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

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

For prescription use only. For in vitro diagnostic use only. For Emergency Use Authorization only.

INTENDED USE

The Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human serum, plasma (Lithium-Heparin, Sodium-Citrate & Acid Citrate Dextrose) and venous whole blood (Lithium-Heparin, Sodium-Citrate & Dipotassium-EDTA). The Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test 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 Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet requirements to perform moderate or high complexity tests.

Results are for the detection of SARS CoV-2 antibodies. IgM and IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are 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 Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test early after infection in 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 Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test 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 a second, different IgG or IgM assay.

The Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

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, frequently have been known to cause severe illness. Human coronaviruses can sometimes cause lower-respiratory tract illnesses, such as pneumonia or bronchitis. Severe illness more common in people with cardiopulmonary disease, diabetes, weakened immune systems, 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 droplets. So far, there are seven 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), all pathogens 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, lack of smell and taste 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 is a lateral flow chromatographic immunoassay. The test cassette consists of a red colored conjugate pad containing recombinant COVID-19 antigen conjugated with colloid gold (SARS-CoV-2 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-SARS-CoV-2, the T1 line is pre-coated with reagents for the detection of IgM anti-SARS-CoV-2 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. SARS-CoV-2 IgM antibodies if present in the specimen will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a red colored T1 line, indicating SARS-CoV-2 IgM positive test result. SARS-CoV-2 IgG antibodies if present in the specimen will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a red colored T2

line, indicating a SARS-CoV-2 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.

STORAGE AND STABILITY

The kit can be stored refrigerated (2°-8°C) or at 25°-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 (3ml)
- Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock, watch, or other timing device
- Pipettor capable of delivering 10µL of serum or plasma specimens
- Disposable gloves, Biohazard disposal container, Collection devices (for serum, plasma)
- External controls: External positive and negative controls (Catalog No: B251PNC) can be ordered directly from Biocan or through authorized distributor.
  Positive controls: Anti-SARS-CoV-2 antibodies (IgM and IgG) in horse serum with proclin. Negative controls: Horse serum with proclin (Instruction for use is provided with the external controls)

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 more than X3 times.
•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, or plasma specimen, prepared from commonly used anticoagulants (Lithium-heparin, Sodium-citrate and Acid Citrate Dextrose).

DIRECTIONS FOR USE

Allow the tests and controls to reach room temperature (15-30°C) prior to testing. Do not open the package until ready to perform the assay. Place the test device on a clean and level surface.

For Serum or Plasma Specimens:
Pipette 10 µL of serum/plasma specimen into the sample well of the test cassette. Then add 2 drops (about 80 µL) of sample buffer from the dropper bottle to the sample well immediately. Avoid air bubbles.

For Venous Whole Blood Specimen:
Pipette 20 µL of whole blood to the sample well of the test cassette. Then add 2 drops (about 80 µL) of sample buffer from the dropper bottle to the sample well immediately. Avoid air bubbles.

Wait for the red lines to appear. The result should be read in 10 to 15 minutes. 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 cassette. The test is positive for SARS CoV 2 IgM antibodies.

IgG POSITIVE: Two distinct red lines appear. The control line (C) and IgG (Test line 2) line are visible on the test cassette. The test is positive for SARS CoV 2 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 cassette. The test is positive for SARS CoV 2 IgM and IgG antibodies.

NEGATIVE: One distinct red line appears. The control line (C) is the only line visible on the test cassette. No SARS CoV 2 IgG or IgM antibodies were detected.

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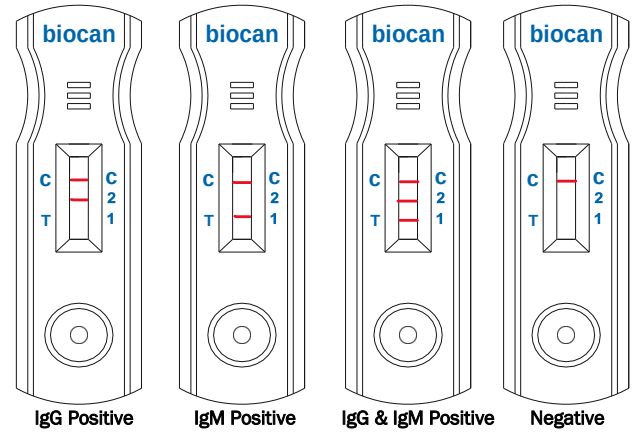
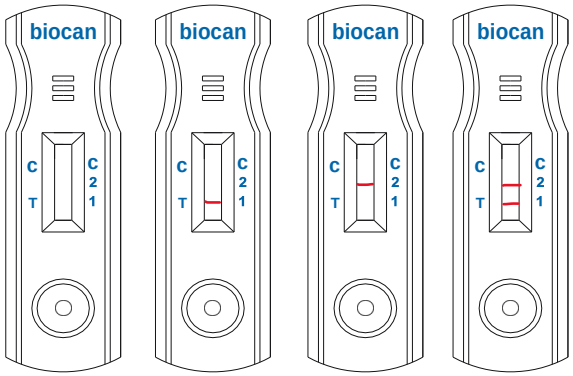
INVALID: Control line fails to appear. The test results are INVALID, if no control line (C) is visible, regardless of the presence or absence of lines in the IgG (2) or IgM (1) region of the cassette. Repeat the test using a new cassette.

