Clinical Validation report of Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva)

Product name: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva)

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.

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 device (saliva) 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 device (saliva) 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 saliva 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（unfrozen）nasopharyngeal swab samples shall be tested via the RT-PCR from the same patient at same time , then the saliva sample test results of the product tested and the

nasopharyngeal swab sample RT-PCR test results 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:

PCR Test is positive;

symptoms are clinically positive;

Negative inclusion:

PCR test is negative;

Sample collection, processing

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

Sample collection procedure: The oral fluid specimen should be collected using the saliva collector provided with the kit.Follow the detailed Directions for Use refer to product IFU. No other collection cup should be used with this assay. Oral fluid collected at any time of the day may be used. **NOTE: Do not place anything in the mouth including food,drink,gum, tobacco,water and mouthwash products for at least 10 minutes prior to collection of oral fluid specimen.**

Specimen preparation:

Take out a sample extraction tube, remove the aluminum foil, Insert the sponge of sample collector with the saliva sample into the tube and twist close the whole cap of sample collector.

4. In vitro diagnostic reagents and reference products for testing

5.1 Test in vitro diagnostic reagents

Name: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva)

Specification:25 tests/kit

LOT: 202010001

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: Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)

Manufacturer: Sansure Biotech Inc.

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

V. Experiment method

1. Open the package with the saliva collector, then remove the saliva collector from the sealed plastic bag.
2. Pre-process the saliva samples according to the instructions of the The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva) , and label the samples randomly.

2.1 Insert the sponge of saliva collector into the mouth, actively swab the inside of the mouth and tongue to collect oral fluid for approximately 10 second until the sponge becomes soft and fully saturated,The sponge will be free from hard spots when fully saturated.

2.2 . Take out a sample extraction tube, remove the aluminum foil. Remove the collector from the mouth and put the saturated oral fluid collector into the extraction tube.

2.3 Screw the cap into the extraction tube tightly so that saliva is squeezed out of the sponge into the extraction tube.

2.4 Gently shake the extraction tube vertically for about 5 seconds to allow saliva mix well with extraction buffer. Take out the saliva collector and discard it.

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 device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch. Put the test device on a clean and flat surface.

3.2 twist open the small white cap from the extraction tube,transfer 3 drop of sample into the sample well of test device vertically.

3.3 Read the result at 10~20 minutes. Don’ t interpret the result after 20 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 device (saliva)	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 device (saliva)	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, 222 patients' samples are included for the unit, all the saliva samples and nasopharyngeal swab samples are tested. Statistics on rapid test results and those of the RT-PCR 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	62	0	62
	Negative	4	156	160
Total Results		66	156	222

Clinical sensitivity = 62/66= 93.94 % (95%CI*84.99% to 98.06%)

Clinical specificity = 156/156＞99.9% (95%CI* 98.98% to 100%)

Accuracy: (62+156)/ (62+0+4+156) *100%=98.20% (95%CI* 95.29% to 99.46%)

P_e= (62*66+62*156)/ 222*222) =0.28

Kappa:(P_0 - P_e)/(1-p_e) =0.97

*:95% confidence interview

According to the above table, 156 are proven negative of 156 negative specimens, 62 are proven positive of 66 positive specimens. The sensitivity and accuracy are more than 90%, indicating favorable consistency with the reference product. The Kappa=0.97＞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	Rapid Test	RT-PCR	Clinical diagnostic
14	39	F	Negative	Positive（N gene)	Infection 25 days
25	43	F	Negative	Positive（N gene)	Infection 16 days
37	36	M	Negative	Positive（N gene)	Infection 28 days
49	30	M	Negative	Positive（RdRP gene)	Infection 22 days

XI Discussion and Conclusions

1.discussion

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

Test results of saliva 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 device (saliva) 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 I :Package Insert

Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva) Package Insert

A RAPID TEST FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS ANTIGENS IN HUMAN .

For professional In Vitro Diagnostic Use Only.

INTENDED USE

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva) is an *in vitro* diagnostic test for the qualitative detection of novel coronavirus antigens in human saliva, 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 device (saliva) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to Novel coronavirus.

The test strip is composed of the following three parts, namely sample pad, reagent pad and reaction membrane. The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coronavirus; the reaction membrane contains the secondary antibodies for Novel coronavirus, and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.

