Novel Coronavirus 2019-nCoV Antigen Test

(Colloidal Gold)

Self-test Performance Study

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.

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1. Background of the Study

Coronaviruses are positive-sense single-stranded RNA viruses, with four genera of α, β, γ, and δ. The novel coronavirus is a new type of coronavirus discovered in Wuhan viral pneumonia cases in 2019. On January 12, 2020, the World Health Organization named the virus as 2019-nCoV, which belongs to the β genus. The S protein of 2019-nCoV is located on the viral surface to form a rod-like structure, and it is one of the main antigen proteins of the virus. The S gene is also the main gene for coronavirus typing. The 2019-nCoV can cause viral pneumonia, with main clinical manifestations of fever, fatigue, and respiratory symptoms such as dry cough. Some patients gradually develop breathing difficulties, and in severe cases, acute respiratory distress syndrome, septic shock, irreversible metabolic acidosis, and coagulopathy may occur.

2.Intended Use and Principle of subject product

This kit is used for in vitro qualitative determination of novel coronavirus antigen in human anterior nasal swab. It is used as rapid investigation for suspected cases of novel coronavirus, can also be used as a reconfirmation method for nucleic acid detection in discharged cases.

This test is also for self-test in non-healthcare settings (such as person's home or certain non-traditional sites such as offices, sporting events, airports, schools etc.) by individuals and results are for the detection of 2019-nCoV antigen.Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for 2019-nCoV by a healthcare provider is necessary.

This kit is based on the Colloidal gold immunochromatographic technology, and uses double antibody sandwich method to detect the novel coronavirus antigen in human anterior nasal swab. The detection line (T line) of the novel coronavirus antigen test cassette was coated with novel coronavirus antibody, and the quality control line (C line) was coated with sheep anti-mouse. During the test, the sample is dropped into the test cassette and the liquid is chromatographed upward under the capillary effect. The novel coronavirus antigen in the sample first binds to the Colloidal gold-labelled novel coronavirus antibody to form a solid phase novel coronavirus antibody-novel coronavirus antigen-labelled novel coronavirus antibody-Colloidal gold complex at the T line position, and form a solid phase sheep anti-mouse-labelled novel coronavirus antibody- Colloidal gold complex was formed at the C line position. After the test is completed, observe the Colloidal gold color reaction of T line and C line to determine results of novel coronavirus antigen in human anterior nasal swab.

3 Purpose of the Study

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.

4 Overall Study protocol

4.1 Establishment of the study protocol

The study protocol was formulated by the applicant in consultation with the clinical institution before the study, and according to the study protocol, the responsibilities of the applicant, the researcher, and the person in charge of statistics were clearly defined. The applicant organization organizes participation in the trial. All researchers were trained in the study protocol.

4.2 Study method introduction

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.

4.3 Investigators

The investigators participating in the study were 3 principal investigators, 3 investigators in charge of statistics, 6 operators used to run the RT-PCR assay and several participants used to assist the study.

4.4 Quality control

(1) The testing process was strictly performed in accordance with the requirements of the kit instructions;

(2) truthfully, detailed, timely, and carefully record all content to ensure that the content of the test record form is complete, true, reliable, and traceable;

(3) Invalid results due to the kit or other reasons should be re-tested;

(4) When the retesting of the sample occurs due to human error operation, instrument failure, and sample addition failure, the retesting result shall prevail, and the reason for retesting shall be indicated.

5 Study Trial Procedures

5.1 Case screening and enrollment

The case enrollment was based on the clinical diagnostic information provided by the clinical institutions/centers. All enrolled cases meet the study requirements for clinical information and specimens.

5.2 Specimens collection and testing

Antigen test: The specimens collection and testing were conducted by individuals in non-healthcare settings accroding to the instruction of use. and the results were recorded.

RT-PCR test: Specimens of all enrolled cases were tested using the RT-PCR Test according to kit instructions, and the results were recorded.

5.3 Statistical analysis of test results

Generate a data table with the information of the case specimen, the corresponding test results of the Antigen Test and RT-PCR Test results of the same case at the same period, the confirmation/exclusion results of COVID-19, the disease processes, and the clinical severity of the disease,etc. After verification, the trial database of the project is established.

6. Trial Specimens

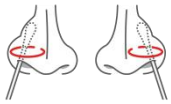
6.1 Specimen types

There is a sample type in this trial: human anterior nasal swab specimens.

6.2 Collection, processing and storage of specimens

Specimens collection, processing, storage should meet the Instructions for Use of the subject product and the comparator method.

6.2.1 Collection and treatment of specimens



Please refer to the instructions.

6.2.2 Storage of specimens

The sample of treated should be tested within 1h. Specimens that can't be detected within 24 hours should be kept at -70℃ or below. Repeated freezing and thawing should be avoided during specimen transportation.

6.3 Entry Criteria of Specimens

6.3.1 Inclusion criteria

(1) The total number of enrolled cases is no less than 200, of which no less than 100 positive COVID-19 cases and no less than 100 negative cases.

(2) Enrolled cases included patients from clinic institutions with definitely clinic information and no less than 30 healthy subjects from non-clinic institutions(eg.staffs in supermarket, students in school).

