Clinical Validation report of Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab)

Product name: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab)

Package Specification: 25 tests/kit

Manufacturer: Hangzhou Realy Tech Co., Ltd

Validated by: Xuzhou infectious disease hospital

File No. MF-K511416D-0010
Version: 1.2
Effective date:2020-10-13

I. Clinical validation time

This clinical evaluation was conducted from July 2020 to Aug 14th,2020.

II. Background information for clinical evaluation

Since December 2019, world has successively discovered multiple cases of patients with new-type coronavirus pneumonia. With the spread of the epidemic, China and abroad have also been found. As an acute respiratory infectious disease, the disease has been included in the Class B infectious diseases stipulated in the Law of the People's Republic of China on the Prevention and Control of Infectious Diseases, and is managed as a Class A infectious disease. Based on the current epidemiological investigation, the incubation period is 1-14 days, mostly 3-7 days.

The main manifestations are fever, dry cough, and fatigue. A few patients have symptoms such as nasal congestion, runny nose, sore throat, myalgia and diarrhea. Severe patients usually have dyspnea and / or hypoxemia one week after the onset of symptoms, and severe patients can quickly progress to acute respiratory distress syndrome, septic shock, difficult to correct metabolic acidosis, coagulation dysfunction and multiple organ Functional failure, etc. It is worth noting that in the course of severe and critically ill patients, there may be moderate to low fever, even without obvious fever.

Mild patients showed only low fever, mild fatigue, and no pneumonia. Judging from the current cases, most patients have a good prognosis, and a few patients are critically ill. The elderly and those with chronic underlying disease have a better prognosis. Symptoms in children are relatively mild.

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab) developed by our company can help diagnose whether patients are infected with the Novel Coronavirus. It has further enriched the detection methods of Novel Coronavirus, expanded the supply of detection reagents, and fully served the needs of epidemic prevention and control.

III. Test purposes

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab) produced by Hangzhou Realy Technology Co., Ltd. was used to verify the feasibility of clinical evaluation and the reliability of test results for Chinese subjects.

The purpose of research of the clinical test is to calculate the consistency percentage of negative/positive and the total consistency percentage and Kappa coefficient by statistically analyzing test results through comparative experimental research.

IV. Test design

1. Test plan selection and reasons

In vitro diagnostic reagents for testing and reference reagents were used to conduct comparative research tests on clinically suspected Novel Coronavirus Nasopharyngeal swab samples, and it was proved that the in vitro diagnostic reagents used in the test can achieve the expected assistance in infection of the Novel Coronavirus.

2. Sample volume required

The total number of clinical trials of this product is not less than 100 cases. The samples is

classified into the positive group and the negative group as per the test results of the reference product. Meanwhile, the samples shall be tested via the qualitative test strip tested and by reference product from the same patient and then the test results of the product tested and the reference product shall be compared, with statistical analysis being made.

3. Sample inclusion/exclusion certification.

The positive group and negative group in this experiment are applicable to the following inclusion/exclusion criteria

Positive group inclusion: Meets 2 of the following 3 criteria, it is inclusion into positive sample group:

Antibody test is positive;

PCR Test is positive;

CT test results and symptoms are clinically positive;

Positive group exclusion:

Samples only Meet 1 of the 3 criteria of inclusion; it is exclusion out of positive sample group.

Negative inclusion: Meets 3 of the following 4 criteria, it is inclusion into negative sample group:

Antibody test is negative;

PCR test is negative;

CT test results and symptoms are clinically negative;

No history of novel coronavirus exposure within 14 day.

Negative exclusion:

Any sample that does not meet the inclusion criteria is excluded out of the negative group.

4. Sample collection, processing and storage

Sample collection: It is applicable to the diagnosis of the Novel coroinavirus from the samples of nasal swabs or nasal aspirates.Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result. Completely insert the sterilized swab supplied in this kit into the nasal basin, and swab several times to collect the epidermal cells of the mucus.It is recommended to collect sample from nasal basin for more accurate results.

5. In vitro diagnostic reagents and reference products for testing

5.1 Test in vitro diagnostic reagents

Name: The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab)

Specification:25 tests/kit

REF: K511416D

LOT: 202007046

Expiry: June,2022(Tentative)

Storage Conditions: Store in a dry place at 2-30°C, protected from light. After opening the inner package, the test card will become invalid due to moisture absorption. Please use it within 1 hour.

Source: Hangzhou Realy Tech Co.,Ltd

5.2 Reference products

Name: 2019-nCoV nucleic acid test kit（RT-PCR）

Manufacturer: Shanghai ZJ Bio-Tech Co., Ltd.

Storage Conditions: Store in a dry place at 2-8°C, protected from light.

V. Experiment method

1. Get the Swab specimens from patients in positive and negative groups.
2. Pre-process the swab samples according to the instructions of the The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab), and label the samples randomly.

2.1 Add 10 drops (about 0.3 ml) of the sample extraction buffer into the extraction tube.

2.2 Place the swab specimen in the SARS-Cov-2 antigen Buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.

2.3 Remove the swab while squeezing the swab head against the inside of Buffer as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.

2.4 Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the Buffer. Place the test device on a clean and level surface.

3. The operation steps of the in vitro diagnostic reagents for the test are as follows. For details, please refer to the product instruction manual:

3.1 remove the test sample and required reagents from the storage conditions and equilibrate to room temperature (15-30°C).

3.2 When preparing for testing, open the aluminum foil bag from the tear. Remove the test card and lay it flat on a horizontal table.

3.3 Label the sample number on the test card.

3.4 Add 3 drops of the solution (approx.80ul) to the sample well and then start the timer.

3.5 Time counting and interpret the results within 10 minutes.

Note: The detection steps need to be completed under protection against infection.

VI. Statistical methods of statistical analysis of clinical research data

A Methods evaluating clinical performance

Whether various indexes can reach the standards of clinical evaluation shall be judged by calculating the consistency percentage of negative/positive and the total consistency percentage in the test results of the product tested and the reference product, to validate the accuracy and applicability of the product in clinical applications. The product tested shall be subject to tests through the sample of different types, with statistics on the results. Meanwhile,different types of sample of the subjects shall be subject to determination by the

product tested synchronously, and then the determination results of both shall be compared. The test results recorded shall be subject to statistical analysis upon completion of determination of all clinical samples,to calculate the consistency percentage of negative/positive and the total consistency percentage. Afterwards, equivalence of both shall be evaluated as per these statistical indexes

B Statistical method

The products launched on the market shall be subject to comparative study and evaluation.Kappa inspection: each sample shall be tested with the product tested and the reference product respectively, and then the consistency in statistical results of these two inspection methods shall be compared through Kappa inspection.

The data shall be subject to Kappa inspection and analysis and the Kappa coefficient shall be calculated.Favorable consistency can be proven if Kappa is＞0.8. The consistency in test results of the product tested and the reference product is evaluated as per the evaluation standards.

VII Standards of clinical evaluation

The coincidence rate shall be calculated by comparing with the reference product whose marketing is approved. The product performance shall meet the following requirements.

