RightSign™ COVID-19 IgG/IgM Rapid Test Cassette
Package Insert

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

【INTENDED USE】

The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette is a rapid lateral flow chromatographic immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human venous whole blood (sodium heparin, potassium EDTA, and sodium citrate), serum or plasma (sodium heparin, potassium EDTA and sodium citrate), and fingerstick whole blood. The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette 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 RightSign™ COVID-19 IgG/IgM Rapid Test Cassette should not be used to diagnose acute SARS-CoV-2 infection.

Testing of serum, plasma and venous whole blood specimens 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.

Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the detection of SARS CoV-2 antibodies. The IgG and IgM 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 results to the appropriate public health authorities.

The sensitivity of RightSign™ COVID-19 IgG/IgM Rapid Test Cassette early after infection is 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 RightSign™ COVID-19 IgG/IgM Rapid Test Cassette 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 second, different IgG or IgM assay.

The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette is only for use under the Food and Drug Administration's Emergency Use Authorization.

【SUMMARY】

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette is a rapid test that utilizes a combination of SARS-COV-2 antigen coated colored particles for the detection of IgG and IgM antibodies to SARS-COV-2 in human whole blood, serum, plasma or fingerstick whole blood.

【PRINCIPLE】

The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette is a lateral flow immunochromatographic assay for the detection of SARS-CoV-2 antibodies in venous whole blood, serum or plasma, and fingerstick whole blood. This test uses anti-human IgM antibody (test line IgM), anti-human IgG (test line IgG) and goat anti-mouse IgG (control line C) immobilized on a nitrocellulose strip. The conjugate pad contains recombinant SARS-CoV-2 antigen (Spike protein RBD domain main antigens of SARS-CoV-2) conjugated with colloid gold.

During testing, the specimen binds with SARS-CoV-2 antigen- conjugated gold colloid coated particles in the test cassette. When a specimen followed by assay buffer is added to the sample well, IgM &/or IgG antibodies if present, will bind to COVID-19 conjugates making an antigen-antibody complex. This complex migrates through nitrocellulose membrane by soft capillary action. When the complex meets the line of the corresponding immobilized antibody (anti-human IgM &/or anti-human IgG) the complex is trapped forming a colored line which indicates a reactive test result. Absence of a colored line in the test region indicates a non-reactive test 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.

【WARNINGS AND PRECAUTIONS】

- For prescription use only. For in vitro diagnostic use only. Do not use after expiration date.
- This test has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA. Testing of serum, plasma and venous whole blood specimens is limited to laboratories certified under CLIA that meet requirements to perform moderate or high complexity tests. Testing of fingerstick whole blood specimens is limited to laboratories certified under CLIA that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency use of 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. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- 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 the procedure 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.
- The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette can be performed using venous whole blood, serum or plasma, and fingerstick whole blood.
- Venous whole blood or plasma could be collected with tube containing Heparin or Citrate.
- To collect Fingerstick Whole Blood Specimen:
  - ✓ Wash the patient's hand with soap and warm water, or clean the finger with an alcohol pad. 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.
  - ✓ To increase blood flow, use the thumb and forefinger to gently apply pressure around the puncture site.
  - ✓ Collect and add the Fingerstick Whole Blood specimen to the test cassette by using a soft capillary, or micropipette measuring 10ul. The soft capillary provided with the test dispenses approximately 10ul in one drop even if more blood is aspirated in the soft capillary.
- 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 specimen collection. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, 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 federal regulations for transportation of etiologic agents.

【MATERIALS 】

Materials provided

Kit components	Format 1	Format 2
Test cassettes	20 cassettes	20 cassettes
Buffer	20 one-off vials with 0.2 ml each	1 vial with 3 ml per vial
Soft Capillary	20 capillaries per kit	20 capillaries per kit
Package Insert	1 Package Insert	1 Package Insert
Procedure Card	1 Procedure Card	1 Procedure Card
Sterile Lancet	20 Lancets	20 Lancets
Alcohol Pad	20 Pads	20 Pads

Note: External Negative and Positive Control are not supplied with this kit. The SARS-COV-2 IgG/IgM External Control Kit can be purchased separately. External positive and negative controls should be tested in accordance with good laboratory practice to confirm the test procedure and to verify proper test performance. Additional testing may be required according to guidelines or local, state, and/or federal regulations (such as 42 CFR 493.1256) or accrediting organizations. Please contact Hangzhou Biotest Biotech or your distributor for information on purchasing these controls.

