Clinical Validation report of Novel coronavirus neutralizing antibody Rapid Test Device (serum/plasma/whole blood)

Product name: Novel coronavirus neutralizing antibody Rapid Test Device (serum/plasma/whole blood)

Package Specification: 25 tests/kit

Manufacturer: Hangzhou Realy Tech Co., Ltd

I. Clinical validation time

This clinical evaluation was conducted from October 2020 to November 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.

SARS-CoV-2 has several structural proteins including spike (S), envelope (E), membrane (M) and nucleocapsid (N). The spike protein (S) contains a receptor binding domain (RBD), which is responsible for recognizing the cell surface receptor, angiotensin converting enzyme-2 (ACE2). It is found that the RBD of the SARS-CoV-2 S protein strongly interacts with the human ACE2 receptor leading to endocytosis into the host cells of the deep lung and viral replication.

Infection with the SARS-CoV-2 initiates an immune response, which includes the production of antibodies in the blood. The secreted antibodies provide protection against future infections from viruses, because they remain in the circulatory system for months to years after infection and will bind quickly and strongly to the pathogen to block cellular infiltration and replication. These antibodies are named neutralizing antibodies.

The Novel coronavirus neutralizing antibody Rapid Test Device developed by our company can help whether the patient has a novel coronavirus neutralizing antibody that can resist the virus in order to evaluate the effect of vaccination. At the same time, the product can provide the neutralizing antibody titer in the patient's blood specimen to help the vaccinator understand the antibody titer during and after the vaccination, at the same time， the result can help the patient identify the current antibody status, and provide the basis for whether to supplement the vaccination in the future.

III. Test purposes

The Novel coronavirus neutralizing antibody Rapid Test Device (serum/plasma/whole blood) 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

Neutralizing antibody is the main effect evaluation indicator of new coronavirus vaccination. The experiment selects blood samples of people who have been vaccinated and people who have not been vaccinated, Evaluate product performance.

In the experiment,using the in-vitro diagnostic reagents to be evaluated, neutralizing antibody titer detection reagents and reference reagents, the blood (serum/plasma/whole blood) samples of clinically injected and non-vaccinated subjects were compared and tested and proved The in vitro diagnostic reagents used in this test can achieve the expected purpose.

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（MNP method）. Meanwhile, the samples shall be tested via the qualitative test strip 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:

Person who Had been injected with a new coronavirus vaccine booster for 20 days.

Negative inclusion:

Person who Had not been injected with any new coronavirus vaccine.

Covid-19 IgG is negative;

4. Sample collection, processing and storage

Sample type: Suitable for human serum, plasma or whole blood (Venous whole blood and fingerstick blood) samples, including plasma or whole blood samples prepared from commonly used anticoagulants (EDTA, heparin, sodium citrate). The collection of specimens is carried out in accordance with the requirements of the local hospital.

Sample processing: Before testing, slowly return the refrigerated or frozen samples to room temperature and mix them carefully. When clearly visible particulate matter is present in the sample, it should be centrifuged to remove sediment before testing. If the sample contains a large amount of lipid, hemolysis or turbidity, please do not use it, so as not to affect the result judgment; For fingerstick blood, please test immediately after collection.

Sample storage: The serum and plasma samples to be tested are stored at 2-8°C for up to 5 days. For long-term storage, store at -20°C. Avoid repeated freeze-thaw samples.

Anti-coagulated whole blood samples should not be stored for more than 72 hours at room temperature; not more than 7 days at 2 to 8°C,

Fingerstick blood should be used immediately.

5. In vitro diagnostic reagents and reference products for testing

5.1 Test in vitro diagnostic reagents

Name: The Novel coronavirus neutralizing antibody Rapid Test Device (serum/plasma/whole blood)

Specification:25 tests/kit

Expiry: October,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	Manufacture	Storage conditions
Novel Coronavirus Novel coronavirus neutralizing antibody Titer test(MNP method)	Hospital laboratory establishment	/
COVID-19 IgG/IgM antibody test device(serum/plasma/whole blood)	Innovita Biological Technology Co.,Ltd	2-30° C

V. Experiment method

Allow the test device,specimen,buffer,and/or controls to reach room temperature (15-30℃) prior to testing.

1. Bring the pouch to room temperature before opening.Remove the test device from the sealed pouch and use it as soon as possible.

2. Place the test device on a clean and level surface.

- For Serum or Plasma Specimens:

Using the provided disposable pipette,and transfer 2 drops of serum/plasma to the specimen well of the test device,then add 1 drop of buffer,and start the timer.

- For Whole Blood (Venipuncture / Fingerstick) Specimens:

Using the provided disposable pipette,and transfer 3 drops of whole blood to the specimen well of the test device,then add 1 drop of buffer, and start the timer.

Note: Specimens can also be applied using a micropipette.

3. Wait for the colored line(s) to appear.Read results at 10 minutes.Do not interpret the result after 15 minutes.

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		Reference Product		Total Results
The Novel coronavirus neutralizing antibody Rapid Test Device (serum/plasma/whole blood)	Result	positive	negative	
	Low positive	A1	B	A+B
	Mid positive	A2		
	High positive	A3		
	negative	C	D	C+D
Total Results（A=A1+A2+A3）		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		Reference Product		Total Results
The Novel coronavirus neutralizing antibody Rapid Test Device (serum/plasma/whole blood)	Result	positive	negative	
	Low positive	A1	B	A+B
	Mid positive	A2		

	High positive	A3		
	negative	C	D	C+D
Total Results（A=A1+A2+A3）		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, 523 test samples are included for the unit and all test samples included are tested by three product . Statistics on test results and those of the product tested are as follows:

Coronavirus neutralizing antibody Rapid Test VS COVID-19 IgG/IgM antibody test device

