SARS-CoV-2 Antigen Detection Kit (Saliva)

Clinic Evaluation Report

Product Name: **SARS-CoV-2 Antigen Detection Kit (Saliva)**

Model No.: **1 test/kit, 2tests/kit, 5tests/kit, 20tests/kit,25tests/kit**

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Revision history

Revision Content	Revision Reason	Revision Date	Revised By	Document No. & Version	Remark

1 Product Review

Product Name: SARS-CoV-2 Antigen Detection Kit (Saliva)

Type：CovAg-S

Specification:1 test/kit, 2tests/kit, 5tests/kit, 20tests/kit,25tests/kit

Manufacturer: NINGBO LVTANG BIOTECHNOLOGYCO.,LTD.

2 Intended Use

This product is used for qualitative detection of SARS-CoV-2 antigen in saliva samples.

The SARS-CoV-2 belongs to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the SARS-CoV-2 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.

3 Technical Principles

This kit uses immunochromatography for detection. The specimen will move forward along the test card under capillary action. If the specimen contains a SARS-CoV-2 antigen, the antigen will bind to the colloidal gold-labeled SARS-CoV-2 monoclonal antibody. The immune complex will be membrane fixed will be SARS-CoV-2 monoclonal antibody capture, form the fuchsia line, display will be SARS-CoV-2 antigen positive; If the line does not show color, the negative result will be displayed. The test card also contains a quality control line C, which shall appear fuchsia regardless of whether there is a detection line.

4 Background of Clinical Evaluation

Typical symptoms: fever, fatigue and dry cough are the main manifestations, and dyspnea may occur in severe cases.

Common symptoms: the incubation period of this disease is generally 3 ~ 7 days,and the longest is not more than 14 days. Fever,fatigue and dry cough are the main manifestations. A few patients have nasal obstruction, runny nose, diarrhea and other symptoms. Severe cases usually have dyspnea after 1 week. Severe cases rapidly progress to acute respiratory distress syndrome, septic shock, metabolic acidosis which is difficult to correct, and coagulation dysfunction.

Other symptoms: Some patients showed only low fever, slight fatigue, etc., no pneumonia, and recovered after 1 week.

5 Section of Clinical Assessment Data

5.1 Overview of the Clinical Evaluation Phase

Clinically evaluate according to the flow chart 1.

5.2 Literature Retrieval

5.2.1 Scope of document retrieval

Literature covering the clinical application, performance, safety and adverse events of the product.

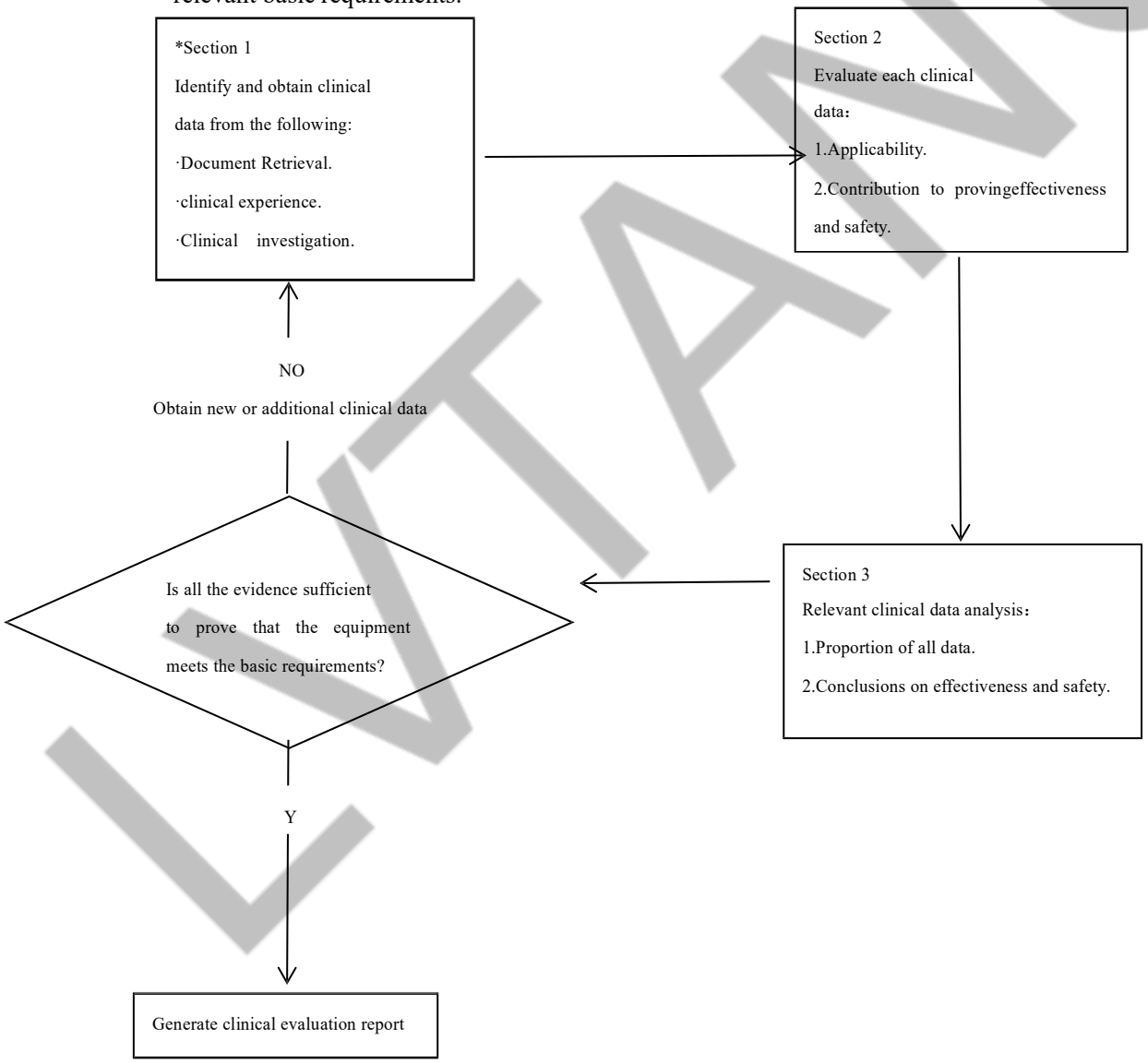
5.2.2 The year-range of document retrieval

2019~ present.

5.2.3 Literature resources:CNKI;Wanfang Database;PUBMED;NMPA.

Flow Chart 1

Meeting the requirements of the coordination standards can be considered to fully meet the relevant basic requirements.



6 Analysis and evaluation of clinical data

6.1Applicability Evaluation

The applicability of the retrieved literature was identified by flow chart 2 and table 1.

