

LYHER[®] Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) (Nasal)

LYHER[®] Novel Coronavirus (COVID-19) Antigen Test Kit(Colloidal Gold)

Clinical Evaluation Report

Product Name: Novel Coronavirus (COVID-19) Antigen Test Kit(Colloidal Gold)

Start Date: October,2020

Finish Date: Jan,2021

Sponsor: Hangzhou Laihe Biotech Co.,Ltd.

Head of Statistics: Yu Hong

Applicant for Registration: Hangzhou Laihe Biotech Co.,Ltd.

Contact person for registration: YanXu

Clinical Trial Protocol Version No.: V1.0

Report Date: Feb. 2021

Contents

Summary.....	1
Abbreviation.....	2
1. Introduction.....	3
2. Objective.....	3
3. Design of the trial.....	3
3.1 Overall design and scheme description of the trial.....	3
3.2 Questionnaire compilation.....	3
3.3 Trial design and study method selection.....	4
3.4 The determination of the comparative method.....	4
3.5 Clinical evaluation method.....	5
3.6 Questionnaire.....	5
4. Results.....	5
4.1 Participants' Information.....	5
5. Discussion and Conclusions.....	8

Summary

According to the *Guidelines for Clinical Trials of In vitro diagnostic reagents(No.16 of 2014)*, We entrusted 3 medical institutions in Liaoning, Heilongjiang and Hebei to perform the clinical evaluation of Novel Coronavirus (COVID-19) Antigen Test Kit(Colloidal Gold)(hereinafter referred to as “Lyher Kit”) developed by Hangzhou Laihe Biotech Co.,Ltd.

The clinical trial was compared with PCR test results and clinical diagnosis results to investigate the consistency of the products of Hangzhou Laihe Biotech Co.,Ltd with the clinical diagnosis results.

A total of 411 patients' Nasal swab were collected in this clinical trial. Lyher Kit were test 152 positive out of 160 PCR positive, 250 negative out of 251 PCR negative. Compared with the results of PCR and clinical diagnosis, the clinical sensitivity of Lyher Kit was 95.00%, the clinical specificity of Lyher Kit was 99.60% , the total coincidence rate was 97.81%, Kappa=0.972. There was no statistically significant difference between the test results of Lyher Kit and the clinical diagnosis results, the results of Lyher Kit were highly consistent with the results of clinical diagnosis and PCR test.

Conclusion: Novel Coronavirus (COVID-19) Antigen Test Kit(Colloidal Gold) produced by Hangzhou Laihe Biotech Co., Ltd showed no statistically significant difference between Lyher Kit test results tested by patients and the clinical diagnosis results, which were highly consistent. That showed Lyher Kit was suitability for no professional use.

Abbreviation

I. Suspected case

Conduct a comprehensive analysis combining the following epidemiological history and clinical manifestations:

1) Epidemiological history

① Travel or residence history in the area where there are confirmed cases within 14 days prior to onset of the disease;

② Have contact with novel Coronavirus infected person (with a positive NAT(nucleic acid test) of SARS-CoV-2) within 14 days before onset of illness

③ Patients with fever or respiratory symptoms who had come into contact with patients from the area where there are confirmed cases, or from communities with case reports, within 14 days before onset of illness;

④ Cluster incidence (2 or more cases of fever and/or respiratory symptoms within 2 weeks in small areas such as homes, offices, school classes, etc.).

2) Clinical manifestation

① Fever and/or respiratory symptoms;

② Have the COVID-19 imaging characteristics;

③ In the early stage of the disease, the total number of white blood cells was normal or decreased, and the lymphocyte count was normal or decreased.

The patient who has any one of the epidemiological history and be conformed to any one of the clinical manifestations. Or who has no clear epidemiological history, but be conformed to have any 2 of the clinical manifestations.

II. Confirmed cases (positive cases)

Suspected cases with one of the following etiological or serological evidence:

1) A positive NAT of SARS-CoV-2;

2) Viral gene sequencing is highly homologous with the novel coronavirus known;

3) Specific IgM and IgG antibodies to SARS-CoV-2 were positive in serum; specific IgG antibody to SARS-CoV-2 changed from negative to positive; or the amount of IgG antibodies increased by 4 times or more in the recovery stage than in the symptom onset stage.

1. Introduction

The incubation period of novel coronavirus infection is 1-14 days, with an average of about 5 days. Some of those infected may have no symptoms at all but still be contagious; Most of the patients will rapidly deteriorate into severe pneumonia, respiratory distress, asphyxia, etc. A small proportion of patients infected with the novel coronavirus may die. In addition, novel coronavirus has been reported to attack the nervous system and the male reproductive system. Therefore, novel coronavirus infection early screening is of great significance for controlling the epidemic and the transition from mild to severe.

Novel Coronavirus antigen can be detected approximately 0 to 3 days after infection (with or without symptoms), which is earlier and more direct than antibody detection. Compared to nucleic acid detection is faster and more convenient.

2. Objective

To evaluate the device suitability for non professional use, Nasal specimens were tested by lay persons and obtained results were compared with the clinical diagnosis results and PCR, to evaluate the sensitivity, specificity and other indicators of the product, and to verify the accuracy of the product in clinical determination, so as to determine whether it meets the requirements of safety and effectiveness.

3. Design of the trial

3.1 Overall design and scheme description of the trial

At least 2 nasal swabs samples shall be collected for each subject after enrollment, one collected by specialist for PCR detection and one collected by patient themselves or their guardian for Lyher test. Samples for PCR test are Blinded before testing, and unblinded after all test are finished.

After the specialist have collected the nasal sample. 411 patients from three sites (137 consumers per site) were chosen. Each testing site had a study administrator to observe or monitor the studies without providing assistance to the participants. Each participant would obtain one test of Lyher kit, which contained a Test device, a Swab, Prepackaged extraction buffer, and a package insert.