Method		COVID-19 IgG/IgM antibody test device（IgG Result）		Total Results
The Novel coronavirus neutralizing antibody Rapid Test Device	Results	Positive	Negative	
	Low Positive	32	0	32
	Mid Positive	72	0	72
	High Positive	40	0	40
	Negative	8	371	379
Total Results		152	371	523
Clinical sensitivity =144/152=94.74 % (95%CI* 89.80% to 97.47%)				
Clinical specificity = 371/371＞99.9% (95%CI* 98.76% to 100%)				
Accuracy: (32+72+40+371)/ (32+72+40+0+371+8) *100%=98.47% (95%CI* 96.96% to 99.28%)				
P_e= (152*144+144*371)/ (523*523) =0.2753				
Kappa:(0.9847 - 0.2753)/(1-0.2753) =0.98				

neutralizing antibody Rapid Test VS neutralizing antibody Titer test

Method	Novel coronavirus neutralizing antibody Titer test(MNP method)	Total Results

The Novel coronavirus neutralizing antibody Rapid Test Device	Results	Positive	Negative	
	Low Positive	32	0	32
	Mid Positive	72	0	72
	High Positive	40	0	40
	Negative	2	377	379
Total Results		146	377	523
Clinical sensitivity =144/146=98.63 % (95%CI* 94.83% to 99.94%)				
Clinical specificity = 377/377＞99.9% (95%CI* 98.78% to 100%)				
Accuracy: (32+72+40+377)/ (32+72+40+0+377+2) *100%=99.62% (95%CI* 98.52% to 99.99%)				
P_e= (146*144+144*377)/ (523*523) =0.2753				
Kappa:(0.9847 - 0.2753)/(1-0.2753) =0.98				

According to the above table, Compare with COVID-19 IgG/IgM antibody test device , 371 are proven negative of 371 negative specimens, 144 are proven positive of 152 positive specimens. The sensitivity and accuracy are more than 90%, indicating favorable consistency with the reference product. The Kappa=0.90 ＞ 0.8,indicating favorable and high consistency of two methods and equivalence of two such systems. Compare with neutralizing antibody Titer test, 377 are proven negative of 377 negative specimens, 144 are proven positive of 146 positive specimens. The sensitivity and accuracy are more than 90%, indicating favorable consistency with the reference product. The Kappa=0.90＞0.8,indicating favorable and high consistency of two methods and equivalence of two such systems.

XI Analysis on Inconsistency in Test Results

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
11	42	M	20	Negative	Positive	Negative
13	29	M	21	Negative	Positive	Negative
23	27	M	21	Negative	Positive	Negative
29	40	M	20	Negative	Positive	Positive
66	27	M	21	Negative	Positive	Negative
90	35	M	21	Negative	Positive	Positive
108	34	F	20	Negative	Positive	Negative
149	38	F	21	Negative	Positive	Negative

XII Discussion and Conclusions

1.discussion

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

Test results of 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, At the same time, according to the comparison of titer, the neutralizing antibody reagent is more suitable for diagnosis and evaluation of the effect after vaccination.

XIII. 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.

XIV. Prediction of adverse events

Because the Novel coronavirus neutralizing antibody Rapid Test Device 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.

ANNEX I: Package Insert

Novel Coronavirus Neutralizing Antibody Rapid Test Device Package Insert

For the qualitative assessment of Coronavirus Disease 2019 (2019-nCOV or COVID-19) neutralizing antibody in human serum/plasma/whole blood.
For professional In Vitro Diagnostic Use Only

INTENDED USE

The Novel coronavirus neutralizing antibody Rapid Test Device is a rapid chromatographic immunoessay for the qualitative detection of neutralizing antibody of Coronavirus Disease 2019 in human whole blood,serum,or plasma as an aid in the Evaluation levels of human anti-novel coronavirus neutralizing antibody titer.

SUMMARY

Coronavirus (CoV) belongs to the genus Nestovirus, Coronavindae,and is divided into three genera:α,β,and γ.The genus α and β are only pathogenic to mammals.The genus γ mainly causes bird infections.CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence that it can be transmitted through the fecal-oral route.
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, or 2019-nCoV) is an enveloped non-segmented positive-sense RNA virus. It is the cause of coronavirus disease 2019 (COVID-19), which is contagious in humans.
SARS-CoV-2 has several structural proteins including spike (S), envelope (E), membrane (M) and nucleocapsid (N). The spike protein (S) contains a receptor binding domain (RBD), which is responsible for recognizing the cell surface receptor, angiotensin converting enzyme-2 (ACE2). It is found that the RBD of the SARS-CoV-2 S protein strongly interacts with the human ACE2 receptor leading to endocytosis into the host cells of the deep lung and viral replication.
Infection with the SARS-CoV-2 initiates an immune response, which includes the production of antibodies in the blood. The secreted antibodies provide protection against future infections from viruses, because they remain in the circulatory system for months to years after infection and will bind quickly and strongly to the pathogen to block cellular infiltration and replication. These antibodies are named neutralizing antibodies.

PRINCIPLE

This kit uses immunochromatography. The test card contains:1)colloidal gold-labeled recombinant novel coronavirus S-RBD antigen, refer control and quality control antibody gold markers; 2) one detection line(T line), one reference line(R line) and one quality Control line (C line) of nitrocellulose membrane.The T line is immobilized with Human ACE2 protein for detecting novel coronavirus neutralizing antibody;the R line is immobilized with reference control antibody; and the C line is immobilized with a quality control antibody.
When an appropriate amount of the test sample is added to the sample hole of the test card, the sample will move forward along the test card under the action of the capillary. If the sample contains Novel coronavirus neutralizing antibody, the antibody will bind to the colloidal gold-labeled novel coronavirus antigen. The rest gold-labeled novel coronavirus antigen in immune complex will be captured by the human ACE2 protein immobilized on the membrane to form a purple-red T line,the intensity of t line inversely proportional to the concentration of antibody.
The test card also contains a quality control line C and a reference line R.The fuchsia quality control line C and reference control line R should appear regardless of whether a test line appears.If the quality control line C does not appear, the test result is invalid, and the sample needs to be tested again with another test card.

