



## Clinical Samples Study Report

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

#### Purpose

Evaluate the performance of Orient Gene COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) for testing clinical samples.

#### Materials

Orient Gene device: COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)  
Lot: 20200203, Exp: 01-2022

#### Clinical samples information

113 blood samples were collected from patients exhibiting pneumonia or respiratory symptoms.

#### Method

The Orient Gene COVID-19 IgG/IgM Rapid Test has been evaluated with the 113 blood samples obtained from patients exhibiting pneumonia or respiratory symptoms. 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

Summary data of Orient Gene COVID-19 IgG/IgM Rapid Test as below.

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

Method		RT-PCR		Total
Orient Gene COVID-19 IgM test	Results	Positive	Negative	
	Positive	87	0	87
	Negative	12	14	26
Total		99	14	113

Regarding the IgG test, we have counted the positive rate of the 36 of 113 patients during the convalescence period.

Method		Number of patients during the convalescence period	Total
Orient gene COVID-19 IgG test	Positive	35	35
	Negative	1	1
Total		36	36

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### Conclusion

The above results showed that:

The sensitivity of IgM test is 87.9% (87/99) and specificity is 100% (14/14) comparison to RT-PCR.

The sensitivity of IgG test is 97.2% (35/36) during the convalescence period.

### Discussion

If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended.

Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.



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