After the test, the patients would fill out a questionnaire to evaluate labeling effectiveness.

3.2 Questionnaire compilation

To evaluate the device, a questionnaire was drafted. It mainly concentrated on personal information, user test procedures. It focuses on four parts:

- (1) Personal information
- (2) Product information
- (3) Test procedure

(4) Testing results by the patients:

According to the characteristics of IVDs, the possible results includes: ① Correct results; ② False negative; ③ False positive. ④Unexpected results. The percentage of ① was calculated and compared with results of the clinical diagnosis results and PCR. Other relevant information is also included in the questionnaire.

3.3 Trial design and study method selection

(1) Sample size and sample size determination basis

To ensure that the results are statistically significant, sufficient positive samples should be covered in this evaluation, such as no less than 100 positive samples of nasal swabs.

(2) Sample selection criteria, inclusion criteria, exclusion criteria

◆ Selection basis

This product is intended used for qualitatively testing novel coronavirus antigens in human nasal specimens.

Clinical sensitivity study samples can be selected from the patients with Covid-19 symptoms within seven days of the onset of symptoms. specimens collected by nasal swab that meet the inclusion criteria.

Clinical specificity study samples can be selected from the asymptomatic people without specific information of Exposure risk.

◆ Inclusion criteria

1) Sensitivity study

A. Have been to the high risk area or have close contact with the confirmed person within 30 days, and

B. Have more than one symptom, such as fever, cough, sore throat, unexplained muscle pain, nausea, nasal congestion, headache, diarrhea, palpitations, chest tightness, White lung, and

C. The total number of white blood cells was normal or decreased, and the lymphocyte count was normal or decreased.

2) Specificity study

A. Asymptomatic people, and

B. Without any risk information of exposure to COVID-19.

◆ Exclusion criteria

3) The collection time of samples for Sensitivity study is more than 7 days from the symptom onset

1) The patient for Sensitivity study is in Serious life-threatening symptoms

2) The collection time of samples is not clear, or clinical information is missing;

3) Insufficient sample size due to error during test operation;

4) Samples such as those contaminated during specimen preservation or transport were found before the test operation;

5) Improperly preserved specimens should be excluded.

◆ Criteria for ruling out the abnormal samples from the selected samples

- 1) Samples that do not meet the requirements of the specimen collection method;
- 2) Samples that have been dried or contaminated;
- 3) The diagnostic information of the sample is found to be missing or untraceable before statistics.
- 4) Samples with incomplete information

3.4 The determination of the comparative method

In order to fully evaluate the clinical performance of this product, NAT and clinical diagnosis results were used as the control.

(1) Product information used in clinical trials:

	The reagent to be evaluated	Comparator
Product Name	Novel Coronavirus (COVID-19) Antigen Test Kit(Colloidal Gold)	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) of Sansure BioTech Inc
Specifications	1 Pcs/Box	
Validity& Storage	Stored in 2~30°C dry place away from light, valid for 18 months. Shall be used as soon as possible within 30 minutes after opening the bag.	
Batch No.	2008034	
Manufacturer	Hangzhou Laihe Biotech Co.,Ltd.	
Samples and Preservation solution	Sample Buffer in the kit	0.9% NaCl

3.5 Clinical evaluation method

The reagents and clinical results are mainly represented in a four-grid table (as shown in Table 1). The table is self-explanatory, that is, it has table titles, table notes and number of cases

SPSS software was used to conduct kappa consistency analysis on the test results of the assessment reagent in clinical results. Kappa value (k) was determined as $k > 0.75$, showing good consistency. $0.40 \leq k \leq 0.75$, good consistency; $K < 0.40$, poor consistency.

3.6 Questionnaire

The questionnaires were gathered and reviewed to evaluate the labeling effectiveness.

4. Results

4.1 Participants' Information

Age distribution of the participants

Age group	Number	% of total
≤20	38	9.25%
21~40	92	22.38%
41~60	182	44.28%
61~80	89	21.65%
Above 80	10	2.43%

Sex of the participants

Gender	Number	% of total
Male	221	53.77%
Female	190	46.23%

Educational background of the participants

Educational group	Number	% of total
Middle School	69	16.79%
High School	191	46.47%
Bachelor	106	25.79%
Others	45	10.95%

Occupational background of the participants

Profession	Number	% of total
Jobless	55	13.38%
Sales	128	31.14%
Clerk	166	40.39%
Others	62	15.09%

Whether used the COVID-19 testing products before?

	Number	% of total
Yes	0	0
No	411	100

The participants' ages range from 9 to 86, and most of them were from 21 to 80. They have also showed different culture background. None of the participants had used a COVID-19 kit before. 68.13% reported that they were high-school graduates or lower and 53.77% participants were male.

4.2 Product Information

All of the participants answered the test kit wasn't expired.

4.3 Test Procedures

4.3.1 Storage of Test Device

All of them knew the test couldn't be placed in the direct sunlight, nor could be frozen. And all of them knew the test device couldn't be reused.

4.3.2 Test Procedure

All of them read the results at 15 minutes. None of them read results after 15 minutes. They all understood how to interpret the results.

The clarity of the package insert, feasibility of the test device was as follows:

Clarity of the Package Insert

Remarks	Very clear	Clear	Ambiguous	Very Ambiguous
Instruction for Use	289	122	0	0
Interpretation of Results	313	98	0	0

Clarity of Test Simplicity

Remarks	Very easy	Easy	Difficult	Very Difficult
Number	276	135	0	0

None of the participants responded that the test was not easy to do.

4.4 Test Results and Accuracy

Site A: Hebei CDC

Site B: Heilongjiang CDC

Site C: Liaoning CDC.

