Clinical evaluation report

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

Wuhan UNscience Biotechnology Co., Ltd.

CONTENTS

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, 149 specimens of cases have been selected, including 29 specimens of patients with clinically confirmed cases of novel coronavirus infection and 120 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. 149 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 50 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：

1. Statistical analysis of 149 clinical samples (29 positive cases and 120 negative cases) showed the sensitivity is 89.655% (95% CI: 72.648%, 97.814%) and specificity is 99.167% (95% CI: 95.444%, 99.979%). The comparison results of 149 clinical samples with nucleic acid test shows that the positive coincidence rate is 93.10% and the negative coincidence rate is 99.17%.

2. In addition, select homologous oropharyngeal swabs, nasal swabs and nasopharyngeal swabs from 50 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 novel coronavirus (SARS-CoV-2) antigen rapid kit (colloidal gold immunochromatography) produced by UNscience is used for in vitro qualitative detection of novel coronavirus (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 novel coronavirus (SARS-CoV-2) antigen. During the test, the sample is dropped into the sample well, and chromatography is performed under the capillary effect. The novel coronavirus (SARS-CoV-2) antigen in the sample combined with the colloidal gold-labeled novel coronavirus (SARS-CoV-2) monoclonal antibody I, and then spread to the test area. It is captured by another coated monoclonal (SARS-CoV-2) 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 parainfluenza virus antibodies, influenza A virus antibodies, influenza B virus antibodies, Chlamydia pneumoniae antibodies, Mycoplasma pneumoniae antibodies, adenovirus antibodies, and respiratory tract Syncytial virus antibody, hepatitis B surface antibody, hepatitis C virus antibody, Treponema pallidum antibody, human immunodeficiency virus antibody, Epstein-Barr virus antibody, measles virus antibody, cytomegalovirus antibody, enterovirus type 71 antibody, mumps virus Antibodies, endemic human coronavirus (HKU1, OC43, NL63, 229E) antibodies, varicella-zoster virus positive samples; proceed with histamine hydrochloride, α-interferon, zanamivir, ribavirin, osestat Samples of patients treated with drugs such as Vivir, Peramivir, Lopinavir, Ritonavir, Arbidol, Levofloxacin, Azithromycin, Ceftriaxone, Meropenem, Tobramycin, etc.

1.4.2.2.3 Sample exclusion criteria

① The sample volumn 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.);

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:

Take out sampling tube and add 10 drops of sample treatment solution into it. 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℃ 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 appears 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

149 cases were included, including 29 cases of novel Coronavirus infection with clinically confirmed patients and 120 cases of clinical excluded cases. No cases were included in accordance with the protocol and no cases of laboratory operation deviation were found. 149 cases were detected and the results were statistically analyzed to calculate the sensitivity and specificity of the methods.

Table 1 Clinical trial results

No.	Age	Days after symptom	Clinical diagnosis	Nucleic acid testing	Sample type	Antigen detection	Sample type
1	38	6	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
2	77	4	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
3	38	7	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
4	49	5	+	+	Oropharyngeal swab	+	Nasopharyngeal swab
5	43	2	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
6	52	2	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
7	47	6	+	+	Nasopharyngeal swab	+	Oropharyngeal swab
8	51	2	+	+	Nasopharyngeal swab	+	Oropharyngeal swab
9	81	6	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
10	25	2	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
11	78	7	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
12	57	7	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
13	78	6	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
14	48	3	+	+	Nasopharyngeal swab	+	Oropharyngeal swab
15	50	6	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
16	30	4	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
17	10	2	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
18	56	3	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
19	48	6	+	+	Oropharyngeal swab	+	Nasopharyngeal swab
20	62	3	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
21	82	7	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
22	11	1	-	-	Nasopharyngeal swab	-	Oropharyngeal swab

