Performance Data

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

1. Accuracy

1.1 Purpose

To evaluate the equivalence of COVID-19 IgG/IgM Rapid Test result and clinical diagnosis.

1.2 Method

By testing clinical samples with known results, to evaluate the accuracy of COVID-19 IgG/IgM Rapid Test (Whole blood/Serum/Plasma).

1.3 Material

COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma)

Cassette Lot1: 2002155，Lot2:2002156，Lot3:2002157

Clinical samples

1.4 Test Procedure

1) Prepare specimens: tests were taken to clinical partner to evaluate, totally 113 specimens.
2) Perform the test according to the test procedure in the package insert

1.5 Result

1) IgM

Method		RT-PCR		total
		positive	negative	
Orient Gene COVID-19 IgM test	positive	87	0	87
	negative	12	14	26
total		99	14	113

2) IgG

Method		Number of patients during the convalescence period	total
Orient Gene COVID-19 IgG test	positive	35	35
	negative	1	1
total		36	36

1.6 Conclusion

According to the result, compares with result of RT-PCR, the diagnostic sensitivity of IgM from COVID-19 IgG/IgM Rapid Test (Whole blood/Serum/Plasma)is 87.9% (87/99), and diagnostic specificity is 100%(14/14)。When the patient is on the recovery, the diagnostic sensitivity of IgG is 97.2% (35/36).

2. Limit of Detection (Analytical sensitivity)

2.1 Purpose

To evaluate the Limit of Detection of COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma)

2.2 Method

1) Collect plasma specimens of COVID-19 infection subjects from different areas. Test these specimens by COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma) and observe

the intensity of the T line. Randomly choose 5 IgM strong positive specimens(T line Grade ≥6) and 5 IgG strong positive specimens((T line Grade ≥8))

2) Dilute the IgM strong positive specimens and IgG strong positive specimens with negative plasma in rate. Prepare 3 diluted specimens for each rate and test each diluted specimen rate by one lot of COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma).Test each rate seven times per lot.

Note: The Orient Gene color card has 10 color bands. It divided into 10 gradients, from 1 to 10, according to the color intensity. 1 means the line is invisible, and 10 means the line is very strong.

2.3 Material

COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma)

Cassette Lot1: 2002155，Lot2:2002156，Lot3:2002157

Plasma specimen after inactivation (56 °C, 30 minutes) (from different areas)

COVID-19 IgM positive plasma specimen

COVID-19 IgG positive plasma specimen

Negative plasma specimens: plasma specimen from subjects without COVID-19 infection

2.4 Test Procedure

Perform the test according to the test procedure in the package insert

2.5 Acceptance Criteria

Acceptable Limit of detection level: Positive agreement ≥90%

2.6 Result

Result of IgM

Specimen	Dilute rate	IgM Results			Total results for each rate	Positive agreement
		Lot 1	Lot 2	Lot 3		
Negative Plasma	Neat	0/7	0/7	0/7	0/21	0%
IgM Positive specimen 1#	Neat	7/7	7/7	7/7	21/21	100%
	1:2	7/7	7/7	7/7	21/21	100%
	1:4	7/7	7/7	7/7	21/21	100%
	1:8	7/7	7/7	7/7	21/21	100%
	1:16	7/7	7/7	7/7	21/21	100%
	1:32	7/7	6/7	7/7	20/21	95.2%
	1:64	1/7	0/7	0/7	1/21	4.8%
	1:128	0/7	0/7	0/7	0/21	0%
IgM Positive Specimen 2#	Neat	7/7	7/7	7/7	21/21	100%
	1:2	7/7	7/7	7/7	21/21	100%
	1:4	7/7	7/7	7/7	21/21	100%
	1:8	7/7	7/7	7/7	21/21	100%
	1:16	7/7	7/7	7/7	21/21	100%
	1:32	7/7	7/7	7/7	21/21	100%
	1:64	0/7	0/7	0/7	0/21	0%
	1:128	0/7	0/7	0/7	0/21	0%
IgM Positive Specimen 3#	Neat	7/7	7/7	7/7	21/21	100%
	1:2	7/7	7/7	7/7	21/21	100%
	1:4	7/7	7/7	7/7	21/21	100%
	1:8	7/7	7/7	7/7	21/21	100%

