For in vitro diagnostics use only

DIAKEY® COVID-19 IgG/IgM Rapid Test

Code No.: PD-02

INTENDED USE

DIAKEY® 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 Coronavirusi 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 method(s) and clinical findings.
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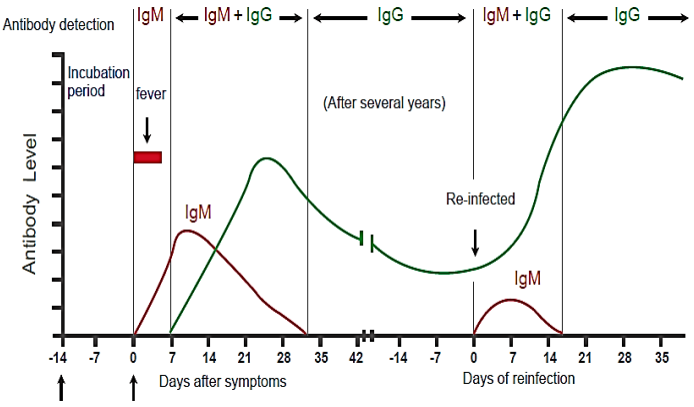
INTRODUCTION

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.4 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 OF THE ASSSAY

DIAKEY® COVID19 IgG/IgM Rapid Test Cassette is a qualitative membrane strip based immunoassay for the detection of antibodies (IgG and IgM) to Novel coronavirus in human Whole Blood/Serum/Plasma. The test cassette consists of: 1) a burgundy colored conjugate pad containing Novel coronavirus recombinant envelope antigens conjugated with Colloid gold (Novel coronavirus conjugates), 2) a nitrocellulose membrane strip containing two test lines (IgG and IgM lines) and a control line (C line). The IgM line is pre-coated with the Mouse anti-Human IgM antibody, IgG line is coated with Mouse anti-Human IgG antibody. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. IgM anti-Novel coronavirus, if present in the specimen, will bind to the Novel coronavirus conjugates. The immunocomplex is then captured by the reagent pre-coated on the IgM band, forming a burgundy colored IgM line, indicating a Novel coronavirus IgM positive test result. IgG anti-Novel coronavirus if present in the specimen will bind to the Novel coronavirus conjugates. The immunocomplex is then captured by the reagent coated on the IgG line, forming a burgundy colored IgG line, indicating a Novel coronavirus IgG positive test result. Absence of any T lines (IgG and IgM) suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS PROVIDED

If whole blood test, sealed pouches each containing a test kit, a ***4 μ***L mini plastic dropper and a desiccant
1. 1 Buffer
2. 1 package insert

If serum/plasma test,sealed pouches each containing a test kit and a desiccant
1. 1 Buffer
2. 1 package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Lancets (for fingerstick whole blood only)
2. Centrifuge and Pipette (for plasma/serum only)
3. Timer

STORAGE AND STABILITY

1. Store as packaged in the sealed pouch at the temperature (4-30℃ or 40-86℉). The kit is stable within the expiration date printed on the labeling.

2. Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.

3. The LOT and the expiration date were printed on the labeling

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 it 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, ie. electric fan or strong air-conditioning.

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.

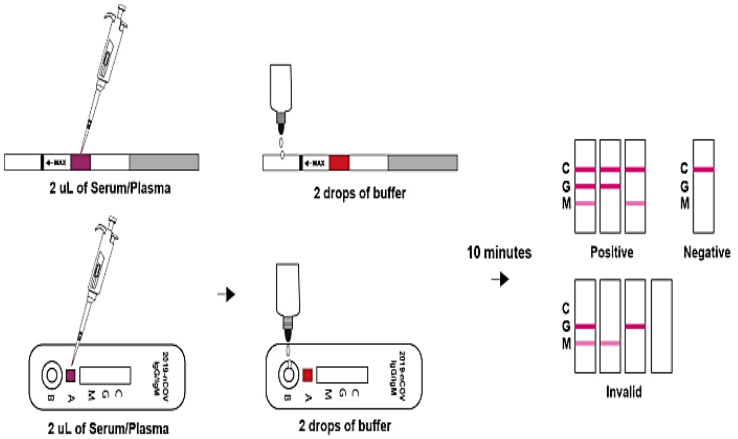
1. Remove the test strip/cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

2. Place the test kit on a clean and level surface.

Strip:Add ***2uL*** of serum/plasma to the sample pad(purple place with Colloi dal gold) of the test strip,then add 2 drops (about 60 µL) of sample buffer to the buffer pad (top of the strip) immediately.

Cassette:
Add 2***uL*** of serum/plasma to the specimen well(A) of the test cassette, then add 2 drops (about 60 µL) of sample buffer to the buffer well (B) immediately.

3. Wait for the colored line(s) to appear. The result should be read at 10 minutes. Positive results may be visible as soon as 2 minutes. Do not interpret the result after 15 minutes.



For Whole Blood Specimen

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

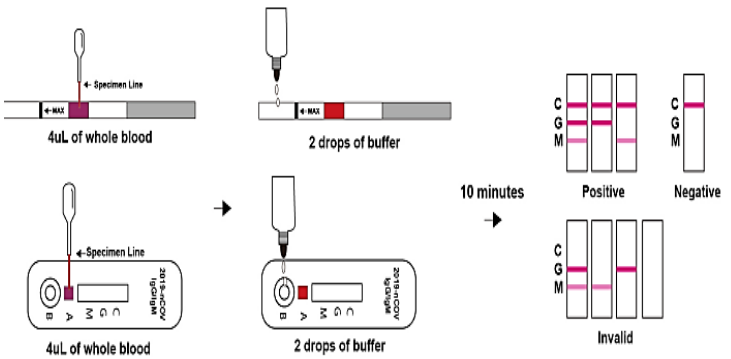
1. Remove the test strip/cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

2. Place the test device on a clean and level surface.

Strip:
Add ***4uL*** of whole blood to the sample pad(purple place with Colloidal g old) of the test strip,then add 2 drops (about 60 µL) of sample buffer to the buff er pad (top of the strip) immediately.

Cassette:
Add ***4u***L of whole blood to the specimen well(A) of the test cassette, then add 2 drops (about 60 µL) of sample buffer to the buffer well (B) immediately.

3. Wait for the colored line(s) to appear. The result should be read at 10 minutes. Positive results may be visible as soon as 2 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF THE RESULTS

Positive: Control line and at least one test line appear on the membrane. The appearance of IgG test line indicates the presence of Novel coronavirus specific IgG antibodies. The appearance of IgM test line indicates the presence of Novel coronavirus specific IgM antibodies. And if both IgG and IgM line appear, it indicates that the presence of both Novel coronavirus specific IgG and IgM antibodies.

Negative: One colored line appears in the control region(C).No apparent colored line appears in the test line region.

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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The COVID-19 IgG/IgM Rapid Test Cassette is limited to provide a qualitative detection. The intensity of the test line does not necessarily correlate to the concentration of the antibody in the blood.

2. The results obtained from this test are intended to be an aid in diagnosis only. Each physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.

3. A negative test result indicates that antibodies to Novel coronavirus are either not present or at levels undetectable by the test.

TECHNICAL ASSISTANCE

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Code Number: PD-02 (Ver.1) Rev. 13. March '20