(3) The enrolled cases should cover a certain number of recovered cases, suspected cases and try to cover patients with various respiratory infectious diseases. The enrolled cases should cover patients with different clinical severity (such as mild, moderate, severe, and critical patients), as well as patients with different disease stages (such as early, middle, and middle-late stage patients).

(4) The specimen meets the requirements for specimen collection, processing and storage.

(5) The relevant information of the specimen is complete, including the case number, age, gender, type of species, collection time, the confirmation or exclusion of the novel coronavirus infection, etc., and the RT-PCR Testing results used for the diagnosis of the disease .

6.3.2 Exclusion criteria of specimens

Cases that do not meet the inclusion criteria, such as

(1) Specimens type does not meet the test requirements;

(2) Does not meet the requirements for collection, processing and storage;

(3) Cases with incomplete clinical information;

(4) Specimens whose quantity does not meet the requirements for testing.

6.3.3 Removal criteria of specimens

(1) Specimens deteriorated;

(2) Specimens that do not meet the entry criteria, or meet the criteria for exclusion but are still tested.

(3)Re-tested specimens due to operational error, instrument failure, and/or sample addition failure. If a retest occurs, remove the earlier result and record the retest result (reasons for a retest should be indicated).

7 Statistical and Analytical Plans

7.1 Data collection

(1) Establish a database in Excel, and enter the traceable information of all specimens, background clinical diagnosis, epidemiological data, onset/visit time, sampling time, and diagnosis/exclusion results, etc.

(2) Check the data. In principle, no data shall be deleted. Any dropouts shall be explained and recorded. The final statistical data shall be locked and backed up.

7.2 Data statistics

Summarize and compare the Antigen Test and RT-PCR Test results in a crosstab (Table 1.), and evaluate the positive consistency rate (sensitivity), negative consistency rate (specificity), and other indicators of Antigen Test and RT-PCR Test results. All inconsistent results shall be fully analyzed based on the confirmation/exclusion results, patient's epidemiological background, clinical symptoms, disease outcome and other information.

Table 1. Statistics of Antigen Test and RT-PCR Test Results

		RT-PCR Test		Total
		Positive (+)	Negative (-)	
Antigen Test	Positive (+)	A	B	A+B
	Negative (-)	C	D	C+D
Total		A+C	B+D	A+B+C+D

Notes: If there are specimens results of the same case in different periods in the above evaluation, any positive Antigen Test result should be taken into analysis. The same analysis method should apply to the statistics of RT-PCR Test results.

(1) Calculation of positive consistency rate (sensitivity), negative consistency rate (specificity) and overall consistency rate (accuracy)

Positive consistency rate (sensitivity) =A/(A+C)×100.00% (95% confidence interval)

Negative consistency rate (specificity) =D/(B+D)×100.00% (95% confidence interval)

Overall consistency rate (accuracy) =(A+D)/(A+B+C+D)×100.00% (95% confidence interval)

The 95% confidence interval is directly calculated using statistical software MedCalc v19.0.7.

(2) Kappa agreement analysis

Calculate the Kappa value of the Antigen Test and RT-PCR Test results by the following formula, compare the Kappa value grading in Table 2. to evaluate the consistency of the Antigen Test and RT-PCR Test results.

Kappa (K)=[N(A+D)--(R1C1+R2C2)] /[N^2--(R1C1+R2C2)]

Table 2. Consistency Judgment

No.	Kappa Value	Consistency Grading
1	<0	Very poor
2	0~0.2	Poor
3	0.21~0.40	Fair
4	0.41~0.60	Good
5	0.61~0.80	Very good
6	0.81~1.00	Excellent

8.Trial Results and Analysis

The confirmed patient specimens from each clinical institution have traceable disease onset dates and all enrolled cases were with RT-PCR Test results to ensure that the collected specimens tested are compatible with a true positive/negative status of the subject.

8.1 Composition and number of trial specimens

This study enrolled a total of 223 clinical cases, including 108 RT-PCR positive cases and 115 RT-PCR negative cases. A total of 223 human anterior nasal swab spec imens were tested in this trial.

In addition, the enrolled cases cover suspected cases, and multiple respiratory infections, as well as patients with different severity of disease (such as mild, common, severe, and critical COVID-19 patients), as well as patients with different disease processes (such as early, middle, middle-late stage patients).

The enrolled population covers children, adults, and the elderly, and cover males and females evenly.

8.2 Statistical analysis of test results

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.

Summarize the Antigen Test and RT-PCR Test results (see Table 3.), and evaluate the positive consistency rate, negative consistency rate, and overall consistency rate of Antigen Test and RT-PCR Test.

Table 3. Statistics of Antigen Test and RT-PCR Test Results
(human anterior nasal swab specimens)

		RT-PCR Test		Total
		Positive (+)	Negative (-)	
Antigen Test	Positive (+)	104	1	105
	Negative (-)	4	114	118
Total		108	115	223

The sensitivity, specificity, overall consistency rate, and Kappa value are calculated as follows:

Statistics	Ratio	Percentage (95% confidence interval)
Positive consistency rate (sensitivity)	104/108	96.30% (90.79%～98.98%)
Negative consistency rate (specificity)	114/115	99.13% (95.25%～99.98%)
Overall consistency rate (accuracy)	218/223	97.76% (94.85%～99.27%)
Kappa value	0.9551, excellent agreement	

The above statistical results show that results between Antigen Test and RT-PCR Test (human anterior nasal swab specimens) are highly consistent. 4 specimens that were positive for the RT-PCR Test were negative for the Antigen Test. The disagreement may because that viral load was below the lower detection limit of the Antigen Test and resulted in a false negative. In addition, 1 specimen that were negative for the RT-PCR Test were positive for the Antigen Test, and the disagreement may be caused by individual differences or medication.

