TECHNICAL FILE

Realy Tech Rapid Test Device

June 2020

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Contents

Rapid Test Device

Intended Use

The 2019-nCOV/COVID-19 IgG/IgM Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of IgG & IgM antibodies for Coronavirus Disease 2019 in human whole blood, serum, or plasma as an aid in the diagnosis of COVID-19 infections.

Manufacturer Overview

Hangzhou Realy Tech Ltd is a diagnostic test company from Hangzhou city in the province of Zhejiang, China. The company has ISO 13485 certification for the production and distribution of clinical analysers and associated diagnostic test kits. Their products include rapid test procedures, chemiluminescent systems and PCR technologies.

The IgG / IgM rapid test device described in this document has been developed by the company in response to the outbreak of Covid-19 in China. The test procedure complies with the EC declaration of conformity in accordance with directive 98/79/EC.

Performance Characteristics

Sensitivity and Specificity

The 2019-nCOV/COVID-19 IgG/IgM Rapid Test Device has been compared to a leading commercial CMIA test using clinical specimens. The results show that the 2019-nCoV/COVID-19 IgG/IgM Rapid Test Device has a high sensitivity and specificity.

For IgG testing

Method		COVID-19 IgG Antibody Test Kit(CMIA)		Total Results
2019-nCOV IgG/IgM Rapid Test Device	Results	Positive	Negative	
	Positive	99	0	99
	Negative	1	100	101
Total Results		100	100	200

Relative Sensitivity:99/100*100%=99% (95%CI*: 94.01%-99.99%)
Relative Specificity:100/100*100%= 100% (95%CI*: 95.56%-100%)
Accuracy:(99+100)/(99+1+100)*100%=99.5% (95%CI*: 96.94%-99.99%)
*Confidence Interval

For IgM testing

Method		COVID-19 IgM Antibody Test Kit(CMIA)		Total Results
2019-nCOV IgG/IgM Rapid Test Device	Results	Positive	Negative	
	Positive	98	1	99
	Negative	2	99	101
Total Results		100	100	200

Relative Sensitivity:98/100*100%=98%(95%CI*:92.56%-99.89%)
Relative Specificity:99/100*100%=99%(95%CI*: 94.01%-99.99%)
Accuracy:(98+99)/(98+2+1+99)*100%=98.5%(95%CI*: 95.48%-99.69%)
*Confidence Interval

Performance Characteristics

Cross-reactivity

The 2019-nCoV/COVID-19 IgG/IgM 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 2019-nCoV/COVID-19 IgG/IgM Rapid Test Device and no interference was observed.

Triglyceride: 5000mg/dL
Ascorbic Acid: 20mg/dL
Hemoglobin 1000mg/dL
Bilirubin: 60mg/dL
Oxalic acid: 100mg/dL
Human serum albumin 2000mg/dL

VALIDATION STUDIES

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Validation Studies

The Realy Tech Rapid Test Device has undergone extensive validation prior to market launch. An independent clinical validation was undertaken at the Municipal Centre for Disease Control and Prevention in Shijiazhuang, China using 200 patients (male and female) covering a wide range of ages (from 13 to 98).

The results of this study demonstrated high levels of Sensitivity and Specificity for the determination of SARS CoV-2 specific IgG and IgM levels in blood samples.

A detailed analytical study was also undertaken to examine precision, sensitivity, interfering substances, cross reactivity, hook effect, test kit transport stability, temperature stability and test sample stability.

The details of these validation studies, plus further Regulatory & Quality information are provided in the remaining sections of this technical file.

Analytical Sensitivity

Testing Report

1. Purpose

The purpose of this proposal is to provide an validation of the analytical sensitivity. The production of at least three consecutive 2019-nCOV/COVID-19 IgG/IgM Rapid Test Device products shall be controlled.

2. General information

Manufacturer:Hangzhou Realy Tech Co.,Ltd.

Product name:2019-nCOV/COVID-19 IgG/IgM Rapid Test Device

Catalogue number:K460216D

3. Material

Positive Control:2019-nCOV-IgM;

Positive Control:2019-nCOV-IgG;

Validation lot 1:NO1G01T;

Validation lot 2:NO1G02T;

Validation lot 3:NO1G03T.

4. Method

Tests the low positive control of 2019-nCOV-IgM,2019-nCOV-IgG and negative sample.Each specimen tests in 11 tests.Read the positive result at 10 min.Do not interpret the result after 15 minutes.

5. QC Acceptance Criteria

Serum/Plasma specimens:C-line≤3min.

Whole blood specimens:C-line≤5min.

C-line≥G8 in 10min.

6. Results

Lot	2019-nCOV-IgM	2019-nCOV-IgG	Negative Sample
	IgM/IgG	IgM/IgG	IgM/IgG
NO1G01T	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-

Lot	2019-nCOV-IgM	2019-nCOV-IgG	Negative Sample
	IgM/IgG	IgM/IgG	IgM/IgG
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
NO1G02T	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
NO1G03T	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-
	+/-	-/+	-/-

7. Conclusion

The 2019-nCOV/COVID-19 IgG/IgM Rapid Test Device can show good performance using the positive and negative samples.

Clinical Validation report of COVID-19 IgG/IgM Rapid Test (Colloidal Gold)

Product name:COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)

Package Specification:25 tests/kit

Manufacturer: Hangzhou Realy Tech Co., Ltd

Validated by: Shijiazhuang Municipal Center For Disease Control And Prevention

Ⅰ Clinical validation time

This clinical evaluation was conducted from February 2020 to March 4th,2020.

Ⅱ Background information for clinical evaluation

Since December 2019, Wuhan City,Hubei Province has successively discovered multiple cases of patients with new-type coronavirus pneumonia.With the spread of the epidemic, other cases in 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 COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold) developed by our company can help diagnose whether patients are infected with the new coronavirus. It has further enriched the detection methods of new coronavirus, expanded the supply of detection reagents, and fully served the needs of epidemic prevention and control.

Ⅲ. Test purposes

The COVID-19 IgG/IgM Rapid Test Device(Colloidal Gold) 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 :calculate the consistency percentage of negative/positive and the total consistency percentage and Kappa coefficient by making statistics of and 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 new-type coronavirus venous whole blood, serum, and plasma samples, and it was proved that the in vitro diagnostic reagents

used in the test can achieve the expected assistance in infection of the new coronavirus.

2. Sample volume required

The total number of clinical trials of this product is not less than 200 cases. The samples is classified into the positive group and the negative group as per the test results of the reference product.Meanwhile,the samples shall be tested via the qualitative test strip tested and the reference one and then the test results of the product tested and the reference product shall be compared,with statistical analysis being made.

4.Sample collection, processing and storage

Sample collection: Suitable for human serum, plasma or whole blood samples,including plasma or whole blood samples prepared from commonly used anticoagulants (EDTA,heparin,sodium citrate).

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.

Sample storage: The serum and plasma samples to be tested are stored at 2-8°C for 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,

5.In vitro diagnostic reagents and reference products for testing

5.1 Test in vitro diagnostic reagents

Name:COVID-19 IgG/IgM Rapid Test Device(Colloidal Gold)

Specification:25 tests/kit

LOT:NO1G06T,NO1G07T,O1G08T

Expiry: August,2020

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:COVID-19 IgM Antibody Test Kit(CMIA)

COVID-19 IgG Antibody Test Kit(CMIA)

Manufacturer: Bioscience(Chongqing) Biological Technology Co., Ltd

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

V. Experiment method

1. Collect 200 whole blood samples from patients with positive and negative persons..
2. The test group uses the in vitro diagnostic reagent products for testing, and the control group uses the "reference reagent" for testing.
3. Each whole blood sample needs to be tested in random order using in vitro diagnostic reagents for the test, and the "reference reagent" confirms the results.
4. The operation steps of the in vitro diagnostic reagents for the test are as follows. For details, please refer to the product instruction manual:

Step 1: If the sample is stored refrigerated or frozen, remove the test sample and required reagents from the storage conditions and equilibrate to room temperature (15-30°C). After thawing, mix the samples thoroughly before testing.

Step 2: When preparing for testing, open the aluminum foil bag from the tear. Remove the test card and lay it flat on a horizontal table.

Step 3: Label the sample number on the test card.

Step 4:Using the **provided 5μL disposable pipette,and transfer 1 drop of serum** to the specimen well of the test device,then **add 1 drop of buffer,**and start the timer.Ensure that no air bubbles are generated during the operation.

Step 5: Time counting and interpret the results within 10 minutes.

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

VI. Statistical methods 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 90%.

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 90%.

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 sample shall be more than 90%.

Method		COVID-19 IgG Antibody Test Kit (CMIA)		Total Results
COVID-19 IgG Rapid Test Device	Results	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%

Method		COVID-19 IgM Antibody Test Kit (CMIA)		Total Results
COVID-19 IgM Rapid Test Device	Results	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		COVID-19 IgG Antibody Test Kit(CMIA)		Total Results
COVID-19 IgG Rapid Test Device	Results	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)

Method		COVID-19 IgM Antibody Test Kit(CMIA)		Total Results
COVID-19 IgM Rapid Test Device	Results	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, 200 test samples (125 for male and 75 for female) are included for the unit and all test samples included are tested. Statistics on test results and those of the product tested are as follows:

For IgG (use serum specimen):

Method		COVID-19 IgG Antibody Test Kit(CMIA)		Total Results
COVID-19 IgG Rapid Test Device	Results	Positive	Negative	
	Positive	99	0	99
	Negative	1	100	101
Total Results		100	100	200

Clinical sensitivity = 99/100*100%=99%

Clinical specificity = 100/100*100%= 100%

Accuracy: (99+100)/(99+1+100)*100%=99.5%

P_e=((100*99)+(99*100))/(200*200)=0.495

Kappa:(P_0 - P_e)/(1-p_e)=0.98

According to the above table,100 are proven negative of 100 negative specimens, 99 are proven positive of 100 positive specimens.The sensitivity and accuracy are more than 95%,indicating favorable consistency with the reference product.The Kappa=0.98 ＞ 0.8,indicating favorable and high consistency of two methods and equivalence of two such systems.

For IgM (use serum specimen):

Method		COVID-19 IgM Antibody Test Kit(CMIA)		Total Results
COVID-19 IgM Rapid Test Device	Results	Positive	Negative	
	Positive	98	1	99
	Negative	2	99	101
Total Results		100	100	200

Clinical sensitivity = 98/100*100%=98%

Clinical specificity = 99/100*100%= 99%

Accuracy: (98+99)/(98+2+1+99)*100%=98.5%

P_e=(100*99+99*100)/(200*200)=0.495

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

According to the above table,99 are proven negative of 100 negative specimens, 98 are proven positive of 100 positive specimens.The sensitivity and accuracy are more than 95%,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.	Gender	Age	COVID-19 IgG/IgM Rapid Test Device		COVID-19 IgG Antibody Test Kit(CMIA)	COVID-19 IgG Antibody Test Kit(CMIA)	Clinical Diagnosis
			IgG	IgM	IgG	IgM	
23	F	45	NEG	NEG	POS	POS	Subsequent visit of pneumonia triggered by COVID-19
24	F	66	POS	NEG	POS	POS	Subsequent visit of pneumonia triggered by COVID-19
27	M	56	NEG	POS	NEG	NEG	Non-pneumonia triggered by COVID-19

For those subjected to subsequent visit, IgM in the blood may be degraded and IgG definite diagnosis is more effective.

XI Discussion and Conclusions

1.discussion

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

Test results of the serum sample of the product tested and the reference product: both the coincidence rate of negative/positive and the total coincidence rate are larger than 90%, 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.

B Statistical analysis results of the product tested for different types of clinical sample

While testing the SARS-CoV-2 antibody through the product tested for different types of clinical sample, the consistency percentages of negative/positive are 100.0% and the total consistency percentage is 100.0%. The Kappa coefficient = 1.00 (>0.8) in the results of Kappa inspection and analysis, indicating favorable and complete consistency of two methods and equivalence of two such systems.

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. Meanwhile, the test results of the product tested for the serum and plasma sample of the same patient are completely identical. Therefore, such product is applicable to qualitative clinical analysis on the SARS-CoV-2 antibody in the serum and plasma sample of humans, 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 COVID-19 IgG/IgM Rapid Test Device(Colloidal Gold) 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 6)" issued by the National Health Committee on February 19, 2020.

Annex 1:Package Insert

COVID-19 IgG/IgM Rapid Test Device

Package Insert

For the qualitative assessment of New Coronavirus (COVID-19) IgG/IgM in human serum/plasma/whole blood.

For professional In Vitro Diagnostic Use Only

INTENDED USE

The COVID-19 IgG/IgM Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of IgG&IgM antibody of New Coronavirus in human whole blood,serum,or plasma as an aid in the diagnosis of COVID-19 infections.

SUMMARY

Coronavirus (CoV) belongs to the genus Nestovirus, Coronaviridae, 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.

So far, there are 7 types of human coronavirus (HCoV) that cause human respiratory diseases: HCoV-229E,HCoV-OC43,SARS-CoV,HCoV-NL63,HCoV-HKU1,MERS-CoV and new coronaviruses (2019) , Is an important pathogen of human respiratory infections. Among them, the new coronavirus (2019) was discovered due to Wuhan virus pneumonia cases in 2019. The clinical manifestations are systemic symptoms such as fever and fatigue, accompanied by dry cough and dyspnea, etc., which can rapidly develop into severe pneumonia, respiratory failure, and acute breathing. Distress syndrome, septic shock, multiple organ failure, severe acid-base metabolism disorders, etc. are even life-threatening.

PRINCIPLE

This kit uses immunochromatography.The test card contains:1) colloidal gold-labeled recombinant new coronavirus antigen and quality control antibody gold markers;2) two detection lines (G and M lines) and one quality Control line (C line) of nitrocellulose membrane. The M line is immobilized with a monoclonal anti-human IgM antibody for detecting a new coronavirus IgM antibody; the G line is immobilized with a reagent for detecting a new coronavirus IgG 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 an IgM antibody, the antibody will bind to the colloidal gold-labeled new coronavirus antigen. The immune complex will be captured by the anti-human IgM antibody immobilized on the membrane to form a purple-red M line,showing that the new coronavirus IgM antibody is positive.

If the sample contains an IgG antibody, the antibody will bind to the colloidal gold-labeled new coronavirus antigen,and the immune complex will be captured by the reagent immobilized on the membrane to form a purple-red G line, indicating that the new coronavirus IgG antibody is positive.

If the test lines G and M are not colored,a negative result is displayed.The test card also

contains a quality control line C.The fuchsia quality control line C should appear regardless of whether a test line appears.The quality control line is a color band of the quality control antibody immune complex. 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.

REAGENTS

The test contains COVID-19 virus envelope protein particles and anti-human IgG,anti-human IgM antibody conjugated gold particles coated on the membrane.

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.

