Clinical Sensitivity and Specificity Study Report

The " COVID-19 IgG/IgM Rapid Test" developed by .is for qualitative detection of antibodies (IgG and IgM) to Novel coronavirus in human Whole Blood/Serum/Plasma. By studying on the statistical coincident rate,we could validate if it could be used for detection of antibodies (IgG and IgM) to Novel coronavirus in human Whole Blood/Serum/Plasma.

1. Method

Regarding the IgM test, Testing was performed on approximately 167 clinical specimens from Professional Point of Care sites, Regarding the IgM test, the result was compared to RT-PCR.Regarding the IgG test, we have counted the positive rate of the 77 patients during the convalescence period.

2. Result

2.1 COVID-19 IgM

Agreement with RT-PCR

COVID-19 IgM		RT-PCR		Total
		Positive	Negative	
CLUNGENE®	Positive	67	1	68
	Negative	10	89	99
Total		77	90	167

Clinical Sensitivity（%）=67/（67+10）*100%=87.01%
Clinical Specificity（%）= 89/（1+89）*100%=98.89%
Total Coincidence Rate（%）= [（67+89）/（67+10+1+89）]=93.41%

2.2 COVID-19 IgG

COVID-19 IgG		Number of patients during the convalescence period	Total
®	Positive	75	75
	Negative	2	2
Total		77	77

Clinical Sensitivity（%）= 75/（75+2）*100%=99.42%

3. Conclusion

The clinical research is a qualitative test comparison to evaluate the clinical use validity and group professional test applicability of the "™ COVID-19 IgG/IgM Rapid Test" developed by

For COVID-19 IgM, when compared to RT-PCR, A statistical comparison was made between the results yielding a sensitivity of 87.01%, a specificity of 98.89% and an accuracy of 93.41%.