1)Coincidence rate of negative: the sample whose test results are negative for both the product tested and the reference product and the proportion in the sample whose test results are negative for the reference product shall be more than 95%.

2)Coincidence rate of positive: the sample whose test results are positive for both the product tested and the reference product and the proportion in the sample whose test results are positive for the reference product shall be more than 85%.

3)Total coincidence rate: the sample whose test results are the same for the product tested and the reference product and its proportion in the total number of samples shall be more than 90%.

Method		2019-nCoV nucleic acid test kit（RT-PCR）		Total Results
The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette(Swab)	Result	positive	negative	
	positive	A	B	A+B
	negative	C	D	C+D
Total Results		A+C	B+D	A+B+C+D

Clinical sensitivity =A/(A+C)*100%
Clinical specificity = D/(B+D)*100%
Accuracy: (A+D)/(A+B+C+D)*100%

If the coincidence rate of positive/negative can meet clinical requirements, two methods or Products are considered as equivalent; If the coincidence rate of positive/negative is greatly different, the clinical scheme should be re-designed.

4)Kappa consistency analysis shall be adopted for statistical analysis of reference reagents.

The results of the product tested are statistical materials and can be per the table below:

Method		2019-nCoV nucleic acid test kit（RT-PCR）		Total Results
The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette(Swab)	Result	positive	negative	
	positive	A	B	A+B
	negative	C	D	C+D
Total Results		A+C	B+D	A+B+C+D

$P_{0=}$ (A+D)/(A+B+C+D)*100%

P_e=((A+B)(A+C) +(A+B)(B+D)) /$(A+B+C+D)^2$

Kappa:(P_0 - P_e)/(1-p_e)

If conducting Kappa consistency analysis for the base data above, high consistency can be judged if the Kappa coefficient is >0.8,and both systems are considered as equivalent. Consistency is considered if 0.4<Kappa coefficient <0.8, and the coincidence rate of positive/negative shall be compared, with statistical analysis being made. Two such systems are considered as inconsistent and in-equivalent if the Kappa coefficient is <0.4.

VIII Provisions for amendments to clinical validation

In general, the clinical validation should not be changed. Any modification to the project during the test should be explained, and the time,reason,process of change, and whether there is a record of the change are explained in detail and its impact on the evaluation of the entire research result is explained.

IX. Results and Analysis of Clinical Tests

In total, 232 test samples are included for the unit and all test samples included are tested. Statistics on test results and those of the product tested are as follows:

Method		2019-nCoV Nucleic Acid Test Kit (RT-PCR)		Total Results
The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab)	Results	Positive	Negative	
	Positive	168	0	168
	Negative	18	450	468
Total Results		186	450	636

Clinical sensitivity = 168/186=90.32% (95%CI*85.15% to 93.87%)

Clinical specificity = 450/450＞99.9% (95%CI*98.48% to 100%)

Accuracy: (168+450)/ (168+0+18+450) *100%=97.17% (95%CI* 95.54% to 98.23%)

P_e= (168*186+318*300)/ (486*486) =0.6

Kappa:(P_0 - P_e)/(1-p_e) =0.93

*:95% confidence interview

According to the above table, 450 are proven negative of 450 negative specimens, 168 are proven positive of 186 positive specimens. The sensitivity and accuracy are more than 90%, indicating favorable consistency with the reference product. The Kappa=0.93＞0.8,indicating favorable and high consistency of two methods and equivalence of two such systems.

X Analysis on Inconsistency in Test Results

NO.	Age	Gender	Novel Coronavirus Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)	Clinical diagnostic
309	23	F	Negative	Positive（N and E gene)	Infection 37 days
310	14	M	Negative	Positive（RdRP and N gene)	Infection 17 days
316	44	M	Negative	Positive（RdRP gene)	Infection 18 days
318	33	F	Negative	Positive（N gene)	Infection 41 days
329	20	M	Negative	Positive（N gene)	Infection 27 days
349	30	M	Negative	Positive（N gene)	Infection 25 days
371	49	M	Negative	Positive（N and E gene)	Infection 12 days
372	39	M	Negative	Positive（RdRP and N gene)	Infection 7 days
378	32	M	Negative	Positive（RdRP gene)	Infection 9 days
380	28	M	Negative	Positive（N gene)	Infection 9 days
405	58	F	Negative	Positive（N gene)	Infection 16 days
411	59	F	Negative	Positive（RdRP and N gene)	Infection 14 days
433	33	F	Negative	Positive（RdRP and N gene)	Infection 6 days
434	44	M	Negative	Positive（RdRP and N gene)	Infection 9 days
447	52	M	Negative	Positive（RdRP gene)	Infection 8 days
449	42	M	Negative	Positive（RdRP gene)	Infection 12 days
454	16	F	Negative	Positive（N gene)	Infection 15 days
309	23	F	Negative	Positive（N and E gene)	Infection 15 days

XI Discussion and Conclusions

1.discussion

A Results of comparative analysis of the product tested and the reference product:

Test results of Swab specimen tested and the reference result: both the coincidence rate of negative/positive and the total coincidence rate are larger than 85%, indicating favorable consistency with the reference product. In the analysis results of Kappa inspection, Kappa was proven >0.8, indicating favorable and high consistency of both methods. Both systems were proven equivalent.

2.Test conclusions

By analyzing the test results of the product tested and the reference product, the consistency

percentage of negative/positive and the total consistency percentage are proven high. Moreover, according to the results of statistical analysis, there is no remarkable difference in test results of both, indicating favorable consistency in diagnosis and equivalence of two such systems and can be used for auxiliary diagnosis of those suffering from pneumonia triggered by COVID-19.

X. Quality control methods

On-site quality control

1）During the course of this study, clinical implementors appointed clinical inspectors to conduct regular on-site supervision visits to the research hospital. Through monitoring visits, it was found that all the contents of the research plan were strictly observed, and the correctness of the research data was also guaranteed. Participating researchers have undergone unified training, unified recording methods and judgment standards. The entire clinical trial process is conducted under strict operation, and the test content is complete and authentic. All observations and findings in the clinical trials have been verified and the data are reliable. The conclusions in the clinical trials are derived from the original data.

2）Quality control of clinical experiment process

During the evaluation, quality control was performed daily to ensure that the product was under control. Strict quality control is performed for each trial to ensure the quality of clinical trials.

XI. Prediction of adverse events

Because the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab) is an in vitro diagnostic reagent product, no direct contact with patients is required in clinical trials, no test report is provided to patients, and the test results are only used for comparative studies. It involves personal privacy, does not serve as a basis for auxiliary diagnosis, does not bring any risk to the subject, and does not cause adverse events.

References：

1.The "Technical Review Points for the Registration of New Coronavirus Antigen / Antibody Detection Reagents in 2019 (Trial)" issued by the State Drug Administration Medical Device Technical Evaluation Center on February 25, 2020；

2. "Pneumonitis Diagnosis and Treatment Program for New Coronavirus Infection (Trial Version 7)" issued by the National Health Committee on February 19, 2020.

Annex 1:Package Insert

Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)
Package Insert

A RAPID TEST FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS ANTIGENS IN NASOPHARYNGEAL SWAB AND OROPHARYNGEAL SWAB.
For professional In Vitro Diagnostic Use Only.