Materials required but not provided

Specimen collection containers	Centrifuge (for plasma only)
Micropipette	Timer
SARS-COV-2 IgG/IgM External Control Kit	

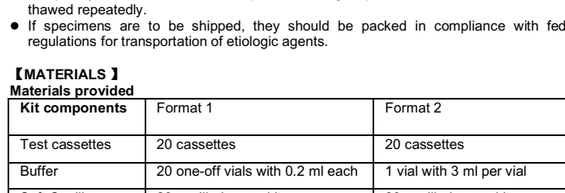
【DIRECTIONS FOR USE】

Direction for use of Serum, Plasma or Venous Whole Blood Specimens

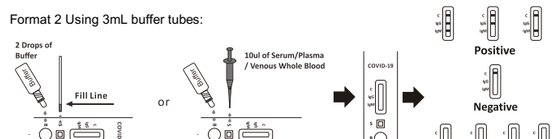
Allow the test cassette, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the test cassette on a clean and level surface.
   - For Serum or Plasma or Venous Whole Blood Specimens:
     - To use a soft capillary: Hold the Soft capillary vertically, draw the specimen up to the Fill Line (approximately 10μl), and transfer the specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80μl) to the buffer well (B) and start the timer. Avoid trapping air bubbles in the specimen well.
     - To use a micropipette: Pipette and dispense 10μl of specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80μl) to the buffer well (B) and start the timer.
3. Wait for the colored line(s) to appear. The test result should be read at 10 minutes. Do not interpret the result after 20 minutes.

Format 1 Using 0.2mL buffer vials:



Format 2 Using 3mL buffer tubes:

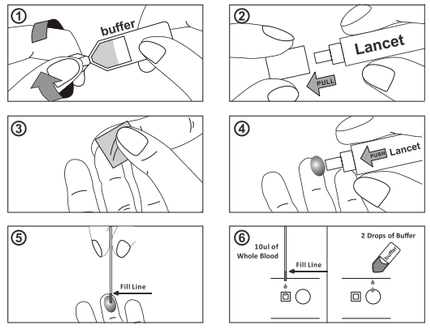


Direction for use of Fingerstick Whole Blood

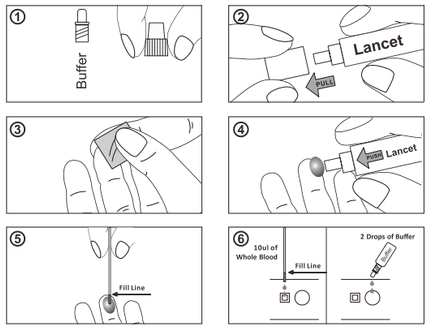
Allow the test cassette, specimen, buffer, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

Open the sealed pouch, remove the test cassette and place it on a clean and level surface. Best results will be obtained if the assay is performed within one hour of removing the cassette from the pouch.

Format 1:



Format 2:



1. Take out the buffer vial, sterile lancet, and other materials. Twist off the tab of the one-off buffer vial without squeezing (for format 1), or unscrew the cap of 3ml vial (for format2). Then place it on a clean and level surface.
2. Carefully pull off the sterile lancet cap.
3. Clean the patient's hands with soap and warm water, or alcohol.. Allow to dry.
4. Use the provided alcohol swab to clean the puncture site.
5. Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
6. Push the sterile lancet firmly onto the chosen site. Let a large drop of free-flowing blood collect at the puncture site. To increase blood flow, use the thumb and forefinger to gently apply pressure around the puncture site.
7. To use the Disposable Soft Capillary:
   Hold and press the disposable soft capillary vertically, aspirate the whole blood from puncture site and draw the whole blood up to the Fill Line (approximately 10μl). Transfer the whole blood to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80μl) to the buffer well (B) and start the timer. Avoid touching the disposable soft capillary directly to the finger. Lay the cassette on flat face.
8. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret results after 20 minutes.

【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

IgG and IgM POSITIVE: * **Three lines appear**. One colored line should be in the control line region (C), one colored line in the IgG test line region and one colored line in the IgM test line region. The color intensities of the lines do not have to match. The result is positive for both SARS-CoV-2 virus specific IgM and IgG.

IgG POSITIVE: * **Two lines appear**. One colored line should be in the control line region (C), and a colored line appears in IgG test line region. The result is positive for SARS-COV-2 virus specific-IgG.

IgM POSITIVE: * **Two lines appear**. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for SARS-COV-2 virus specific-IgM antibodies.

*NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of SARS-COV-2 antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s) should be considered positive.

NEGATIVE: **One colored line should be in the control line region (C)**. No line appears in IgG and IgM test line region(s). The result is negative for SARS-CoV-2 virus specific antibodies.

