Technical File

COVID-19 IgG/IgM Rapid Test Cassette

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HANGZHOU BIOTEST BIOTECH CO,.LTD.

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Section 1 Information of manufacturer

Manufacturer:

Name： HANGZHOU BIOTEST BIOTECH CO.,LTD

Address：#17, Futai Road,Zhongtai Street, Yuhang District, Hangzhou, P.R.China

About Us:

Established on 28 November 2008, Hangzhou Biotest Biotech Co.,Ltd is extension of Hangzhou KangYu pharmaceutical packaging Co., LTD. There is RMB 15 million for the registered capital. The company is located in the west-hangzhou of beautiful scenery in China: #17,Futai Road,Zhongtai Street, Yuhang District, Hangzhou, P.R.China.There is a convenient traffic.

Our company mainly engages in the research and development of immunology diagnostic technology. The company is building the new factory. There is a land area of 13,333 sq. meters for the building factories and offices and a total construction area of 21,000 sq. meters. It is proposed to build 5 single buildings, including 1 office building, 1 research building and 3 blocks of building for the production workshops. After the completion of the project，it will be used to manufacture the products in vitro diagnostic device, including the company's five big series products （Fertility， Infectious Diseases，Drug of Abuse，Tumor Marker and Cardiac Marker）. There will be annual production of 10 million kits of the second and third kinds of 6840 in vitro diagnostic device (medical device) according to the packing requirements, or 330 million pcs(33pcs per kit).

Appendix No.	List of Registrations	Document No.	Authority
1	Business License	9133010079969193XF	Hangzhou Industry and Commerce Administration Bureau
2	Manufacturing license(Device)	20150004	SFDA of Zhejiang China
3	Certificate for EN ISO 13485:2016	Q5170677434014	TUV-SUD

Section 2 Product Description

2.1 Product Name：
COVID-19 IgG/IgM Rapid Test Cassette(Whole Blood/ Serum/ Plasma)

2.2 Brand Name: RightSign

2.3 Intended Use
The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum, or plasma as an aid in the diagnosis of primary and secondary SARS-COV-2 infections. For professional in vitro diagnostic use only.

2.4 Summary
COVID-19(Corona Virus Disease) is the infectious disease caused by the most recently discovered coronavirus. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019. The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, runny nose, sore throat or diarrhea. These symptoms are usually mild and begin gradually. Some people become infected but don't develop any symptoms and don't feel unwell. Most people (about 80%) recover from the disease without needing special treatment. Around 1 out of every 6 people who gets COVID-19 becomes seriously ill and develops difficulty breathing. Older people, and those with underlying medical problems like high blood pressure, heart problems or diabetes, are more likely to develop serious illness. About 2% of people with the disease have died. People with fever, cough and difficulty breathing should seek medical attention. People can catch COVID-19 from others who have the virus. The disease can spread from person to person through small droplets from the nose or mouth which are spread when a person with COVID-19 coughs or exhales. These droplets land on objects and surfaces around the person. Other people then catch COVID-19 by touching these objects or surfaces, then touching their eyes, nose or mouth. People can also catch COVID-19 if they breathe in droplets from a person with COVID-19 who coughs out or exhales droplets. Most estimates of the incubation period for COVID-19 range from 1-14 days.
The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) 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, or plasma.

2.5 Principles
The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 antibodies in whole blood, serum, or plasma. 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 SARS-CoV-2 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 SARS-CoV-2, a colored line will appear in IgG test line region. In the IgM component, anti-human IgM is coated in IgM test line region. During testing, the specimen reacts with anti-human IgM. IgM antibodies to SARS-CoV-2, if present in the specimen, reacts with the anti-human IgM and the SARS-CoV-2 antigen-coated particles in the test cassette, and

this complex is captured by the anti-human IgM, forming a colored line in IgM test line region.
Therefore, if the specimen contains IgG antibodies to SARS-CoV-2, a colored line will appear in IgG test line region. If the specimen contains IgM antibodies to SARS-CoV-2, a colored line will appear in IgM test line region. If the specimen does not contain antibodies to SARS-CoV-2, 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.

