

Clinical evaluation report

Product name: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal gold Immunoassay)

Wuhan UNscience Biotechnology Co., Ltd.

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SUMMARY

Product name: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal gold Immunoassay).

Main researcher: Wuhan UNscience Biotechnology Co., Ltd.

Research purpose: The purpose of this test is to conduct clinical validation trials with SARS-CoV-2 antigen rapid test kit (Colloidal gold Immunoassay) produced by Wuhan UNscience Biotechnology Co., Ltd. according to Clinical investigation of medical devices for human subjects-Good clinical practice (ISO 14155:2011), Guidelines on medical devices Evaluation of clinical data: A guide for manufacturers and Notified Body, to evaluate whether the clinical application performance of the test reagent and the reference reagent on the market are equivalent.

Test description: The sample types in this experimental study are oropharyngeal swabs, nasal swabs and nasopharyngeal swabs. The test uses clinical comparison and data analysis with the gold standard to analyze whether the results are equivalent. Then use the test reagent to determine the oropharyngeal swab, nasal swab and nasopharyngeal swab samples to evaluate whether the test results of the oropharyngeal swab, nasal swab and nasopharyngeal swab are consistent.

From May 2020, 424 specimens of cases have been selected, including 140 specimens of patients with clinically confirmed cases of novel coronavirus infection and 284 specimens of clinically excluded cases. None of the patients were included that did not meet the protocol, and no cases of laboratory operation deviation were found. 424 cases were detected and the results were statistically analyzed to calculate the sensitivity and specificity of the methods; then use the test reagent to determine 100 oropharyngeal swab, nasal swab and nasopharyngeal swab samples from the same source to evaluate whether the test results are consistent, and obtain the following research results and conclusion:

Statistical analysis of 424 clinical samples (140 positive cases and 284 negative cases) showed the sensitivity is 96.429% (95%CI: 91.862%, 98.830%) and specificity is 99.648% (95%CI: 98.054%, 99.991%). The comparison results of 424 clinical samples with nucleic acid test shows that the positive coincidence rate is 96.43% and

the negative coincidence rate is 99.65%.

In addition, select homologous oropharyngeal swabs, nasal swabs and nasopharyngeal swabs from 100 subjects to compare, it shows that the consistent detection rate between oropharyngeal swabs, nasal swabs and nasopharyngeal swabs is 100% (95%CI: -100%, 100%).

The results indicate a high degree of consistency between this product and clinical diagnosis results.

ABBREVIATION

SARS-CoV-2 The novel coronavirus

1 Basic content

1.1 Introduction

The novel coronavirus (SARS-CoV-2) is a new type of coronavirus, which was named by the World Health Organization. It causes viral pneumonia with fever, fatigue, dry cough and sore throat as the main manifestations. In more severe cases, it can lead to pneumonia, severe acute respiratory syndrome, kidney failure, and even death. However, there is no specific treatment for it currently. In view of the epidemic trend of the virus in the world now, the rapid distinction between the infected and healthy people become the focus of epidemic prevention work.

The testing products on the market mainly include three categories: fluorescence quantitative PCR method, chemical/magnetic particle luminescence method and colloidal gold immunochromatographic method. Among them, the fluorescent quantitative PCR method is mainly used to measure the viral nucleic acid, while the chemical/magnetic particle luminescence method and the colloidal gold immunochromatography method are mainly for the antibodies detection in the infected cases.

The SARS-CoV-2 antigen rapid test kit (colloidal gold immunochromatography) produced by UNscience is used for in vitro qualitative detection of SARS-CoV-2 antigen in human oropharyngeal swabs, nasal swabs and nasopharyngeal swabs.

This kit adopts the sandwich method and the technical principle of colloidal gold immunochromatography to qualitative determine the SARS-CoV-2 antigen. During the test, the sample is dropped into the sample well, and chromatography is performed under the capillary effect. The SARS-CoV-2 antigen in the sample combined with the colloidal gold-labeled SARS-CoV-2 monoclonal antibody I, and then spread to the test area. It is captured by another coated antibody (SARS-CoV-2 monoclonal antibody II), to form a complex and gather in the test area (T line). The quality control area is coated with the goat anti-mouse antibody, and the colloidal gold-labeled antibody is captured to form a complex and aggregate in the quality control area (C line). If the C line does not show color, it indicates that the result is invalid, and this sample needs to be tested again.

1.2 Research objective

The purpose of this experiment is to take clinical test to SARS-CoV-2 Antigen Rapid Test Kit (Colloidal gold Immunoassay) produced by Wuhan UNscience Biotechnology Co., Ltd. in accordance with Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011), Guidelines on medical devices Evaluation of clinical data: A guide for manufacturers and Notified Body, to evaluate whether the test reagent is equivalent to the clinical application performance of the listed reference reagent.

1.3 Experimental management

1.3.1 Quality control in clinical studies

1.3.1.1 Experimental control

The person in charge of the project is responsible for this clinical evaluation test, and the test process shall strictly comply with the clinical evaluation project schemes.

The personnel who participate in the observation and collection of clinical data should have professional knowledge and skills and be fixed accordingly.

The researchers have a full understanding of each parameters in the clinical trial schemes after pre-clinical evaluation trial training. The required objective parameters should be inspected in accordance with the time and method specified in the schemes.

The researchers from Wuhan UNscience should be in charge of the whole operation of trial projected and record the data.

The researchers should verify the data that significantly deviates from the acceptable range, and make necessary explanations for it.

The researchers in charge of the clinical project check the progress of clinical trials regularly and verify the data and records carefully.

Supervision: During the trial process, the researchers in charge of the clinical project monitors and visits the clinical evaluation trial site regularly to ensure that the trial personnel conduct the experiment in accordance with the regulations and trial

evaluation schemes, and also to make sure the trial process records are complete, true and traceable.

1.3.1.2 Quality control of clinical case diagnosis

The Confirmed cases and excluded cases are determined by the Treatment of Novel Coronavirus Pneumonia (Trial Edition 7), issued by National Health Commission China, on March 3rd, 2020.