SPECIMEN COLLECTION AND PREPARATION

1. The Novel coronavirus neutralizing antibody Rapid Test Device is intended for use with human whole blood, serum or plasma specimens only.
2. Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
3. Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage,serum or plasma specimens should be kept below -20°C.Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days after collection.Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
4. Containers containing anticoagulants such as EDTA,citrate,or heparin should be used for whole blood storage.
5. Bring specimens to room temperature prior to testing.Frozen specimens must be completely thawed and mixed well prior to testing.Avoid repeated freezing and thawing of specimens.
6. If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
7. Icteric,lipemic,hemolyzed,heat treated and contaminated sera may cause erroneous results.
8. When collecting finger stick blood with a lancet and alcohol pad,Please discard the first drop of whole blood.

MATERIALS

Materials provided

- Test Devices
- 25uL Disposable pipette
- Buffer
- Package insert

Materials required but not provided

- Specimen collection containers
- Micropipette
- Lancets (for finger stick whole blood only)
- Centrifuge (for plasma only)
- Timer
- Alcohol pad

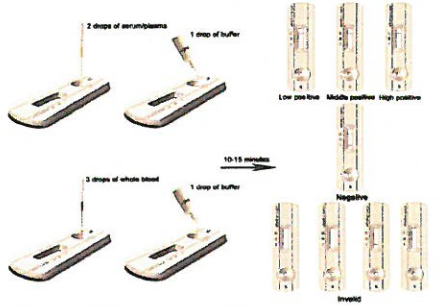
DIRECTIONS FOR USE

Allow the test device,specimen,buffer,and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening.Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface.

- For **Serum or Plasma Specimens:**
  Using the **provided 25μL disposable pipette,and transfer 2 drops of serum/plasma** to the specimen well of the test device,then **add 1 drop of buffer,**and start the timer.
- For **Whole Blood (Venipuncture/Fingerstick) Specimens:**
  Using the **provided 25μL disposable pipette,**and **transfer 3 drops of whole blood (approximately 75μL)** to the specimen well of the test device,then **add 1 drop of buffer,** and start the timer.
  Note: Specimens can also be applied using a micropipette.

3. Wait for the colored line(s) to appear.**Read results at 10 minutes.Do not interpret the result after 15 minutes.**



INTERPRETATION OF RESULTS

Low POSITIVE:"The colored line in the control line region (C) and reference line region (R) appears and a colored line appears in test line region (T) , and the intensity of T line is weaker than C line but stronger than R line. The result is low positive and Neutralizing antibodies provide week protection.
Middle POSITIVE:"The colored line in the control line region (C) and reference line region (R) appears and a colored line appears in test line region (T) , and the intensity of T line is weaker than R line. The result is middle positive and Neutralizing antibodies provide middle protection.
High POSITIVE:"The colored line in the control line region (C) and reference line region (R) appears and no colored line appears in test line region (T) .The result is high positive and Neutralizing antibodies provide high protection.
NEGATIVE: The colored line in the control line region (C) and reference line region(R) appears and a colored line appears in test line region (T) , and the intensity of T line is stronger than C line. The result is negative and no Neutralizing antibodies in your body, you are easily infected with the novel coronavirus.If you are exposed to the virus, .
INVALID: There is no line appeared in the C region.
Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure.Review the procedure and repeat the procedure with a new test device. If the problem persists,discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal positive procedural control.It confirms sufficient specimen volume and correct procedural technique.
Control standards are not supplied with this kit;however,it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

EXPECTED RESULTS AFTER VACCINATION

The new coronavirus neutralizing antibody is a protective antibody, which is produced by the human body after natural immunity and vaccine injection, and protects the human body from the new coronavirus infection .According to the development of the international new coronavirus vaccine, the recommendations for using this reagent to monitor the content of new coronavirus neutralizing antibodies in the human body are as follows:

Expected Result during vaccination	Novel coronavirus neutralizing antibody Rapid Test Device			
	Low Positive	Mid Positive	High Positive	Negative
Days before Dose 1				√
21 Days after Dose 1	√	√		
7 Days after Dose 2		√	√	
14 Days after Dose 2		√	√	

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Method		Novel coronavirus neutralizing antibody Rapid Test Device				Total
	Result	Low positive	Mid positive	High positive	Negative	
Rapid test device	Positive	32	72	40	8	152
	Negative	0	0	0	371	371
Total		32	72	40	379	523

The Novel coronavirus neutralizing antibody Rapid Test Device has been compared to a leading commercial COVID-19 IgG testing using clinical specimens from Naturally infected patients.
Relative Sensitivity:144/152=94.73%
Relative Specificity:371/371=99.9%

Cross-reactivity

The Novel coronavirus neutralizing antibody Rapid Test Device has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-HIV anti-rheumatoid factor, anti-M. Pneumonia, anti-Chlamydiapneumoniae and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using The Novel coronavirus neutralizing antibody Rapid Test Device and no interference was observed.
Triglyceride 5000mg/dL Ascorbic Acid 20mg/dL Hemoglobin 1000mg/dL
Bilirubin: 80mg/dL Oxalic acid: 100mg/dL Human serum albumin 2000mg/dL

PRECAUTIONS

1. For professional in vitro diagnostic use only. Do not use the kit beyond the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use the test if the pouch is damaged.
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
6. The used test should be discarded according to local regulations.
7. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus.
8. Result from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

LIMITATION OF USE

1. The accuracy of the test depends on the sample collection process. Improper sample collection, improper storage of samples, stale samples, or repeated freeze-thaw cycles of samples will affect the test results.
2. The test result of this kit is for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests, and treatment responses.
3. It is recommended to review the suspicious negative results by using nucleic acid detection or virus culture identification methods.