9.Discussion and Conclusions

9.1 Trial implementation centers

This Antigen Tests were conducted by individuals themselves in clinic institutions and several non-clinic institutions. The RT-PCR Tests were conducted by investigator in professional laboratory.

9.2 Amounts of specimens in the trial

223 human anterior nasal swab specimens were tested in this trial, 108 RT-PCR positive and 115 negatives for RT-PCR Test. The enrollment cases cover suspected cases, and cases with other respiratory infections. The enrollment cases cover different severities of disease (i.e. mild, moderate, severe, and critical), different disease stages (i.e. early, middle, middle-late stages), and also cover different ages (children, adults, and elders).

9.3 Analysis of test results

Statistical analysis of the results of the Antigen Test of human anterior nasal swab specimens and the results of RT-PCR Test, positive consistency rate

(sensitivity), negative consistency rate (specificity): ,overall consistency rate (accuracy),Kappa value were:96.30%, 99.13%, and 97.76%; 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.

10. Appendices

See the appendix "Clinical Trial Specimens Information and Test Results Record Sheet" for the original information and test results of the trial specimens.

Clinical Trial Specimens Information and Test Results Record Sheet(anterior nasal swab)												
NO.	Age/Y	Sex	Spec date	Onset date	Disease stage/days	confirmed/excluded result	Clinical diagnosis information	Antigen Test	RT-PCR Test results			
									FAM	VIC	Cy5	+/-
S001	13	male	2020/10/10	2020/10/7	3	confirmed	COVID-19 (moderate)	+	21.04	21.61	25.27	+
S002	56	female	2020/10/13	2020/10/11	2	confirmed	COVID-19 (moderate)	+	21.12	21.81	25.15	+
S003	38	male	2020/10/13	NA	NA	NA	supermarket staff	-	ND	ND	25.96	-
S004	40	female	2020/10/14	2020/10/11	3	confirmed	COVID-19 (mild)	+	21.02	21.91	25.27	+
S005	70	female	2020/10/14	2020/10/11	3	confirmed	COVID-19 (critical)	+	21.20	22.07	24.84	+
S006	22	male	2020/10/14	NA	NA	NA	student in school	-	ND	ND	25.09	-
S007	57	male	2020/10/14	NA	NA	excluded	fever	-	ND	ND	25.05	-
S008	70	female	2020/10/15	2020/10/11	4	confirmed	COVID-19	+	21.17	21.47	25.79	+
S009	9	male	2020/10/16	NA	NA	excluded	sore throat, cough	-	ND	ND	25.04	-
S010	11	male	2020/10/16	NA	NA	excluded	fever; bacteria infection	-	40.91	ND	26.91	-
S011	38	male	2020/10/16	NA	NA	excluded	fungal lung infection; hemoptysis	-	ND	ND	24.96	-
S012	39	male	2020/10/16	NA	NA	excluded	influenza	-	41.03	ND	27.02	-
S013	58	female	2020/10/16	NA	NA	excluded	fever; lung inflammation; influenza	-	ND	ND	25.00	-
S014	90	female	2020/10/16	NA	NA	excluded	fever; upper respiratory infection	-	ND	ND	26.06	-
S015	9	male	2020/10/16	NA	NA	excluded	fever	+	ND	41.29	27.99	-
S016	17	female	2020/10/23	NA	NA	NA	student in school	-	41.37	ND	26.87	-
S017	88	male	2020/10/23	NA	NA	excluded	fever; lung inflammation	-	ND	ND	27.10	-
S018	47	female	2020/10/24	NA	NA	excluded	lung inflammation	-	ND	ND	25.22	-
S019	55	male	2020/10/24	NA	NA	excluded	fever	-	41.29	ND	24.84	-
S020	7	male	2020/10/25	NA	NA	excluded	fever	-	ND	ND	27.99	-
S021	26	male	2020/10/25	NA	NA	excluded	upper respiratory infection	-	ND	41.08	25.00	-
S022	30	female	2020/10/25	NA	NA	excluded	cough	-	ND	ND	26.98	-
S023	34	male	2020/10/25	NA	NA	excluded	fever	-	40.90	ND	26.11	-
S024	38	male	2020/10/25	NA	NA	excluded	fever	-	ND	ND	25.89	-
S025	49	female	2020/10/25	NA	NA	NA	supermarket staff	-	ND	ND	25.04	-

