (venipuncture) samples collected by healthcare professionals at the point-of-care.

**BaCKGROuND**
2019-Novel Coronavirus belongs to the new genus SARS-CoV-2, which has an envelope, the particles are round or oval, often polygonic, and the diameter is 60-140nm. Its genetic characteristics are significantly different from SARS-CoV and MERs-CoV. Current research shows that it has more than 85% homology with bat SARS-like coronavirus (bat-SL-CoVZC45). After infection with 2019-nCoV, the common symptoms are fatigue, dry cough, dyspnea etc. Some patients present with mild symptoms, some severe cases with fever, and some have severe manifestations. Some patients have mild symptoms and no fever. Most patients have a good prognosis, while a few are in critical condition or even die.

Both IgG and IgM are antibodies that are produced by the immune system to provide protection against the 2019-nCoV. The level of IgM antibody begins to rise within 1 week and achieves the peak at 2-3 weeks after the initial infection. IgG appears later than IgM (usually in 14 days after infection) and achieves the peak at 5 weeks, lasting for 6 months or even several years.

**PRINCIPLE OF DETECTION**
This product is based on capture and solid-phase immunochromatographic methods for determination. The specimen (whole blood / serum / plasma) flows from the blood separator through to the conjugate release pad (which occurs the conjugation reaction between IgG / IgM antibody in the specimen and the antigen colloidal gold of 2019-nCoV) to form an immune complex of IgG / IgM antibody and colloidal gold-labeled antigen due to capillary action. Then migrate to a capture zone of nitrocellulose membrane-immobilized antibody (mouse-anti-human IgM / IgG antibody, T1 line) to form an immune complex of colloidal gold-labeled antigen, IgM antibody and mouse-anti-human IgM antibody, thereby generating a T2 red line. The remaining unattached immune complex moves upward, combining with C line (quality control line) to indicate the completion of this reaction.

**COMPONENTS**

<table>
<thead>
<tr>
<th>Components</th>
<th>Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Cassette</td>
<td>Aluminum foil pouch, desiccant, test strip and plastic card, Test strip comprising: binding paper, nitrocellulose membrane, specimen separator, colloidal gold labeled pad and PVC, IgG line (Test line), coating 0.1 mg/mL mouse-anti-human IgG antibody, IgM line (Test line), coating 0.1 mg/mL mouse-anti-human IgM antibody, C line (Quality control line), coating 1.0 mg/mL goat anti-mouse IgG. Conjugate release pad containing 40:20 2019-nCoV antigen-coated colloidal gold conjugates.</td>
</tr>
<tr>
<td>Specimen Dilution</td>
<td>HEPES Buffer containing tween (0.1 M), 5 mL/bottle.</td>
</tr>
<tr>
<td>Dropper</td>
<td>50 droppers/pack.</td>
</tr>
</tbody>
</table>

**MATERIALS REQUIRED BUT NOT SUPPLIED**
Clock or Timer

**STORAGE & SHELF LIFE**
This kit should be stored at 4°C to 30°C for 18 months in a sealed condition. Once the inner packaging of strip is opened (4°C~30°C, humidity < 65%), it must be used within 1 month. It is recommended to mark the opening date of the specimen dilution buffer.

**sAmPLING & HANDLING**
1. Suitable specimen type: serum, plasma, and whole blood.
2. Sediment and suspended matter in the specimen may affect the test result. It should be removed by centrifugation at 3000 g for 10 minutes.
3. If non-hematocrit, lipemic, hemolytic specimens should not be used. Whole blood samples can be treated with heparin sodium or EDTA anticoagulant. After specimen collection, the test should be completed within the first day, if not, please follow the storage protocol for whole blood samples, store at 2°C-8°C for 3 days.

**INTERRUPTING TEST RESULTS**

<table>
<thead>
<tr>
<th>Test results are analyzed as follows:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Negative result: Only red quality control line (C line) appears in the detection area.</td>
</tr>
<tr>
<td>2. IgM positive, IgG positive result: Three clear red lines appear in the detection area, one is the quality control line (C line), one is T2 detection line, and the other is T1 detection line.</td>
</tr>
<tr>
<td>3. IgM positive, IgG negative result: Two clear red lines appear in the detection area, one is the quality control line (C line) and another is T1 detection line.</td>
</tr>
<tr>
<td>4. IgM negative, IgG positive result: Two clear red lines appear in the detection area, one is the quality control line (C line) and another is T2 detection line.</td>
</tr>
<tr>
<td>5. Invalid result: No red quality control line (C line) appears in the detection area (e.g. without any red lines or only test lines (T1, T2 line), indicating that the test error or test result is invalid, and the test should be retested.</td>
</tr>
</tbody>
</table>

**LIMITATIONS OF TEST METHODS**
1. The test results of this product are only for clinical reference and should not be used as the only basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their signs / symptoms, medical history, treatment reactions and epidemiology and other laboratory tests. It is recommended to repeat the test for suspicious samples at intervals.
2. The accuracy of detection is affected by specimen collection process. Improper sample collection and storage process will affect the test results and should avoid high temperature and direct sunlight.
3. This product provides a qualitative test for the novel coronavirus IgM antibody and IgG antibody in the sample, but not quantified detection.
4. Due to the limitation of the testing methodologies, it cannot rule out the possibility of the novel coronavirus infection based on negative results. It is recommended to combine other test results and clinical symptom to make an accurate diagnosis.