	1:16	7/7	7/7	7/7	21/21	100%
	1:32	7/7	7/7	7/7	21/21	100%
	1:64	0/7	0/7	0/7	0/21	0%
	1:128	0/7	0/7	0/7	0/21	0%
IgM Positive Specimen 4#	Neat	7/7	7/7	7/7	21/21	100%
	1:2	7/7	7/7	7/7	21/21	100%
	1:4	7/7	7/7	7/7	21/21	100%
	1:8	7/7	7/7	7/7	21/21	100%
	1:16	7/7	7/7	7/7	21/21	100%
	1:32	7/7	7/7	6/7	20/21	95.2%
	1:64	0/7	1/7	0/7	1/21	4.8%
	1:128	0/7	0/7	0/7	0/21	0%
IgM Positive Specimen 5#	Neat	7/7	7/7	7/7	21/21	100%
	1:2	7/7	7/7	7/7	21/21	100%
	1:4	7/7	7/7	7/7	21/21	100%
	1:8	7/7	7/7	7/7	21/21	100%
	1:16	7/7	7/7	7/7	21/21	100%
	1:32	7/7	7/7	7/7	21/21	100%
	1:64	5/7	6/7	5/7	16/21	76.2%
	1:128	0/7	0/7	0/7	0/21	0%

Result of IgG

Specimen	**Dilute rate**	**IgM Results**			**Total results for each rate**	**Positive agreement**
		Lot 1	**Lot 2**	**Lot 3**		
Negative Plasma	Neat	-	-	-	0/21	0%
IgG Positive Specimen 1#	Neat	7/7	7/7	7/7	21/21	100%
	1:2	7/7	7/7	7/7	21/21	100%
	1:4	7/7	7/7	7/7	21/21	100%
	1:8	7/7	7/7	7/7	21/21	100%
	1:16	7/7	7/7	7/7	21/21	100%
	1:32	7/7	7/7	7/7	21/21	100%
	1:64	0/7	1/7	1/7	2/21	9.5%
	1:128	0/7	0/7	0/7	0/21	0%
IgG Positive Specimen 2#	Neat	7/7	7/7	7/7	21/21	100%
	1:2	7/7	7/7	7/7	21/21	100%
	1:4	7/7	7/7	7/7	21/21	100%
	1:8	7/7	7/7	7/7	21/21	100%
	1:16	7/7	7/7	7/7	21/21	100%
	1:32	7/7	7/7	7/7	21/21	100%
	1:64	0/7	1/7	0/7	1/21	4.8%
	1:128	0/7	0/7	0/7	0/21	0%
IgG Positive Specimen 3#	Neat	7/7	7/7	7/7	21/21	100%
	1:2	7/7	7/7	7/7	21/21	100%
	1:4	7/7	7/7	7/7	21/21	100%
	1:8	7/7	7/7	7/7	21/21	100%
	1:16	7/7	7/7	7/7	21/21	100%
	1:32	7/7	7/7	7/7	21/21	100%
	1:64	6/7	6/7	7/7	19/21	90.5%
	1:128	0/7	0/7	0/7	0/21	0%
IgG Positive	Neat	7/7	7/7	7/7	21/21	100%
	1:2	7/7	7/7	7/7	21/21	100%

Specimen 4#	1:4	7/7	7/7	7/7	21/21	100%
	1:8	7/7	7/7	7/7	21/21	100%
	1:16	7/7	7/7	7/7	21/21	100%
	1:32	7/7	7/7	7/7	21/21	100%
	1:64	0/7	0/7	0/7	0/21	0%
	1:128	0/7	0/7	0/7	0/21	0%
IgG Positive Specimen 5#	Neat	7/7	7/7	7/7	21/21	100%
	1:2	7/7	7/7	7/7	21/21	100%
	1:4	7/7	7/7	7/7	21/21	100%
	1:8	7/7	7/7	7/7	21/21	100%
	1:16	7/7	7/7	7/7	21/21	100%
	1:32	7/7	7/7	7/7	21/21	100%
	1:64	0/7	0/7	0/7	0/21	0%
	1:128	0/7	0/7	0/7	0/21	0%

2.7Conclusion

From the study above:

On IgM positive specimen: test the diluted specimens of each rate by COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) and select the diluted specimen which presents over or equal to 90% positive agreement as the acceptable limit of detection. Therefore, the lowest detectable IgM concentration in the clinical specimen is equal to the diluted specimen.