1.3.1.3 Laboratory quality control

The quality control of the Tuberculosis diagnostic laboratory is carried out according to the requirement of laboratory quality control regulated in the Clinical Technical Operation (fascicule Tuberculosis) compiled by Chinese Medical Association.

The quality control of the laboratory for testing products for clinical research shall comply with the specific requirements of basic laboratory operation specifications and product specifications, including basic temperature and humidity control, calibration of measuring instruments and equipment, etc. If the quality control conditions that do not meet the requirements of the product specification appear during the test, the re-inspection shall be required, and the qualified quality control data can be used only after passing the test.

Before and during the study, the applicant provided positive and negative reference materials to review and verify the specimen testing personnel and laboratory conditions.

1.3.2 Biosafety

Laboratory operations and specimen handling are conducted in accordance with the operating specifications of grade II (and above) bio-safety laboratories. The conductor is under grade III bio-safety protection.

1.3.3 Clinical data management and statistical analysis

The double-blind method was adopted in this clinical study. The study specimens of the selected cases were indicated serial number by clinical examiner, and sent to laboratory for testing. The case information and test data during the study were kept

separately by clinicians and inspectors. At the end of the study, case information and test data were collected in the department of the main investigator to uncover the blindness, and the results were judged and analyzed.

The person in charge of the laboratory appoints special test personnel and review personnel to be responsible for testing and recording the test data of each case.

1.4 Experimental design

1.4.1 The overall design and plan of the experiment

The selected samples in this trial refer to the “the Treatment of Novel Coronavirus Pneumonia (Trial Edition 7), issued by National Health Commission China, on March 3rd, 2020”, using the gold standard and the assessment result comparison method to comprehensively evaluate the clinical diagnostic performance of the products to be registered.

1.4.2 Test design and test method selection

1.4.2.1 Determination of the gold standard

The gold standard of new coronavirus diagnosis:

Suspected cases determined through epidemiological investigation and clinical symptoms, with pathogenic or serological evidence are confirmed cases.

1. Real-time fluorescent RT-PCR detection of new coronavirus nucleic acid positive;
2. Viral gene sequencing, highly homologous to the known new coronavirus;
3. New coronavirus-specific IgM antibodies and IgG antibodies are positive in serum;
4. New coronavirus-specific IgG antibody in serum changes from negative to positive or is 4 times or higher than the acute period in recovery period.

The gold standard for diagnosis of excluded cases: suspected cases determined by epidemic virus investigation and clinical symptoms, two consecutive new coronavirus nucleic acid tests are negative (at least 24 hours interval), and the specificity of new coronavirus is still negative 7 days after the onset of disease, that is exclude cases.

1.4.2.2 Sample selection criteria and exclusion criteria

The selected samples all refer to the requirements of the diagnosis and treatment specifications for confirmed and excluded cases, and the hospital will issue diagnosis and exclusion opinions on the cases.

1.4.2.2.1 Sample type

Normally collected oropharyngeal swab, nasal swab and nasopharyngeal swab samples.

1.4.2.2.2 Sample selection criteria

① The samples are the remaining samples after the routine testing of the laboratory department, which comes from designated hospitals;

② All samples are collected from clinically positive (confirmed) and negative (excluded) cases;

③ Interfering samples mainly choose samples with *Staphylococcus aureus*, *Streptococcus pneumoniae*, Measles virus, Mumps virus, Adenovirus type 3, *Mycoplasma pneumoniae*, Parainfluenza virus type 2, Metapneumovirus, Coronavirus OC43, Coronavirus 229E, *Bacillus parapertussis*, Type B influenza virus Victoria line, Type B influenza virus Y line, Type A influenza virus H1N1, Type A influenza virus H3N2, Avian influenza virus H7N9, Avian influenza H5N1 virus, Epstein barr virus, Enterovirus CA16 and Rhinovirus; Samples of patients treated with drugs such as Histamine dihydrochloride, Zanamivir, Ribavirin, IFN- α , Oseltamivir, Paramivir, Lopinavir, Ritonavir, Arbidol, Levofloxacin, Azithromycin, Ceftriaxone, MeropeneM and Tobramycin, etc.

1.4.2.2.3 Sample exclusion criteria

① The sample volume is not enough to complete all the tests;

② Samples that have been contaminated, damaged or potentially contaminated or damaged;

③ Samples with incomplete patient information (such as sample type, department, preliminary diagnosis conclusion, etc.);

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- ④ Samples that have not been collected, stored or stored for too long as required;
 - ⑤ Samples with duplicate patient information (same patient).

1.4.2.2.4 Sample rejection criteria

- ① Samples whose test results cannot be obtained due to reagents or human factors;

1.4.3 Collection, storage and transportation of samples

SAMPLE REQUIREMENTS:

① Oropharyngeal swab: The head of the person is slightly tilted, with mouth wide open, exposing the pharyngeal tonsils on both sides. Use the swab to gently wipe the tonsils on both sides for at least 3 times, and then wipe the posterior pharyngeal wall up and down at least 3 times.

② Nasal swab: Prior to collecting the nasal swab, the patient should be instructed to blow their nose. Carefully insert the swab into the nostril with the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril), and rotate the swab against the nasal wall several times and then remove it from the nostril.

③ Nasopharyngeal swab: Carefully insert the swab into the nostril with the most secretion under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab several times then remove it from the nasopharynx (in case of reflex cough, stop for 1 minute).

SAMPLE PREPARATION:

Uncover the sealing membrane of the sample treatment solution. Put the swab into sampling tube, make sure the swab soaked in the solution. Rotate and squeeze the swab on the wall and bottom of the tube 10 times, squeeze the swab tip along the inner wall of the sample tube to keep as much solution in the tube as possible. Remove the swab and test. It is recommended to test immediately after sample collection and processing. If the test cannot be performed timely, the processed samples can be stored at 2-8°C for 48h.

All samples were heat-inactivated at 56°C for 30 minutes after collection.

1.4.4 Information about products used in clinical trials

Research reagents

Product Name: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal gold Immunoassay)

Size: 25T/kit

Manufacturer: Wuhan UNscience Co. Ltd.

