

## COVID-19 IgG/IgM Test Cassette

sensitivity and specificity.and Accuracy  
report

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## Method

The COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) was compared with a commercial PCR; the results show that COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) has a high sensitivity and specificity and Accuracy

### Performance of IgG Specimen

Method		PCR		Total Result
COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma)	Results	IgG Positive	IgG Negative	
	IgG Positive	96	0	96
	IgG Negative	4	100	104
Total Result		100	100	200

Relative sensitivity: 96% (95%CI\*:86.3%~99.5%);

Relative specificity: 100% (95%CI\*:94.2%~100%);

Accuracy: 98% (95%CI\*: 92.9%~99.7%) \*Confidence Intervals

### Performance of IgM Specimen

Method		PCR		Total Result
COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	IgM Positive	94	0	94
	IgM Negative	6	100	106
Total Result		100	100	200

Relative sensitivity: 94.0% (95%CI\*:75.7%~95.5%);

Relative specificity: 100.0% (95%CI\*:94.2%~100%);

Accuracy: 97% (95%CI\*: 87.4%~97.8%). \*Confidence Intervals

## Conclusion

The COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) products have been compared with a commercial PCR using clinical specimen. The results show that the relative sensitivity of the COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) is 96% for IgG and 94 % for IgM.the relative specificity is 100% for IgG and100% for IgM. For the Plasma samples, The results show that the relative sensitivity of the COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) is 96% for IgG and 94 % for IgM.the relative specificity is 100% for IgG and 100% for IgM. The results show that the Accuracy of COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) is 98% for IgG and 97% for IgM.