NOTES ON THE INTERPREATION OF RESULTS: The qualitative test cannot be used to determine a quantitative value nor the rate of increase in IgG or IgM.





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 flow of reagents and directions were followed.
External negative and positives controls are available for purchase as described in the Materials Required But Not Provided Section. The controls should be run with each new lot when patient testing is conducted to confirm the test performance.

PERFORMANCE CHARACTERISTICS

1) *Analytical Sensitivity and Specificity*

a) Reactivity/Inclusivity:
Although mutations in the SARS-CoV-2 genome have been identified as the virus has spread, no serologically unique strains have been described relative to the originally isolated virus (this research is exceptionally limited at present).

b) Cross-Reactivity and Interferences:
Biocan has tested 161 known negative samples collected in the United States prior to December 2019 with high rates of vaccination. The negative percent agreement (NPA)/specificity is 99.4% is greater than 95%, this means that cross-reactivity for the following analytes does not need to be assessed.

anti-influenza A (IgG and IgM)
anti-influenza B (IgG and IgM)
anti-HCV (IgG and IgM)
anti-HBV (IgG and IgM)
anti-Haemophilus influenzae (IgG and IgM)
anti-229E (alpha coronavirus)
anti-NL63 (alpha coronavirus)
anti-OC43 (beta coronavirus)
anti-HKU1 (beta coronavirus)
ANA
anti-respiratory syncytial virus (IgG and IgM)
anti-HIV

Cross-reactivity with HIV+ specimen was tested on June 3, 2020 at the Frederick National Laboratory for Cancer Research (FNLCR) sponsored by the National Cancer Institute (NCI). A total of ten (10) HIV positive specimens were tested. All were found to be SARS-CoV-2 IgG/IgM negative.

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Five patient samples of EDTA plasma with medium to weak values in SARS-CoV-2 IgG and IgM antibodies were spiked with high levels of potentially interfering substances. In addition, five patient serum samples negative for SARS-CoV-2 IgG and IgM antibodies were spiked with high levels of potentially interfering substances. No false positive or false negative results were seen at the following concentrations.

Name of Substance	Concentration
Hemoglobin	1000 mg/dL
Bilirubin	10 mg/dL
Ascorbic Acid	20 mg/dL

2) Clinical Agreement Study:
Study 1: Biocan Diagnostics Clinical Agreement Validation

The clinical performance of the Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test was evaluated by testing a total of 233 retrospective serum samples all collected in the United States from hospital facilities or plasma centers—72 serum samples from PCR positive patients exhibiting symptoms of Covid-19 and 161 negative serum samples collected at blood banks prior to December 2019. The SARS-CoV-2 positive specimens were from previously symptomatic patients. The time from collection of positive serum specimens from each individual to testing ranged from 9-60 days with an average of 28 days.

All Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody testing was performed at an independent laboratory in the United States from May to July 2020 or at the Biocan laboratory in late July. Tell Me Fast Novel Coronavirus (COVID19) IgG/IgM Ab Test results for IgM and IgG detection were compared to the results of EUA authorized RT-PCR assays for SARS-CoV-2 from oropharyngeal swabs. Confidence intervals for sensitivity and specificity were calculated per score method described in CLSI EP12-A2 (2008). Overall study results are shown in the tables below.

Method			RT PCR		
			Positive	Negative	Subtotal
Tell me Fast Novel Coronavirus (Covid-19) IgG/IgM Antibody Test	Positive	IgG+/IgM+	62	1	63
		IgG-/IgM+	0	0	0
		IgG+/IgM-	10	0	10
	Negative	IgG-/IgM-	0	160	160
	Subtotal			161	233

Method			RT PCR		
			Positive	Negative	Subtotal
Tell Me Fast Novel Coronavirus (Covid-19) IgG/IgM Test	Positive	IgG+/IgM+	62	1	63
		IgG-/IgM+	0	0	0
		IgG+/IgM-	10	0	10
	Negative	IgG-/IgM-	0	160	160
	Subtotal		72	161	233