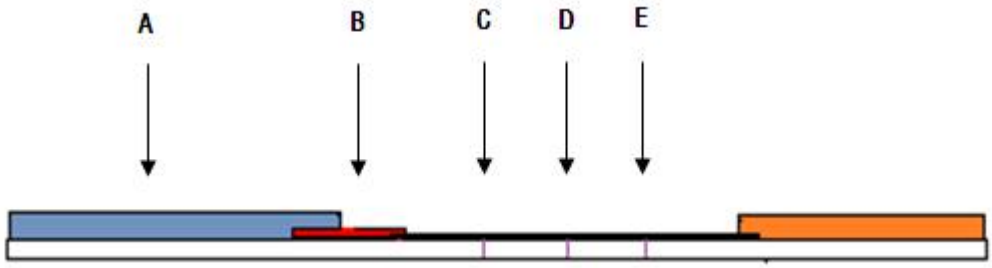


Figure 1: Test Principle

As shown in illustration above, the specimen (A) migrates via capillary action along the membrane to react with the colored conjugate (B). SARS-COV-2 IgG antibodies or SARS-COV-2 IgM antibodies or both present in the specimen bind to the conjugate, forming a colored antibody-antigen complex. The anti-human IgG and anti-human IgM were immobilized in the test zone of the membrane captures the complex (C and/or D). The formation of a visible colored line in the test region indicates a positive result (C and/or D). The absence of a colored line in the test zones(C and D) suggests a negative result. In the control zone of the membrane, immobilized reagents capture colored conjugate regardless of test specimen composition. The resulting visible red line (E) confirms that the assay is functioning correctly.

2.6 Performance and Specification：
COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-COV-2 in human whole blood, serum, or plasma as an aid in the diagnosis of primary and secondary COVID-19 infections.
Neither the quantitative value nor the rate of increase in COVID-19 IgG and/or IgM antibodies can be determined by this qualitative test.
2.6.1 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.
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.
Humidity and temperature can adversely affect results.
2.6.2Storage 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.

2.6.3 Specimen Collection and Preparation.

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, 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 cassette by using a dropper or micropipette measuring 10ul. The dropper provided with the test dispenses approximately 10ul in one drop even if more blood is aspirated in the dropper.

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. 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 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.

2.6.4 Standard testing procedure

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

Bring the pouch to room temperature before opening. Remove the test cassette from the sealed pouch and use it within one hour.

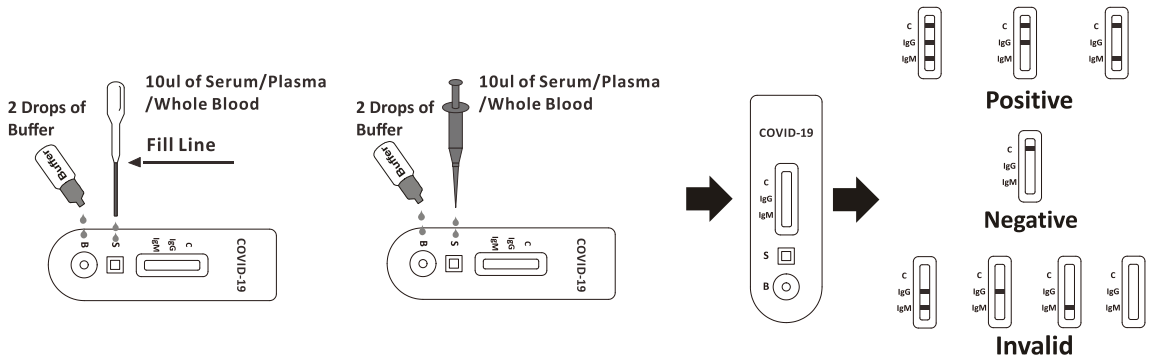
Place the test cassette on a clean and level surface.

For Serum or Plasma or Whole Blood Specimens:

To use a dropper: Hold the dropper 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.

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.