Lot. No.: 20200509

Reference reagents

The COVID-19 RT-PCR test kits used by the reference hospitals on the samples test are mainly Novel Coronavirus 2019-nCoV nucleic acid detection kit (fluorescence PCR method) from BGI BIOTECHNOLOGY (WUHAN) CO., LTD. This product has registered in NMPA and got the approval No. 20203400060.

1.4.5 Methods of quality control for product testing

The minimum detection range of reference product of S1 should be negative, S3 should be positive, and S2 can be negative or positive.

1.4.6 Result judgment

Observe and record the results after 10 minutes.

Positive: Both the test line (T line) and the quality control line (C line) appear colors.

Negative: The test line (T line) appears no color and the quality control line (C line) appears color.

Invalid: The quality control line (C line) does not appear color, indicating that this test is invalid, it should be tested again.

1.4.7 Statistical analysis

Statistical analysis was performed using MEDCALC software. Percentage of diagnostic performance indicators such as sensitivity, specificity, positive consistency, negative consistency and overall consistency were reported and their 95% confidence intervals were calculated.

1.4.8 Modification of the scheme during the test

There was no modification of the scheme during the test.

1.5 Clinical trial results and analysis

1.5.1 Comparative test results

424 cases were included, including 140 cases of novel coronavirus infection with clinically confirmed patients and 284 cases of clinical excluded cases. No cases were included in accordance with the protocol and no cases of laboratory operation deviation were found. 424 cases were detected and the results were statistically analyzed to calculate the sensitivity and specificity of the methods.

Table 1 Clinical trial results

Patient No.	Age	Symptom onset	Clinical diagnosis	PCR	Ct value	SARS-CoV-2 Ag	Sample type
1	83	2	-	-	ND	-	Oropharyngeal swabs
2	25	1	-	-	ND	-	Oropharyngeal swabs
3	24	3	-	-	ND	-	Oropharyngeal swabs
4	65	2	-	-	ND	-	Oropharyngeal swabs
5	64	7	-	-	ND	-	Oropharyngeal swabs
6	63	2	-	-	ND	-	Oropharyngeal swabs
7	21	5	-	-	ND	-	Oropharyngeal swabs
8	80	6	-	-	ND	-	Oropharyngeal swabs
9	14	1	-	-	ND	-	Oropharyngeal swabs
10	40	6	-	-	ND	-	Oropharyngeal swabs
11	82	7	-	-	ND	-	Oropharyngeal swabs
12	80	4	-	-	ND	-	Oropharyngeal swabs
13	12	6	-	-	ND	-	Oropharyngeal swabs
14	5	7	-	-	ND	-	Oropharyngeal swabs
15	64	1	-	-	ND	-	Oropharyngeal swabs
16	17	4	-	-	ND	-	Oropharyngeal swabs
17	19	4	-	-	ND	-	Oropharyngeal swabs
18	89	2	-	-	ND	-	Oropharyngeal swabs
19	87	6	-	-	ND	-	Oropharyngeal swabs
20	66	3	-	-	ND	-	Oropharyngeal swabs
21	22	1	-	-	ND	-	Oropharyngeal swabs
22	71	5	-	-	ND	-	Oropharyngeal swabs
23	1	4	-	-	ND	-	Oropharyngeal swabs

24	16	4	-	-	ND	-	Oropharyngeal swabs
25	70	7	-	-	ND	-	Oropharyngeal swabs
26	88	3	-	-	ND	-	Oropharyngeal swabs
27	89	4	-	-	ND	-	Oropharyngeal swabs
28	37	6	-	-	ND	-	Oropharyngeal swabs
29	4	2	-	-	ND	-	Oropharyngeal swabs
30	62	6	-	-	ND	-	Oropharyngeal swabs
31	10	2	-	-	ND	-	Oropharyngeal swabs
32	12	7	-	-	ND	-	Oropharyngeal swabs
33	33	4	-	-	ND	-	Oropharyngeal swabs
34	22	7	-	-	ND	-	Oropharyngeal swabs
35	13	3	-	-	ND	-	Oropharyngeal swabs
36	45	3	-	-	ND	-	Oropharyngeal swabs
37	24	4	-	-	ND	-	Oropharyngeal swabs
38	11	5	-	-	ND	-	Oropharyngeal swabs
39	33	2	-	-	ND	-	Oropharyngeal swabs
40	30	3	-	-	ND	-	Oropharyngeal swabs
41	50	1	-	-	ND	-	Oropharyngeal swabs
42	15	4	-	-	ND	-	Oropharyngeal swabs
43	13	7	-	-	ND	-	Oropharyngeal swabs
44	90	6	-	-	ND	-	Oropharyngeal swabs
45	9	5	-	-	ND	-	Oropharyngeal swabs
46	57	6	-	-	ND	-	Oropharyngeal swabs
47	44	7	-	-	ND	-	Oropharyngeal swabs
48	30	2	-	-	ND	-	Oropharyngeal swabs
49	56	1	-	-	ND	-	Oropharyngeal swabs
50	34	6	-	-	ND	-	Oropharyngeal swabs
51	67	4	-	-	ND	-	Oropharyngeal swabs
52	38	3	-	-	ND	-	Oropharyngeal swabs
53	29	2	-	-	ND	-	Oropharyngeal swabs
54	28	3	-	-	ND	-	Oropharyngeal swabs
55	69	5	-	-	ND	-	Oropharyngeal swabs
56	46	5	-	-	ND	-	Oropharyngeal swabs
57	23	7	-	-	ND	-	Oropharyngeal swabs
58	1	1	-	-	ND	-	Oropharyngeal swabs
59	79	7	-	-	ND	-	Oropharyngeal swabs
60	49	6	-	-	ND	-	Oropharyngeal swabs
61	0	4	-	-	ND	-	Oropharyngeal swabs
62	30	7	-	-	ND	-	Oropharyngeal swabs
63	29	3	-	-	ND	-	Oropharyngeal swabs
64	83	1	-	-	ND	-	Oropharyngeal swabs
65	6	1	-	-	ND	-	Oropharyngeal swabs
66	44	6	-	-	ND	-	Oropharyngeal swabs

