Clinical Evaluation Report

Product name: Rapid COVID-19 Antigen Test (Colloidal Gold)

Company name: Anbio (Xiamen) Biotechnology Co., Ltd.

Duration of experiment: September 01, 2020 to February 05, 2021

Draft / Date： Xinhui Zheng / February 02, 2021

Reviewed By / Date: Jieli Zhang / February 02, 2021

Approved By / Date： Daming Wang / February 05, 2021

Signature: Daming Wang

Sign on: February 05, 2021

Place: Xiamen, China

Contents

1. Objective

Anbio (Xiamen) Biotechnology Co., Ltd. intends to introduce Rapid COVID-19 Antigen Test (Colloidal Gold) into the market. The objective of this study was designed to evaluate the user performance of COVID-19 Antigen Colloidal Gold Test.

The test results of samples from clinical cases were compared with RT-PCR results of cases to verify the clinical performance of the test reagent.

2. Background information for clinical evaluation

The novel coronaviruses belong to the β genus of Coronaviridae. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in a few cases.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. The antigen is generally detectable in upper respiratory samples or lower respiratory samples during the acute phase of infection. The positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. The positive results do not rule out bacterial infection or co-infection with other viruses. The antigen detected may not be the definite cause of disease. The negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. The negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with SARS-CoV-2 and confirmed with a molecular assay, if necessary, for patient management.

3. Materials and Equipment

(1) Rapid COVID-19 Antigen Test (Colloidal Gold)
Lot: #2020086131 (A1), #2020086132 (A2), #2020086133 (A3)
Manufacturer: Anbio (Xiamen) Biotechnology Co., Ltd.

(2) Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV
Lot: #S1572054
Manufacturer: BGI Genomics Co, Ltd.

(3) Real time fluorescence quantitative PCR
Type: ABI 7500
Manufacturer: Applied Biosystems

(4) Clinical specimens

4. Evaluation Sites

(1) POC in Guangzhou, China
(2) POC in Xiamen, China
(3) POC in Beijing, China

The above POC sites are the designated laboratory for COVID-19 testing, and each POC site is operated by 3 - 5 professionals.

5. Number of clinical specimens

Tab1 Number of clinical specimens

Group	PCR result (nasopharyngeal swab)	Sample type	Number	Collection Day
1	Positive	Saliva	At least 100 cases	2020/9/1 to 2021/2/3
2	Negative	Saliva	At least 100 cases	2020/9/1 to 2021/2/3

6. Criteria for Participant

(1) Gender: Male or female.

(2) Age: No restriction, neonates are excluded.

(3) Days from Symptom Onset

Days from Symptom Onset	0-7 days	＞7 days
Percentage	85%	15%

(4) Mild patients: Minor respiratory symptoms, no fever and there is no pneumonia in imaging.

Moderate patients: Respiratory symptoms, Fever and pneumonia can be seen on imaging.

Severe patients: Breathless, RR≥30 times/min, or Finger oxygen saturation≤93% when inhaling air in resting state, or PaO_2/FiO^2≤300mmHg, or Lung imaging showed that the lesions progressed significantly by 50% within 24-48 hours.

Critically ill patients: Respiratory failure occurs and requires mechanical ventilation, or shock, or combined occurrence of other organ failure requires ICU monitoring and treatment.

(5) Test within 24 hours after sample collection.

7. Clinical specimens' storage

(1) Applicable clinical specimen's type: nasal swab specimen

(2) Storage: Samples should be tested as soon as possible after collection. Processed samples (add Extraction Solution) are stable for up to 24 hours at room temperature or 2°C to 8°C and cannot be frozen.

(3) The specimens must be balanced to room temperature before testing.

8. Operation

8.1 Limit of Detection (LoD)

(1)The LOD for the Rapid COVID-19 Antigen Test for rapid detection of SARS-CoV-2 was established using limiting dilutions of heat-inactivated SARS-CoV-2 virus. The material was supplied frozen at a concentration of $3.40x10^5$ $TCID_{50}$/mL.

In this study, designed to estimate the LOD of the assay when using a direct saliva, the starting material was spiked into a volume of pooled human saliva obtained from healthy donors and confirmed negative for SARS-CoV-2. An initial range finding study was performed testing devices with 3 batchs using a 10-fold dilution series of 3 replicates per concentration. At each dilution, 1mL samples were added to Saliva collection device then tested in the assay using the procedure appropriate for patient saliva specimens. A concentration was chosen between the last dilution to give 3 positive results and the first to give 3 negative results. Using this concentration, the LOD was

further refined with a dilution series of 3 replicates per concentration.

Choose 3 concentrations (negative, LOD, 2 LOD) repeat the test for each concentration 20 times. Calculate the positive rate, the lowest concentration where the positive rate is greater than or equal to 95% is LOD.

This study included the use of three different lots of the Rapid COVID-19 Antigen Test.

(2) Clinical sample verification

Test clinically confirmed population samples to determine the $TCID_{50}$ of samples. Select 30 samples with concentration between 2.215 $x10^2$ $TCID_{50}$/mL and 4.24 $x10^2$ $TCID_{50}$/mL, select 30 samples with concentration between 4.25 $x10^2$ $TCID_{50}$/mL and 8.5 $x10^2$ $TCID_{50}$/mL for testing.

8.2 Cross-Reactivity

8.2.1 Cross reactivity sample preparation

(1) Preparation of saliva samples (negative): In a certain amount of pooled human saliva obtained from healthy donors and confirmed negative for SARS-CoV-2, add interfering substances (according to the final concentration in Table 1).

(2) Preparation of saliva samples (positive): a certain amount of pooled human saliva obtained from donors and confirm that the SARS-CoV-2 concentrations are 3 LOD and 1.5 LOD, add interfering substances (according to the final concentration in Table 1).

8.2.2 Test clinical specimens with three lots of Rapid COVID-19 Antigen Test (Colloidal Gold) according to the Instruction for Use. Each sample was tested 3 times per batch. Record the results respectively. Positive signals are recorded as “+” and negative signals are recorded as “-”.

8.2.3 Check if there were “-” for C line, which indicates invalid test results. If any invalid test were observed, the invalid results should be abandoned, and the specimen should be tested again. If the second test of the specimen were still invalid, the specimen should be abandoned from the experiment.

8.2.4 Check if there was “+” for T line, which indicates a positive result. Otherwise it is a negative result. Count and record the number of positive result(s) (Np) and negative result(s) (Nn).

8.2.5 Calculate the ratio of negative results versus total tests (Nn%) with formula Nn%= Nn/(Np+Nn)*100%;Calculate the ratio of positive results versus total tests (Np%) with formula Np%= Np/(Np+Nn)*100%.