Measure	Estimate	95% Confidence Interval
IgG Sensitivity	100%	94.9-100%
IgM Sensitivity	86.1%	76.3-92.3%
Overall IgG or IgM Sensitivity	100%	94.9-100%
IgG Specificity	99.4%	96.6-99.9%
IgM Specificity	99.4%	96.6-99.9%
Overall IgG or IgM Specificity	99.4%	96.6-99.9%

IgG
Positive Percent agreement (PPA): 100% (72/72) (95%CI: 94.9%~100%)
Negative Percent agreement (NPA): 99.4% (160/161) (95%CI: 96.6%~99.9%)
IgM
Positive Percent agreement (PPA): 86.1% (62/72) (95%CI: 76.3%~92.3%)
Negative Percent agreement (NPA): 99.4% (160/161) (95%CI: 96.6%~99.9%)

Combined (either IgG+ or IgM+)
Positive Overall agreement (POA): 100% (72/72) (95%CI: 94.9%~100%)
Negative Overall agreement (NOA): 99.4% (160/161) (95%CI: 96.6%~99.9%)

Combined (either IgG+ or IgM+) at 5.0% Prevalence
Positive Predictive Value (PPV): 89.8% (95%CI: 59.5%~98.1%)
Negative Predictive Value (NPV): 100% (95%CI: 99.7%~100%)

IgG and IgM PPA stratified by days post onset of symptoms is presented in the following table:

		IgG			IgM		
Days from Symptoms	PCR Positive	Antibody Positive	PPA*	95% CI	Antibody Positive	PPA*	95% CI
≤7	0	0	0	NA	0	0	NA
8-14	18	18	100%	82.4-100%	16	88.9%	67.2-96.9%
≥15	54	54	100%	93.4-100%	46	85.2%	73.4-92.3%
Total	72				62		

		IgG			IgM		
Days from Symptoms	PCR Positive	Antibody Positive	PPA*	95% CI	Antibody Positive	PPA*	95% CI
≤ 7	0	0	0	NA	0	0	NA
8-14	18	18	100%	82.4-100%	16	88.9%	67.2-96.9%
≥15	54	54	100%	93.4-100%	46	85.2%	73.4-92.3%
Total	72				62		

* PPA = Positive Percent Agreement

Study 2: Independent Clinical Agreement Validation

Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test was tested on June 2, 2020 at the Frederick National Laboratory for Cancer Research (FNLCR) sponsored by the National Cancer Institute (NCI). The test was validated against a panel of previously frozen samples consisting of 30 SARS-CoV-2 antibody-positive serum samples and 80 antibody-negative serum and plasma samples. Each of the 30 antibody-positive samples were confirmed with a nucleic acid amplification test (NAAT) and both IgM and IgG antibodies were confirmed to be present in all 30 samples. The presence of antibodies in the samples was confirmed by several methods prior to testing with the Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test. The presence of IgM and IgG antibodies specifically was confirmed by one or more comparator methods. Antibody-positive samples were selected at different antibody titers. All antibody-negative samples were collected prior to 2020 and include: i) Seventy (70) samples selected without regard to clinical status, "Negatives" and ii) Ten (10) samples selected from banked serum from HIV+ patients, "HIV+". Confidence intervals for sensitivity and specificity were calculated per a score method described in CLSI EP12-A2 (2008). For evaluation of cross-reactivity with HIV+, it was evaluated whether an increased false positive rate among antibody-negative samples with HIV was statistically higher than the false positive rate among antibody-negative samples without HIV (for this, a confidence interval for the difference in false positive rates was calculated per a score method described by Altman). The results and data analysis are shown in the tables below.

Method			RT PCR		
			Positive	Negative	Subtotal
Tell me Fast Novel Coronavirus (Covid-19) IgG/IgM Antibody Test	Positive	IgG+/IgM+	27	1	28
		IgG-/IgM+	0	0	0
		IgG+/IgM-	1	2	3
	Negative	IgG-/IgM-	2	76	78
	Subtotal		30	79	

Method			RT PCR		
			Positive	Negative	Subtotal
Tell Me Fast Novel Coronavirus (Covid-19) IgG/IgM Test	Positive	IgG+/IgM+	27	1	28
		IgG-/IgM+	0	0	0
		IgG+/IgM-	1	2	3
	Negative	IgG-/IgM-	2	76	78
	Subtotal		30	79	

Measure	Estimate	95% Confidence Interval
IgG Sensitivity	93.3%	78.7-98.2%
IgM Sensitivity	90.0%	74.4-96.5%
Overall IgG or IgM Sensitivity	93.3%	78.7-98.2%
IgG Specificity	96.2%	89.4-98.7%
IgM Specificity	98.7%	93.2-99.8%
Overall IgG or IgM Specificity	96.2%	89.4-98.7%