67	28	3	-	-	ND	-	Oropharyngeal swabs
68	36	2	-	-	ND	-	Oropharyngeal swabs
69	22	3	-	-	ND	-	Oropharyngeal swabs
70	31	2	-	-	ND	-	Oropharyngeal swabs
71	46	1	-	-	ND	-	Oropharyngeal swabs
72	45	1	-	-	ND	-	Oropharyngeal swabs
73	18	1	-	-	ND	-	Oropharyngeal swabs
74	36	1	-	-	ND	-	Oropharyngeal swabs
75	39	3	-	-	ND	-	Oropharyngeal swabs
76	48	3	-	-	ND	-	Oropharyngeal swabs
77	84	5	-	-	ND	-	Oropharyngeal swabs
78	29	1	-	-	ND	-	Oropharyngeal swabs
79	52	5	-	-	ND	-	Oropharyngeal swabs
80	7	3	-	-	ND	-	Oropharyngeal swabs
81	37	6	-	-	ND	-	Oropharyngeal swabs
82	58	1	-	-	ND	-	Oropharyngeal swabs
83	24	6	-	-	ND	-	Oropharyngeal swabs
84	30	3	-	-	ND	-	Oropharyngeal swabs
85	14	3	-	-	ND	-	Oropharyngeal swabs
86	51	6	-	-	ND	-	Oropharyngeal swabs
87	46	4	-	-	ND	-	Oropharyngeal swabs
88	31	3	-	-	ND	-	Oropharyngeal swabs
89	86	4	-	-	ND	-	Oropharyngeal swabs
90	12	7	-	-	ND	-	Oropharyngeal swabs
91	70	4	-	-	ND	-	Oropharyngeal swabs
92	82	5	-	-	ND	-	Oropharyngeal swabs
93	61	1	-	-	ND	-	Oropharyngeal swabs
94	50	4	-	-	ND	-	Oropharyngeal swabs
95	51	5	-	-	ND	-	Oropharyngeal swabs
96	35	1	-	-	ND	-	Oropharyngeal swabs
97	57	1	-	-	ND	-	Oropharyngeal swabs
98	62	7	-	-	ND	-	Oropharyngeal swabs
99	32	5	-	-	ND	-	Oropharyngeal swabs
100	36	7	-	-	ND	-	Oropharyngeal swabs
101	52	6	-	-	ND	-	Oropharyngeal swabs
102	60	3	-	-	ND	-	Oropharyngeal swabs
103	8	6	-	-	ND	-	Oropharyngeal swabs
104	41	6	-	-	ND	-	Oropharyngeal swabs
105	2	6	-	-	ND	-	Oropharyngeal swabs
106	39	7	-	-	ND	-	Oropharyngeal swabs
107	53	3	-	-	ND	-	Oropharyngeal swabs
108	26	7	-	-	ND	-	Oropharyngeal swabs
109	76	4	-	-	ND	-	Oropharyngeal swabs

110	62	1	-	-	ND	-	Oropharyngeal swabs
111	42	7	-	-	ND	-	Oropharyngeal swabs
112	47	7	-	-	ND	-	Oropharyngeal swabs
113	42	1	-	-	ND	-	Oropharyngeal swabs
114	12	3	-	-	ND	-	Oropharyngeal swabs
115	58	3	-	-	ND	-	Oropharyngeal swabs
116	87	3	-	-	ND	-	Oropharyngeal swabs
117	26	2	-	-	ND	-	Oropharyngeal swabs
118	28	1	-	-	ND	-	Oropharyngeal swabs
119	23	1	-	-	ND	-	Oropharyngeal swabs
120	7	5	-	-	ND	-	Oropharyngeal swabs
121	57	6	-	-	ND	-	Oropharyngeal swabs
122	49	5	-	-	ND	-	Oropharyngeal swabs
123	48	1	-	-	ND	-	Oropharyngeal swabs
124	26	4	-	-	ND	-	Oropharyngeal swabs
125	22	2	-	-	ND	-	Oropharyngeal swabs
126	37	5	-	-	ND	-	Oropharyngeal swabs
127	46	3	-	-	ND	-	Oropharyngeal swabs
128	72	5	-	-	ND	-	Oropharyngeal swabs
129	55	3	-	-	ND	-	Oropharyngeal swabs
130	18	2	-	-	ND	-	Oropharyngeal swabs
131	29	4	-	-	ND	-	Oropharyngeal swabs
132	72	1	-	-	ND	-	Oropharyngeal swabs
133	55	1	-	-	ND	-	Oropharyngeal swabs
134	23	2	-	-	ND	-	Oropharyngeal swabs
135	43	1	-	-	ND	-	Oropharyngeal swabs
136	59	4	-	-	ND	-	Oropharyngeal swabs
137	85	2	-	-	ND	-	Oropharyngeal swabs
138	12	1	-	-	ND	-	Oropharyngeal swabs
139	8	5	-	-	ND	-	Oropharyngeal swabs
140	37	5	-	-	ND	-	Oropharyngeal swabs
141	53	1	-	-	ND	-	Oropharyngeal swabs
142	9	2	-	-	ND	-	Oropharyngeal swabs
143	47	1	-	-	ND	-	Oropharyngeal swabs
144	12	7	-	-	ND	-	Oropharyngeal swabs
145	66	2	-	-	ND	-	Oropharyngeal swabs
146	36	5	-	-	ND	-	Oropharyngeal swabs
147	85	3	-	-	ND	-	Oropharyngeal swabs
148	73	5	-	-	ND	-	Oropharyngeal swabs
149	21	3	-	-	ND	-	Oropharyngeal swabs
150	23	5	-	-	ND	-	Oropharyngeal swabs
151	45	1	-	-	ND	-	Oropharyngeal swabs
152	10	2	-	-	ND	-	Oropharyngeal swabs