23	79	3	+	+	Nasopharyngeal swab	+	Oropharyngeal swab
24	45	3	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
25	31	4	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
26	13	1	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
27	62	4	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
28	0	3	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
29	22	3	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
30	72	1	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
31	54	7	+	+	Nasopharyngeal swab	+	Oropharyngeal swab
32	41	7	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
33	32	7	+	+	Oropharyngeal swab	+	Nasopharyngeal swab
34	74	6	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
35	78	6	+	+	Nasopharyngeal swab	+	Oropharyngeal swab
36	45	2	+	+	Nasopharyngeal swab	-	Oropharyngeal swab
37	23	1	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
38	55	3	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
39	82	1	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
40	10	4	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
41	76	7	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
42	5	3	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
43	64	3	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
44	50	4	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
45	83	6	+	+	Oropharyngeal swab	+	Nasopharyngeal swab
46	39	7	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
47	69	5	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
48	60	4	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
49	9	3	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
50	83	7	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
51	81	5	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
52	24	3	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
53	26	6	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
54	53	7	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
55	61	3	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
56	69	5	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
57	72	4	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
58	58	7	+	+	Oropharyngeal swab	+	Nasopharyngeal swab
59	47	3	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
60	24	4	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
61	35	5	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
62	80	6	+	+	Oropharyngeal swab	+	Nasopharyngeal swab
63	17	4	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
64	81	3	+	+	Nasopharyngeal swab	+	Oropharyngeal swab
65	64	7	+	+	Nasopharyngeal swab	+	Oropharyngeal swab

66	37	1	+	+	Nasopharyngeal swab	+	Oropharyngeal swab
67	22	2	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
68	2	1	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
69	61	4	+	+	Nasopharyngeal swab	+	Oropharyngeal swab
70	79	3	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
71	73	1	+	+	Oropharyngeal swab	-	Nasopharyngeal swab
72	55	4	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
73	69	2	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
74	41	4	+	+	Oropharyngeal swab	-	Nasopharyngeal swab
75	28	1	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
76	26	6	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
77	77	6	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
78	44	7	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
79	75	1	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
80	50	3	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
81	30	3	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
82	31	4	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
83	15	3	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
84	56	5	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
85	67	2	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
86	27	1	-	-	Oropharyngeal swab	+	Nasopharyngeal swab
87	59	5	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
88	65	6	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
89	30	1	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
90	58	4	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
91	62	2	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
92	31	2	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
93	83	3	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
94	68	4	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
95	24	5	+	+	Oropharyngeal swab	+	Nasopharyngeal swab
96	52	3	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
97	53	6	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
98	82	4	+	+	Nasopharyngeal swab	+	Oropharyngeal swab
99	31	5	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
100	56	5	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
101	52	1	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
102	38	5	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
103	10	1	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
104	75	3	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
105	29	3	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
106	46	1	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
107	55	1	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
108	30	3	-	-	Oropharyngeal swab	-	Nasopharyngeal swab

109	79	1	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
110	19	3	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
111	32	2	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
112	63	5	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
113	46	1	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
114	38	1	+	+	Nasopharyngeal swab	+	Oropharyngeal swab
115	35	4	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
116	24	3	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
117	58	4	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
118	64	7	+	+	Nasopharyngeal swab	+	Oropharyngeal swab
119	75	6	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
120	39	3	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
121	65	4	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
122	46	2	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
123	32	2	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
124	51	3	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
125	43	5	+	+	Nasopharyngeal swab	+	Oropharyngeal swab
126	54	4	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
127	44	1	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
128	35	2	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
129	62	7	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
130	69	5	+	+	Nasopharyngeal swab	+	Oropharyngeal swab
131	62	4	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
132	57	4	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
133	28	4	+	+	Oropharyngeal swab	+	Nasopharyngeal swab
134	53	1	+	+	Nasopharyngeal swab	+	Oropharyngeal swab
135	58	2	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
136	71	5	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
137	35	7	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
138	60	1	+	+	Oropharyngeal swab	+	Nasopharyngeal swab
139	53	2	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
140	18	4	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
141	72	3	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
142	46	6	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
143	72	1	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
144	80	2	+	+	Nasopharyngeal swab	+	Oropharyngeal swab
145	53	3	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
146	45	3	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
147	9	2	-	-	Oropharyngeal swab	-	Nasopharyngeal swab
148	59	5	-	-	Nasopharyngeal swab	-	Oropharyngeal swab
149	35	5	-	-	Oropharyngeal swab	-	Nasopharyngeal swab