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Measure	Estimate	95% Confidence Interval
IgG Sensitivity	93.3%	78.7-98.2%
IgM Sensitivity	90.0%	74.4-96.5%
Overall IgG or IgM Sensitivity	93.3%	78.7-98.2%
IgG Specificity	96.2%	89.4-98.7%
IgM Specificity	98.7%	93.2-99.8%
Overall IgG or IgM Specificity	96.2%	89.4-98.7%

IgG
Positive Percent agreement (PPA): 93.3% (28/30) (95%CI: 78.7%~98.2%)
Negative Percent agreement (NPA): 96.2% (76/79) (95%CI: 89.4%~98.7%)

IgM
Positive Percent agreement (PPA): 90% (27/30) (95%CI: 74.4%~96.5%)
Negative Percent agreement (NPA): 98.7% (78/79) (95%CI: 93.2%~99.8%)

Overall (either IgG+ or IgM+)
Positive Percent agreement (PPA): 93.3% (28/30) (95%CI: 78.7%~98.2%)
Negative Percent agreement (NPA): 96.2% (76/79) (95%CI: 89.4%~98.7%)

Combined (either IgG+ or IgM+) at 5.0% Prevalence
Positive Predictive Value (PPV): 56.4% (95%CI: 28.1%~79.9%)
Negative Predictive Value (NPV): 99.6% (95%CI: 98.8%~99.9%)

CONDITIONS OF AUTHORIZATION FOR LABORATORIES

The Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Recipients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

Authorized laboratories using the Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test ("your product" in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

1. Authorized laboratories* using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
2. Authorized laboratories using your product will use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
3. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
4. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
5. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Biocan Diagnostics Inc. (email: sales@rapidtest.ca) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
6. All laboratory personnel using your product must be appropriately trained in immunochromatographic techniques and use appropriate laboratory and personal protective equipment when handling this kit and use this product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.
7. Biocan Diagnostics Inc., authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

*The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests" as "authorized laboratories."

WARNINGS AND PRECAUTIONS

1. For use under Emergency Use Authorization only. For IN VITRO Diagnostic use only.
2. This test has not been FDA cleared or approved; the test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests.
3. This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV2, not for any other viruses or pathogens.
4. 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 Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the authorization is terminated or revoked sooner.
5. Do not use the product beyond the expiration date.

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6. Do not use the product if the pouch is damaged or the seal is broken.
7. Immediately use after opening the test device in the pouch.
8. Immediately add the assay buffer to the test device after the specimen is applied.
9. In order to obtain accurate results, the test procedure must follow this package insert. Do not use if the test device package is damaged.
10. Read the Product Insert completely before using this assay. Follow the instructions carefully as not doing so may result in inaccurate test results.
11. Specimen processing should be performed in accordance with standard laboratory procedures and biosafety guidelines for handling and disposal of potentially infectious material. For laboratory in vitro diagnostic research use only. Do not use after expiration date.
12. Do not eat, drink or smoke in the area where the specimens or kits are handled.
13. 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.
14. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.

LIMITATIONS

1. Use under an Emergency Use Authorization only. For prescription use only.
2. Use of this test is limited to laboratory personnel who have been trained. Not for home use or point of care (POC) use.
3. The test is limited to the qualitative detection of anti-COVID-19 antibody levels in human serum, plasma (Lithium-Heparin, Sodium-Citrate & Acid Citrate Dextrose) or venous whole blood (Lithium-Heparin, Sodium-Citrate & Dipotassium-EDTA) and does not indicate the quantity of the antibodies. The intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen.
4. The test results should be interpreted between 10 and 15 minutes after addition of buffer. The test results should not be interpreted after 20 minutes.
5. Negative results do not preclude SARS-CoV2 infection and should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected in the first several days of infection; the sensitivity of this test 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.
7. A negative result may be obtained if the specimen is inadequate or antibody concentration is below the sensitivity/detection limit of the test. Therefore, it is recommended that all negative test results undergo confirmatory testing using other method and/or qualified assays.
8. The test may have lower sensitivity for IgG and IgM detection in symptomatic individuals prior to 15 days since symptom onset.
9. Direct testing with a molecular diagnostic test should be performed to evaluate for acute SARS-CoV-2 infection in symptomatic individuals.
10. Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV2 infection or to determine infection status.
11. It is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.
12. A positive results may not indicate previous SARS-CoV-2 infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an adaptive immune response. 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.
13. This test will only indicate the presence of SARS-CoV-2 IgM and/or IgG antibodies in the specimen.
14. This device has been evaluated for use with human specimen material only
15. It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to reinfection.
16. This test should not be used for screening of donated blood.

For Product Information, Literature and/or SDS please email:
sales@rapidtes.ca
Manufactured by:
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Web Site: www.rapidtest.ca

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