Flow Chart 2

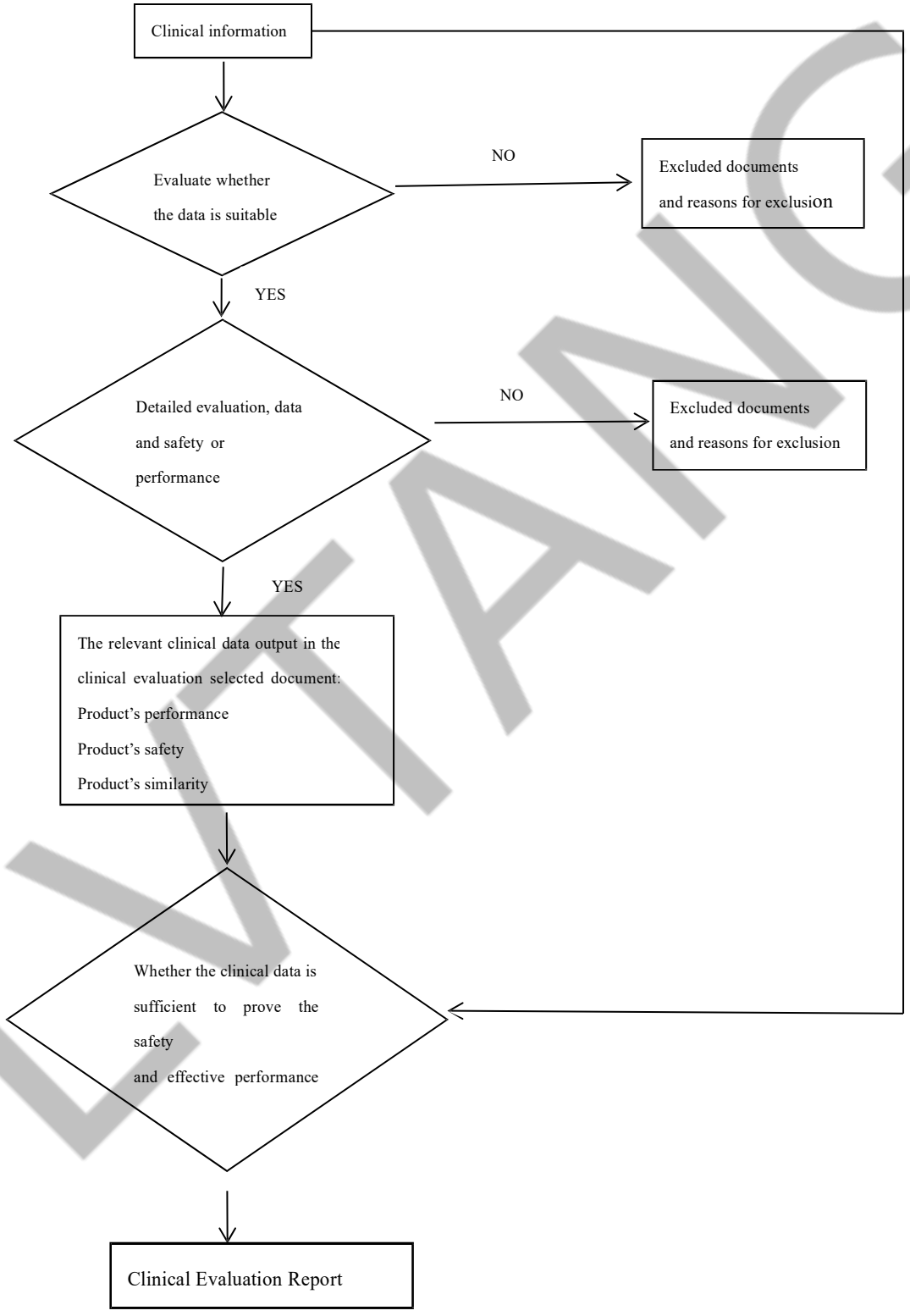


Table 1: Literature Applicability Evaluation Criteria

Applicability Standard	Description	Classification System
Proper product	Is the data generated from the product to be evaluated?	□ D1 Actual instrument ■ D2 Equal instrument □ D3 Other instrument
Proper clinical application	Is the intended use of the product same?	□ A1 Same usage ■ A2 Nuance □ A3 Great difference
Proper patient population	Does the patient population collecting data represent the intended application population?	□ P1 Applicable ■ P2 Partially applicable □ P3 Different
Proper patient population	Does the patient population collecting data represent the intended application population?	□ P1 Applicable ■ P2 Partially applicable □ P3 Different
Selection report/data sorting	Does the report or data include enough information for a rational and objective evaluation?	■ R1 High quality □ R2 Minor defect □ R3 Lack of information

6.2 Literature Search Results

The literature related to the intended evaluation of the device is as follows:

1) Test report
2) 5 pcs of reference
3) Adverse Event Report

The kit is found to have no adverse events for similar products within the range of retrieval.

6.3 Data Evaluation

6.3.1 Evaluation Criteria of Data Contribution Rate

Table 2: Evaluation Criteria of Data Contribution Rate

Data Contribution Criteria	Description	Classification System
Data source type	Is the research method appropriate?	■ T1 Yes □ T2 No
Result measurement	Does the reported result reflect the expected performance of the product?	■ T1 Yes □ T2 No
Statistical significance	Have the statistical analysis been done? Is the statistical analysis method appropriate?	■ S1 Yes □ S2 No
Clinical significance	Is the significance of clinical observation important?	■ C1 Yes □ C2 No

6.3.2Data Contribution Rate Evaluation

Table 3: Data Contribution Rate Evaluat

Draft evaluation	Cited References	Data Source	Description	Classification system
	Analytical Performance Study	Ningbo Lvtang Biotechnology Co.,Ltd.	Performance research includes testing and verification studies of technical requirements indicators.	D1 Draft evaluation Device D2 Similar Device
	QAQC Process Control File	Ningbo Lvtang Biotechnology Co.,Ltd.	Inspect the product to ensure that the product meets performance requirements.	D1 Draft evaluation Device D2 Similar Device D3 Other
	Stability Study Report	Ningbo Lvtang Biotechnology Co.,Ltd.	Verify the stability of the product's packaging, transportation and storage life to ensure the safety and effectiveness of the product	■ D1 Draft evaluation device □ D2 Similar Device □ D3 Other
2.Post-marketing adverse events	Adverse event report	Website of national adverse drug reaction monitoring center.	No adverse events were reported	□D1 Draft evaluation Device D2 Similar Device D3 Other
3. Residual risk and potential risk	Risk analysis and Control Summary	Ningbo Lvtang Biotechnology Co.,Ltd.	It was suitable for the analysis of the product	D1 Draft evaluation Device D2 Similar Device D3 Other

7 Introduction of Clinical trials

7.1 To prove the Kits' safety and effectiveness, clinical trials are necessary.

7.2 Clinical trials were conducted in March 15,2020~May 21,2020

7.3 The clinical trial medical unit is Wuhan Zhongshan Hospital,Wuhan No.3 People's Hospital,Shanghai Public Health Clinical Center.

8 Performance

8.1 Saliva:clinical results(professional test)

A total of 437 various types of samples are tested. Compared with the COVID-19 Coronavirus Real Time PCR Kit (RT-PCR), the SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Method) (See below Table for details)shows Sensitivity: 91.67%（95%CI：88.15%-95.19%）, Specificity:99.64%（95%CI：98.2%-100%）, Accuracy: 96.80%（95%CI：94.12%-99.48%）.

Clinical sample		COVID-19 Coronavirus Real Time PCR Kit (RT-PCR)(Nasopharyngeal swab)		Total
		Positive	Negative	
SARS-CoV-2 Antigen Detection Kit (Saliva)	Positiv	143(a)	1(b)	144
	Negativ	13(c)	280(d)	293
Total		156	281	437

Sensitivity: 91.67%（95%CI：88.15%-95.19%）

Specificity:99.64%（95%CI：98.2%-100%）

Accuracy: 96.80%（95%CI：94.12%-99.48%）

Coincidence rate analysis:

Positive coincidence rate=a/(a+c) ×100%=91.67%（95%CI：88.15%-95.19%）

Negative coincidence rate=d/(b+d) ×100%=99.64%（95%CI：98.2%-100%）

Accuracy=(a+d)/(a+b+c+d) ×100%=96.80%（95%CI：94.12%-99.48%）

Sensitivity=a/(a+c) ×100%=91.67%

Specificity=d/(d+b) ×100%=99.64%

Please see the attachment<Clinic Evaluation Report> for more details.

8.2 Saliva:clinical results(Selt- test)

In total 60 tests users were included in the summative evaluation.Since the summative evaluation is designed as a coherent study, more subjects are recruited in advance than specified to ensure the required minimum number of participants. Test user IDs are already assigned during the recruitment phase. As a consequence Test user IDs greater than the required number occur in the evaluation.

