**For Prescription Use Only.**
**For In-Vitro Diagnostic Use Only**

# reOpenTest

## COVID-19 IgG IgM Rapid Test Kit

(Colloidal Gold)

CE IVD

### INTENT OF USE

The reOpenTest COVID-19 IgG IgM Rapid Test Kit is a rapid lateral flow chromatographic immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in in human venous whole blood (sodium heparin, EDTA, and sodium citrate), serum or plasma (sodium heparin, potassium EDTA and sodium citrate). The reOpenTest COVID-19 IgG IgM Rapid Test Kit is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The reOpenTest COVID-19 IgG IgM Rapid Test Kit should not be used to diagnose acute SARS-CoV-2 infection.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C 263a, that meet the requirements to perform moderate or high complexity tests.

Results are for the detection of SARS CoV-2 antibodies. The IgG and IgM antibodies to SARSCoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies is present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

The sensitivity of reOpenTest COVID-19 IgG IgM Rapid Test Kit early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for reOpenTest COVID-19 IgG IgM Rapid Test Kit may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG or IgM assay.

### SUMMARY AND EXPLAINATION

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases. The reOpenTest COVID-19 IgG IgM Rapid Test Kit is a rapid test that utilizes a combination of SARS-COV-2 antigen coated colored particles for the detection of IgG and IgM antibodies to SARS-COV-2 in human whole blood, serum or plasma.

### PRINCIPLE OF THE TEST

The reOpenTest COVID-19 IgG IgM Rapid Test Kit is a lateral flow immunochromatographic assay for the detection of SARS-CoV-2 antibodies in venous whole blood, serum or plasma. This test uses anti-human IgM antibody (test line IgM), anti-human IgG (test line IgG) and goat anti-mouse IgG (control line C) immobilized on a nitrocellulose strip. The conjugate pad contains recombinant SARS-CoV-2 antigen (Spike protein RBD domain main antigens of SARS-CoV-2) conjugated with colloid gold. During testing, the specimen binds with SARS-CoV-2 antigen- conjugated gold colloid coated particles in the test cassette. When a specimen followed by assay buffer is added to the sample well, IgM &/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 (antihuman IgM &/or anti-human IgG) the complex is trapped forming a colored line which confirm a reactive test result. Absence of a colored line in the test region indicates a non-reactive test result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

### REAGENTS AND MATERIALS SUPPLIED

| Materials | COVA10C | COVA100 |
|---|---|---|
| **Test Cassette**<br>* Individual foil pack | 60 | 25 |
| **Extraction Buffer (80µl Pack)** | 60 | 25 |
| **Dropper** | 60 | 25 |
| **Alcohol Pad** | 60 | 25 |
| **Lancet** | 60 | 25 |
| **Individual IFU** | 60 | N/A |
| **Package Insert** | 1 | 1 |

### MATERIALS NOT SUPPLIED IN KIT

- Timer or watch

### WARNINGS AND PRECAUTIONS

- For prescription use only. For in vitro diagnostic use only. Do not use after expiration date.
- This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.
- Humidity and temperature can adversely affect results.

### KIT STORAGE AND STABILITY

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

### SPECIMEN COLLECTION AND PREPARATION

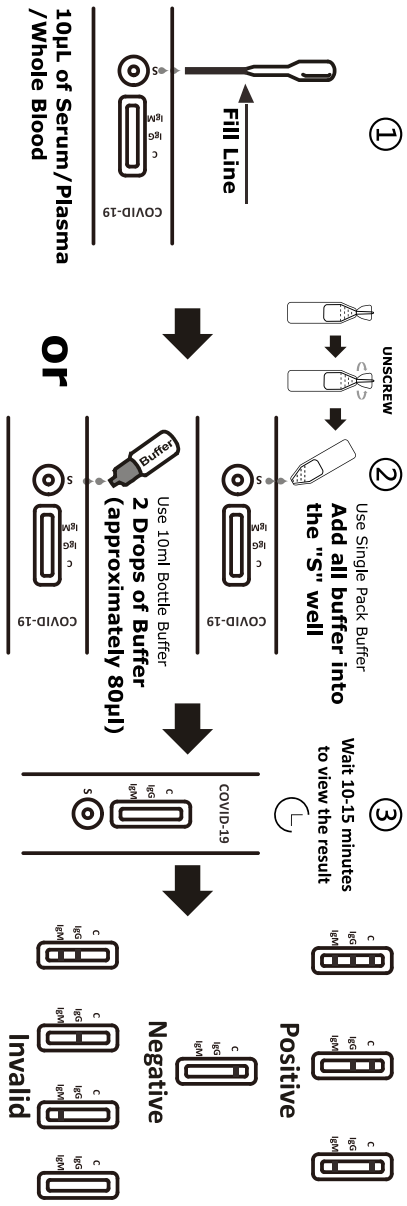
- The reOpenTest COVID-19 IgG IgM Rapid Test Kit can be performed using whole blood, serum or plasma.
- Whole blood or plasma could be collected with tube containing Heparin or Citrate.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- 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.
- 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.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

### TEST PROCEDURE

*(Please refer to the illustration)*

***Allow the test cassette, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing:***

1. Bring the pouch to room temperature before opening. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the test cassette on a clean and level surface.
   ***For Serum or Plasma or Whole Blood Specimens:***
   To use a dropper: Hold the dropper vertically, draw the specimen up to the Fill Line (approximately 10µl), and transfer the specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80µl) or 80µL individual buffer to the well (S) and start the timer. Avoid trapping air bubbles in the specimen well.
   To use a micropipette: Pipette and dispense 10µl of specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80µl) or 80µL individual buffer to the well (S) and start the timer.
3. Wait for the colored line(s) to appear. The test result should be read at 10 minutes. Do not interpret the result after 20 minutes.



