COVID-19 IgG/IgM Rapid Test Kit
(Whole Blood/Serum/Plasma)
For Professional Use
Doc. No.: IFU-COVID-19 IgG/IGM. A/1-20200328

INTENDED USE
COVID-19 IgG/IgM Rapid Test Kit (Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19 IgG/IgM Rapid Test Kit (Whole Blood/Serum/Plasma) must be confirmed with alternative testing methods(s) and clinical findings.

INTRODUCTION
Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases. Seven coronavirus species are known to cause human disease. Four viruses - 229E, OC43, NL63, and HKU1 - are prevalent and typically cause common cold symptoms in immunocompetent individuals. The three other strains - severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV) and 2019 Novel Coronavirus (COVID-19) - are zoonotic in origin and have been linked to sometimes fatal illness. IgG and IgM antibodies to 2019 Novel Coronavirus can be detected with 2-3 weeks after exposure. IgG remains positive, but the antibody level drops overtime.

PRINCIPLE
The COVID-19 IgG/IgM Rapid Test Kit (Whole Blood/Serum/Plasma) is a lateral flow immunochromatographic assay. The test uses anti-human IgG antibody (test line IgG), anti-human IgM antibody (test line IgM) and goat-anti-rabbit IgG (control line C) immobilized on a nitrocellulose strip. The burgundy colored conjugate pad contains colloidal gold conjugated to recombinant COVID-19 antigens conjugated with colloidal gold (COVID-19 conjugates) and rabbit IgGgold conjugates. When a specimen followed by assay buffer is added to the sample well, IgG and/or IgM antibodies if present, will bind to COVID-19 conjugates making antigens antibodies complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the corresponding immobilized antibody (anti-human IgG or anti-human IgM; anti-rabbit IgG), the complex is trapped forming a burgundy colored band which confirms 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/anti-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 repeated with another device.

MATERIALS SUPPLIED
If whole blood test, sealed pouches each containing a test kit, a 10 µL mini plastic dropper and a desiccant 1 Buffer 1 package insert If serum/plasma test, sealed pouches each containing a test kit and a desiccant 1 Buffer 1 package insert

MATERIAL REQUIRED BUT NOT PROVIDED
1. Lancets (for fingertip whole blood only)
2. Centrifuge and Pipette (for plasma/serum only)
3. Timer

STORAGE AND STABILITY
The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS
1. For professional in vitro diagnostic use only. Do not use after expiration date.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use if the pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Do not perform the test in a room with strong air flow, electric fan or strong air-conditioning.

SPECIMEN COLLECTION
1. COVID-19 IgG/IgM Rapid Test Kit (Whole Blood/Serum/Plasma) can be performed using either whole blood, serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE
For Serum or Plasma Specimens:
Allow test kit, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
1. Remove the test strip/cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test kit on a clean and level surface.
3. Strip:
   Add 10 µL of serum/plasma to the sample pad of the test strip, then add 2 drops (about 60 µL) of sample buffer to the sample pad immediately.
4. Cassette:
   Add 10µL of serum/plasma to the specimen well(s) of the test cassette, then add 2 drops (about 60 µL) of sample buffer to the well(s) immediately.
5. Wait for the colored line to appear. The result should be read at 15 minutes. Positive results may be visible as soon as 5 minutes.
For Whole Blood Specimen

Allow test kit, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test strip/cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.
   Strip: Add 10 μL of whole blood to the sample pad of the test strip, then add 2 drop (about 60 μL) of sample buffer to the sample pad immediately.
   Cassette: Add 10 μL of whole blood to the specimen well(s) of the test cassette, then add 2 drop (about 60 μL) of sample buffer to the well(s) immediately.
3. Wait for the colored line to appear. The result should be read at 15 minutes. Positive results may be visible as soon as 2 minutes.

INTERPRETATION OF RESULTS

NEGATIVE: If only the C band is present, the absence of any burgundy color in the both T bands (IgG and IgM) indicates that no anti-COVID-19 antibodies are detected in the specimen. The result is negative.

IgM POSITIVE: In addition to the presence of C band, if only IgM band is developed, the test indicates for the presence of IgM anti-COVID-19 in the specimen. The result is IgM anti-COVID-19 positive.

IgG POSITIVE: In addition to the presence of C band, if only IgG band is developed, the test indicates for the presence of IgG anti-COVID-19 in the specimen. The result is IgG anti-COVID-19 positive.

IgG and IgM POSITIVE: In addition to the presence of C band, both IgG and IgM bands are developed, the test indicates for the presence of both IgG and IgM anti-COVID-19 in the specimen. The result is IgG and IgM anti-COVID-19 positive.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. Use fresh samples whenever possible. Frozen and thawed samples (especially repeatedly) contain particles that can block the membrane. This slows the flow of reagents and can lead to high background color, making the interpretation of results difficult.
2. Optimal assay performance requires strict adherence to the assay procedure described in this insert sheet. Deviations from this procedure may lead to aberrant results.
3. A negative result for an individual subject indicates absence of detectable anti-COVID-19 antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with COVID-19.
4. A negative result can occur if the quantity of the anti-COVID-19 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

Relative Sensitivity: 96.68%, Relative Specificity: 100%, Overall Agreement: 99%

WARNING STATEMENT

- 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 or other interference factors.
- Not for the screening of donated blood.
- This product has not been reviewed by the FDA.

REFERENCE


<table>
<thead>
<tr>
<th>IVD</th>
<th>For in vitro diagnostic use only</th>
<th>See instruction for use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Store between 2-8°C</td>
<td>Do not reuse</td>
<td></td>
</tr>
<tr>
<td>LOT</td>
<td>Batch number</td>
<td>Expiry data</td>
</tr>
<tr>
<td>Authorized representative</td>
<td>Tests per kit</td>
<td></td>
</tr>
<tr>
<td>Keep dry</td>
<td>Keep away from sunlight</td>
<td></td>
</tr>
</tbody>
</table>

Nantong Egens Biotechnology Co., Ltd.
Building 15, Building 12(west), No. 1692 Xinghua Avenue, Nantong Economy & Technology Development Zone. 226010 Nantong, PEOPLE'S REPUBLIC OF CHINA