The test user sample is representative and shows the following demographic characteristics:

	Number of Test Users
Gender	
Female	31
Male	29
Age	
Group 1 = 15 to 30 years	18
Group 1 = 15 to 30 years	13
Group2 = 30 to 60 years	30
Group 3= 60 to 80 years	17
Median (years)	43
Range (years)	18-75
Education Level	

Group 0 = no degree	0
Group 1 = school graduation or vocational education	10
Group 2 = master craftsman/technician training	25
Group 3 = bachelor's degree	10
Group 4 = master's degree	8
Group 5 = doctoral degree	7
Professional Background (educational or occupational)	
Medical background	0
Non-medical background	60
COVID-19 RT-PCR Results in the Past 7 Days	
Positive	30
Negative	30

After counting the results of the above-mentioned self-test by non-professionals,arrange for the above-mentioned participants to go to the hospital for PCR testing,and all the test results are counted as follows:

Professional test		Professional test		Total
		Positive	Negative	
Self-test	Positive	30	0	30
	Negative	0	30	30
Total		30	30	60

Sensitivity= 30/(30 + 0) × 100% =1 00%; 95% Cl: 88 4%- 100.0%
Specificity = 30/ (0 + 30) × 100% =100%; 95% Cl: 88.4% - 100.0%

8.3 Research on interfering substances and cross-reaction

SARS-CoV-2 Antigen Detection Kit with influenza A H1N1, influenza A H3N2, influenza A H5N1, influenza B Yamagata, influenza B Victoria, respiratory syncytial virus type A, respiratory syncytial virus type B, rhinovirus A, rhinovirus B, adenovirus type 1, adenovirus type 2, adenovirus type 3.Adenovirus type 4, adenovirus type 5, adenovirus type 7, EBV, measles virus, human cytomegalovirus, rotavirus, norovirus, mumps virus, varicella-zoster virus, Mycoplasma pneumoniae, coronavirus HKU1, OC43, NL63, 229E and MERS antigen-positive samples do not cross-react.

The results of the SARS-CoV-2 Antigen Detection Kit were independent of allergic symptoms (histamine hydrochloride), antivirals (a-interferon, zanamivir, ribavirin, oseltamivir, paramivir, lopinavir, ritonavir, abiraterol), antibiotics (levofloxacin, azithromycin, ceftriaxone, meropenem), systemic antimicrobials (Tobramycin) interference samples do not cross-react.

8.3.1 Interference and cross-reaction (Test samples with all types of potential interferences) Cross-reaction studies

Cross-reaction study

8.3.1.1 Test samples

No.	Name	Source	Sample name	Batch/model	Concentration
1	Influenza A H1N1	zeptometrix	Influenza A H1N1 (New Cal/20/99) Culture Fluid (1 mL)	#0810036CF	1×10^6PFU/mL
2	Influenza A H1N1 (Seasonal)	zeptometrix	Influenza A H1N1 (Seasonal) Culture Fluid (1 mL)	#0810037CF	1×10^6PFU/mL
3	Influenza A H3N2	zeptometrix	Influenza A H3N2 (Brisbane/10/07) Culture Fluid (1 mL)	#0810138CF	1×10^6PFU/mL
4	Influenza A H5N1	zeptometrix	Influenza A H5N1 Culture Fluid (1 mL)	#0810148CF	1×10^6PFU/mL
5	Influenza B Yamagata	zeptometrix	Influenza B (Yamagata/16/88) Culture Fluid (1 mL)	#0810518CF	1×10^5PFU/mL
6	Influenza B Victoria	zeptometrix	Influenza B (Victoria/2/87) Culture Fluid (1 mL)	#0810571CF	1×10^6PFU/mL
7	Haemophilus Influenzae	zeptometrix	Haemophilus Influenzae Culture Fluid (1 mL)	#0810178CF	5.20×10^6 CFU/mL
8	Respiratory Syncytial Virus Type A	zeptometrix	Respiratory Syncytial Virus Type A (RSV-A) Culture Fluid (1 mL)	#0810040ACF	5.50×10^7PFU/mL
9	Respiratory Syncytial Virus Type B	zeptometrix	Respiratory Syncytial Virus Type B (RSV-B) Culture Fluid (1 mL)	#0810040CF	$2.80\times10^6TCID_{50}$/mL
10	Rhinovirus Type 1A	zeptometrix	Rhinovirus Type 1A Culture Fluid (1 mL)	#0810012CFN	1.00×10^6PFU/mL
11	Rhinovirus B14	zeptometrix	Rhinovirus B14 Culture Fluid (1 mL)	#0810284CF	1.04×10^6PFU/mL
12	Adenovirus Type 1	zeptometrix	Adenovirus Type 1 Culture Fluid (1 mL)	#0810050CF	$4.05\times10^7TCID_{50}$/mL
13	Adenovirus Type 2	zeptometrix	Adenovirus Type 2 Culture Fluid (1 mL)	#0810110CF	$6.13\times10^7TCID_{50}$/mL
14	Adenovirus Type 3	zeptometrix	Adenovirus Type 3 Culture Fluid (1 mL)	#0810062CF	$5.01\times10^7TCID_{50}$/mL
15	Adenovirus Type 4	zeptometrix	Adenovirus Type 4 Culture Fluid (1 mL)	#0810070CF	$7.30\times10^7TCID_{50}$/mL
16	Adenovirus Type 5	zeptometrix	Adenovirus Type 5 Culture Fluid (1 mL)	#0810020CF	$1.05\times10^8TCID_{50}$/mL
17	Adenovirus Type 7A	zeptometrix	Adenovirus Type 7A Culture Fluid (1 mL)	#0810021CF	$2.80\times10^6TCID_{50}$/mL
18	Epstein-Barr Virus	zeptometrix	Epstein-Barr Virus (EBV) Culture Fluid (1 mL)	#0810008CF	$7.80\times10^6TCID_{50}$/mL
19	Measles Virus	zeptometrix	Measles Virus Culture Fluid (1 mL)	#0810025CF	$2.24\times10^7TCID_{50}$/mL
20	Cytomegalovirus	zeptometrix	Cytomegalovirus (CMV) (Strain: AD-169) Culture Fluid (1 mL)	#0810003CF	$3.35\times10^7TCID_{50}$/mL
21	Rotavirus	zeptometrix	Rotavirus Culture Fluid (1 mL)	#0810041CF	$6.04\times10^7TCID_{50}$/mL
22	Norovirus	zeptometrix	Norovirus Group I (Recombinant) Culture Fluid (1 mL)	#0810086CF	7.02×10^7TCID50/mL
23	Enterovirus A71	zeptometrix	Enterovirus A71 Culture Fluid (1 mL)	#0810187	1.00×10^6PFU/mL
24	Mycobacterium Tuberculosis	zeptometrix	Mycobacterium Tuberculosis Culture Fluid (1 mL)	#0810136	1×10^5 bacteria/mL
25	Mumps Virus	zeptometrix	Mumps Virus (Isolate 1) Culture Fluid (1 mL)	#0810079CF	1×10^6 PFU/mL
26	Streptococcus Pyogenes	zeptometrix	Streptococcus Pyogenes Culture Fluid (1 mL)	#0810213	3.6×10^6 CFU/mL
27	Streptococcus Pneumoniae	zeptometrix	Streptococcus Pneumoniae Culture Fluid (1 mL)	#0810214	4.2×10^6 CFU/mL
28	Candida Albicans	zeptometrix	Candida Albicans Culture Fluid (1 mL)	#0810103	1.00×10^7 CFU/mL
29	Varicella Zoster Virus	zeptometrix	Varicella Zoster Virus (VZV) Strain: 82 Culture Fluid (1 mL)	#0810167CF	$3.21\times10^7TCID_{50}$/mL
30	Mycoplasma Pneumoniae	zeptometrix	Mycoplasma Pneumoniae M129, Titered (1 Ml)	#0801579	1.2×10^6 CFU/mL
31	Chlamydia Pneumoniae	zeptometrix	Chlamydia Pneumoniae, Titered (1 Ml)	#0801580	2.30×10^6 IFU/mL
32	Bordetella Pertussis	zeptometrix	Bordetella Pertussis Culture Fluid (1 Ml)	#0801321	1×10^4 bacteria/mL
33	Legionella Pneumophila	zeptometrix	Legionella Pneumophila Culture Fluid (1 Ml)	#0801421	1×10^5 bacteria/mL
34	Staphylococcus Aureus	zeptometrix	Staphylococcus Aureus Culture Fluid (1 Ml)	#0805021	3.2×10^8 CFU/mL
35	Staphylococcus Epidermidis	zeptometrix	Staphylococcus Epidermidis Culture Fluid (1 Ml)	#0805022	2.1×10^8 CFU/mL
36	Candida Albicans	zeptometrix	Candida Albicans Culture Fluid (1 Ml)	#0805026	1×10^7 CFU/mL
37	Parainfluenza Virus 1	zeptometrix	Parainfluenza Virus 1 Culture Fluid (1 Ml)	#0801021	7.3×10^6 PFU/mL
38	Parainfluenza Virus 2	zeptometrix	Parainfluenza Virus 2 Culture Fluid (1 Ml)	#0801022	1×10^6 PFU/mL
39	Parainfluenza Virus 3	zeptometrix	Parainfluenza Virus 3 Culture Fluid (1 Ml)	#0801023	5.8×10^6 PFU/mL
40	Parainfluenza Virus 4	zeptometrix	Parainfluenza Virus 4 Culture Fluid (1 Ml)	#0801024	2.6×10^6 PFU/mL
41	Coronavirus HKU1	zeptometrix	Coronavirus HKU1 Culture Fluid (1mL)	#0800305CF	1×10^6 PFU/mL
42	Coronavirus OC43	zeptometrix	Coronavirus OC43 Culture Fluid (1mL)	#0800328CF	1×10^6 PFU/mL