**PRODUCT PERFORMANCE INDICATOR**
1. **Lowest limit of detection**
Test with the in-house LOD references. S1 and S2 are positive for novel coronavirus IgG antibody, negative for IgM antibody. S3 is negative for novel coronavirus IgG antibody, positive for IgM antibody. S4 and S5 are positive for novel coronavirus IgG antibody, negative for IgM antibody, and S6 is negative for novel coronavirus IgG antibody, positive for IgM antibody.

2. **Negative coincidence rate**
Test with the in-house negative references, and the results are all negative for novel coronavirus IgG/IgM antibodies, with a coincidence rate of 100%.

3. **Positive coincidence rate**
Test with the in-house positive references. PC01-PC05 are all positive for novel coronavirus IgG/IgM antibodies, with a coincidence rate of 100%, P06-P10 are all negative for novel coronavirus IgG antibody, and positive for IgM antibody, with a coincidence rate of 100%; PC11-PC15 are all positive for novel coronavirus IgM antibody, and all positive for IgG antibody, with a coincidence rate of 100%.

4. **Precision**
Intra-batch difference: Test with the in-house repetitive references. CV1 and CV2 are positive for novel coronavirus IgG antibody and negative for IgM antibody. CV3 and CV4 are negative for novel coronavirus IgG antibody and positive for IgM antibody, with uniform color development.
Inter-batch difference: Test with the in-house repetitive references. The results of the kit of three batch numbers are shown as follows: CV1 and CV2 are positive for novel coronavirus IgM antibody and negative for IgG antibody. CV3 and CV4 are negative for novel coronavirus IgG antibody and positive for IgM antibody, with uniform color development.

5. **Analytical specificity**
5.1 Cross-reactivity Specificity
This product will not cross react with positive samples of human coronavirus HKU1, NL63, OC43, 229E, influenza A/H1N1 virus, H3N2, H1N1, influenza B, rhinovirus, respiratory syncytial virus, parainfluenza, virus, reovirus species A, B and C, adenovirus (types 1, 2, 3, 4, 5, 7), and coronavirus (enterovirus species B). enterovirus 71 (enterovirus species A), enterovirus 68 (EV-68) (enterovirus species D). EB virus, measles virus, human cytomegalovirus, variola, norovirus, mumps virus, varicella-zoster virus, mycoplasma pneumoniae, chlamydia pneumoniae IgG / IgM antibodies.

5.2 Class Specificity

**CLASSIFICATION**
This kit is classified as Class III, according to the Chinese Medical Device Classification Standards (2017-08-13).

**LIMITATIONS**
6. Hook effect
When bilirubin ≥0.2 g/L, triglyceride ≥10 g/L, hemoglobin ≤5 g/L, rheumatoid factor ≤500 IU/mL, antinuclear antibody titer ≤1:240, anti-mitochondrial antibody titer ≤1:160, HAMA ≤20 ng/mL, total IgG ≤50 mg/L and total IgM ≤5 mg/L, they will not interfere with the test results. Oseltamivir, levofloxacin, ceftriaxone, zanamivir, interferon, ribavirin, peramivir, lopinavir, ritonavir, arbidol, azithromycin, meropenem, tobramycin, histamine hydrochloride, phenylephrine, oxymetazoline, interferon, interferon, interferon, interferon, interferon.

7. After specific IgM positive sample is destroyed, the IgM antibody test result is negative, and the IgG antibody test is not affected.

8. Heparin sodium and EDTA anticoagulants have no effect on the detection of this kit.

9. If novel coronavirus pneumonia is highly suspected but the antibody test result is negative, the sample should be re-tested.

10. For virus infection samples from different regions, the lowest limit of detection and detection repeatability of the reagent comply with the requirements.

11. Clinical study
The clinical trial of this product was carried out in 5 sites based on the criteria for disease confirmation/recovery specified in the Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia. The enrolled cases were suspected cases of novel coronavirus infection, including 297 confirmed cases and 469 excluded cases, with 51 early cases in confirmed cases. Clinical sensitivity of this product: 91.54% (95% CI: 86.87%, 94.65%) and specificity: 97.02% (95% CI: 94.74%, 98.33%). The samples for clinical evaluation were serum, plasma and whole blood, and 100% of the samples showed clinical effect, which basically confirmed that the clinical performance of the product can meet the emergency needs of the epidemic. The clinical data for the product after marketing will be further collected to confirm the clinical performance of the product.

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**COMPANY PROFILE**

Vazyme is a China-based biotechnology company with global ambitions, with a focus on innovation and intellectual property. Vazyme’s products include but are not limited to COVID-19 test kits, rapid diagnostic tests, antibody detection kits, and R&D reagents. It is a leader in the global infectious disease diagnostic market with an extensive product portfolio. Vazyme is committed to providing high-quality products and services for healthcare professionals worldwide.