8.2.6 Information about Cross Reactivity of potential reactants

Tab1 List of cross reactivity species

S.N.	Potential cross-reactant	Species	Concentration tested
1	H1N1(2009)	A-H1N1-2009	10^6pfu/mL
2	Seasonal H1N1 influenza virus	A-H1N1	10^6pfu/mL
3	H3N2 influenza virus	A-H3N2	10^6pfu/mL
4	H5N1 avian influenza virus	A-H5N1	10^6pfu/mL
5	H7N9 avian influenza virus	A-H7N9	10^6pfu/mL
6	Influenza B Yamagata	B-Yamagata	10^6pfu/mL
7	Influenza B Victoria	B-Victoria	10^6pfu/mL
8	Respiratory syncytial virus type A	RSV-A2	10^6pfu/mL

9	Respiratory syncytial virus type B	RSV-B	10^6pfu/mL
10	Enterovirus A	CV-A10	10^6pfu/mL
11	Enterovirus B	Echovirus 6	10^6pfu/mL
12	Enterovirus C	CV-A21	10^6pfu/mL
13	Enterovirus D	EV-D68	10^6pfu/mL
14	Parainfluenza virus type 1	HPIVs-1	10^6pfu/mL
15	Parainfluenza virus type 2	HPIVs-2	10^6pfu/mL
16	Parainfluenza virus type 3	HPIVs-3 VR-93	10^6pfu/mL
17	Rhinovirus A	HRV-9 VR-489	10^6pfu/mL
18	Rhinovirus B	HRV-52 VR-1162 HRV-3 VR-1113	10^6pfu/mL
19	Rhinovirus C	HRV-16 VR-283	10^6pfu/mL
20	Adenovirus type 1	HAdV-1 VR-1	10^6pfu/mL
21	Adenovirus type 2	HAdV-2 VR-846	10^6pfu/mL
22	Adenovirus type 3	HAdV-3	10^6pfu/mL
23	Adenovirus type 4	HAdV-4 VR-1572	10^6pfu/mL
24	Adenovirus type 5	HAdV-5 VR-1578/1516	10^6pfu/mL
25	Adenovirus type 7	HAdV-7 VR-7	10^6pfu/mL
26	Adenovirus type 55	HAdV-55	10^6pfu/mL
27	Human metapneumovirus	HMPV	10^6pfu/mL
28	Epstein-Barr virus	HHV-4 VR-1492	10^6pfu/mL
29	Measles virus	MV VR-24	10^6pfu/mL
30	Human cytomegalovirus	HHV-5 VR-977	10^6pfu/mL
31	Rotavirus	RV VR-2018	10^6pfu/mL
32	Norovirus	NOR	10^6pfu/mL
33	Mumps virus	MuV VR-106	10^6pfu/mL
34	Varicella-zoster virus	VZV VR-1367	10^6pfu/mL

35	Legionella	33152	10^7cfu/mL
36	Bordetella pertussis	BAA-589	10^7cfu/mL
37	Haemophilus influenzae	Hib	10^7cfu/mL
38	Staphylococcus aureus	CGMCC 1.2910	10^7cfu/mL
39	Streptococcus pneumoniae	CGMCC 1.8722	10^7cfu/mL
40	Streptococcus pyogenes	CGMCC 1.8868	10^7cfu/mL
41	Klebsiella pneumoniae	CGMCC 1.1736	10^7cfu/mL
42	Mycobacterium tuberculosis	25177	10^7cfu/mL
43	Mycoplasma pneumoniae	39505	10^7cfu/mL
44	Chlamydia pneumoniae	VR-2282	10^7cfu/mL
45	Aspergillus fumigatus	AF293	10^7cfu/mL
46	Candida albicans	SC5314	10^7cfu/mL
47	Candida glabrata	ATCC 2001	10^7cfu/mL
48	Cryptococcus neoformans	H99	10^7cfu/mL
49	Cryptococcus gutii	R265	10^7cfu/mL
50	Pneumocystis jirovecii (PJP)	CGMCC 1.9054	10^7cfu/mL
51	Coronavirus229E	VR-740	10^6pfu/mL
52	CoronavirusOC43	VR-1558	10^6pfu/mL
53	CoronavirusNL63	COV-NL63	10^6pfu/mL
54	Coronavirus HKU1	COV-HKU1	10^6pfu/mL
55	Coronavirus MERS	MERS	10^8TU/mL
56	Coronavirus SARS	SARS	10^8TU/mL
57	Pooled human nasal wash	/	10^7cfu/mL

8.3 Interference Substances Study

8.3.1 Interference sample preparation

(1) Preparation of saliva samples（negative): In a certain amount of pooled human saliva obtained from healthy donors and confirmed negative for SARS-CoV-2, add interfering substances (according to the final concentration in Table 2).

(2) Preparation of saliva samples (positive): a certain amount of pooled human saliva obtained from donors and confirm that the SARS-CoV-2 concentration is 3 LOD, add interfering substances (according to the final concentration in Table 2).

8.3.2 Test the interference samples with three lots of Rapid COVID-19 Antigen Test (Colloidal Gold) according to the Instruction for Use. Each sample was tested 5 times per batch. Record the results respectively. Positive signals are recorded as “+” and negative signals are recorded as “-”.

8.3.3 Check if there were “-” for C line, which indicates invalid test results (Ri). Count the total number of Ri.

8.3.4 Check if there were “+” for T line while testing negative samples. Any “+” should be regard as false positive (Fp). Count the total number of Fp. Check if there were “-” for T line while testing positive samples. Any “-” should be regard as false negative (Fn). Count the total number of Fn.

8.4 Clinical Trials

(1) Specimens collection and information record

The main researchers of the clinical institutions designate special personnel to select the eligible cases according to the enrollment criteria, and collect the clinical information of the enrolled specimens, including: age, gender, clinical symptoms, clinical classification(mild or moderate), sample collection time and other information. The specimens are numbered according to the sequence before and after grouping, i.e. Specimens number.

(2) Specimens blinding

The main researchers of the clinical institution designated the person to randomly number the specimens in the group with the random number generating tool, record the random number of the specimens and the corresponding specimens number, and the person arranged the specimens according to the sequence of the random number, and handed them to the test operator for testing according to this sequence, noting that the person and the test operator cannot be the same person.

(3) Testing

The test operator shall test the specimens and operate according to the instructions. RT-PCR test is used for in-vitro qualitative detection of novel coronavirus (2019-nCoV) ORF1ab, N gene and E gene in nasopharyngeal swab, oropharyngeal swab, sputum, and alveolar lavage fluid samples.