No.	Name	Source	Sample name	Batch/model	Concentration
43	Coronavirus NL63	zeptometrix	Coronavirus NL63 Culture Fluid (1mL)	#0800366CF	1×10^6 PFU/mL
44	Coronavirus 229E	zeptometrix	Coronavirus 229E Culture Fluid (1mL)	#0800311CF	1×10^6 PFU/mL
45	Coronavirus MERS-Cov	zeptometrix	MERS-Cov Culture Fluid (1mL)	#0800312CF	1×10^6 PFU/mL

8.3.1.2 Test reagent

Three consecutive batches of SARS-CoV-2 Antigen Detection Kit (Saliva) , batch numbers: 2020818, 2020819, 2020820, packaging specification: 1 test/kit, 2tests/kit, 5tests/kit, 20tests/kit,25tests/kit.

8.3.1.3 Test method

Three consecutive batches of reagents produced by our company are used to test the above samples to observe whether cross-reactiion occurs.

8.3.1.4 Test results

Table 1 Cross-reaction study results of other viruses

Batch No. / Test result / Sample	20200818	20200819	20200820
Influenza A H1N1	-	-	-
Influenza A H1N1 (Seasonal)	-	-	-
Influenza A H3N2	-	-	-
Influenza A H5N1	-	-	-
Influenza B Yamagata	-	-	-
Influenza B Victoria	-	-	-
Haemophilus Influenzae	-	-	-
Respiratory Syncytial Virus Type A	-	-	-
Respiratory Syncytial Virus Type B	-	-	-
Rhinovirus Type 1A	-	-	-
Rhinovirus B14	-	-	-
Adenovirus Type 1	-	-	-
Adenovirus Type 2	-	-	-
Adenovirus Type 3	-	-	-
Adenovirus Type 4	-	-	-
Adenovirus Type 5	-	-	-
Adenovirus Type 7A	-	-	-
Epstein-Barr Virus	-	-	-
Measles Virus	-	-	-
Cytomegalovirus	-	-	-
Rotavirus	-	-	-
Norovirus	-	-	-
Enterovirus A71	-	-	-
Mycobacterium Tuberculosis	-	-	-
Mumps Virus	-	-	-
Streptococcus Pyogenes	-	-	-
Streptococcus Pneumoniae	-	-	-
Candida Albicans	-	-	-
Varicella Zoster Virus	-	-	-
Mycoplasma Pneumoniae	-	-	-
Chlamydia Pneumoniae	-	-	-
Bordetella Pertussis	-	-	-
Legionella Pneumophila	-	-	-
Staphylococcus Aureus	-	-	-
Staphylococcus Epidermidis	-	-	-
Candida Albicans	-	-	-
Parainfluenza Virus 1	-	-	-

Batch No. / Test result / Sample	20200818	20200819	20200820
Parainfluenza Virus 2	-	-	-
Parainfluenza Virus 3	-	-	-
Parainfluenza Virus 4	-	-	-
Coronavirus HKU1	-	-	-
Coronavirus OC43	-	-	-
Coronavirus NL63	-	-	-
Coronavirus 229E	-	-	-
Coronavirus MERS-Cov	-	-	-

Note: "-" indicates a negative result.

Analysis: The above positive samples are tested negative, indicating that the kits have no cross-reaction with samples positive for Influenza A H1N1, Influenza A H1N1 (Seasonal), Influenza A H3N2, Influenza A H5N1, Influenza B Yamagata, Influenza B Victoria, Haemophilus Influenzae, Respiratory Syncytial Virus Type A, Respiratory Syncytial Virus Type B, Rhinovirus Type 1A, Rhinovirus B14, Adenovirus Type 1, Adenovirus Type 2, Adenovirus Type 3, Adenovirus Type 4, Adenovirus Type 5, Adenovirus Type 7A, Epstein-Barr Virus, Measles Virus, Cytomegalovirus, Rotavirus, Norovirus, Enterovirus A71, Mycobacterium Tuberculosis, Mumps Virus, Streptococcus Pyogenes, Streptococcus Pneumoniae, Candida Albicans, Varicella Zoster Virus, Mycoplasma Pneumoniae, Chlamydia Pneumoniae, Bordetella Pertussis, Legionella Pneumophila, Staphylococcus Aureus, Staphylococcus Epidermidis, Candida Albicans, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Coronavirus HKU1, Coronavirus OC43, Coronavirus NL63, Coronavirus 229E and Coronavirus MERS-Cov during test.

8.3.1.5 Conclusion

SARS-CoV-2 AntigenDetection Kit has no cross-reaction with samples positive for Influenza A H1N1, Influenza A H1N1 (Seasonal), Influenza A H3N2, Influenza A H5N1, Influenza B Yamagata, Influenza B Victoria, Haemophilus Influenzae, Respiratory Syncytial Virus Type A, Respiratory Syncytial Virus Type B, Rhinovirus Type 1A, Rhinovirus B14, Adenovirus Type 1, Adenovirus Type 2, Adenovirus Type 3, Adenovirus Type 4, Adenovirus Type 5, Adenovirus Type 7A, Epstein-Barr Virus, Measles Virus, Cytomegalovirus, Rotavirus, Norovirus, Enterovirus A71, Mycobacterium Tuberculosis, Mumps Virus, Streptococcus Pyogenes, Streptococcus Pneumoniae, Candida Albicans, Varicella Zoster Virus, Mycoplasma Pneumoniae, Chlamydia Pneumoniae, Bordetella Pertussis, Legionella Pneumophila, Staphylococcus Aureus, Staphylococcus Epidermidis, Candida Albicans, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Coronavirus HKU1, Coronavirus OC43, Coronavirus NL63, Coronavirus 229E and Coronavirus MERS-Cov.