Clinical Trial Specimens Information and Test Results Record Sheet(anterior nasal swab)												
NO.	Age/Y	Sex	Spec date	Onset date	Disease stage/days	confirmed/excluded result	Clinical diagnosis information	Antigen Test	RT-PCR Test results			
									FAM	VIC	Cy5	+/-
S026	43	female	2020/10/26	2021/1/11	15	confirmed	COVID-19 (moderate)	-	21.99	22.87	26.00	+
S027	53	female	2020/10/26	2021/1/11	15	confirmed	COVID-19 (moderate)	+	23.60	23.59	24.82	+
S028	26	female	2020/10/26	NA	NA	excluded	cough	-	41.90	ND	26.18	-
S029	46	male	2020/10/26	NA	NA	excluded	cough; fever	-	ND	40.92	24.87	-
S030	69	male	2020/10/26	NA	NA	excluded	fever	-	ND	ND	25.96	-
S031	11	female	2020/10/27	NA	NA	excluded	fever	-	ND	ND	27.89	-
S032	12	female	2020/10/27	NA	NA	NA	student in school	-	ND	ND	26.95	-
S033	13	male	2020/10/27	NA	NA	NA	student in school	-	ND	ND	24.89	-
S034	19	female	2020/10/27	NA	NA	NA	student in school	-	ND	ND	24.82	-
S035	27	male	2020/10/27	NA	NA	excluded	fever	-	ND	ND	27.13	-
S036	31	female	2020/10/27	NA	NA	excluded	fever	-	ND	ND	24.86	-
S037	31	male	2020/10/27	NA	NA	excluded	gastrointestinal bleeding; inflammation	-	ND	ND	26.03	-
S038	33	male	2020/10/27	NA	NA	NA	supermarket staff	-	ND	ND	27.94	-
S039	33	female	2020/10/27	NA	NA	excluded	fever, sore throat	-	ND	ND	24.85	-
S040	37	female	2020/10/27	NA	NA	excluded	fever; stomach ache	-	ND	ND	25.11	-
S041	46	male	2020/10/27	NA	NA	excluded	fever; bacterial infection; influenza	-	ND	40.89	27.94	-
S042	47	female	2020/10/27	NA	NA	NA	supermarket staff	-	ND	ND	28.13	-
S043	50	female	2020/10/27	NA	NA	excluded	difficulty breathing	-	ND	ND	25.94	-
S044	58	male	2020/10/27	NA	NA	excluded	fever	-	ND	ND	27.06	-
S045	66	male	2020/10/27	NA	NA	excluded	extranodal NK/T-cell lymphoma	-	ND	ND	26.91	-
S046	44	male	2020/10/27	NA	NA	NA	supermarket staff	-	ND	ND	25.01	-
S047	70	male	2020/10/27	NA	NA	excluded	fever; lung inflammation	-	ND	ND	26.95	-
S048	72	male	2020/10/27	NA	NA	excluded	fever; lung inflammation	-	ND	ND	26.94	-
S049	90	male	2020/10/27	NA	NA	excluded	fever, headache	-	41.92	ND	26.25	-
S050	92	male	2020/10/27	NA	NA	excluded	fever	-	ND	ND	28.12	-

Clinical Trial Specimens Information and Test Results Record Sheet(anterior nasal swab)												
NO.	**Age/Y**	**Sex**	**Spec date**	**Onset date**	**Disease stage/days**	**confirmed/excluded result**	**Clinical diagnosis information**	**Antigen Test**	**RT-PCR Test results**			
									FAM	**VIC**	**Cy5**	**+/-**
S051	10	male	2020/10/28	NA	NA	NA	student in school	-	ND	ND	27.12	-
S052	22	female	2020/10/28	NA	NA	excluded	cough	-	ND	40.82	25.21	-
S053	23	male	2020/10/28	NA	NA	NA	supermarket staff	-	ND	ND	24.88	-
S054	25	female	2020/10/28	NA	NA	excluded	cough	-	ND	ND	28.02	-
S055	26	female	2020/10/28	NA	NA	excluded	fever	-	ND	ND	25.91	-
S056	29	female	2020/10/28	NA	NA	excluded	COVID-19 discharged cases	-	ND	ND	26.09	-
S057	29	male	2020/10/28	NA	NA	excluded	COVID-19 discharged cases	-	ND	40.83	27.98	-
S058	31	female	2020/10/28	NA	NA	excluded	fever	-	ND	ND	26.93	-
S059	34	female	2020/10/28	NA	NA	excluded	COVID-19 discharged cases	-	ND	40.75	28.12	-
S060	35	male	2020/10/28	NA	NA	excluded	COVID-19 discharged cases	-	ND	ND	25.93	-
S061	36	female	2020/10/28	NA	NA	excluded	fever	-	41.10	ND	25.95	-
S062	37	female	2020/10/28	NA	NA	excluded	fever	-	ND	ND	24.92	-
S063	63	female	2020/10/28	NA	NA	excluded	fever	-	ND	ND	25.16	-
S064	66	female	2020/10/28	NA	NA	excluded	fever	-	ND	40.78	25.06	-
S065	52	male	2020/10/29	2021/1/11	18	confirmed	COVID-19 (moderate)	-	23.60	24.08	25.74	+
S066	64	male	2020/11/5	2020/11/4	1	confirmed	COVID-19	+	24.79	24.53	25.82	+
S067	57	female	2020/11/6	2020/11/4	2	confirmed	COVID-19 (moderate)	+	25.01	24.90	26.97	+
S068	73	male	2020/11/11	2020/11/8	3	confirmed	COVID-19	+	25.92	26.02	26.72	+
S069	82	male	2020/11/16	2020/11/15	1	confirmed	COVID-19	+	23.83	24.05	27.14	+
S070	73	male	2020/11/16	2020/11/11	5	confirmed	fever	+	24.68	25.16	26.74	+
S071	87	male	2020/11/16	2020/11/11	5	confirmed	fever	+	25.08	25.67	27.11	+
S072	47	female	2020/11/16	NA	NA	excluded	sore throat, inflammation	-	ND	ND	24.80	-
S073	49	male	2020/11/16	NA	NA	excluded	sore throat, inflammation	-	ND	ND	26.99	-
S074	70	male	2020/11/16	NA	NA	excluded	sore throat, inflammation	-	ND	ND	28.13	-