STORAGE AND STABILITY

- The original packaging should be stored at 4~ 30℃, to avoid light, keep dry.
- The test device is stable through the expiration date printed on the sealed pouch.The test device must remain in the sealed pouch until use.**DO NOT FREEZE.**
- Do not use beyond the expiration date, especially at temperatures above 30℃ or under high humidity conditions, should be used immediately once it is opened.

SPECIMEN COLLECTION AND PREPARATION

1. The COVID-19 IgG/IgM 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.

MATERIALS

Materials provided

Test Devices	Buffer
5μL Disposable plastic pipette	Package insert

Materials required but not provided

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

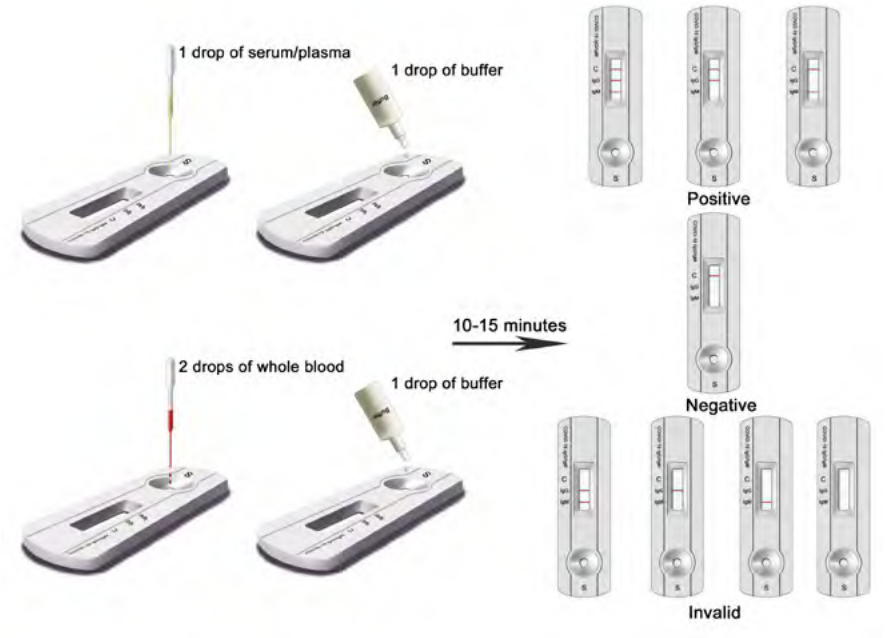
DIRECTIONS FOR USE

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 5μL disposable pipette,and transfer 1 drop 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 5μL disposable pipette**,and **transfer 2 drops of whole blood (approximately 20μL)** 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

IgG POSITIVE:*The colored line in the control line region (C) appears and a colored line appears in test line region IgG. The result is positive for COVID-19-IgG antibodies.

IgM POSITIVE:*The colored line in the control line region (C) appears and a colored line appears in test line region IgM. The result is positive for COVID-19-IgM antibodies and is indicative of primary COVID-19 infection.

IgG AND IgM POSITIVE:*The colored line in the control line region (C) appears and two-colored lines should appear in test line regions IgG and IgM. The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies.

***NOTE:** The intensity of the color in the test line region(s) IgG and/or IgM will vary depending on the concentration of COVID-19 antibodies in the specimen. Therefore, any shade of color in the test line region(s) IgG and/or IgM should be considered positive.

NEGATIVE: The colored line in the control line region (C) appears. No line appears in test line regions IgG or IgM.

INVALID: There is no line appear 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.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The COVID-19 IgG/IgM Rapid Test Device has been compared to a leading commercial RT-PCR testing using clinical specimens.The results show that the COVID-19 IgG/IgM Rapid Test Device has a high sensitivity and specificity.

For IgG testing:

Method		COVID-19 IgG Antibody Test Kit(CMIA)		Total Results
COVID-19 IgG Rapid Test Device	Results	Positive	Negative	
	Positive	99	0	99
	Negative	1	100	101
Total Results		100	100	200

Clinical sensitivity = 99/100*100%=99%

Clinical specificity = 100/100*100%= 100%

Accuracy: (99+100)/(99+1+100)*100%=99.5%

For IgM testing:

Method		COVID-19 IgM Antibody Test Kit(CMIA)		Total Results
COVID-19 IgM Rapid Test Device	Results	Positive	Negative	
	Positive	98	1	99
	Negative	2	99	101
Total Results		100	100	200

Clinical sensitivity = 98/100*100%=98%

Clinical specificity = 99/100*100%= 99%

Accuracy: (98+99)/(98+2+1+99)*100%=98.5%

Cross-reactivity

The COVID-19 IgG/IgM Rapid Test Device has been tested for anti-influenza A virus,anti-influenza B virus,anti-RSV,anti-Adenovirus,HBsAg,anti-Syphilis,anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the COVID-19 IgG/IgM Rapid Test Device and no interference was observed.

Triglyceride: 100 mg/dL Ascorbic Acid:20mg/dl Hemoglobin 1000mg/dL

Bilirubin: 100mg/dL Total cholesterol: 6mmol/L

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
REF	Catalogue number	Σ	The number of test

HANGZHOU REALY TECH CO., LTD.
4th Floor,#12 Building,Eastern Medicine Town,
Xiasha Economic&TechnologyDevelopment,
310018Hangzhou,Zhejiang,P.R.China

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

CE

Number:1101271601
Version:1.0
Effective Date:

Annex 2: Data of Clinical Tests (use the serum samples)

NO.	Gender	Age	COVID-19 IgG/IgM Rapid Test Device		COVID-19 IgG Antibody Test Kit(CMIA)	COVID-19 IgG Antibody Test Kit(CMIA)
			IgG	IgM	IgG	IgM
1	F	23	-	-	-	-
2	M	13	-	-	-	-
3	F	32	-	-	-	-
4	M	32	-	-	-	-
5	F	56	-	-	-	-
6	F	45	-	-	-	-
7	M	32	-	-	-	-
8	M	43	-	-	-	-
9	F	21	-	-	-	-
10	F	35	-	-	-	-
11	F	25	-	-	-	-
12	M	75	-	-	-	-
13	M	45	-	-	-	-
14	M	35	-	-	-	-
15	M	67	-	-	-	-
16	M	43	-	-	-	-
17	M	67	-	-	-	-
18	M	33	-	-	-	-
19	M	25	-	-	-	-
20	F	76	-	-	-	-
21	F	54	+	+	+	+
22	F	65	+	+	+	+
23	F	45	-	-	+	+
24	F	66	+	-	+	+
25	M	65	+	+	+	+
26	M	43	+	+	+	+
27	M	56	-	+	-	-
28	F	64	+	+	+	+
29	F	33	+	+	+	+
30	F	33	+	+	+	+
31	F	87	+	+	+	+
32	M	32	+	+	+	+
33	M	45	+	+	+	+
34	F	54	+	+	+	+
35	M	22	+	+	+	+
36	F	25	-	-	-	-
37	F	45	-	-	-	-
38	M	33	+	+	+	+
39	M	44	+	+	+	+
40	M	33	+	+	+	+
41	M	24	+	+	+	+

42	F	15	+	+	+	+
43	F	89	+	+	+	+
44	M	54	-	-	-	-
45	M	33	-	-	-	-
46	F	36	-	-	-	-
47	M	76	-	-	-	-
48	M	47	-	-	-	-
49	F	98	-	-	-	-
50	M	45	+	+	+	+
51	F	34	+	+	+	+
52	F	56	+	+	+	+
53	F	76	+	+	+	+
54	M	75	+	+	+	+
55	M	33	+	+	+	+
56	M	56	+	+	+	+
57	M	43	+	+	+	+
58	M	65	-	-	-	-
59	M	44	-	-	-	-
60	M	54	-	-	-	-
61	M	87	-	-	-	-
62	M	46	-	-	-	-
63	M	86	-	-	-	-
64	M	54	-	-	-	-
65	M	54	-	-	-	-
66	M	46	-	-	-	-
67	M	5	+	+	+	+
68	M	2	+	+	+	+
69	M	34	+	+	+	+
70	M	77	+	+	+	+
71	M	33	+	+	+	+
72	M	78	+	+	+	+
73	M	32	+	+	+	+
74	M	44	+	+	+	+
75	M	77	-	-	-	-
76	F	22	+	+	+	+
77	F	35	+	+	+	+
78	M	64	+	+	+	+
79	M	23	+	+	+	+
80	M	36	-	-	-	-
81	M	76	+	+	+	+
82	M	34	+	+	+	+
83	M	98	+	+	+	+
84	M	56	+	+	+	+
85	M	79	-	-	-	-

86	M	65	+	+	+	+
87	F	21	+	+	+	+
88	F	70	+	+	+	+
89	M	45	+	+	+	+
90	M	75	-	-	-	-
91	M	63	+	+	+	+
92	M	66	+	+	+	+
93	M	22	+	+	+	+
94	M	43	+	+	+	+
95	M	46	-	-	-	-
96	M	12	+	+	+	+
97	F	32	+	+	+	+
98	F	65	-	-	-	-
99	M	56	-	-	-	-
100	M	21	-	-	-	-
101	F	24	-	-	-	-
102	F	24	-	-	-	-
103	F	73	-	-	-	-
104	F	43	-	-	-	-
105	F	75	-	-	-	-
106	F	24	-	-	-	-
107	F	34	-	-	-	-
108	F	57	-	-	-	-
109	M	35	+	+	+	+
110	M	65	+	+	+	+
111	M	4	+	+	+	+
112	M	14	-	-	-	-
113	F	34	+	+	+	+
114	M	98	+	+	+	+
115	M	87	+	+	+	+
116	F	32	+	+	+	+
117	M	23	+	+	+	+
118	M	65	-	-	-	-
119	M	76	-	-	-	-
120	M	86	-	-	-	-
121	F	45	-	-	-	-
122	M	46	+	+	+	+
123	M	23	+	+	+	+
124	F	54	+	+	+	+
125	F	3	+	+	+	+
126	F	44	+	+	+	+
127	F	22	-	-	-	-
128	F	54	-	-	-	-
129	M	43	+	+	+	+

130	M	44	+	+	+	+
131	M	54	-	-	-	-
132	M	33	-	-	-	-
133	M	65	-	-	-	-
134	M	34	-	-	-	-
135	M	54	-	-	-	-
136	M	56	-	-	-	-
137	M	76	-	-	-	-
138	M	65	-	-	-	-
139	F	54	-	-	-	-
140	F	35	-	-	-	-
141	F	58	-	-	-	-
142	M	87	-	-	-	-
143	M	34	-	-	-	-
144	M	12	-	-	-	-
145	F	32	-	-	-	-
146	M	17	-	-	-	-
147	F	98	-	-	-	-
148	F	34	-	-	-	-
149	F	23	-	-	-	-
150	M	45	+	+	+	+
151	M	76	+	+	+	+
152	M	45	+	+	+	+
153	M	32	+	+	+	+
154	M	23	+	+	+	+
155	M	34	+	+	+	+
156	M	56	+	+	+	+
157	M	45	+	+	+	+
158	M	65	+	+	+	+
159	M	32	+	+	+	+
160	F	34	+	+	+	+
161	F	84	+	+	+	+
162	M	35	-	-	-	-
163	F	24	-	-	-	-
164	F	14	-	-	-	-
165	M	45	-	-	-	-
166	M	43	+	+	+	+
167	M	22	+	+	+	+
168	M	23	+	+	+	+
169	M	12	-	-	-	-
170	M	23	-	-	-	-
171	F	34	+	+	+	+
172	F	45	+	+	+	+

173	F	23	+	+	+	+
174	F	24	+	+	+	+
175	F	25	+	+	+	+
176	M	26	+	+	+	+
177	M	28	-	-	-	-
178	F	67	-	-	-	-
179	F	88	-	-	-	-
180	M	65	-	-	-	-
181	M	45	-	-	-	-
182	M	34	-	-	-	-
183	M	90	-	-	-	-
184	F	69	-	-	-	-
185	F	67	+	+	+	+
186	F	54	+	+	+	+
187	M	25	+	+	+	+
188	F	21	+	+	+	+
189	M	45	-	-	-	-
190	F	23	-	-	-	-
191	F	67	+	+	+	+
192	M	56	+	+	+	+
193	M	15	+	+	+	+
194	F	32	-	-	-	-
195	F	89	-	-	-	-
196	F	32	+	+	+	+
197	M	54	+	+	+	+
198	M	76	-	-	-	-
199	M	68	-	-	-	-
200	M	16	+	+	+	+

Cross-reactivity study of

COVID-19 IgG/IgM test device

1.0 Study purposes

Verify cross-reactivity of COVID-19 IgG/IgM test device with Positive specimens of different respiratory diseases

2.0 Material

2.1 Test in vitro diagnostic reagents

Name: COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)

Specification:25 tests/kit

LOT:NO1G01T, NO1G02T, NO1G03T

Expiry: August,2020(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

2.2 Specimen

RSV Positive serum specimen 5 pcs

Adeno positive serum specimen 5pcs

Flu A positive serum specimen 5 pcs

Flu B positive serum specimen 5 pcs

MP positive serum specimen 5 pcs

CP positive serum specimen 5 pcs

RF positive serum specimen 10 pcs

HIV positive serum specimen 5 pcs

TP positive serum specimen 5 pcs

HCV positive serum specimen 5 pcs

HBsAg positive serum specimen 5 pcs

3.0 Experiment method

3.1 Instructions for use

Directions for use and interpretation of results according to the package insert.

3.2 Experimental procedures

4.2.1 Use different batches of test device to test the different clinical positive specimens and record the test results at the 15 min.