(4) Unblinding

At the end of the test, according to the corresponding relationship between random number and specimens’ number, record the test results.

(5) Result determination

The test results should be statistically analyzed with clinical diagnosis to evaluate the clinical application performance of the product.

9. Control method

(1) Before the start of clinical research, the enterprise shall train the researchers to make them familiar with and master the operation method and technical performance of the product, to minimize the test error.

(2) Researchers should strictly follow the product's operation specifications and related requirements for testing to ensure that the testing error can be minimized.

(3) The supervisors shall check the relevant activities and documents of the clinical trial, whether the trial is conducted in accordance with the test scheme, standard operating procedures and relevant regulations, and whether the test data is recorded in a timely, clear, accurate and complete manner.

10. Data management

(1) Traceability of data, filling, and transfer of case report form

Ensure the traceability of clinical trial data. According to the original observation records of the subjects, the researchers recorded the data in the case report form in a timely, complete, accurate

and clear manner. The supervisor shall monitor whether the trial is carried out in accordance with the plan, confirm that the case report form is filled in correctly and completely, and is consistent with the original data. In case of any mistake or omission, the researcher shall be required to correct it in time. The original record shall be kept clear and visible during modification, and the correction shall be signed and dated by the researcher.

(2) Data entry and modification

To ensure the accuracy of data, two data entry personnel are responsible for independent entry and proofreading. During the data analysis, for the questions in the case report form, the researcher should answer and return them as soon as possible, and the statistician should modify, confirm, and input them according to the researcher's answers.

(3) Lock of database

At the end of the test, after data entry, the researcher and the sponsor check the data, and lock the data after confirming that the data set is correct, and then lock the data for statistical analysis.

11. Results and Statistical Analysis

11.1 Results for Limit of Detection (LoD)

(1) LOD of human saliva specimen matrix

Tab2 Results of 10-fold dilution series

	$TCID_{50}$	A1			A2			A3		
1	$3.40x10^5$/mL	+	+	+	+	+	+	+	+	+
2	$3.40x10^4$/mL	+	+	+	+	+	+	+	+	+
3	$3.40x10^3$/mL	+	+	+	+	+	+	+	+	+
4	$3.40x10^2$/mL	-	+	-	-	-	-	-	+	-
5	3.40x10/mL	-	-	-	-	-	-	-	-	-
6	3.40/mL	-	-	-	-	-	-	-	-	-

Tab3 Results of fold dilution series

	$TCID_{50}$	A1			A2			A3		
1	$3.40x10^3$/mL	+	+	+	+	+	+	+	+	+
2	$1.70x10^3$/mL	+	+	+	+	+	+	+	+	+
3	$8.5x10^2$/mL	+	+	+	+	+	+	+	+	+
4	$4.25x10^2$/mL	+	+	+	+	+	+	+	+	+
5	$3.40x10^2$/mL	-	-	+	-	+	-	-	-	-
6	$2.125x10^2$/mL	-	-	-	-	-	-	-	-	-

Tab4 Repeat test results for LOD

	$8.5x10^2$ $TCID_{50}$/mL			$4.25x10^2$ $TCID_{50}$/mL			$3.40x10^2$ $TCID_{50}$/mL		
	A1	A2	A3	A1	A2	A3	A1	A2	A3
1	+	+	+	+	+	+	-	-	-
2	+	+	+	+	+	+	-	-	-
3	+	+	+	+	+	+	-	-	-
4	+	+	+	+	+	+	-	-	-
5	+	+	+	+	+	+	-	-	-
6	+	+	+	+	+	+	-	-	-
7	+	+	+	+	-	+	-	-	-
8	+	+	+	+	+	-	-	-	-

9	+	+	+	+	+	+	-	-	-
10	+	+	+	+	+	+	+	-	-
11	+	+	+	+	+	+	-	+	-
12	+	+	+	+	+	+	-	-	-
13	+	+	+	+	+	+	-	-	-
14	+	+	+	+	+	+	-	-	-
15	+	+	+	+	+	+	-	-	-
16	+	+	+	+	+	+	+	-	-
17	+	+	+	+	+	+	-	-	-
18	+	+	+	+	+	+	-	-	-
19	+	+	+	+	+	+	-	-	-
20	+	+	+	+	+	+	-	-	-
Positive rate	100% (60/60)			96.7% (58/60)			5% (3/60)		

(2) Clinical sample verification

Tab5 Saliva specimen ($2.215x10^2$ $TCID_{50}$/mL~$4.24x10^2$ $TCID_{50}$/mL) test results

Test	A1	A2	A3	Test	A1	A2	A3
1	-	-	-	16	-	-	-
2	-	-	-	17	-	-	-
3	-	-	-	18	-	-	-
4	-	-	-	19	-	-	-
5	-	-	-	20	-	-	-
6	-	-	-	21	-	-	-
7	-	-	-	22	-	-	-
8	-	-	-	23	-	-	-
9	-	-	-	24	-	-	-
10	-	-	-	25	-	-	-
11	-	-	-	26	-	-	-
12	-	-	-	27	-	-	-
13	-	-	-	28	-	-	-
14	-	-	-	29	-	-	-
15	-	-	-	30	-	-	-

Tab6 Saliva specimen ($4.25x10^2$ $TCID_{50}$/mL~$8.5x10^2$ $TCID_{50}$/mL) test results

Test	A1	A2	A3	Test	A1	A2	A3
1	+	+	+	16	+	+	+
2	+	+	+	17	+	+	+
3	+	+	+	18	+	+	+
4	+	+	+	19	+	+	+
5	+	+	+	20	+	+	+
6	+	+	+	21	+	+	+
7	+	+	+	22	+	+	+
8	+	+	+	23	+	+	+
9	+	+	+	24	+	+	+

10	+	+	+	25	+	+	+
11	+	+	+	26	+	+	+
12	+	+	+	27	+	+	+
13	+	+	+	28	+	+	+
14	+	+	+	29	+	+	+
15	+	+	+	30	+	+	+

