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

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

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 use by clinical laboratories, healthcare workers for point of care testing and not for home testing. This is a preliminary screening presumptive test and final diagnosis should be based after examination with other qualified assays. This test is not a definitive test for COVID-19 and the information contained herein has not been reviewed by FDA.

Results are for the detection of SARS-CoV-2 antibodies. IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although levels over the course of infection are not well characterized. IgG antibodies to SARS-CoV-2 become detectable later following infection. Positive results for both IgG and IgM could occur after infection and can be indicative of acute or recent infection. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities. 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. At this time, it is unknown for how long IgM or IgG antibodies may persist following infection.

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 evidence 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.

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 red colored conjugate pad containing recombinant COVID-19 antigen conjugated with colloid gold (COVID-19 conjugates), quality control antibody gold conjugates, nitrocellulose membrane strip containing two test lines (T1 and T2) and a control line (C). The T2 line is pre-coated with monoclonal anti-human IgG for the detection of IgG anti-COVID-19, the T1 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 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 red 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 red 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.

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

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 strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

MATERIALS

MATERIALS PROVIDED
- Test Strip with desiccant in individual pouch or 50 tests per vail
- Sample Diluent buffer Bottle (8ml)
- Instructions for use
- Plastic pipette (50)
- Reference chart for line position

MATERIALS REQUIRED BUT NOT PROVIDED
- Disposable gloves and timer

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.
•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

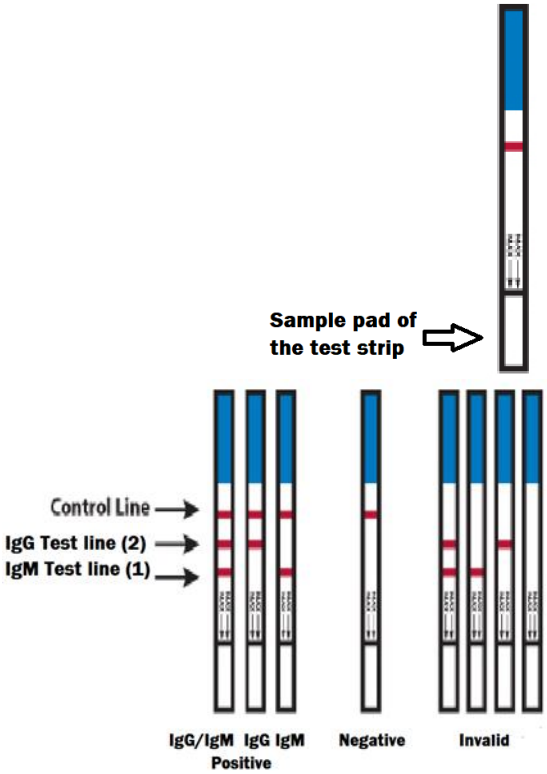
Allow the tests and controls to reach to room temperature (15-30ºC) prior to testing. Do not open the package until ready to perform the assay.

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 well of the test strip.

2. Add 2 drops of diluent buffer to the 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. Reference chart is provided to verify line position (C, T1 & T2)



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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 red 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 and not for a definitive diagnosis. The expected sensitivity of test for IgM & IgG should be 92% and specificity at 99.5% when compared to PCR.

CROSS REACTIVITY

No cross-reactivity has been observed with the Biocan Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody test with Influenza A & B, HCV, HIV, HBsAg, CMV, Rubella, Toxoplasma, HSV-1, HSV-2, RSV, Adenovirus and Rotavirus.

Notes for Clinical Use in United States

Laboratories and healthcare providers must include this information in their patient test report as specified in FDA guidance:

- This test has not been reviewed by the FDA.
- 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.
- 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.
- 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.
- Not for the screening of donated blood

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.
3. This test is not a definitive test for COVID-19 and the information contained herein has not been reviewed by FDA.
4. This test should not be used for screening donor blood.

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

CE

	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

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