

COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) Package Insert

A rapid test for the qualitative detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum or plasma specimens.

For professional medical institutions use only. Not for self testing.

【INTENDED USE】

The COVID-19 IgG/IgM Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum or plasma specimen.

【SUMMARY】

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases.² Six coronavirus species are known to cause human disease.³ Four viruses — 229E, OC43, NL63, and HKU1 — are prevalent and typically cause common cold symptoms in immunocompetent individuals.³ The two other strains — severe acute respiratory syndrome coronavirus and Middle East respiratory syndrome coronavirus — are zoonotic in origin and have been linked to sometimes fatal illness.⁴

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.⁵ 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.⁵

【PRINCIPLE】

The COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/ Plasma) is a qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to COVID-19 in whole blood, serum or plasma specimen. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with COVID-19 antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region, if the specimen contains IgG antibodies to COVID-19. A colored line will appear in IgG test line region as a result of this. Similarly, anti-human IgM is coated in IgM test line region and if specimen contains IgM antibodies to COVID-19, the conjugate-specimen complex reacts with anti-human IgM. A colored line appears in IgM test line region as a result.

Therefore, if the specimen contains COVID-19 IgG antibodies, a colored line will appear in IgG test line region. If the specimen contains COVID-19 IgM antibodies, a colored line will appear in IgM test line region. If the specimen does not contain COVID-19 antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains: anti-human IgM and anti-human IgG as the capture reagent; COVID-19 antigen as the detection reagent. A mouse anti-goat IgG is employed in the control line system.

【PRECAUTIONS】

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures 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 assayed.
- Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (4-30°C). The test is stable to the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/ Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect **Fingerstick Whole Blood Specimens**:
 - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
 - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
 - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
 - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test by using a **capillary tube**:
 - Touch the end of the capillary tube to the blood until filled to approximately 10µL. Avoid air bubbles.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 7 days, for long term storage, serum/plasma specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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 local regulations covering the transportation of etiological agents.
- EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the

anticoagulant for collecting the specimen.

【MATERIALS】

Test cassettes	Materials provided	Materials required but not provided
Specimen collection containers	Centrifuge (for plasma only)	Capillary tubes
Lancets (for fingerstick whole blood only)	Timer	Pipette

【DIRECTIONS FOR USE】

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

- Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
- Place the cassette on a clean and level surface.

For **Serum or Plasma** specimen:

- To use a dropper: Hold the dropper vertically, draw the specimen to the fill line (approximately 10µL), and transfer the specimen to the specimen well (S), then add 2 drops of buffer (approximately 70 µL), and start the timer.
- To use a pipette: To transfer 10 µL of specimen to the specimen well(S), then add 2 drops of buffer (approximately 70 µL), and start the timer

For **Venipuncture Whole Blood** specimen:

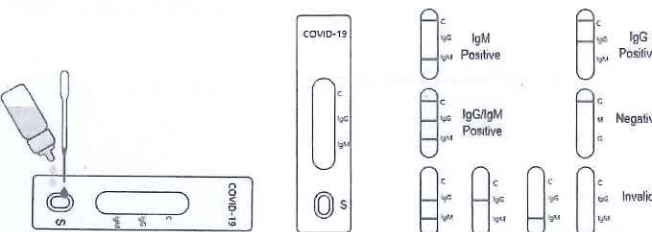
- To use a dropper: Hold the dropper vertically, draw the specimen about 1 cm above the fill line and transfer 1 full drop (approx. 10µL) of specimen to the sample well(S). Then add 2 drops of buffer (approximately 70 µL) and start the timer.
- To use a pipette: To transfer 10 µL of whole blood to the specimen well(S), then add 2 drops of buffer (approximately 70 µL), and start the timer

For **Fingerstick Whole Blood** specimen:

- To use a dropper: Hold the dropper vertically, draw the specimen about 1 cm above the fill line and transfer 1 full drop (approx. 10µL) of specimen to the sample well(S). Then add 2 drops of buffer (approximately 70 µL) and start the timer.
- To use a capillary tube: Fill the capillary tube and transfer approximately 10 µL of fingerstick whole blood specimen to the specimen well (S) of test cassette, then add 2 drops of buffer (approximately 70 µL) and start the timer. See illustration below.

- Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.

Note: It is suggested not to use the buffer, beyond 6 months after opening the vial.



【INTERPRETATION OF RESULTS】

IgG POSITIVE: Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgG line region.

IgM POSITIVE: Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgM line region.

IgG and IgM POSITIVE: Three colored lines appear. One colored line should always appear in the control line region (C) and two test lines should be in the IgG line region and IgM line region.

*NOTE: The intensity of the color in the test line regions may vary depending on the concentration of COVID-19 antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the IgG region and IgM 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

- The COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for detection of IgG and IgM antibody to COVID-19 in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgG or IgM antibodies to COVID-19 can be determined by this qualitative test.
- The COVID-19 IgG/IgM Test Cassette (Whole blood/Serum/Plasma) will only indicate the presence of IgG and IgM antibodies to COVID-19 in the specimen and should not be used as the sole criteria for the diagnosis of COVID-19 infections.
- As with all diagnostic tests, all results must be considered with other clinical information

available to the physician.

- If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of COVID-19 infection.
- The test process and scope of the test must follow the principle of the Instruction manual.
- The results obtained with this test should be s. and the results should be interpreted in conjunction with clinical finding, and the results from other laboratory tests and evaluation.
- This test should not be used for screening of donated blood.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) was compared with a leading commercial PCR; the results show that COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) has a high sensitivity and specificity.

IgG Result

Method	PCR		Total Results
	Positive	Negative	
COVID-19 IgG/IgM Test Cassette	48	0	48
	2	50	52
Total Result	50	50	100

Relative Sensitivity: 96% (95%CI*: 86.3%-99.5%)

*Confidence

Interval Relative Specificity: 100% (95%CI*: 94.2%-100%)

Accuracy: 98% (95%CI*: 92.9%-99.7%)

IgM Result

Method	PCR		Total Results
	Positive	Negative	
COVID-19 IgG/IgM Test Cassette	44	0	44
	6	50	56
Total Result	50	50	100

Relative Sensitivity: 88.0% (95%CI*: 75.7%-95.5%)

*Confidence

Interval Relative Specificity: 100% (95%CI*: 94.2%-100%)

Accuracy: 94% (95%CI*: 87.4%-97.8%)

Cross-reactivity

The COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed.

Triglyceride: 50 mg/dL

Ascorbic Acid: 20mg/dL

Hemoglobin 1000mg/dL

Bilirubin:

60mg/dL Total cholesterol : 6mmol/L

【BIBLIOGRAPHY】

- World Health Organization (WHO). WHO Statement Regarding Cluster of Pneumonia Cases
- Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164. PMID:22094080 DOI:10.1016/B978-0-12-385885-6.00009-2
- Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016;24:490-502. PMID:27012512 DOI:10.1016/j.tim.2016.03.003
- Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019;17:181-192. PMID:3053194 DOI:10.1038/s41579-018-0118-9

World Health Organization (WHO). Coronavirus. <https://www.who.int/health-topics/coronavirus>

Index of Symbols

	Consult instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 4-30°C		Lot Number		Catalog #

HANGZHOU TESTSEA BIOTECHNOLOGY CO., LTD.
3rd Floor, Building 6, No. 8-2 Keji Road,
Yuhang District, Hangzhou, China.

LOTUS NL B.V.
Koningin Julianaplein 10, Le Verd,
2595AA, The Hague,
Netherlands.

Number: 20200005
Effective Date: 2020-03-02

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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.⁵ 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.⁵

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The COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to COVID-19 in whole blood, serum or plasma specimen. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with COVID-19 antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region, if the specimen contains IgG antibodies to COVID-19. A colored line will appear in IgG test line region as a result of this. Similarly, anti-human IgM is coated in IgM test line region and if specimen contains IgM antibodies to COVID-19, the conjugate-specimen complex reacts with anti-human IgM. A colored line appears in IgM test line region as a result.

