BIOGATELABS

COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P) English

For professional and in vitro diagnostic use only.

[INTENDED USE]

The COVID-19 IgG/IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to COVID-19 in human Whole Blood/Serum/Plasma. It provides an aid in the diagnosis of infection with COVID-19.

[SUMMARY]

Early January 2020, a COVID-19 (SARS-CoV-2, formerly known as 2019-nCoV) was identified as the infectious agent causing an outbreak of viral pneumonia in Wuhan, China, where the first cases had their symptom onset in December 2019.

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases.Six coronavirus species are known to cause human disease. Four viruses-229E, OC43, NL63, and HKU1 are prevalent and typically cause common cold symptoms in immunocompetent individuals. The two other strains severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV) are zoonotic in origin and have been linked to sometimes fatal illness.

Coronaviruses are zoonotic, meaning they are transmitted between animals and people. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.

Standard recommendations to prevent infection spread include regular hand washing, covering mouth and nose when coughing and sneezing, thoroughly cooking meat and eggs. Avoid close contact with anyone showing symptoms of respiratory illness such as coughing and sneezing.

[PRINCIPLE]

The COVID-19 IgG/IgM Rapid Test Cassette is a qualitative membrane strip based immunoassay for the detection of antibodies (IgG and IgM) to COVID-19 in human Whole Blood/Serum/Plasma. The test cassette consists of: 1) a burgundy colored conjugate pad containing COVID-19 recombinant envelope antigens conjugated with Colloid gold (COVID-19 conjugates), 2) a nitrocellulose membrane strip containing two test lines (IgG and IgM lines) and a control line (C line). The IgM line is pre-coated with the Mouse anti-Human IgM antibody, IgG line is coated with Mouse anti-Human IgG antibody. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. IgM anti-COVID-19, if present in the specimen, will bind to the COVID-19 conjugates. The immunocomplex is then captured by the reagent pre-coated on the IgM band, forming a burgundy colored IgM line, indicating a COVID-19 IgM positive test result. IgG anti-COVID-19 if present in the specimen will bind to the COVID-19 conjugates. The immunocomplex is then captured by the reagent coated on the IgG line, forming a burgundy colored IgG line, indicating a COVID-19 IgG positive test result. Absence of any T lines (IgG and IgM) suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

[WARNINGS AND PRECAUTIONS]

- For in vitro diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use after the expiration date.
- Please read all the information in this leaflet before performing the test.
- The test cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cassette should be discarded according to federal, state and local regulations.

[COMPOSITION]

The test contains a membrane strip coated with Mouse anti-Human IgM antibody and Mouse anti-Human IgG antibody on the test line, and a dye pad which contains colloidal gold coupled with COVID-19 recombinant antigen. The quantity of tests was printed on the labeling.

Materials Provided

•Test cassette •Package insert
•Buffer

Materials Required But Not Provided

•Specimen collection container •Timer

[STORAGE AND STABILITY]

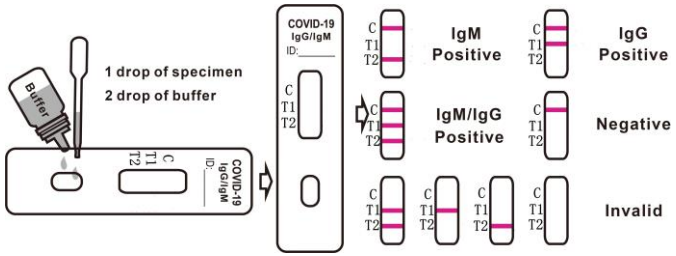
- Store as packaged in the sealed pouch at the temperature (4-30℃ or 40-86℉). The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
- The LOT and the expiration date were printed on the labeling.

[SPECIMEN]

- The test can be used to test Whole Blood/Serum/Plasma specimens.
- To collect whole blood, serum or plasma specimens following regular clinical laboratory procedures.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Store specimens at 2-8℃ (36-46℉) if not tested immediately. Store specimens at 2-8℃ up to 7 days. The specimens should be frozen at -20℃ (-4℉) for longer storage. Do not freeze whole blood specimens.
- Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.
- Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

[TEST PROCEDURE]

- Allow the test device and specimens to equilibrate to temperature (15-30℃or 59-86℉) prior to testing.
- Remove the test cassette from the sealed pouch. Place the test device on a clean, flat surface.
- Label device with the specimen's ID number.
- Hold the dropper vertically and transfer 1 drop of specimen (approximately 10μl) to the specimen well(S) of the test device, then add 2 drops of buffer (approximately 70μl) and start the timer. See the illustration below.
- Wait for colored lines to appear. Interpret the test results in 15 minutes. Do not read results after 20 minutes. To avoid confusion, discard the test device after interpreting the result.



(The picture is for reference only, please refer to the material object.)

