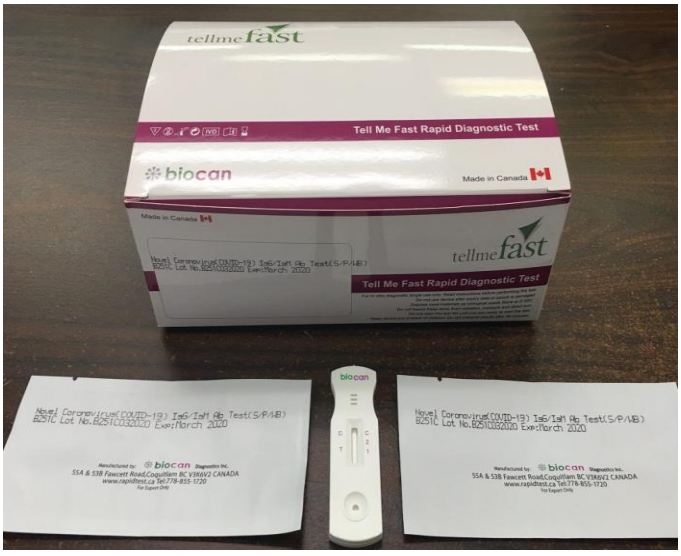
biocan

Proudly Canadian

Responding fast to Coronavirus (COVID-19) outbreak Biocan has a launched a rapid test capable of delivering fast results in just minutes to detect the Coronavirus COVID-19 IgG/IgM Antibodies in human whole blood, plasma or serum sample. This test is easy to use and cost effective.

Now detect Novel Coronavirus (COVID-19) infection in just minutes with the Biocan Tell Me Fast COVID-19 IgG/IgM Antibody Test.



-- Test Requires only 10µL of human serum, plasma or whole blood (including finger prick)

-- Detects and differentiates between an IgM and IgG COVID-19 virus infection for a primary and past infection.

-- Easy to use and results in 10 minutes

-- Cost effective and no instruments needed to perform the test. Test be performed at doctor's office, clinics, labs, field setting, mobile testing, hospitals, labs, cruise ships, airports, ports etc.

-- Stable at 2 to 30 C. No cold chain needed for transportation.

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. In comparison to PCR test specimens tested from 1 to 3 days of infection the IgM positive rate should 16% and the IgG positive rate should be 16%. Specimens tested from 4 to 7 days, the IgM positive rate should be 85.7% and the IgG positive rate 92.8%. Specimens in the range of 8 days to 14 days the IgM & IgM positive rate should be 90%. IgG can be detected for a longer period of time. ***More testing data to be availble soon.***

Biocan Diagnostics Inc based in Canada has a launched a rapid test for easy and fast detection of the highly contagious Coronavirus (COVID-19). Biocan is an ISO 13485:2016 MDSAP certified manufacturer of various rapid in vitro diagnostics tests made under stringent quality control in our facility near Vancouver, Canada. As part of our corporate mission we have launched the COVID-19 IgG/IgM Ab Rapid Test at a very reasonable cost to make it affordable to where it is need most to stop the spread of this novel coronavirus, which has now affected a very large number of people worldwide and is spreading at a very fast rate.

Coronavirus (COVID-19) IgG/IgM Antibody Test

(Serum/Plasma/Whole Blood) Cassette Format
Instructions for Use Catalog Number: B251C

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 presumptive preliminary screening and all results should be confirmed with other qualified assays.

INTENDED USE

Biocan Tell Me Fast Coronavirus (COVID-19) IgG/IgM Antibody 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. This test is intended for laboratory in vitro diagnostic use and is a preliminary screening presumptive test and final diagnosis should be based after examination with other qualified assays. This test may be reactive with coronaviruses under the subgenus Sarbecovirus that includes 2019-nCoV, SARS-CoV and bat SARS-like coronaviruses since there are a lack of 2019-nCOV positive controls and the genetic diversity of 2019-nCoV in humans and animals is yet to be fully determined.

SUMMERY

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 Rapid Test is a lateral flow chromatographic immunoassay. The test cassette 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 IgG for the detection of IgG anti-COVID-19, T2 line is pre-coated with reagents for the detection of IgM 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 well of the cassette, the specimen migrates by capillary action across the cassette. 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 T2 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 T1 line, indicating a COVID-19 IgG positive test result. Absence of any test lines (T1 and T2) suggests a negative result. The test cassette 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 cassette.

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 cassette with desiccant in individual pouch (25 tests per box)
- Sample Diluent buffer Bottle (5ml)
- Instructions for use

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

SPECIMEN COLLECTION AND PREPARATION

Catalog: B251C REV. 03/2020
Manufactured by: Biocan Diagnostics Inc 55A & 53B Fawcett Road V3K6V2 BC Canada
www.rapidtest.ca

•Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non- hemolyzed specimens can be used.
•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, 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 device on a clean and level surface. Pipette 10μL of serum, plasma or whole blood into the sample well of the test device.

2. Add 2 drops of diluent buffer to sample well of the test device.

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 2) line are visible on the test cassette. The test is positive for COVID-19 IgM antibodies.

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

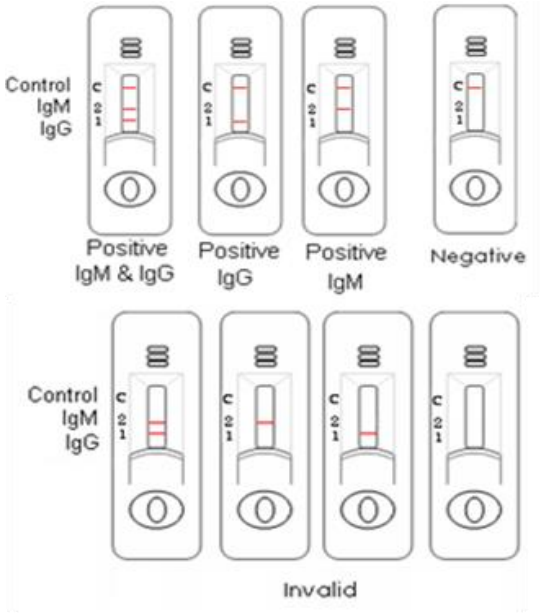
IgM and IgG POSITIVE: Three distinct red lines appear. The control line (C), IgM (M) and IgG (G) lines are visible on the test cassette. The test is positive for COVID-19 IgM and IgG antibodies.

NEGATIVE: One distinct red line appears. The control line (C) is the only line visible on the test cassette. 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 (G) or IgM (M) region of the cassette. Repeat the test using a new cassette.

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. In comparison to PCR test specimens tested from 1 to 3 days of infection the IgM positive rate should 16% and the IgG positive rate should be 16%. Specimens tested from 4 to 7 days, the IgM positive rate should be 85.7% and the IgG positive rate 92.8%. Specimens in the range of 8 days to 14 days the IgM & IgM positive rate should be 90%. IgG can be detected for a longer period of time.

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.

	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

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

Catalog: B251C REV. 03/2020
Manufactured by: Biocan Diagnostics Inc 55A & 53B Fawcett Road V3K6V2 BC Canada
www.rapidtest.ca