Therefore, if the specimen contains COVID-19 IgG antibodies, a colored line will appear in IgG test line region. If the specimen contains COVID-19 IgM antibodies, a colored line will appear in IgM test line region. If the specimen does not contain COVID-19 antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains: anti-human IgM and anti-human IgG as the capture reagent; COVID-19 antigen as the detection reagent. A mouse anti-goat IgG is employed in the control line system.

【PRECAUTIONS】

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- To collect **Fingerstick Whole Blood Specimens**:
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 - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
 - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
 - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test by using a **capillary tube**:
 - Touch the end of the capillary tube to the blood until filled to approximately 10µL. Avoid air bubbles.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 7 days, for long term storage, serum/plasma specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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 local regulations covering the transportation of etiological agents.
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【MATERIALS】

Test cassettes	Materials provided	Materials required but not provided
Specimen collection containers	Centrifuge (for plasma only)	Capillary tubes
Lancets (for fingerstick whole blood only)	Timer	Pipette

【DIRECTIONS FOR USE】

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

- Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
- Place the cassette on a clean and level surface.

For **Serum or Plasma** specimen:

- To use a dropper: Hold the dropper vertically, draw the specimen to the fill line (approximately 10µL), and transfer the specimen to the specimen well (S), then add 2 drops of buffer (approximately 70 µL), and start the timer.
- To use a pipette: To transfer 10 µL of specimen to the specimen well(S), then add 2 drops of buffer (approximately 70 µL), and start the timer

For **Venipuncture Whole Blood** specimen:

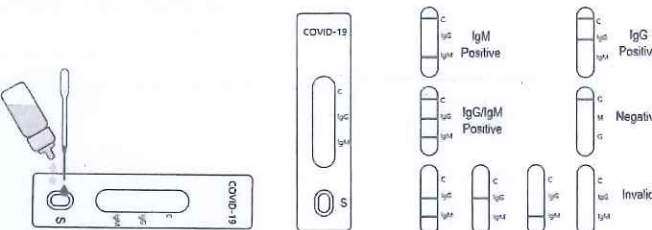
- To use a dropper: Hold the dropper vertically, draw the specimen about 1 cm above the fill line and transfer 1 full drop (approx. 10µL) of specimen to the sample well(S). Then add 2 drops of buffer (approximately 70 µL) and start the timer.
- To use a pipette: To transfer 10 µL of whole blood to the specimen well(S), then add 2 drops of buffer (approximately 70 µL), and start the timer

For **Fingerstick Whole Blood** specimen:

- To use a dropper: Hold the dropper vertically, draw the specimen about 1 cm above the fill line and transfer 1 full drop (approx. 10µL) of specimen to the sample well(S). Then add 2 drops of buffer (approximately 70 µL) and start the timer.
- To use a capillary tube: Fill the capillary tube and transfer approximately 10 µL of fingerstick whole blood specimen to the specimen well (S) of test cassette, then add 2 drops of buffer (approximately 70 µL) and start the timer. See illustration below.

- Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.

Note: It is suggested not to use the buffer, beyond 6 months after opening the vial.



【INTERPRETATION OF RESULTS】

IgG POSITIVE: Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgG line region.

IgM POSITIVE: Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgM line region.

IgG and IgM POSITIVE: Three colored lines appear. One colored line should always appear in the control line region (C) and two test lines should be in the IgG line region and IgM line region.

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NEGATIVE: One colored line appears in the control line region (C). No line appears in the IgG region and IgM 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

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Ascorbic Acid: 20mg/dL

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Bilirubin:

60mg/dL Total cholesterol : 6mmol/L

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- World Health Organization (WHO). WHO Statement Regarding Cluster of Pneumonia Cases
 - Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164. PMID:22094080 DOI:10.1016/B978-0-12-385885-6.00009-2
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	Store between 4-30°C		Lot Number		Catalog #

【EC REP】

HANGZHOU TESTSEA BIOTECHNOLOGY CO., LTD.
3rd Floor, Building 6, No. 8-2 Keji Road,
Yuhang District, Hangzhou, China.

LOTUS NL B.V.
Koningin Julianaplein 10, Le Veld,
2595AA, The Hague,
Netherlands.

Number: 20200005
Effective Date: 2020-03-02