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

【QUALITY CONTROL】

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal valid procedural control, it confirms adequate membrane wicking. 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. Refer to Control Instructions for Use.

【LIMITATIONS】

For use under an Emergency Use Authorization Only

1. Use of the RightSign™ COVID-19 IgG/IgM Rapid Test Cassette is limited to laboratory or POC personnel who have been trained. Not for home use.
2. The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette is for in vitro diagnostic use only. The test should be used for the detection of SARS-COV-2 antibodies in whole blood, serum, plasma or fingerstick whole blood specimens only..
3. The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of SARS-CoV-2 virus specific antibodies in the serum, plasma or whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
4. Reading test results earlier than 10 minutes after the addition of Buffer may yield erroneous results. Do not interpret the result after 20 minutes.
5. The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette will only indicate the presence of SARS-COV-2 antibodies in the specimen and should not be used as the sole criteria for the diagnosis of SARS-COV-2.
6. In the early onset of symptom, anti-SARS-COV-2 IgM and IgG antibody concentrations may be below detectable levels.
7. The test may have lower sensitivity for IgG detection in symptomatic individuals prior to 14 days since symptom onset.
8. Results from immunosuppressed patients should be interpreted with caution.
9. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
10. A negative result for individual subject indicates absence of detectable anti-SARS-CoV-2 antibodies. 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; the sensitivity of the RightSign™ COVID-19 IgG/IgM Rapid Test Cassette 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. Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made. A negative result can occur if the quantity of the anti-SARS-CoV-2 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.
11. Some specimens containing unusually high titer of rheumatoid factor may affect expected results.
12. 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. 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.
14. This test should not be used for the screening of donated blood.
15. There may be false positive risk with the plasma in EDTA tube after 24hours.
16. The sensitivity of the test is impacted after being open for one hour-the intensity of the test line becomes weak. Testing must be performed within one hour after opening the pouch.
17. A positive result 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 immune response.

【Conditions of Authorization for the Laboratory】

The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, 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 RightSign™ COVID-19 IgG/IgM Rapid Test Cassette ("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 Hangzhou Biotest Biotech Co.,Ltd (info.usa@biotests.com.cn) 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 your 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. 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 authorized laboratories as the following: Testing of serum, plasma and venous whole blood specimens 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.

Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation."

【PERFORMANCE CHARACTERISTICS】

POSITIVE AGREEMENT:

Positive agreement was evaluated using specimens collected from symptomatic subjects. All subjects were confirmed positive for SARS-COV-2 by RT-PCR. The positive population consisted of the following subjects.

- Living in Site A during the COVID-19 pandemic.
- Living in Site B-1 during the COVID-19 pandemic.
- Living in Site B-2 during the COVID-19 pandemic

Table1. IgM PPA (Per site and sites combined):

Site	**Days post symptom onset**	**# PCR positive at any time**	**RightSign™ COVID-19 IgG/IgM Rapid Test Cassette**		
			# positive results	**PPA**	**95%CI**
A & B-2 (Serum)	≤7	9	6	66.67%	(35.42% -87.94%)

	8-14	83	77	96.25%	(89.55% - 98.72%)
	≥15	158	150	94.94%	(90.33% - 97.41%)
B-1 (Plasma)	unknown	70	63	90.00%	(80.77% - 95.07%)
Sites combined	-	320	296	92.50%	(89.08% - 94.91%)

Table2. IgG PPA (Per site and sites combined):

Site	Days post symptom onset	# PCR positive at any time	RightSign™ COVID-19 IgG/IgM Rapid Test Cassette		
			# positive results	PPA	95%CI
A & B-2 (Serum)	≤7	9	6	66.67%	(35.42% - 87.94%)
	8-14	83	76	91.57%	(83.60% - 95.85%)
	≥15	158	152	96.20%	(91.96% - 98.25%)
B-1 (Plasma)	unknown	70	59	84.29%	(74.01% -90.99%)
Sites combined	-	320	293	91.56%	(88.00% - 94.14%)

CI means confidence interval

NEGATIVE AGREEMENT

Negative agreement was evaluated using 210 samples collected from symptomatic subjects and all were confirmed negative for SARS-COV-2 by RT-PCR. The excluded cases consisted of the following subjects.

- Living in Site A during the COVID-19 pandemic.
- Living in Site B-1 during the COVID-19 pandemic.
- Living in Site C during the COVID-19 pandemic

The overall NPA/specificity of the RightSign™ COVID-19 IgG/IgM Rapid Test Cassette is 98.10% (206/210); [95% CI; (95.12% - 99.26%)].