153	38	5	-	-	ND	-	Oropharyngeal swabs
154	15	4	-	-	ND	-	Oropharyngeal swabs
155	42	3	-	-	ND	-	Oropharyngeal swabs
156	20	6	-	-	ND	-	Oropharyngeal swabs
157	75	3	-	-	ND	-	Oropharyngeal swabs
158	56	7	-	-	ND	-	Oropharyngeal swabs
159	63	3	-	-	ND	-	Oropharyngeal swabs
160	24	6	-	-	ND	-	Oropharyngeal swabs
161	45	6	-	-	ND	-	Oropharyngeal swabs
162	44	7	-	-	ND	-	Oropharyngeal swabs
163	48	5	-	-	ND	-	Oropharyngeal swabs
164	5	7	-	-	ND	-	Oropharyngeal swabs
165	55	7	-	-	ND	-	Oropharyngeal swabs
166	68	2	-	-	ND	-	Oropharyngeal swabs
167	33	4	-	-	ND	-	Oropharyngeal swabs
168	53	2	-	-	ND	-	Oropharyngeal swabs
169	49	6	-	-	ND	-	Oropharyngeal swabs
170	11	1	-	-	ND	-	Oropharyngeal swabs
171	50	7	-	-	ND	-	Oropharyngeal swabs
172	36	4	-	-	ND	-	Oropharyngeal swabs
173	42	4	-	-	ND	-	Oropharyngeal swabs
174	25	6	-	-	ND	-	Oropharyngeal swabs
175	57	2	-	-	ND	-	Oropharyngeal swabs
176	25	5	-	-	ND	-	Oropharyngeal swabs
177	58	6	-	-	ND	-	Oropharyngeal swabs
178	14	6	-	-	ND	-	Oropharyngeal swabs
179	25	2	-	-	ND	-	Oropharyngeal swabs
180	26	5	-	-	ND	-	Oropharyngeal swabs
181	84	2	-	-	ND	-	Oropharyngeal swabs
182	45	5	-	-	ND	-	Oropharyngeal swabs
183	23	3	-	-	ND	-	Oropharyngeal swabs
184	27	4	-	-	ND	-	Oropharyngeal swabs
185	22	6	-	-	ND	-	Oropharyngeal swabs
186	56	3	-	-	ND	-	Oropharyngeal swabs
187	24	1	-	-	ND	-	Oropharyngeal swabs
188	61	7	-	-	ND	-	Oropharyngeal swabs
189	76	1	-	-	ND	-	Oropharyngeal swabs
190	3	1	-	-	ND	-	Oropharyngeal swabs
191	54	4	-	-	ND	-	Oropharyngeal swabs
192	2	6	-	-	ND	-	Oropharyngeal swabs
193	16	6	-	-	ND	-	Oropharyngeal swabs
194	2	1	-	-	ND	-	Oropharyngeal swabs
195	34	4	-	-	ND	-	Oropharyngeal swabs

196	70	7	-	-	ND	-	Oropharyngeal swabs
197	30	4	-	-	ND	-	Oropharyngeal swabs
198	51	3	-	-	ND	-	Oropharyngeal swabs
199	29	3	-	-	ND	-	Oropharyngeal swabs
200	74	7	-	-	ND	-	Oropharyngeal swabs
201	9	7	-	-	ND	-	Oropharyngeal swabs
202	42	6	-	-	ND	-	Oropharyngeal swabs
203	3	4	-	-	ND	-	Oropharyngeal swabs
204	87	3	-	-	ND	-	Oropharyngeal swabs
205	88	7	-	-	ND	-	Oropharyngeal swabs
206	3	4	-	-	ND	-	Oropharyngeal swabs
207	61	3	-	-	ND	-	Oropharyngeal swabs
208	83	7	-	-	ND	-	Oropharyngeal swabs
209	47	3	-	-	ND	+	Oropharyngeal swabs
210	45	2	-	-	ND	-	Oropharyngeal swabs
211	23	4	-	-	ND	-	Oropharyngeal swabs
212	16	6	-	-	ND	-	Oropharyngeal swabs
213	12	6	-	-	ND	-	Oropharyngeal swabs
214	67	4	-	-	ND	-	Oropharyngeal swabs
215	37	1	-	-	ND	-	Oropharyngeal swabs
216	23	6	-	-	ND	-	Oropharyngeal swabs
217	26	4	-	-	ND	-	Oropharyngeal swabs
218	1	6	-	-	ND	-	Oropharyngeal swabs
219	82	7	-	-	ND	-	Oropharyngeal swabs
220	33	1	-	-	ND	-	Oropharyngeal swabs
221	55	7	-	-	ND	-	Oropharyngeal swabs
222	49	6	-	-	ND	-	Oropharyngeal swabs
223	13	1	-	-	ND	-	Oropharyngeal swabs
224	43	2	-	-	ND	-	Oropharyngeal swabs
225	89	7	-	-	ND	-	Oropharyngeal swabs
226	62	4	-	-	ND	-	Oropharyngeal swabs
227	36	3	-	-	ND	-	Oropharyngeal swabs
228	6	5	-	-	ND	-	Oropharyngeal swabs
229	47	5	-	-	ND	-	Oropharyngeal swabs
230	34	3	-	-	ND	-	Oropharyngeal swabs
231	13	1	-	-	ND	-	Oropharyngeal swabs
232	15	1	-	-	ND	-	Oropharyngeal swabs
233	33	1	-	-	ND	-	Oropharyngeal swabs
234	44	5	-	-	ND	-	Oropharyngeal swabs
235	50	4	-	-	ND	-	Oropharyngeal swabs
236	29	3	-	-	ND	-	Oropharyngeal swabs
237	22	5	-	-	ND	-	Oropharyngeal swabs
238	23	1	-	-	ND	-	Oropharyngeal swabs

