

**Clinical Evaluation Report**  
2019-nCoV IgG/IgM rapid test cassette  
(Whole blood/Serum/Plasma)

**Introduction**

The purpose of the report is to evaluate the performance of Orient gene 2019-nCoV IgG/IgM rapid test cassette (Whole blood/Serum/Plasma) for testing clinical samples (sample type is plasma, serum and whole blood).

The Orient gene 2019-nCoV IgG/IgM rapid test device has been evaluated in three hospitals respectively comparison to RT-PCR or clinical diagnosis.

**Materials**

Orient gene device: 2019-nCoV IgG/IgM rapid test cassette (Whole Blood/Serum/Plasma)

Lot: 2002189, Exp: 02-2022

**Clinical samples information**

Total 99 blood samples were collected from the recruited 60 patients of novel coronavirus pneumonia.

**Method**

20 of 60 patients provided plasma samples for testing, 20 of 60 patients provided serum samples for testing and the remaining 20 patients provided whole blood/serum/plasma samples for sample type consistency testing. All samples have been tested in single with Orient gene device, the results were compared to RT-PCR or clinical diagnosis (including chest Computed Tomography and clinical signs etc.) of "Diagnosis and treatment of novel coronavirus pneumonia".

**Test procedure**

Followed the package insert.

**Results**

1. The result of serum samples as below.

Regarding the IgM test, the result comparison to RT-PCR.

Method		RT-PCR		Total
		Positive	Negative	
Orient gene 2019-nCoV IgM test	Positive	17	0	17
	Negative	13	10	23
Total		30	10	40

Sensitivity of IgM: 56.7% (17/30)

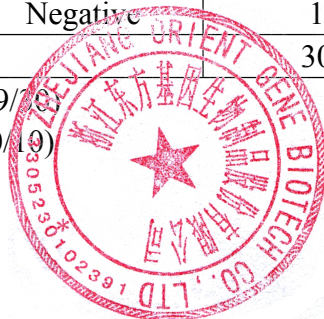
Specificity of IgM: 100% (10/10)

Regarding the IgG test, the result comparison to RT-PCR.

Method		RT-PCR		Total
		Positive	Negative	
Orient gene 2019-nCoV IgG test	Positive	29	0	29
	Negative	1	10	11
Total		30	10	40

Sensitivity of IgG: 96.7% (29/30)

Specificity of IgG: 100% (10/10)



2. The result of plasma samples as below.

Regarding the IgM test, the result comparison to RT-PCR.

Method		RT-PCR		Total
		Positive	Negative	
Orient gene 2019-nCoV IgM test	Positive	28	0	28
	Negative	11	0	11
Total		39	0	39

Sensitivity of IgM: 71.8% (28/39)

Regarding the IgG test, the result comparison to RT-PCR.

Method		RT-PCR		Total
		Positive	Negative	
Orient gene 2019-nCoV IgG test	Positive	36	0	36
	Negative	3	0	3
Total		39	0	39

Sensitivity of IgG: 92.3% (36/39)

3. The result of sample type consistency testing of whole blood/serum/plasma.

		Number of Positive/Tested		
		Serum	Plasma	Whole blood
Orient gene 2019-nCoV IgM/IgG test	IgM	12/20	12/19	10/20
	IgG	20/20	19/19	19/20
Total		20	19*	20

\* 1 of 20 patient only provided serum and whole blood sample for testing, no plasma sample for testing.

4. Summary results of all samples

Regarding the IgM test, the result comparison to RT-PCR.

Method		RT-PCR		Total
		Positive	Negative	
Orient gene 2019-nCoV IgM test	Positive	55	0	55
	Negative	34	10	44
Total		89	10	99

Sensitivity of IgM: 61.8% (55/89)

Specificity of IgM: 100% (10/10)

Regarding the IgG test, the result comparison to RT-PCR.

Method		RT-PCR		Total
		Positive	Negative	
Orient gene 2019-nCoV IgG test	Positive	84	0	84
	Negative	5	10	15
Total		89	10	99

Sensitivity of IgG: 94.4% (84/89)

Specificity of IgG: 100% (10/10)

**Conclusion**

The above results showed that:

Compared with RT-PCR, the sensitivity of IgM test is 61.8% (55/89) and specificity is 100%(10/10), the sensitivity of IgG test is 94.4% (84/89) and specificity is 100%(10/10).