Table 3. IgM NPA (Per site and sites combined):

Site	# PCR negative	RightSign™ COVID-19 IgG/IgM Rapid Test Cassette		
		# negative results	NPA	95%CI
A (Serum)	150	146	97.33%	(93.34% - 98.96%)
B -1 (Plasma)	10	10	100.00%	(72.25% -100.00%)
C (Serum)	50	50	100.00%	(92.87% - 100.00%)
Sites combined	210	206	98.10%	(95.12% - 99.26%)

Table 4. IgG NPA (Per site and sites combined):

Site	# PCR Negative	RightSign™ COVID-19 IgG/IgM Rapid Test Cassette		
		# negative results	NPA	95%CI
A (Serum)	150	149	99.33%	(96.32% - 99.88%)
B -1 (Plasma)	10	10	100.00%	(72.25% -100.00%)
C (Serum)	50	50	100.00%	(92.87% - 100.00%)
Sites combined	210	209	99.52%	(97.38% - 99.99%)

CI means confidence interval

SEROCONVERSION:

The sensitivity and specificity of the RightSign™ COVID-19 IgG/IgM Rapid Test Cassette was evaluated on samples from individuals residing in Site C for Diagnosis and Treatment of Infectious Disease. The sensitivity was evaluated on 104 samples from 30 hospitalized patients. All the studied cases are confirmed by RT-PCR. Of these objectives, seven subjects were both IgM and IgG positive at the first sample test, twenty subjects seroconverted during observation and three subjects never seroconverted. The sensitivity was 90% (27/30) for the subjects tested.

Table 5. IgM PPA (Site C)

Site	Days post symptom onset	# PCR positive at any time	RightSign™ COVID-19 IgG/IgM Rapid Test Cassette		
			# positive results	PPA	95%CI
C	≤7	32	10	31.25%	16.12%-50.01%
	8~14	27	14	51.85%	31.95%-71.33%
	≥15	45	43	95.56%	84.85%-99.46%

Table 6. IgG PPA (Site C)

Site	Days post symptom onset	# PCR positive at any time	RightSign™ COVID-19 IgG/IgM Rapid Test Cassette		
			# positive results	PPA	95%CI
C	≤7	32	5	15.63%	5.28%-32.79%
	8~14	27	12	44.44%	25.48%-64.67%
	≥15	45	41	91.11%	78.78%-97.52%