Clinical Trial Specimens Information and Test Results Record Sheet(anterior nasal swab)												
NO.	Age/Y	Sex	Spec date	Onset date	Disease stage/days	confirmed/excluded result	Clinical diagnosis information	Antigen Test	RT-PCR Test results			
									FAM	VIC	Cy5	+/-
S075	73	male	2020/11/18	2020/11/16	2	confirmed	COVID-19 (moderate)	+	29.03	28.31	27.16	+
S076	39	male	2020/11/18	NA	NA	excluded	cough; lung inflammation	-	ND	ND	26.87	-
S077	58	male	2020/11/18	NA	NA	excluded	fever; inflammation	-	ND	ND	26.95	-
S078	71	male	2020/11/19	2020/11/17	2	confirmed	COVID-19 (critical)	+	25.99	26.46	26.83	+
S079	65	male	2020/11/19	2020/11/14	5	confirmed	Family members of patients	+	22.14	22.23	27.14	+
S080	25	male	2020/11/20	NA	NA	excluded	fever	-	41.91	ND	24.84	-
S081	29	male	2020/11/20	NA	NA	NA	supermarket staff	-	ND	ND	27.03	-
S082	35	male	2020/11/20	NA	NA	excluded	fever	-	ND	ND	25.88	-
S083	43	female	2020/11/20	NA	NA	excluded	fever	-	ND	ND	26.09	-
S084	79	male	2020/11/20	NA	NA	excluded	fever	-	ND	ND	24.88	-
S085	7	female	2020/11/21	NA	NA	excluded	fever, cough	-	ND	ND	25.08	-
S086	56	male	2020/11/21	NA	NA	excluded	fever, cough	-	ND	ND	24.96	-
S087	61	male	2020/11/21	NA	NA	excluded	fever; bacterial infection	-	ND	41.37	24.84	-
S088	68	female	2020/11/22	NA	NA	excluded	fever	-	ND	ND	26.09	-
S089	80	female	2020/11/22	NA	NA	excluded	bacterial pneumonia	-	ND	ND	24.97	-
S090	15	male	2020/11/23	NA	NA	NA	student in school	-	40.99	ND	25.12	-
S091	9	female	2020/11/27	2020/11/26	1	confirmed	COVID-19 (moderate)	-	22.35	22.55	26.98	+
S092	11	female	2020/11/28	2020/11/27	1	confirmed	COVID-19 (moderate)	+	22.62	22.58	27.47	+
S093	12	female	2020/11/28	2020/11/27	1	confirmed	COVID-19 (moderate)	+	22.93	23.91	26.60	+
S094	21	male	2020/11/28	2020/11/27	1	confirmed	COVID-19 (critical)	+	22.33	22.03	27.08	+
S095	56	male	2020/11/28	2020/11/27	1	confirmed	COVID-19 (moderate)	+	22.84	23.64	27.17	+
S096	66	male	2020/11/30	2020/11/27	3	confirmed	COVID-19 (mild)	+	22.89	23.44	26.93	+
S097	79	female	2020/11/30	2020/11/27	3	confirmed	COVID-19 (moderate)	+	22.74	23.59	26.95	+
S098	89	female	2020/11/30	2020/11/22	8	confirmed	COVID-19 (mild)	+	22.67	22.96	27.19	+
S099	90	male	2020/11/30	2020/11/22	8	confirmed	COVID-19 (mild)	+	22.92	22.19	27.02	+
S100	71	female	2020/12/1	2020/11/27	4	confirmed	COVID-19	+	22.96	22.11	26.89	+
S101	39	male	2020/12/7	2020/12/3	4	confirmed	fever	+	23.62	24.24	27.21	+