4.0 Results of experiment data

Data of experiment results

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
RSV-1	–	–	–	–	–	–
RSV-2	–	–	–	–	–	–
RSV-3	–	–	–	–	–	–
RSV-4	–	–	–	–	–	–
RSV-5	–	–	–	–	–	–
Adeno-1	–	–	–	–	–	–
Adeno-2	–	–	–	–	–	–
Adeno-3	–	–	–	–	–	–
Adeno-4	–	–	–	–	–	–
Adeno-5	–	–	–	–	–	–
FLU A-1	–	–	–	–	–	–
FLU A-2	–	–	–	–	–	–
FLU A-3	–	–	–	–	–	–
FLU A-4	–	–	–	–	–	–
FLU A-5	–	–	–	–	–	–
FLU B-1	–	–	–	–	–	–
FLU B-2	–	–	–	–	–	–
FLU B-3	–	–	–	–	–	–
FLU B-4	–	–	–	–	–	–
FLU B-5	–	–	–	–	–	–
MP-1	–	–	–	–	–	–
MP-2	–	–	–	–	–	–
MP-3	–	–	–	–	–	–
MP-4	–	–	–	–	–	–
MP-5	–	–	–	–	–	–

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
CP-1	–	–	–	–	–	–
CP-2	–	–	–	–	–	–
CP-3	–	–	–	–	–	–
CP-4	–	–	–	–	–	–
CP-5	–	–	–	–	–	–
RF-1	–	–	–	–	–	–
RF-2	–	–	–	–	–	–
RF-3	–	–	–	–	–	–
RF-4	–	–	–	–	–	–
RF-5	–	–	–	–	–	–
RF-6	–	–	–	–	–	–
RF-7	–	–	–	–	–	–
RF-8	–	–	–	–	–	–
RF-9	–	–	–	–	–	–
RF-10	–	–	–	–	–	–
HIV-1	–	–	–	–	–	–
HIV-2	–	–	–	–	–	–
HIV-3	–	–	–	–	–	–
HIV-4	–	–	–	–	–	–
HIV-5	–	–	–	–	–	–
TP-1	–	–	–	–	–	–
TP-2	–	–	–	–	–	–
TP-3	–	–	–	–	–	–
TP-4	–	–	–	–	–	–
TP-5	–	–	–	–	–	–
HCV-1	–	–	–	–	–	–
HCV-2	–	–	–	–	–	–
HCV-3	–	–	–	–	–	–
HCV-4	–	–	–	–	–	–
HCV-5	–	–	–	–	–	–
HBsAg-1	–	–	–	–	–	–
HBsAg-2	–	–	–	–	–	–

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
HBsAg-3	–	–	–	–	–	–
HBsAg-4	–	–	–	–	–	–
HBsAg-5	–	–	–	–	–	–

5.0 Conclusion

The above results show that there is no cross-reactivity of RSV, Adeno, FLU A, FLUB, MP, CP, RF, HIV, TP, HCV, HBsAg, when test by COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)

Doose hook study

1. Purpose

Validation whether the Hook effect exists in the products of 2019-nCOV/COVID-19 IgG/IgM Rapid Test Device.

2. General information

Manufacturer:Hangzhou Realy Tech Co.,Ltd.

Product name:2019-nCOV/COVID-19 IgG/IgM Rapid Test Device

Catalogue number:K460216D

3. Material

Validation lot1: NO1G01T;

Validation lot2: NO1G02T;

Validation lot3: NO1G03T;

2019-nCOV-IgM Strong positive sample;

2019-nCOV-IgG Strong positive sample;

Negative sample (N1).

4. Method

1） Prepare 2019-nCOV-IgM strong positive samples and 2019-nCOV-IgG strong positive samples,then diluted each specimen with Negative sample (N1) according to the dilution ratio.Dilute the sample until cut off ratio.

2） Refer to the INSTRUCTION FOR USE section in package insert of the 2019-nCOV/COVID-19 IgG/IgM Rapid Test Device

3） Run each specimen with triple tests.

5. QC Acceptance Criteria

There is no Hook effect.

Serum/Plasma specimens:C-line≤3min.

Whole blood specimens:C-line≤5min.

C-line≥G8 in 10min.

6. Results

2019-nCOV-IgM Strong positive sample

Dilution ratio	NO1G01T			NO1G02T			NO1G03T		
	IgM/IgG			IgM/IgG			IgM/IgG		
1:2	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
1:4	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
1:8	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
1:16	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
1:32	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
1:64	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
1:128	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
1:256	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
1:521	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
1:1024	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-

C-line State:10″

D-line Appearing Time:≤1′07″

2019-nCOV-IgG Strong positive sample

Dilution ratio	NO1G01T			NO1G02T			NO1G03T		
	IgM/IgG			IgM/IgG			IgM/IgG		
1:2	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
1:4	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
1:8	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
1:16	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
1:32	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
1:64	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
1:128	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
1:256	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
1:521	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
1:1024	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
1:2084	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+

C-line State:10″

C-line Appearing Time: ≤58″

7. Conclusion

From the above result, The gradient of validation lot are obvious and there is no dose hook effect.

Interfering Substances Study Report

1. Purpose

Study whether clinical common specimens,drugs or reagents interfere with the performance of the 2019-nCOV IgG/IgM Rapid Test Device.

2. General information

Manufacturer:Hangzhou Realy Tech Co.,Ltd.

Product name:2019-nCOV IgG/IgM Rapid Test Device

Catalogue number:K460216D

3. Material

Dropper,

Product：

Product		**Lot**
2019-nCOV IgG/IgM Rapid Test Device	Lot 1	NO1G01T
	Lot 2	NO1G02T
	Lot 3	NO1G03T

Reference panel：

Specimen	Lot	Specimen	Lot	Specimen	Lot
N1	202002087	L1	202003001	L3	202003001

4. Method

1) The 2019-nCOV IgG positive reference panel L1, IgM positive reference panel L3 and negative reference panel N1 were used to dilute the interfering substances to the following concentrations:

Interfering substances	Lot	Concentration	Lot after configuration
Ascorbic acid	MKBH4682V	0.2mg/ml	200299
Hemoglobin	069K7545	10mg/ml	200299
Bilirubin	SLBK6048V	0.6mg/ml	200299
Oxalic acid	SHBC1518V	1mg/ml	200299
Human serum albumin	D00160957-0904	20mg/ml	200299
Triglyceride	LC08933V	50mg/ml	200299

2) Operate according to the package insert of the product.

3) Test each specimen with triple tests.

4) Read the positive result at 10 min and negative result at 15 min. Do not interpret the result after 15 minutes.

5. Results

Product	Reference panel	Interference substances													
		Blank		Ascorbic acid		Hemoglobin		Bilirubin		Oxalic acid		Human serum albumin		Triglyceride	
		/		0.2mg/ml		10mg/ml		0.6mg/ml		1mg/ml		20mg/ml		50mg/ml	
		T1(IgG	T2(IgM	T1(IgG	T2(IgM	T1(IgG	T2(IgM	T1(IgG	T2(IgM	T1(IgG	T2(IgM	T1(IgG	T2(IgM	T1(IgG	T2(IgM
Lot 1	N1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	L1	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A
		+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A
		+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A
	L3	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+
		N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+
		N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+
Lot2	N1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-

Product	Reference panel	Interference substances													
		Blank		Ascorbic acid		Hemoglobin		Bilirubin		Oxalic acid		Human serum albumin		Triglyceride	
		/		0.2mg/ml		10mg/ml		0.6mg/ml		1mg/ml		20mg/ml		50mg/ml	
		T1(IgG	T2(IgM	T1(IgG	T2(IgM	T1(IgG	T2(IgM	T1(IgG	T2(IgM	T1(IgG	T2(IgM	T1(IgG	T2(IgM	T1(IgG	T2(IgM
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	L1	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A
		+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A
		+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A
	L3	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+
		N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+
		N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+
Lot 3	N1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
	L1	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A
		+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A
		+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A
	L3	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+

Product	Reference panel	Interference substances													
		Blank		Ascorbic acid		Hemoglobin		Bilirubin		Oxalic acid		Human serum albumin		Triglyceride	
		/		0.2mg/ml		10mg/ml		0.6mg/ml		1mg/ml		20mg/ml		50mg/ml	
		T1(IgG	T2(IgM	T1(IgG	T2(IgM	T1(IgG	T2(IgM	T1(IgG	T2(IgM	T1(IgG	T2(IgM	T1(IgG	T2(IgM	T1(IgG	T2(IgM
		N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+
		N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+	N/A	+
C line appearing time:≤1′17″,C line state:≥G9.															

6. Conclusion

The results indicated that these interfering substances have no interference phenomenon to 2019-nCOV IgG/IgM Rapid Test Device and meet the acceptance criteria.

Precision study

1. Purpose

The purpose of this proposal is to provide an validation of the Precision study.The production of at least three consecutive 2019-nCOV/COVID-19 IgG/IgM Rapid Test Device products shall be controlled.

2. General information

Manufacturer:Hangzhou Realy Tech Co.,Ltd.

Product name:2019-nCOV/COVID-19 IgG/IgM Rapid Test Device

Catalogue number:K460216D

3. Material:

Validation lot 1:NO1G01T;

Validation lot 2:NO1G02T;

Validation lot 3:NO1G03T;

Operator1;Operator2;Operator3;

Negative Control: N1;

Low positive Control: 2019-nCOV-IgM (LM);

Low positive Control: 2019-nCOV-IgG (LG);

High positive Control:2019-nCOV-IgM (HM);

High positive Control:2019-nCOV-IgG(HG).

4. Methods

1） Refer to the DIRECTIONS FOR USE section of the package insert.

2） Precision study should follow the steps:3pcs/person/concentration/*3lots*10days.and this study must be operated by three different persons from QC department.

5. Interpretation of results

Positive result:≥G3

Negative result:<G3

Note: *G3* is a color strip of the Standard colorimetric card.

6. QC Acceptance Criteria

Product performance is not affected by intra-assay and inter-assay.

Serum/Plasma specimens:C-line≤3min.

Whole blood specimens:C-line≤5min.

C-line≥G8 in 10min.

Note: *G8* is a color strip of the Standard colorimetric card.

7. Results

Lot1: NO1G01T;

Day/Operator	Sample	1	2	3
		IgM/IgG	IgM/IgG	IgM/IgG
Day1 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day1 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day1 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day2 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day2 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day2 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+

Day/Operator	Sample	1	2	3
		IgM/IgG	IgM/IgG	IgM/IgG
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day3 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day3 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day3 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day4 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day4 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day4 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+

Day/Operator	Sample	1	2	3
		IgM/IgG	IgM/IgG	IgM/IgG
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day5 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day5 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day5 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day6 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day6 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day6 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+

Day/Operator	Sample	1	2	3
		IgM/IgG	IgM/IgG	IgM/IgG
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day7 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day7 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day7 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day8 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day8 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day8 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+

Day/Operator	Sample	1	2	3
		IgM/IgG	IgM/IgG	IgM/IgG
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day9 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day9 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day9 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day10 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day10 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day10 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+

Day/Operator	Sample	1	2	3
		IgM/IgG	IgM/IgG	IgM/IgG
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+

Lot2:NO1G02T;

Day/operator	Sample	1	2	3
		IgM/IgG	IgM/IgG	IgM/IgG
Day1 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day1 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day1 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day2 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day2 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-

Day/operator	Sample	1	2	3
		IgM/IgG	IgM/IgG	IgM/IgG
	HG	-/+	-/+	-/+
Day2 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day3 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day3 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day3 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day4 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day4 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-

Day/operator	Sample	1	2	3
		IgM/IgG	IgM/IgG	IgM/IgG
	HG	-/+	-/+	-/+
Day4 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day5 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day5 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day5 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day6 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day6 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-

Day/operator	Sample	1	2	3
		IgM/IgG	IgM/IgG	IgM/IgG
	HG	-/+	-/+	-/+
Day6 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day7 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
	N1	-/-	-/-	-/-
Day7 Operator2	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
	N1	-/-	-/-	-/-
Day7 Operator3	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
	N1	-/-	-/-	-/-
Day8 Operator1	N1	+/-	+/-	+/-
	LM	-/+	-/+	-/+
	LG	+/-	+/-	+/-
	HM	-/+	-/+	-/+
	HG	-/-	-/-	-/-
Day8 Operator2	N1	+/-	+/-	+/-
	LM	-/+	-/+	-/+
	LG	+/-	+/-	+/-

Day/operator	Sample	1	2	3
		IgM/IgG	IgM/IgG	IgM/IgG
	HM	-/+	-/+	-/+
	HG	-/-	-/-	-/-
Day8 Operator3	N1	+/-	+/-	+/-
	LM	-/+	-/+	-/+
	LG	+/-	+/-	+/-
	HM	-/+	-/+	-/+
	HG	-/-	-/-	-/-
Day9 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day9 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day9 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day10 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day10 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+

Day/operator	Sample	1	2	3
		IgM/IgG	IgM/IgG	IgM/IgG
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day10 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+

Lot3:NO1G03T;

Day/operator	Sample	1	2	3
		IgM/IgG	IgM/IgG	IgM/IgG
Day1 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day1 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day1 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day2 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-

Day/operator	Sample	1	2	3
		IgM/IgG	IgM/IgG	IgM/IgG
	HG	-/+	-/+	-/+
Day2 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day2 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day3 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day3 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day3 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day4 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-

Day/operator	Sample	1	2	3
		IgM/IgG	IgM/IgG	IgM/IgG
	HG	-/+	-/+	-/+
Day4 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day4 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day5 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day5 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day5 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day6 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-

Day/operator	Sample	1	2	3
		IgM/IgG	IgM/IgG	IgM/IgG
	HG	-/+	-/+	-/+
Day6 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day6 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day7 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day7 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day7 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day8 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-

Day/operator	Sample	1	2	3
		IgM/IgG	IgM/IgG	IgM/IgG
	HG	-/+	-/+	-/+
Day8 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day8 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day9 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day9 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day9 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day10 Operator1	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-

Day/operator	Sample	1	2	3
		IgM/IgG	IgM/IgG	IgM/IgG
	HG	-/+	-/+	-/+
Day10 Operator2	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+
Day10 Operator3	N1	-/-	-/-	-/-
	LM	+/-	+/-	+/-
	LG	-/+	-/+	-/+
	HM	+/-	+/-	+/-
	HG	-/+	-/+	-/+

8. Conclusion

The result of the test shows that operated by three different persons at 10days is conform to acceptable criteria.

Real time and Accelerated Stability Study

1. Purpose

To investigate the performance of the 2019-nCOV/COVID-19 IgG/IgM Rapid Test Device under the influence of normal temperature and high temperature storage conditions over time, which is the production, packaging, storage, transportation conditions and expiration date of the kit.The determination provides a scientific basis to ensure the safety and effectiveness of this kit.

2. Determination of stability

Refer to the expiration date of the marketed product and combine with the actual situation of the company's kit to conduct a stability test. The test results obtained serve as the initial basis for determining the expiration date of this kit.

The tentative validity period of this kit is:store at 2-30℃ in the dark for 24 months.

3. Content

3.1 long term stability

1.1.1 Testing items

Items	Requirements
Negative Coincidence Rate	Use the company's internal negative control disk N1-N20 for testing, requiring products to be negative
IgG Positive Coincidence Rate	Use the company's IgG positive quality control L1\L2\M1\M2 for testing, requiring products to be positive
IgM Positive Coincidence Rate	Use the company's IgM positive quality control L3\L4\M3\M4 for testing, requiring products to be positive
Running time	C line appearing time＜120″
Product Background	Background clear,not affect the interpretation of results

3.1.2 Investigation time and time interval setting

The investigation period of the long-term stability test of this kit is 36 months. The time interval of the inspection is every 6 months in the first 12 months, every 4 months in the middle 12 months, and every 3 months in the next 12 months to ensure the objective and repeatability of the test results.

3.1.3 LOT of stability study product

Using 3 consecutive batches of products,LOT:NO1G12T,NO1G13T,NO1G14T

3.1.4 Package and storage conditions

- The packaging of the long-term stability test of this kit is the same as the packaging to be marketed.
- 2~30℃ storage.