Table 7: Seroconversion

Case (Patient) ID No.	Sample ID No.	nCoV-2 RT-PCR Results	Days Between Symptoms Onset and Blood Collection	RightSign™ COVID-19 IgG/IgM Rapid Test Cassette		
				IgM(+)	IgG(+)	IgM(+) and /or IgG(+)
CJG-2000004116	CJG-2000004116-01	+	7	-	-	-
	CJG-2000004116-02	N/A	10	-	-	-
	CJG-2000004116-03	+	18	+	+	+
CSC-2000004214	CSC-2000004214-01	+	10	+	+	+
	CSC-2000004214-02	N/A	13	+	+	+
	CSC-2000004214-03	N/A	18	+	+	+
	CSC-2000004214-04	-	32	+	+	+
CZ-05148433	CZ-05148433-01	+	7	-	-	-
	CZ-05148433-02	-	8	+	+	+
	CZ-05148433-03	+	22	+	+	+
GJ-03013432	GJ-03013432-01	+	1	+	+	+
	GJ-03013432-02	+	2	+	+	+
	GJ-03013432-03	-	9	+	+	+
GXM-05143619	GXM-05143619-01	+	4	-	-	-
	GXM-05143619-02	N/A	6	+	+	+
	GXM-05143619-03	+	9	-	+	+
HHZ-05150218	HHZ-05150218-01	+	11	+	+	+
	HHZ-05150218-02	+	13	+	+	+
	HHZ-05150218-03	+	22	+	+	+
	HHZ-05150218-04	N/A	24	+	+	+
HSJ-03886796	HSJ-03886796-01	+	2	-	-	-
	HSJ-03886796-02	+	5	-	-	-
	HSJ-03886796-03	+	7	+	-	+
	HSJ-03886796-05	N/A	11	+	+	+
	HSJ-03886796-04	+	20	+	+	+
JXJ-2000004055	JXJ-2000004055-01	+	8	-	-	-
	JXJ-2000004055-04	-	14	+	-	+
	JXJ-2000004055-03	+	20	+	+	+
	JXJ-2000004055-02	N/A	24	+	+	+
LE-01613279	LE-01613279-01	-	7	-	-	-
	LE-01613279-02	+	14	-	-	-
	LE-01613279-03	-	33	+	+	+
LH-05079034	LH-05079034-01	+	6	-	-	-
	LH-05079034-02	+	7	+	+	+
	LH-05079034-03	+	20	+	+	+
LMX-05148953	LMX-05148953-06	N/A	7	-	-	-
	LMX-05148953-01	+	8	-	-	-
	LMX-05148953-02	+	10	-	-	-
	LMX-05148953-03	+	11	+	-	+
	LMX-05148953-07	N/A	13	+	+	+
	LMX-05148953-04	N/A	16	+	+	+
	LMX-05148953-05	N/A	24	+	+	+
	LMX-05148953-08	-	33	+	+	+
MRG-2000004008	MRG-2000004008-01	+	4	-	-	-
	MRG-2000004008-02	+	21	+	+	+
	MRG-2000004008-03	N/A	26	+	+	+
MXR-2000004129	MXR-2000004129-01	+	11	+	+	+
	MXR-2000004129-02	N/A	22	+	+	+
	MXR-2000004129-03	+	25	+	+	+
SBZ-2000004184	SBZ-2000004184-01	+	7	-	-	-
	SBZ-2000004184-02	N/A	8	-	-	-
	SBZ-2000004184-03	+	10	-	-	-
SGH-2000004035	SGH-2000004035-01	+	5	-	-	-
	SGH-2000004035-02	+	19	+	+	+
	SGH-2000004035-03	+	24	+	+	+
SWD-2000004137	SWD-2000004137-01	+	15	+	+	+
	SWD-2000004137-02	N/A	19	+	+	+
	SWD-2000004137-03	+	23	+	+	+
	SWD-2000004137-04	-	68	+	+	+
WCD-2000004024	WCD-2000004024-01	+	2	-	-	-
	WCD-2000004024-02	N/A	14	-	-	-
	WCD-2000004024-03	+	22	-	-	-
WCJ-05151120	WCJ-05151120-01	+	6	+	+	+
	WCJ-05151120-02	+	15	+	+	+
	WCJ-05151120-03	N/A	21	+	+	+
	WCJ-05151120-04	+	27	+	+	+
WH-2000004159	WH-2000004159-01	+	7	-	-	-
	WH-2000004159-02	+	10	-	-	-
	WH-2000004159-03	+	14	+	-	+
	WH-2000004159-04	-	29	+	+	+
WJQ-05149865	WJQ-05149865-01, WJQ-05149865-04	+	0	-	-	-
	WJQ-05149865-02	+	1	-	-	-
	WJQ-05149865-03	+	2	+	-	+
	WJQ-05149865-05	N/A	15	+	+	+
WMM-05148912	WMM-05148912-01	+	2	-	-	-
	WMM-05148912-02	+	18	+	+	+
	WMM-05148912-03	+	20	+	+	+
WYC-2000004016	WYC-2000004016-01	+	35	+	-	+
	WYC-2000004016-02	+	41	+	+	+
	WYC-2000004016-03	-	55	+	+	+
XYS-00987017	XYS-00987017-01	+	11	-	-	-
	XYS-00987017-02	+	21	+	+	+
	XYS-00987017-03	+	23	+	+	+
XZC-2000004086	XZC-2000004086-01	+	9	-	-	-
	XZC-2000004086-02	+	25	+	-	+
	XZC-2000004086-03	-	35	-	+	+
YYQ-05148957	YYQ-05148957-01	N/A	3	+	-	+
	YYQ-05148957-02	+	7	+	+	+
	YYQ-05148957-03	+	42	+	+	+
YYX-2000004130	YYX-2000004130-01	+	4	-	-	-
	YYX-2000004130-02	N/A	6	-	-	-
	YYX-2000004130-03	+	15	+	+	+
YZM-2000004131	YZM-2000004131-01	+	4	-	-	-
	YZM-2000004131-02	+	8	+	+	+
	YZM-2000004131-03	N/A	16	+	+	+
ZFS-2000004005	ZFS-2000004005-01	+	13	+	+	+
	ZFS-2000004005-02	+	16	+	+	+
	ZFS-2000004005-03	N/A	17	+	+	+
ZJH-00823994	ZJH-00823994-01	+	3	-	-	-
	ZJH-00823994-02	-	7	-	-	-
	ZJH-00823994-03	N/A	11	-	-	-
ZLQ-05150650	ZLQ-05150650-03	+	7	-	-	-
	ZLQ-05150650-01	+	19	+	-	+

Fingerstick Whole Blood Clinical Performance

The fingerstick whole blood clinical study was conducted in point-of-care (POC) sites. A total of thirty-two (32) subjects were studied who had negative PCR results within one week of test; all of these subjects also tested negative with the RightSign™ COVID-19 IgG/IgM Rapid Test Cassette. A total of 45 symptomatic subjects were studied who had positive PCR results; 41 of these subjects tested positive for IgG with the RightSign™ COVID-19 IgG/IgM Rapid Test Cassette, 40 of these subjects tested positive for IgM with the RightSign™ COVID-19 IgG/IgM Rapid Test Cassette.