INTENDED USE

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is an *in vitro* diagnostic test for the qualitative detection of novel coronavirus antigens in Nasopharyngeal swab and Oropharyngeal swab, using the rapid immunochromatographic method. The identification is based on the monoclonal antibodies specific for the novel coronvirus antigen. It will provide information for clinical doctors to prescribe correct medications.

SUMMARY

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.

PRINCIPLE

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to Novel coroinavirus.
The test device is composed of the following three parts, namely sample pad, reagent pad and reaction membrane. The whole strip is fixed inside a plastic device. The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coroinavirus;the reaction membrane contains the secondary antibodies for Novel coroinavirus, and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.
When the sample is added into the sample window,conjugates dried in the reagent pad are dissolved and migrate along with the sample. If Novel coroinavirus is present in the sample, a complex formed between the anti- Novel coroinavirus conjugate and the virus will be caught by the specific anti- Novel coroinavirus monoclonal coated on the T region.
Whether the sample contains the virus or not, the solution continues to migrate to encounter another reagent (an anti-mouse IgG antibody) that binds the remaining conjugates, thereby producing a red line on the region C.

REAGENTS

The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coroinavirus; the reaction membrane contains the secondary antibodies for Novel coroinavirus,and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use after the expiration date.
- Ensure foil pouch containing test device is not damaged before opening for use.
- Perform test at room temperature 15 to 30°C.
- Wear gloves when hanging the samples, avoid touching the reagent membrane and sample window.
- All samples and used accessories should be treated as infectious and discarded according to local regulations.
- Avoid using bloody samples.

STORAGE AND STABILITY

Store the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) at room temperature or refrigerated (2-30°C). Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

SPECIMEN COLLECTION AND PREPARATION

1. Specimen collection:
It is applicable to the diagnosis of the Novel coroinavirus from the samples of Nasopharyngeal swab.Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

For nasopharyngeal swab completely insert the sterilized swab supplied in this kit into the nasal basin, and swab several times to collect the epidermal cells of the mucus.
For oropharyngeal swab completely insert the sterilized swab supplied in this kit into the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.
It is recommended to collect sample from Nasopharyngeal for more accurate results.
2. Specimen preparation:
1) Take out 1 bottle of Sample Extraction Buffer, remove the bottle cap, add all the extraction buffer into the extraction tube.
2) **Nasopharyngeal and oropharyngeal Swabbing**
Insert the swab into the extraction tube which contains Sample Extraction Buffer. Rotate the swab inside the tube using a circular motion to roll the side of the extraction tube so that liquid is expressed and reabsorbed from the swab, remove the swab. The extracted solution will be used as test sample.

MATERIALS

Materials provided

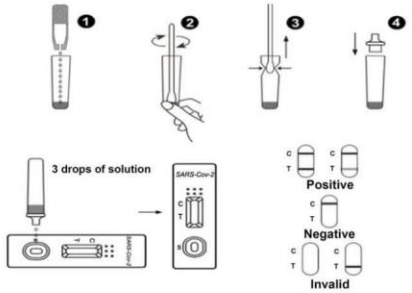
- Test Device
- Package Insert
- Tube Stand
- Sterilized Swab
- Nozzle with Filter
- Extraction Tube
- Sample Extraction Buffer

Materials required but not provided

- Timer

DIRECTIONS FOR USE

Allow the test, specimen, extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.
1.Remove the test device from the sealed foil pouch and use it as soon as possible. Place the test device on a clean and level surface. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Unscrew the whole cap of the specimen collection tube.
3. Take out 1 bottle of Sample Extraction Buffer, remove the bottle cap, add all the extraction buffer into the extraction tube.
4.Place the sterilized swab specimen in the sample extraction buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.
5.Remove the sterilized swab while squeezing the sterilized swab head against the inside of Buffer as you remove it to expel as much liquid as possible from the swab. Discard the sterilized swab in accordance with your biohazard waste disposal protocol.
6. Screw on and tighten the cap onto the specimen collection tube, then **shake the specimen collection tube vigorously** to mix the specimen and the sample extraction buffer. See illustration 4.
7.Add 3 drops of the solution (approx.80ul) to the sample well and then start the timer. Read the result at 10~20 minutes. Don't interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
POSITIVE: Two red lines appear. One red line appears in the control region(C), and one red line in the test region(T). The shade of color may vary, but it should be considered positive whenever there is even a faint line.
NEGATIVE: Only one red line appears in the control region(C), and no line in the test region(T). The negative result indicates that there are no Novel coroinavirus particles in the sample or the number of viral particles is below the detectable range.
INVALID: No red line appears in the control region(C). The test is invalid even if there is a line on test region(T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

- The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is an acute-phase screening test for qualitative detection. Sample collected may contain antigen concentration below the reagent's sensitivity threshold, so a negative test result does not exclude infection with novel coronavirus.
- The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) detects viable and non-viable novel coronavirus antigen. Test performance depends on antigen load in the sample and may not correlate with cell culture performed on the same sample. A positive test does not rule out the possibility that other pathogens may be present, therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
- A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if poor quality specimen is obtained.
- Performance of the test has not been established for monitoring antiviral treatment of novel coronavirus.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results are not intended to rule in other coronavirus infection except the SARS-Cov-2.
- Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children List.
- A negative result may occur if the concentration of antigen in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS-Cov-2 infection, and should be confirmed by viral culture or PCR.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

Clinical evaluation was performed to compare the results obtained by Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) and PCR. The results were summarized below:

Table: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) vs. PCR

Method		2019-nCoV Nucleic Acid Test Kit (RT-PCR)		Total Results
The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab)	Results	Positive	Negative	
	Positive	168	0	168
	Negative	18	450	468
Total Results		186	450	636

Clinical sensitivity = 168/186=90.32% (95%CI*85.15% to 93.87%)
Clinical specificity = 450/450>99.9% (95%CI*98.46% to 100%)
Accuracy: (168+450)/(168+0+18+450)*100%=97.17% (95%CI* 95.54% to 98.23%)
*Confidence Interval

Limit of Detection (LoD)

2019-nCoV Strain Tested	Realy Tech product				
Stock 2019-nCoV Concentration	1 X 10^5 $TCID_{50}$/mL				
Dilution	1/100	1/200	1/400	1/800	1/1600
Concentration in Dilution tested ($TCID_{50}$/ml)	1X10^3	5X10^2	2.5X 10^2	1.25X10^2	6.25X10^1
Call rates of 20 replicates near cut-off	100(20/20)	100(20/20)	100(20/20)	95(19/20)	10(2/20)
Limit of etection (LoD) per Virus Strain	1.25 X 10^2 $TCID_{50}$/mL				

Cross Reaction

The test results are below the corresponding concentration of the substances in the table below, which has no effect on the negative and positive test results of this reagent, and there is no cross-reaction.