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 for use
LOT	Batch code	CE	Meet the requirements of EC Directive 98/79/EC
REF	Catalogue number	Σ	The number of test

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: 1101441601
Version: 1.0
Effective date: 2020-12-24

ANNEX II: Data of Clinical Tests

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
1	49	F	26	Low positive	Positive	Positive
2	32	F	22	Mid positive	Positive	Positive
3	31	F	22	Mid positive	Positive	Positive
4	32	F	26	Mid positive	Positive	Positive
5	21	F	37	High positive	Positive	Positive
6	51	M	27	Mid positive	Positive	Positive
7	22	F	24	Mid positive	Positive	Positive
8	46	F	25	Low positive	Positive	Positive
9	48	F	28	Mid positive	Positive	Positive
10	18	F	25	Low positive	Positive	Positive
11	42	M	20	Negative	Positive	Negative
12	23	F	30	High positive	Positive	Positive
13	29	M	21	Negative	Positive	Negative
14	24	M	22	Mid positive	Positive	Positive
15	28	F	26	Mid positive	Positive	Positive
16	34	M	35	High positive	Positive	Positive
17	38	F	27	Mid positive	Positive	Positive
18	34	F	24	Mid positive	Positive	Positive
19	50	M	35	High positive	Positive	Positive
20	40	F	39	High positive	Positive	Positive
21	43	F	22	Mid positive	Positive	Positive
22	28	F	23	Mid positive	Positive	Positive

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
23	27	M	21	Negative	Positive	Negative
24	46	F	22	Low positive	Positive	Positive
25	26	F	21	Mid positive	Positive	Positive
26	44	F	22	Low positive	Positive	Positive
27	46	F	26	Mid positive	Positive	Positive
28	43	F	23	Mid positive	Positive	Positive
29	40	M	20	Negative	Positive	Positive
30	35	F	26	Mid positive	Positive	Positive
31	18	M	31	High positive	Positive	Positive
32	36	M	37	High positive	Positive	Positive
33	20	M	37	High positive	Positive	Positive
34	18	F	22	Mid positive	Positive	Positive
35	39	M	37	High positive	Positive	Positive
36	42	F	28	High positive	Positive	Positive
37	43	M	30	High positive	Positive	Positive
38	24	F	21	Mid positive	Positive	Positive
39	38	M	27	Mid positive	Positive	Positive
40	42	F	21	Low positive	Positive	Positive
41	33	M	21	Low positive	Positive	Positive
42	45	F	26	Mid positive	Positive	Positive
43	50	F	28	Mid positive	Positive	Positive
44	42	M	29	High positive	Positive	Positive

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
45	19	F	29	High positive	Positive	Positive
46	21	M	27	Mid positive	Positive	Positive
47	43	F	34	High positive	Positive	Positive
48	50	M	24	Mid positive	Positive	Positive
49	39	M	27	Mid positive	Positive	Positive
50	47	F	31	High positive	Positive	Positive
51	49	F	28	Mid positive	Positive	Positive
52	48	F	36	High positive	Positive	Positive
53	28	F	26	Low positive	Positive	Positive
54	41	F	22	Mid positive	Positive	Positive
55	20	M	22	Low positive	Positive	Positive
56	40	F	24	Mid positive	Positive	Positive
57	35	M	23	Mid positive	Positive	Positive
58	38	M	25	Mid positive	Positive	Positive
59	50	M	26	Mid positive	Positive	Positive
60	48	F	28	Mid positive	Positive	Positive
61	37	F	28	Low positive	Positive	Positive
62	43	F	24	Mid positive	Positive	Positive
63	31	M	21	Mid positive	Positive	Positive
64	38	M	35	High positive	Positive	Positive
65	33	M	28	Low positive	Positive	Positive
66	27	M	21	Negative	Positive	Negative
67	31	M	25	Low positive	Positive	Positive

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
68	46	M	36	High positive	Positive	Positive
69	30	F	23	Mid positive	Positive	Positive
70	44	F	38	High positive	Positive	Positive
71	35	M	30	High positive	Positive	Positive
72	28	F	23	Low positive	Positive	Positive
73	49	F	31	High positive	Positive	Positive
74	50	F	21	Mid positive	Positive	Positive
75	31	M	21	Mid positive	Positive	Positive
76	24	M	40	High positive	Positive	Positive
77	30	M	26	Mid positive	Positive	Positive
78	35	F	26	Mid positive	Positive	Positive
79	20	F	22	Mid positive	Positive	Positive
80	19	F	25	Mid positive	Positive	Positive
81	31	M	38	High positive	Positive	Positive
82	43	F	36	High positive	Positive	Positive
83	46	F	22	Mid positive	Positive	Positive
84	48	F	23	Low positive	Positive	Positive
85	38	M	26	Mid positive	Positive	Positive
86	35	F	26	Mid positive	Positive	Positive
87	49	M	22	Mid positive	Positive	Positive
88	31	M	28	Low positive	Positive	Positive
89	37	F	28	Mid positive	Positive	Positive
90	35	M	21	Negative	Positive	Positive

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
91	31	F	25	Low positive	Positive	Positive
92	49	M	33	High positive	Positive	Positive
93	35	M	35	High positive	Positive	Positive
94	34	F	27	Low positive	Positive	Positive
95	50	F	31	High positive	Positive	Positive
96	49	M	33	High positive	Positive	Positive
97	35	F	23	Mid positive	Positive	Positive
98	39	F	21	Mid positive	Positive	Positive
99	33	M	23	Mid positive	Positive	Positive
100	37	F	35	Mid positive	Positive	Positive
101	38	F	35	High positive	Positive	Positive
102	30	M	27	Low positive	Positive	Positive
103	29	F	32	Mid positive	Positive	Positive
104	22	M	30	Mid positive	Positive	Positive
105	22	M	26	Low positive	Positive	Positive
106	43	F	21	Low positive	Positive	Positive
107	24	M	35	High positive	Positive	Positive
108	34	F	20	Negative	Positive	Negative
109	36	F	39	High positive	Positive	Positive
110	33	M	28	Low positive	Positive	Positive
111	24	F	35	High positive	Positive	Positive
112	44	F	24	Low positive	Positive	Positive
113	50	M	28	Low positive	Positive	Positive