2.6.5 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), and two colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of secondary SARS-COV-2 infection.

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 and is probably indicative of secondary SARS-COV-2 infection.

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 and is indicative of primary SARS-COV-2 infection.

*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).

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.

2.6.6 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 confirming 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.

2.6.7 Limitations

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of SARS-COV-2 antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in SARS-COV-2 antibody concentration can be determined by this qualitative test.

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) 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.

In the early onset of fever, anti-SARS-COV-2 IgM concentrations may be below detectable levels.
The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
Results from immunosuppressed patients should be interpreted with caution.
As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of SARS-COV-2 infection.

2.7 User
Professional

2.8 IBLIOGRAPHY
N/A

Section 3 Technical Report

3.1 Sample correlation

Sample:

The COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/ Serum/ Plasma) has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. Results were confirmed by a leading commercial product test.

Method:

Draw the serum/plasma/whole blood 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. Read results at 10 minutes. Do not interpret results after 20 minutes.

Results:

IgG Results：

Method		PCR		Total Results
COVID-19 IgG/IgM Rapid Test Cassette for IgG	Results	Positive	Negative	
	Positive	37	1	38
	Negative	1	142	143
Total Results		38	143	181

Sensitivity: 97.4% (95%CI: 86.2%~99.9%)*

Specificity: 99.3% (95%CI: 96.2%~99.9%)*

Accuracy: 98.9% (95%CI: 96.1%~99.9%)*

Confidence Interval

IgM Results：

Method		PCR		Total Results
COVID-19 IgG/IgM Rapid Test Cassette for IgM	Results	Positive	Negative	
	Positive	33	2	35
	Negative	5	141	146
Total Results		38	143	181

Sensitivity: 86.8 %(95%CI: 71.9%-95.6%)*

Specificity: 98.6 %(95%CI: 95.0%~99.8%)*

Accuracy: 96.1 %(95%CI: 92.2%~98.4%)*

*Confidence interval

Conclusion:

The COVID-19 IgG/IgM Rapid Test Cassette products have been compared to a leading commercial product test using clinical specimens. The results show that relative to leading product tests, the COVID-19 IgG/IgM Rapid Test Cassette shows 97.4% relative sensitivity and 99.3% relative specificity for IgG and 86.8% relative sensitivity and 98.6% relative specificity for IgM.

3.2 Interfering Substances

Analytes were spiked into negative serum (product confirmed) at the concentrations listed. The specimens were tested in triplicate with visual interpretations occurring at 10minutes after specimen application. Results are presented in table below.

Table: Interfering Substances study

COVID-19 IgG/IgM		**COV2002001-R**			**COV2002002-R**			**COV2002003-R**		
Analytes	**Concentration**	**Negative**			**Negative**			**Negative**		
Acetaminophen	20 mg/dL	1	1	1	1	1	1	1	1	1
Caffeine	20 mg/dL	1	1	1	1	1	1	1	1	1
Albumin	2 g/dL	1	1	1	1	1	1	1	1	1
Acetylsalicylic Acid	20 mg/dL	1	1	1	1	1	1	1	1	1
Gentisic Acid	20 mg/dL	1	1	1	1	1	1	1	1	1
Ethanol	1%	1	1	1	1	1	1	1	1	1
Ascorbic Acid	2g/dL	1	1	1	1	1	1	1	1	1
Creatine	200mg/d	1	1	1	1	1	1	1	1	1
Bilirubin	1g/dL	1	1	1	1	1	1	1	1	1
Hemoglobin	1000mg/dl	1	1	1	1	1	1	1	1	1
Oxalic Acid	60mg/dL	1	1	1	1	1	1	1	1	1
Uric acid	20mg/ml	1	1	1	1	1	1	1	1	1

Conclusion:

No substances showed any interference with the test. There were no differences observed between the results at 10 minutes.

3.3 Cross Reactivity

The COVID-19 IgG/IgM Rapid 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. Visual interpretations were recorded at 10 minutes after specimen application. Results are presented in Table below.