11.2 Results for Cross Reactivity Study

Tab7 Test results of saliva specimens with common respiratory infections

S.N.	A1			A2			A3		
1	-	-	-	-	-	-	-	-	-
2	-	-	-	-	-	-	-	-	-
3	-	-	-	-	-	-	-	-	-
4	-	-	-	-	-	-	-	-	-
5	-	-	-	-	-	-	-	-	-
6	-	-	-	-	-	-	-	-	-
7	-	-	-	-	-	-	-	-	-
8	-	-	-	-	-	-	-	-	-
9	-	-	-	-	-	-	-	-	-
10	-	-	-	-	-	-	-	-	-
11	-	-	-	-	-	-	-	-	-
12	-	-	-	-	-	-	-	-	-
13	-	-	-	-	-	-	-	-	-
14	-	-	-	-	-	-	-	-	-
15	-	-	-	-	-	-	-	-	-
16	-	-	-	-	-	-	-	-	-
17	-	-	-	-	-	-	-	-	-
18	-	-	-	-	-	-	-	-	-
19	-	-	-	-	-	-	-	-	-
20	-	-	-	-	-	-	-	-	-
21	-	-	-	-	-	-	-	-	-
22	-	-	-	-	-	-	-	-	-
23	-	-	-	-	-	-	-	-	-
24	-	-	-	-	-	-	-	-	-
25	-	-	-	-	-	-	-	-	-
26	-	-	-	-	-	-	-	-	-
27	-	-	-	-	-	-	-	-	-
28	-	-	-	-	-	-	-	-	-
29	-	-	-	-	-	-	-	-	-
30	-	-	-	-	-	-	-	-	-
31	-	-	-	-	-	-	-	-	-
32	-	-	-	-	-	-	-	-	-
33	-	-	-	-	-	-	-	-	-
34	-	-	-	-	-	-	-	-	-

35	-	-	-	-	-	-	-	-	-
36	-	-	-	-	-	-	-	-	-
37	-	-	-	-	-	-	-	-	-
38	-	-	-	-	-	-	-	-	-
39	-	-	-	-	-	-	-	-	-
40	-	-	-	-	-	-	-	-	-
41	-	-	-	-	-	-	-	-	-
42	-	-	-	-	-	-	-	-	-
43	-	-	-	-	-	-	-	-	-
44	-	-	-	-	-	-	-	-	-
45	-	-	-	-	-	-	-	-	-
46	-	-	-	-	-	-	-	-	-
47	-	-	-	-	-	-	-	-	-
48	-	-	-	-	-	-	-	-	-
49	-	-	-	-	-	-	-	-	-
50	-	-	-	-	-	-	-	-	-
51	-	-	-	-	-	-	-	-	-
52	-	-	-	-	-	-	-	-	-
53	-	-	-	-	-	-	-	-	-
54	-	-	-	-	-	-	-	-	-
55	-	-	-	-	-	-	-	-	-
56	-	-	-	-	-	-	-	-	-
57	-	-	-	-	-	-	-	-	-

Tab8 Test Results of Nn% (saliva)

Cross reactant	Total tests	Positive results	Negative results	Nn%
H1N1(2009)	9	0	9	100%
Seasonal H1N1 influenza virus	9	0	9	100%
H3N2 influenza virus	9	0	9	100%
H5N1 avian influenza virus	9	0	9	100%
H7N9 avian influenza virus	9	0	9	100%
Influenza B Yamagata	9	0	9	100%
Influenza B Victoria	9	0	9	100%
Respiratory syncytial virus type A	9	0	9	100%
Respiratory syncytial virus type B	9	0	9	100%
Enterovirus A	9	0	9	100%
Enterovirus B	9	0	9	100%
Enterovirus C	9	0	9	100%
Enterovirus D	9	0	9	100%
Parainfluenza virus type 1	9	0	9	100%
Parainfluenza virus type 2	9	0	9	100%

Parainfluenza virus type 3	9	0	9	100%
Rhinovirus A	9	0	9	100%
Rhinovirus B	9	0	9	100%
Rhinovirus C	9	0	9	100%
Adenovirus type 1	9	0	9	100%
Adenovirus type 2	9	0	9	100%
Adenovirus type 3	9	0	9	100%
Adenovirus type 4	9	0	9	100%
Adenovirus type 5	9	0	9	100%
Adenovirus type 7	9	0	9	100%
Adenovirus type 55	9	0	9	100%
Human metapneumovirus	9	0	9	100%
Epstein-Barr virus	9	0	9	100%
Measles virus	9	0	9	100%
Human cytomegalovirus	9	0	9	100%
Rotavirus	9	0	9	100%
Norovirus	9	0	9	100%
Mumps virus	9	0	9	100%
Varicella-zoster virus	9	0	9	100%
Legionella	9	0	9	100%
Bordetella pertussis	9	0	9	100%
Haemophilus influenzae	9	0	9	100%
Staphylococcus aureus	9	0	9	100%
Streptococcus pneumoniae	9	0	9	100%
Streptococcus pyogenes	9	0	9	100%
Klebsiella pneumoniae	9	0	9	100%
Mycobacterium tuberculosis	9	0	9	100%
Mycoplasma pneumoniae	9	0	9	100%
Chlamydia pneumoniae	9	0	9	100%
Aspergillus fumigatus	9	0	9	100%
Candida albicans	9	0	9	100%
Candida glabrata	9	0	9	100%
Cryptococcus neoformans	9	0	9	100%
Cryptococcus gutii	9	0	9	100%
Pneumocystis jirovecii (PJP)	9	0	9	100%
Coronavirus229E	9	0	9	100%
CoronavirusOC43	9	0	9	100%
CoronavirusNL63	9	0	9	100%
Coronavirus HKU1	9	0	9	100%
Coronavirus MERS	9	0	9	100%
Coronavirus SARS	9	0	9	100%
Pooled human nasal wash	9	0	9	100%

Tab9 Test results of saliva specimens (1.5 LOD)

S.N.	A1			A2			A3		
1	+	+	+	+	+	+	+	+	+
2	+	+	+	+	+	+	+	+	+
3	+	+	+	+	+	+	+	+	+
4	+	+	+	+	+	+	+	+	+
5	+	+	+	+	+	+	+	+	+
6	+	+	+	+	+	+	+	+	+
7	+	+	+	+	+	+	+	+	+
8	+	+	+	+	+	+	+	+	+
9	+	+	+	+	+	+	+	+	+
10	+	+	+	+	+	+	+	+	+
11	+	+	+	+	+	+	+	+	+
12	+	+	+	+	+	+	+	+	+
13	+	+	+	+	+	+	+	+	+
14	+	+	+	+	+	+	+	+	+
15	+	+	+	+	+	+	+	+	+
16	+	+	+	+	+	+	+	+	+
17	+	+	+	+	+	+	+	+	+
18	+	+	+	+	+	+	+	+	+
19	+	+	+	+	+	+	+	+	+
20	+	+	+	+	+	+	+	+	+
21	+	+	+	+	+	+	+	+	+
22	+	+	+	+	+	+	+	+	+
23	+	+	+	+	+	+	+	+	+
24	+	+	+	+	+	+	+	+	+
25	+	+	+	+	+	+	+	+	+
26	+	+	+	+	+	+	+	+	+
27	+	+	+	+	+	+	+	+	+
28	+	+	+	+	+	+	+	+	+
29	+	+	+	+	+	+	+	+	+
30	+	+	+	+	+	+	+	+	+
31	+	+	+	+	+	+	+	+	+
32	+	+	+	+	+	+	+	+	+
33	+	+	+	+	+	+	+	+	+
34	+	+	+	+	+	+	+	+	+
35	+	+	+	+	+	+	+	+	+
36	+	+	+	+	+	+	+	+	+
37	+	+	+	+	+	+	+	+	+
38	+	+	+	+	+	+	+	+	+
39	+	+	+	+	+	+	+	+	+
40	+	+	+	+	+	+	+	+	+
41	+	+	+	+	+	+	+	+	+
42	+	+	+	+	+	+	+	+	+