239	54	2	-	-	ND	-	Oropharyngeal swabs
240	78	3	-	-	ND	-	Oropharyngeal swabs
241	61	2	-	-	ND	-	Oropharyngeal swabs
242	43	4	-	-	ND	-	Oropharyngeal swabs
243	35	7	-	-	ND	-	Oropharyngeal swabs
244	79	5	-	-	ND	-	Oropharyngeal swabs
245	61	2	-	-	ND	-	Oropharyngeal swabs
246	41	2	-	-	ND	-	Oropharyngeal swabs
247	24	2	-	-	ND	-	Oropharyngeal swabs
248	1	5	-	-	ND	-	Oropharyngeal swabs
249	3	6	-	-	ND	-	Oropharyngeal swabs
250	33	2	-	-	ND	-	Oropharyngeal swabs
251	3	2	-	-	ND	-	Oropharyngeal swabs
252	40	2	-	-	ND	-	Oropharyngeal swabs
253	40	6	-	-	ND	-	Oropharyngeal swabs
254	39	1	-	-	ND	-	Oropharyngeal swabs
255	43	4	-	-	ND	-	Oropharyngeal swabs
256	44	3	-	-	ND	-	Oropharyngeal swabs
257	84	1	-	-	ND	-	Oropharyngeal swabs
258	40	5	-	-	ND	-	Oropharyngeal swabs
259	4	5	-	-	ND	-	Oropharyngeal swabs
260	36	5	-	-	ND	-	Oropharyngeal swabs
261	79	5	-	-	ND	-	Oropharyngeal swabs
262	28	1	-	-	ND	-	Oropharyngeal swabs
263	62	2	-	-	ND	-	Oropharyngeal swabs
264	12	2	-	-	ND	-	Oropharyngeal swabs
265	85	6	-	-	ND	-	Oropharyngeal swabs
266	52	4	-	-	ND	-	Oropharyngeal swabs
267	32	2	-	-	ND	-	Oropharyngeal swabs
268	74	2	-	-	ND	-	Oropharyngeal swabs
269	22	4	-	-	ND	-	Oropharyngeal swabs
270	90	1	-	-	ND	-	Oropharyngeal swabs
271	52	6	-	-	ND	-	Oropharyngeal swabs
272	56	3	-	-	ND	-	Oropharyngeal swabs
273	36	2	-	-	ND	-	Oropharyngeal swabs
274	44	1	-	-	ND	-	Oropharyngeal swabs
275	27	7	-	-	ND	-	Oropharyngeal swabs
276	41	7	-	-	ND	-	Oropharyngeal swabs
277	20	7	-	-	ND	-	Oropharyngeal swabs
278	64	7	-	-	ND	-	Oropharyngeal swabs
279	38	2	-	-	ND	-	Oropharyngeal swabs
280	60	1	-	-	ND	-	Oropharyngeal swabs
281	39	6	-	-	ND	-	Oropharyngeal swabs

282	53	1	-	-	ND	-	Oropharyngeal swabs
283	50	2	-	-	ND	-	Oropharyngeal swabs
284	88	4	-	-	ND	-	Oropharyngeal swabs
285	5	3	+	+	30	+	Oropharyngeal swabs
286	26	5	+	+	30	+	Oropharyngeal swabs
287	21	3	+	+	26	+	Oropharyngeal swabs
288	55	2	+	+	31	+	Oropharyngeal swabs
289	75	2	+	+	31	+	Oropharyngeal swabs
290	53	4	+	+	25	+	Oropharyngeal swabs
291	57	1	+	+	31	+	Oropharyngeal swabs
292	35	7	+	+	27	+	Oropharyngeal swabs
293	55	4	+	+	28	+	Oropharyngeal swabs
294	2	5	+	+	30	+	Oropharyngeal swabs
295	19	4	+	+	29	+	Oropharyngeal swabs
296	58	1	+	+	32	+	Oropharyngeal swabs
297	57	2	+	+	30	+	Oropharyngeal swabs
298	64	1	+	+	31	+	Oropharyngeal swabs
299	65	6	+	+	29	+	Oropharyngeal swabs
300	83	2	+	+	31	+	Oropharyngeal swabs
301	47	2	+	+	30	+	Oropharyngeal swabs
302	9	2	+	+	32	+	Oropharyngeal swabs
303	45	7	+	+	26	+	Oropharyngeal swabs
304	48	2	+	+	27	+	Oropharyngeal swabs
305	8	2	+	+	29	+	Oropharyngeal swabs
306	83	3	+	+	23	+	Oropharyngeal swabs
307	82	7	+	+	23	+	Oropharyngeal swabs
308	26	1	+	+	33	+	Oropharyngeal swabs
309	90	3	+	+	26	+	Oropharyngeal swabs
310	36	2	+	+	29	+	Oropharyngeal swabs
311	74	5	+	+	25	+	Oropharyngeal swabs
312	61	2	+	+	28	+	Oropharyngeal swabs
313	53	2	+	+	35	+	Oropharyngeal swabs
314	2	4	+	+	29	+	Oropharyngeal swabs
315	3	1	+	+	29	+	Oropharyngeal swabs
316	11	6	+	+	29	+	Oropharyngeal swabs
317	48	4	+	+	24	+	Oropharyngeal swabs
318	1	7	+	+	24	+	Oropharyngeal swabs
319	26	5	+	+	25	+	Oropharyngeal swabs
320	38	2	+	+	30	+	Oropharyngeal swabs
321	71	2	+	+	28	+	Oropharyngeal swabs
322	57	6	+	+	27	+	Oropharyngeal swabs
323	75	2	+	+	29	+	Oropharyngeal swabs
324	4	3	+	+	32	+	Oropharyngeal swabs