Table 8: IgG PPA for RightSign™ COVID-19 IgG/IgM Rapid Test Cassette

Sample	Days post symptom onset	# PCR positive at any time	RightSign™ COVID-19 IgG/IgM Rapid Test Cassette		
			# positive results	PPA	95%CI*
Fingerstick Whole Blood	≤7	3	3	100.00%	(36.84%, 100.00%)
	8-14	8	6	75.00%	(34.91%, 96.81%)
	≥15	34	32	94.12%	(80.32%, 99.28%)
	Total	45	41	91.11%	(78.78%, 97.52%)

*CI means confidence interval.

Table 9: IgM PPA for RightSign™ COVID-19 IgG/IgM Rapid Test Cassette

Sample	Days post symptom onset	# PCR positive at any time	RightSign™ COVID-19 IgG/IgM Rapid Test Cassette		
			# positive results	PPA	95%CI*
Fingerstick Whole Blood	≤7	3	2	66.67%	(9.43%, 99.16%)
	8-14	8	8	100.00%	(68.77%, 100.00%)
	≥15	34	30	88.24%	(72.55%, 96.70%)
	Total	45	40	88.89%	(75.95%, 96.29%)

*CI means confidence interval

The overall NPA/specificity of RightSign™ COVID-19 IgG/IgM Rapid Test Cassette is 100% (32/32); [95%: (91.06% - 100%)] in fingerstick whole blood samples.

Table 10: IgG NPA for RightSign™ COVID-19 IgG/IgM Rapid Test Cassette

Sample	# PCR negative	RightSign™ COVID-19 IgG/IgM Rapid Test Cassette		
		# negative results	NPA	95%CI*
Fingerstick Whole Blood	32	32	100.00%	(91.06% - 100.00%)

*CI means confidence interval

Table 11: IgM NPA for RightSign™ COVID-19 IgG/IgM Rapid Test Cassette

Site	# PCR negative	RightSign™ COVID-19 IgG/IgM Rapid Test Cassette		
		# negative results	NPA	95%CI*
Fingerstick Whole Blood	32	32	100.00%	(91.06% - 100.00%)

*CI means confidence interval

Independent Clinical Agreement Validation

The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette was tested on 2020-04-21 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 was 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 orthogonal methods prior to testing with the RightSign™ COVID-19 IgG/IgM Rapid Test Cassette. 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+”. Testing was performed by one operator using one lot of the RightSign™ COVID-19 IgG/IgM Rapid Test Cassette. 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 below.

Table 12. Summary Results

RightSign™ COVID-19 IgG/IgM Rapid Test Cassette		Comparator Method			Total
		Positive (IgM/IgG) +	Negative (IgM/IgG)-	Negative, HIV+	
Positive	IgM +/ IgG+	28	0	0	28
	IgM+, IgG-	2	0	0	2
	IgM-, IgG+	0	0	0	0
Negative	IgM- / IgG)-	0	70	10	80
Total (n=110)		30	70	10	110

Table 13. Summary Statistics

Measure	Estimate	Confidence Interval
IgM+ Sensitivity (PPA)	(30/30) 100%	(88.7%; 100%)
IgM- Specificity (NPA)	(80/80) 100%	(95.4%; 100%)
IgG+ Sensitivity (PPA)	(28/30) 93.3%	(78.7%; 98.2%)
IgG- Specificity (NPA)	(80/80)100%	(95.4%; 100%)
Combined Sensitivity	(30/30) 100%	(88.7%; 100%)
Combined Specificity	(80/80)100%	(95.4%; 100%)
Combined PPV for prevalence = 5%	100%	(50.5%; 100%)
Combined NPV for prevalence = 5%	100%	(99.4%; 100%)
Cross-reactivity with HIV+	(0/10) 0% not detected	N/A

Cross-reactivity

The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette has been tested with the following potentially cross-reactive substances.

Table 14: Cross-reactive Study Data of RightSign™ COVID-19 IgG/IgM Rapid Test Cassette.