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
114	19	M	36	Mid positive	Positive	Positive
115	47	F	39	Mid positive	Positive	Positive
116	19	F	32	Mid positive	Positive	Positive
117	41	M	39	Mid positive	Positive	Positive
118	45	M	37	High positive	Positive	Positive
119	42	F	36	High positive	Positive	Positive
120	40	M	32	Mid positive	Positive	Positive
121	18	M	39	Mid positive	Positive	Positive
122	26	F	34	Mid positive	Positive	Positive
123	19	M	23	Low positive	Positive	Positive
124	24	M	33	Mid positive	Positive	Positive
125	37	F	28	Low positive	Positive	Positive
126	18	M	25	Low positive	Positive	Positive
127	35	F	34	Mid positive	Positive	Positive
128	37	M	31	Mid positive	Positive	Positive
129	38	F	35	High positive	Positive	Positive
130	29	M	37	Mid positive	Positive	Positive
131	18	F	25	Low positive	Positive	Positive
132	22	F	34	High positive	Positive	Positive
133	34	M	30	Mid positive	Positive	Positive
134	47	M	40	Mid positive	Positive	Positive
135	18	F	28	Mid positive	Positive	Positive
136	19	F	31	High positive	Positive	Positive

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
137	18	F	39	Mid positive	Positive	Positive
138	32	M	31	Mid positive	Positive	Positive
139	39	F	24	Low positive	Positive	Positive
140	48	M	38	High positive	Positive	Positive
141	32	F	26	Low positive	Positive	Positive
142	22	M	40	High positive	Positive	Positive
143	41	F	25	Low positive	Positive	Positive
144	21	M	34	Mid positive	Positive	Positive
145	37	F	34	High positive	Positive	Positive
146	44	M	28	Low positive	Positive	Positive
147	29	M	34	Mid positive	Positive	Positive
148	18	M	32	Mid positive	Positive	Positive
149	38	F	21	Negative	Positive	Negative
150	41	F	35	Mid positive	Positive	Positive
151	47	M	34	Mid positive	Positive	Positive
152	27	M	21	Low positive	Positive	Positive
153	23	M	N/A	Negative	Negative	Negative
154	35	F	N/A	Negative	Negative	Negative
155	44	M	N/A	Negative	Negative	Negative
156	29	F	N/A	Negative	Negative	Negative
157	43	M	N/A	Negative	Negative	Negative
158	54	F	N/A	Negative	Negative	Negative
159	40	M	N/A	Negative	Negative	Negative

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
160	31	F	N/A	Negative	Negative	Negative
161	33	F	N/A	Negative	Negative	Negative
162	20	F	N/A	Negative	Negative	Negative
163	37	M	N/A	Negative	Negative	Negative
164	45	M	N/A	Negative	Negative	Negative
165	26	M	N/A	Negative	Negative	Negative
166	26	M	N/A	Negative	Negative	Negative
167	24	F	N/A	Negative	Negative	Negative
168	37	M	N/A	Negative	Negative	Negative
169	47	F	N/A	Negative	Negative	Negative
170	21	F	N/A	Negative	Negative	Negative
171	53	M	N/A	Negative	Negative	Negative
172	47	M	N/A	Negative	Negative	Negative
173	35	F	N/A	Negative	Negative	Negative
174	56	M	N/A	Negative	Negative	Negative
175	20	M	N/A	Negative	Negative	Negative
176	59	M	N/A	Negative	Negative	Negative
177	54	F	N/A	Negative	Negative	Negative
178	45	F	N/A	Negative	Negative	Negative
179	38	F	N/A	Negative	Negative	Negative
180	39	F	N/A	Negative	Negative	Negative
181	23	F	N/A	Negative	Negative	Negative
182	53	F	N/A	Negative	Negative	Negative

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
183	52	F	N/A	Negative	Negative	Negative
184	45	M	N/A	Negative	Negative	Negative
185	33	F	N/A	Negative	Negative	Negative
186	29	M	N/A	Negative	Negative	Negative
187	48	M	N/A	Negative	Negative	Negative
188	45	F	N/A	Negative	Negative	Negative
189	20	M	N/A	Negative	Negative	Negative
190	53	M	N/A	Negative	Negative	Negative
191	21	M	N/A	Negative	Negative	Negative
192	41	M	N/A	Negative	Negative	Negative
193	53	F	N/A	Negative	Negative	Negative
194	19	F	N/A	Negative	Negative	Negative
195	52	F	N/A	Negative	Negative	Negative
196	20	M	N/A	Negative	Negative	Negative
197	54	F	N/A	Negative	Negative	Negative
198	59	F	N/A	Negative	Negative	Negative
199	25	F	N/A	Negative	Negative	Negative
200	26	F	N/A	Negative	Negative	Negative
201	33	F	N/A	Negative	Negative	Negative
202	52	F	N/A	Negative	Negative	Negative
203	46	M	N/A	Negative	Negative	Negative
204	36	M	N/A	Negative	Negative	Negative
205	44	F	N/A	Negative	Negative	Negative