3.2 Accelerated stability

3.2.1 Testing items

Items	Requirements
Negative Coincidence Rate	Use the company's internal negative control disk N1-N20 for testing, requiring products to be negative
IgG Positive Coincidence Rate	Use the company's IgG positive quality control L1\L2\M1\M2 for testing, requiring products to be positive
IgM Positive Coincidence Rate	Use the company's IgM positive quality control L3\L4\M3\M4 for testing, requiring products to be positive
Running time	C line appearing time＜120″
Product Background	Background clear,not affect the interpretation of results

3.2.2 Setting of investigation time and time interval

3.2.2.1 Store the reagent to be tested under the required storage conditions (55 ℃). If the temperature exceeds the required range, adjust it.

3.2.2.2 Remove the reagent from the incubator every specified number of days.

3.2.2.3

0 day and the last day study:

Test all reference panel (buffer,N1~N20,IgGL1,L2,M1,M2,IgM L3,L4,M3,M4),each reference panel is tested once.

Other study point:

Negative reference panel N1, IgG positive reference panel L1, and IgM positive reference panel L2 were tested each time, and each reference panel was tested 3 times.

Accelerate the stability evaluation of the product according to the following schedule.

Accelerated stability										
Study point		1	2	3	4	5	6	7	8	9
Time point (day)	55℃	0	9	16	24	31	38	46	49	53

3.2.3 LOT of Accelerated stability study product

Using 3 consecutive batches of products,LOT:NO1G12T，NO1G13T，NO1G14T

3.2.4 Package and storage conditions

- The packaging of the long-term stability test of this kit is the same as the packaging to be marketed.
- 2~30℃storage..

3.3 Stability study information and data

3.3.1.Study basis information

Product name	2019-nCOV/COVID-19 IgG/IgM Rapid Test Device
Specification	25test/kit
Production information	

Product name	LOT
2019-nCOV/COVID-19 IgG/IgM Rapid Test Device	NO1G12T
2019-nCOV/COVID-19 IgG/IgM Rapid Test Device	NO1G13T
2019-nCOV/COVID-19 IgG/IgM Rapid Test Device	NO1G14T

4. Stability study data and results

4.1 long term stability

0 day Result

Reference panel		LOT	LOT1		LOT2		LOT3	
			T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
Negative Reference panel	N1	202002087	—	—	—	—	—	—
	N2	202002087	—	—	—	—	—	—
	N3	202002087	—	—	—	—	—	—
	N4	202002087	—	—	—	—	—	—
	N5	202002087	—	—	—	—	—	—
	N6	202002087	—	—	—	—	—	—
	N7	202002087	—	—	—	—	—	—
	N8	202002087	—	—	—	—	—	—
	N9	202002087	—	—	—	—	—	—
	N10	202002087	—	—	—	—	—	—
	N11	202002087	—	—	—	—	—	—
	N12	202002087	—	—	—	—	—	—
	N13	202002087	—	—	—	—	—	—
	N14	202002087	—	—	—	—	—	—
	N15	202002087	—	—	—	—	—	—
	N16	202002087	—	—	—	—	—	—

Reference panel		LOT	LOT1		LOT2		LOT3	
			T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
	N17	202002087	—	—	—	—	—	—
	N18	202002087	—	—	—	—	—	—
	N19	202002087	—	—	—	—	—	—
	N20	202002087	—	—	—	—	—	—
Positive Reference panel								
	L1	202003001	+	N/A	+	N/A	+	N/A
	L2	202003001	+	N/A	+	N/A	+	N/A
	L3	202003001	N/A	+	N/A	+	N/A	+
	L4	202003001	N/A	+	N/A	+	N/A	+
	M1	202003001	++	N/A	++	N/A	++	N/A
	M2	202003001	++	N/A	++	N/A	++	N/A
	M3	202003001	N/A	++	N/A	++	N/A	++
	M4	202003001	N/A	++	N/A	++	N/A	++
C line appearing time:≤1′49″,C line statue:G9. Conclusion:Conformity.								

4.2 Accelerated stability

0 Day Result

Reference panel		LOT	LOT1		LOT2		LOT3	
			T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
Negative Reference panel	N1	202002087	—	—	—	—	—	—
	N2	202002087	—	—	—	—	—	—
	N3	202002087	—	—	—	—	—	—
	N4	202002087	—	—	—	—	—	—
	N5	202002087	—	—	—	—	—	—
	N6	202002087	—	—	—	—	—	—
	N7	202002087	—	—	—	—	—	—
	N8	202002087	—	—	—	—	—	—
	N9	202002087	—	—	—	—	—	—
	N10	202002087	—	—	—	—	—	—

Reference panel		LOT	LOT1		LOT2		LOT3	
			T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
	N11	202002087	—	—	—	—	—	—
	N12	202002087	—	—	—	—	—	—
	N13	202002087	—	—	—	—	—	—
	N14	202002087	—	—	—	—	—	—
	N15	202002087	—	—	—	—	—	—
	N16	202002087	—	—	—	—	—	—
	N17	202002087	—	—	—	—	—	—
	N18	202002087	—	—	—	—	—	—
	N19	202002087	—	—	—	—	—	—
	N20	202002087	—	—	—	—	—	—
Positive Reference panel								
	L1	202003001	+	N/A	+	N/A	+	N/A
	L2	202003001	+	N/A	+	N/A	+	N/A
	L3	202003001	N/A	+	N/A	+	N/A	+
	L4	202003001	N/A	+	N/A	+	N/A	+
	M1	202003001	++	N/A	++	N/A	++	N/A
	M2	202003001	++	N/A	++	N/A	++	N/A
	M3	202003001	N/A	++	N/A	++	N/A	++
	M4	202003001	N/A	++	N/A	++	N/A	++
C line appearing line:≤1′49″,C line statue:G9. Conclusion:Conformity.								

55℃ Stability Result

Time point	Reference panel	LOT	LOT1		LOT2		LOT3	
			T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
9 day	N1	202002087	—	—	—	—	—	—
	L1	202003001	+	N/A	+	N/A	+	N/A
	L3	202003001	N/A	+	N/A	+	N/A	+
C line appearing line≤1′38″,C line statue:G9. Conclusion:Conformity.								

Time point	Reference panel	LOT	LOT1		LOT2		LOT3	
			T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
16 day	N1	202002087	—	—	—	—	—	—
	L1	202003001	+	N/A	+	N/A	+	N/A
	L3	202003001	N/A	+	N/A	+	N/A	+
C line appearing line≤1′36″,C line statue:G9. Conclusion:Conformity.								

Time point	Reference panel	LOT	LOT1		LOT2		LOT3	
			T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
24 day	N1	202002087	—	—	—	—	—	—
	L1	202003001	+	N/A	+	N/A	+	N/A
	L3	202003001	N/A	+	N/A	+	N/A	+
C line appearing line≤1′40″,C line statue:G9. Conclusion:Conformity.								

Time point	Reference panel	LOT	LOT1		LOT2		LOT3	
			T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
31 day	N1	202002087	—	—	—	—	—	—
	L1	202003001	+	N/A	+	N/A	+	N/A
	L3	202003001	N/A	+	N/A	+	N/A	+
C line appearing line≤1′40″,C line statue:G9. Conclusion:Conformity.								

5. Conclusion

The novel coronavirus is a newly discovered virus. The company began research and development in early February 2020.Based on the market demand of the product, it is urgently needed to be listed, but due to the short time, long-term stability is not sufficient to support product stability.

But according to the acceleration stability, the product can support the validity period of 24 months, so this product meets the market demand based on the acceleration stability result of the product.

Study on the specimen variety of COVID-19 IgG/IgM Products

1.0 Study purposes

Verify the consistency of test results of different types of samples

2.0 Material

Test in vitro diagnostic reagents

Name: COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)

Specification:25 tests/kit

LOT:NO1G01T, NO1G02T, NO1G03T

Expiry: August,2020

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 Realytech Co.,Ltd

3.0 Sample collection, processing and storage

3.1 Sample collection:

Select 10 COVID-19 positive patients and 10 COVID-19 negative patients, separately collect blood veins with blood collection tubes containing EDTA anticoagulant and no anticoagulant, and place them at room temperature to naturally precipitate serum and plasma

3.2 Sample processing

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.

4.0 Experiment method

4.1 I**nstructions for use**

Directions for use and interpretation of results according to the package insert.

4.2 **Experimental procedures**

4.2.1 Use different batches of test device to test the whole blood specimens in the two kinds of blood collection tubes, and record the test results at the specified time.

4.2.2 After placing the two specimens for 1h, take the supernatant specimens, use different batches of testing reagents to test, and record the test results at the specified time.

5.0 Results of experiment data

Data of experiment results

Lot 1

NO.	Clinical diagnostics	Whole blood (EDTA)	Whole blood	Serum	plasma
1	Neg	Neg	Neg	Neg	Neg
2	Neg	Neg	Neg	Neg	Neg
3	Neg	Neg	Neg	Neg	Neg
4	Neg	Neg	Neg	Neg	Neg
5	Neg	Neg	Neg	Neg	Neg
6	Neg	Neg	Neg	Neg	Neg
7	Neg	Neg	Neg	Neg	Neg
8	Neg	Neg	Neg	Neg	Neg
9	Neg	Neg	Neg	Neg	Neg
10	Neg	Neg	Neg	Neg	Neg
11	Pos	Pos	Pos	Pos	Pos
12	Pos	Pos	Pos	Pos	Pos
13	Pos	Pos	Pos	Pos	Pos
14	Pos	Pos	Pos	Pos	Pos
15	Pos	Pos	Pos	Pos	Pos
16	Pos	Pos	Pos	Pos	Pos
17	Pos	Pos	Pos	Pos	Pos
18	Pos	Pos	Pos	Pos	Pos
19	Pos	Pos	Pos	Pos	Pos
20	Pos	Pos	Pos	Pos	Pos

Lot 2

NO.	Clinical diagnostics	Whole blood (EDTA)	Whole blood	Serum	plasma
1	Neg	Neg	Neg	Neg	Neg
2	Neg	Neg	Neg	Neg	Neg
3	Neg	Neg	Neg	Neg	Neg
4	Neg	Neg	Neg	Neg	Neg
5	Neg	Neg	Neg	Neg	Neg
6	Neg	Neg	Neg	Neg	Neg
7	Neg	Neg	Neg	Neg	Neg
8	Neg	Neg	Neg	Neg	Neg
9	Neg	Neg	Neg	Neg	Neg
10	Neg	Neg	Neg	Neg	Neg
11	Pos	Pos	Pos	Pos	Pos
12	Pos	Pos	Pos	Pos	Pos
13	Pos	Pos	Pos	Pos	Pos
14	Pos	Pos	Pos	Pos	Pos

15	Pos	Pos	Pos	Pos	Pos
16	Pos	Pos	Pos	Pos	Pos
17	Pos	Pos	Pos	Pos	Pos
18	Pos	Pos	Pos	Pos	Pos
19	Pos	Pos	Pos	Pos	Pos
20	Pos	Pos	Pos	Pos	Pos

Lot 3

NO.	Clinical diagnostics	Whole blood (EDTA)	Whole blood	Serum	plasma
1	Neg	Neg	Neg	Neg	Neg
2	Neg	Neg	Neg	Neg	Neg
3	Neg	Neg	Neg	Neg	Neg
4	Neg	Neg	Neg	Neg	Neg
5	Neg	Neg	Neg	Neg	Neg
6	Neg	Neg	Neg	Neg	Neg
7	Neg	Neg	Neg	Neg	Neg
8	Neg	Neg	Neg	Neg	Neg
9	Neg	Neg	Neg	Neg	Neg
10	Neg	Neg	Neg	Neg	Neg
11	Pos	Pos	Pos	Pos	Pos
12	Pos	Pos	Pos	Pos	Pos
13	Pos	Pos	Pos	Pos	Pos
14	Pos	Pos	Pos	Pos	Pos
15	Pos	Pos	Pos	Pos	Pos
16	Pos	Pos	Pos	Pos	Pos
17	Pos	Pos	Pos	Pos	Pos
18	Pos	Pos	Pos	Pos	Pos
19	Pos	Pos	Pos	Pos	Pos
20	Pos	Pos	Pos	Pos	Pos

6.0 Conclusion

The above results show that for the same patient, collecting different specimen types does not affect the test results of this reagent. This test kit is suitable for human whole blood, serum and plasma samples.

Study Report of Storage and stability of specimens for COVID-19 IgG/IgM test device

1.0 Study purposes

Verify the Storage and stability of specimens of whole blood, serum, plasma for COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)

2.0 Material

2.1 Test in vitro diagnostic reagents

Name: COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)

Specification:25 tests/kit

LOT: NO1G01T; NO1G02T; NO1G03T

Expiry: August,2020(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

2.2 Specimen

COVID-19 positive serum specimen 10 pcs

COVID-19 positive plasma specimen 10 pcs

COVID-19 negative serum specimen 10 pcs

COVID-19 negative plasma specimen 10 pcs

3.0 Experiment method

3.1 Instructions for use

Directions for use and interpretation of results according to the package insert.

3.2 Specimen prepare

Separate each standard product according to the following table, and then put it into the corresponding storage environment to save;

Specimen	Room temperature	2 to 8 ℃	-20℃
NO#	2*20ul	3*20ul	5*20ul

3.3 Test procedure

Refer to the table below, take out the specimen at the specified time, leave it at room temperature for 30 minutes, and then test the corresponding specimen according to the package insert.