8.3.2 Study of interfering substances

During the use of SARS-CoV-2 Antigen Detection Kit (Saliva) , since the test object is mouthwash sample, the test results may be interfered by the following substances, such as blood, saliva (mucin), allergic symptom relief medication (Histamine Dihydrochloride), antiviral drugs (Interferon a, Zanamivir, Ribavirin, Oseltamivir, Peramivir, Lopinavir, Ritonavir, Arbidol), antibiotics (Levofloxacin, Azithromycin, Ceftriaxone, Meropenem), systemic antibacterial drug (Tobramycin), Phenylephrine, Oxymetazoline, 0.9% Sodium Chloride, Natural Soothing Alkali, Beclomethasone, Dexamethasone, Haloperidol, Triamcinolone, Budesonide, Mometasone, Fluticasone, Fluticasone Propionate, etc.

8.3.2.1 Test samples

(1) Blood: Use a nasopharyngeal swab to dip whole blood from a healthy person to simulate the amount of blood in the nasal cavity or oral cavity;

(2) Saliva (mucin): Prepare artificial saliva, dip it with an oropharyngeal swab for testing.

Table 2 Saliva formula

KCL	$Ca_3(PO4)_2$	K_2HPO_4	K_2SO_4	Na_2SO_4	Mucin	BSA	Distilled water
2.4g	0.02g	1.4g	0.9g	0.8g	50mg	5g	1000mL

A small amount of 0.5‰ sodium azide is used as preservative.

(3) Drug interference

The concentration of the test drug is determined according to the Chinese Pharmacopoeia (2005 edition) or the drug usage and dosage in the drug package insert. The following drugs are added to the negative sample and the weakly positive sample (lowest LOD reference L2) at 10 times the blood concentration. The effects of the following drugs on the test results are investigated.

Table 3 Drug dosage

Drug classification	Drug name	Dosage	Interference experiment concentration
Allergic symptom relief medication	Histamine Dihydrochloride	0.1mg/time	0.25mg/L
Antiviral drugs	Interferon a	0.5ml/time	5mg/mL
	Zanamivir	10mg/time	5mg/mL
	Ribavirin	0.3g/time	5mg/mL
	Oseltamivir	75mg/time	5mg/mL
	Peramivir	300mg/time	5mg/mL
	Lopinavir	200mg/time	5mg/mL
	Ritonavir	50mg/time	5mg/mL
	Arbidol	0.2g/time	5mg/mL
Antibiotics	Levofloxacin	0.5g/time	5mg/mL
	Azithromycin	1g/time	5mg/mL
	Ceftriaxone	1g/time	5mg/mL
	Meropenem	200mg/time	5mg/mL
Systemic antibacterial drug	Tobramycin	0.1ml/time	0.25ml/L
Other drugs	Phenylephrine	1g/time	20% (v/v)
	Oxymetazoline	1g/time	20% (v/v)
	0.9% Sodium Chloride	/	20% (v/v)
	Natural Soothing Alkali	1g/time	20% (v/v)
	Beclomethasone	1g/time	20% (v/v)
	Dexamethasone	1g/time	20% (v/v)

Drug classification	Drug name	Dosage	Interference experiment concentration
	Haloperidol	1g/time	20% (v/v)
	Triamcinolone	1g/time	20% (v/v)
	Budesonide	1g/time	20% (v/v)
	Mometasone	1g/time	20% (v/v)
	Fluticasone	1g/time	20% (v/v)
	Fluticasone Propionate	1g/time	20% (v/v)

Note: All the above doses are based on an adult with a weight of 60 kg and a blood volume of 4000 mL, and the tissue fluid content is lower than blood. (The volume of blood in human body is about 7-8% of body weight; if the body weight is 60 kg, the volume of blood is about 4000-4800 mL.)

8.3.2.2 Test reagent

Three consecutive batches of SARS-CoV-2 Antigen Detection Kit (Saliva) , batch numbers: 2020818, 2020819, 2020820, packaging specification: 1 test/kit, 2tests/kit, 5tests/kit, 20tests/kit,25tests/kit.

8.3.2.3 Test method

(1) Take the above blood and saliva into the weakly positive reference L2 and negative sample respectively in a ratio of 1:1, and pipette the mixed samples into the test cassette to observe the test results.

(2) Take the main active ingredients of the above-mentioned drugs, dissolve and add them to the weak positive reference L2 and negative sample in a ratio of 1:1, and pipette the mixed samples into the test cassette to observe the test results.

8.3.2.4 Test results

Table 4 Results of study on the effects of blood and saliva

Interfering substance	Main active ingredient	Dosage	Test sample	Batch No.		
				20200818	20200819	20200820
Blood	/	/	Negative	-	-	-
			Weakly positive	+	+	+
Saliva	Mucin	/	Negative	-	-	-
			Weakly positive	+	+	+

Analysis: It can be seen from the results of the above table that the reagent sampling is not affected by blood and saliva.

Table 5 Results of study on the effects of drugs

Drug classification	Drug name	Dosage	Test sample	Batch No.		
				20200818	20200819	20200820
Allergic symptom relief medication	Histamine Dihydrochloride	0.25mg/L	Negative	-	-	-
			Weakly positive	+	+	+
Antiviral drugs	Interferon a	5mg/mL	Negative	-	-	-
			Weakly positive	+	+	+
	Zanamivir	5mg/mL	Negative	-	-	-
			Weakly positive	+	+	+
	Ribavirin	5mg/mL	Negative	-	-	-
			Weakly positive	+	+	+

Drug classification	Drug name	Dosage	Test sample	Batch No.		
				20200818	20200819	20200820
	Oseltamivir	5mg/mL	Negative	-	-	-
			Weakly positive	+	+	+
	Peramivir	5mg/mL	Negative	-	-	-
			Weakly positive	+	+	+
	Lopinavir	5mg/mL	Negative	-	-	-
			Weakly positive	+	+	+
	Ritonavir	5mg/mL	Negative	-	-	-
			Weakly positive	+	+	+
	Arbidol	5mg/mL	Negative	-	-	-
			Weakly positive	+	+	+
Antibiotics	Levofloxacin	5mg/mL	Negative	-	-	-
			Weakly positive	+	+	+
	Azithromycin	5mg/mL	Negative	-	-	-
			Weakly positive	+	+	+
	Ceftriaxone	5mg/mL	Negative	-	-	-
			Weakly positive	+	+	+
	Meropenem	5mg/mL	Negative	-	-	-
			Weakly positive	+	+	+
Systemic antibacterial drug	Tobramycin	0.25ml/L	Negative	-	-	-
			Weakly positive	+	+	+
Other drugs	Phenylephrine	20% (v/v)	Negative	-	-	-
			Weakly positive	+	+	+
	Oxymetazoline	20% (v/v)	Negative	-	-	-
			Weakly positive	+	+	+
	0.9% Sodium Chloride	20% (v/v)	Negative	-	-	-
			Weakly positive	+	+	+
	Natural Soothing Alkali	20% (v/v)	Negative	-	-	-
			Weakly positive	+	+	+
	Beclomethasone	20% (v/v)	Negative	-	-	-
			Weakly positive	+	+	+
	Dexamethasone	20% (v/v)	Negative	-	-	-
			Weakly positive	+	+	+
	Haloperidol	20% (v/v)	Negative	-	-	-
			Weakly positive	+	+	+
	Triamcinolone	20% (v/v)	Negative	-	-	-
			Weakly positive	+	+	+
	Budesonide	20% (v/v)	Negative	-	-	-
			Weakly positive	+	+	+
	Mometasone	20% (v/v)	Negative	-	-	-
			Weakly positive	+	+	+
	Fluticasone	20% (v/v)	Negative	-	-	-
			Weakly positive	+	+	+
	Fluticasone Propionate	20% (v/v)	Negative	-	-	-
			Weakly positive	+	+	+

Analysis: It can be seen from the results of the above table that the test results of this reagent are not interfered by allergic symptom relief medication (Histamine Dihydrochloride), antiviral drugs (Interferon a, Zanamivir, Ribavirin, Oseltamivir, Peramivir, Lopinavir, Ritonavir, Arbidol), antibiotics

(Levofloxacin, Azithromycin, Ceftriaxone, Meropenem), systemic antibacterial drug (Tobramycin), Phenylephrine, Oxymetazoline, 0.9% Sodium Chloride, Natural Soothing Alkali, Beclomethasone, Dexamethasone, Haloperidol, Triamcinolone, Budesonide, Mometasone, Fluticasone, Fluticasone Propionate, etc.

