1. Description of the overall design of the test

In this study, the same products that have been approved to be marketed in China were selected as the comparative reagent and compared with the clinical test reagent to prove that the clinical test reagent is equivalent to the marketed products. The blind rule was used throughout the test. After the completion of the test, the test results were statistically analyzed, and the clinical application performance of the reagent in the clinical test was evaluated.

2. Test design and data analysis

A. Sample size and the basis for determining sample size

This product is a qualitative product, the total sample size can be selected not less than 100 cases, and the method of single test using reagent to be evaluated and contrast reagent/reference method respectively. Qualitative products should meet at least 30% positive samples and 20% suspected samples. Acceptable standards for clinical performance indicators should be set before the experiment. If the results of the comparative study cannot meet the preset standards, the sample size should be appropriately expanded for evaluation.

B. Inclusion requirements for clinical trial samples

The sample is not limited to age or sex, but requires a certain number of positive, negative and suspected cases

C. Blind requirement

The number of selected samples shall be numbered by the sample manager, the test sequence shall be randomly disrupted, and then the test operator shall use the assessment reagent and comparison reagent to conduct synchronous test on the same sample. The clinical diagnosis and other information of selected samples shall be kept confidential to the operator before the test to ensure the blind method; after the test is completed, the blinding shall be removed.

D. Sample collection, storage and transportation methods

a) **Sample collection** :

According to the clinical indications, we should select the samples of patients with related diseases and normal people, and all of them are the remaining samples after the clinical laboratory test report.

The sample used for testing must be appropriate not less than 0.5ml, so as to be enough for repeated test.

b) **Sample preservation**：

The samples can be kept stable for 7 days at 2 ℃ ~ 8 ℃ and 30 days at - 20 ℃. Sample should be restored to room temperature before testing.

E. Establishment of comparative test products

The reagents used by the comparison manufacturers have been approved by the State Food and Drug Administration for listing, and the effect is good in the market, and the methodology is the same as the reagents used in this clinical trial, so it is selected as the comparison reagent.

F. All products for clinical trials

Reagent information record

Item	Information Recording	
Contrast Reagent	**Manufacturer**	Guangzhou Wondfo Biotechnology
	Name of reagent	Novel coronavirus (2019-nCoV) antibody detection kit (colloidal gold method)
	Principlesof methodology	Colloidal gold method
	Registration Certificate No.	202003400176
Test Reagent	**Manufacturer**	Singuway Biotech Inc.
	Name of reagent	COVID-19 IgG/IgM Detection Kit（Colloidal Gold）Instruction
	Principles of methodology	Colloidal gold method

J. Data Management

The original records shall be kept by a specially assigned person in two forms of paper version and electronic version