## INTERPRETATION OF RESULTS

- **IgG and IgM POSITIVE**: * **Three lines appear**. One colored line should be in the control line region (C), and two-colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match.
- **IgG POSITIVE**: * **Two lines appear**. One colored line should be in the control line region (C), and a colored line appears in IgG test line region. The result is positive for SARS-COV-2 virus specific-IgG.
- **IgM POSITIVE**: * **Two lines appear**. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for SARS-COV-2 virus specific-IgM antibodies.
  ***NOTE**: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of SARS-COV-2 antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s) should be considered positive.
- **NEGATIVE**: **One colored line should be in the control line region (C)**. No line appears in IgG and IgM test line region(s).
- **INVALID**: **Control line fails to appear**. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## LIMITATIONS

- Use of the reOpenTest COVID-19 IgG IgM Rapid Test Kit is limited to laboratory personnel who have been trained. Not for home use.
- The reOpenTest COVID-19 IgG IgM Rapid Test Kit is for in vitro diagnostic use only. The test should be used for the detection of SARS-COV-2 antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in SARSCOV-2 antibody concentration can be determined by this qualitative test.
- The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of SARS-CoV-2 virus specific antibodies in the serum, plasma or whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
- Reading test results earlier than 10 minutes after the addition of Buffer may yield erroneous results. Do not interpret the result after 20 minutes.
- The reOpenTest COVID-19 IgG IgM Rapid Test Kit will only indicate the presence of SARS-COV-2 antibodies in the specimen and should not be used as the sole criteria for the diagnosis of SARS-COV-2.
- In the early onset of symptom, anti-SARS-COV-2 IgM and IgG antibody concentrations may be below detectable levels.
- The test may have lower sensitivity for IgG detection in symptomatic individuals prior to 14 days since symptom onset.
- Results from immunosuppressed patients should be interpreted with caution.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- A negative result for individual subject indicates absence of detectable anti-SARS-CoV-2 antibodies. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions, IgM antibodies may not be detected in the first few days of infection; the sensitivity of the reOpenTest COVID-19 IgG IgM Rapid Test Kit early after infection is unknown. False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made. A negative result can occur if the quantity of the anti-SARS-CoV-2 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.
- Some specimens containing unusually high titer of rheumatoid factor may affect expected results.
- 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.
- 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.
- Not for the screening of donated blood.
- There may be false positive risk with the plasma in EDTA tube after 24hours.
- The sensitivity of the test is impacted after being open for one hour-the intensity of the T line becomes weak. Testing must be performed within one hour after opening the pouch.

## PERFORMANCE CHARACTERISTICS

- **Sensitivity and Specificity**

The reOpenTest COVID-19 IgG IgM Rapid Test Kit was compared with a leading commercial PCR; the results show that reOpenTest COVID-19 IgG IgM Rapid Test Kit has high sensitivity and specificity.

| Method | | PCR | | Total Results |
|---|---|---|---|---|
| reOpenTest COVID-19 IgG IgM Rapid Test | Results | Positive | Negative | |
| | Positive | 171 | 2 | 173 |
| | Negative | 10 | 270 | 280 |
| **Total Result** | | 181 | 272 | 453 |

**Relative Sensitivity: 94.48%（95%CI：90.07%～97.32%）**
**Relative Specificity: 99.26%（95%CI：97.37%～99.91%）**
**Accuracy: 97.35%（95%CI：95.42%～98.62%）**

- **Cross-reactivity**

The reOpenTest COVID-19 IgG IgM Rapid Test Kit has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAb, anti-H.Pylori, and anti-HIV positive specimens. The results showed no cross-reactivity.

- **Interfering Substances**

The following compounds have been tested using the reOpenTest COVID-19 IgG IgM Rapid Test Kit and no interference was observed.

| Interfering Substances | Concentration | Interfering Substances | Concentration |
|---|---|---|---|
| Triglyceride | 50 mg/dL | Ascorbic Acid | 20mg/dL |
| Hemoglobin | 1000mg/dL | Bilirubin | 60mg/dL |

## REFERENCE


- Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011; 81:85-164. PMID:22094080 DOI:10.1016/B978-0-12-385885-6.00009-2.
- Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016; 24:490-502. PMID:27012512 DOI:10.1016 / j.tim.2016.03.003.
- Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.PMID:30531947 DOI:10.1038/s41579-018-0118-9.


reOpenTest

**REF COVA100 / COVA10C**

## ORDERING

1. Contact reOpenTest's distributors or
2. Visit reOpenTest website: http://www.reopentest.com
3. E-mail: sales@reopentest.com

## CUSTOMER SERVICE

Contact your local representative
or find country-specific contact information with
E-mail: service@reopentest.com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CE Mark
IVD In vitro diagnostic medical
Read instructions for use
REF Catalogue number
LOT Batch code
Use by
Manufacturer
EC REP Authorized Representative in the European Community / European Union
Contains sufficient for <n> tests
Do not re-use
Do not use if package is damaged
Keep away from sunlight
Keep Dry
Keep away from rain
Temperature limit
Caution