Clinical Study Report

Product Name: Coronavirus Disease 2019 Antibody (IgM/IgG) Combined Test Kit

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MedicalSystem Biotechnology Co., Ltd.

Content

1. Introduce

Test fresh specimens using Coronavirus Disease 2019 Antibody (IgM/IgG) Combined Test Kit. Test result is compared with clinical diagnostic result.

2. General information

2.1 Duration

2020/02/24-2020/02/27

2.2 Site

Medicalsystem Clinical Laboratories (Xinyu) Co., Ltd.
The Third People's Hospital of Hubei Province

2.3 Product information

See Table 1.

Table1 Product Information

Product Name	Coronavirus Disease 2019 Antibody (IgM/IgG) Combined Test Kit
Manufacture	MedicalSystem Biotechnology Co., Ltd.
Lot No.	20200217
Package specification	25T

2.4 Precautions

1. The operators should get familiar with the instruments and the evaluation plan.
2. Exercise the normal precautions required for handling all laboratory reagents.
2. Do not ingest, avoid contact with eyes, skin and mucous membranes.
3. Disposal of all waste material should be in accordance with local guidelines.
4. Avoid the formation of foam in all reagents and samples (specimens, calibrators, and

controls).

3. Method

3.1 Sample Information

3.1.1 Sample Selection Criteria

Diagnosed / excluded patients with COVID-19 infection (eg, Window period, treatment period and rehabilitation period) according to *Laboratory guidelines for novel coronavirus infection in pneumonia* and *Diagnosis and treatment of pneumonia with new coronavirus infection* are selected Age and sex are not limited. Sample information needs to be completed, including age, gender, sample type, sample collection date, test date, clinical diagnosis, etc.

3.1.2 Sample Size

In the clinical study, test result of MedicalSystem kit is compared with clinically recommended methods. The clinical sensitivity of IgM is expected to be more than 80% t and the sensitivity is more than 90%, the clinical specificity is expected to reach 90%, and the allowable error Δ is 0.05. The minimum sample size of the IgM group (n1), IgG group (n2), and excluded case group (n3) is estimated as below:

$$n_1 = \frac{1.96^2 \times 0.80 \times (1-0.80)}{0.05^2} = 246$$

$$n_2 = \frac{1.96^2 \times 0.90 \times (1-0.90)}{0.05^2} = 138$$

$$n_3 = \frac{1.96^2 \times 0.90 \times (1-0.90)}{0.05^2} = 138$$

According to the formula above, positive samples of IgM group is not less than 246 as IgM is more than IgM, and the negative samples should be not less than 138. The number of confirmed cases should not be less than 246, and the number of excluded cases should not be less than 138, the total number of cases is not less than 384.

3.1.3 Sample Collection and Storage

Serum, plasma and whole blood are recommended. Here we use serum as samples.
Serum and plasma should be separated immediately after collection to avoid hemolysis. The separated serum and plasma should be tested as soon as possible. Stored at 2-8℃ are recommended. If longer than 3 days, stored at -20℃. Be careful to restore to room temperature before test. Avoid repeated freeze-thaw cycles. Hemolytic and heat-inactivated samples are not acceptable.
Whole blood needs to be collected by tubes with anticoagulation (EDTA and sodium citrateare recommended). Shake for later use. Whole blood samples are stable for 7 days when store at 2 -8℃. Samples stored more than 7 days are not suitable.

3.2 Performance Characteristics

The performance of the product includes sensitivity, specificity and Kappa analysis.

3.2.1 Acceptable standard

Clinical sensitivity and specificity is not less than 90%, k value of Kappa analysis is more than 0.75.

3.2.2 Analysis method

Refer to the reference range and test results of the clinical diagnostic results, divide all above clinical specimens to two groups: normal group and non-normal group. In the non-normal group, count the number of positive result as the True Positive (Abbr. as TP) and the number of negative result as the False Negative (Abbr. as FN); In the normal group, count the number of positive result as the True Negative (Abbr. as TN) and the number of negative result as the False Positive (Abbr. as FP).
The clinical sensitivity is calculated according to the following formula:

$$\text{Clinical sensitivity} = \frac{\text{TP}}{\text{TP} + \text{FN}} \times 100\%$$

The clinical specificity is calculated according to the following formula:

$$\text{Clinical specificity} = \frac{\text{TN}}{\text{TN} + \text{FP}} \times 100\%$$

K value is calculated by SPSS 19.0.

4. Results

4.1 Data

A total of 800 samples of 708 cases were tested in this clinical study. Among the 800samples, a total of 40 samples from 19 cases with incomplete information or repeated test are excluded. As a result, 760 samples from 689 cases were included in the statistics. Details are listed in the below.

Table 2 Test result

		Clinical Case		
		Confirmed	Excluded	Total
COVID-19 Antibody (IgM/IgG) Combined Test Kit	Positive	280	39	319
	Negtive	6	435	441
	Total	286	474	760

4.2 Result Analysis

The sensitivity is 97.90 %, the specificity is 91.77% and the total consistent is 94.08%. The K value of Kappa analysis is 0.877, which means the test results of the kit are in reasonable comparability with the confirmed / excluded results.

5. Conclusion

The clinical test result means the kit are in reasonable comparability with the confirmed / excluded results.