Beijing Savant Biotechnology Co., Ltd.

New Coronavirus (SARS-CoV-2) N Protein Detection Kit (Fluorescence Immunochromatography)

Clinical Trial Report

Submitter: Beijing Savant Biotechnology Co., Ltd.

14#, 4F, No. 2 Kechuang East 5th Street, Tongzhou District, Beijing,China

TABLE OF CONTENTS

1. Purpose.....3
2. Study Design and Criteria.....4
3. Testing Method.....5
4. Testing procedure.....6
5. Statistical method.....7
6. Results and analysis.....9

1. PURPOSE

To evaluate the clinical performance of the New Coronavirus (SARS-CoV-2) N protein Detection Kit (Fluorescence Immunochromatography).

2. STUDY DESIGN AND CRITERIA

The clinical acceptance criteria is that the positive, negative and total percentage agreement of test method versus nucleic acid method should be ≥ 80%.

3. TESTING METHOD

In this study, a clinical trial was conducted at the Chongqing Infectious Disease Specialist Hospital and the Chongqing Infectious Disease Diagnosis and Treatment Authority, the Chongqing Public Health Medical Center, Wuhan Huo shen shan Hospital and Beijing Center for Disease Control and Prevention .

4. TESTING PROCEDURE

The samples were collected as oropharyngeal swabs. The collection method was as follows: a swab was used to simultaneously wipe both sides of pharyngeal tonsils and posterior pharyngeal wall. After collection, the oropharyngeal swab sample was immersed in 0.5mL of sample preservation solution and stirred. The swab was manually squeezed several times against sample preservation solution container to ensure the swab was fully soaked in the sample preservation solution. The liquid portion obtained was the sample to be tested. The samples were tested and visual inspection with UV-light.

The oropharyngeal swab samples used for nucleic acid method testing were collected at the same time, and the nucleic acid methods followed the already existing commercial devices and reagents protocols in the testing institution.

Table 1: Test Reagents and Instruments

	Antigen Test Method	Nucleic Acid Method	Nucleic Acid Method
Clinical institution	Chongqing Public Health Medical Center Wuhan Huo shen shan Hospital Beijing Center for Disease Control and Prevention	Chongqing Public Health Medical Center	Beijing Center for Diseases Prevention
Reagent manufacturer	Beijing Savant Biotechnology Co., Ltd.	Sansure Biotech Inc.	Beijing Applied Biological Technology Co., Ltd.
Reagent name	New coronavirus (SARS-CoV-2) N protein detection kit (fluorescence immunochromatography)	Novel coronavirus 2019-nCoV nucleic acid detection kit (fluorescent PCR method)	Novel coronavirus 2019-nCoV nucleic acid detection kit (fluorescent PCR method)
Reagent type	50 pcs /package	-	-
Lot NO.	20200209	-	-
Device manufacturer	Beijing Savant Biotechnology Co., Ltd.	Shanghai Hongshi Medical Technology Co., Ltd	B-1st,Zhengdan International Building,No.33 Kexueyuan Road,Changping,Beijing.
Device name		Real-Time PCR System	Real-Time PCR System
Device type		SLAN-48P	ABI7500

5. STATISTICAL METHOD

After test results were read according to the product manual, statistical analysis of the test results was performed in the form of a 2 × 2 table to calculate the positive, negative and total percentage agreement of test method versus nucleic acid method.

Table 2: 2×2 Table

		Clinical Diagnosis		
		Positive	Negative	Total
Test Method or Nucleic Acid	Positive	A	B	A+B
	Negative	C	D	C+D
	Total	A+C	B+D	A+B+C+D

Note: A is the number of samples that are tested Positive by the test method and determined to be Positive by the reference method, B is the number of samples that are tested Positive by the test method but determined to be Negative by the reference method, C is the number of samples that are tested Negative by the test method but determined to be Positive by the reference method, and D is the number of samples that are tested Negative by the test method and determined to be Negative by the reference method.

Positive Percentage Agreement (Clinical Sensitivity): A/(A + C)

Negative Percentage Agreement (Clinical Specificity): D/(B + D)

Total Percentage Agreement: A+D/(A+B+C+D)

95% confidence interval analysis of positive, negative and total Percentage Agreement：

$$\text{Lower limit of confidence interval} = (Q_1 - Q_2)/Q_3 \times 100\%$$

$$\text{Upper limit of confidence interval} = (Q_1 + Q_2)/Q_3 \times 100\%$$

Among them, Positive Percentage Agreement (Clinical Sensitivity):

$$Q_1 = 2 \times \mathrm{A} + 1.96^2$$

$$Q_2 = 1.96 \times \sqrt{1.96^2 + 4 \times A \times C/(A + C)}$$

$$Q_3 = 2 \times (\mathrm{A} + \mathrm{C} + 1.96^2)$$

Negative Percentage Agreement (Clinical Specificity):

$$Q_1 = 2 \times \mathrm{D} + 1.96^2$$

$$Q_2 = 1.96 \times \sqrt{1.96^2 + 4 \times B \times D/(B+D)}$$

$$Q_3 = 2 \times (\mathrm{B} + \mathrm{D} + 1.96^2)$$

Total Percentage Agreement:

$$Q_1 = 2 \times （\mathrm{A} + \mathrm{D}) + 1.96^2$$

$$Q_2 = 1.96 \times \sqrt{1.96^2 + 4 \times (A+D) \times (B+C)/(A+B+C+D)}$$

$$Q_3 = 2 \times (A + B + C + D + 1.96^2)$$

6. RESULTS AND ANALYSIS

6.1 Analysis of results in a hospital in Wuhan

1）Comparison with nucleic acid test results

		Nucleic acid test results		
		Positive	Negative	Total
Trial reagents	Positive	25	0	25
	Negative	0	0	0
	Total	25	0	25

2）Calculation of the coincidence rate of trail reagent：

Sensitivity＝100%

Specificity＝100%

Total coincidence rate＝100%

6.2 Analysis of results in a hospital in Chongqing

1）Comparison with nucleic acid test results

		Nucleic acid test results		
		Positive	Negative	Total
Trial reagents	Positive	60	0	60
	Negative	8	160	168
	Total	68	160	228

2）Calculation of the coincidence rate of trail reagent：

Sensitivity＝88.24%

Specificity＝100.00%

Total coincidence rate＝96.49%

6.3 Analysis of the results of a disease prevention and control center

1）Comparison with nucleic acid test results

		Nucleic acid test results		
		Positive	Negative	Total
Trial reagents	Positive	10	1	11
	Negative	2	61	63
	Total	12	62	74

2）Calculation of the coincidence rate of trail reagent：

Sensitivity＝83.33%

Specificity＝98.39%

Total coincidence rate＝95.95%

6.4 Summary analysis

1）Comparison with nucleic acid test results

		Nucleic acid test results		
		Positive	Negative	Total
Trial reagents	Positive	95	1	96
	Negative	10	221	231
	Total	105	222	327

2）Calculation of the coincidence rate of trail reagent：

Sensitivity＝90.48%（The mean CT value was 30.9）

Specificity＝99.55%

Total coincidence rate＝96.64%

95% confidence interval calculation of coincidence rate：

Positive coincidence confidence interval：83.35%-94.74%

Negative coincidence confidence interval：97.49%-99.92%