8.3.2.5 Conclusion

(1) The Sampling of SARS-CoV-2 Antigen Detection Kit (Saliva) is not affected by blood and saliva;

(2) The test results of SARS-CoV-2 Antigen Detection Kit (Saliva) are not interfered by allergic symptom relief medication (Histamine Dihydrochloride), antiviral drugs (Interferon a, Zanamivir, Ribavirin, Oseltamivir, Peramivir, Lopinavir, Ritonavir, Arbidol), antibiotics (Levofloxacin, Azithromycin, Ceftriaxone, Meropenem), systemic antibacterial drug (Tobramycin), Phenylephrine, Oxymetazoline, 0.9% Sodium Chloride, Natural Soothing Alkali, Beclomethasone, Dexamethasone, Haloperidol, Triamcinolone, Budesonide, Mometasone, Fluticasone, Fluticasone Propionate, etc.

8.3.2.6 Explanation

Table 6 Saliva formula

KCL	$Ca_3(PO4)_2$	K_2HPO_4	K_2SO_4	Na_2SO_4	Mucin	BSA	Distilled water
2.4g	0.02g	1.4g	0.9g	0.8g	50mg	5g	1000mL

A small amount of 0.5‰ sodium azide is used as preservative.

3) Drug interference

The concentration of the test drug is determined according to the Chinese Pharmacopoeia (2005 edition) or the drug usage and dosage in the drug package insert. The following drugs are added to the weakly positive sample at 10 times the blood concentration. The effects of the following drugs on the test results are investigated.

Table 7 Drug dosage

Drug classification	Drug name	Dosage	Interference experiment concentration
Allergic symptom relief medication	Histamine Dihydrochloride	0.1mg/time	0.25mg/L
Antiviral drugs	Interferon a	0.5ml/time	5mg/mL
	Zanamivir	10mg/time	5mg/mL
	Ribavirin	0.3g/time	5mg/mL
	Oseltamivir	75mg/time	5mg/mL
	Peramivir	300mg/time	5mg/mL
	Lopinavir	200mg/time	5mg/mL
	Ritonavir	50mg/time	5mg/mL
	Arbidol	0.2g/time	5mg/mL
Antibiotics	Levofloxacin	0.5g/time	5mg/mL
	Azithromycin	1g/time	5mg/mL
	Ceftriaxone	1g/time	5mg/mL
	Meropenem	200mg/time	5mg/mL
Systemic antibacterial drug	Tobramycin	0.1ml/time	0.25ml/L
Other drugs	Phenylephrine	1g/time	20% (v/v)
	Oxymetazoline	1g/time	20% (v/v)
	0.9% Sodium Chloride	/	20% (v/v)
	Natural Soothing Alkali	1g/time	20% (v/v)
	Beclomethasone	1g/time	20% (v/v)
	Dexamethasone	1g/time	20% (v/v)
	Haloperidol	1g/time	20% (v/v)
	Triamcinolone	1g/time	20% (v/v)
	Budesonide	1g/time	20% (v/v)
	Mometasone	1g/time	20% (v/v)
	Fluticasone	1g/time	20% (v/v)
	Fluticasone Propionate	1g/time	20% (v/v)

Note: All the above doses are based on an adult with a weight of 60 kg and a blood volume

of 4000 mL, and the tissue fluid content is lower than blood. (The volume of blood in human body is about 7-8% of body weight; if the body weight is 60 kg, the volume of blood is about 4000-4800 mL.)

8.3.2.7 Test method

(1) Take the above blood and saliva into the weakly positive sample in a ratio of 1:1, and pipette the mixed samples into the test cassette to observe the test results.

(2) Take the main active ingredients of the above-mentioned drugs, dissolve and add them to the weakly positive sample in a ratio of 1:1, and pipette the mixed samples into the test cassette to observe the test results.

8.3.2.8 Test results

Table 8 Results of study on the effects of blood and saliva

Interfering substance	Main active ingredient	Dosage	Test sample	Batch No.		
				20200818	20200819	20200820
Blood	/	/	+	+	+	+
Saliva	Mucin	/	+	+	+	+

Table 9 Results of study on the effects of drugs

Drug classification	Drug name	Dosage	Test sample	Batch No.		
				20200818	20200819	20200820
Allergic symptom relief medication	Histamine Dihydrochloride	0.25mg/L	+	+	+	+
Antiviral drugs	Interferon a	5mg/mL	+	+	+	+
	Zanamivir	5mg/mL	+	+	+	+
	Ribavirin	5mg/mL	+	+	+	+
	Oseltamivir	5mg/mL	+	+	+	+
	Peramivir	5mg/mL	+	+	+	+
	Lopinavir	5mg/mL	+	+	+	+
	Ritonavir	5mg/mL	+	+	+	+
	Arbidol	5mg/mL	+	+	+	+
Antibiotics	Levofloxacin	5mg/mL	+	+	+	+
	Azithromycin	5mg/mL	+	+	+	+
	Ceftriaxone	5mg/mL	+	+	+	+
	Meropenem	5mg/mL	+	+	+	+
Systemic antibacterial drug	Tobramycin	0.25ml/L	+	+	+	+
Other drugs	Phenylephrine	20% (v/v)	+	+	+	+
	Oxymetazoline	20% (v/v)	+	+	+	+
	0.9% Sodium Chloride	20% (v/v)	+	+	+	+
	Natural Soothing Alkali	20% (v/v)	+	+	+	+
	Beclomethasone	20% (v/v)	+	+	+	+
	Dexamethasone	20% (v/v)	+	+	+	+
	Haloperidol	20% (v/v)	+	+	+	+
	Triamcinolone	20% (v/v)	+	+	+	+
	Budesonide	20% (v/v)	+	+	+	+
	Mometasone	20% (v/v)	+	+	+	+
	Fluticasone	20% (v/v)	+	+	+	+
	Fluticasone Propionate	20% (v/v)	+	+	+	+

Complete the specific content of the review points:

1) Cross-reaction test a: Cross-reaction study on endemic human Coronavirus HKU1, OC43, NL63 and 229E shows no cross-interference occurred.

2) Cross-reaction test b: H1N1, H5N1, H7N9 and Rhinovirus 55 strains have not been found for the time being, so there is no study conducted.

3) Because this product is used to detect antigens, the cross-reaction of high-concentration specific IgG antibodies and specific IgM antibodies is not applicable.

4) Currently, as the clinically cut-off positive samples are not easy to be obtained, this study uses clinically negative samples and the lowest LOD reference L2. However, our company is cooperating with the Eighth People's Hospital of Guangdong Province and the Guangzhou Institute of Biomedicine and Health, Chinese Academy of Sciences, and will continue to collect weakly positive samples of SARS-CoV-2 novel coronavirus antigen for verification. Due to interfering substances, such as bilirubin, blood lipids, heme, antinuclear antibodies, rheumatoid factor, antimitochondrial antibodies, HAMA, total IgG, total IgM, blood from patients with systemic lupus erythematosus, nasal spray or nasal drops, phenylephrine, oxymetazoline, sodium chloride (with preservatives), nasal skin steroids, beclomethasone, dexamethasone, flunisolide, triamcinolone, budesonide, mometasone and fluticasone, are not suitable for interference analysis of mouthwash samples, so there is no evaluation conducted.

