Novel Coronavirus 2019-nCoV Antigen Test

(Colloidal Gold)

Clinical Study Report

Subject Product: Novel Coronavirus 2019-nCoV Antigen Test

(Colloidal Gold)

Test start time: Oct.10 th, 2020

Test completion time: Feb. 03th, 2021

Model specifications: 40T/kit

Submitted by: Beijing Hotgen Biotech Co., Ltd.

Beijing Hotgen Biotech Co., Ltd.

Summary of Research Report

Clinical trial sponsor	Beijing Hotgen Biotech Co., Ltd.
Clinical trial name	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)
Clinical trial facility	The Key laboratory of Biological Emergency and Clinical POCT (Beijing)
Purpose of clinical trials	The purpose of this study was to investigate the self-test performance of "Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)" produced by Beijing Hotgen Biotech Co., Ltd. to detect novel coronavirus (2019-nCoV) antigen in human anterior nasal swab specimens.
Clinical trial methods	The subject product of this study is "Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)" (*hereinafter referred to as "Antigen Test"*) produced by Beijing Hotgen Biotech Co., Ltd. The product selected for the comparison is RT-PCR Kit. Results of the Antigen Test and RT-PCR Test are compared to evaluate the consistency between the Antigen Test and RT-PCR Test. Cases with different test results were comprehensively analyzed by combining the patients' epidemiological background, clinical symptoms, disease outcome, and other information. In this way, the performance of the Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) (produced by Beijing Hotgen Biotech Co., Ltd) to detect the novel coronavirus (2019-nCoV) antigen in human anterior nasal swab specimens was evaluated. The specimens collection and testing for antigen test were conducted by individuals in non-healthcare settings while the collection and testing of the specimens for RT-PCT were accomplished by the investigators. The anterior nasal swab specimens used for antigen test were prospectively collected. Patients were sequentially and randomly enrolled .All collected specimens can be traced back to the corresponding clinical information, including case number, age, gender, type of specimens, collection time, confirmation or exclusion of the novel coronavirus infection, and the RT-PCR Test results for disease diagnosis.
Test kit name, specifications	Name: Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) Specification: 40 Tests/Kit;
Sample size	This study enrolled a total of 223 human anterior nasal swab specimens, of which 108 were positives for RT-PCR Test, 115 negatives for RT-PCR Test; As for data collection of the corresponding RT-PCR Test results.
Judgment method	Visual observation
Evaluation method	(1) The total coincidence rate of the diagnosis results of the assessment system and the reference system is greater than 80%. (2) The Kappa value of the consistency between the diagnostic results of the assessment system and the reference system is greater than 0.75.
Results and conclusions	1、The sensitivity , spesitivity , and accuracy of the diagnostic results of the assessment system and the reference system are: Human anterior nares swab specimens, 96.30%, 99.13%, and 97.76%

		Nucleic Acid Test results		Total
		Positive (+)	Negative (-)	
Antigen Test	Positive (+)	104	1	105
	Negative (-)	4	114	118
Total		108	115	223

Sensitivity: 96.30% (90.79%～98.98%)
Specificity: 99.13% (95.25%～99.98%)
Accuracy: 97.76% (94.85%～99.27%)

2、The consistency coefficient Kappa result of the diagnostic results between the assessment system and the reference system is below:

Human anterior nares swab specimens: Kappa（K）=0.9551;

In summary, individuals self-test in non-healthcare settings by using the Antigen Test kit , the Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) produced by Beijing Hotgen Biotech Co., Ltd. to detect human anterior nasal swab specimens, the results showed excellent agreement with the RT-PCR Test results. The comparison test results of human anterior nasal swab specimens are highly consistent. Therefore, the Antigen Test kit has a good self-test performance.

Verification unit:

The Key laboratory of Biological Emergency and Clinical POCT (Beijing)

生物应急与临床POCT 北京市重点实验室

Feb.03th , 2021

Note: The Key laboratory of Biological Emergency and Clinical POCT (Beijing) was jointly declared by Beijing Hotgen Biotech Co.,Ltd and institute of Microbiology of the Academy of Military Medical Sciences. It was announced on the website of the Beijing Municipal science & Technnology Commission on May 30, 2014.

Sensitivity verification of Novel Coronavirus 2019-nCoV

Antigen Test (Colloidal Gold)

Purpose

Use inactivated new coronavirus to evaluate the sensitivity of Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

Experimental Materials

1. 1 batch of colloidal gold test paper;
2. Inactivated virus: 10^5 pfu/mL.

Experimental steps

Sample: Mixing ratio of sample diluent

Concentration number	Virus content in sample (pfu/mL)	Sample: Mixing ratio of sample diluent
1	0	1：9
2	10^2	1：9
3	2.5×10^2	1：9
4	5×10^2	1：9
5	10^3	1：9
6	10^4	1：9

1. After mixing the sample and diluent, incubate at room temperature for 1 min.
2. Take 100μL of sample and observe the result after 15min reaction.

Test results

Concentration number	Virus content in sample (pfu/mL)	Sample: Mixing ratio of sample diluent	Result
1	0	1：9	-
2	10^2	1：9	±
3	2.5×10^2	1：9	+
4	5×10^2	1：9	+
5	10^3	1：9	++
6	10^4	1：9	+++

In conclusion

Colloidal gold experiment results: 10^2 pfu/mL has a shallow band, negative without background, the sensitivity is 2.5×10^2 pfu/mL.

The Key laboratory of Biological Emergency and Clinical POCT (Beijing)

Aug.17th,2020