325	17	2	+	+	28	+	Oropharyngeal swabs
326	53	7	+	+	28	+	Oropharyngeal swabs
327	12	1	+	+	29	+	Oropharyngeal swabs
328	85	3	+	+	29	+	Oropharyngeal swabs
329	22	5	+	+	29	+	Oropharyngeal swabs
330	35	7	+	+	23	+	Oropharyngeal swabs
331	83	3	+	+	26	+	Oropharyngeal swabs
332	32	5	+	+	27	+	Oropharyngeal swabs
333	30	4	+	+	24	+	Oropharyngeal swabs
334	54	2	+	+	29	+	Oropharyngeal swabs
335	6	1	+	+	32	+	Oropharyngeal swabs
336	74	6	+	+	28	+	Oropharyngeal swabs
337	31	1	+	+	31	+	Oropharyngeal swabs
338	39	3	+	+	28	+	Oropharyngeal swabs
339	3	3	+	+	27	+	Oropharyngeal swabs
340	38	1	+	+	32	+	Oropharyngeal swabs
341	26	6	+	+	23	+	Oropharyngeal swabs
342	28	1	+	+	30	+	Oropharyngeal swabs
343	89	2	+	+	34	+	Oropharyngeal swabs
344	54	6	+	+	24	+	Oropharyngeal swabs
345	80	4	+	+	29	+	Oropharyngeal swabs
346	3	3	+	+	32	+	Oropharyngeal swabs
347	10	7	+	+	28	+	Oropharyngeal swabs
348	64	7	+	+	27	+	Oropharyngeal swabs
349	89	7	+	+	24	+	Oropharyngeal swabs
350	36	5	+	+	29	+	Oropharyngeal swabs
351	31	3	+	+	34	+	Oropharyngeal swabs
352	54	2	+	+	33	+	Oropharyngeal swabs
353	23	2	+	+	29	+	Oropharyngeal swabs
354	5	6	+	+	25	+	Oropharyngeal swabs
355	52	7	+	+	27	+	Oropharyngeal swabs
356	43	3	+	+	30	+	Oropharyngeal swabs
357	30	5	+	+	24	+	Oropharyngeal swabs
358	57	3	+	+	32	+	Oropharyngeal swabs
359	24	1	+	+	30	+	Oropharyngeal swabs
360	40	3	+	+	31	-	Oropharyngeal swabs
361	76	5	+	+	25	+	Oropharyngeal swabs
362	73	2	+	+	29	+	Oropharyngeal swabs
363	39	4	+	+	26	+	Oropharyngeal swabs
364	86	4	+	+	29	+	Oropharyngeal swabs
365	30	5	+	+	23	+	Oropharyngeal swabs
366	56	4	+	+	25	+	Oropharyngeal swabs
367	22	1	+	+	35	-	Oropharyngeal swabs

368	58	6	+	+	24	+	Oropharyngeal swabs
369	47	2	+	+	29	+	Oropharyngeal swabs
370	47	3	+	+	29	+	Oropharyngeal swabs
371	32	4	+	+	24	+	Oropharyngeal swabs
372	19	2	+	+	29	+	Oropharyngeal swabs
373	10	2	+	+	35	+	Oropharyngeal swabs
374	83	7	+	+	33	-	Oropharyngeal swabs
375	63	6	+	+	27	+	Oropharyngeal swabs
376	21	3	+	+	27	+	Oropharyngeal swabs
377	76	4	+	+	29	+	Oropharyngeal swabs
378	24	3	+	+	32	+	Oropharyngeal swabs
379	78	3	+	+	28	+	Oropharyngeal swabs
380	87	3	+	+	33	+	Oropharyngeal swabs
381	49	6	+	+	25	+	Oropharyngeal swabs
382	52	6	+	+	25	+	Oropharyngeal swabs
383	85	1	+	+	33	+	Oropharyngeal swabs
384	44	3	+	+	26	+	Oropharyngeal swabs
385	6	4	+	+	27	+	Oropharyngeal swabs
386	53	1	+	+	31	+	Oropharyngeal swabs
387	38	4	+	+	23	+	Oropharyngeal swabs
388	34	7	+	+	32	+	Oropharyngeal swabs
389	9	2	+	+	32	+	Oropharyngeal swabs
390	74	6	+	+	23	+	Oropharyngeal swabs
391	37	5	+	+	33	+	Oropharyngeal swabs
392	54	4	+	+	30	+	Oropharyngeal swabs
393	52	2	+	+	28	+	Oropharyngeal swabs
394	23	5	+	+	28	+	Oropharyngeal swabs
395	46	6	+	+	26	+	Oropharyngeal swabs
396	11	3	+	+	32	+	Oropharyngeal swabs
397	39	6	+	+	27	+	Oropharyngeal swabs
398	37	3	+	+	30	+	Oropharyngeal swabs
399	26	3	+	+	28	-	Oropharyngeal swabs
400	28	5	+	+	24	+	Oropharyngeal swabs
401	52	3	+	+	25	+	Oropharyngeal swabs
402	27	5	+	+	28	+	Oropharyngeal swabs
403	84	1	+	+	29	+	Oropharyngeal swabs
404	11	5	+	+	23	+	Oropharyngeal swabs
405	43	6	+	+	31	+	Oropharyngeal swabs
406	75	4	+	+	30	+	Oropharyngeal swabs
407	60	2	+	+	30	+	Oropharyngeal swabs
408	32	5	+	+	27	+	Oropharyngeal swabs
409	66	5	+	+	26	+	Oropharyngeal swabs
410	38	2	+	+	33	-	Oropharyngeal swabs

411	36	2	+	+	28	+	Oropharyngeal swabs
412	52	5	+	+	31	+	Oropharyngeal swabs
413	22	3	+	+	26	+	Oropharyngeal swabs
414	12	3	+	+	29	+	Oropharyngeal swabs
415	57	2	+	+	29	+	Oropharyngeal swabs
416	47	2	+	+	33	+	Oropharyngeal swabs
417	8	2	+	+	30	+	Oropharyngeal swabs
418	77	3	+	+	29	+	Oropharyngeal swabs
419	28	4	+	+	24	+	Oropharyngeal swabs
420	14	1	+	+	30	+	Oropharyngeal swabs
421	52	1	+	+	30	+	Oropharyngeal swabs
422	49	2	+	+	30	+	Oropharyngeal swabs
423	46	2	+	+	30	+	Oropharyngeal swabs
424	31	1	+	+	33	+	Oropharyngeal swabs

1.5.2 Coincidence rate statistics with reference system

Statistically analyze on 424 samples, the statistical results of the coincidence rate with the reference system are as follows:

Table 2. Coincidence rate with the reference system

Compared with nucleic acid test results			
	Pos by PCR	Neg by PCR	Total
Pos by CoV2Ag-25	135	1	136
Neg by CoV2Ag-25	5	283	288
Total	140	284	424
Positive Coincidence Rate	96.43%		
Negative Coincidence Rate	99.65%		

1.5.3 Sensitivity and specificity

Make statistics on 424 samples by software “Medcalc”, which includes 140 clinically confirmed cases and 284 excluded cases. There are 136 positive results, and 288 negative results with rapid kit. The clinical sensitivity and specificity of this product is 96.429% (95%CI: 91.862%, 98.830%) and 99.648% (95%CI: 98.054%, 99.991%).