Virus/Bacteria/Parasite	Strain	Concentration
MERS-coronavirus	N/A	72 μg/mL
Adenovirus	Type 1	1.5 x $10^6$$TCID_{50}$/mL
	Type 3	7.5 x $10^6$$TCID_{50}$/mL
	Type 5	4.5 x $10^6$$TCID_{50}$/mL
	Type 7	1.0 x $10^6$$TCID_{50}$/mL
	Type 8	1.0 x $10^6$$TCID_{50}$/mL
	Type 11	2.5 x $10^6$$TCID_{50}$/mL
	Type 18	2.5 x $10^6$$TCID_{50}$/mL
	Type 23	6.0 x $10^6$$TCID_{50}$/mL
	Type 55	1.5 x $10^6$$TCID_{50}$/mL
Influenza A	H1N1 Denver	3.0 x $10^6$$TCID_{50}$/mL
	H1N1 WS/33	2.0 x $10^6$$TCID_{50}$/mL
	H1N1 A/Mal/302/54	1.5 x $10^6$$TCID_{50}$/mL
	H1N1 New Caledonia	7.6 x $10^6$$TCID_{50}$/mL
	H3N2 A/Hong Kong/8/68	4.6 x $10^6$$TCID_{50}$/mL
Influenza B	Nevada/03/2011	1.5 x $10^6$$TCID_{50}$/mL
	B/Lee/40	8.5 x $10^6$$TCID_{50}$/mL
	B/Taiwan/2/62	4.0 x $10^6$$TCID_{50}$/mL
Respiratory syncytial virus	N/A	2.5 x $10^6$$TCID_{50}$/mL
Legionella pneumophila	Bloomington-2	1 x 10^5 PFU/mL
	Los Angeles-1	1 x 10^5 PFU/mL
	82A3105	1 x 10^5 PFU/mL
Rhinovirus A16	N/A	1.5 x $10^6$$TCID_{50}$/mL
Mycobacterium tuberculosis	K	1 x 10^5PFU/mL
	Erdman	1 x 10^5PFU/mL
	HN878	1 x 10^5PFU/mL
	CDC1551	1 x 10^5PFU/mL
	H37Rv	1 x 10^5PFU/mL
Streptococcus pneumonia	4752-98 [Maryland (D1)6B-17]	1 x 10^5PFU/mL
	178 [Poland 23F-16]	1 x 10^5PFU/mL
	262 [CIP 104340]	1 x 10^5PFU/mL
	Slovakia 14-10 [29055]	1 x 10^5PFU/mL

Streptococcus pyrogens	Typing strain T1 [NCIB 11841, SF 130]	1 x 10^5PFU/ml
Mycoplasma pneumoniae	Mutant 22	1 x 10^5PFU/ml
	FH strain of Eaton Agent [NCTC 10119]	1 x 10^5PFU/ml
	36M129-B7	1 x 10^5PFU/ml
Coronavirus	229E	1.5 x 10^5 $TCID_{50}$/ml
	OC43	1.5 x 10^5 $TCID_{50}$/ml
	NL63	1.5 x 10^5 $TCID_{50}$/ml
	HKU1	1.5 x 10^5 $TCID_{50}$/ml
Human etapneumovirus (hMPV) 3 Type B1	Peru2-2002	1.5 x 10^5 $TCID_{50}$/ml
Human Metapneumovirus (hMPV) 16 Type A1	IA10-2003	1.5 x 10^5 $TCID_{50}$/ml
Parainfluenza virus	Type 1	1.5 x 106 $TCID_{50}$/ml
	Type 2	1.5 x 106 $TCID_{50}$/ml
	Type 3	1.5 x 106 $TCID_{50}$/ml
	Type 4A	1.5 x 106 $TCID_{50}$/ml

Interfering Substances Reaction

When tested using the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab), there was no interference between the device reagents and the Potential interference substances listed in below table that would create false positive or negative results for SARS-Cov-2 antigen:

Substance	Concentration	Substance	Concentration
Mucin	100μg/mL	Acetylsalicylic acid	3.0 mM
Whole Blood	5% (v/v)	Ibuprofen	2.5 mM
Biotin	100μg/mL	Mupirocin	10 mg/mL
Neo-Synephrine (Phenylephrine)	5%(v/v)	Tobramycin	10μg/mL
Afrin Nasal Spray (Oxymetazoline)	5%(v/v)	Erythromycin	50uM
Saline Nasal Spray	5%(v/v)	Ciprofloxacin	50uM
Homeopathic	5%(v/v)	Ceftriaxone	110mg/mL
Sodium Cromoglycate	10 mg/mL	Meropenem	3.7μg/mL
Olopatadine Hydrochloride	10 mg/mL	Tobramycin	100μg/mL
Zanamivir	5 mg/mL	Histamine Hydrochloride	100μg/mL
Oseltamivir	10 mg/mL	Peramivir	1mmol/mL
Artemether-lumefantrine	50uM	Flunisolide	100μg/mL
Doxycycline hyclate	50uM	Budesonide	0.64nmol/ L
Quinine	150uM	Fluticasone	0.3ng/mL
Lamivudine	1 mg/mL	Lopinavir	6μg/mL
Ribavirin	1 mg/mL	Ritonavir	8.2mg/mL
Daclatasvir	1 mg/mL	Abidor	417.8ng/mL
Acetaminophen	150uM	Pooled human nasal wash	N/A

SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instruction foe use
LOT	Batch code	CE	Meet the requirements of EC Directive 98/79/EC

HANGZHOU REALY TECH CO., LTD.
4th Floor, #12 Building, Eastern Medicine Town,
Xiasha Economic &Technology Development,
310018 Hangzhou, Zhejiang, P. R. China
Website: www.realytech.com

EC REP **Luxus Lebenswelt GmbH**
Kochstr.1,47877, Willich, Germany

CE

Number:1101381601
Version:1.604
Effective Date:2020-10-07

Annex 2: Data of Clinical Tests

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
1	21	M	Negative	Negative(Ct/Cq）>43
2	24	M	Negative	Negative(Ct/Cq）>43
3	29	F	Negative	Negative(Ct/Cq）>43
4	58	F	Negative	Negative(Ct/Cq）>43
5	14	M	Negative	Negative(Ct/Cq）>43
6	21	M	Negative	Negative(Ct/Cq）>43
7	23	M	Negative	Negative(Ct/Cq）>43
8	15	M	Negative	Negative(Ct/Cq）>43
9	42	F	Negative	Negative(Ct/Cq）>43
10	83	M	Negative	Negative(Ct/Cq）>43
11	54	M	Negative	Negative(Ct/Cq）>43
12	86	F	Negative	Negative(Ct/Cq）>43
13	54	M	Negative	Negative(Ct/Cq）>43
14	30	F	Negative	Negative(Ct/Cq）>43
15	68	M	Negative	Negative(Ct/Cq）>43
16	64	M	Negative	Negative(Ct/Cq）>43
17	67	F	Negative	Negative(Ct/Cq）>43
18	30	M	Negative	Negative(Ct/Cq）>43
19	30	F	Negative	Negative(Ct/Cq）>43
20	23	M	Negative	Negative(Ct/Cq）>43