1.5.2 Coincidence rate statistics with reference system

Statistically analyze on 149 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			
	Positive tested by BGI	Negative by BGI	Total
Positive tested by UNScience	26	1	27
Negative tested by UNScience	3	119	122
Total	29	120	149
Positive coincidence rate	89.66%		
Negative coincidence rate	99.16%		

1.5.3 Sensitivity and specificity

Make statistics on 149 samples by software “Medcalc”, which includes 29 clinically confirmed cases and 120 excluded cases. There are 27 positive results, and 120 negative results. The clinical sensitivity and specificity of this product is 89.655% (95%CI: 72.648%, 97.814%) and 99.167% (95%CI: 95.444%, 99.979%).

Table 3. Product sensitivity and specificity

Sensitivity	89.655%	72.648% to 97.814%
Specificity	99.167%	95.444% to 99.979%
AUC	0.944	0.894 to 0.975
Positive Likelihood Ratio	107.586	15.219 to 760.534
Negative Likelihood Ratio	0.104	0.036 to 0.305
Disease prevalence	19.463%	13.439% to 26.741%
Positive Predictive Value	96.296%	78.623% to 99.459%
Negative Predictive Value	97.541%	93.143% to 99.144%

1.5.4 Results in homology

Apply the examination reagent to determine 50 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

No.	Age	Days of symptoms onset	Result	Sampling type	Result	Sampling type	Result	Sampling type
1	51	4	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
2	50	7	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
3	52	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
4	46	6	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
5	65	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
6	55	7	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
7	59	5	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
8	64	6	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
9	46	6	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
10	59	2	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
11	45	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
12	42	2	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
13	59	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
14	45	2	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
15	62	7	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
16	57	1	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
17	72	4	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
18	74	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
19	31	6	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
20	67	6	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
21	68	7	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
22	41	5	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
23	57	6	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
24	63	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
25	40	7	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
26	56	4	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
27	53	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
28	71	4	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
29	74	1	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
30	49	1	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
31	62	4	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
32	30	6	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab

33	42	7	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
34	70	7	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
35	30	6	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
36	43	2	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
37	70	1	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
38	59	1	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
39	75	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
40	52	2	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
41	60	7	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
42	41	6	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
43	68	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
44	47	4	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
45	43	7	+	Oropharyngeal swab	+	Nasopharyngeal swab	+	Nasal swab
46	61	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
47	39	4	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
48	67	7	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
49	63	3	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab
50	35	2	-	Oropharyngeal swab	-	Nasopharyngeal swab	-	Nasal swab

1.5.5 Homologous consistency

Analyze on detection results of 50 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	50
Consistency correlation coefficient	1.0000
95% confidence interval	-1.0000 - -1.0000
Pearson ρ （precise）	1.0000
Deviation correction factorC_b（accuracy）	1.0000

1.6 Discussion and Conclusions

Select 149 cases including 29 cases of clinically confirmed patients of novel Coronavirus infection and 120 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 149 cases, statistically analyze the results and calculate the sensitivity and specificity. Then determine the 50 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 149 clinical samples (including 29 positive cases and 120 negative cases), the sensitivity is 89.655% (95%CI: 72.648%, 97.814%) and specificity is 99.167% (95%CI: 95.444%, 99.979%). The 149 clinical samples detection results, which are compared with nucleic acid test results, the positive coincidence rate is 93.10% and the negative coincidence rate is 99.17%.
2. The test results of homologous oropharyngeal swabs, nasal swabs and nasopharyngeal swabs from 50 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.