When the test device was inserted into saliva sample,conjugates dried in the reagent pad are dissolved and migrate along with the sample. If Novel coronavirus is present in the sample, a complex formed between the anti- Novel coronavirus conjugate and the virus will be caught by the specific anti- Novel coronavirus 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 coronavirus; the reaction membrane contains the secondary antibodies for Novel coronavirus 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 device (saliva) 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:

The oral fluid specimen should be collected using the saliva collector provided with the kit.Follow the detailed Directions for Use below.No other collection cup should be used with this assay. Oral fluid collected at any time of the day may be used.

2. Specimen preparation:

Take out a sample extraction tube, remove the aluminum foil. Insert the sponge of sample collector with the saliva sample into the tube and twist close the whole cap of sample collector.

MATERIALS

Materials provided

- test device
- Saliva collector
- Extraction Tube with extraction buffer
- Package Insert
- Tube Stand

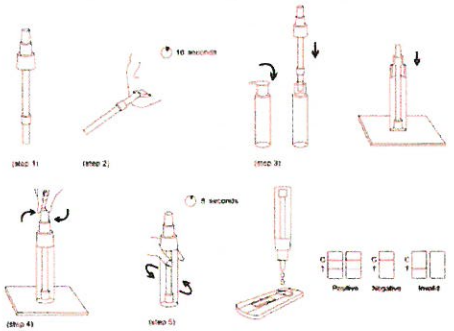
Materials required but not provided

- Timer

DIRECTIONS FOR USE

Allow the test device, specimen, extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.Do not place anything in the mouth including food,drink,gum, tobacco,water and mouthwash products for at least 10 minutes prior to collection of oral fluid specimen.

1. Open the package with the saliva collector, then remove the saliva collector from the sealed plastic bag.
2. Insert the sponge of saliva collector into the mouth, actively swab the inside of the mouth and tongue to collect oral fluid for approximately 10 second until the sponge becomes soft and fully saturated.The sponge will be free from hard spots when fully saturated.
3. Take out a sample extraction tube, remove the aluminum foil. Remove the collector from the mouth and put the saturated oral fluid collector into the extraction tube.
4. screw the cap into the extraction tube tightly so that saliva is squeezed out of the sponge into the extraction tube.
5. Gently shake the extraction tube vertically for about 5 seconds to allow saliva mix well with extraction buffer. Take out the saliva collector and discard it.
6. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch. Put the test device on a clean and flat surface.
7. twist open the small white cap from the extraction tube.transfer 3 drop of sample into the sample well of test device vertically.
8. 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 coronavirus 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 device (saliva) 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 device (saliva) 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 device (saliva) and PCR. The results were summarized below.

Table Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva) vs. PCR

Method		2019-nCoV Nucleic Acid Test Kit (RT-PCR)		Total Results
The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva)	Results	Positive	Negative	
	Positive	62	0	62
	Negative	4	156	160
Total Results		66	156	222

Clinical sensitivity = 62/66= 93.94 % (95%CI*84.99% to 98.06%)

Clinical specificity =156/156 >99.9% (95%CI* 98.98% to 100%)

Accuracy: (62+156)/ (62+0+4+156) *100%=98.20% (95%CI* 95.29% to 99.46%)

*Confidence Interval

Limit of Detection (LoD)

