

Clinical Comparison Result Summary

One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG antibody compared to RT-PCR

1. Diagnostic performance of IgG/IgM antibody in Serum

		RT-PCR		Total	IgG/IgM antibody in serum	
		Positive	Negative		Sensitivity	
IgM/IgG rapid test	Positive	203	35	238	Specificity	96,0%
	Negative	3	835	838	PPV	85,3%
Total		206	870	1076	NPV	99,6%

2. Diagnostic performance of IgG/IgM antibody in Plasma

		RT-PCR		Total	IgG/IgM antibody in plasma	
		Positive	Negative		Sensitivity	
IgM/IgG rapid test	Positive	72	4	76	Specificity	98,1%
	Negative	3	212	215	PPV	94,7%
Total		75	216	291	NPV	98,6%

3. Diagnostic performance of IgG/IgM antibody in Whole Blood

		RT-PCR		Total	IgG/IgM antibody in blood	
		Positive	Negative		Sensitivity	
IgM/IgG rapid test	Positive	71	4	75	Specificity	98,1%
	Negative	4	212	216	PPV	93,4%
Total		75	216	291	NPV	98,6%

Internal Use only