

## Clinical Trial Summary of COVID-19 IgG/IgM Rapid Test Device (Whole Blood/Serum/Plasma)

COVID-19 IgG/IgM Rapid Test Device (Whole Blood/Serum/Plasma) clinical trials were performed at two sites in China from February 2020 to March 2020. These clinical trials were aimed to evaluate the performance of COVID-19 IgG/IgM Rapid Test Device (Whole Blood/Serum/Plasma) by comparing with PCR.

### 1. Clinical Trial Location:

- a. Zhejiang Provincial Center for Disease Control and Prevention
- b. The First Hospital of Zhejiang Province

### 2. Clinical Specimens

79 specimens were collected from patients exhibiting pneumonia or respiratory symptoms. 83 specimens were also collected from convalescent patients. 227 negative specimens were collected in the study.

### 3. Methods

COVID-19 IgG/IgM Rapid Test Device (Whole Blood/Serum/Plasma) was used to run the clinical specimens collected. The results were recorded and compared with the results obtained by PCR.

### 4. Commercial kits used for Comparison

PCR test kit

### 5. Test Results

Clinical specimens were used to test the performance of COVID-19 IgG/IgM Rapid Test Device (Whole Blood/Serum/Plasma).

#### Clinical Summary of COVID-19 IgG/IgM

For IgM detection:

Method		PCR+	PCR-	Total
COVID-19 IgG/IgM Rapid Test	IgM+	74	2	76
	IgM-	5	225	230
Total		79	227	306

Relative sensitivity: 93.7% (86.0%-97.3%)\*

Relative specificity: 99.1% (96.8%-99.8%)\*

Overall agreement: 97.7% (95.4%-98.9%)\*

\*95% Confidence Interval

For IgG detection:

Method		Convalescent samples	PCR-	Total
COVID-19 IgG/IgM	IgG+	82	3	85
Rapid Test	IgG-	1	224	225
Total		83	227	310

Relative sensitivity: 98.8% (93.5%-99.8%)\*

Relative specificity: 98.7% (96.2%-99.5%)\*

Overall agreement: 98.7% (96.7%-99.5%)\*

\*95% Confidence Interval

## 6. Conclusion

By the data obtained from these clinical investigations, we conclude that COVID-19 IgG/IgM Rapid Test Device (Whole Blood/Serum/Plasma) has relatively high sensitivity, specificity and accuracy. It is a fast and convenient, which requires only room temperature storage conditions. It does not need any instrument to read the result. The background of the test is clean and the interpretation of test result is clear-cut. The test has been determined to be effective and safe.

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