Table: Cross Reactivity Study

COVID-19 IgG/IgM / **Specimens**	**COV2002001-R**			**COV2002002-R**			**COV2002003-R**		
	Neg. Serum			Neg. Serum			Neg. Serum		
3 anti-influenza A virus	1	1	1	1	1	1	1	1	1
3 anti-influenza B virus	1	1	1	1	1	1	1	1	1
3 anti-RSV	1	1	1	1	1	1	1	1	1
3 anti-Adenovirus	1	1	1	1	1	1	1	1	1
3 HBsAg	1	1	1	1	1	1	1	1	1
3 anti-Syphilis	1	1	1	1	1	1	1	1	1
3 anti-H. Pylori	1	1	1	1	1	1	1	1	1
3 anti-HIV	1	1	1	1	1	1	1	1	1
3 anti-HCV	1	1	1	1	1	1	1	1	1

Conclusion:

There was no cross-reaction with 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 at 10minutes.

3.4 Anticoagulant study:

Method:

To test the samples collected from 10 volunteers with COVID-19 IgG/IgM Rapid Test (Whole blood/Serum/plasma) respectively. From each healthy volunteer, 6 kinds anticoagulant are used to collect whole blood samples. Namely K2EDTA treated plasma, Sodium / Potassium citrate treated plasma, Sodium / Lithium heparin treated plasma and Sodium oxalate treated plasma was collected respectively. One test was run for each sample, and read the result at 15minutes.

*Direction for testing:

For Whole blood/serum/plasma: 1drop (approximately 10μl) of Serum/Plasma+2drops (approximately 80ul) of buffer. Read the results at 10 min.

Results:

Lot#COV2002001-R

Item	Time	Serum		K_2EDTA				Sodium citrate				Potassium citrate				Sodium heparin				Lithium heparin				Sodium oxalate			
				Plasma		WB		Plasma		WB		Plasma		WB		Plasma		WB		Plasma		WB		Plasma		WB	
		IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM
1	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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2	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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3	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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4	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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5	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
6	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
7	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
8	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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9	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear					
10	**10mins**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear					

Comment: - means negative result.

Conclusion:

The result showed no difference among different anticoagulant tube to collect Whole blood/serum/plasma samples in this study

3.5 Temperature Flex

Materials:

COVID-19 IgG/IgM Rapid test (Whole blood/serum/plasma) product:

Lot 1: COV2002001-R;

Lot 2: COV2002002-R;

Lot 3: COV2002003-R;

Method:

10 negative serum samples will be tested with COVID-19 IgG/IgM Rapid test (Whole blood/serum/plasma) product stored at -20°C, 2~8°C, RT, 37°C and 45°C. The results have been read at the prescribed read time.

Results:

Treatment temperature(°C)	COV2002001-R									
	N1	N2	N3	N4	N5	N6	N7	N8	N9	N1
-20	1	1	1	1	1	1	1	1	1	1
2~8	1	1	1	1	1	1	1	1	1	1
RT	1	1	1	1	1	1	1	1	1	1
37	1	1	1	1	1	1	1	1	1	1
45	1	1	1	1	1	1	1	1	1	1
Treatment temperature(°C)	COV2002002-R									
	N1	N2	N3	N4	N5	N6	N7	N8	N9	N1
-20	1	1	1	1	1	1	1	1	1	1
2~8	1	1	1	1	1	1	1	1	1	1
RT	1	1	1	1	1	1	1	1	1	1
37	1	1	1	1	1	1	1	1	1	1
45	1	1	1	1	1	1	1	1	1	1
Treatment temperature(°C)	COV2002003-R									
	N1	N2	N3	N4	N5	N6	N7	N8	N9	N1
-20	1	1	1	1	1	1	1	1	1	1
2~8	1	1	1	1	1	1	1	1	1	1
RT	1	1	1	1	1	1	1	1	1	1
37	1	1	1	1	1	1	1	1	1	1
45	1	1	1	1	1	1	1	1	1	1

Conclusion:

The data showed that COVID-19 IgG/IgM Rapid test (Whole blood/serum/plasma) product can yield correct results when tested from -20ºC to 45 ºC at 30 minutes with the samples for serum samples. But the sensitive of product will influence significantly at -20ºC and 2~8°C. Performing the test at RT will be better.