	1 point	2 point	3 point	4 point	5 point
Room temperature	1 hour	2th hour	N/A	N/A	N/A
2 to 8 ℃	1day	2th day	3th day	N/A	N/A
-20℃	3th day	7th day	14th day	21th day	28th day

4.0 Results of experiment data

Data of experiment results

Serum positive-1

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	+	+	+	+	+	+
1 hour	+	+	+	+	+	+
2th hour	+	+	+	+	+	+
1day	+	+	+	+	+	+
2th day	+	+	+	+	+	+
3th day	+	+	+	+	+	+
3th day	+	+	+	+	+	+
7th day	+	+	+	+	+	+
14th day	+	+	+	+	+	+
21th day	+	+	+	+	+	+
28th day	+	+	+	+	+	+

Serum positive-2

product	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)		
	LOT1	LOT2	LOT3

	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	+	-	+	-	+	-
1 hour	+	-	+	-	+	-
2th hour	+	-	+	-	+	-
1day	+	-	+	-	+	-
2th day	+	-	+	-	+	-
3th day	+	-	+	-	+	-
3th day	+	-	+	-	+	-
7th day	+	-	+	-	+	-
14th day	+	-	+	-	+	-
21th day	+	-	+	-	+	-
28th day	+	-	+	-	+	-

Serum positive-3

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	+	+	+	+	+	+
1 hour	+	+	+	+	+	+
2th hour	+	+	+	+	+	+
1day	+	+	+	+	+	+
2th day	+	+	+	+	+	+
3th day	+	+	+	+	+	+
3th day	+	+	+	+	+	+
7th day	+	+	+	+	+	+
14th day	+	+	+	+	+	+
21th day	+	+	+	+	+	+
28th day	+	+	+	+	+	+

Serum positive-4

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	+	+	+	+	+	+
1 hour	+	+	+	+	+	+
2th hour	+	+	+	+	+	+

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
1day	+	+	+	+	+	+
2th day	+	+	+	+	+	+
3th day	+	+	+	+	+	+
3th day	+	+	+	+	+	+
7th day	+	+	+	+	+	+
14th day	+	+	+	+	+	+
21th day	+	+	+	+	+	+
28th day	+	+	+	+	+	+

Serum positive-5

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	+	-	+	-	+	-
1 hour	+	-	+	-	+	-
2th hour	+	-	+	-	+	-
1day	+	-	+	-	+	-
2th day	+	-	+	-	+	-
3th day	+	-	+	-	+	-
3th day	+	-	+	-	+	-
7th day	+	-	+	-	+	-
14th day	+	-	+	-	+	-
21th day	+	-	+	-	+	-
28th day	+	-	+	-	+	-

Plasma positive-1

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	+	+	+	+	+	+
1 hour	+	+	+	+	+	+
2th hour	+	+	+	+	+	+
1day	+	+	+	+	+	+

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
2th day	+	+	+	+	+	+
3th day	+	+	+	+	+	+
3th day	+	+	+	+	+	+
7th day	+	+	+	+	+	+
14th day	+	+	+	+	+	+
21th day	+	+	+	+	+	+
28th day	+	+	+	+	+	+

Plasma positive-2

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	+	+	+	+	+	+
1 hour	+	+	+	+	+	+
2th hour	+	+	+	+	+	+
1day	+	+	+	+	+	+
2th day	+	+	+	+	+	+
3th day	+	+	+	+	+	+
3th day	+	+	+	+	+	+
7th day	+	+	+	+	+	+
14th day	+	+	+	+	+	+
21th day	+	+	+	+	+	+
28th day	+	+	+	+	+	+

Plasma positive-3

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	+	+	+	+	+	+
1 hour	+	+	+	+	+	+
2th hour	+	+	+	+	+	+
1day	+	+	+	+	+	+
2th day	+	+	+	+	+	+

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
3th day	+	+	+	+	+	+
3th day	+	+	+	+	+	+
7th day	+	+	+	+	+	+
14th day	+	+	+	+	+	+
21th day	+	+	+	+	+	+
28th day	+	+	+	+	+	+

Plasma positive-4

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	+	-	+	-	+	-
1 hour	+	-	+	-	+	-
2th hour	+	-	+	-	+	-
1day	+	-	+	-	+	-
2th day	+	-	+	-	+	-
3th day	+	-	+	-	+	-
3th day	+	-	+	-	+	-
7th day	+	-	+	-	+	-
14th day	+	-	+	-	+	-
21th day	+	-	+	-	+	-
28th day	+	-	+	-	+	-

Plasma positive-5

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	+	+	+	+	+	+
1 hour	+	+	+	+	+	+
2th hour	+	+	+	+	+	+
1day	+	+	+	+	+	+
2th day	+	+	+	+	+	+
3th day	+	+	+	+	+	+

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
3th day	+	+	+	+	+	+
7th day	+	+	+	+	+	+
14th day	+	+	+	+	+	+
21th day	+	+	+	+	+	+
28th day	+	+	+	+	+	+

Serum negative-1

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	-	-	-	-	-	-
1 hour	-	-	-	-	-	-
2th hour	-	-	-	-	-	-
1day	-	-	-	-	-	-
2th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
7th day	-	-	-	-	-	-
14th day	-	-	-	-	-	-
21th day	-	-	-	-	-	-
28th day	-	-	-	-	-	-

Serum negative -2

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	-	-	-	-	-	-
1 hour	-	-	-	-	-	-
2th hour	-	-	-	-	-	-
1day	-	-	-	-	-	-
2th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
7th day	-	-	-	-	-	-
14th day	-	-	-	-	-	-
21th day	-	-	-	-	-	-
28th day	-	-	-	-	-	-

Serum negative -3

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	-	-	-	-	-	-
1 hour	-	-	-	-	-	-
2th hour	-	-	-	-	-	-
1day	-	-	-	-	-	-
2th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
7th day	-	-	-	-	-	-
14th day	-	-	-	-	-	-
21th day	-	-	-	-	-	-
28th day	-	-	-	-	-	-

Serum negative -4

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	-	-	-	-	-	-
1 hour	-	-	-	-	-	-
2th hour	-	-	-	-	-	-
1day	-	-	-	-	-	-
2th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
7th day	-	-	-	-	-	-

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
14th day	-	-	-	-	-	-
21th day	-	-	-	-	-	-
28th day	-	-	-	-	-	-

Serum negative -5

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	-	-	-	-	-	-
1 hour	-	-	-	-	-	-
2th hour	-	-	-	-	-	-
1day	-	-	-	-	-	-
2th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
7th day	-	-	-	-	-	-
14th day	-	-	-	-	-	-
21th day	-	-	-	-	-	-
28th day	-	-	-	-	-	-

Plasma negative -1

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	-	-	-	-	-	-
1 hour	-	-	-	-	-	-
2th hour	-	-	-	-	-	-
1day	-	-	-	-	-	-
2th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
7th day	-	-	-	-	-	-
14th day	-	-	-	-	-	-

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
21th day	-	-	-	-	-	-
28th day	-	-	-	-	-	-

Plasma negative -2

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	-	-	-	-	-	-
1 hour	-	-	-	-	-	-
2th hour	-	-	-	-	-	-
1day	-	-	-	-	-	-
2th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
7th day	-	-	-	-	-	-
14th day	-	-	-	-	-	-
21th day	-	-	-	-	-	-
28th day	-	-	-	-	-	-

Plasma negative -3

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	-	-	-	-	-	-
1 hour	-	-	-	-	-	-
2th hour	-	-	-	-	-	-
1day	-	-	-	-	-	-
2th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
7th day	-	-	-	-	-	-
14th day	-	-	-	-	-	-
21th day	-	-	-	-	-	-

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
28th day	-	-	-	-	-	-

Plasma negative -4

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	-	-	-	-	-	-
1 hour	-	-	-	-	-	-
2th hour	-	-	-	-	-	-
1day	-	-	-	-	-	-
2th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
7th day	-	-	-	-	-	-
14th day	-	-	-	-	-	-
21th day	-	-	-	-	-	-
28th day	-	-	-	-	-	-

Plasma negative-5

product / specimen	COVID-19 IgG/IgM Rapid Test Device (Colloidal Gold)					
	LOT1		LOT2		LOT3	
	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)	T1(IgG)	T2(IgM)
0 hour	-	-	-	-	-	-
1 hour	-	-	-	-	-	-
2th hour	-	-	-	-	-	-
1day	-	-	-	-	-	-
2th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
3th day	-	-	-	-	-	-
7th day	-	-	-	-	-	-
14th day	-	-	-	-	-	-
21th day	-	-	-	-	-	-
28th day	-	-	-	-	-	-

5.0 Conclusion

The above results show that the specimen is stable when store at room temperature for 2 hours, at 2 to 8℃ for 3 days and -20℃ for 28 days.

Transport Simulation Stability Study

1. Purpose

Validate the product transport simulation stability.

2. General information

Manufacturer:Hangzhou Realy Tech Co.,Ltd.

Product name:2019-nCOV IgG/IgM/COVID-19 Rapid Test Device

Catalogue number:K460216D

3. Material

Validation lot 1: NO1G01T;

Validation lot 2: NO1G02T;

Negative Control: N1;

Positive Control: 2019-nCOV IgG, PG;

Positive Control: 2019-nCOV IgM, PM.

4. Methods

a. 3XFT: Perform 3 freeze/thaw cycles and at the last thaw ,transfer to the recommended storage temperatures in the insert or designate temperature(generally store at retain room(4-30℃)) for the remainder of the study.(Freeze: keep the goods in refrigerator for 48 hours (at least);Thaw: take the goods from refrigerator and keep it in room temperature at least 8 hours).

b. 2 Days @ 55℃: Place test strips in a 55℃ oven for 2 days and transfer to the recommended storage temperatures in the insert or designate temperature (generally store at retain room(4-30℃))for the remainder of the study.

Following table illustrate the designated time points when the stability test will be performed. (Refer to the document of QP-8001)

Transport simulation	Day			Month						
	0	30**	60**	6*	12*	18*	21*	24*	25*	Expiry date+1 Month
3XFT	X	X	X	X	X	X	X	X	X	X
2 Days @ 55℃	X	X	X	X	X	X	X	X	X	X

- 0 day is the time before the products were taken from the designated challenged environment.
- Test time point date(day)=the date of “0 day” + the time of “**”

- Test time point date(month)=manufacture date + the time of "*"
- Every test point date should be preset.
- Product need to remove from the designed environment and completed the test within a week when a time point reached.
- The test time point of target expiry date must be added in the schedule.

5. Interpretation of results

Positive result:≥G3

Negative result:<G3

Note: *G3* is a color strip of the Standard colorimetric card.

6. QC Acceptance Criteria

The accelerated stability of 45℃ have be stopped because the accelerated stability of 55℃ is qualified in 53 days.

Serum/Plasma specimens:C-line≤3min.

Whole blood specimens:C-line≤5min.

C-line≥G8 in 10min.

Note: *G8* is a color strip of the Standard colorimetric card.

7. Result

3XFT

Validation lot 1:NO1G01T

Time point	Controls	1	2	3	4	5	6	7	8
		IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG
Day 0	PM	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
	PG	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
	N1	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
Day 30	PM	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
	PG	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
	N1	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
Day 60	PM	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
	PG	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
	N1	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
Month 6	PM								
	PG								
	N1								

Time point	Controls	1	2	3	4	5	6	7	8
		IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG
Month 12	PM								
	PG								
	N1								
Month 18	PM								
	PG								
	N1								
Month 21	PM								
	PG								
	N1								
Month 24	PM								
	PG								
	N1								
Month 25	PM								
	PG								
	N1								

Validation lot 2:NO1G02T

Time point	Controls	1	2	3	4	5	6	7	8
		IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG
Day 0	PM	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
	PG	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
	N1	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
Day 30	PM	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
	PG	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
	N1	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
Day 60	PM	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
	PG	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
	N1	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
Month 6	PM								
	PG								

Time point	Controls	1	2	3	4	5	6	7	8
		IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG
	N1								
Month 12	PM								
	PG								
	N1								
Month 18	PM								
	PG								
	N1								
Month 21	PM								
	PG								
	N1								
Month 24	PM								
	PG								
	N1								
Month 25	PM								
	PG								
	N1								

2 Days @ 55℃

Validation lot 1:NO1G01T

Time point	Controls	1	2	3	4	5	6	7	8
		IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG
Day 0	PM	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
	PG	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
	N1	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
Day 30	PM	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
	PG	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
	N1	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
Day 60	PM	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
	PG	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
	N1	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

Time point	Controls	1	2	3	4	5	6	7	8
		IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG
Month 6	PM								
	PG								
	N1								
Month 12	PM								
	PG								
	N1								
Month 18	PM								
	PG								
	N1								
Month 21	PM								
	PG								
	N1								
Month 24	PM								
	PG								
	N1								
Month 25	PM								
	PG								
	N1								

Validation lot 2:NO1G02T

Time point	Con trols	1	2	3	4	5	6	7	8
		IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG
Day 0	PM	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
	PG	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
	N1	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
Day 30	PM	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
	PG	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+
	N1	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
Day 60	PM	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
	PG	-/+	-/+	-/+	-/+	-/+	-/+	-/+	-/+

Time point	Controls	1	2	3	4	5	6	7	8
		IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG	IgM/IgG
	N1	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
Month 6	PM								
	PG								
	N1								
Month 12	PM								
	PG								
	N1								
Month 18	PM								
	PG								
	N1								
Month 21	PM								
	PG								
	N1								
Month 24	PM								
	PG								
	N1								
Month 25	PM								
	PG								
	N1								

8. Conclusion

We will conduct the study according to the above plan.

REGULATORY & QUALITY

Applicable Standards

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2016-12-15)
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN 375:2001	Information supplied by the manufacturer with in vitro diagnostic reagents for professional use
EN ISO 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 17511:2003	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials (ISO 17511:2003)
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)

EC Declaration of Conformity

in accordance with Directive 98/79/EC

Manufacturer:

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

Product/s	*Catalogue number*
2019-nCOV IgG/IgM Rapid Test Device	K460216D

Category: Other Devices (All devices except Annex II and self-testing devices)

Conformity assessment route: Annex III,except Point 6,of Directive

Applicable Standards:EN ISO 13485:2016;EN ISO 15223-1:2016; EN ISO 14971:2012 ;EN ISO 13612:2002;EN ISO 17511:2003; EN ISO 18113-1:2011;EN ISO 18113-2:2011,EN ISO 23640:2015.

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Luxus Lebenswelt GmbH,located at Kochstr. 1, 47877, Willich, Germany to act as our European Authorised Representative as defined in the aforementioned Directive.

Hangzhou 2020.3.17

(Place and date of issue)

(Signature and position)
Signed for and on behalf of the manufacturer

Annex 1:Package Insert

COVID-19 IgG/IgM Rapid Test Device

Package Insert

For the qualitative assessment of New Coronavirus (COVID-19) IgG/IgM in human serum/plasma/whole blood.

For professional In Vitro Diagnostic Use Only

INTENDED USE

The COVID-19 IgG/IgM Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of IgG&IgM antibody of New Coronavirus in human whole blood,serum,or plasma as an aid in the diagnosis of COVID-19 infections.

SUMMARY

Coronavirus (CoV) belongs to the genus Nestovirus, Coronaviridae, 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.

So far, there are 7 types of human coronavirus (HCoV) that cause human respiratory diseases: HCoV-229E,HCoV-OC43,SARS-CoV,HCoV-NL63,HCoV-HKU1,MERS-CoV and new coronaviruses (2019) , Is an important pathogen of human respiratory infections. Among them, the new coronavirus (2019) was discovered due to Wuhan virus pneumonia cases in 2019. The clinical manifestations are systemic symptoms such as fever and fatigue, accompanied by dry cough and dyspnea, etc., which can rapidly develop into severe pneumonia, respiratory failure, and acute breathing. Distress syndrome, septic shock, multiple organ failure, severe acid-base metabolism disorders, etc. are even life-threatening.

PRINCIPLE

This kit uses immunochromatography.The test card contains:1) colloidal gold-labeled recombinant new coronavirus antigen and quality control antibody gold markers;2) two detection lines (G and M lines) and one quality Control line (C line) of nitrocellulose membrane. The M line is immobilized with a monoclonal anti-human IgM antibody for detecting a new coronavirus IgM antibody; the G line is immobilized with a reagent for detecting a new coronavirus IgG 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 an IgM antibody, the antibody will bind to the colloidal gold-labeled new coronavirus antigen. The immune complex will be captured by the anti-human IgM antibody immobilized on the membrane to form a purple-red M line,showing that the new coronavirus IgM antibody is positive.

