Novel Coronavirus (COVID-19) IgG/IgM Antibody Test

(Serum/Plasma/Whole Blood) Strip Format
Instructions for Use Catalog Number: B251S

A rapid test for the qualitative detection and differentiation of novel coronavirus (COVID-19) IgG & IgM antibodies in human whole blood, serum and plasma samples. For preliminary screening and all results should be confirmed with other qualified assays.

INTENDED USE

Biocan Tell Me Fast Coronavirus (COVID-19) IgG/IgM Antibody Rapid Test is a rapid, qualitative, membrane-based immunochromatographic in vitro assay intended for detection and differentiation of novel coronavirus (COVID-19) IgG & IgM antibodies with human serum, plasma or whole blood samples (including finger prick). This test is intended for laboratory in vitro diagnostic use and is a preliminary screening test and final diagnosis should be based after examination with other qualified assays.

SUMMARY

Human coronaviruses are common throughout the world. Seven different coronaviruses, that scientists know of, can infect people and make them sick. Some human coronaviruses were identified many years ago and some have been identified recently. Human coronaviruses commonly cause mild to moderate illness in people worldwide. Three newer human coronaviruses, MERS-CoV, SARS-CoV and 2019-nCoV, have been known to frequently cause severe illness. Human coronaviruses can sometimes cause lower-respiratory tract illnesses, such as pneumonia or bronchitis. This is more common in people with cardiopulmonary disease, people with weakened immune systems, infants, and older adults.

Coronavirus (CoV) belongs to the genus Nestovirus, Coronaviridae, and is divided into three genera: α, β, and γ. The α and β gene are only pathogenic to mammals. The γ gene mainly causes bird infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also some evident that it can be transmitted through the fecal-oral route. So far, there are 7 types of human coronaviruses (HCoV) that cause human respiratory diseases: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and Novel Coronavirus (COVID-19) (2019) , it's an important pathogen of human respiratory infections. Among them, the COVID-19 was discovered in 2019 from Wuhan virus pneumonia outbreak. The clinical manifestations are systemic symptoms such as fever and fatigue, accompanied by dry cough, dyspnea and so on. These manifestations can quickly develop into severe pneumonia, respiratory failure, acute respiratory distress syndrome (ARDS), septic shock, multiple organ failure, severe acid-base metabolism disorders, etc., and even life-threatening.

IgM is the primary antibody to appear in the human immune system soon after infected. The detection of IgM during acute infection has the advantages of high sensitivity, early diagnosis, and ability to determine whether the suspected person is infected. The detection of Coronavirus (COVID-19) IgM antibody has important clinical significance to effective control of the large-scale spread of COVID-19. IgM antibody produces after several days of virus infection and can be detected as early as one week or even 3 days, the time it appears varies from individual to individual. IgG antibody generally begins to produce 7-14 days after virus infected and can be detected up to several months and in some cases can maintain lifetime even.

PRINCIPLE OF THE TEST

Biocan Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Rapid Test Strip is a lateral flow chromatographic immunoassay. The test Strip consists of a pink colored conjugate pad containing recombinant COVID-19 antigen conjugated with colloid gold (COVID-19 conjugates) and quality control antibody gold conjugates and a nitrocellulose membrane strip containing two test lines (T1 and T2) and a control line (C). The T1 line is pre-coated with monoclonal anti-human IgM for the detection of IgM anti-COVID-19, T2 line is pre-coated with reagents for the detection of IgG anti-COVID-19 and the C line is pre-coated with quality control antibody. When an adequate volume of test specimen is dispensed into the sample pad of the test strip, the specimen migrates by capillary action across the test strip. COVID-19 IgM antibodies if present in the specimen will bind to the COVID-19 conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a pink colored T1 line, indicating COVID-19 IgM positive test result. COVID-19 IgG antibodies if present in the specimen will bind to the COVID-19 conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a pink colored T2 line, indicating a COVID-19 IgG positive test result. Absence of any test lines (T1 and T2) suggests a negative result. The test strip also contains a quality control line C. Regardless of the presence or absence of a detection band, the red quality control band C should appear. If the quality control band C does not appear, the test result is invalid, and the sample needs to be tested again with another test strip.

PRECAUTIONS

- Specimen processing should be performed in accordance with pertaining national biological safety regulations and following the recommended WHO guidelines on biosafety and biosecurity. For laboratory in vitro diagnostic research use only. Do not use after expiration date.
- 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 testing 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 being tested.

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.