Potentially cross-reactive substances	Number of Samples	RightSign™ COVID-19 IgG/IgM Rapid Test Cassette					
		IgM			IgG		
		NEG	POS	Agreement	NEG	POS	Agreement
Anti-FLU A	24	24	0	100%	24	0	100%
Anti-FLU B	30	30	0	100%	30	0	100%
Anti-Respiratory Syncytial Virus	15	15	0	100%	18	0	100%
Anti-Adenovirus	5	5	0	100%	5	0	100%
Anti-HBsAg	3	3	0	100%	3	0	100%
Anti-Syphilis	3	3	0	100%	3	0	100%
Anti-H. Pylori	3	3	0	100%	3	0	100%
Anti-HIV	6	6	0	100%	6	0	100%
Anti-HCV	6	6	0	100%	6	0	100%
Anti-SARS-COV	1	1	0	100%	0	1	0%
HAMA	13	13	0	100%	13	0	100%
RF	33	31	2	93.90%	33	0	100%
H1N1	3	3	0	100%	3	0	100%
H3N2	3	3	0	100%	3	0	100%
H7N9	3	3	0	100%	3	0	100%
Anti-HBV	6	6	0	100%	6	0	100%
Antinuclear antibody (ANA)	10	10	0	100%	10	0	100%
Anti-Haemophilus influenzae	5	5	0	100%	5	0	100%
Human coronavirus HKU1	2	2	0	100%	2	0	100%
Human coronavirus NL63	1	1	0	100%	1	0	100%
Human coronavirus OC43	2	2	0	100%	2	0	100%
Human coronavirus 229E	2	2	0	100%	2	0	100%
Anti-Rhinovirus	31	31	0	100%	31	0	100%

Anti-SARS-COV and RF show potential risk of cross reactivity with the samples.

Interfering Substances

The following potentially interfering substances were added to COVID-19 negative and spiked positive specimens.

Table 15: Interference Study Data of RightSign™ COVID-19 IgG/IgM Rapid Test Cassette.

Analytes	Concentration	Result			
		Negative Specimen		Spiked with Positive Specimen	
		IgG line	IgM line	IgG line	IgM line
Acetaminophen	20 mg/dL	Negative	Negative	Positive	Positive
Caffeine	20 mg/dL	Negative	Negative	Positive	Positive
Albumin	2 g/dL	Negative	Negative	Positive	Positive
Acetylsalicylic Acid	20 mg/dL	Negative	Negative	Positive	Positive
Gentisic Acid	20 mg/dL	Negative	Negative	Positive	Positive
Ethanol	1%	Negative	Negative	Positive	Positive
Ascorbic Acid	2g/dL	Negative	Negative	Positive	Positive
Creatine	200mg/dl	Negative	Negative	Positive	Positive
Bilirubin	1g/dL	Negative	Negative	Positive	Positive
Hemoglobin	1000mg/dl	Negative	Negative	Positive	Positive
Oxalic Acid	60mg/dL	Negative	Negative	Positive	Positive
Uric acid	20mg/ml	Negative	Negative	Positive	Positive

None of the substances at the concentration tested interfered in the assay.

【BIBLIOGRAPHY】

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011; 81:85-164.
2. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. TrendsMicrobiol 2016; 24:490-502.

Manufactured by: Hangzhou Biotest Biotech Co.,Ltd.
No.17, Futai Road, Zhongtai Street, Yuhang District, Hangzhou, P.R. China

Revision:
Effective Date:

RightSign™ COVID-19 IgG/IgM Rapid Test Cassette (Format 2)

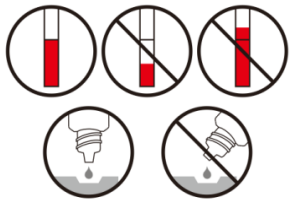
Quick Reference Guide

Test Procedure

Preparation

Test pouch | Buffer | Sterile lancet | Disposable capillary | Alcohol swab | Disposable Gloves | Timer (Not Provided)

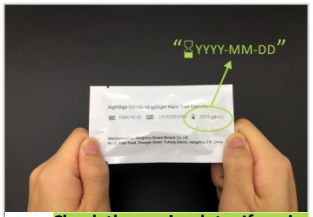
Blood Volume Check



Assay Diluent Volume Check

Note:

1. This test has not been cleared or approved, but has been authorized for use with fingerstick whole blood specimens by laboratories certified under CLIA that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
2. This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens. The emergency use of 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. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
3. The user should be trained in the procedure. Wear appropriate protective attire for your safety when handling patient samples.
4. Read the complete Quick Reference Instructions before performing the test. For technical assistance, please call +1 (858) 866 8382.
5. Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG or IgM assay.