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
206	43	F	N/A	Negative	Negative	Negative
207	42	F	N/A	Negative	Negative	Negative
208	53	M	N/A	Negative	Negative	Negative
209	31	F	N/A	Negative	Negative	Negative
210	51	M	N/A	Negative	Negative	Negative
211	39	M	N/A	Negative	Negative	Negative
212	24	F	N/A	Negative	Negative	Negative
213	59	M	N/A	Negative	Negative	Negative
214	60	M	N/A	Negative	Negative	Negative
215	54	F	N/A	Negative	Negative	Negative
216	30	M	N/A	Negative	Negative	Negative
217	44	F	N/A	Negative	Negative	Negative
218	52	M	N/A	Negative	Negative	Negative
219	22	M	N/A	Negative	Negative	Negative
220	59	M	N/A	Negative	Negative	Negative
221	29	M	N/A	Negative	Negative	Negative
222	47	F	N/A	Negative	Negative	Negative
223	58	M	N/A	Negative	Negative	Negative
224	35	F	N/A	Negative	Negative	Negative
225	48	M	N/A	Negative	Negative	Negative
226	39	F	N/A	Negative	Negative	Negative
227	34	F	N/A	Negative	Negative	Negative
228	54	F	N/A	Negative	Negative	Negative

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
229	45	F	N/A	Negative	Negative	Negative
230	41	F	N/A	Negative	Negative	Negative
231	22	M	N/A	Negative	Negative	Negative
232	57	M	N/A	Negative	Negative	Negative
233	23	F	N/A	Negative	Negative	Negative
234	46	F	N/A	Negative	Negative	Negative
235	24	M	N/A	Negative	Negative	Negative
236	35	F	N/A	Negative	Negative	Negative
237	48	F	N/A	Negative	Negative	Negative
238	40	F	N/A	Negative	Negative	Negative
239	53	M	N/A	Negative	Negative	Negative
240	56	F	N/A	Negative	Negative	Negative
241	50	M	N/A	Negative	Negative	Negative
242	25	M	N/A	Negative	Negative	Negative
243	19	F	N/A	Negative	Negative	Negative
244	23	M	N/A	Negative	Negative	Negative
245	34	M	N/A	Negative	Negative	Negative
246	47	F	N/A	Negative	Negative	Negative
247	37	F	N/A	Negative	Negative	Negative
248	35	F	N/A	Negative	Negative	Negative
249	23	M	N/A	Negative	Negative	Negative
250	36	F	N/A	Negative	Negative	Negative
251	37	F	N/A	Negative	Negative	Negative

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
252	31	M	N/A	Negative	Negative	Negative
253	36	F	N/A	Negative	Negative	Negative
254	43	F	N/A	Negative	Negative	Negative
255	35	M	N/A	Negative	Negative	Negative
256	30	F	N/A	Negative	Negative	Negative
257	30	M	N/A	Negative	Negative	Negative
258	53	F	N/A	Negative	Negative	Negative
259	25	F	N/A	Negative	Negative	Negative
260	41	F	N/A	Negative	Negative	Negative
261	19	M	N/A	Negative	Negative	Negative
262	58	F	N/A	Negative	Negative	Negative
263	18	F	N/A	Negative	Negative	Negative
264	25	M	N/A	Negative	Negative	Negative
265	47	M	N/A	Negative	Negative	Negative
266	43	M	N/A	Negative	Negative	Negative
267	46	M	N/A	Negative	Negative	Negative
268	30	F	N/A	Negative	Negative	Negative
269	53	F	N/A	Negative	Negative	Negative
270	50	M	N/A	Negative	Negative	Negative
271	53	M	N/A	Negative	Negative	Negative
272	52	F	N/A	Negative	Negative	Negative
273	36	M	N/A	Negative	Negative	Negative
274	45	F	N/A	Negative	Negative	Negative

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
275	47	F	N/A	Negative	Negative	Negative
276	47	M	N/A	Negative	Negative	Negative
277	54	F	N/A	Negative	Negative	Negative
278	27	M	N/A	Negative	Negative	Negative
279	46	F	N/A	Negative	Negative	Negative
280	26	F	N/A	Negative	Negative	Negative
281	52	F	N/A	Negative	Negative	Negative
282	33	M	N/A	Negative	Negative	Negative
283	57	F	N/A	Negative	Negative	Negative
284	58	F	N/A	Negative	Negative	Negative
285	43	M	N/A	Negative	Negative	Negative
286	23	F	N/A	Negative	Negative	Negative
287	32	F	N/A	Negative	Negative	Negative
288	18	M	N/A	Negative	Negative	Negative
289	25	F	N/A	Negative	Negative	Negative
290	28	F	N/A	Negative	Negative	Negative
291	27	F	N/A	Negative	Negative	Negative
292	30	F	N/A	Negative	Negative	Negative
293	48	F	N/A	Negative	Negative	Negative
294	52	M	N/A	Negative	Negative	Negative
295	25	F	N/A	Negative	Negative	Negative
296	36	M	N/A	Negative	Negative	Negative
297	46	F	N/A	Negative	Negative	Negative

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
298	43	M	N/A	Negative	Negative	Negative
299	27	M	N/A	Negative	Negative	Negative
300	54	F	N/A	Negative	Negative	Negative
301	29	M	N/A	Negative	Negative	Negative
302	29	F	N/A	Negative	Negative	Negative
303	24	M	N/A	Negative	Negative	Negative
304	39	F	N/A	Negative	Negative	Negative
305	41	M	N/A	Negative	Negative	Negative
306	24	F	N/A	Negative	Negative	Negative
307	34	M	N/A	Negative	Negative	Negative
308	58	M	N/A	Negative	Negative	Negative
309	24	F	N/A	Negative	Negative	Negative
310	35	M	N/A	Negative	Negative	Negative
311	37	M	N/A	Negative	Negative	Negative
312	49	M	N/A	Negative	Negative	Negative
313	57	F	N/A	Negative	Negative	Negative
314	44	M	N/A	Negative	Negative	Negative
315	33	F	N/A	Negative	Negative	Negative
316	33	M	N/A	Negative	Negative	Negative
317	41	F	N/A	Negative	Negative	Negative
318	49	F	N/A	Negative	Negative	Negative
319	53	F	N/A	Negative	Negative	Negative
320	42	M	N/A	Negative	Negative	Negative