MATERIALS

MATERIALS PROVIDED
- Test strips (50 tests strip per vial)
- Sample Diluent buffer Bottle (6ml)
- Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED
- Disposable gloves
- Timer
- Pipette

SPECIMEN COLLECTION AND PREPARATION

•Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non- hemolyzed specimens can be used.

Catalog: B251S REV. 03/2020
Manufactured by: Biocan Diagnostics Inc 55A & 53B Fawcett Road V3K6V2 BC Canada
www.rapidtest.ca

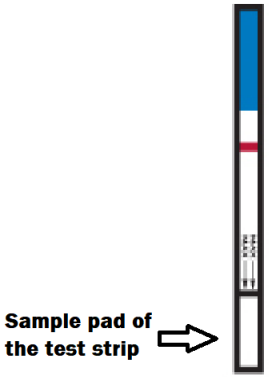
•Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, serum & plasma specimens should be kept below -20°C.
•Bring specimens to room 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 the transportation of etiologic agents. The test can be performed using serum, plasma or whole Blood (including finger prick) specimen, including plasma or whole blood samples prepared from commonly used anticoagulants (EDTA, heparin, sodium citrate).

DIRECTIONS FOR USE

Allow the tests and controls to reach to room temperature (15-30ºC) prior to testing. Do not open the package until ready to perform the assay.

1. Place the test strip on a clean and level surface. Pipette 10μL of serum, plasma or 20μL whole blood (including finger prick) into the sample pad of the test strip.
2. Add 2 drops of diluent buffer to sample pad of the test strip.
3. Wait for the red lines to appear. The test result should be read between 10 and 15 minutes.

Note: Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

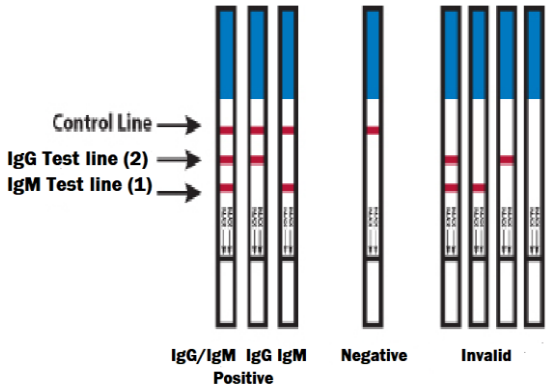
IgM POSITIVE: Two distinct red lines appear. The control line (C) and IgM (Test line 1) line are visible on the test strip. The test is positive for COVID-19 IgM antibodies.

IgG POSITIVE: Two distinct red lines appear. The control line (C) and IgG (Test line 2) line are visible on the test strip. The test is positive for COVID-19 IgG antibodies.

IgM and IgG POSITIVE: Three distinct red lines appear. The control line (C), IgM (1) and IgG (2) lines are visible on the test strip. The test is positive for COVID-19 IgM and IgG antibodies.
NEGATIVE: One distinct red line appears. The control line (C) is the only line visible on the test strip. No COVID-19 IgG or IgM antibodies were detected.

INVALID: Control line fails to appear. The test results are INVALID, if no control line (C) is visible, regardless of the presence or absence of lines in the IgG (2) or IgM (1) region of the test strip. Repeat the test using a new test strip.

NOTES ON THE INTERPREATION OF RESULTS
The intensity of the red color in the test line regions will vary depending on the concentration of IgG and IgM present in the specimen. However, neither the quantitative value nor the rate of increase in IgG or IgM can be determined by this qualitative test.



QUALITY CONTROL
Internal procedural controls are included in the test. A pink line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

PERFORMANCE
Currently we only recommend using this test for presumptive preliminary screening purposes only. The expected sensitivity of test for IgM & IgG should be 92% and specificity at 99.5% when compared to PCR.

LIMITATIONS
1. This test provides a presumptive diagnosis for Novel Coronavirus (COVID-19) infection. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated and verified by other qualified assays.
2. A negative result may be obtained if the specimen is inadequate or antibody concentration is below the sensitivity of the test. Therefore, it is recommended that all negative test results undergo confirmatory testing using other method and/or qualified assays.

CE EC REP Wellkang Ltd (www.CE-marking.eu)
29 Harley St., London W1G 9QR, UK

	Storage temperature	LOT	Lot number
IVD	In vitro diagnostic device		Expiry date
	Read instruction before use		Manufacturer
	Protect from light and moisture		Do not reuse

Catalog: B251S REV. 03/2020
Manufactured by: Biocan Diagnostics Inc 55A & 53B Fawcett Road V3K6V2 BC Canada
www.rapidtest.ca