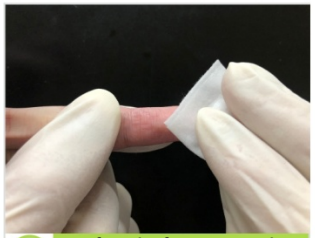


1 Check the expiry date. If expiry date has passed, use another kit. Allow the cassette to reach room temperature prior to use.

2 Put on the gloves. Use new gloves for each patient.

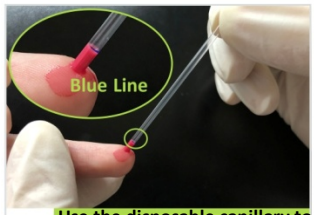
3 Open the test pouch and write the patient's ID on the test cassette.

4 Carefully pull off the sterile lancet cap.



5 Disinfect the finger tip with alcohol swab.

6 Push the sterile lancet firmly onto the chosen site.



7 Use the disposable capillary to draw the whole blood up to the Fill Line. Avoid touching capillary to finger.

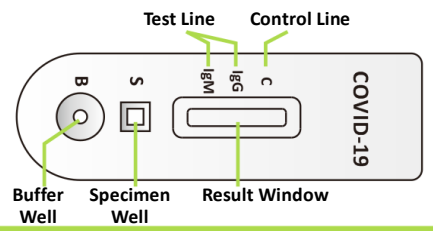
8 Ensure cassette is on a flat surface. Transfer fingerstick whole blood specimen to the specimen well ("S").

9 Add 2 drops of buffer to Buffer well("B").

10 Read results at 10 minutes.

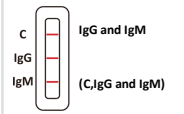
11 Do not read the result after 20 minutes.

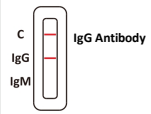
12 All used tests, specimens and potentially contaminated materials should be discarded according to local regulations.

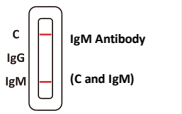


Overview of the Cassette

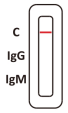
Positive







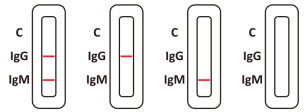
Negative



Only one colored line appears

Invalid

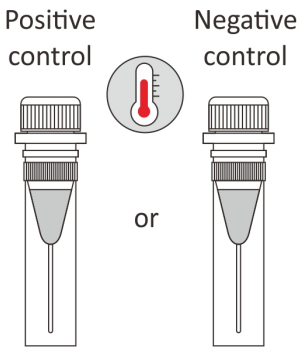
Control line fails to appear.



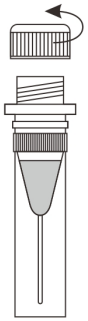
BiotesT
Hangzhou Biotest Biotech Co., Ltd.
No.17, Futai Road, Zhongtai Street,
Yuhang District, Hangzhou, P.R. China
Made in China

RightSign™ SARS-CoV-2 IgG/IgM External Control Kit

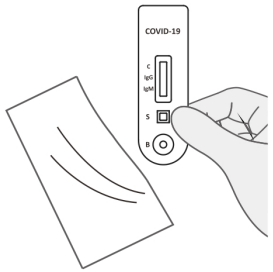
Quick Reference Guide



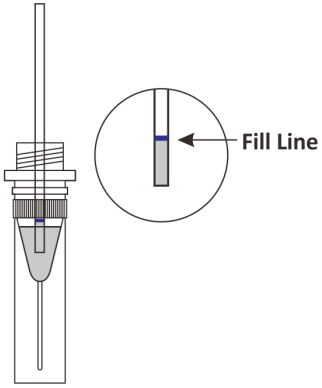
1 Allow the controls to reach use. Mix gently before use.



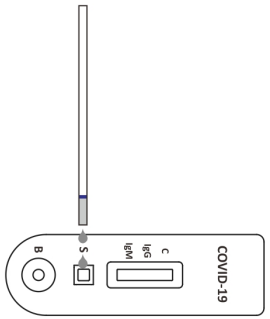
2 Unscrew the cap of positive control or negative control.



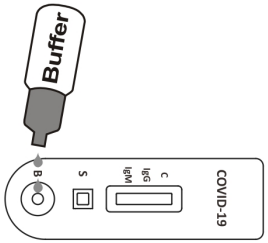
3 Remove the test cassette and surface. Use it within one hour.



4 Use the disposable capillary to draw negative or positive control up to the Fill Line.



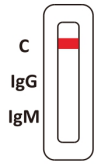
5 Add 10 ul of negative or specimen well (”S”).



6 Transfer 2 drops to the buffer well (”B”).

7 Read results at 10 minutes. Do not interpret results after 20 minutes.

For positive control



For negative control