3.6 Variation Study

Negative and positive (P1) specimens were run in replicates of 10 in three separate lots of products. Results were read as positive or negative at 10 minutes after specimen application.

Results:

COVID-19 IGG/IGM Rapid Test

	Lot1#: COV2002001-R		**Lot2#: COV2002002-R**		**Lot3#: COV2002003-R**	
Times	**Negative**	**P1**	**Negative**	**P1**	**Negative**	**P1**
	10min	**10min**	**10min**	**10min**	**10min**	**10min**
1	-	IgG+,IgM+	-	IgG+,IgM+	-	IgG+,IgM+
2	-	IgG+,IgM+	-	IgG+,IgM+	-	IgG+,IgM+
3	-	IgG+,IgM+	-	IgG+,IgM+	-	IgG+,IgM+
4	-	IgG+,IgM+	-	IgG+,IgM+	-	IgG+,IgM+
5	-	IgG+,IgM+	-	IgG+,IgM+	-	IgG+,IgM+
6	-	IgG+,IgM+	-	IgG+,IgM+	-	IgG+,IgM+
7	-	IgG+,IgM+	-	IgG+,IgM+	-	IgG+,IgM+
8	-	IgG+,IgM+	-	IgG+,IgM+	-	IgG+,IgM+
9	-	IgG+,IgM+	-	IgG+,IgM+	-	IgG+,IgM+
10	-	IgG+,IgM+	-	IgG+,IgM+	-	IgG+,IgM+

Conclusion:

100% of actual results were consistent with expected results. No distinct difference was detected in intra lots and inter-lot.

3.7Accelerated Stability

Lot 1: COV2002001-R

Lot2: COV2002002-R

Lot3: COV2002003-R

Accelerated Stability of the COVID-19 IgG/IgM Rapid Test was evaluated using samples from three different batches. These were placed in an incubator with the temperature calibrated at 55℃and relative humidity (RH) calibrated at 60%. A series of stability tests were performed at 0, 7, 14, 21, 28, 35 days. COVID-19 IgG/IgM Rapid Tests were assayed using negative and positive (P1) specimens. Testing at each specific time interval consisted of triplicates for each specimen. The tests were performed according to the directions for use.

Timeline for Accelerate Stability Study

Day / Temp.	0day	7days	14 days	21 days	28 days	35 days
55℃	√	√	√	√	√	√

Results:

Accelerated Stability Study Results at 55℃.

Accelerated Stability Study Results at 55℃.											
Day	**Specimen**		**Batch No.**								
			COV2002001-R			COV2002002-R			COV2002002-R		
0	**Negative**	**IgG**	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	P1	**IgG**	+	+	+	+	+	+	+	+	+
		IgM	+	+	+	+	+	+	+	+	+
7	**Negative**	**IgG**	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	P1	**IgG**	+	+	+	+	+	+	+	+	+
		IgM	+	+	+	+	+	+	+	+	+
14	**Negative**	**IgG**	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	P1	**IgG**	+	+	+	+	+	+	+	+	+
		IgM	+	+	+	+	+	+	+	+	+
21	**Negative**	**IgG**	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-

	P1	**IgG**	+	+	+	+	+	+	+	+	+
		IgM	+	+	+	+	+	+	+	+	+
28	**Negative**	**IgG**	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	P1	**IgG**	+	+	+	+	+	+	+	+	+
		IgM	+	+	+	+	+	+	+	+	+
35	**Negative**	**IgG**	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	P1	**IgG**	+	+	+	+	+	+	+	+	+
		IgM	+	+	+	+	+	+	+	+	+

Note: - means negative result, + means positive result

Conclusion:

COVID-19 IgG/IgM Rapid Test is stable at 55℃ for 35 days. These data were plotted on an Arrhenius Plot and the shelf life of this product was determined to be at least 24 months from the date of manufacture.