On IgG positive specimen: test the diluted specimens of each rate by COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) and select the diluted specimen which presents over or equal to 90% positive agreement as the acceptable limit of detection. Therefore, the lowest detectable IgG concentration in the clinical specimen is equal to the diluted specimen.

3. Interfering Substance

3.1Purpose

To evaluate the interference of common substances found in blood with COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)

3.2Method

Through the detection of common clinical specimens such as hemolysis specimens, lipid blood specimens, jaundice specimens with hemoglobin, triglyceride, and bilirubin, and common substances in human bloods such as ascorbic acid and human serum albumin, to evaluate the interference of these substances with the product.

3.3Material

COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma)

Cassette Lot1: 2002155，Lot2:2002156，Lot3:2002157

Specimens and interfering substances

3.4Test Procedure

1) Prepare specimens: negative serum specimen and limit of detection standard L3

2) Prepare interfering substances with high concentrations

Name of substances	Concentration

Ascorbic Acid	2000mg/dL
Hemoglobin	10000mg/dL
Bilirubin	1000mg/dL
Albumin	20000mg/dL
Triglyceride	1000mg/dL

3) Dilute the high concentration substances in the above table with specimens mentioned in section 4-1) to the following concentration (according to the relevant medical level, considering of similar products in market, the test concentration selected in this test are as follows).

Name of substances	**Concentration**
Ascorbic Acid	20mg/dL
Hemoglobin	1000mg/dL
Bilirubin	10mg/dL
Albumin	2000mg/dL
Triglyceride	500mg/dL

4) Perform the test according to the test procedure in the package insert.

3.5 Result

Note: "3+"=3 positive results, "3-" =3 negative results

Analyte	Lot / Concentration	Lot 1		Lot 2		Lot 3	
		Negative specimen	L3	Negative specimen	L3	Negative specimen	L3
	0mg/dL	3-	3+	3-	3+	3-	3+
Ascorbic Acid	20mg/dL	3-	3+	3-	3+	3-	3+
Hemoglobin	1000mg/dL	3-	3+	3-	3+	3-	3+
Bilirubin	10mg/dL	3-	3+	3-	3+	3-	3+
Albumin	2000mg/dL	3-	3+	3-	3+	3-	3+
Triglyceride	500mg/dL	3-	3+	3-	3+	3-	3+

3.6Conclusion

According to the results, all the substances above won't interfere the results of COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma).

4. Cross Reactivity

4.1 Purpose

To evaluate the cross-reactivity of COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma)

4.2Test Method

Through the detection of influenza A / B virus, respiratory syncytial virus, adenovirus, rhinovirus, human metapneumovirus, Mycoplasma pneumoniae, Chlamydia pneumoniae and bacterial pneumonia patients' blood specimens, to find if the product has cross reaction to these positive specimens. Each specimens will be tested once per lot

4.3Material

COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma)

Cassette Lot1: 2002155，Lot2:2002156，Lot3:2002157

Cross-reactivity specimens: influenza A / B virus, respiratory syncytial virus, adenovirus, rhinovirus, human metapneumovirus, Mycoplasma pneumoniae, Chlamydia pneumoniae and bacterial pneumonia patients' blood samples collected from hospital.