Table 1 Lyher Results from Patients and PCR

Test Results of Lyher Kit	Clinical diagnosis(PCR results)		
	Positive(+)	Negative(-)	Total
Positive(+)	152	1	153
Negative(-)	8	250	258
Total	160	251	411

Clinical Sensitivity: $152 / (152+8) \times 100\% = 95.00\%$

95% CI: $p \pm 1.96 \times [p(1-p) / n]^{1/2} = [90.39\% - 97.82\%]$

Clinical Specificity: $250 / (250+1) \times 100\% = 99.60\%$

95% CI: $p \pm 1.96 \times [p(1-p) / n]^{1/2} = [97.80\% - 99.99\%]$

Total coincidence rate: $(152+250) / (152+8+1+250) \times 100\% = 97.81\%$

95% CI: $p \pm 1.96 \times [p(1-p) / n]^{1/2} = [95.88\% - 98.99\%]$

Consistency analysis by the value of Kappa:

Kappa=0.972(K > 0.75), It can be considered that the Lyher Kit and clinical diagnosis results are consistent.

Table 2 Sensitivity by CT values

CT value	N	Positive	% Positive	CI 95%	
CT≤25	93	93	100.00%	96.11%	100.00%
25<CT≤30	51	51	100.00%	93.02%	100.00%
33≥CT>30	16	8	50.00%	24.65%	75.35%
Total	160	152	95.00%	90.39%	97.82%

5. Discussion and Conclusions

A total of 411 patients' Nasal swab were collected in this clinical trial. Lyher Kit were tested 152 positive out of 160 PCR positive, 250 negative out of 251 PCR negative. Compared with the results of PCR and clinical diagnosis, the clinical sensitivity of Lyher Kit was 95.00%, the clinical specificity of Lyher Kit was 99.60%, the total coincidence rate was 97.81%, Kappa=0.972. There was no statistically significant difference between the test results of Lyher Kit and the clinical diagnosis results, the results of Lyher Kit were highly consistent with the results of clinical diagnosis and PCR test.

Conclusion: Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) produced by Hangzhou Laihe Biotech Co., Ltd showed no statistically significant difference between Lyher Kit test results tested by patients and the clinical diagnosis results, which were highly consistent. That showed Lyher Kit was suitability for no professional use.

LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) (Nasal)

Appendix: test results

No.	Sex	Age	Date of sample collected and test	Days from symptom onset	Lyher result	CT value of PCR	PCR Result	Site
Nasal-001	Male	50	2021.01.24	NA	-	NA	-	C
Nasal-002	Male	44	2021.01.24	0	+	27.4685	+	B
Nasal-003	Male	61	2021.01.24	6	+	22.0954	+	C
Nasal-004	Female	51	2021.01.24	1	+	21.0238	+	C
Nasal-005	Female	49	2021.01.24	1	+	24.1336	+	A
Nasal-006	Male	39	2021.01.24	NA	-	NA	-	A
Nasal-007	Female	24	2021.01.23	NA	-	NA	-	B
Nasal-008	Female	57	2021.01.24	4	+	20.8892	+	C
Nasal-009	Male	59	2021.01.24	NA	-	NA	-	C
Nasal-010	Male	81	2021.01.24	NA	-	NA	-	C
Nasal-011	Male	46	2021.01.21	NA	-	NA	-	A
Nasal-012	Male	39	2021.01.28	4	+	21.9027	+	C
Nasal-013	Female	76	2021.01.25	NA	-	NA	-	C
Nasal-014	Male	17	2021.01.24	6	+	19.5308	+	C
Nasal-015	Female	45	2021.01.24	NA	-	NA	-	A
Nasal-016	Female	46	2021.01.24	6	+	18.6062	+	B
Nasal-017	Female	46	2021.01.24	3	+	24.7154	+	A
Nasal-018	Male	24	2021.01.24	5	+	25.3558	+	B
Nasal-019	Female	29	2021.01.24	4	+	25.3621	+	B
Nasal-020	Male	15	2021.01.24	2	+	18.6812	+	B
Nasal-021	Male	74	2021.01.25	NA	-	NA	-	C
Nasal-022	Male	69	2021.01.25	NA	-	NA	-	C
Nasal-023	Male	31	2021.01.24	2	+	23.2692	+	A
Nasal-024	Male	26	2021.01.24	1	+	25.0513	+	C
Nasal-025	Male	80	2021.01.24	NA	-	NA	-	A
Nasal-026	Male	78	2021.01.24	NA	-	NA	-	C
Nasal-027	Male	49	2021.01.23	NA	-	NA	-	B
Nasal-028	Male	16	2021.01.24	NA	-	NA	-	A
Nasal-029	Female	53	2021.01.24	NA	-	NA	-	A
Nasal-030	Male	15	2021.01.28	NA	-	NA	-	C
Nasal-031	Female	58	2021.01.24	NA	-	NA	-	B
Nasal-032	Male	53	2021.01.28	3	+	27.4751	+	A
Nasal-033	Female	33	2021.01.24	5	+	19.0564	+	B
Nasal-034	Male	49	2021.01.28	NA	-	NA	-	B
Nasal-035	Male	49	2021.01.28	NA	-	NA	-	B
Nasal-036	Female	56	2021.01.28	NA	-	NA	-	C
Nasal-037	Male	41	2021.01.21	NA	-	NA	-	A

LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) (Nasal)