43	+	+	+	+	+	+	+	+	+
44	+	+	+	+	+	+	+	+	+
45	+	+	+	+	+	+	+	+	+
46	+	+	+	+	+	+	+	+	+
47	+	+	+	+	+	+	+	+	+
48	+	+	+	+	+	+	+	+	+
49	+	+	+	+	+	+	+	+	+
50	+	+	+	+	+	+	+	+	+
51	+	+	+	+	+	+	+	+	+
52	+	+	+	+	+	+	+	+	+
53	+	+	+	+	+	+	+	+	+
54	+	+	+	+	+	+	+	+	+
55	+	+	+	+	+	+	+	+	+
56	+	+	+	+	+	+	+	+	+
57	+	+	+	+	+	+	+	+	+

Tab10 Test Results of Np% (1.5 LOD)

Cross reactant	Total tests	Positive results	Negative results	Np%
H1N1(2009)	9	9	0	100%
Seasonal H1N1 influenza virus	9	9	0	100%
H3N2 influenza virus	9	9	0	100%
H5N1 avian influenza virus	9	9	0	100%
H7N9 avian influenza virus	9	9	0	100%
Influenza B Yamagata	9	9	0	100%
Influenza B Victoria	9	9	0	100%
Respiratory syncytial virus type A	9	9	0	100%
Respiratory syncytial virus type B	9	9	0	100%
Enterovirus A	9	9	0	100%
Enterovirus B	9	9	0	100%
Enterovirus C	9	9	0	100%
Enterovirus D	9	9	0	100%
Parainfluenza virus type 1	9	9	0	100%
Parainfluenza virus type 2	9	9	0	100%
Parainfluenza virus type 3	9	9	0	100%
Rhinovirus A	9	9	0	100%
Rhinovirus B	9	9	0	100%
Rhinovirus C	9	9	0	100%
Adenovirus type 1	9	9	0	100%
Adenovirus type 2	9	9	0	100%
Adenovirus type 3	9	9	0	100%
Adenovirus type 4	9	9	0	100%

Adenovirus type 5	9	9	0	100%
Adenovirus type 7	9	9	0	100%
Adenovirus type 55	9	9	0	100%
Human metapneumovirus	9	9	0	100%
Epstein-Barr virus	9	9	0	100%
Measles virus	9	9	0	100%
Human cytomegalovirus	9	9	0	100%
Rotavirus	9	9	0	100%
Norovirus	9	9	0	100%
Mumps virus	9	9	0	100%
Varicella-zoster virus	9	9	0	100%
Legionella	9	9	0	100%
Bordetella pertussis	9	9	0	100%
Haemophilus influenzae	9	9	0	100%
Staphylococcus aureus	9	9	0	100%
Streptococcus pneumoniae	9	9	0	100%
Streptococcus pyogenes	9	9	0	100%
Klebsiella pneumoniae	9	9	0	100%
Mycobacterium tuberculosis	9	9	0	100%
Mycoplasma pneumoniae	9	9	0	100%
Chlamydia pneumoniae	9	9	0	100%
Aspergillus fumigatus	9	9	0	100%
Candida albicans	9	9	0	100%
Candida glabrata	9	9	0	100%
Cryptococcus neoformans	9	9	0	100%
Cryptococcus gutii	9	9	0	100%
Pneumocystis jirovecii (PJP)	9	9	0	100%
Coronavirus229E	9	9	0	100%
CoronavirusOC43	9	9	0	100%
CoronavirusNL63	9	9	0	100%
Coronavirus HKU1	9	9	0	100%
Coronavirus MERS	9	9	0	100%
Coronavirus SARS	9	9	0	100%
Pooled human nasal wash	9	9	0	100%

Tab11 Test results of saliva specimens (3 LOD)

S.N.	A1			A2			A3		
1	+	+	+	+	+	+	+	+	+
2	+	+	+	+	+	+	+	+	+
3	+	+	+	+	+	+	+	+	+
4	+	+	+	+	+	+	+	+	+
5	+	+	+	+	+	+	+	+	+
6	+	+	+	+	+	+	+	+	+
7	+	+	+	+	+	+	+	+	+

8	+	+	+	+	+	+	+	+	+
9	+	+	+	+	+	+	+	+	+
10	+	+	+	+	+	+	+	+	+
11	+	+	+	+	+	+	+	+	+
12	+	+	+	+	+	+	+	+	+
13	+	+	+	+	+	+	+	+	+
14	+	+	+	+	+	+	+	+	+
15	+	+	+	+	+	+	+	+	+
16	+	+	+	+	+	+	+	+	+
17	+	+	+	+	+	+	+	+	+
18	+	+	+	+	+	+	+	+	+
19	+	+	+	+	+	+	+	+	+
20	+	+	+	+	+	+	+	+	+
21	+	+	+	+	+	+	+	+	+
22	+	+	+	+	+	+	+	+	+
23	+	+	+	+	+	+	+	+	+
24	+	+	+	+	+	+	+	+	+
25	+	+	+	+	+	+	+	+	+
26	+	+	+	+	+	+	+	+	+
27	+	+	+	+	+	+	+	+	+
28	+	+	+	+	+	+	+	+	+
29	+	+	+	+	+	+	+	+	+
30	+	+	+	+	+	+	+	+	+
31	+	+	+	+	+	+	+	+	+
32	+	+	+	+	+	+	+	+	+
33	+	+	+	+	+	+	+	+	+
34	+	+	+	+	+	+	+	+	+
35	+	+	+	+	+	+	+	+	+
36	+	+	+	+	+	+	+	+	+
37	+	+	+	+	+	+	+	+	+
38	+	+	+	+	+	+	+	+	+
39	+	+	+	+	+	+	+	+	+
40	+	+	+	+	+	+	+	+	+
41	+	+	+	+	+	+	+	+	+
42	+	+	+	+	+	+	+	+	+
43	+	+	+	+	+	+	+	+	+
44	+	+	+	+	+	+	+	+	+
45	+	+	+	+	+	+	+	+	+
46	+	+	+	+	+	+	+	+	+
47	+	+	+	+	+	+	+	+	+
48	+	+	+	+	+	+	+	+	+
49	+	+	+	+	+	+	+	+	+
50	+	+	+	+	+	+	+	+	+