Clinical Trial Specimens Information and Test Results Record Sheet(anterior nasal swab)												
NO.	Age/Y	Sex	Spec date	Onset date	Disease stage/days	confirmed/excluded result	Clinical diagnosis information	Antigen Test	RT-PCR Test results			
									FAM	VIC	Cy5	+/-
S102	56	male	2020/12/7	2020/12/3	4	confirmed	fever	+	25.76	26.59	26.80	+
S103	73	female	2020/12/7	2020/12/3	4	confirmed	fever	+	25.34	25.92	26.63	+
S104	7	male	2020/12/11	2020/12/9	2	confirmed	COVID-19	+	22.74	23.05	26.75	+
S105	48	male	2020/12/11	2020/12/9	2	confirmed	COVID-19 (moderate)	+	25.04	25.62	26.99	+
S106	82	female	2020/12/11	2020/12/9	2	confirmed	COVID-19 (critical)	+	24.77	25.11	26.79	+
S107	58	female	2020/12/12	2020/12/10	2	confirmed	COVID-19 (mild)	+	24.13	24.8	27.11	+
S108	16	female	2020/12/12	2020/12/9	3	confirmed	COVID-19 (severe)	+	29.11	28.26	27.36	+
S109	19	female	2020/12/12	2020/12/9	3	confirmed	COVID-19 (moderate)	+	24.51	24.97	26.94	+
S110	44	male	2020/12/12	2020/12/9	3	confirmed	COVID-19 (moderate)	+	25.19	25.61	27.12	+
S111	45	male	2020/12/12	2020/12/9	3	confirmed	COVID-19 (moderate)	+	24.59	24.86	27.28	+
S112	47	female	2020/12/12	2020/12/9	3	confirmed	COVID-19 (moderate)	+	22.33	22.84	27.00	+
S113	48	male	2020/12/12	2020/12/9	3	confirmed	COVID-19 (moderate)	+	23.77	23.66	26.82	+
S114	51	male	2020/12/12	2020/12/9	3	confirmed	COVID-19 (moderate)	+	28.02	27.97	26.82	+
S115	50	male	2020/12/13	2021/1/29	15	confirmed	COVID-19 (mild)	-	25.11	25.55	27.01	+
S116	63	male	2020/12/14	NA	NA	excluded	fever; upper respiratory infection; cough; pains	-	ND	ND	28.05	-
S117	27	male	2020/12/15	NA	NA	excluded	fever; influenza	-	ND	40.82	26.05	-
S118	57	male	2020/12/15	NA	NA	excluded	fever	-	ND	ND	26.04	-
S119	13	female	2020/12/16	2020/12/11	5	confirmed	fever	+	23.62	23.68	26.92	+
S120	14	male	2020/12/16	2020/12/11	5	confirmed	fever	+	24.23	24.26	27.36	+
S121	61	male	2020/12/16	2020/12/11	5	confirmed	fever	+	23.21	24.06	26.86	+
S122	69	male	2020/12/16	2020/12/11	5	confirmed	fever	+	23.76	24.32	26.67	+
S123	10	male	2020/12/16	NA	NA	NA	student in school	-	ND	ND	28.13	-
S124	23	female	2020/12/16	NA	NA	excluded	fever	-	ND	ND	26.26	-
S125	24	male	2020/12/16	NA	NA	excluded	fever	-	ND	ND	26.03	-
S126	30	male	2020/12/16	NA	NA	excluded	fever, cough	-	ND	ND	25.00	-
S127	34	female	2020/12/16	NA	NA	excluded	fever	-	ND	ND	27.91	-
S128	38	female	2020/12/16	NA	NA	excluded	fever	-	ND	ND	25.10	-

Clinical Trial Specimens Information and Test Results Record Sheet(anterior nasal swab)												
NO.	Age/Y	Sex	Spec date	Onset date	Disease stage/days	confirmed/excluded result	Clinical diagnosis information	Antigen Test	RT-PCR Test results			
									FAM	VIC	Cy5	+/-
S129	42	male	2020/12/16	NA	NA	NA	supermarket staff	-	ND	ND	25.00	-
S130	71	female	2020/12/16	NA	NA	excluded	fever	-	ND	ND	27.11	-
S131	39	female	2020/12/17	2020/12/8	9	confirmed	COVID-19 (severe)	+	28.06	27.50	26.85	+
S132	16	male	2020/12/26	NA	NA	NA	student in school	-	ND	ND	28.13	-
S133	22	female	2020/12/26	NA	NA	excluded	fever	-	ND	ND	28.03	-
S134	23	male	2020/12/26	NA	NA	excluded	fever; backache	-	ND	ND	27.11	-
S135	41	male	2020/12/26	NA	NA	excluded	fever	-	ND	ND	24.87	-
S136	54	female	2020/12/26	NA	NA	excluded	fever	-	ND	ND	26.10	-
S137	65	male	2020/12/26	NA	NA	excluded	fever	-	ND	42.15	25.09	-
S138	67	male	2020/12/26	NA	NA	excluded	fever; lung inflammation	-	ND	ND	26.12	-
S139	86	male	2020/12/26	NA	NA	excluded	fever, headache	-	ND	ND	26.93	-
S140	22	female	2020/12/27	NA	NA	excluded	fever	-	41.08	ND	27.09	-
S141	12	male	2020/12/27	NA	NA	NA	student in school	-	ND	ND	26.87	-
S142	31	male	2020/12/27	NA	NA	excluded	fever	-	ND	41.11	26.03	-
S143	35	female	2020/12/27	NA	NA	excluded	fever	-	ND	ND	25.89	-
S144	38	female	2020/12/27	NA	NA	NA	supermarket staff	-	ND	ND	28.13	-
S145	43	female	2020/12/27	NA	NA	excluded	cough	-	ND	41.16	25.13	-
S146	48	male	2020/12/27	NA	NA	excluded	fever	-	ND	ND	24.90	-
S147	58	female	2020/12/27	NA	NA	excluded	COVID-19 discharged cases	-	ND	ND	24.97	-
S148	58	female	2020/12/27	NA	NA	excluded	fever	-	ND	ND	25.12	-
S149	66	female	2020/12/27	NA	NA	excluded	cough	-	ND	ND	26.88	-
S150	67	male	2020/12/27	NA	NA	NA	customer of supermarket	-	ND	ND	27.88	-
S151	69	male	2020/12/27	NA	NA	excluded	cirrhosis of the liver	-	ND	ND	25.88	-
S152	82	female	2020/12/27	NA	NA	excluded	fever	-	ND	ND	26.09	-
S153	57	female	2021/1/3	2020/12/26	8	confirmed	COVID-19 (moderate)	+	25.85	26.27	26.07	+
S154	15	female	2021/1/5	2020/12/30	6	confirmed	close contact of confirmed cases	+	23.85	24.44	25.96	+