Table 3. Product sensitivity and specificity

Sensitivity	96.429%	91.862% to 98.830%
Specificity	99.648%	98.054% to 99.991%
AUC	0.980	0.962 to 0.991
Positive Likelihood Ratio	273.857	38.698 to 1938.001
Negative Likelihood Ratio	0.036	0.015 to 0.085
Disease prevalence	33.019%	28.557% to 37.720%
Positive Predictive Value	99.265%	95.019% to 99.895%
Negative Predictive Value	98.264%	95.989% to 99.258%

1.5.4 Conclusion on Ct value, age, day onset

140 positive samples ct values were analyzed, coincidence rates as follows:

Range of Ct value	POS by PCR	POS by CoV2Ag-25	Coincidence Rate
23-25	27	27	100.00%
26-29	60	59	98.33%
30-33	48	45	93.75%
34-35	5	4	80.00%

424 samples were analyzed, POSTIVE coincidence rates by age as follows:

Age	Amount	POS by PCR	POS by CoV2Ag-25	POSTIVE Coincidence Rate
0-20	83	26	26	100.00%
21-60	245	82	78	95.12%
61-90	96	32	31	96.88%

424 samples were analyzed, POSTIVE coincidence rates by symptom onset days as follows:

Days onset	Amount	POS by PCR	POS by CoV2Ag-25	POSTIVE Coincidence Rate
1	67	18	17	94.44%
2	74	33	32	96.97%
3	69	27	25	92.59%
4	56	17	17	100.00%
5	53	18	18	100.00%
6	55	15	15	100.00%
7	50	12	11	91.67%

1.5.4 Results in homology

Apply the examination reagent to determine 100 samples of the homologous oropharyngeal swabs, nasal swabs and nasopharyngeal swabs, and evaluate whether the detection results of different sampling sites are consistent. The results are as follows:

Table 4. Results in homology

Patient No.	Age	Days of symptoms onset	Result	Sampling type	Result	Sampling type	Result	Sampling type
1	38	1	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
2	61	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
3	1	4	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
4	83	3	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
5	46	6	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
6	22	5	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
7	17	2	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
8	45	2	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
9	59	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
10	75	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
11	59	1	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
12	3	3	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
13	53	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
14	68	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
15	47	4	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
16	50	7	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
17	46	6	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
18	52	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
19	54	2	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
20	19	4	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
21	59	5	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
22	12	1	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
23	42	7	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
24	85	3	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
25	2	4	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
26	12	7	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
27	74	1	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
28	71	2	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
29	30	6	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab

30	64	7	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
31	49	1	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
32	83	2	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
33	48	2	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
34	26	1	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
35	32	5	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
36	36	2	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
37	67	7	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
38	3	1	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
39	35	2	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
40	60	7	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
41	70	7	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
42	26	5	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
43	47	2	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
44	63	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
45	51	4	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
46	13	7	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
47	62	4	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
48	11	6	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
49	26	6	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
50	43	7	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
51	31	6	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
52	57	1	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
53	75	2	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
54	38	2	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
55	56	4	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
56	39	3	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
57	57	6	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
58	74	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
59	53	2	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
60	74	5	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
61	14	1	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
62	52	2	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
63	59	2	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
64	8	2	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
65	9	2	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
66	45	7	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
67	72	4	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
68	67	6	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
69	68	7	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
70	61	2	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
71	40	7	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
72	71	4	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab

73	39	4	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
74	4	3	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
75	74	6	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
76	82	7	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
77	70	1	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
78	42	2	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
79	48	4	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
80	62	7	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
81	30	4	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
82	43	2	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
83	45	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
84	65	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
85	53	7	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
86	63	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
87	55	7	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
88	45	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
89	6	1	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
90	1	7	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
91	41	6	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
92	41	5	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
93	70	7	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
94	35	7	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
95	57	6	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
96	64	6	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
97	90	3	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
98	30	6	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
99	31	1	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
100	83	3	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab

1.5.5 Homologous consistency

Analyze on detection results of 100 samples of oropharyngeal swabs, nasal swabs and nasopharyngeal swabs and the results are as follows:

Homologous consistency of oropharyngeal swabs, nasal swabs and nasopharyngeal swabs:

Variable Y	Oropharyngeal swab
Variable X	Nasopharyngeal swab
Variable Z	Nasal swab

The sampling size	100
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Consistency correlation coefficient	1.0000
95% confidence interval	-1.0000 - -1.0000
Pearson ρ (precise)	1.0000
Deviation correction factor C_b (accuracy)	1.0000

1.6 Discussion and Conclusions

Select 424 cases including 140 cases of clinically confirmed patients of novel coronavirus infection and 284 cases of clinical excluded patients. No cases selected that are not in accordance with the protocol, no cases of laboratory operation deviation are found. Detect in 424 cases, statistically analyze the results and calculate the sensitivity and specificity. Then determine the 100 samples of homologous oropharyngeal swabs, nasal swabs and nasopharyngeal swabs with assessment reagent to evaluate whether the detection results are consistent. The following results and conclusions are obtained:

1. Statistically analyze on 140 clinically confirmed cases and 284 excluded cases. There are 136 positive results, and 288 negative results. The clinical sensitivity and specificity of this product is 96.429% (95%CI: 91.862%, 98.830%) and 99.648% (95%CI: 98.054%, 99.991%).
2. The test results of homologous oropharyngeal swabs, nasal swabs and nasopharyngeal swabs from 100 subjects are compared. The results show that the consistent detection rate between oropharyngeal swabs, nasal swabs and nasopharyngeal swabs is 100% (95%CI: -100%, 100%).

The results show that the product is highly consistent with the clinical diagnosis.

2 A description of special circumstances in clinical studies

None.

3 Writing time of the Clinical report

The clinical report was completed on November 16, 2020.