If the sample contains an IgG antibody, the antibody will bind to the colloidal gold-labeled new coronavirus antigen,and the immune complex will be captured by the reagent immobilized on the membrane to form a purple-red G line, indicating that the new coronavirus IgG antibody is positive.

If the test lines G and M are not colored,a negative result is displayed.The test card also

contains a quality control line C.The fuchsia quality control line C should appear regardless of whether a test line appears.The quality control line is a color band of the quality control antibody immune complex. 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.

REAGENTS

The test contains COVID-19 virus envelope protein particles and anti-human IgG,anti-human IgM antibody conjugated gold particles coated on the membrane.

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.

STORAGE AND STABILITY

- The original packaging should be stored at 4~ 30℃, to avoid light, keep dry.
- The test device is stable through the expiration date printed on the sealed pouch.The test device must remain in the sealed pouch until use.**DO NOT FREEZE.**
- Do not use beyond the expiration date, especially at temperatures above 30℃ or under high humidity conditions, should be used immediately once it is opened.

SPECIMEN COLLECTION AND PREPARATION

1. The COVID-19 IgG/IgM 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.

MATERIALS

Materials provided

Test Devices	Buffer
5μL Disposable plastic pipette	Package insert

Materials required but not provided

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

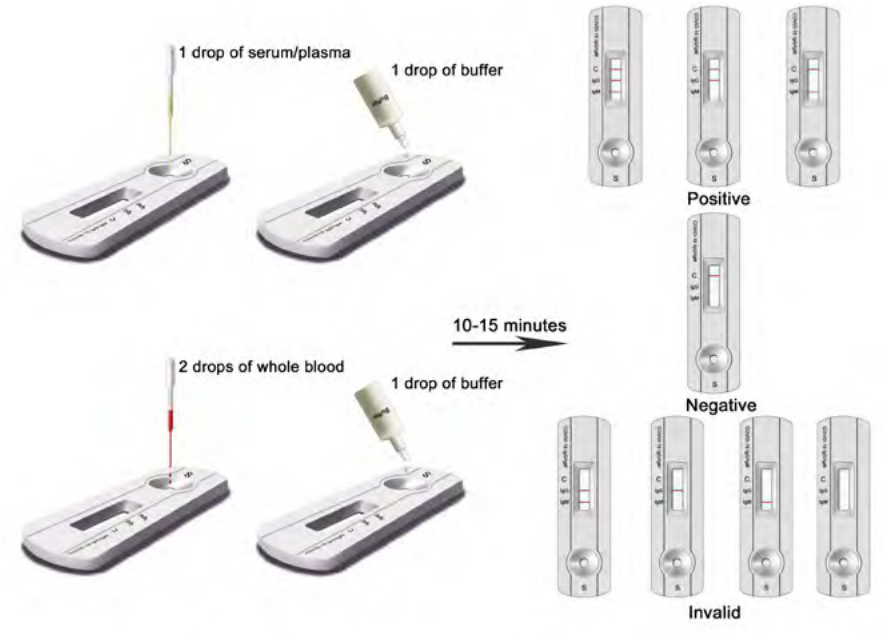
DIRECTIONS FOR USE

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 5μL disposable pipette,and transfer 1 drop 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 5μL disposable pipette**,and **transfer 2 drops of whole blood (approximately 20μL)** 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

IgG POSITIVE:*The colored line in the control line region (C) appears and a colored line appears in test line region IgG. The result is positive for COVID-19-IgG antibodies.

IgM POSITIVE:*The colored line in the control line region (C) appears and a colored line appears in test line region IgM. The result is positive for COVID-19-IgM antibodies and is indicative of primary COVID-19 infection.

IgG AND IgM POSITIVE:*The colored line in the control line region (C) appears and two-colored lines should appear in test line regions IgG and IgM. The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies.

***NOTE:** The intensity of the color in the test line region(s) IgG and/or IgM will vary depending on the concentration of COVID-19 antibodies in the specimen. Therefore, any shade of color in the test line region(s) IgG and/or IgM should be considered positive.

NEGATIVE: The colored line in the control line region (C) appears. No line appears in test line regions IgG or IgM.

INVALID: There is no line appear 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.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The COVID-19 IgG/IgM Rapid Test Device has been compared to a leading commercial RT-PCR testing using clinical specimens.The results show that the COVID-19 IgG/IgM Rapid Test Device has a high sensitivity and specificity.

For IgG testing:

Method		COVID-19 IgG Antibody Test Kit(CMIA)		Total Results
COVID-19 IgG Rapid Test Device	Results	Positive	Negative	
	Positive	99	0	99
	Negative	1	100	101
Total Results		100	100	200

Clinical sensitivity = 99/100*100%=99%

Clinical specificity = 100/100*100%= 100%

Accuracy: (99+100)/(99+1+100)*100%=99.5%

For IgM testing:

Method		COVID-19 IgM Antibody Test Kit(CMIA)		Total Results
COVID-19 IgM Rapid Test Device	Results	Positive	Negative	
	Positive	98	1	99
	Negative	2	99	101
Total Results		100	100	200

Clinical sensitivity = 98/100*100%=98%

Clinical specificity = 99/100*100%= 99%

Accuracy: (98+99)/(98+2+1+99)*100%=98.5%

Cross-reactivity

The COVID-19 IgG/IgM Rapid Test Device has been tested for anti-influenza A virus,anti-influenza B virus,anti-RSV,anti-Adenovirus,HBsAg,anti-Syphilis,anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the COVID-19 IgG/IgM Rapid Test Device and no interference was observed.

Triglyceride: 100 mg/dL Ascorbic Acid:20mg/dl Hemoglobin 1000mg/dL

Bilirubin: 100mg/dL Total cholesterol: 6mmol/L

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
REF	Catalogue number	Σ	The number of test

HANGZHOU REALY TECH CO., LTD.
4th Floor,#12 Building,Eastern Medicine Town,
Xiasha Economic&TechnologyDevelopment,
310018Hangzhou,Zhejiang,P.R.China

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

CE

Number:1101271601
Version:1.0
Effective Date:

Essential Requirements

according to Directive 98/79/EC ANNEX I,on in vitro diagnostic medical devices

2019-nCOV IgG/IgM Rapid Test Device

Drafted by: Zhang Yanyan

Reviewed by: Liu Gang

Approved by: Ding Pengfei

Version: 2.0

Hangzhou Realy Tech Co., Ltd.

2020.4.28

Essential Requirements acc. to Annex I of the IVDD (98/79/EC)		A/NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature	OK/Fail
A.	***GENERAL REQUIREMENTS***				
1.	The device must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise, directly or indirectly, the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, or the safety of property. Any risks which may be associated with their use must be acceptable when weighed against the benefits to the patient and be compatible with a high level of protection of health and safety.	A	EN ISO 13485:2016 EN ISO 14971:2012	Risk Management Report	OK
2.	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: - eliminate or reduce risks as far as possible (inherently safe design and construction) - where appropriate take adequate protection measures including alarms if necessary, in relation to risks that can not be eliminated. - inform users of the residual risks due to shortcomings of the protection measures adopted.	A	EN ISO 13485:2016 EN ISO 14971:2012	Risk Management Report	OK

3.	The devices must be designed and manufactured in such a way that they are suitable for the purposes referred to in Article 1(2)(b), as specified by the manufacturer, taking account of the generally acknowledged state of the art. They must achieve the performances, in particular, where appropriate, in terms of analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility, including control of known relevant interference, and limits of detection, stated by the manufacturer. The traceability of values assigned to calibrators and/or control materials must be assured through available reference measurement procedures and/or available reference materials of a higher order.	A	EN 13612:2002 EN ISO 17511:2003	Performance test report Traceabliity files	OK
4.	The characteristics and performance referred to in sections 1 and 3 must not be adversely affected to such a degree that the health or the safety of the patients or the user and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer,when the device is subjected to the stresses which can occur during normal conditions of use. When no lifetime is stated, the same applies for the lifetime reasonably to be expected of a device of that kind, having regard to the intended purpose and the anticipated use of the device.	A	EN ISO 23640:2015	Stability test report	OK
5.	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage (temperature, humidity, etc.) taking into account the instructions and information provided by the manufacturer.	A	EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 23640:2015 EN ISO 18113-2:2011 EN ISO 15223-1:2016	Risk Management Report Labelling Stability test report	OK

B.	***DESIGN AND MANUFACTURING REQUIREMENTS***				
1. 1.1	**Chemical and Physical** The devices must be designed and manufactured in such a way as to achieve the characteristics and performances referred to in Section A on the "General Requirements". Particular attention must be paid to the possibility of impairment of analytical performance due to incompatibility between the materials and the specimens (such as biological tissues, cells, body fluids and micro-organisms) intended to be used with the device, taking account of its intended purpose.	NA	/	Our product does not directly contact with the patients.	/
1.2	The devices must be designed, manufactured and packed in such a way as to reduce as far as possible the risk posed by product leakage, contaminants and residues to the persons involved in the transport, storage and use of the devices, taking account of the intended purpose of the product.	A	EN ISO 14971:2012 EN ISO 13485:2016	Risk Management Report Labelling MSDS	/
2. 2.1	**Infection and microbial contamination** The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or other persons. The design must allow easy handling and, where necessary, reduce as far as possible contamination of, and leakage from, the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen. The manufacturing processes must be appropriate for these purposes.	A	EN ISO 14971:2012 EN ISO 18113-2:2011 EN ISO 15223-1:2016	Risk Management Report Labelling	OK
2.2	Where a device incorporates biological substances, the risks of infection must be reduced as far as possible by selecting appropriate donors and appropriate substances	NA	/	Our product does not	

	and by using appropriate validated inactivation, conservation, test and control procedures.			incorporates biological substances.	/
2.3	Devices labellingled either as 'STERILE' or as having a special microbiological state must be designed, manufactured and packed in an appropriate pack, according to procedures suitable for ensuring that they remain in the appropriate microbiological state indicated on the labelling when placed on the market, under the storage and transport conditions specified by the manufacturer, until the protective packaging is damaged or opened.	NA	/	Our product is not either for 'STERILE' or having a special microbiological state.	/
2.4	Devices labellingled either as 'STERILE' or as having a special microbiological state must have been processed by an appropriate, validated method.	NA	/	Our product is not either for 'STERILE' or having a special microbiological state.	/
2.5	Packaging systems for devices other than those referred to in section 2.3 must keep the product without deterioration at the level of cleanliness indicated by the manufacturer and, if the devices are to be sterilised prior to use, reduce as far as possible the risk of microbial contamination. Steps must be taken to reduce as far as possible microbial contamination during selection and handling of raw materials, manufacture, storage and distribution where the performance of the device can be adversely affected by such contamination.	NA	/	Our product is not applicable.	/
2.6	Devices intended to be sterilized, must be manufactured in appropriately controlled (e.g. environmental) conditions.	NA	/	Our product is not for sterile.	/
2.7	Packaging systems for non-sterile devices must keep the product without deterioration in the level of cleanliness stipulated and, if the devices are to be sterilized prior to use,	NA	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK

	minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.				
3 3.1	**Manufacturing and environmental properties** If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on the use must be indicated on the labelling or in the instructions for use.	NA	/	Our product is not for use in combination with other device or equipment.	/
3.2	Devices must be designed and manufactured in such a way as to reduce as far as possible the risks linked to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use	A	EN ISO 14971:2012	Risk Management Report	OK
3.3	Devices must be designed and manufactured in such a way as to remove or reduce as far as possible: - the risk of injury linked to their physical features (in particular aspects of volume x pressure, dimension and, where appropriate, ergonomic features), - risks linked to reasonably foreseeable external influences, such as magnetic fields, external electrical effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure or acceleration or accidental penetration of substances into the device. Devices must be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity of electromagnetic disturbance to enable them to operate as intended.	A	EN ISO 14971:2012	Risk Management Report	OK

3.4	Devices must be designed and manufactured in such a way as to reduce as far as possible the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.	A	EN ISO 14971:2012	Risk Management Report	OK
3.5	Devices must be designed and manufactured in such a way as to facilitate the management of safe waste disposal.	A	EN ISO 14971:2012 EN ISO 18113-2:2011 EN ISO 15223-1:2016	Risk Management Report Package Insert	OK
3.6	The measuring, monitoring or display scale (including colour change and other visual indicators) must be designed and manufactured in line with ergonomic principles, taking account of the intended purpose of the device.	A	EN ISO 14971:2012 EN ISO 18113-2:2011 EN ISO 15223-1:2016	Risk Management Report Package Insert	OK
4 4.1	**Devices which are instruments or apparatus with measuring function** Devices which are instruments or apparatus having a primary analytical measuring function must be designed and manufactured in such a way as to provide adequate stability and accuracy of measurement within appropriate accuracy limits, taking into account the intended purpose of the device and of available and appropriate reference measurement procedures and materials. The accuracy limits have to be specified by the manufacturer.	NA	/	Our products has no measuring function.	/
4.2	When values are expressed numerically, they must be given in legal units conforming to the provisions of Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement.	NA	/	Our products has no measuring function.	/