51	+	+	+	+	+	+	+	+	+
52	+	+	+	+	+	+	+	+	+
53	+	+	+	+	+	+	+	+	+
54	+	+	+	+	+	+	+	+	+
55	+	+	+	+	+	+	+	+	+
56	+	+	+	+	+	+	+	+	+
57	+	+	+	+	+	+	+	+	+

Tab12 Test Results of Np% (3 LOD)

Cross reactant	Total tests	Positive results	Negative results	Np%
H1N1(2009)	9	9	0	100%
Seasonal H1N1 influenza virus	9	9	0	100%
H3N2 influenza virus	9	9	0	100%
H5N1 avian influenza virus	9	9	0	100%
H7N9 avian influenza virus	9	9	0	100%
Influenza B Yamagata	9	9	0	100%
Influenza B Victoria	9	9	0	100%
Respiratory syncytial virus type A	9	9	0	100%
Respiratory syncytial virus type B	9	9	0	100%
Enterovirus A	9	9	0	100%
Enterovirus B	9	9	0	100%
Enterovirus C	9	9	0	100%
Enterovirus D	9	9	0	100%
Parainfluenza virus type 1	9	9	0	100%
Parainfluenza virus type 2	9	9	0	100%
Parainfluenza virus type 3	9	9	0	100%
Rhinovirus A	9	9	0	100%
Rhinovirus B	9	9	0	100%
Rhinovirus C	9	9	0	100%
Adenovirus type 1	9	9	0	100%
Adenovirus type 2	9	9	0	100%
Adenovirus type 3	9	9	0	100%
Adenovirus type 4	9	9	0	100%
Adenovirus type 5	9	9	0	100%
Adenovirus type 7	9	9	0	100%
Adenovirus type 55	9	9	0	100%
Human metapneumovirus	9	9	0	100%
Epstein-Barr virus	9	9	0	100%
Measles virus	9	9	0	100%
Human cytomegalovirus	9	9	0	100%
Rotavirus	9	9	0	100%

Norovirus	9	9	0	100%
Mumps virus	9	9	0	100%
Varicella-zoster virus	9	9	0	100%
Legionella	9	9	0	100%
Bordetella pertussis	9	9	0	100%
Haemophilus influenzae	9	9	0	100%
Staphylococcus aureus	9	9	0	100%
Streptococcus pneumoniae	9	9	0	100%
Streptococcus pyogenes	9	9	0	100%
Klebsiella pneumoniae	9	9	0	100%
Mycobacterium tuberculosis	9	9	0	100%
Mycoplasma pneumoniae	9	9	0	100%
Chlamydia pneumoniae	9	9	0	100%
Aspergillus fumigatus	9	9	0	100%
Candida albicans	9	9	0	100%
Candida glabrata	9	9	0	100%
Cryptococcus neoformans	9	9	0	100%
Cryptococcus gutii	9	9	0	100%
Pneumocystis jirovecii (PJP)	9	9	0	100%
Coronavirus229E	9	9	0	100%
CoronavirusOC43	9	9	0	100%
CoronavirusNL63	9	9	0	100%
Coronavirus HKU1	9	9	0	100%
Coronavirus MERS	9	9	0	100%
Coronavirus SARS	9	9	0	100%
Pooled human nasal wash	9	9	0	100%

11.3 Results for Interference Substances Study

Tab13 Results of testing interference saliva samples(negative)

	Substances	Concentration	A1					A2					A3				
1	Whole Blood	10%(v/v)	-	-	+	+	-	-	-	-	-	+	-	-	-	-	-
		4%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	Mucin	1%(v/v)	+	+	+	-	+	+	+	+	-	-	+	+	+	+	+
		0.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.25%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	Ricola (Menthol)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	Sucrets (Dyclonin)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	Sucrets (Menthol)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	Chloraseptic (Menthol)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	Chloraseptic (Benzocaine)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	Naso GEL (NeilMed)	5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	CVS Nasal Drops (Phenylephrine)	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	Afrin (Oxymetazoline)	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	CVS Nasal Spray (Cromolyn)	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	Nasal Gel (Oxymetazoline)	10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	Zicam	5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	Homeopathic (Alkalol)	1:10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1:15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1:20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	Fisherman's Friend	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	Sore Throat Phenol Spray	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	Tobramycin	4μg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2μg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1μg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	Mupirocin	10mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	Fluticasone Propionate	5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

20	Tamiflu (Oseltamivir Phosphate)	5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Tab14 Results of testing interference saliva samples (positive)

	Substances	Concentration	A1					A2					A3				
1	Whole Blood	10%(v/v)	+	-	+	+	+	-	-	-	+	+	+	-	-	+	+
		4%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
2	Mucin	1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.25%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
3	Ricola (Menthol)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
4	Sucrets (Dyclonin)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
5	Sucrets (Menthol)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
6	Chloraseptic (Menthol)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Chloraseptic (Benzocaine)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
8	Naso GEL (NeilMed)	5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
9	CVS Nasal Drops (Phenylephrine)	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
10	Afrin (Oxymetazoline)	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
11	CVS Nasal Spray (Cromolyn)	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
12	Nasal Gel (Oxymetazoline)	10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
13	Zicam	5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Homeopathic (Alkalol)	1:10	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1:15	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1:20	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
15	Fisherman's Friend	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
16	Sore Throat Phenol Spray	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
17	Tobramycin	4μg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2μg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1μg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
18	Mupirocin	10mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
19	Fluticasone Propionate	5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
20	Tamiflu (Oseltamivir Phosphate)	5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Tab15 Results summary of interference experiment

Substances	Concentration	Ri	Fp	Fn
Whole Blood	10%(v/v)	0	20%	40%
	4%(v/v)	0	0	0
	1%(v/v)	0	0	0
Mucin	1%(v/v)	0	80%	0
	0.5%(v/v)	0	0	0
	0.25%(v/v)	0	0	0
Ricola (Menthol)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Sucrets (Dyclonin)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Sucrets (Menthol)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Chloraseptic (Menthol)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Chloraseptic	1.5mg/mL	0	0	0