[INTERPRETATION OF RESULTS]

Positive: Control line and at least one test line appear on the membrane. The appearance of IgG test line indicates the presence of COVID-19 specific IgG antibodies. The appearance of IgM test line indicates the presence of COVID-19 specific IgM antibodies. And if both IgG and IgM line appear, it indicates that the presence of both COVID-19 specific IgG and IgM antibodies.

Negative: One colored line appears in the control region(C).No apparent colored line appears in the test line region.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

[QUALITY CONTROL]

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

[LIMITATIONS]

- The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to COVID-19 in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
- The COVID-19 IgG/IgM rapid test is limited to the qualitative detection of antibodies to COVID-19 in human serum, plasma or whole blood. The intensity of the test line does not have a linear correlation with the antibody titer in the specimen.
- A nonreactive result for an individual subject indicates absence of detectable COVID-19 antibodies. However, a nonreactive test result does not preclude the possibility of exposure to COVID-19.
- A nonreactive result can occur if the quantity of COVID-19 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
- If the symptoms persist while the result from COVID-19 IgM/IgG Antibody rapid test is nonreactive, it is recommended to re-sample the patient a few days later or test with an alternative test method.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

[PERFORMANCE CHARACTERISTICS]

Accuracy

Summary data of COVID-19 IgG/IgM Rapid Test as below:
Regarding the IgM test,the result comparison to RT-PCR.

COVID-19 IgM:

COVID-19 IgM		RT-PCR		Total
		Positive	Negative	
	Positive	246	35	281
	Negative	5	314	319
Total		251	349	600

A statistical comparison was made between the results yielding a sensitivity of 87.54%, a specificity of 98.43% and an accuracy of 93.33%

Regarding the IgG test, we have counted the positive rate of the 600 patients during the convalescence period.

COVID-19 IgG:

COVID-19 IgG		RT-PCR		Total
		Positive	Negative	
	Positive	261	20	281
	Negative	3	316	319
Total		264	336	600

A statistical comparison was made between the results yielding a sensitivity of92.88%, a specificity of 99.06% and an accuracy of 96.17%

Cross-Reactivity and Interference

1.Cross-reactivity：Specimens which tested positive with following various agents from patients were investigated with COVID-19 IgM/IgG Ab Rapid Test. The results showed no cross reactivity.

COVID-19 IgM	COVID-19 IgG
Mycoplasma pneumoniae IgM Ab	Mycoplasma pneumoniae IgG Ab
Influenza A IgM Ab	Parainfluenza IgG Ab
Influenza B IgM Ab	Respiratory Syncytial virus IgG Ab
Parainfluenza IgM Ab	Adenovirus IgG Ab
Respiratory Syncytial virus IgM Ab	Chlamydia pneumoniae IgG Ab
Adenovirus IgM Ab	
Chlamydia pneumoniae IgM Ab	

2. Interference：The test result of COVID-19 IgM/IgG Ab Rapid Test do not be interfered with the substance at the following concentration:

Substance	**Concentration**
Hemoglobin	≤ 10g/L
Triglyceride	≤ 6mmol/L
Bilirubin	≤ 1000μmol/L
No interference from rheumatoid factors, antinuclear antibodies and antimitochondrial antibodies.	

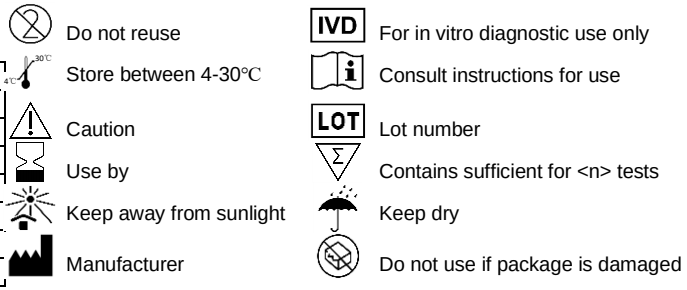
3.Some other common biological analytes were spiked into the COVID-19 positive and negative specimens and tested separately. No significant interference was observed at the levels listed in the table below.

Analytes	Conc. (μg/ml)	Specimens	
		Positive	Negative
Acetaminophen	200	+	-
Acetoacetic Acid	200	+	-
Acetylsalicylic Acid	200	+	-
Benzoylecgonine	100	+	-
Caffeine	200	+	-
EDTA	800	+	-
Ethanol	1.0%	+	-
Gentisic Acid	200	+	-
β - Hydroxybutyrate	20,000	+	-
Methanol	10.0%	+	-
Phenothiazine	200	+	-
Phenylpropanolamine	200	+	-
Salicylic Acid	200	+	-

Reproducibility

Reproducibility studies were performed for COVID-19 IgG/IgM Rapid Test at three physician office laboratories (POL). Sixty (60) clinical serum specimens, 20 negative, 20 borderline positive and 20 positive, were used in this study. Each specimen was run in triplicate for three days at each POL. The intra-assay agreements were 100%. The inter-site agreement was 100 %.

Index of Symbol



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