

Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-CoV-2
Clinical report summary

- Comparative analysis of clinical diagnosis results with test reagent results.

The detection results of test reagent(IgG/IgM) and clinical diagnostic results are shown in the following table:

		clinical diagnosis results		Total
		confirmed diagnosis	exclusion	
Test reagent results	Positive (+)	186	8	194
	Negative (-)	16	372	388
Total number		202	380	582

Sensitivity: 92.08%; (95%CI: 87.52%~95.07%)

Specificity: 97.89%; (95%CI: 95.90%~98.93%)

Total clinical coincidence rate: 95.88%. (95%CI: 93.94%~97.21%)

- Comparative analysis of test reagent results with nucleic acid test results

The detection results of test reagent(IgG/IgM) and the nucleic acid test results were shown in the following table:

		Nucleic acid test results		Total
		Positive (+)	Negative (-)	
Test reagent results	Positive (+)	116	78	194
	Negative (-)	10	378	388
Total number		126	456	582

Positive coincidence rate: 92.06%; (95%CI: 86.01%~95.63%)

Negative coincidence rate: 82.89%; (95%CI: 79.17%~86.07%)

Total coincidence rate: 84.88%; (95%CI: 81.74%~87.56%)

- Analysis of results of continuous samples collected from the same patient at different time points.

Statistical analysis of test results were shown in the following table::

Test reagent results	Number of cases	Percentage
Earlier than the nucleic acid test results	3	15%
Same as the nucleic acid test results	14	70%
Later than the nucleic acid test results	3	15%

The above results showed that there was no statistically significant difference between the detection reagent and the clinical diagnosis results.