5 5.1	**Protection against radiation** Devices shall be designed, manufactured and packaged in such a way that exposure of users and other persons to the emitted radiation is minimised.	NA	/	Our product is not effected by radiation.	/
5.2	When devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must as far as possible be: --designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted, --fitted with visual displays and/or audible warnings of such emissions.	NA	/	Our product is not effected by radiation.	/
5.3	The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the user, and on ways of avoiding misuse and of eliminating the risks inherent in installation.	NA	/	Our product is not effected by radiation.	/
6 6.1	**Requirements for medical devices connected to or equipped with an energy source** Devices incorporating electronic programmable systems, including software, must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use.	NA	/	Our product is not connected to or equipped with an energy source.	/
6.2	Devices must be designed and manufactured in such a way as to minimise the risks of creating electromagnetic perturbation which could impair the operation of other devices or equipment in the usual environment.	NA	/	Our product is not connected to or equipped with an energy source.	/
6.3	Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed and maintained correctly.	NA	/	Our product is not connected to or equipped with an	/

				energy source.	
6.4 6.4.1	***Protection against mechanical and thermal risks*** Devices must be designed and manufactured in such a way as to protect the user against mechanical risks. Devices must be sufficiently stable under the foreseen operating conditions. They must be suitable to withstand stresses inherent in the foreseen working environment, and to retain this resistance during the expected life of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer. Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means must be incorporated. Any guards or other means included with the device to provide protection, in particular against moving parts, must be secure and must not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.	NA	/	Our product is not applicable.	/
6.4.2	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	NA	/	Our product do not generate vibration.	/
6.4.3	Devices must be designed and manufactured in such a way as to reduce as far as possible the risks arising from the noise emitted, taking account of technical progress	NA	/	Our product is not applicable.	/

	and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.				
6.4.4	Terminals and connectors to electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and manufactured in such a way as to minimise all possible risks.	NA	/	Our product is not applicable.	/
6.4.5	Accessible parts of the devices (excluding the parts of areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	NA	/	Our product is not applicable.	/
7	**Requirements for devices for self-testing** Devices for self-testing must be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in users? technique and environment. The information and instructions provided by the manufacturer should be easily understood and applied by the user.	NA	/	Our product is not for self-testing.	/
7.1	Devices for self-testing must be designed and manufactured in such a way as to: - ensure that the device is easy to use by the intended lay user at all stages of the procedure, and - reduce as far as practicable the risk of user error in the handling of the device and in the interpretation of the results.	NA	/	Our product is not for self-testing.	/
7.2	Devices for self-testing must, where reasonably possible, include user control, i.e. a	NA	/	Our product is not for	

	procedure by which the user can verify that, at the time of use, the product will perform as intended.			self-testing.	/
8 8.1	**<u>Information supplied by the manufacturer</u>** Each device must be accompanying by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the data on the labelling and in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely and properly must be set out on the device itself and/or, where appropriate, on the sales packaging. If individual full labellingling of each unit is not practicable, the information must be set out on the packaging and/or in the instructions for use supplied with one or more devices. Instructions for use must accompany or be included in the packaging of one or more devices. In duly justified and exceptional cases no such instructions for use are needed for a device if it can be used properly and safely without them.	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 14971:2012	Labelling Risk Management Report	OK
8.2	Where appropriate, the information to be supplied should take the form of symbols. Any symbol and identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colour used must be described in the documentation supplied with the device.	A	EN ISO 18113-2:2011 EN ISO 15223-1: 2012	Labelling	OK
8.3	In the case of devices containing or a preparation which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form	A	EN ISO 14971:2012	Risk Management Report	OK

	under which they are present, relevant danger symbols and labelling requirements of Directive 67/548/EEC and Directive 88/379/EEC shall apply. Where there is insufficient space to put all the information on the device itself or on its labelling, the relevant danger symbols shall be put on the labelling and the other information required by those Directives shall be given in the instructions for use. The provisions of the aforementioned Directives on the safety data sheet shall apply, unless all relevant information as appropriate is already made available by the instructions for use.		EN ISO 18113-2:2011	Labelling	
8.4	The labelling must bear the following particulars which may take the form of symbols as appropriate: a) the name or trade name and address of the manufacturer. For devices imported into the Community with a view to their distribution in the Community, the labelling, the outer packaging, or the instructions for use shall contain in addition the name and address of the authorised representative of the manufacturer;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	b) the details strictly necessary for the user to uniquely identify the device and the contents of the packaging;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	c) where appropriate, the word 'STERILE' or a statement indicating any special microbiological state or state of cleanliness;	NA	Our product is not for 'STERILE'		
	d) the batch code, preceded by the word 'LOT' or the serial number;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK

	e) if necessary, an indication of the date by which the device or part of it should be used, in safety, without degradation of performance, expressed as the year, the month and, where relevant, the day, in that order;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	f) in case of devices for performance evaluation, the words ' for performance evaluation only';	NA	/	Not for performance evaluation only product	/
	g) where appropriate, a statement indicating the *in vitro* use of the device;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	h) any particular storage and/or handling conditions;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	i) where applicable, any particular operating instructions;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	j) appropriate warnings and/or precautions to take;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	k) if the device is intended for self-testing, that fact must be clearly stated.	NA	/	Our products is not for self-testing.	/
8.5	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state the intended purpose in the instructions for use and, if appropriate, on the labelling.	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
8.6	Wherever reasonable and practicable, the devices and separate components must be identified, where appropriate in terms of batches, to allow all appropriate action to	A	EN ISO 18113-2:2011	Labelling	OK

	detect any potential risk posed by the devices and detachable components.		EN ISO 15223-1:2016		
8.7	Where appropriate, the instructions for use must contain the following particulars: a) the details referred to in section 8.4 with the exception of points d) and e);	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	b) composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	c) the storage conditions and shelf life following the first opening of the primary container, together with the storage conditions and stability of working reagents;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	d) the performances referred to in section 3 of part A;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	e) an indication of any special equipment required including information necessary for the identification of that special equipment for proper use;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	f) the type of specimen to be used, any special conditions of collection, pre-treatment and, if necessary, storage conditions and instructions for the preparation of the patient;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	g) a detailed description of the procedure to be followed in using the device;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK

	h) the measurement procedure to be followed with the device including as appropriate: - the principle of the method, - the specific analytical performance characteristics (e.g. sensitivity, specificity, accuracy, repeatability, reproducibility, limits of detection and measurement range, including information needed for the control of known relevant interferences), limitations of the method and information about the use of available reference measurement procedures and materials by the user,	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	- the details of any further procedure or handling needed before the device can be used (for example, reconstitution, incubation, dilution, instrument checks, etc.), - the indication whether any particular training is required;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	i) the mathematical approach upon which the calculation of the analytical result is made;	NA	/	The result of our product is judging by the naked eye	/
	j) measures to be taken in the event of changes in the analytical performance of the device;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	k) information appropriate to users on: - internal quality control including specific validation procedures, - the traceability of the calibration of the device;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	l) the reference intervals for the quantities being determined, including a description of the appropriate reference population;	NA	/	Our product is for qualitative detection.	/

	m) if the device must be used in combination with or installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe and proper combination;	NA	/	Our product is not applicable.	/
	n) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely; information about safe waste disposal;	NA	/	Our product is not applicable.	/
	o) details of any further treatment or handling needed before the device can be used (for example, sterilisation, final assembly, etc.);	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	p) the necessary instructions in the event of damage to the protective packaging and details of appropriate methods of resterilisation or decontamination;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	q) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and resterilisation or decontamination, and any restriction on the number of reuses;	NA	/	Our product is for single use.	/
	r) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;	NA	/	Our product is not effected by the situation.	/

	s) precautions to be taken against any special, unusual risks related to the use or disposal of the device including special protective measures; where the device includes substances of human or animal origin, attention must be drawn to their potential infectious nature;	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK
	t) specifications for devices for self-testing: - the results need to be expressed and presented in a way that is readily understood by a lay person; information needs to be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result) and on the possibility of false positive or false negative result, - specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device, - the information provided must include a statement clearly directing that the user should not take any decision of medical relevance without first consulting his or her medical practitioner, - the information must also specify that when the device for self-testing is used for the monitoring of an existing disease, the patient should only adapt the treatment if he has received the appropriate training to do so;	NA	/	Our product is not for self-testing.	/
	u) date of issue or latest reversion of the instructions for use.	A	EN ISO 18113-2:2011 EN ISO 15223-1:2016	Labelling	OK

Material Safety Data Sheet for 2019-nCOV/COVID-19 IgG/IgM Rapid Test Device

File number:MS-0054 Version:A0 Date:2020.04.21

1. Identification of the substance/preparation and of the company/undertaking

Identification of the substance or preparation

Trade name:2019-nCOV/COVID-19 IgG/IgM Rapid Test Device

Use of the substance/preparation: In vitro diagnostic medical device.For professional use only.

Company/undertaking identification:
Hangzhou Realy Tech Co., Ltd.
28# 3rd Baiyang Street,
Hangzhou Economic & Technological Development Area,
Hangzhou, 310018, P. R. China
Tel: + 86-571-56050793
Fax: + 86-571-56050794
Email: info@realytech.com

Further information obtainable from: For further information,contact your local distributor/supplier.

2. Hazards identification

Hazard description:
Preparation not classified as dangerous according to Directive (EC) No.1272/2008.

Classification system:
The classification is according to the latest editions of the EU-lists,and extended by company and literature data.

Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200:
As an article, the device is exempt from OSHA's Hazard Communication Standard 29 CFR 1910.1200.

3. Composition/information on ingredients

Chemical characterization
Description:
In vitro diagnostics medical device.Test strip impregnated with dried chemical/biochemical reagents.

Dangerous components:

Component	CAS No.	EINECS No.	Classification	Concentration
Tris (hydroxymethyl) aminomethane	77-86-1	201-064-4	Xi, R 36/37/38	1-2 %

Additional information:
Each device is packaged in a foil pouch.
For the wording of the listed risk phrases refer to section 16

4. First-aid measures

General Information:
The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip.
After skin contact:
Wash with soap and water and rinse thoroughly.
After eye contact:
Rinse opened eye for several minutes under running water.
After ingestion:
If desiccant or other components are swallowed seek medical attention.

5. Fire-fighting measures

Suitable extinguishing agents:
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire-extinguishing methods suitable to surrounding conditions.
Special hazards caused by the substance, its products of combustion or resulting gases:
In case of fire, the following can be released: Hazardous fumes and vapours, Carbon oxides (CO_x), Nitrogen oxides (NO_x),
Protective equipment:
Wear full protective suit and self-contained respiratory protective device when extinguishing fires.
Additional information:
The device contains combustible materials.

6. Accidental release measures

Person-related safety precautions:
Refer to Section 8 for protective measures when handling the spillage.
Measures for environmental protection:
Avoid release to the environment.
Measures for cleaning/collecting:
Collect material and dispose of as waste according to Section 13.

7. Handling and storage

Information for safe handling:
Keep out of reach of children.
Storage:
Store in the original container at 2-30℃.
Requirements to be met by storerooms and receptacles:
No special requirements.

8. Exposure controls/personal protection

Ingredients with limit values that require monitoring in the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

Additional information:
The lists valid during the creation of this MSDS were used as a basis for this assessment.

Personal protective equipment:
General protective and hygienic measures:
Specimens should be handled as potentially infectious materials. Refer to EU directive 2000/54/EC or US Regulation 29 CFR 1910.1030 for information on handling bio-hazardous materials.
Wash hands before breaks and at the end of work. Clean work areas with hypochlorite or other disinfecting agent.

Respiratory protection:
Required, if there is a risk of splashing or aerosol generation during sample handling
Protection of hands:
Disposable gloves (for sample handling)
Material of gloves: Latex/natural rubber.
Penetration time of glove material: Glove resistance is not critical as the gloves are intended to provide protection against the sample material.
Eye protection:
Safety glasses or face shield, where there is a risk of splashing during sample handling
Body protection:
Lab coat

9. Physical and chemical properties

General Information
Form: The device is an article containing solid components
Appearance: Laminated test strip, which may be housed in a plastic holder.
Odour: Odourless
Flash point: Not applicable.
Self-igniting: Product is not self-igniting.
Danger of explosion: Product does not present an explosion hazard.

10. Stability and reactivity

Stability: The product is stable in accordance with the recommended storage conditions.
Materials to be avoided: None
Hazardous reactions: No dangerous reactions known.
Hazardous decomposition products: No dangerous decomposition products known.

11. Toxicological information

Acute toxicity:
Quantitative data on the toxic effects of this product is not available.

Primary effects:
After skin contact: No irritating effects anticipated.
After eye contact: Contact with the chemicals impregnated in the test strip may cause mild irritation.
Sensitization: No sensitizing effects known.

12. Ecological information

Environmental Toxicity:
Quantitative data on the toxic effects of this product is not available.

Persistence and Degradability:
The device contains plastic and other components that are not readily degradable.

13. Disposal considerations

Product:
Used devices and other contaminated materials should be disposed of as potentially biohazardous waste.
To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

European waste catalogue:
18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.

Packaging:

Disposal must be made in accordance with local waste management regulations.
Non-contaminated packaging materials may be recycled.Contact your local service providers for further information.

14. Transport information

This product is not hazardous when transported by sea,land or air.This substance is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road(ADR)and by Rail(RID),of the International Maritime Dangerous Goods Code(IMDG),and of the International Air Transport Association (IATA) regulations.
Under the IATA Dangerous Goods Regulation Edition 61.

15. Regulatory information

Labelling according to EU guidelines:

Safety data sheet available for professional user on request.

Note:

The preparation is exempt from the above labelling requirements in accordance to Article 12.2 of Directive 99/45/EC as the form in which it is placed on the market does not present any significant risk to man or the environment when used according to the instructions for use.

US Hazard warnings according to 16 CFR 1600 and ANSI Standard Z129.1:

Not required.

Chemical inventory listings relevant to US regulations:

Carcinogen listings

IARC:	None of the ingredients is listed.
NTP:	None of the ingredients is listed.
ACGIH:	None of the ingredients is listed.
OSHA:	None of the ingredients is listed.
EPA	None of the ingredients is listed.

Californian Proposition 65

Chemicals known to cause cancer:	None of the ingredients is listed.
Chemicals known to cause reproductive toxicity:	None of the ingredients is listed.

SARA

Section 355 (extremely hazardous substances):	None of the ingredients is listed.
Section 313 (specific toxic chemical listings):	None of the ingredients is listed.

16. Other information

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Relevant R-phrases

22 Harmful if swallowed.
41 Risk of serious damage to eyes.

1. Identification of the substance/preparation and of the company/undertaking

Identification of the substance or preparation

Trade name: 2019-nCOV IgG/IgM/COVID-19 Rapid Test Device,Buffer

Use of the substance/preparation: In vitro diagnostic medical device.For professional use only.

Company/undertaking identification:
Hangzhou Realy Tech Co., Ltd.
28# 3rd Baiyang Street,
Hangzhou Economic & Technological Development Area,
Hangzhou, 310018, P. R. China
Tel: + 86-571-56050793
Fax: + 86-571-56050794
Email: info@realytech.com

Further information obtainable from: For further information,contact your local distributor/supplier.

2. Hazards identification

Hazard description:
Preparation not classified as dangerous according to Directive (EC) No.1272/2008.

Classification system:
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200:
As an article, the device is exempt from OSHA's Hazard Communication Standard 29 CFR 1910.1200.

3. Composition/information on ingredients

Chemical characterization
Description:
Aqueous preparation containing the hazardous components listed below.

Dangerous components:
None
Additional information:
Each device is packaged in a foil pouch.
For the wording of the listed risk phrases refer to section 16.

4. First-aid measures

General Information:
The following first aid measures are only relevant in the event of serious misuse,whereby the device is disassembled and there is exposure to the chemicals in the test strip.
After skin contact:
Wash with soap and water and rinse thoroughly.
After eye contact:
Rinse opened eye for several minutes under running water.
After ingestion:
Wash out of mouth with water. If desiccant or other components are swallowed seek medical attention.

5. Fire-fighting measures

Suitable extinguishing agents:
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire-extinguishing methods suitable to surrounding conditions.
Special hazards caused by the substance, its products of combustion or resulting gases:
In case of fire, the following can be released: Hazardous fumes and vapours, Carbon oxides (CO_x), Nitrogen oxides (NO_x),
Protective equipment:
Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

6. Accidental release measures

Person-related safety precautions:
Refer to Section 8 for protective measures when handling the spillage.
Measures for environmental protection:
Avoid release to the environment.
Measures for cleaning/collecting:
Collect material and dispose of as waste according to Section 13.

