Oranoxis

Rapid-Cov

SARS-CoV-19 IgM/IgG Antibody in Human Blood Rapid Test
Rx Only

Intended Use

The Oranoxis Rapid-Cov test is a rapid test for qualitative detection IgG and IgM antibodies to COVID-19 in human whole blood, serum, or plasma.

The lateral flow immunoassay device is designed for mass population SARS-CoV-2 antibody testing and can be applied regularly to monitor at -risk populations, acting as a primary form of testing of infection or a secondary form of PCR SARS-CoV-2 test confirmation.

This assay provides only a preliminary analytical test result. A more specific alternate testing method must be used while considering the patient's clinical characteristics in order to obtain a confirmed analytical result.

(For In Vitro Use Only)

Test Principles

CovWipe-19 consists of independent IgG and IgM components. The sample of human blood is added to the sample port of the test kit. The test kit reconstitutes the recombinant SARS-CoV-2 Spike Protein. As the mixture migrates chromatographically by capillary action, the IgM or IgG antibodies to SARS-CoV-2 present in the sample reacts with labeled recombinant SARS-CoV-2 Spike Protein. Anti-Human IgM antibody coated in the IgM test zone of the nitrocellulose membrane reacts with SARS-CoV-2 IgM in the tested sample. Similarly, anti-Human IgG antibody coated on the IgG test zone in the nitrocellulose membrane reacts with SARS-CoV-2 IgG-gold complex in the sample. Finally, antibody coated in the control zone of the nitrocellulose membrane captures a portion of the control protein complex and this can be used as a control to normalize the reactivity of the lateral flow device. Colored lines will appear in the respective IgM, IgG or control test zones that can be visually inspected for reactivity.

Materials

Each package contains:

1. Rapid-Cov
2. 10 µL Blood dropper
3. Diluent dropper bottle (1 per carton of 20)

Materials recommended but not provided:

- Personal Protective Equipment
- Timer

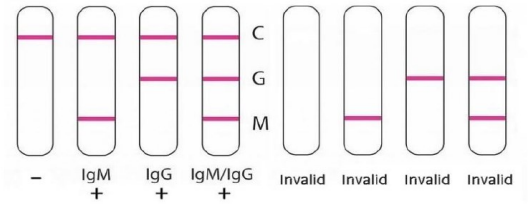
Directions for Use

1. Bring the sample to be tested (serum/plasma) to room temperature

2. Pipette 10µL of the patient sample into the sample port.

3. 10 seconds later, slowly add 2 drops of diluent into the sample port

4. Start a timer for 15 minutes. Read results at 15 minutes. It is recommended to re-read results at 30 minutes to capture possible early-stage responses to infection. Faint lines at 30 minutes may indicate early stages of infection.



Test Limitations

1. This product produces a qualitative result.

2. Detection of a result is limited by the amount of antibody present in the sample. A negative result may be generated if the IgG or IgM antibody concentration is lower than the detection limit of the assay.

3. This product uses a colloidal gold immunolabeled antigen antibody on a nitrocellulose membrane that is quantified by detection in an immunoassay analyzer. Samples containing high triglyceride, bilirubin or hemolysis concentrations will impact the migration of the sample across the nitrocellulose membrane. This may lead to erroneous results. Therefore, samples containing any of the following interfering substances should not be used for testing:

a) Severe lipemia: the concentration of triglycerides exceeds 4000mg/dL

b) Severe jaundice: the concentrations of bilirubin exceeding 40mg/dL

c) Severe hemolysis: the concentration f hemoglobin exceeds 600mg/dL

4. Human anti-mouse antibodies (HAMA) may appear in patients who have been exposed to environments containing mice or rat populations. The methodology of this device has been formulated to minimize the impact of these interferents on results. However, care must be taken when patients are known to contain these antibodies.

Quality Control

Each lot is tested before release. Oranoxis is a FDA Registered Medical Device Manufacturing Facility with ISO 13485:2016 certifications. For batch release records, registration numbers, certification numbers, CE information, etc. please email info@oranoxis.com.

Precautions

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. The lateral flow chromatographic device has been designed for professional in vitro use only.
6. Samples with severe hemolysis, lipemia and/or elevated bilirubin should not be used.
7. Results should not be reported from test reagents that have been damaged, results that are not clear, expired product and/or in single package, the mark is unclear, and if reading occur outside the valid 10 – 15 minute reading time.
8. Instructions should be followed as written. After the testing has begun, the procedure cannot be terminated. If the test has been terminated, the test cannot be resumed. If retesting is required, a new test cuvette must be used.
9. Invalid results must be retested.
10. All samples and waste should be treated as biohazardous material.
11. A new vacutainer blood collection tube should be used for every sample collection. After use, the vacutainer blood collection tube should be treated as biohazardous material.
12. SARS-CoV-2 IgM/IgG Antibody test results cannot be used as an absolute basis for the diagnosis of SARS-CoV-2 and should be interpreted based on clinical characteristics and other test results.

References

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4. Zhu N, A Novel Coronavirus from Patients with Pneumonia in China, 2019. DOI: 10.1056/NEJMoa2001017
5. Huang C, et al. Clinical features of patients infected with 2019 novel coronavirus in
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