2019-nCoV Strain Tested	Realy Tech product					
Stock 2019-nCoV Concentration	1 X 10^7 $TCID_{50}$/mL					
Dilution	1/100	1/200	1/400	1/800	1/1600	1/3200
Concentration in Dilution tested ($TCID_{50}$/ml)	8X10^4	4X10^4	2.5X10^4	1.25X10^4	6.25X10^3	3.25X10^3
Cell rates of 20 replicates near cut-off	100(20/20)	100(20/20)	100(20/20)	95(19/20)	10(2/20)	0(0/20)
Limit of detection (LoD) per Virus Strain	1.25 X 10^4 $TCID_{50}$/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 $10^4$$TCID_{50}$/mL
	Type 3	7.5 x $10^4$$TCID_{50}$/mL
	Type 5	4.5 x $10^4$$TCID_{50}$/mL
	Type 7	1.0 x $10^4$$TCID_{50}$/mL
	Type 8	1.0 x $10^4$$TCID_{50}$/mL
	Type 11	2.5 x $10^4$$TCID_{50}$/mL
	Type 18	2.5 x $10^4$$TCID_{50}$/mL
	Type 23	6.0 x $10^4$$TCID_{50}$/mL
	Type 55	1.5 x $10^4$$TCID_{50}$/mL
Influenza A	H1N1 Denver	3.0 x $10^4$$TCID_{50}$/mL
	H1N1 WS/33	2.0 x $10^4$$TCID_{50}$/mL
	H1N1 A/Mal/302/54	1.5 x $10^4$$TCID_{50}$/mL
	H1N1 New Caledonia	7.6 x $10^4$$TCID_{50}$/mL
	H3N2 A/Hong Kong/8/58	4.6 x $10^4$$TCID_{50}$/mL
Influenza B	Nevada/03/2011	1.5 x $10^4$$TCID_{50}$/mL
	B/Lee/40	8.5 x $10^4$$TCID_{50}$/mL
	B/Taiwan/2/62	4.0 x $10^4$$TCID_{50}$/mL
Respiratory syncytial virus	N/A	2.5 x $10^4$$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 $10^4$$TCID_{50}$/mL
Mycobacterium tuberculosis	K	1 x 10^5PFU/mL
	Erdman	1 x 10^5PFU/mL
	HN878	1 x 10^5PFU/mL
	CDC1551	1 x 10^5PFU/mL
	H37Rv	1 x 10^5PFU/mL
Streptococcus pneumonia	4752-98 [Maryland (D1)6B-17]	1 x 10^5PFU/mL
	178 [Poland 23F-16]	1 x 10^5PFU/mL
	252 [CIP 104340]	1 x 10^5PFU/mL
	Slovakia 14-10 [29055]	1 x 10^5PFU/mL
Streptococcus pyrogens	Typing strain T1 [NCIB 11841, SF 130]	1 x 10^5PFU/ml
Mycoplasma pneumoniae	Mutant 22	1 x 10^5PFU/ml
	FHstrainofEatonAgent [NCTC 10119]	1 x 10^5PFU/ml
	36M129-B7	1 x 10^5PFU/ml
Coronavirus	229E	1.5 x$10^6$$TCID_{50}$/ml
	OC43	1.5 x$10^6$$TCID_{50}$/ml
	NL63	1.5 x $10^6$$TCID_{50}$/ml
	HKU1	1.5 x $10^6$$TCID_{50}$/ml

Human etapneumovirus (hMPV) 3 Type B1	Peru2-2002	1.5 x 10^5TCID$_{50}$/ml
Human Metapneumovirus (hMPV) 16 Type A1	IA10-2003	1.5 x 10^5TCID$_{50}$/ml
Parainfluenza virus	Type 1	1.5 x 106TCID$_{50}$/ml
	Type 2	1.5 x 106TCID$_{50}$/ml
	Type 3	1.5 x 106TCID$_{50}$/ml
	Type 4A	1.5 x 106TCID$_{50}$/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	8μg/mL
Ribavirin	1 mg/mL	Ritonavir	8.2mg/mL
Daclatasvir	1 mg/mL	Abidor	617.8ng/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:1101441601
Version:1.0
Effective Date:2020-11-13

Annex II: Data of Clinical Tests

NO.	Age	Gender	Rapid Test	(RT-PCR)
1	49	F	Positive	Positive（RdRP and N gene)
2	32	F	Positive	Positive（RdRP and N gene)
3	31	F	Positive	Positive（RdRP and N gene)
4	32	F	Positive	Positive（RdRP and N gene)
5	21	F	Positive	Positive（RdRP and N gene)
6	51	M	Positive	Positive（RdRP and N gene)
7	22	F	Positive	Positive（RdRP and N gene)
8	46	F	Positive	Positive（RdRP and N gene)
9	23	F	Positive	Positive（RdRP and N gene)
10	14	M	positive	Positive（RdRP and N gene)
11	42	M	Positive	Positive（RdRP and N gene)
12	51	M	Positive	Positive（RdRP and N gene)
13	80	M	Positive	Positive（RdRP and N gene)
14	39	F	Negative	Positive（N gene)
15	67	M	Positive	Positive（RdRP and N gene)
16	44	M	positive	Positive（RdRP gene)
17	26	F	Positive	Positive（RdRP and N gene)
18	33	F	positive	Positive（N gene)
19	38	F	Positive	Positive（RdRP and N gene)
20	36	F	Positive	Positive（RdRP and N gene)
21	3	F	Positive	Positive（RdRP and N gene)
22	35	F	Positive	Positive（RdRP and N gene)