9 Conclusion

The kit which its working principle is clear, the design is finalized, the process is mature, the clinical application is extensive, and no serious adverse event records and/or product defects have been found. The performance indicators of the product's safety and effectiveness have been established in the test report and have been fully verified without passing the clinical trial. At the same time, the product is of the same clinical use and the same operating object with the same kind of registered and marketed products, and is substantially equivalent in terms of basic principle, structure composition, product manufacturing materials, main performance indicators, application scope, use method and so on.

Therefore, compared to other similar products, The kit does not reduce the clinical effectiveness, nor increase the clinical safety risk. The production and application technology of this product is mature, and its functional principle, expected clinical use effect have been fully affirmed in the relevant clinical application field.

In conclusion,The kit can meet the expected use and ensure the safety and effectiveness of its clinical use.

Attachment 1 Professionals test results of saliva samples

Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit		Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit		Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit	
		Ct	Result			Ct	Result			Ct	Result
2020030001	3+	21	positive	2020040001	2+	23	positive	2020050001	+	/	positive
2020030002	-	/	negative	2020040002	3+	22	positive	2020050002	-	/	negative
2020030003	-	/	negative	2020040003	1+	25	positive	2020050003	-	/	negative
2020030004	-	/	negative	2020040004	-	/	negative	2020050004	-	/	negative
2020030005	-	/	negative	2020040005	-	/	negative	2020050005	2+	22	negative
2020030006	3+	23	positive	2020040006	-	/	negative	2020050006	3+	19	negative
2020030007	2+	25	positive	2020040007	-	/	negative	2020050007	3+	21	negative
2020030008	3+	21	positive	2020040008	-	/	negative	2020050008	3+	20	negative
2020030009	1+	27	positive	2020040009	-	/	negative	2020050009	-	/	negative
2020030010	-	/	negative	2020040010	-	/	negative	2020050010	-	/	negative
2020030011	-	/	negative	2020040011	-	/	negative	2020050011	-	/	negative
2020030012	-	/	negative	2020040012	-	/	negative	2020050012	-	/	negative
2020030013	-	30	positive	2020040013	3+	20	positive	2020050013	2+	24	positive
2020030014	3+	22	negative	2020040014	3+	19	positive	2020050014	-	/	negative
2020030015	-	/	negative	2020040015	2+	23	positive	2020050015	-	/	negative
2020030016	-	/	negative	2020040016	2+	24	positive	2020050016	-	/	negative

Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit		Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit		Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit	
		Ct	Result			Ct	Result			Ct	Result
2020030017	-	/	negative	2020040017	3+	21	positive	2020050017	-	/	negative
2020030018	3+	23	negative	2020040018	-	/	negative	2020050018	-	/	negative
2020030019	1+	26	positive	2020040019	-	/	negative	2020050019	2+	25	positive
2020030021	3+	20	positive	2020040021	1+	29	positive	2020050021	-	/	negative
2020030022	-	/	negative	2020040022	3+	21	positive	2020050022	3+	22	positive
2020030023	-	/	negative	2020040023	3+	20	positive	2020050023	-	/	negative
2020030024	-	/	negative	2020040020	-	/	negative	2020050024	-	/	negative
2020030025	2+	28	positive	2020040025	-	/	negative	2020050025	3+	23	positive
2020030026	3+	21	positive	2020040026	-	/	negative	2020050026	-	/	negative
2020030027	3+	19	positive	2020040027	3+	22	positive	2020050027	-	/	negative
2020030028	3+	21	positive	2020040028	2+	21	positive	2020050028	3+	20	positive
2020030029	2+	24	positive	2020040029	3+	20	positive	2020050029	-	/	negative
2020030030	-	/	negative	2020040020	-	/	negative	2020050030	-	/	negative
2020030031	-	/	negative	2020040031	-	/	negative	2020050031	-	/	negative
2020030032	-	/	negative	2020040032	-	/	negative	2020050032	3+	19	positive
2020030033	3+	21	positive	2020040033	2+	23	positive	2020050033	3+	21	positive
2020030034	1+	29	positive	2020040034	3+	21	positive	2020050034	-	/	negative

Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit		Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit		Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit	
		Ct	Result			Ct	Result			Ct	Result
2020030035	3+	18	positive	2020040035	2+	23	positive	2020050035	-	/	negative
2020030036	3+	19	positive	2020040036	1+	30	positive	2020050036	-	/	negative
2020030037	-	/	negative	2020040037	-	/	negative	2020050037	-	/	negative
2020030038	3+	21	positive	2020040038	-	/	negative	2020050038	+	31	positive
2020030039	1+	28	positive	2020040039	-	/	negative	2020050039	3+	22	positive
2020030040	-	/	negative	2020040040	-	/	negative	2020050040	2+	23	positive
2020030041	+	29	positive	2020040041	2+	23	positive	2020050041	-	/	negative
2020030042	-	/	negative	2020040042	-	32	positive	2020050042	-	/	negative
2020030043	-	/	negative	2020040043	1+	27	positive	2020050043	1+	29	positive
2020030044	3+	21	positive	2020040040	-	/	negative	2020050044	-	/	negative
2020030045	-	/	negative	2020040045	-	/	negative	2020050045	-	/	negative
2020030046	3+	20	positive	2020040046	-	/	negative	2020050046	-	/	negative
2020030047	-	31	positive	2020040047	1+	28	positive	2020050047	1+	31	positive
2020030048	3+	18	positive	2020040048	3+	19	positive	2020050048	3+	20	positive
2020030049	1+	27	positive	2020040049	3+	21	positive	2020050049	-	/	negative
2020030050	-	/	negative	2020040050	-	/	negative	2020050050	-	/	negative
2020030051	-	/	negative	2020040051	-	/	negative	2020050051	-	/	negative

Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit		Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit		Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit	
		Ct	Result			Ct	Result			Ct	Result
2020030052	-	/	negative	2020040052	-	/	negative	2020050052	-	/	negative
2020030053	-	/	negative	2020040053	2+	26	positive	2020050053	-	/	negative
2020030054	-	/	negative	2020040054	-	/	negative	2020050054	-	/	negative
2020030055	-	/	negative	2020040055	-	/	negative	2020050055	3+	18	positive
2020030056	-	/	negative	2020040056	3+	20	positive	2020050056	2+	23	positive
2020030057	-	/	negative	2020040057	-	/	negative	2020050057	1+	27	positive
2020030058	1+	29	positive	2020040058	-	/	negative	2020050058	-	/	negative
2020030059	2+	22	positive	2020040051	-	/	negative	2020050059	-	/	negative
2020030060	-	/	negative	2020040060	-	/	negative	2020050060	-	/	negative
2020030061	-	/	negative	2020040061	3+	21	positive	2020050061	3+	21	positive
2020030062	-	/	negative	2020040062	-	32	positive	2020050062	-	/	negative
2020030063	-	/	negative	2020040063	3+	21	positive	2020050063	-	/	negative
2020030064	3+	21	positive	2020040064	-	/	negative	2020050064	-	/	negative
2020030065	1+	29	positive	2020040065	-	/	negative	2020050065	-	/	negative
2020030066	-	/	negative	2020040066	-	/	negative	2020050066	-	/	negative
2020030067	3+	24	positive	2020040067	3+	24	positive	2020050067	3+	24	positive
2020030068	-	32	positive	2020040068	-	/	negative	2020050068	-	/	negative

Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit		Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit		Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit	
		Ct	Result			Ct	Result			Ct	Result
2020030069	-	/	negative	2020040069	-	/	negative	2020050069	-	/	negative
2020030070	3+	21	positive	2020040070	3+	19	positive	2020050070	-	/	negative
2020030071	-	/	negative	2020043007	-	/	negative	2020053007	-	/	negative
2020030072	-	/	negative	2020040072	1+	26	positive	2020050072	-	/	negative
2020030073	-	/	negative	2020040073	-	/	negative	2020050073	3+	21	positive
2020030074	-	/	negative	2020040074	-	/	negative	2020050074	-	/	negative
2020030075	-	/	negative	2020040075	-	/	negative	2020050075	-	/	negative
2020030076	1+	28	positive	2020040076	-	/	negative	2020050076	1+	30	positive
2020030077	-	/	negative	2020040077	-	/	negative	2020050077	-	/	negative
2020030078	3+	22	positive	2020040078	-	/	negative	2020050078	3+	21	positive
2020030079	-	/	negative	2020040079	-	/	negative	2020050079	-	32	positive
2020030080	-	/	negative	2020040080	-	/	negative	2020050080	-	/	negative
2020030081	3+	23	positive	2020040081	3+	21	positive	2020050081	3+	24	positive
2020030082	-	/	negative	2020040082	-	/	negative	2020050082	-	/	negative
2020030083	-	/	negative	2020040083	-	/	negative	2020050083	-	/	negative
2020030084	-	/	negative	2020040084	-	/	negative	2020050084	-	/	negative
2020030085	-	/	negative	2020040085	3+	23	positive	2020050085	-	/	negative

Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit		Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit		Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit	
		Ct	Result			Ct	Result			Ct	Result
2020030086	-	/	negative	2020040086	-	/	negative	2020050086	-	/	negative
2020030087	1+	29	positive	2020040087	-	/	negative	2020050087	2+	26	positive
2020030088	-	/	negative	2020040088	-	/	negative	2020050088	-	/	negative
2020030089	3+	21	positive	2020040089	3+	21	positive	2020050089	3+	21	positive
2020030090	-	/	negative	2020040090	-	/	negative	2020050090	-	32	positive
2020030091	-	/	negative	2020040091	2+	26	positive	2020050091	-	/	negative
2020030092	3+	21	positive	2020040092	3+	21	positive	2020050092	3+	21	positive
2020030093	-	/	negative	2020040093	-	/	negative	2020050093	-	/	negative
2020030094	-	/	negative	2020040094	-	/	negative	2020050094	-	/	negative
2020030095	-	/	negative	2020040095	3+	22	positive	2020050095	-	/	negative
2020030096	-	/	negative	2020040096	-	/	negative	2020050096	-	/	negative
2020030097	-	/	negative	2020040097	-	/	negative	2020050097	-	/	negative
2020030098	2+	26	positive	2020040098	-	/	negative	2020050098	2+	27	positive
2020030099	-	/	negative	2020040099	-	/	negative	2020050099	-	/	negative
2020030100	3+	21	positive	2020040100	1+	29	positive	2020050100	3+	21	positive
2020030101	-	/	negative	2020040101	-	/	negative	2020050101	-	32	positive
2020030102	-	/	negative	2020040102	-	/	negative	2020050102	-	/	negative

Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit		Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit		Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit	
		Ct	Result			Ct	Result			Ct	Result
2020030103	3+	21	positive	2020040103	-	/	negative	2020050103	3+	21	positive
2020030104	-	/	negative	2020040104	-	/	negative	2020050104	-	/	negative
2020030105	-	/	negative	2020040105	-	/	negative	2020050105	2+	25	positive
2020030106	-	/	negative	2020040106	-	/	negative	2020050106	-	/	negative
2020030107	-	/	negative	2020040107	3+	21	positive	2020050107	-	/	negative
2020030108	-	/	negative	2020040108	-	/	negative	2020050108	-	/	negative
2020030109	2+	26	positive	2020040109	1+	29	positive	2020050109	-	/	negative
2020030110	-	/	negative	2020040110	-	/	negative	2020050110	-	/	negative
2020030111	3+	21	positive	2020040111	3+	21	positive	2020050111	3+	21	positive
2020030112	-	32	positive	2020040112	-	/	negative	2020050112	-	/	negative
2020030113	-	/	negative	2020040113	-	/	negative	2020050113	-	/	negative
2020030114	3+	23	positive	2020040114	2+	26	positive	2020050114	2+	27	positive
2020030115	-	/	negative	2020040115	-	/	negative	2020050115	-	/	negative
2020030116	-	/	negative	2020040116	-	/	negative	2020050116	-	/	negative
2020030117	-	/	negative	2020040117	-	/	negative	2020050117	-	/	negative
2020030118	-	/	negative	2020040118	-	32	positive	2020050118	-	/	negative
2020030119	-	/	negative	2020040119	-	/	negative	2020050119	-	/	negative

Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit		Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit		Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit	
		Ct	Result			Ct	Result			Ct	Result
2020030120	-	/	negative	2020040120	1+	28	positive	2020050120	1+	29	positive
2020030121	-	/	negative	2020040121	-	/	negative	2020050121	-	/	negative
2020030122	3+	21	positive	2020040122	3+	21	positive	2020050122	2+	27	positive
2020030123	-	/	negative	2020040123	-	/	negative	2020050123	-	32	positive
2020030124	-	/	negative	2020043012	-	/	negative	2020053012	-	/	negative
2020030125	3+	22	positive	2020040125	2+	24	positive	2020050125	3+	22	positive
2020030126	-	/	negative	2020040126	-	/	negative	2020050126	-	/	negative
2020030127	-	/	negative	2020040127	-	/	negative	2020050127	-	/	negative
2020030128	1+	26	positive	2020040128	-	/	negative	2020050128	-	/	negative
2020030129	-	/	negative	2020040129	-	/	negative	2020050129	-	/	negative
2020030130	-	/	negative	2020040130	-	/	negative	2020050130	-	/	negative
2020030131	2+	26	positive	2020040131	-	/	negative	2020050131	-	/	negative
2020030132	-	/	negative	2020040132	-	/	negative	2020050132	-	/	negative
2020030133	3+	21	positive	2020040133	-	/	negative	2020050133	3+	21	positive
2020030134	-	/	negative	2020040134	-	/	negative	2020050134	-	32	positive
2020030135	-	/	negative	2020040135	3+	21	positive	2020050135	1+	27	positive
2020030136	3+	20	positive	2020030136	3+	19	positive	2020050136	3+	23	positive

Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit		Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit		Sample Nr.	SARS-CoV-2 Antigen Detection Kit	COVID-19 Coronavirus Real Time PCR Kit	
		Ct	Result			Ct	Result			Ct	Result
2020030137	-	/	negative	2020040137	1+	28	positive	2020050137	-	/	negative
2020030138	-	/	negative	2020040138	-	/	negative	2020050138	-	/	negative
2020030139	-	/	negative	2020040139	-	/	negative	2020050139	-	/	negative
2020030140	-	/	negative	2020040140	-	/	negative	2020050140	-	/	negative
2020030141	-	/	negative	2020040141	-	/	negative	2020050141	-	/	negative
2020030142	-	/	negative	2020040142	2+	26	positive				
2020030143	-	/	negative	2020040143	-	/	negative				
2020030144	3+	21	positive	2020040144	3+	20	positive				
2020030145	-	32	positive	2020040145	-	/	negative				
2020030146	-	/	negative	2020040146	-	/	negative				
2020030147	3+	21	positive	2020040147	3+	22	positive				
2020030148	-	/	negative								
2020030149	-	/	negative								

Note: "-" indicates the negative result, "1+, 2+, 3+" indicate positive result, the intensity increases from "1+" to "3+". Ct Value： Cycle threshold