Clinical Trial Specimens Information and Test Results Record Sheet(anterior nasal swab)												
NO.	Age/Y	Sex	Spec date	Onset date	Disease stage/days	confirmed/excluded result	Clinical diagnosis information	Antigen Test	RT-PCR Test results			
									FAM	VIC	Cy5	+/-
S155	17	female	2021/1/5	2020/12/30	6	confirmed	close contact of confirmed cases	+	24.20	24.45	25.74	+
S156	21	male	2021/1/5	2020/12/30	6	confirmed	Anshan infectious disease hospital confirmed; referral to isolation ward	+	23.95	24.36	26.04	+
S157	22	female	2021/1/5	2020/12/30	6	confirmed	close contact of confirmed cases	+	24.11	23.68	26.10	+
S158	32	male	2021/1/5	2020/12/30	6	confirmed	fever	+	23.96	24.83	26.16	+
S159	33	male	2021/1/5	2020/12/30	6	confirmed	fever	+	23.80	24.00	26.05	+
S160	34	male	2021/1/5	2020/12/27	9	confirmed	COVID-19 (critical)	+	20.84	20.03	24.58	+
S161	35	female	2021/1/5	2020/12/27	9	confirmed	COVID-19 (critical)	+	21.18	22.05	25.35	+
S162	69	male	2021/1/5	2020/12/26	10	confirmed	COVID-19 (moderate)	+	24.21	24.73	26.08	+
S163	25	female	2021/1/8	2020/12/31	8	confirmed	Respiratory infection	+	26.94	27.23	26.72	+
S164	26	male	2021/1/8	2020/12/31	8	confirmed	Respiratory infection	+	25.03	25.26	27.11	+
S165	71	male	2021/1/12	2021/1/9	3	confirmed	COVID-19 (mild)	+	21.19	21.21	25.29	+
S166	70	female	2021/1/14	2021/1/9	5	confirmed	fever	+	21.19	21.38	25.08	+
S167	25	male	2021/1/15	2021/1/9	6	confirmed	fever	+	20.94	20.49	26.05	+
S168	10	male	2021/1/18	2021/1/16	2	confirmed	COVID-19 CT confirmed pneumonia	+	20.14	20.9	25.18	+
S169	36	male	2021/1/18	2021/1/16	2	confirmed	COVID-19 (moderate)	+	20.12	20.86	24.95	+
S170	68	female	2021/1/18	2021/1/16	2	confirmed	COVID-19 (severe)	+	20.12	20.69	25.14	+
S171	70	female	2021/1/18	2021/1/16	2	confirmed	COVID-19 (moderate)	+	19.93	20.69	25.10	+
S172	83	female	2021/1/18	2021/1/16	2	confirmed	COVID-19 CT confirmed pneumonia	+	19.81	20.84	25.03	+
S173	40	female	2021/1/18	2021/1/9	9	confirmed	COVID-19 CT confirmed pneumonia	+	21.11	20.76	26.08	+
S174	41	male	2021/1/18	2021/1/9	9	confirmed	COVID-19 (moderate)	+	20.97	20.51	25.71	+
S175	65	male	2021/1/19	2021/1/15	4	confirmed	COVID-19	+	21.07	21.08	25.88	+
S176	69	male	2021/1/20	2021/1/18	2	confirmed	COVID-19 (moderate)	+	20.92	21.20	25.68	+