NO.	Age	Gender	Rapid Test	(RT-PCR)
23	23	F	Positive	Positive（RdRP and N gene)
24	43	M	Positive	Positive（RdRP and N gene)
25	43	F	Negative	Positive（N gene)
26	46	F	Positive	Positive（RdRP and N gene)
27	55	F	Positive	Positive（RdRP and N gene)
28	22	F	Positive	Positive（RdRP and N gene)
29	20	M	positive	Positive（N gene)
30	42	M	Positive	Positive（RdRP and N gene)
31	56	F	Positive	Positive（RdRP and N gene)
32	55	M	Positive	Positive（RdRP and N gene)
33	26	F	Positive	Positive（RdRP and N gene)
34	54	M	Positive	Positive（RdRP and N gene)
35	43	F	Positive	Positive（RdRP and N gene)
36	69	M	Positive	Positive（RdRP and N gene)
37	36	M	Negative	Positive（N gene)
38	37	F	Positive	Positive（RdRP and N gene)
39	44	F	Positive	Positive（RdRP and N gene)
40	43	F	Positive	Positive（RdRP and N gene)
41	67	F	Positive	Positive（RdRP and N gene)
42	51	F	Positive	Positive（RdRP and N gene)
43	75	F	Positive	Positive（RdRP and N gene)
44	60	F	Positive	Positive（RdRP and N gene)

