

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)

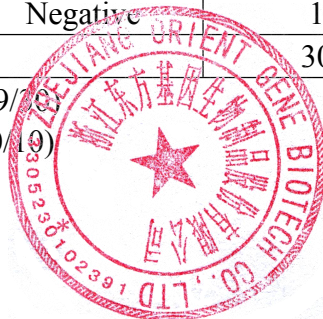
Specificity of IgM: 100% (10/10)

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).