7. Handling and storage

Information for safe handling:
Observe the general safety regulations when handing chemicals.
Avoid contact with the eyes, skin and mucous membranes.
Keep out of reach of children.
Storage:
Store in the original container at 2-30℃.
Requirements to be met by storerooms and receptacles:
No special requirements.

8. Exposure controls/personal protection

Ingredients with limit values that require monitoring in the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

Additional information:
The lists valid during the creation of this MSDS were used as a basis for this assessment.

Personal protective equipment:
General protective and hygienic measures:
Specimens should be handled as potentially infectious materials.Refer to EU directive 2000/54/EC or US Regulation 29 CFR 1910.1030 for information on handling bio-hazardous materials.
Wash hands before breaks and at the end of work. Clean work areas with hypochlorite or other disinfecting agent.
Respiratory protection:
Required, if there is a risk of splashing or aerosol generation during sample handling

Protection of hands:
Disposable gloves (for sample handling)

Material of gloves: Latex/natural rubber.

Penetration time of glove material: Glove resistance is not critical as the gloves are intended to provide protection against the sample material.

Eye protection:
Safety glasses or face shield, where there is a risk of splashing during sample handling

Body protection:
Lab coat

9. Physical and chemical properties

General Information
Form: Liquid
Colour: Colourless
Odour: Odourless
Flash point: Not applicable.
Self-igniting: Product is not self-igniting.
Danger of explosion: Product does not present an explosion hazard.
pH-value at 20℃: 7.4

10. Stability and reactivity

Stability: The product is stable in accordance with the recommended storage conditions.
Materials to be avoided: None
Hazardous reactions: Preparation contains sodium azide, which may react with lead to form explosive compounds. Contact with acids may liberate trace amounts of toxic (azide) gas. Hazardous polymerisation will not occur.
Hazardous decomposition products: No dangerous decomposition products known.

11. Toxicological information

Acute toxicity:
Quantitative data on the toxic effects of this product is not available.

Primary effects:
After skin contact: No irritating effects anticipated.
After eye contact: Contact with the chemicals impregnated in the test strip may cause mild irritation.
Sensitization: No sensitizing effects known.

12. Ecological information

Environmental Toxicity:
Quantitative data on the toxic effects of this product is not available.

Persistence and Degradability:
The product contains plastic and other components that are not readily degradable.

13. Disposal considerations

Product:
Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
To avoid the possible build-up of azide compounds, flush waste-pipes with water after the disposal of undiluted reagent.

European waste catalogue:
18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.

Packaging:
Disposal must be made in accordance with local waste management regulations.

Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

14. Transport information

This product is not hazardous when transported by sea,land or air.This substance is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR)and by Rail (RID),of the International Maritime Dangerous Goods Code(IMDG),and of the International Air Transport Association (IATA) regulations.
Under the IATA Dangerous Goods Regulation Edition 61.

15. Regulatory information

Labelling according to EU guidelines:
Safety data sheet available for professional user on request.

Note:
The preparation is exempt from the above labelling requirements in accordance to Article 12.2 of Directive 99/45/EC as the form in which it is placed on the market does not present any significant risk to man or the environment when used according to the instructions for use.

US Hazard warnings according to 16 CFR 1600 and ANSI Standard Z129.1:
Not required.

Chemical inventory listings relevant to US regulations:

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EPA	None of the ingredients is listed.

Californian Proposition 65

Chemicals known to cause cancer:	None of the ingredients is listed.
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Section 355 (extremely hazardous substances):	None of the ingredients is listed.
Section 313 (specific toxic chemical listings):	None of the ingredients is listed.

16. Other information

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Relevant R-phrases
22 Harmful if swallowed.
41 Risk of serious damage to eyes.

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 094846 0002 Rev. 01

Holder of Certificate: **Hangzhou Realy Tech Co., Ltd.**
4th Floor, #12 Building
Eastern Medicine Town
Xiasha Economic&Technology Development
310018 Hangzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Hangzhou Realy Tech Co., Ltd.
4th Floor, #12 Building, Eastern Medicine Town, Xiasha Economic&Technology Development, 310018 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design, Development, Production and Distribution of POCT Analyzers and Related Diagnostic Kits**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH19105604

Valid from: 2020-03-05
Valid until: 2023-01-23

Date, 2020-03-05

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Supplier Creditability & Capacity Audit Report

Report:			
Supplier Name	Hangzhou Realy Tech Co., Ltd. 杭州睿丽科技有限公司		
Supplier Address	Floor 4, Building 12, Eastern Medicine Town, Xiasha Economic & Technological Development Area, Hangzhou City, Zhejiang Province, China		
Client Information	/		
Name of Assessor	Dick Huang	Reviewed by	Roger Wang
Audited Date	11 May, 2020	Expiry Date	10 May, 2021

Assessment Scope:

Section 1: Company Profile
Section 2: Personnel
Section 3: Main Market
Section 4: Manufacturing Ability
Section 5: Certificate
Section 6: Quality Control Management
Section 7: Development Plan
Section 8: Production Flow Chart
Section 9: Attachment

Comments

Hangzhou Realy Tech Co., Ltd. is a manufacturer with 90 employees; it was established in 2015, located in Floor 4, Building 12, Eastern Medicine Town, Xiasha Economic & Technological Development Area, Hangzhou City, Zhejiang Province, China. The company has passed ISO13485 Certification. The workshops occupy an area of more than 3,200 square meters. The COVID-19 IgG/IgM Rapid Test Device produced from March 2020.

Important Notes:

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Section 1: Company Profile

1.1 Basic Information			
Name of Supplier	Hangzhou Realy Tech Co., Ltd. 杭州睿丽科技有限公司		
Address in License	Room 506, Building 4, No. 600, No. 21 Street, Baiyang Street, Economic & Technological Development Area, Hangzhou City, Zhejiang Province, China		
Audited Address	Floor 4, Building 12, Eastern Medicine Town, Xiasha Economic & Technological Development Area, Hangzhou City, Zhejiang Province, China		
Main Product	COVID-19 IgG/IgM Rapid Test Device		
Industry experience	3 Months		
License Number	913301013219351652	Corporate Representative	Mr. Pengfei Ding
Registration Date	08 Jan., 2015	Expiry Date	08 Jan., 2015
Registered Capital	RMB 4,500,960	Paid-in Capital	/
Area of Office	200 square meters	Area of Workshop	3,000 square meters
1.2 Contact Way			
Company Representative	Mr. Bruce Wu / Sales Manager		
Tel. number	86-15957492339		
E-mail	bruce2339@163.com	URL	www.realytech.com
1.3 Nature of Enterprise			
Type of Ownership	[X] Privately Owner [ ] Public Company [ ] Joint Venture [ ] Stated Owned [ ] Others		
Type of Company	[ ] Manufacturer [ ] Foreign trader [X] Both		
Subsidiary Factory	N/A		
Relationship with Subsidiary Factory	N/A		
Overview	 		

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Section 2: Personnel

2.1 Company Org Chart

2.2 Headcount and Key Staff

According to	[ ] Attendance record [X] Members list [ ] On-site observation [ ] Others			
Headcount	Department	Full time	Part time	Total
	General Manager	1	0	1
	Finance Dept.	2	0	2
	Admin Dept.	4	0	4
	Sales Dept.	7	0	7
	Production Dept.	52	0	52
	Q.C. Dept.	4	0	4
	Purchase Dept.	5	0	5
	Tech. Dept.	15	0	15
	Total	90		
Key Staff	Full Name	Position	Working experience in this filed	
	Mr. Pengfei Ding	General Manager	About 5 years working experience	
	Gang Liu	Factory Director	About 5 years working experience	
	Brain Chen	Export Manager	5 years foreign trading experience	
Training Procedure and Plan for Staff	[X] All staff [ ] Key staff [ ] No Training records [ ] Others			
Are there uniforms for all staff in company?	Yes			

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Section 3: Main Market

3.1 Foreign Trading Staff

There were 7 foreign trading members in the company.

Education Level	Headcount
Doctor	0
Master	0
University	3
Junior college	4
Technical secondary school	0

Working Experience	Headcount
Over 20 Years	0
Over 10 Years	0
Over 5 Years	4
2-5 Years	3
1Year	0

English Level	Headcount
TEM-8	0
CET-6	7
CET-4	0
CET-3	0
PETS-3	0

Export means: [X] Directly export through own export right
[ ] Export business operated by other foreign trading company
[ ] Others

3.2 Export Information

Item	Content	
Main Market	Area	% of Total Business Volume (last year)
	North America	5
	South America	25
	West Europe	30
	East Europe	10
	East Asia (Japanese/ Korea)	0
	Africa	5
	Australia	0
	Southeast Asia	10
	Mideast	5
	Others	10
	Domestic	0
Sales Volume	Annual volume in last year	Confidential
	Export volume in last year	Confidential
	Estimated export in this year	Confidential
Key Client	Confidential	Confidential
Lead time	From PO Confirmation to Ex works	14 Days

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Section 4: Manufacturing Ability

4.1 Main Facilities

	Facility name	Brand/Model	Quantity	Year made	Condition
Please list the major machinery / utilities on site.	Constant Temperature Oven 恒温箱	N/A	20	2	Acceptable
	Cutting Machine 剪切机	N/A	5	2	Acceptable
	Filling Machine 灌装机	N/A	4	2	Acceptable

4.2 Main Test Instruments

	Facility name	Brand/Model	Quantity	Year made	Condition
Please list the major test instruments on site.	Confidential	Confidential	Confidential	Confidential	Confidential

4.3 Output

	Product	Monthly output	Yearly output
Output in last year	COVID-19 IgG/IgM Rapid Test Device 新冠病毒 IgG/IgM 快速检测装置	0	0
Output in this year	COVID-19 IgG/IgM Rapid Test Device 新冠病毒 IgG/IgM 快速检测装置	30,000,000 Pcs	70,000,000 Pcs

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Section 5: Certificate

5.1 Management System Certificate				
Certificate	Number	Expiry date	Certifying Body	Scope
ISO13485:2016	Q5094846000 2Rev.01	23 Jan., 2023	TUV SUD	Design, Development, Production and Distribution of POCT Analyzers and Related Diagnostic Kits

5.2 Product Certificate				
Certificate	Number	Issued date	Certifying Body	Product and model / type
N/A	N/A	N/A	N/A	N/A

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Section 6: Quality Control Management

Item	Content	Grading			Observations /Comments
		Poor	Mid	Good	
6.1	Are the environmental conditions such as tidiness and cleanliness being controlled and suitable for the operation performed?			√	Refer to site observation; the environmental condition was suitable for the operation performed.
6.2	Are the following items /documents provided at appropriate location and under control when necessary? - Work Instructions /procedures - Workmanship standard /acceptance - Golden sample			√	The company had made the relevant work instruction and standard. Refer to site observation; there were Work Instructions for each procedure.
6.3	Does the company establish and implement an effective suppliers/ sub-contractors assessment procedure (which covers the acceptable criteria of supplier/ sub-contractor)?			√	The company had established this procedure for supplier assessment and have complete records.
6.4	Are written instructions available for incoming material inspections /testing? Is the relevant records maintained?			√	Refer to on-site observation; there were documented instructions for incoming material inspection. And inspection records were maintained well.
6.5	Are written inspections /testing instructions available for finished products? Is the relevant records maintained?			√	The company had established finished products inspection standards and has inspection records.
6.6	Is there a procedure to conduct random product inspection after final packaging in place?		√		All inspection procedures were implemented before packaging.
6.7	Are non-conforming units clearly marked/ segregated to prevent accidental dispatch?		√		Refer to site observation; non-conforming units would be marked with label. But there were no marked area for non-conforming unit in workshop and warehouse。

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6.8	Is there a clear procedure for handling customer complaint?			√	Refer to relevant documentation; the company had a clear procedure for handling customer complaint.
6.9	Can the finished/packaged product be traced by lot identification to the appropriate raw materials test reports?			√	The company had established identification and traceability control procedures, which could be traced to the raw material test records by the order number.
6.10	Are corrective & preventive actions mechanism established and implemented effectively (including the suppliers/ sub-contractors' control, incoming inspection, process control, final inspection and customer complaint)?			√	The company had established corrective & preventive control procedures and records were kept well.

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Section 7: Development Plan

7.1		
Item	Actions	Time Frame
1	The company is going to expand the oversea markets.	2020

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Section 8: Production Flow Chart

8.1Product: COVID-19 IgG/IgM Rapid Test Device		
		
1. Configuring Reagent 配置试剂	2. Cutting Test Paper 试纸分切	3. Filling 灌装
		
4.Packing 包装	4. Finished Products 成品	

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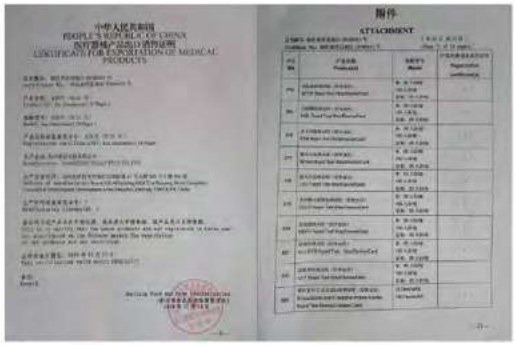
Section 9: Attachment

9.1 Photos of Document and Certificate

Business License	Export Certificate
	
ISO13485 Certification	**Production Certificate of Medical Products**
	
Exportation Certificate of Medical Products	**Declaration of Conformity**
	

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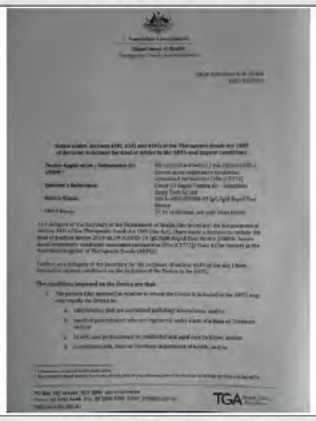
Consumer Testing Services
B-15/F, No. 900, Yishan Road, Xuhui District, Shanghai, China 200233 t (86-21) 61156703 f (86-21) 61152274 www.cn.sgs.com
中国·上海·徐汇区宜山路900号B-15层 邮编: 200233 t (86-21) 61156703 f (86-21) 61152274 e as.cn@sgs.com

Sales Area License	Sales Area License
	
Sales Area License	**Sales Area License**
	

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9.2 Photos of Company and Product Sample

Company Gate	Office
	
Workshop	**Workshop**
	
Warehouse	**Warehouse**
	

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Product Sample	Product Sample
	
Product Sample	**Product Sample**
	
Product Sample	**Product Sample**
	

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Product Sample	Product Sample
	

-- End of the Report --

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