NO.	Age	Gender	Rapid Test	(RT-PCR)
45	25	M	Positive	Positive（RdRP and N gene)
46	75	F	Positive	Positive（RdRP and N gene)
47	43	F	Positive	Positive（RdRP and N gene)
48	30	F	Positive	Positive（RdRP and N gene)
49	30	M	Negative	Positive（RdRP gene)
50	26	F	Positive	Positive（RdRP and N gene)
51	32	F	Positive	Positive（RdRP and N gene)
52	73	M	Positive	Positive（RdRP and N gene)
53	58	F	Positive	Positive（RdRP and N gene)
54	66	F	Positive	Positive（RdRP and N gene)
55	29	F	Positive	Positive（RdRP and N gene)
56	56	M	Positive	Positive（RdRP and N gene)
57	24	M	Positive	Positive（N gene)
58	36	M	Positive	Positive（RdRP and N gene)
59	70	F	Positive	Positive（RdRP and N gene)
60	45	M	Positive	Positive（RdRP and N gene)
61	38	F	Positive	Positive（RdRP and N gene)
62	42	M	Positive	Positive（RdRP and N gene)
63	55	M	Positive	Positive（RdRP and N gene)
64	33	M	Positive	Positive（RdRP and N gene)
65	39	M	Positive	Positive（RdRP and N gene)
66	58	F	Positive	Positive（N gene)
67	77	F	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
68	62	F	Negative	Negative(Ct/Cq）>40
69	81	M	Negative	Negative(Ct/Cq）>40
70	18	F	Negative	Negative(Ct/Cq）>40
71	71	F	Negative	Negative(Ct/Cq）>40
72	37	M	Negative	Negative(Ct/Cq）>40
73	44	F	Negative	Negative(Ct/Cq）>40
74	79	M	Negative	Negative(Ct/Cq）>40
75	67	M	Negative	Negative(Ct/Cq）>40
76	61	F	Negative	Negative(Ct/Cq）>40
77	59	F	Negative	Negative(Ct/Cq）>40
78	28	F	Negative	Negative(Ct/Cq）>40
79	82	M	Negative	Negative(Ct/Cq）>40
80	63	F	Negative	Negative(Ct/Cq）>40
81	53	M	Negative	Negative(Ct/Cq）>40
82	43	M	Negative	Negative(Ct/Cq）>40
83	46	M	Negative	Negative(Ct/Cq）>40
84	46	F	Negative	Negative(Ct/Cq）>40
85	21	F	Negative	Negative(Ct/Cq）>40
86	46	F	Negative	Negative(Ct/Cq）>40
87	71	M	Negative	Negative(Ct/Cq）>40
88	60	F	Negative	Negative(Ct/Cq）>40
89	31	F	Negative	Negative(Ct/Cq）>40
90	72	M	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
91	62	M	Negative	Negative(Ct/Cq）>40
92	39	F	Negative	Negative(Ct/Cq）>40
93	45	M	Negative	Negative(Ct/Cq）>40
94	21	M	Negative	Negative(Ct/Cq）>40
95	33	M	Negative	Negative(Ct/Cq）>40
96	83	M	Negative	Negative(Ct/Cq）>40
97	15	M	Negative	Negative(Ct/Cq）>40
98	59	M	Negative	Negative(Ct/Cq）>40
99	54	M	Negative	Negative(Ct/Cq）>40
100	84	F	Negative	Negative(Ct/Cq）>40
101	84	F	Negative	Negative(Ct/Cq）>40
102	42	F	Negative	Negative(Ct/Cq）>40
103	63	F	Negative	Negative(Ct/Cq）>40
104	29	M	Negative	Negative(Ct/Cq）>40
105	50	M	Negative	Negative(Ct/Cq）>40
106	74	F	Negative	Negative(Ct/Cq）>40
107	43	M	Negative	Negative(Ct/Cq）>40
108	68	M	Negative	Negative(Ct/Cq）>40
109	29	M	Negative	Negative(Ct/Cq）>40
110	54	M	Negative	Negative(Ct/Cq）>40
111	49	M	Negative	Negative(Ct/Cq）>40
112	20	M	Negative	Negative(Ct/Cq）>40
113	26	M	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
114	22	M	Negative	Negative(Ct/Cq）>40
115	32	F	Negative	Negative(Ct/Cq）>40
116	28	M	Negative	Negative(Ct/Cq）>40
117	44	M	Negative	Negative(Ct/Cq）>40
118	57	F	Negative	Negative(Ct/Cq）>40
119	64	F	Negative	Negative(Ct/Cq）>40
120	39	F	Negative	Negative(Ct/Cq）>40
121	38	F	Negative	Negative(Ct/Cq）>40
122	73	M	Negative	Negative(Ct/Cq）>40
123	45	M	Negative	Negative(Ct/Cq）>40
124	61	M	Negative	Negative(Ct/Cq）>40
125	13	F	Negative	Negative(Ct/Cq）>40
126	64	F	Negative	Negative(Ct/Cq）>40
127	26	F	Negative	Negative(Ct/Cq）>40
128	28	M	Negative	Negative(Ct/Cq）>40
129	58	M	Negative	Negative(Ct/Cq）>40
130	35	F	Negative	Negative(Ct/Cq）>40
131	51	M	Negative	Negative(Ct/Cq）>40
132	60	M	Negative	Negative(Ct/Cq）>40
133	17	M	Negative	Negative(Ct/Cq）>40
134	18	F	Negative	Negative(Ct/Cq）>40
135	15	M	Negative	Negative(Ct/Cq）>40
136	52	M	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
137	33	M	Negative	Negative(Ct/Cq）>40
138	41	F	Negative	Negative(Ct/Cq）>40
139	11	M	Negative	Negative(Ct/Cq）>40
140	19	F	Negative	Negative(Ct/Cq）>40
141	10	F	Negative	Negative(Ct/Cq）>40
142	62	F	Negative	Negative(Ct/Cq）>40
143	68	F	Negative	Negative(Ct/Cq）>40
144	38	M	Negative	Negative(Ct/Cq）>40
145	59	M	Negative	Negative(Ct/Cq）>40
146	76	F	Negative	Negative(Ct/Cq）>40
147	24	M	Negative	Negative(Ct/Cq）>40
148	68	M	Negative	Negative(Ct/Cq）>40
149	82	F	Negative	Negative(Ct/Cq）>40
150	64	F	Negative	Negative(Ct/Cq）>40
151	59	M	Negative	Negative(Ct/Cq）>40
152	59	M	Negative	Negative(Ct/Cq）>40
153	83	M	Negative	Negative(Ct/Cq）>40
154	58	F	Negative	Negative(Ct/Cq）>40
155	68	M	Negative	Negative(Ct/Cq）>40
156	77	M	Negative	Negative(Ct/Cq）>40
157	47	F	Negative	Negative(Ct/Cq）>40
158	71	M	Negative	Negative(Ct/Cq）>40
159	21	F	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
160	52	M	Negative	Negative(Ct/Cq）>40
161	70	M	Negative	Negative(Ct/Cq）>40
162	63	M	Negative	Negative(Ct/Cq）>40
163	59	M	Negative	Negative(Ct/Cq）>40
164	26	M	Negative	Negative(Ct/Cq）>40
165	36	F	Negative	Negative(Ct/Cq）>40
166	47	F	Negative	Negative(Ct/Cq）>40
167	45	M	Negative	Negative(Ct/Cq）>40
168	29	F	Negative	Negative(Ct/Cq）>40
169	30	M	Negative	Negative(Ct/Cq）>40
170	25	F	Negative	Negative(Ct/Cq）>40
171	73	M	Negative	Negative(Ct/Cq）>40
172	76	M	Negative	Negative(Ct/Cq）>40
173	25	M	Negative	Negative(Ct/Cq）>40
174	49	F	Negative	Negative(Ct/Cq）>40
175	62	M	Negative	Negative(Ct/Cq）>40
176	38	M	Negative	Negative(Ct/Cq）>40
177	33	M	Negative	Negative(Ct/Cq）>40
178	39	M	Negative	Negative(Ct/Cq）>40
179	69	M	Negative	Negative(Ct/Cq）>40
180	79	F	Negative	Negative(Ct/Cq）>40
181	32	M	Negative	Negative(Ct/Cq）>40
182	35	M	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
183	39	M	Negative	Negative(Ct/Cq）>40
184	61	F	Negative	Negative(Ct/Cq）>40
185	10	F	Negative	Negative(Ct/Cq）>40
186	37	M	Negative	Negative(Ct/Cq）>40
187	52	F	Negative	Negative(Ct/Cq）>40
188	41	M	Negative	Negative(Ct/Cq）>40
189	74	M	Negative	Negative(Ct/Cq）>40
190	51	F	Negative	Negative(Ct/Cq）>40
191	56	M	Negative	Negative(Ct/Cq）>40
192	62	F	Negative	Negative(Ct/Cq）>40
193	60	F	Negative	Negative(Ct/Cq）>40
194	54	F	Negative	Negative(Ct/Cq）>40
195	81	F	Negative	Negative(Ct/Cq）>40
196	79	F	Negative	Negative(Ct/Cq）>40
197	73	F	Negative	Negative(Ct/Cq）>40
198	35	F	Negative	Negative(Ct/Cq）>40
199	76	F	Negative	Negative(Ct/Cq）>40
200	23	M	Negative	Negative(Ct/Cq）>40
201	13	F	Negative	Negative(Ct/Cq）>40
202	14	M	Negative	Negative(Ct/Cq）>40

