

**Comparative Test Report
COVID-19 (SARS-CoV-2) IgM Ab Rapid Test
(Immunochromatography/Colloidal Gold)**

1. Method

In this trial, 1300 clinical samples were selected. There were 300 positive samples and 1000 negative samples. The SARS-CoV-2 IgM Ab rapid test and the SARS-CoV-2 PCR test were detected simultaneously, and the positive coincidence rate, negative coincidence rate, and total coincidence rate were calculated.

2. Result

- 1) 300 cases of positive samples confirmed by Nucleic Acid Test: tested with SARS-CoV-2 IgM Ab rapid test, 281 cases were positive, 19 cases were negative.
- 2) 1000 cases of negative samples confirmed by Nucleic Acid Test: tested with SARS-CoV-2 IgM Ab rapid test, 972 cases were negative, 28 cases were positive.

3. Performance Analysis

Results statistics

SARS-CoV-2 IgM Ab Rapid test	PCR Test		Total
	Positive	Negative	
Positive	273	40	313
Negative	27	960	987
Total	300	1000	1300

SARS-CoV-2 IgM Ab rapid test Analysis of coincidence rate of SARS-CoV-2 IgM Ab rapid test and PCR Test in serum samples:	
Diagnostic sensitivity	91.0% (87.2% - 94.0%) [*] , 95% Confidence Interval [†]
Diagnostic specificity	96.0% (94.6% - 97.1%) [*] , 95% Confidence Interval [†]
Total coincidence rate	94.8% ((93.5% - 96.0%)

4. Conclusion

SARS-CoV-2 IgM Ab rapid test kit diagnostic sensitivity is 93.6%, the diagnostic specificity is 97.2%, total coincidence rate is 96.3%.

**Comparative Test Report
COVID-19 (SARS-CoV-2) IgG Ab Rapid Test
(Immunochromatography/Colloidal Gold)**

1. Method

In this trial, 1300 clinical samples were selected. There were 300 positive samples and 1000 negative samples.

The SARS-CoV-2 IgG Ab rapid test and the SARS-CoV-2 PCR test were detected simultaneously, and the positive coincidence rate, negative coincidence rate, and total coincidence rate were calculated.

2. Result

- 1) 300 cases of positive samples confirmed by PCR Test: tested with SARS-CoV-2 IgG Ab rapid test, 287 cases were positive, 13 cases were negative.
- 2) 1000 cases of negative samples confirmed by PCR Test: tested with SARS-CoV-2 IgG Ab rapid test, 977 cases were negative, 23 cases were positive.

3. Performance Analysis

Results statistics table

SARS-CoV-2 IgM Ab Rapid test	PCR Test		Total
	Positive	Negative	
Positive	287	23	310
Negative	13	977	990
Total	300	1000	1300

SARS-CoV-2 IgG Ab rapid test Analysis of coincidence rate of SARS-CoV-2 IgG Ab rapid test and PCR Test in serum samples:	
Sensitivity	95.6% (92.7% - 97.6%)*, * 95% Confidence Interval
Specificity	97.7% (96.5% - 98.5%)*, * 95% Confidence Interval
Total coincidence rate	97.2% (96.1% - 98%)*

4. Conclusion

SARS-CoV-2 IgG Ab rapid test kit diagnostic sensitivity is 95.6%, the diagnostic specificity is 97.7%, total coincidence rate is 97.2%.
immunological seroconversion can occur.