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
21	55	M	Negative	Negative(Ct/Cq）>43
22	65	M	Negative	Negative(Ct/Cq）>43
23	75	M	Negative	Negative(Ct/Cq）>43
24	56	F	Negative	Negative(Ct/Cq）>43
25	66	M	Negative	Negative(Ct/Cq）>43
26	22	M	Negative	Negative(Ct/Cq）>43
27	56	F	Negative	Negative(Ct/Cq）>43
28	31	M	Negative	Negative(Ct/Cq）>43
29	30	F	Negative	Negative(Ct/Cq）>43
30	70	M	Negative	Negative(Ct/Cq）>43
31	87	F	Negative	Negative(Ct/Cq）>43
32	35	F	Negative	Negative(Ct/Cq）>43
33	61	M	Negative	Negative(Ct/Cq）>43
34	31	M	Negative	Negative(Ct/Cq）>43
35	21	M	Negative	Negative(Ct/Cq）>43
36	92	M	Negative	Negative(Ct/Cq）>43
37	29	M	Negative	Negative(Ct/Cq）>43
38	28	F	Negative	Negative(Ct/Cq）>43
39	18	M	Negative	Negative(Ct/Cq）>43
40	29	F	Negative	Negative(Ct/Cq）>43

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
41	52	F	Negative	Negative(Ct/Cq）>43
42	62	M	Negative	Negative(Ct/Cq）>43
43	57	F	Negative	Negative(Ct/Cq）>43
44	55	F	Negative	Negative(Ct/Cq）>43
45	73	M	Negative	Negative(Ct/Cq）>43
46	62	M	Negative	Negative(Ct/Cq）>43
47	64	M	Negative	Negative(Ct/Cq）>43
48	74	M	Negative	Negative(Ct/Cq）>43
49	26	M	Negative	Negative(Ct/Cq）>43
50	51	F	Negative	Negative(Ct/Cq）>43
51	50	M	Negative	Negative(Ct/Cq）>43
52	16	F	Negative	Negative(Ct/Cq）>43
53	59	M	Negative	Negative(Ct/Cq）>43
54	14	F	Negative	Negative(Ct/Cq）>43
55	29	M	Negative	Negative(Ct/Cq）>43
56	39	M	Negative	Negative(Ct/Cq）>43
57	61	M	Negative	Negative(Ct/Cq）>43
58	62	F	Negative	Negative(Ct/Cq）>43
59	70	M	Negative	Negative(Ct/Cq）>43
60	57	M	Negative	Negative(Ct/Cq）>43
61	26	M	Negative	Negative(Ct/Cq）>43

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
62	72	M	Negative	Negative(Ct/Cq）>43
63	16	M	Negative	Negative(Ct/Cq）>43
64	23	M	Negative	Negative(Ct/Cq）>43
65	53	F	Negative	Negative(Ct/Cq）>43
66	55	M	Negative	Negative(Ct/Cq）>43
67	32	M	Negative	Negative(Ct/Cq）>43
68	77	M	Negative	Negative(Ct/Cq）>43
69	21	M	Negative	Negative(Ct/Cq）>43
70	39	M	Negative	Negative(Ct/Cq）>43
71	11	F	Negative	Negative(Ct/Cq）>43
72	25	M	Negative	Negative(Ct/Cq）>43
73	27	M	Negative	Negative(Ct/Cq）>43
74	40	M	Negative	Negative(Ct/Cq）>43
75	24	M	Negative	Negative(Ct/Cq）>43
76	36	F	Negative	Negative(Ct/Cq）>43
77	81	M	Negative	Negative(Ct/Cq）>43
78	16	F	Negative	Negative(Ct/Cq）>43
79	86	F	Negative	Negative(Ct/Cq）>43
80	31	F	Negative	Negative(Ct/Cq）>43
81	60	M	Negative	Negative(Ct/Cq）>43
82	35	M	Negative	Negative(Ct/Cq）>43

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
83	69	F	Negative	Negative(Ct/Cq）>43
84	29	M	Negative	Negative(Ct/Cq）>43
85	24	M	Negative	Negative(Ct/Cq）>43
86	27	F	Negative	Negative(Ct/Cq）>43
87	50	M	Negative	Negative(Ct/Cq）>43
88	38	F	Negative	Negative(Ct/Cq）>43
89	25	F	Negative	Negative(Ct/Cq）>43
90	53	F	Negative	Negative(Ct/Cq）>43
91	15	M	Negative	Negative(Ct/Cq）>43
92	18	M	Negative	Negative(Ct/Cq）>43
93			Negative	Negative(Ct/Cq）>43
94	18	M	Negative	Negative(Ct/Cq）>43
95	33	F	Negative	Negative(Ct/Cq）>43
96	68	M	Negative	Negative(Ct/Cq）>43
97	31	M	Negative	Negative(Ct/Cq）>43
98	55	F	Negative	Negative(Ct/Cq）>43
99	46	M	Negative	Negative(Ct/Cq）>43
100	71	M	Negative	Negative(Ct/Cq）>43
101	24	F	Negative	Negative(Ct/Cq）>43
102	51	M	Negative	Negative(Ct/Cq）>43
103	43	M	Negative	Negative(Ct/Cq）>43

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
104	80	M	Negative	Negative(Ct/Cq）>43
105	71	F	Negative	Negative(Ct/Cq）>43
106	49	M	Negative	Negative(Ct/Cq）>43
107	64	M	Negative	Negative(Ct/Cq）>43
108	54	M	Negative	Negative(Ct/Cq）>43
109	23	M	Negative	Negative(Ct/Cq）>43
110	52	F	Negative	Negative(Ct/Cq）>43
111	32	M	Negative	Negative(Ct/Cq）>43
112	19	M	Negative	Negative(Ct/Cq）>43
113	16	F	Negative	Negative(Ct/Cq）>43
114	23	M	Negative	Negative(Ct/Cq）>43
115	51	F	Negative	Negative(Ct/Cq）>43
116	25	M	Negative	Negative(Ct/Cq）>43
117	77	F	Negative	Negative(Ct/Cq）>43
118	22	M	Negative	Negative(Ct/Cq）>43
119	57	M	Negative	Negative(Ct/Cq）>43
120	18	M	Negative	Negative(Ct/Cq）>43
121	61	M	Negative	Negative(Ct/Cq）>43
122	30	M	Negative	Negative(Ct/Cq）>43
123	64	M	Negative	Negative(Ct/Cq）>43
124	57	M	Negative	Negative(Ct/Cq）>43

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
125	71	M	Negative	Negative(Ct/Cq）>43
126	31	M	Negative	Negative(Ct/Cq）>43
127	50	M	Negative	Negative(Ct/Cq）>43
128	58	M	Negative	Negative(Ct/Cq）>43
129	25	M	Negative	Negative(Ct/Cq）>43
130	75	M	Negative	Negative(Ct/Cq）>43
131	52	F	Negative	Negative(Ct/Cq）>43
132	46	M	Negative	Negative(Ct/Cq）>43
133	16	M	Negative	Negative(Ct/Cq）>43
134	28	M	Negative	Negative(Ct/Cq）>43
135	76	M	Negative	Negative(Ct/Cq）>43
136	13	F	Negative	Negative(Ct/Cq）>43
137	45	M	Negative	Negative(Ct/Cq）>43
138	38	M	Negative	Negative(Ct/Cq）>43
139	49	M	Negative	Negative(Ct/Cq）>43
140	16	M	Negative	Negative(Ct/Cq）>43
141	70	M	Negative	Negative(Ct/Cq）>43
142	33	M	Negative	Negative(Ct/Cq）>43
143	54	F	Negative	Negative(Ct/Cq）>43
144	66	M	Negative	Negative(Ct/Cq）>43
145	46	M	Negative	Negative(Ct/Cq）>43