NO.	Age	Gender	Rapid Test	(RT-PCR)
203	43	M	Negative	Negative(Ct/Cq）>40
204	30	F	Negative	Negative(Ct/Cq）>40
205	57	M	Negative	Negative(Ct/Cq）>40
206	30	F	Negative	Negative(Ct/Cq）>40
207	65	M	Negative	Negative(Ct/Cq）>40
208	66	F	Negative	Negative(Ct/Cq）>40
209	38	F	Negative	Negative(Ct/Cq）>40
210	49	M	Negative	Negative(Ct/Cq）>40
211	23	F	Negative	Negative(Ct/Cq）>40
212	51	M	Negative	Negative(Ct/Cq）>40
213	64	F	Negative	Negative(Ct/Cq）>40
214	67	M	Negative	Negative(Ct/Cq）>40
215	34	M	Negative	Negative(Ct/Cq）>40
216	55	M	Negative	Negative(Ct/Cq）>40
217	58	M	Negative	Negative(Ct/Cq）>40
218	67	F	Negative	Negative(Ct/Cq）>40
219	20	F	Negative	Negative(Ct/Cq）>40
220	42	M	Negative	Negative(Ct/Cq）>40
221	59	M	Negative	Negative(Ct/Cq）>40
222	12	M	Negative	Negative(Ct/Cq）>40

Director:
Date: 2020.12.10
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