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
321	33	F	N/A	Negative	Negative	Negative
322	21	F	N/A	Negative	Negative	Negative
323	31	F	N/A	Negative	Negative	Negative
324	37	M	N/A	Negative	Negative	Negative
325	33	M	N/A	Negative	Negative	Negative
326	54	F	N/A	Negative	Negative	Negative
327	42	M	N/A	Negative	Negative	Negative
328	38	M	N/A	Negative	Negative	Negative
329	52	F	N/A	Negative	Negative	Negative
330	18	F	N/A	Negative	Negative	Negative
331	59	F	N/A	Negative	Negative	Negative
332	56	F	N/A	Negative	Negative	Negative
333	27	M	N/A	Negative	Negative	Negative
334	57	M	N/A	Negative	Negative	Negative
335	38	M	N/A	Negative	Negative	Negative
336	40	F	N/A	Negative	Negative	Negative
337	29	F	N/A	Negative	Negative	Negative
338	44	F	N/A	Negative	Negative	Negative
339	47	M	N/A	Negative	Negative	Negative
340	50	F	N/A	Negative	Negative	Negative
341	40	F	N/A	Negative	Negative	Negative
342	46	M	N/A	Negative	Negative	Negative
343	22	M	N/A	Negative	Negative	Negative

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
344	41	F	N/A	Negative	Negative	Negative
345	27	F	N/A	Negative	Negative	Negative
346	58	M	N/A	Negative	Negative	Negative
347	40	M	N/A	Negative	Negative	Negative
348	39	F	N/A	Negative	Negative	Negative
349	21	M	N/A	Negative	Negative	Negative
350	48	F	N/A	Negative	Negative	Negative
351	60	F	N/A	Negative	Negative	Negative
352	55	M	N/A	Negative	Negative	Negative
353	29	M	N/A	Negative	Negative	Negative
354	32	M	N/A	Negative	Negative	Negative
355	35	M	N/A	Negative	Negative	Negative
356	36	M	N/A	Negative	Negative	Negative
357	45	M	N/A	Negative	Negative	Negative
358	38	F	N/A	Negative	Negative	Negative
359	31	F	N/A	Negative	Negative	Negative
360	32	M	N/A	Negative	Negative	Negative
361	40	F	N/A	Negative	Negative	Negative
362	30	F	N/A	Negative	Negative	Negative
363	60	M	N/A	Negative	Negative	Negative
364	35	M	N/A	Negative	Negative	Negative
365	43	F	N/A	Negative	Negative	Negative
366	21	F	N/A	Negative	Negative	Negative

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
367	53	M	N/A	Negative	Negative	Negative
368	52	M	N/A	Negative	Negative	Negative
369	22	F	N/A	Negative	Negative	Negative
370	42	M	N/A	Negative	Negative	Negative
371	35	M	N/A	Negative	Negative	Negative
372	37	F	N/A	Negative	Negative	Negative
373	58	F	N/A	Negative	Negative	Negative
374	46	F	N/A	Negative	Negative	Negative
375	59	F	N/A	Negative	Negative	Negative
376	31	F	N/A	Negative	Negative	Negative
377	29	F	N/A	Negative	Negative	Negative
378	41	F	N/A	Negative	Negative	Negative
379	22	M	N/A	Negative	Negative	Negative
380	50	F	N/A	Negative	Negative	Negative
381	42	M	N/A	Negative	Negative	Negative
382	57	M	N/A	Negative	Negative	Negative
383	49	F	N/A	Negative	Negative	Negative
384	24	F	N/A	Negative	Negative	Negative
385	35	M	N/A	Negative	Negative	Negative
386	29	M	N/A	Negative	Negative	Negative
387	49	M	N/A	Negative	Negative	Negative
388	25	M	N/A	Negative	Negative	Negative
389	53	F	N/A	Negative	Negative	Negative

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
390	41	M	N/A	Negative	Negative	Negative
391	34	F	N/A	Negative	Negative	Negative
392	25	F	N/A	Negative	Negative	Negative
393	34	M	N/A	Negative	Negative	Negative
394	19	M	N/A	Negative	Negative	Negative
395	27	F	N/A	Negative	Negative	Negative
396	57	F	N/A	Negative	Negative	Negative
397	26	F	N/A	Negative	Negative	Negative
398	24	F	N/A	Negative	Negative	Negative
399	39	F	N/A	Negative	Negative	Negative
400	48	M	N/A	Negative	Negative	Negative
401	52	M	N/A	Negative	Negative	Negative
402	35	M	N/A	Negative	Negative	Negative
403	24	F	N/A	Negative	Negative	Negative
404	48	F	N/A	Negative	Negative	Negative
405	42	F	N/A	Negative	Negative	Negative
406	25	M	N/A	Negative	Negative	Negative
407	33	M	N/A	Negative	Negative	Negative
408	41	M	N/A	Negative	Negative	Negative
409	42	M	N/A	Negative	Negative	Negative
410	54	M	N/A	Negative	Negative	Negative
411	58	M	N/A	Negative	Negative	Negative
412	52	F	N/A	Negative	Negative	Negative