Nasal-038	Male	56	2021.01.24	5	+	28.4376	+	B
Nasal-039	Female	34	2021.01.21	0	-	32.4308	+	A
Nasal-040	Male	45	2021.01.28	NA	-	NA	-	C
Nasal-041	Male	72	2021.01.24	NA	-	NA	-	B
Nasal-042	Male	53	2021.01.24	NA	-	NA	-	A
Nasal-043	Male	46	2021.01.24	0	+	18.6937	+	A
Nasal-044	Female	43	2021.01.24	NA	-	NA	-	C
Nasal-045	Female	48	2021.01.24	NA	-	NA	-	C
Nasal-046	Male	65	2021.01.24	NA	-	NA	-	B
Nasal-047	Female	62	2021.01.28	0	+	21.9783	+	A
Nasal-048	Female	64	2021.01.24	NA	-	NA	-	A
Nasal-049	Female	62	2021.01.24	NA	-	NA	-	B
Nasal-050	Female	79	2021.01.24	NA	-	NA	-	B
Nasal-051	Female	68	2021.01.24	NA	-	NA	-	B
Nasal-052	Male	65	2021.01.24	NA	-	NA	-	C
Nasal-053	Female	16	2021.01.24	0	+	29.756	+	C
Nasal-054	Female	52	2021.01.28	NA	-	NA	-	A
Nasal-055	Male	28	2021.01.21	NA	-	NA	-	A
Nasal-056	Female	68	2021.01.24	NA	-	NA	-	B
Nasal-057	Female	70	2021.01.28	NA	-	NA	-	A
Nasal-058	Male	15	2021.01.24	NA	-	NA	-	A
Nasal-059	Male	56	2021.01.24	7	+	20.3624	+	C
Nasal-060	Male	30	2021.01.24	NA	-	NA	-	A
Nasal-061	Male	55	2021.01.23	4	+	24.2383	+	B
Nasal-062	Female	9	2021.01.24	NA	-	NA	-	A
Nasal-063	Male	70	2021.01.25	NA	-	NA	-	C
Nasal-064	Female	50	2021.01.28	NA	-	NA	-	C
Nasal-065	Male	54	2021.01.21	NA	-	NA	-	A
Nasal-066	Female	67	2021.01.24	NA	-	NA	-	C
Nasal-067	Female	41	2021.01.21	6	+	27.639	+	A
Nasal-068	Female	38	2021.01.24	NA	-	NA	-	B
Nasal-069	Female	37	2021.01.24	4	+	19.9647	+	B
Nasal-070	Male	63	2021.01.23	NA	-	NA	-	B
Nasal-071	Female	50	2021.01.24	6	+	20.2669	+	C
Nasal-072	Female	18	2021.01.24	4	+	26.1709	+	C
Nasal-073	Male	54	2021.01.21	6	+	28.0365	+	A
Nasal-074	Female	53	2021.01.28	NA	-	NA	-	C
Nasal-075	Male	55	2021.01.28	NA	-	NA	-	B
Nasal-076	Male	76	2021.01.28	NA	-	NA	-	B
Nasal-077	Female	53	2021.01.23	7	+	19.5017	+	B
Nasal-078	Male	81	2021.01.24	NA	-	NA	-	A
Nasal-079	Female	67	2021.01.28	0	+	27.1837	+	B

LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) (Nasal)

Nasal-080	Female	15	2021.01.24	NA	-	NA	-	A
Nasal-081	Female	83	2021.01.24	0	+	27.4048	+	A
Nasal-082	Female	43	2021.01.21	NA	-	NA	-	A
Nasal-083	Male	63	2021.01.24	NA	-	NA	-	B
Nasal-084	Female	46	2021.01.28	NA	-	NA	-	A
Nasal-085	Male	53	2021.01.24	2	+	26.8556	+	B
Nasal-086	Female	40	2021.01.24	NA	-	NA	-	C
Nasal-087	Female	35	2021.01.23	NA	-	NA	-	B
Nasal-088	Female	51	2021.01.23	NA	-	NA	-	B
Nasal-089	Female	47	2021.01.28	NA	-	NA	-	B
Nasal-090	Male	64	2021.01.28	NA	-	NA	-	B
Nasal-091	Male	72	2021.01.25	NA	-	NA	-	C
Nasal-092	Female	49	2021.01.24	NA	-	NA	-	B
Nasal-093	Male	80	2021.01.25	NA	-	NA	-	C
Nasal-094	Female	57	2021.01.24	NA	-	NA	-	B
Nasal-095	Female	38	2021.01.24	NA	-	NA	-	B
Nasal-096	Male	12	2021.01.24	3	+	19.6307	+	C
Nasal-097	Male	23	2021.01.24	NA	-	NA	-	C
Nasal-098	Male	39	2021.01.24	NA	-	NA	-	A
Nasal-099	Female	38	2021.01.23	5	+	23.7307	+	B
Nasal-100	Female	34	2021.01.28	5	+	25.4776	+	B
Nasal-101	Female	53	2021.01.24	NA	-	NA	-	C
Nasal-102	Male	26	2021.01.24	6	+	19.4161	+	A
Nasal-103	Male	57	2021.01.24	NA	-	NA	-	A
Nasal-104	Male	13	2021.01.28	NA	-	NA	-	A
Nasal-105	Male	43	2021.01.23	NA	-	NA	-	B
Nasal-106	Male	72	2021.01.24	NA	-	NA	-	C
Nasal-107	Male	43	2021.01.21	3	+	25.3664	+	A
Nasal-108	Female	18	2021.01.25	6	+	22.997	+	C
Nasal-109	Female	57	2021.01.28	NA	-	NA	-	B
Nasal-110	Female	24	2021.01.21	NA	-	NA	-	A
Nasal-111	Male	69	2021.01.21	NA	-	NA	-	A
Nasal-112	Female	52	2021.01.28	NA	-	NA	-	A
Nasal-113	Female	51	2021.01.24	NA	-	NA	-	A
Nasal-114	Female	72	2021.01.25	6	+	19.9357	+	C
Nasal-115	Male	47	2021.01.23	NA	-	NA	-	B
Nasal-116	Male	25	2021.01.24	0	+	25.3252	+	C
Nasal-117	Female	9	2021.01.21	3	+	19.5584	+	A
Nasal-118	Male	57	2021.01.24	NA	-	NA	-	A
Nasal-119	Male	32	2021.01.21	6	+	27.368	+	A
Nasal-120	Female	58	2021.01.24	NA	-	NA	-	C
Nasal-121	Female	81	2021.01.28	2	+	28.1606	+	A

LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) (Nasal)

Nasal-122	Male	54	2021. 01. 24	NA	-	NA	-	A
Nasal-123	Male	58	2021. 01. 24	NA	-	NA	-	A
Nasal-124	Male	50	2021. 01. 24	NA	-	NA	-	C
Nasal-125	Male	51	2021. 01. 28	NA	-	NA	-	C
Nasal-126	Female	78	2021. 01. 21	NA	-	NA	-	A
Nasal-127	Female	42	2021. 01. 21	NA	-	NA	-	A
Nasal-128	Male	46	2021. 01. 25	NA	-	NA	-	C
Nasal-129	Female	47	2021. 01. 28	NA	-	NA	-	A
Nasal-130	Male	51	2021. 01. 24	2	+	22. 2623	+	B
Nasal-131	Female	55	2021. 01. 24	NA	-	NA	-	C
Nasal-132	Female	48	2021. 01. 25	1	+	27. 0692	+	C
Nasal-133	Female	26	2021. 01. 24	1	+	21. 051	+	A
Nasal-134	Female	53	2021. 01. 24	NA	-	NA	-	B
Nasal-135	Female	47	2021. 01. 23	NA	-	NA	-	B
Nasal-136	Female	65	2021. 01. 24	NA	-	NA	-	B
Nasal-137	Male	46	2021. 01. 24	2	+	24. 7247	+	A
Nasal-138	Female	58	2021. 01. 24	NA	-	NA	-	B
Nasal-139	Male	33	2021. 01. 24	NA	-	NA	-	C
Nasal-140	Male	56	2021. 01. 24	0	+	20. 6137	+	A
Nasal-141	Male	35	2021. 01. 21	2	+	26. 5908	+	A
Nasal-142	Female	69	2021. 01. 24	NA	-	NA	-	B
Nasal-143	Male	49	2021. 01. 24	NA	-	NA	-	C
Nasal-144	Female	42	2021. 01. 23	NA	-	NA	-	B
Nasal-145	Male	46	2021. 01. 24	NA	-	NA	-	C
Nasal-146	Male	34	2021. 01. 24	NA	-	NA	-	A
Nasal-147	Female	24	2021. 01. 24	NA	-	NA	-	C
Nasal-148	Male	57	2021. 01. 28	NA	-	NA	-	C
Nasal-149	Female	56	2021. 01. 25	NA	-	NA	-	C
Nasal-150	Male	64	2021. 01. 25	NA	-	NA	-	C
Nasal-151	Female	42	2021. 01. 28	NA	-	NA	-	C
Nasal-152	Female	36	2021. 01. 24	2	+	21. 5564	+	B
Nasal-153	Female	31	2021. 01. 24	7	+	27. 5403	+	A
Nasal-154	Female	47	2021. 01. 24	3	+	21. 7945	+	B
Nasal-155	Female	47	2021. 01. 24	1	+	19. 4857	+	C
Nasal-156	Female	70	2021. 01. 24	2	+	20. 4832	+	C
Nasal-157	Male	63	2021. 01. 24	NA	-	NA	-	A
Nasal-158	Female	68	2021. 01. 24	NA	-	NA	-	B
Nasal-159	Male	57	2021. 01. 25	7	+	24. 406	+	C
Nasal-160	Male	54	2021. 01. 28	1	+	24. 3075	+	A
Nasal-161	Male	11	2021. 01. 24	NA	-	NA	-	A
Nasal-162	Male	23	2021. 01. 28	NA	-	NA	-	A
Nasal-163	Male	20	2021. 01. 24	NA	-	NA	-	C

LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) (Nasal)

Nasal-164	Male	76	2021.01.24	NA	-	NA	-	A
Nasal-165	Male	69	2021.01.21	NA	-	NA	-	A
Nasal-166	Male	55	2021.01.23	NA	-	NA	-	B
Nasal-167	Male	59	2021.01.23	NA	-	NA	-	B
Nasal-168	Male	52	2021.01.24	NA	-	NA	-	C
Nasal-169	Male	43	2021.01.25	NA	+	NA	-	C
Nasal-170	Female	56	2021.01.24	5	+	30.5052	+	C
Nasal-171	Female	46	2021.01.21	NA	-	NA	-	A
Nasal-172	Male	56	2021.01.24	0	+	21.6222	+	A
Nasal-173	Male	50	2021.01.21	NA	-	NA	-	A
Nasal-174	Male	52	2021.01.24	NA	-	NA	-	B
Nasal-175	Male	26	2021.01.28	NA	-	NA	-	B
Nasal-176	Male	35	2021.01.24	NA	-	NA	-	B
Nasal-177	Female	45	2021.01.28	NA	-	NA	-	A
Nasal-178	Male	51	2021.01.23	NA	-	NA	-	B
Nasal-179	Female	42	2021.01.24	7	+	20.5102	+	C
Nasal-180	Female	55	2021.01.24	7	+	20.73	+	B
Nasal-181	Male	67	2021.01.24	NA	-	NA	-	C
Nasal-182	Female	71	2021.01.24	NA	-	NA	-	C
Nasal-183	Male	17	2021.01.24	6	+	31.4963	+	A
Nasal-184	Female	29	2021.01.24	NA	-	NA	-	C
Nasal-185	Male	56	2021.01.23	0	+	27.9183	+	B
Nasal-186	Female	60	2021.01.24	NA	-	NA	-	C
Nasal-187	Male	60	2021.01.24	4	+	25.0434	+	B
Nasal-188	Male	15	2021.01.24	NA	-	NA	-	C
Nasal-189	Male	59	2021.01.23	NA	-	NA	-	B
Nasal-190	Male	19	2021.01.28	NA	-	NA	-	C
Nasal-191	Male	65	2021.01.24	5	+	23.4669	+	B
Nasal-192	Male	25	2021.01.21	NA	-	NA	-	A
Nasal-193	Male	70	2021.01.24	NA	-	NA	-	B
Nasal-194	Female	65	2021.01.25	NA	-	NA	-	C
Nasal-195	Female	33	2021.01.24	NA	-	NA	-	A
Nasal-196	Male	49	2021.01.24	1	+	27.4625	+	C
Nasal-197	Female	48	2021.01.25	NA	-	NA	-	C
Nasal-198	Female	59	2021.01.25	6	+	21.0937	+	C
Nasal-199	Female	23	2021.01.24	4	+	27.7002	+	B
Nasal-200	Female	20	2021.01.24	NA	-	NA	-	A
Nasal-201	Female	21	2021.01.28	3	+	18.1507	+	C
Nasal-202	Female	59	2021.01.24	NA	-	NA	-	A
Nasal-203	Female	59	2021.01.24	NA	-	NA	-	C
Nasal-204	Female	10	2021.01.24	0	-	32.0855	+	A
Nasal-205	Female	36	2021.01.21	NA	-	NA	-	A

LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) (Nasal)

Nasal-206	Female	63	2021.01.25	NA	-	NA	-	C
Nasal-207	Male	35	2021.01.24	4	+	30.5986	+	C
Nasal-208	Female	47	2021.01.28	5	-	31.1922	+	C
Nasal-209	Male	47	2021.01.21	NA	-	NA	-	A
Nasal-210	Male	55	2021.01.28	NA	-	NA	-	B
Nasal-211	Female	34	2021.01.28	1	+	20.9289	+	C
Nasal-212	Male	65	2021.01.24	NA	-	NA	-	B
Nasal-213	Male	63	2021.01.24	NA	-	NA	-	B
Nasal-214	Male	27	2021.01.24	4	+	29.5979	+	B
Nasal-215	Female	56	2021.01.25	NA	-	NA	-	C
Nasal-216	Male	69	2021.01.24	NA	-	NA	-	B
Nasal-217	Male	69	2021.01.23	5	+	22.5292	+	B
Nasal-218	Female	74	2021.01.25	NA	-	NA	-	C
Nasal-219	Male	16	2021.01.23	NA	-	NA	-	B
Nasal-220	Female	26	2021.01.24	3	+	23.572	+	C
Nasal-221	Male	26	2021.01.24	NA	-	NA	-	C
Nasal-222	Female	63	2021.01.21	NA	-	NA	-	A
Nasal-223	Female	57	2021.01.23	3	+	19.0047	+	B
Nasal-224	Male	36	2021.01.24	NA	-	NA	-	C
Nasal-225	Female	39	2021.01.24	4	+	21.5688	+	A
Nasal-226	Male	53	2021.01.24	NA	-	NA	-	B
Nasal-227	Female	58	2021.01.24	NA	-	NA	-	C
Nasal-228	Female	68	2021.01.24	NA	-	NA	-	B
Nasal-229	Male	13	2021.01.28	NA	-	NA	-	B
Nasal-230	Male	17	2021.01.25	NA	-	NA	-	C
Nasal-231	Male	33	2021.01.21	1	+	27.4725	+	A
Nasal-232	Female	12	2021.01.24	3	+	23.6257	+	A
Nasal-233	Female	63	2021.01.25	NA	-	NA	-	C
Nasal-234	Male	52	2021.01.25	3	+	21.8401	+	C
Nasal-235	Male	46	2021.01.25	2	+	21.8294	+	C
Nasal-236	Female	74	2021.01.24	NA	-	NA	-	A
Nasal-237	Female	61	2021.01.24	6	+	28.2262	+	C
Nasal-238	Male	48	2021.01.28	2	+	24.2764	+	A
Nasal-239	Male	20	2021.01.28	7	+	26.7801	+	C
Nasal-240	Male	54	2021.01.28	NA	-	NA	-	A
Nasal-241	Male	64	2021.01.25	NA	-	NA	-	C
Nasal-242	Female	22	2021.01.28	NA	-	NA	-	B
Nasal-243	Female	21	2021.01.24	NA	-	NA	-	A
Nasal-244	Female	45	2021.01.24	3	+	22.9609	+	B
Nasal-245	Male	77	2021.01.24	6	+	27.8613	+	A
Nasal-246	Female	55	2021.01.24	NA	-	NA	-	C
Nasal-247	Male	54	2021.01.24	2	+	29.6636	+	C

LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) (Nasal)