(Benzocaine)	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Naso GEL (NeilMed)	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
	1%(v/v)	0	0	0
CVS Nasal Drops (Phenylephrine)	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
Afrin (Oxymetazoline)	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
CVS Nasal Spray (Cromolyn)	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
Nasal Gel (Oxymetazoline)	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
Zicam	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
	1%(v/v)	0	0	0
Homeopathic (Alkalol)	1:10	0	0	0
	1:15	0	0	0
	1:20	0	0	0
Fisherman’s Friend	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Sore Throat Phenol Spray	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
Tobramycin	4μg/mL	0	0	0
	2μg/mL	0	0	0
	1μg/mL	0	0	0
Mupirocin	10mg/mL	0	0	0
	5mg/mL	0	0	0
	2.5mg/mL	0	0	0
Fluticasone Propionate	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
	1%(v/v)	0	0	0
Tamiflu (Oseltamivir Phosphate)	5mg/mL	0	0	0
	2.5mg/mL	0	0	0
	1mg/mL	0	0	0
	2.5mg/mL	0	0	0
	1mg/mL	0	0	0

11.4 Results for Clinical Trials

11.4.1 Results analysis table

Tab16 Analysis table of clinical specimens' results (Saliva)

		PCR result		
		Positive	Negative	Total
Rapid COVID-19 Antigen Test (Colloidal Gold) result	Positive	524(a)	0(b)	524(a+b)
	Negative	26(c)	123(d)	149(c+d)
	Total	550(a+c)	123(b+d)	673(a+b+c+d)

11.4.2Coincidence rate and 95% confidence interval

Tab17 Coincidence rate and 95% confidence interval

	Coincidence rate	95% confidence interval
Clinical sensitivity	95.27%	93.15%~96.89%
Clinical specificity	100%	97.05%~100%
Total coincidence rate	96.14%	94.39%~97.46%

11.4.3 Statistical Analysis

Kappa value (K) calculation

K = 0.8805 > 0.75 indicates that the high consistency of two methods and equivalence of two such systems.

11.4.4 Separate analysis

(1) Clinical classification

Tab18 Analysis table of different Clinical classification

	Mild	Moderate	Severe	Critically ill
PCR result	437	76	25	12
Product result	418	69	25	12
PPA	95.65%	90.79%	100%	100%

(2) Clinical classification

Tab19 Analysis table of different days from symptom onset

	0-7 days	>7 days
PCR result	486	64
Product result	465	59
PPA	95.68%(95% CI:93.47%~97.31%)	92.19%(95% CI:82.70%~97.42%)

Simultaneous PCR and antigen testing were performed on 486 patients with new coronavirus infections whose symptoms appeared within 0-7 days. The sensitivity of antigen detection is 95.68% (95% CI: 93.47%~97.31%).

11.4.5 Determination of diagnostic sensitivity (0-7 days after the onset of symptoms)

	Statistics
Sample number	Antigen-positive:465, Antigen-negative:21
Ct value average(PCR-positive)	34.68
Ct value average(antigen-positive / PCR-positive)	34.53
Ct value average(antigen-negative / PCR-positive)	37.54

Ct value average(Detection rate> 90%)	34.21

12. Conclusion

12.1 Limit of Detection (LoD)

	Estimated LOD/Cut off	No. Positive/Total	% Positive
saliva specimen	4.25 x10^2 $TCID_{50}$/mL	58/60	96.7%

The LOD/Cut-off value of the Rapid COVID-19 Antigen Test (Colloidal Gold) is 4.25 x10^2 $TCID_{50}$/mL.

12.2 Cross-Reactivity

None of the viral and microbial pathogens tested at the concentrations indicated interfere with the test results of negative or positive samples in Rapid COVID-19 Antigen Test (Colloidal Gold).

Tab20 Non-interfering Viruses / Microbials

S.N.	Viruses / Microbials	Species	Concentration tested
1	H1N1(2009)	A-H1N1-2009	10^6pfu/mL
2	Seasonal H1N1 influenza virus	A-H1N1	10^6pfu/mL
3	H3N2 influenza virus	A-H3N2	10^6pfu/mL
4	H5N1 avian influenza virus	A-H5N1	10^6pfu/mL
5	H7N9 avian influenza virus	A-H7N9	10^6pfu/mL
6	Influenza B Yamagata	B-Yamagata	10^6pfu/mL
7	Influenza B Victoria	B-Victoria	10^6pfu/mL
8	Respiratory syncytial virus type A	RSV-A2	10^6pfu/mL
9	Respiratory syncytial virus type B	RSV-B	10^6pfu/mL
10	Enterovirus A	CV-A10	10^6pfu/mL
11	Enterovirus B	Echovirus 6	10^6pfu/mL
12	Enterovirus C	CV-A21	10^6pfu/mL
13	Enterovirus D	EV-D68	10^6pfu/mL
14	Parainfluenza virus type 1	HPIVs-1	10^6pfu/mL
15	Parainfluenza virus type 2	HPIVs-2	10^6pfu/mL
16	Parainfluenza virus type 3	HPIVs-3 VR-93	10^6pfu/mL
17	Rhinovirus A	HRV-9 VR-489	10^6pfu/mL
18	Rhinovirus B	HRV-52 VR-1162 HRV-3 VR-1113	10^6pfu/mL

19	Rhinovirus C	HRV-16 VR-283	10^6pfu/mL
20	Adenovirus type 1	HadV-1 VR-1	10^6pfu/mL
21	Adenovirus type 2	HadV-2 VR-846	10^6pfu/mL
22	Adenovirus type 3	HadV-3	10^6pfu/mL
23	Adenovirus type 4	HadV-4 VR-1572	10^6pfu/mL
24	Adenovirus type 5	HAdV-5 VR-1578/1516	10^6pfu/mL
25	Adenovirus type 7	HAdV-7 VR-7	10^6pfu/mL
26	Adenovirus type 55	HAdV-55	10^6pfu/mL
27	Human metapneumovirus	HMPV	10^6pfu/mL
28	Epstein-Barr virus	HHV-4 VR-1492	10^6pfu/mL
29	Measles virus	MV VR-24	10^6pfu/mL
30	Human cytomegalovirus	HHV-5 VR-977	10^6pfu/mL
31	Rotavirus	RV VR-2018	10^6pfu/mL
32	Norovirus	NOR	10^6pfu/mL
33	Mumps virus	MuV VR-106	10^6pfu/mL
34	Varicella-zoster virus	VZV VR-1367	10^6pfu/mL
35	Legionella	33152	10^7cfu/mL
36	Bordetella pertussis	BAA-589	10^7cfu/mL
37	Haemophilus influenzae	Hib	10^7cfu/mL
38	Staphylococcus aureus	CGMCC 1.2910	10^7cfu/mL
39	Streptococcus pneumoniae	CGMCC 1.8722	10^7cfu/mL
40	Streptococcus pyogenes	CGMCC 1.8868	10^7cfu/mL
41	Klebsiella pneumoniae	CGMCC 1.1736	10^7cfu/mL
42	Mycobacterium tuberculosis	25177	10^7cfu/mL
43	Mycoplasma pneumoniae	39505	10^7cfu/mL
44	Chlamydia pneumoniae	VR-2282	10^7cfu/mL
45	Aspergillus fumigatus	AF293	10^7cfu/mL
46	Candida albicans	SC5314	10^7cfu/mL