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
146	40	M	Negative	Negative(Ct/Cq）>43
147	25	M	Negative	Negative(Ct/Cq）>43
148	20	M	Negative	Negative(Ct/Cq）>43
149	79	M	Negative	Negative(Ct/Cq）>43
150	32	M	Negative	Negative(Ct/Cq）>43
151	15	M	Negative	Negative(Ct/Cq）>43
152	25	F	Negative	Negative(Ct/Cq）>43
153	44	M	Negative	Negative(Ct/Cq）>43
154	96	M	Negative	Negative(Ct/Cq）>43
155	31	M	Negative	Negative(Ct/Cq）>43
156	28	M	Negative	Negative(Ct/Cq）>43
157	30	F	Negative	Negative(Ct/Cq）>43
158	51	M	Negative	Negative(Ct/Cq）>43
159	96	M	Negative	Negative(Ct/Cq）>43
160	46	M	Negative	Negative(Ct/Cq）>43
161	56	M	Negative	Negative(Ct/Cq）>43
162	33	M	Negative	Negative(Ct/Cq）>43
163	15	F	Negative	Negative(Ct/Cq）>43
164	25	M	Negative	Negative(Ct/Cq）>43
165	52	F	Negative	Negative(Ct/Cq）>43
166	31	F	Negative	Negative(Ct/Cq）>43

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
167	57	M	Negative	Negative(Ct/Cq）>43
168	31	M	Negative	Negative(Ct/Cq）>43
169	57	F	Negative	Negative(Ct/Cq）>43
170	22	M	Negative	Negative(Ct/Cq）>43
171	35	M	Negative	Negative(Ct/Cq）>43
172	74	M	Negative	Negative(Ct/Cq）>43
173	51	M	Negative	Negative(Ct/Cq）>43
174	59	M	Negative	Negative(Ct/Cq）>43
175	56	M	Negative	Negative(Ct/Cq）>43
176	47	M	Negative	Negative(Ct/Cq）>43
177	50	M	Negative	Negative(Ct/Cq）>43
178	57	F	Negative	Negative(Ct/Cq）>43
179	32	M	Negative	Negative(Ct/Cq）>43
180	56	M	Negative	Negative(Ct/Cq）>43
181	65	M	Negative	Negative(Ct/Cq）>43
182	78	M	Negative	Negative(Ct/Cq）>43
183	29	M	Negative	Negative(Ct/Cq）>43
184	50	F	Negative	Negative(Ct/Cq）>43
185	2	F	Negative	Negative(Ct/Cq）>43
186	6	M	Negative	Negative(Ct/Cq）>43
187	19	F	Negative	Negative(Ct/Cq）>43

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
188	27	M	Negative	Negative(Ct/Cq）>43
189	59	M	Negative	Negative(Ct/Cq）>43
190	59	M	Negative	Negative(Ct/Cq）>43
191	35	F	Negative	Negative(Ct/Cq）>43
192	6	M	Negative	Negative(Ct/Cq）>43
193	68	M	Negative	Negative(Ct/Cq）>43
194	69	F	Negative	Negative(Ct/Cq）>43
195	55	M	Negative	Negative(Ct/Cq）>43
196	2	F	Negative	Negative(Ct/Cq）>43
197	70	M	Negative	Negative(Ct/Cq）>43
198	81	M	Negative	Negative(Ct/Cq）>43
199	76	M	Negative	Negative(Ct/Cq）>43
200	22	M	Negative	Negative(Ct/Cq）>43
201	41	男	Negative	Negative(Ct/Cq）>43
202	16	女	Negative	Negative(Ct/Cq）>43
203	49	女	Negative	Negative(Ct/Cq）>43
204	49	男	Negative	Negative(Ct/Cq）>43
205	20	男	Negative	Negative(Ct/Cq）>43
206	25	女	Negative	Negative(Ct/Cq）>43
207	38	女	Negative	Negative(Ct/Cq）>43
208	52	男	Negative	Negative(Ct/Cq）>43

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
209	28	女	Negative	Negative(Ct/Cq）>43
210	57	男	Negative	Negative(Ct/Cq）>43
211	14	男	Negative	Negative(Ct/Cq）>43
212	59	女	Negative	Negative(Ct/Cq）>43
213	27	男	Negative	Negative(Ct/Cq）>43
214	26	男	Negative	Negative(Ct/Cq）>43
215	29	男	Negative	Negative(Ct/Cq）>43
216	25	女	Negative	Negative(Ct/Cq）>43
217	24	男	Negative	Negative(Ct/Cq）>43
218	14	女	Negative	Negative(Ct/Cq）>43
219	42	男	Negative	Negative(Ct/Cq）>43
220	39	女	Negative	Negative(Ct/Cq）>43
221	60	女	Negative	Negative(Ct/Cq）>43
222	17	男	Negative	Negative(Ct/Cq）>43
223	39	女	Negative	Negative(Ct/Cq）>43
224	43	女	Negative	Negative(Ct/Cq）>43
225	21	女	Negative	Negative(Ct/Cq）>43
226	43	女	Negative	Negative(Ct/Cq）>43
227	44	女	Negative	Negative(Ct/Cq）>43
228	36	女	Negative	Negative(Ct/Cq）>43
229	51	女	Negative	Negative(Ct/Cq）>43

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
230	23	女	Negative	Negative(Ct/Cq）>43
231	22	男	Negative	Negative(Ct/Cq）>43
232	30	男	Negative	Negative(Ct/Cq）>43
233	48	女	Negative	Negative(Ct/Cq）>43
234	35	男	Negative	Negative(Ct/Cq）>43
235	23	女	Negative	Negative(Ct/Cq）>43
236	22	男	Negative	Negative(Ct/Cq）>43
237	58	男	Negative	Negative(Ct/Cq）>43
238	40	女	Negative	Negative(Ct/Cq）>43
239	47	男	Negative	Negative(Ct/Cq）>43
240	60	男	Negative	Negative(Ct/Cq）>43
241	25	男	Negative	Negative(Ct/Cq）>43
242	13	女	Negative	Negative(Ct/Cq）>43
243	48	男	Negative	Negative(Ct/Cq）>43
244	21	男	Negative	Negative(Ct/Cq）>43
245	44	女	Negative	Negative(Ct/Cq）>43
246	57	男	Negative	Negative(Ct/Cq）>43
247	18	女	Negative	Negative(Ct/Cq）>43
248	41	男	Negative	Negative(Ct/Cq）>43
249	15	女	Negative	Negative(Ct/Cq）>43
250	53	女	Negative	Negative(Ct/Cq）>43