Nasal-248	Female	66	2021.01.24	NA	-	NA	-	A
Nasal-249	Female	68	2021.01.24	NA	-	NA	-	B
Nasal-250	Male	48	2021.01.21	NA	-	NA	-	A
Nasal-251	Male	16	2021.01.28	NA	-	NA	-	B
Nasal-252	Female	55	2021.01.24	0	+	26.5306	+	A
Nasal-253	Female	49	2021.01.25	6	+	27.5729	+	C
Nasal-254	Female	44	2021.01.24	6	+	19.6767	+	B
Nasal-255	Male	73	2021.01.24	NA	-	NA	-	C
Nasal-256	Male	68	2021.01.24	NA	-	NA	-	B
Nasal-257	Female	19	2021.01.24	NA	-	NA	-	C
Nasal-258	Female	83	2021.01.25	4	+	24.1636	+	C
Nasal-259	Female	51	2021.01.24	6	-	30.6568	+	C
Nasal-260	Female	62	2021.01.28	NA	-	NA	-	B
Nasal-261	Female	47	2021.01.24	3	+	30.226	+	A
Nasal-262	Female	27	2021.01.24	3	-	31.6534	+	B
Nasal-263	Female	41	2021.01.21	6	+	27.9405	+	A
Nasal-264	Male	43	2021.01.28	NA	-	NA	-	B
Nasal-265	Male	54	2021.01.24	NA	-	NA	-	A
Nasal-266	Male	23	2021.01.21	1	+	21.8319	+	A
Nasal-267	Male	34	2021.01.24	1	+	19.2275	+	B
Nasal-268	Female	72	2021.01.24	NA	-	NA	-	A
Nasal-269	Female	40	2021.01.24	6	+	25.2575	+	A
Nasal-270	Female	56	2021.01.24	NA	-	NA	-	A
Nasal-271	Male	86	2021.01.28	NA	-	NA	-	B
Nasal-272	Male	83	2021.01.24	5	+	24.0097	+	C
Nasal-273	Male	64	2021.01.24	NA	-	NA	-	C
Nasal-274	Female	11	2021.01.24	NA	-	NA	-	C
Nasal-275	Female	53	2021.01.23	NA	-	NA	-	B
Nasal-276	Female	29	2021.01.24	1	+	27.506	+	C
Nasal-277	Male	10	2021.01.24	NA	-	NA	-	A
Nasal-278	Male	68	2021.01.24	NA	-	NA	-	B
Nasal-279	Male	49	2021.01.24	5	+	24.5746	+	B
Nasal-280	Male	19	2021.01.24	7	+	19.4471	+	B
Nasal-281	Female	47	2021.01.25	2	+	26.3638	+	C
Nasal-282	Female	41	2021.01.25	NA	-	NA	-	C
Nasal-283	Female	21	2021.01.24	5	+	21.5131	+	B
Nasal-284	Male	33	2021.01.28	NA	-	NA	-	C
Nasal-285	Male	38	2021.01.24	2	+	25.623	+	A
Nasal-286	Male	60	2021.01.24	NA	-	NA	-	A
Nasal-287	Male	35	2021.01.21	5	+	24.9024	+	A
Nasal-288	Male	60	2021.01.24	4	-	30.8604	+	B
Nasal-289	Male	54	2021.01.25	NA	-	NA	-	C

LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) (Nasal)

Nasal-290	Male	30	2021.01.21	2	+	22.7754	+	A
Nasal-291	Male	45	2021.01.28	NA	-	NA	-	C
Nasal-292	Female	10	2021.01.28	7	+	27.5401	+	B
Nasal-293	Female	74	2021.01.24	NA	-	NA	-	B
Nasal-294	Male	64	2021.01.21	0	+	20.2817	+	A
Nasal-295	Female	77	2021.01.28	NA	-	NA	-	B
Nasal-296	Female	68	2021.01.24	NA	-	NA	-	B
Nasal-297	Female	30	2021.01.23	5	+	23.471	+	B
Nasal-298	Male	53	2021.01.24	1	+	22.2257	+	C
Nasal-299	Male	53	2021.01.23	NA	-	NA	-	B
Nasal-300	Male	23	2021.01.21	NA	-	NA	-	A
Nasal-301	Male	49	2021.01.24	2	+	24.2652	+	B
Nasal-302	Male	49	2021.01.28	NA	-	NA	-	A
Nasal-303	Male	17	2021.01.28	2	+	25.0975	+	B
Nasal-304	Male	25	2021.01.28	NA	-	NA	-	C
Nasal-305	Male	47	2021.01.24	NA	-	NA	-	A
Nasal-306	Male	60	2021.01.28	6	+	26.7577	+	B
Nasal-307	Female	39	2021.01.24	0	+	20.0692	+	A
Nasal-308	Male	62	2021.01.21	NA	-	NA	-	A
Nasal-309	Male	29	2021.01.24	NA	-	NA	-	C
Nasal-310	Male	41	2021.01.21	3	+	18.8736	+	A
Nasal-311	Male	71	2021.01.24	7	-	31.4349	+	A
Nasal-312	Male	46	2021.01.24	NA	-	NA	-	A
Nasal-313	Male	55	2021.01.24	6	+	24.8795	+	A
Nasal-314	Male	63	2021.01.24	NA	-	NA	-	B
Nasal-315	Female	53	2021.01.28	NA	-	NA	-	A
Nasal-316	Female	26	2021.01.24	NA	-	NA	-	A
Nasal-317	Male	50	2021.01.24	NA	-	NA	-	C
Nasal-318	Male	48	2021.01.24	NA	-	NA	-	C
Nasal-319	Male	33	2021.01.21	NA	-	NA	-	A
Nasal-320	Male	68	2021.01.24	NA	-	NA	-	B
Nasal-321	Female	56	2021.01.23	NA	-	NA	-	B
Nasal-322	Male	24	2021.01.21	0	+	20.3712	+	A
Nasal-323	Male	57	2021.01.23	NA	-	NA	-	B
Nasal-324	Female	57	2021.01.23	7	+	25.1092	+	B
Nasal-325	Female	81	2021.01.24	NA	-	NA	-	A
Nasal-326	Male	74	2021.01.28	NA	-	NA	-	A
Nasal-327	Female	34	2021.01.24	3	+	25.5422	+	B
Nasal-328	Female	59	2021.01.24	NA	-	NA	-	A
Nasal-329	Male	77	2021.01.24	6	+	22.6422	+	C
Nasal-330	Male	32	2021.01.28	NA	-	NA	-	C
Nasal-331	Male	39	2021.01.28	NA	-	NA	-	A

LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) (Nasal)