47	Candida glabrata	ATCC 2001	10^7cfu/mL
48	Cryptococcus neoformans	H99	10^7cfu/mL
49	Cryptococcus gutii	R265	10^7cfu/mL
50	Pneumocystis jirovecii (PJP)	CGMCC 1.9054	10^7cfu/mL
51	Coronavirus229E	VR-740	10^6pfu/mL
52	CoronavirusOC43	VR-1558	10^6pfu/mL
53	CoronavirusNL63	COV-NL63	10^6pfu/mL
54	Coronavirus HKU1	COV-HKU1	10^6pfu/mL
55	Coronavirus MERS	MERS	10^8TU/mL
56	Coronavirus SARS	SARS	10^8TU/mL
57	Pooled human nasal wash	/	10^7cfu/mL

12.3 Interference Substances Study

None of the substances tested at the concentrations indicated interfere with the test results of negative or positive samples in Rapid COVID-19 Antigen Test (Colloidal Gold).

Tab21 Non-interfering Substances

S.N.	Substance Name	Concentration	S.N.	Substance Name	Concentration
1	Whole Blood	4%(v/v)	11	CVS Nasal Spray (Cromolyn)	15%(v/v)
2	Mucin	0.5%(v/v)	12	Nasal Gel (Oxymetazoline)	10%(v/v)
3	Ricola (Menthol)	1.5mg/mL	13	Zicam	5%(v/v)
4	Sucrets (Dyclonin)	1.5mg/mL	14	Homeopathic (Alkalol)	1:10
5	Sucrets (Menthol)	1.5mg/mL	15	Fisherman's Friend	1.5mg/mL
6	Chloraseptic (Menthol)	1.5mg/mL	16	Sore Throat Phenol Spray	15%(v/v)
7	Chloraseptic (Benzocaine)	1.5mg/mL	17	Tobramycin	4μg/mL
8	Naso GEL (NeilMed)	5%(v/v)	18	Mupirocin	10mg/mL
9	CVS Nasal Drops (Phenylephrine)	15%(v/v)	19	Fluticasone Propionate	5%(v/v)
10	Afrin (Oxymetazoline)	15%(v/v)	20	Tamiflu (Oseltamivir Phosphate)	5mg/mL

12.4 Clinical Trials

(1) In summary, 572 samples were tested in this clinical trial, Among them, there were 562 cases with product test results consistent with RT-PCR result in this clinical trial, included 221 cases were positive, 341 cases were negative.

(2) There were overall 10 cases of product test results inconsistent with RT-PCR result in this clinical trial due to the difference in methodologies used.

Tab22 Inconsistent results

No.	Sampling day	Age	Sex (F/M)	Days from Symptom Onset	Clinical classification	Saliva result	PCR result			
							Ct value (RdRP)	Ct value (N gene)	Ct value (E gene)	result
3	2020/9/1	67	F	2	Moderate	-	36	37	39	+
19	2020/9/11	42	F	9	Mild	-	38	38	36	+
42	2020/10/1	51	F	4	Mild	-	36	/	38	+
50	2020/10/1	60	M	4	Mild	-	37	41	/	+
51	2020/10/1	47	F	2	Mild	-	39	/	37	+
80	2020/10/9	27	F	6	Mild	-	37	37	36	+
89	2020/10/9	37	M	2	Mild	-	38	39	/	+
90	2020/10/9	71	M	2	Mild	-	39	/	/	+
99	2020/10/9	62	M	4	Moderate	-	39	38	38	+
115	2020/10/16	59	F	1	Mild	-	34	35	36	+
122	2020/11/2	42	F	3	Mild	-	37	/	38	+
124	2020/11/2	64	M	8	Moderate	-	40	36	38	+
135	2020/11/2	31	M	1	Moderate	-	37	40	38	+
143	2020/11/13	18	F	4	Mild	-	35	35	38	+
146	2020/11/13	31	M	6	Moderate	-	35	35	/	+
165	2020/11/16	64	M	8	Mild	-	35	37	37	+
166	2020/11/16	33	F	2	Moderate	-	36	38	37	+
171	2020/11/16	50	F	1	Moderate	-	39	/	/	+
182	2020/11/21	54	F	5	Mild	-	37	38	40	+
203	2020/11/25	56	F	10	Mild	-	39	41	40	+
215	2020/11/30	31	M	3	Mild	-	37	39	38	+
269	2020/12/05	17	F	2	Mild	-	39	41	39	+
281	2020/12/05	11	F	2	Mild	-	39	/	40	+
334	2020/12/10	77	F	2	Mild	-	39	38	41	+
395	2020/12/13	71	F	14	Mild	-	39	39	38	+
522	2021/01/07	23	M	1	Mild	-	40	41	/	+

(3) The sensitivity, specificity and total coincidence rate of product testing and RT-PCR result are 95.27%,100% and 96.14%, respectively. The sensitivity is more than 95%, the specificity is more than 99%.

(4) K = 0.8805 > 0.75 indicates that the high consistency of two methods and equivalence of two such systems.

(5) 486 patients with new coronavirus infections whose symptoms appeared within 0-7 days. The

sensitivity of antigen detection is 95.68%(95% CI:93.47%~97.31%).

(6) 486 patients with new coronavirus infections whose symptoms appeared within 0-7 days. The Ct value average (PCR-positive) is 34.68; the Ct value average (antigen-positive / PCR-positive) Is 34.53; the Ct value average (antigen-negative / PCR-positive) is 37.54; Diagnostic sensitivity: The Cut-off value (Ct value average) of this reagent is 34.21 (Detection rate> 90%).

(7) The specificity rate of antigen testing and RT-PCR result are 100% for 123 Non-infected.