4.4Procedure

Perform the test according to the test procedure in the package insert

4.5 Result

Note: "-" = negative result

Lot / Specimen	Lot 1	Lot 2	Lot 3
5 influenza A virus positive specimen	5-	5-	5-
4 influenza B virus positive specimen	4-	4-	4-
3 respiratory syncytial virus positive specimen	3-	3-	3-
2 adenovirus positive specimen	2-	2-	2-
1 rhinovirus positive specimen	-	-	-
2 human metapneumovirus positive specimen	2-	2-	2-
5 Mycoplasma pneumoniae positive specimen	5-	5-	5-
4 Chlamydia pneumoniae positive specimen	4-	4-	4-
3 bacterial pneumonia positive specimen	3-	3-	3-

4.6Conclusion

The COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma) showed no cross-reaction with these substances above.

5. Precision (Intra-assay)

5.1 Purpose

To evaluate the precision of COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma) in lot

5.2 Method

Use the same batch of tests to test the reference products of different concentrations to quantify the signal strength of the detection line (T line), and observe the precision in lot. Three lots were assayed by three operators respectively. Testing at each lot consisted of 10 replicates for each specimen.

5.3 Material

COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma)

Cassette Lot1: 2002155，Lot2:2002156，Lot3:2002157

Clinical positive specimens

5.4Test Procedure

Perform the test according to the test procedure in the package insert

5.5 Result

Note: The Orient Gene color card has 10 color bands. It divided into 10 gradients, from 1 to 10, according to the color intensity. 1 means the line is invisible, and 10 means the line is very strong.

Lot1: 2002155

		Samples		
		N1	IgG-J	IgM-J
Test	1	1	5	5
	2	1	5	5
	3	1	5	4
	4	1	5	5
	5	1	5	5
	6	1	5	4
	7	1	6	5
	8	1	5	5
	9	1	6	5
	10	1	5	5
CV		0	0	0.088

Lot1: 2002156

		Samples		
		N1	IgG-J	IgM-J
Test	1	1	5	5
	2	1	5	5
	3	1	5	5
	4	1	5	5
	5	1	5	5
	6	1	5	5
	7	1	6	5
	8	1	5	4
	9	1	5	5
	10	1	5	5
CV		0	0	0.065

Lot1: 2002157

		Samples		
		N1	IgG-J	IgM-J
Test	1	1	5	5
	2	1	6	5
	3	1	5	5

	4	1	5	4
	5	1	5	5
	6	1	5	5
	7	1	6	5
	8	1	5	5
	9	1	5	5
	10	1	5	5
CV		0	0.062	0.065

5.6Conclusion

The precision is fine and acceptable of COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma), and the CV is less than 0.1.

6. Precision (Inter-assay)

6.1 Purpose

To evaluate the precision of COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma) between lot.

6.2 Method

Use different batches of test to test the reference products of different concentrations to quantify the signal strength of the detection line (T line), and observe the precision between lots.

6.3Material

COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma)
Cassette Lot1: 2002155，Lot2:2002156，Lot3:2002157

6.4Test Procedure

Perform the test according to the test procedure in the package insert

6.5 Result

Note: The Orient Gene color card has 10 color bands. It divided into 10 gradients, from 1 to 10, according to the color intensity. 1 means the line is invisible, and 10 means the line is very strong.

		N1		
		Lot 1	Lot 2	Lot 3
Test	1	1	1	1
	2	1	1	1
	3	1	1	1
	4	1	1	1
	5	1	1	1
	6	1	1	1
	7	1	1	1
	8	1	1	1
	9	1	1	1
	10	1	1	1

CV	0

		IgG-J		
		Lot 1	Lot 2	Lot 3
Test	1	5	5	5
	2	5	5	6
	3	5	5	5
	4	6	5	5
	5	5	5	5
	6	5	6	5
	7	6	5	5
	8	5	5	6
	9	6	5	5
	10	5	5	5
CV		0.078		

		IgM-J		
		Lot 1	Lot 2	Lot 3
Test	1	5	5	5
	2	5	5	5
	3	4	5	4
	4	5	5	5
	5	5	5	5
	6	5	4	5
	7	4	5	5
	8	5	5	5
	9	5	5	4
	10	5	5	5
CV		0.078		

6.6 Conclusion

The precision is fine and acceptable of COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma), and the CV is less than 0.1.