Nasal-332	Male	69	2021.01.24	NA	-	NA	-	B
Nasal-333	Female	54	2021.01.24	NA	-	NA	-	B
Nasal-334	Male	52	2021.01.24	5	+	23.3863	+	B
Nasal-335	Male	40	2021.01.28	NA	-	NA	-	C
Nasal-336	Male	29	2021.01.24	NA	-	NA	-	C
Nasal-337	Female	56	2021.01.25	2	+	21.4198	+	C
Nasal-338	Female	45	2021.01.25	NA	-	NA	-	C
Nasal-339	Female	39	2021.01.24	6	+	24.7336	+	B
Nasal-340	Male	83	2021.01.28	NA	-	NA	-	A
Nasal-341	Male	25	2021.01.24	1	+	21.2502	+	A
Nasal-342	Female	42	2021.01.24	7	+	30.1521	+	C
Nasal-343	Male	48	2021.01.28	1	+	21.3847	+	C
Nasal-344	Male	68	2021.01.24	NA	-	NA	-	B
Nasal-345	Female	19	2021.01.23	4	+	19.7352	+	B
Nasal-346	Female	50	2021.01.24	NA	-	NA	-	A
Nasal-347	Female	47	2021.01.24	1	+	20.1837	+	B
Nasal-348	Male	58	2021.01.28	NA	-	NA	-	A
Nasal-349	Male	86	2021.01.24	3	+	22.9506	+	C
Nasal-350	Male	31	2021.01.24	5	+	21.0605	+	A
Nasal-351	Male	45	2021.01.24	NA	-	NA	-	C
Nasal-352	Female	54	2021.01.25	NA	-	NA	-	C
Nasal-353	Female	68	2021.01.24	NA	-	NA	-	B
Nasal-354	Female	28	2021.01.28	7	+	21.3955	+	B
Nasal-355	Male	52	2021.01.28	NA	-	NA	-	C
Nasal-356	Female	40	2021.01.24	5	+	20.4587	+	C
Nasal-357	Female	28	2021.01.24	4	+	24.8814	+	B
Nasal-358	Female	41	2021.01.24	1	+	30.306	+	C
Nasal-359	Female	68	2021.01.24	NA	-	NA	-	B
Nasal-360	Male	55	2021.01.24	1	+	24.0282	+	A
Nasal-361	Female	18	2021.01.23	NA	-	NA	-	B
Nasal-362	Male	68	2021.01.24	NA	-	NA	-	B
Nasal-363	Male	12	2021.01.24	NA	-	NA	-	A
Nasal-364	Female	62	2021.01.24	NA	-	NA	-	B
Nasal-365	Female	67	2021.01.28	NA	-	NA	-	C
Nasal-366	Male	50	2021.01.24	5	-	31.7439	+	B
Nasal-367	Female	33	2021.01.24	NA	-	NA	-	B
Nasal-368	Male	80	2021.01.28	NA	-	NA	-	C
Nasal-369	Male	29	2021.01.24	NA	-	NA	-	C
Nasal-370	Male	10	2021.01.24	NA	-	NA	-	A
Nasal-371	Female	48	2021.01.24	0	+	20.9483	+	A
Nasal-372	Female	35	2021.01.28	NA	-	NA	-	C
Nasal-373	Male	25	2021.01.24	NA	-	NA	-	A

LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) (Nasal)

Nasal-374	Female	33	2021.01.23	1	+	24.2543	+	B
Nasal-375	Female	43	2021.01.24	NA	-	NA	-	A
Nasal-376	Female	36	2021.01.21	4	+	19.0601	+	A
Nasal-377	Female	32	2021.01.21	NA	-	NA	-	A
Nasal-378	Male	68	2021.01.24	NA	-	NA	-	B
Nasal-379	Male	72	2021.01.24	4	+	31.6461	+	A
Nasal-380	Male	80	2021.01.23	NA	-	NA	-	B
Nasal-381	Female	66	2021.01.24	NA	-	NA	-	B
Nasal-382	Male	39	2021.01.28	4	+	22.5501	+	B
Nasal-383	Female	60	2021.01.24	0	+	24.1182	+	A
Nasal-384	Female	47	2021.01.25	1	+	27.9431	+	C
Nasal-385	Female	39	2021.01.24	3	+	28.6531	+	C
Nasal-386	Female	52	2021.01.24	7	+	28.8807	+	C
Nasal-387	Male	56	2021.01.23	NA	-	NA	-	B
Nasal-388	Male	73	2021.01.21	NA	-	NA	-	A
Nasal-389	Female	49	2021.01.28	NA	-	NA	-	B
Nasal-390	Male	15	2021.01.24	0	+	18.732	+	A
Nasal-391	Male	52	2021.01.24	4	+	18.9577	+	A
Nasal-392	Male	52	2021.01.28	NA	-	NA	-	C
Nasal-393	Male	38	2021.01.24	0	+	27.6159	+	B
Nasal-394	Male	21	2021.01.28	NA	-	NA	-	A
Nasal-395	Male	79	2021.01.25	4	+	28.1282	+	C
Nasal-396	Female	56	2021.01.23	NA	-	NA	-	B
Nasal-397	Female	65	2021.01.24	NA	-	NA	-	B
Nasal-398	Female	49	2021.01.28	3	+	18.6102	+	B
Nasal-399	Male	55	2021.01.24	2	+	25.3079	+	B
Nasal-400	Male	54	2021.01.24	3	+	22.8082	+	A
Nasal-401	Male	59	2021.01.24	NA	-	NA	-	A
Nasal-402	Male	59	2021.01.24	6	+	30.9146	+	B
Nasal-403	Female	36	2021.01.24	5	+	23.3255	+	C
Nasal-404	Male	18	2021.01.24	1	+	22.1462	+	C
Nasal-405	Male	66	2021.01.24	NA	-	NA	-	B
Nasal-406	Female	58	2021.01.24	4	+	27.6494	+	C
Nasal-407	Female	48	2021.01.21	NA	-	NA	-	A
Nasal-408	Male	51	2021.01.28	NA	-	NA	-	A
Nasal-409	Female	48	2021.01.25	NA	-	NA	-	C
Nasal-410	Male	78	2021.01.25	6	+	27.8824	+	C
Nasal-411	Male	48	2021.01.23	NA	-	NA	-	B