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
251	43	男	Negative	Negative(Ct/Cq）>43
252	30	男	Negative	Negative(Ct/Cq）>43
253	33	女	Negative	Negative(Ct/Cq）>43
254	58	男	Negative	Negative(Ct/Cq）>43
255	55	男	Negative	Negative(Ct/Cq）>43
256	42	男	Negative	Negative(Ct/Cq）>43
257	46	女	Negative	Negative(Ct/Cq）>43
258	15	女	Negative	Negative(Ct/Cq）>43
259	58	女	Negative	Negative(Ct/Cq）>43
260	40	女	Negative	Negative(Ct/Cq）>43
261	34	男	Negative	Negative(Ct/Cq）>43
262	18	男	Negative	Negative(Ct/Cq）>43
263	54	女	Negative	Negative(Ct/Cq）>43
264	31	男	Negative	Negative(Ct/Cq）>43
265	48	女	Negative	Negative(Ct/Cq）>43
266	39	女	Negative	Negative(Ct/Cq）>43
267	28	男	Negative	Negative(Ct/Cq）>43
268	38	女	Negative	Negative(Ct/Cq）>43
269	60	男	Negative	Negative(Ct/Cq）>43
270	37	男	Negative	Negative(Ct/Cq）>43
271	30	女	Negative	Negative(Ct/Cq）>43
272	57	男	Negative	Negative(Ct/Cq）>43

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
273	21	女	Negative	Negative(Ct/Cq）>43
274	34	男	Negative	Negative(Ct/Cq）>43
275	21	男	Negative	Negative(Ct/Cq）>43
276	34	女	Negative	Negative(Ct/Cq）>43
277	16	女	Negative	Negative(Ct/Cq）>43
278	24	女	Negative	Negative(Ct/Cq）>43
279	51	女	Negative	Negative(Ct/Cq）>43
280	57	女	Negative	Negative(Ct/Cq）>43
281	32	女	Negative	Negative(Ct/Cq）>43
282	52	女	Negative	Negative(Ct/Cq）>43
283	23	男	Negative	Negative(Ct/Cq）>43
284	58	女	Negative	Negative(Ct/Cq）>43
285	29	男	Negative	Negative(Ct/Cq）>43
286	12	女	Negative	Negative(Ct/Cq）>43
287	55	女	Negative	Negative(Ct/Cq）>43
288	27	女	Negative	Negative(Ct/Cq）>43
289	59	女	Negative	Negative(Ct/Cq）>43
290	28	女	Negative	Negative(Ct/Cq）>43
291	23	男	Negative	Negative(Ct/Cq）>43
292	25	男	Negative	Negative(Ct/Cq）>43
293	15	男	Negative	Negative(Ct/Cq）>43
294	34	女	Negative	Negative(Ct/Cq）>43

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
295	52	女	Negative	Negative(Ct/Cq）>43
296	24	男	Negative	Negative(Ct/Cq）>43
297	45	男	Negative	Negative(Ct/Cq）>43
298	36	女	Negative	Negative(Ct/Cq）>43
299	57	女	Negative	Negative(Ct/Cq）>43
300	48	女	Negative	Negative(Ct/Cq）>43
301	49	F	Positive	Positive（RdRP and N gene)
302	32	F	Positive	Positive（RdRP and N gene)
303	31	F	Positive	Positive（RdRP and N gene)
304	32	F	Positive	Positive（RdRP and N gene)
305	21	F	Positive	Positive（RdRP and N gene)
306	51	M	Positive	Positive（RdRP and N gene)
307	22	F	Positive	Positive（RdRP and N gene)
308	46	F	Positive	Positive（RdRP and N gene)
309	23	F	Negative	Positive（N and E gene)
310	14	M	Negative	Positive（RdRP and N gene)
311	42	M	Positive	Positive（RdRP and N gene)
312	51	M	Positive	Positive（RdRP and N gene)
313	80	M	Positive	Positive（RdRP and N gene)
314	39	F	Positive	Positive（RdRP and N gene)
315	67	M	Positive	Positive（RdRP and N gene)
316	44	M	Negative	Positive（RdRP gene)

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
317	26	F	Positive	Positive（RdRP and N gene)
318	33	F	Negative	Positive（N gene)
319	38	F	Positive	Positive（RdRP and N gene)
320	36	F	Positive	Positive（RdRP and N gene)
321	3	F	Positive	Positive（RdRP and N gene)
322	35	F	Positive	Positive（RdRP and N gene)
323	23	F	Positive	Positive（RdRP and N gene)
324	43	M	Positive	Positive（RdRP and N gene)
325	43	F	Positive	Positive（RdRP and N gene)
326	46	F	Positive	Positive（RdRP and N gene)
327	55	F	Positive	Positive（RdRP and N gene)
328	22	F	Positive	Positive（RdRP and N gene)
329	20	M	Negative	Positive（N gene)
330	42	M	Positive	Positive（RdRP and N gene)
331	56	F	Positive	Positive（RdRP and N gene)
332	55	M	Positive	Positive（RdRP and N gene)
333	26	F	Positive	Positive（RdRP and N gene)
334	54	M	Positive	Positive（RdRP and N gene)
335	43	F	Positive	Positive（RdRP and N gene)
336	69	M	Positive	Positive（RdRP and N gene)
337	36	M	Positive	Positive（RdRP and N gene)
338	37	F	Positive	Positive（RdRP and N gene)

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
339	44	F	Positive	Positive（RdRP and N gene)
340	43	F	Positive	Positive（RdRP and N gene)
341	67	F	Positive	Positive（RdRP and N gene)
342	51	F	Positive	Positive（RdRP and N gene)
343	75	F	Positive	Positive（RdRP and N gene)
344	60	F	Positive	Positive（RdRP and N gene)
345	25	M	Positive	Positive（RdRP and N gene)
346	75	F	Positive	Positive（RdRP and N gene)
347	43	F	Positive	Positive（RdRP and N gene)
348	30	F	Positive	Positive（RdRP and N gene)
349	30	M	Negative	Positive（N gene)
350	26	F	Positive	Positive（RdRP and N gene)
351	32	F	Positive	Positive（RdRP and N gene)
352	73	M	Positive	Positive（RdRP and N gene)
353	58	F	Positive	Positive（RdRP and N gene)
354	66	F	Positive	Positive（RdRP and N gene)
355	29	F	Positive	Positive（RdRP and N gene)
356	56	M	Positive	Positive（RdRP and N gene)
357	24	M	Positive	Positive（N and E gene)
358	36	M	Positive	Positive（RdRP and N gene)
359	70	F	Positive	Positive（RdRP and N gene)
360	45	M	Positive	Positive（RdRP and N gene)