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
413	20	F	N/A	Negative	Negative	Negative
414	32	F	N/A	Negative	Negative	Negative
415	43	M	N/A	Negative	Negative	Negative
416	18	F	N/A	Negative	Negative	Negative
417	31	M	N/A	Negative	Negative	Negative
418	18	M	N/A	Negative	Negative	Negative
419	53	F	N/A	Negative	Negative	Negative
420	52	M	N/A	Negative	Negative	Negative
421	42	M	N/A	Negative	Negative	Negative
422	24	F	N/A	Negative	Negative	Negative
423	19	F	N/A	Negative	Negative	Negative
424	29	F	N/A	Negative	Negative	Negative
425	57	M	N/A	Negative	Negative	Negative
426	49	M	N/A	Negative	Negative	Negative
427	47	F	N/A	Negative	Negative	Negative
428	36	F	N/A	Negative	Negative	Negative
429	57	M	N/A	Negative	Negative	Negative
430	49	F	N/A	Negative	Negative	Negative
431	33	F	N/A	Negative	Negative	Negative
432	36	M	N/A	Negative	Negative	Negative
433	40	F	N/A	Negative	Negative	Negative
434	19	F	N/A	Negative	Negative	Negative
435	48	M	N/A	Negative	Negative	Negative

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
436	36	M	N/A	Negative	Negative	Negative
437	57	M	N/A	Negative	Negative	Negative
438	48	F	N/A	Negative	Negative	Negative
439	24	M	N/A	Negative	Negative	Negative
440	44	M	N/A	Negative	Negative	Negative
441	32	M	N/A	Negative	Negative	Negative
442	20	M	N/A	Negative	Negative	Negative
443	60	F	N/A	Negative	Negative	Negative
444	57	M	N/A	Negative	Negative	Negative
445	38	M	N/A	Negative	Negative	Negative
446	56	F	N/A	Negative	Negative	Negative
447	39	F	N/A	Negative	Negative	Negative
448	56	M	N/A	Negative	Negative	Negative
449	18	F	N/A	Negative	Negative	Negative
450	58	F	N/A	Negative	Negative	Negative
451	41	F	N/A	Negative	Negative	Negative
452	29	F	N/A	Negative	Negative	Negative
453	46	F	N/A	Negative	Negative	Negative
454	42	F	N/A	Negative	Negative	Negative
455	32	M	N/A	Negative	Negative	Negative
456	33	M	N/A	Negative	Negative	Negative
457	42	M	N/A	Negative	Negative	Negative
458	31	F	N/A	Negative	Negative	Negative

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
459	32	M	N/A	Negative	Negative	Negative
460	19	M	N/A	Negative	Negative	Negative
461	46	M	N/A	Negative	Negative	Negative
462	58	M	N/A	Negative	Negative	Negative
463	59	M	N/A	Negative	Negative	Negative
464	20	F	N/A	Negative	Negative	Negative
465	36	M	N/A	Negative	Negative	Negative
466	22	F	N/A	Negative	Negative	Negative
467	32	M	N/A	Negative	Negative	Negative
468	46	F	N/A	Negative	Negative	Negative
469	30	F	N/A	Negative	Negative	Negative
470	24	F	N/A	Negative	Negative	Negative
471	18	M	N/A	Negative	Negative	Negative
472	46	M	N/A	Negative	Negative	Negative
473	23	M	N/A	Negative	Negative	Negative
474	48	F	N/A	Negative	Negative	Negative
475	38	F	N/A	Negative	Negative	Negative
476	47	M	N/A	Negative	Negative	Negative
477	27	F	N/A	Negative	Negative	Negative
478	46	M	N/A	Negative	Negative	Negative
479	24	F	N/A	Negative	Negative	Negative
480	45	F	N/A	Negative	Negative	Negative
481	45	M	N/A	Negative	Negative	Negative

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
482	21	F	N/A	Negative	Negative	Negative
483	55	M	N/A	Negative	Negative	Negative
484	27	F	N/A	Negative	Negative	Negative
485	47	M	N/A	Negative	Negative	Negative
486	33	F	N/A	Negative	Negative	Negative
487	45	M	N/A	Negative	Negative	Negative
488	52	M	N/A	Negative	Negative	Negative
489	29	M	N/A	Negative	Negative	Negative
490	54	F	N/A	Negative	Negative	Negative
491	56	M	N/A	Negative	Negative	Negative
492	50	F	N/A	Negative	Negative	Negative
493	21	F	N/A	Negative	Negative	Negative
494	35	F	N/A	Negative	Negative	Negative
495	39	M	N/A	Negative	Negative	Negative
496	30	M	N/A	Negative	Negative	Negative
497	56	F	N/A	Negative	Negative	Negative
498	47	F	N/A	Negative	Negative	Negative
499	18	F	N/A	Negative	Negative	Negative
500	52	M	N/A	Negative	Negative	Negative
501	32	F	N/A	Negative	Negative	Negative
502	26	M	N/A	Negative	Negative	Negative
503	43	M	N/A	Negative	Negative	Negative
504	54	M	N/A	Negative	Negative	Negative

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
505	27	M	N/A	Negative	Negative	Negative
506	52	F	N/A	Negative	Negative	Negative
507	30	M	N/A	Negative	Negative	Negative
508	28	M	N/A	Negative	Negative	Negative
509	57	F	N/A	Negative	Negative	Negative
510	58	M	N/A	Negative	Negative	Negative
511	24	M	N/A	Negative	Negative	Negative
512	49	M	N/A	Negative	Negative	Negative
513	24	M	N/A	Negative	Negative	Negative
514	36	M	N/A	Negative	Negative	Negative

NO.	Age	Gender	Days from Dose	Rapid Test	COVID IgG	Titer Test
515	35	F	N/A	Negative	Negative	Negative
516	42	M	N/A	Negative	Negative	Negative
517	55	F	N/A	Negative	Negative	Negative
518	32	M	N/A	Negative	Negative	Negative
519	20	M	N/A	Negative	Negative	Negative
520	42	F	N/A	Negative	Negative	Negative
521	58	M	N/A	Negative	Negative	Negative
522	48	M	N/A	Negative	Negative	Negative
523	27	F	N/A	Negative	Negative	Negative

Director:
Date: 2020.12.30
Seal of company signature