Clinical Trial Specimens Information and Test Results Record Sheet(anterior nasal swab)												
NO.	Age/Y	Sex	Spec date	Onset date	Disease stage/days	confirmed/excluded result	Clinical diagnosis information	Antigen Test	RT-PCR Test results			
									FAM	VIC	Cy5	+/-
S177	18	male	2021/1/21	2021/1/11	10	confirmed	Respiratory infection, heart failure	+	21.15	21.26	25.78	+
S178	78	female	2021/1/21	2021/1/11	10	confirmed	COVID-19 (moderate)	+	20.81	20.87	25.98	+
S179	14	female	2021/1/23	2021/1/20	3	confirmed	COVID-19 (moderate)	+	21.90	21.84	26.02	+
S180	68	male	2021/1/23	2021/1/20	3	confirmed	fever, lung inflammation	+	22.01	21.82	26.29	+
S181	17	female	2021/1/24	2021/1/21	3	confirmed	COVID-19 CT confirmed pneumonia	+	21.95	22.26	25.89	+
S182	51	male	2021/1/24	2021/1/20	4	confirmed	Chaoyang CDC confirmed; referral to isolation ward	+	21.86	22.2	25.99	+
S183	60	male	2021/1/24	2021/1/20	4	confirmed	Family members of patients	+	21.85	22.93	26.04	+
S184	37	female	2021/1/24	2021/1/15	9	confirmed	COVID-19 (moderate)	+	22.19	22.98	26.16	+
S185	38	female	2021/1/24	2021/1/15	9	confirmed	COVID-19 (severe)	+	22.07	22.74	25.78	+
S186	65	female	2021/1/25	2021/1/22	3	confirmed	COVID-19 (moderate)	+	21.94	22.29	26.03	+
S187	67	male	2021/1/25	2021/1/15	10	confirmed	COVID-19 (moderate)	+	21.95	22.79	26.42	+
S188	71	male	2021/1/25	2021/1/15	10	confirmed	COVID-19 (moderate)	+	22.06	21.94	25.81	+
S189	72	male	2021/1/25	2021/1/15	10	confirmed	COVID-19 (moderate)	+	22.01	22.57	26.18	+
S190	44	female	2021/1/26	2021/1/22	4	confirmed	fever	+	22.09	22.88	25.54	+
S191	73	female	2021/1/26	2021/1/22	4	confirmed	fever	+	22.00	22.06	25.69	+
S192	60	female	2021/1/27	2021/1/24	3	confirmed	fever, inflammation	+	22.00	22.17	25.85	+
S193	52	male	2021/1/27	2021/1/15	12	confirmed	COVID-19 (moderate)	+	21.87	22.42	26.27	+
S194	54	female	2021/1/27	2021/1/15	12	confirmed	COVID-19 (moderate)	+	22.03	22.68	25.80	+
S195	8	male	2021/1/27	NA	NA	excluded	sore throat, cough	-	ND	ND	25.91	-
S196	14	female	2021/1/27	NA	NA	excluded	upper respiratory infection	-	ND	ND	27.89	-
S197	23	male	2021/1/27	NA	NA	excluded	pancytopenia; inflammation	-	41.07	ND	26.91	-
S198	53	male	2021/1/27	NA	NA	excluded	sore throat, inflammation	-	41.23	ND	26.90	-
S199	56	male	2021/1/27	NA	NA	excluded	sore throat, inflammation	-	42.38	ND	26.25	-

Clinical Trial Specimens Information and Test Results Record Sheet(anterior nasal swab)												
NO.	Age/Y	Sex	Spec date	Onset date	Disease stage/days	confirmed/excluded result	Clinical diagnosis information	Antigen Test	RT-PCR Test results			
									FAM	VIC	Cy5	+/-
S200	40	male	2021/1/27	NA	NA	NA	supermarket staff	-	ND	ND	26.12	-
S201	68	male	2021/1/27	NA	NA	excluded	inflammatory fever	-	ND	ND	27.12	-
S202	71	male	2021/1/27	NA	NA	NA	customer of supermarket	-	ND	ND	24.91	-
S203	91	female	2021/1/27	NA	NA	NA	customer of supermarket	-	ND	ND	27.05	-
S204	20	female	2021/1/28	2021/1/27	1	confirmed	COVID-19 (severe)	+	20.02	20.92	25.08	+
S205	53	male	2021/1/28	2021/1/27	1	confirmed	COVID-19 (moderate)	+	19.98	20.14	25.09	+
S206	33	male	2021/1/28	2021/1/19	9	confirmed	COVID-19 CT confirmed pneumonia	+	22.02	22.14	26.04	+
S207	23	male	2021/1/28	NA	NA	excluded	bacterial infection; fever	-	ND	ND	26.09	-
S208	60	male	2021/1/29	2021/1/26	3	confirmed	COVID-19 (mild)	+	20.15	20.96	24.54	+
S209	73	male	2021/1/29	2021/1/26	3	confirmed	COVID-19 (moderate)	+	20.11	21.13	24.94	+
S210	36	male	2021/1/29	2021/1/24	5	confirmed	fever	+	22.91	22.11	26.00	+
S211	7	male	2021/1/30	2021/1/29	1	confirmed	COVID-19 (critical)	+	23.10	23.71	25.14	+
S212	47	male	2021/1/30	2021/1/29	1	confirmed	COVID-19 (moderate)	+	23.07	23.31	24.92	+
S213	55	female	2021/1/30	2021/1/29	1	confirmed	COVID-19 (moderate)	+	23.13	23.76	24.94	+
S214	56	female	2021/1/30	2021/1/29	1	confirmed	COVID-19	+	22.82	23.11	25.05	+
S215	70	male	2021/1/30	2021/1/29	1	confirmed	COVID-19 (moderate)	+	22.89	23.34	25.00	+
S216	77	female	2021/1/30	2021/1/20	10	confirmed	COVID-19 (moderate)	+	23.15	23.39	25.89	+
S217	50	female	2021/1/31	2021/1/29	2	confirmed	COVID-19 (moderate)	+	22.99	23.43	24.66	+
S218	53	male	2021/1/31	2021/1/29	2	confirmed	COVID-19 (moderate)	+	25.17	25.10	27.07	+
S219	55	male	2021/1/31	2021/1/29	2	confirmed	COVID-19 (moderate)	+	22.88	23.71	25.28	+
S220	60	female	2021/1/31	2021/1/29	2	confirmed	COVID-19 (moderate)	+	23.00	24.47	25.11	+
S221	61	female	2021/1/31	2021/1/29	2	confirmed	fever	+	22.90	23.24	25.33	+
S222	20	female	2021/2/2	2021/1/24	9	confirmed	upper respiratory infection	+	22.78	23.74	24.95	+
S223	56	male	2021/2/3	2021/1/26	8	confirmed	COVID-19 (moderate)	+	23.82	23.99	26.28	+