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
361	38	F	Positive	Positive（RdRP and N gene)
362	42	M	Positive	Positive（RdRP and N gene)
363	55	M	Positive	Positive（RdRP and N gene)
364	33	M	Positive	Positive（RdRP and N gene)
365	39	M	Positive	Positive（RdRP and N gene)
366	58	F	Positive	Positive（N and E gene)
367	20	F	Positive	Positive（RdRP and N gene)
368	42	M	Positive	Positive（RdRP and N gene)
369	27	F	Positive	Positive（RdRP and N gene)
370	49	M	Positive	Positive（RdRP and N gene)
371	49	M	Negative	Positive（N and E gene)
372	39	M	Negative	Positive（RdRP and N gene)
373	17	F	Positive	Positive（RdRP and N gene)
374	60	M	Positive	Positive（RdRP and N gene)
375	44	M	Positive	Positive（RdRP and N gene)
376	49	F	Positive	Positive（RdRP and N gene)
377	11	M	Positive	Positive（RdRP and N gene)
378	32	M	Negative	Positive（RdRP gene)
379	51	F	Positive	Positive（RdRP and N gene)
380	28	M	Negative	Positive（N gene)
381	31	F	Positive	Positive（RdRP and N gene)
382	50	M	Positive	Positive（RdRP and N gene)

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
383	47	M	Positive	Positive（RdRP and N gene)
384	44	F	Positive	Positive（N and E gene)
385	10	F	Positive	Positive（RdRP and N gene)
386	24	M	Positive	Positive（RdRP and N gene)
387	22	F	Positive	Positive（RdRP and N gene)
388	47	F	Positive	Positive（RdRP and N gene)
389	26	M	Positive	Positive（RdRP and N gene)
390	43	F	Positive	Positive（RdRP and N gene)
391	55	M	Positive	Positive（RdRP and N gene)
392	50	F	Positive	Positive（RdRP and N gene)
393	26	M	Positive	Positive（RdRP and N gene)
394	51	F	Positive	Positive（RdRP and N gene)
395	20	F	Positive	Positive（RdRP and N gene)
396	44	M	Positive	Positive（RdRP and N gene)
397	38	F	Positive	Positive（RdRP and N gene)
398	38	F	Positive	Positive（RdRP and N gene)
399	39	M	Positive	Positive（RdRP and N gene)
400	30	F	Positive	Positive（RdRP and N gene)
401	57	F	Positive	Positive（RdRP and N gene)
402	45	M	Positive	Positive（RdRP and N gene)
403	41	F	Positive	Positive（RdRP and N gene)
404	26	F	Positive	Positive（RdRP and N gene)

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
405	58	F	Negative	Positive（N gene)
406	39	F	Positive	Positive（RdRP and N gene)
407	60	F	Positive	Positive（RdRP and N gene)
408	11	M	Positive	Positive（RdRP and N gene)
409	12	F	Positive	Positive（RdRP and N gene)
410	17	M	Positive	Positive（RdRP and N gene)
411	59	F	Negative	Positive（RdRP and N gene)
412	15	M	Positive	Positive（RdRP and N gene)
413	53	F	Positive	Positive（RdRP and N gene)
414	10	M	Positive	Positive（RdRP and N gene)
415	25	F	Positive	Positive（RdRP and N gene)
416	39	M	Positive	Positive（RdRP and N gene)
417	56	M	Positive	Positive（RdRP and N gene)
418	49	M	Positive	Positive（RdRP and N gene)
419	20	M	Positive	Positive（RdRP and N gene)
420	25	M	Positive	Positive（RdRP and N gene)
421	37	F	Positive	Positive（RdRP and N gene)
422	52	F	Positive	Positive（RdRP and N gene)
423	60	F	Positive	Positive（RdRP and N gene)
424	25	M	Positive	Positive（RdRP and N gene)
425	19	F	Positive	Positive（RdRP and N gene)
426	32	M	Positive	Positive（RdRP and N gene)

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
427	28	F	Positive	Positive（RdRP and N gene)
428	52	F	Positive	Positive（RdRP and N gene)
429	40	F	Positive	Positive（RdRP and N gene)
430	28	F	Positive	Positive（RdRP and N gene)
431	31	F	Positive	Positive（RdRP and N gene)
432	48	M	Positive	Positive（RdRP and N gene)
433	33	F	Negative	Positive（RdRP and N gene)
434	44	M	Negative	Positive（RdRP and N gene)
435	34	F	Positive	Positive（RdRP and N gene)
436	18	M	Positive	Positive（RdRP and N gene)
437	59	M	Positive	Positive（RdRP and N gene)
438	18	M	Positive	Positive（RdRP and N gene)
439	38	M	Positive	Positive（RdRP and N gene)
440	20	F	Positive	Positive（RdRP and N gene)
441	54	F	Positive	Positive（RdRP and N gene)
442	43	F	Positive	Positive（RdRP and N gene)
443	23	M	Positive	Positive（RdRP and N gene)
444	27	F	Positive	Positive（RdRP and N gene)
445	39	M	Positive	Positive（RdRP and N gene)
446	60	M	Positive	Positive（RdRP and N gene)
447	52	M	Negative	Positive（RdRP gene)
448	49	M	Positive	Positive（RdRP and N gene)

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
449	42	M	Negative	Positive（RdRP gene)
450	32	F	Positive	Positive（RdRP and N gene)
451	59	M	Positive	Positive（RdRP and N gene)
452	33	F	Positive	Positive（RdRP and N gene)
453	15	F	Positive	Positive（RdRP and N gene)
454	16	F	Negative	Positive（N gene)
455	24	M	Positive	Positive（RdRP and N gene)
456	52	F	Positive	Positive（RdRP and N gene)
457	60	M	Positive	Positive（RdRP and N gene)
458	24	M	Positive	Positive（RdRP and N gene)
459	36	F	Positive	Positive（RdRP and N gene)
460	19	F	Positive	Positive（RdRP and N gene)
461	33	F	Positive	Positive（RdRP and N gene)
462	53	M	Positive	Positive（RdRP and N gene)
463	43	M	Positive	Positive（RdRP and N gene)
464	12	F	Positive	Positive（RdRP and N gene)
465	14	M	Positive	Positive（RdRP and N gene)
466	56	M	Positive	Positive（RdRP and N gene)
467	52	F	Positive	Positive（RdRP and N gene)
468	32	F	Positive	Positive（RdRP and N gene)
469	50	M	Positive	Positive（RdRP and N gene)
470	18	F	Positive	Positive（RdRP and N gene)

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
471	35	F	Positive	Positive（RdRP and N gene)
472	12	M	Positive	Positive（RdRP and N gene)
473	14	F	Negative	Positive（RdRP and N gene)
474	13	F	Positive	Positive（RdRP and N gene)
475	42	M	Positive	Positive（RdRP and N gene)
476	13	F	Positive	Positive（RdRP and N gene)
477	14	F	Positive	Positive（RdRP and N gene)
478	60	M	Positive	Positive（RdRP and N gene)

NO.	Age	Gender	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
479	13	F	Positive	Positive（RdRP and N gene)
480	51	M	Positive	Positive（RdRP and N gene)
481	56	M	Positive	Positive（RdRP and N gene)
482	14	F	Positive	Positive（RdRP and N gene)
483	45	F	Positive	Positive（RdRP and N gene)
484	24	F	Positive	Positive（RdRP and N gene)
485	15	M	Positive	Positive（RdRP and N gene)
486	51	F	Positive	Positive（RdRP and N gene)