COVID-19 Antibody Rapid Test Kit (Colloidal Gold Immunochromatography Method)

1 – Labeling and packaging arts

Labels on the product package are as follows:

COVID-19 Antibody Rapid Test Kit

(Colloidal Gold Immunochromatography Method）

☐ Cassette ☐ Strip

1 Test

Global WholeHealth Partners Corp.

Address: 1402 North El Camino Real, San Clemente, CA 92672

COVID-19 Antibody Rapid Test Kit

(Colloidal Gold Immunochromatography Method）

☐ Cassette ☐ Strip



1 Test

Global WholeHealth Partners Corp

Address: 1402 North El Camino Real, San Clemente, CA 92672

2 - Instructions for use / user manual

COVID-19 Antibody Rapid Test Kit (Colloidal Gold Immunochromatography Method)

Instruction for Use

For professional use only

Please read the instruction for use carefully before performing the test or use after consulting your doctor.

INTENDED USE

COVID-19 Antibody Rapid Test Kit (Colloidal Gold Immunochromatography Method)

is used for qualitative detection of SARS-CoV-2 virus total antibodies in human whole blood / serum / plasma samples. The test device is intended for professional use only.

Clinical manifestations of COVID-19 are fever, fatigue and other systemic symptoms, accompanied by dry cough, dyspnea, etc., which can rapidly develop into severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multiple organ failure, severe acid-base metabolic disorder, and even life-threatening.

PACKAGE

Cassette: 1 test/pouch,40 tests /box.

Strip: 1 test/pouch, 40 tests/ box.

50 tests /Strip Tube; 100 tests /box.

Active Materials

Bioactive materials Recombinant SARS-CoV-2 virus antigens, Goat anti-mouse IgG, mouse IgG.

Chemicals: Phosphate Buffer, NaCl, Casein, Proclin300.

Raw and auxiliary materials: nitrocellulose membrane, colloidal gold binding pad, PVC base plate, absorbent paper, sample pad.

PRINCIPLE

COVID-19 Antibody Rapid Test Kit (Colloidal Gold Immunochromatography Method)takes the proteins of SARS-CoV-2 virus as the coating antigen and labeling antigen, and use the double antigen sandwich principle to test the specificity antibody of SARS-CoV-2 virus in clinical samples. Colloidal gold is labeled with SARS-CoV-2 virus antigens and mouse IgG, NC membrane is coated with SARS-CoV-2 virus antigens (test line T) and Goat anti mouse IgG (quality control line C). When the positive sample is tested, COVID-19 antibody in the sample is combined with the colloidal gold labeled antigens to form a complex. The complex moves forward along the strip by capillary force. When passing through the test line, the complex is combined with the pre-coated antigens to form a sandwich and the color appears, while the gold labeled mouse IgG continues moving forward and reacts with the quality control line(anti-mouse IgG).

PRECAUTIONS

1) Please read the instruction carefully before performing the test. Pay attention to the position of the C and the T line.

2) Do not reuse the test device.

3) Do not use expired devices.

4) Once open the pouch, the test should be carried out as soon as possible. The strip (or cassette) should not be exposed in the air for long time once taken out of pouch.

5) Do not use if the pouch is opened or damaged before testing.

6) All samples and wastes shall be treated as infectious substances.

MATERIAL

Material provided:

For cassette format:

1) 40 test devices sealed in an aluminum foil pouch with a desiccant;

2) One Instruction of use.

3) One 4 ml Drop bottle with sample diluent buffer.

For strip format:

Two format for strip test:

(1) 50 individual pouched test strip with aluminum foil. One Instruction of use., One 4 ml Drop bottle with sample diluent buffer. 50 tests/box.

(2) Two strip barrels, each contains 50 test strips.2 desiccants per strip barrel. One Instruction of use. Two 4 ml drop bottle with sample diluent buffer. 100 tests/box.

STORAGE AND STABILITY

1) The test kit should be stored at 2°C -30°C. DO NOT FREEZE.

2) The shelf-life of the kit is 18 months.

3) Sample Diluent buffer is recommend to store at 2-8 °C.

4) Shipping: Room temperature transportation.

SPECIMEN PREPARATION

1) Collection: For vein blood specimen collection, follows routine medical procedure. For fingertip blood collection, using a lancet. The serum / plasma specimens is used directly.

2) Storage: The specimen can be stored up to 7 day at 4℃. If longer period of time storage is needed, stored at - 20℃ or below. Repeated freeze-thaw cycle should be avoid.

3) Refrigerated specimen should be brought be to room temperature before use. Shake gently and mix well before to perform test. Obvious precipitation in the specimen can be treated by brief centrifugation. Deteriorated, severe hemolysis or lipemia specimen is not recommended for use.

TEST PROCEDURE

1) Test device and specimen should be brought to room temperature (15-30℃,20 minutes) prior to testing. Do not open pouches until ready to perform the assay.

2) Take the test strips(or cassettes) out from the foil pouch/strip barrel. lay flat on the operation table.

3) Slowly add 20μl serum/plasma/whole blood specimen to the sample well (s). Add two drops of sample dilution buffer. Start to count time, and read the result within 15 minutes. Strong positive sample will show a visible red color band at test line almost within 1 minute, weak positive sample usually appears within 5-7 minutes. If a very faint line appears at 15 minute, repeat teat is recommended.

WARNING: Do not read after 15 minutes. Longer than 15 minutes sometimes may observe a very faint or indistinguishably line at test line for some negative samples. It may lead to an incorrect result.

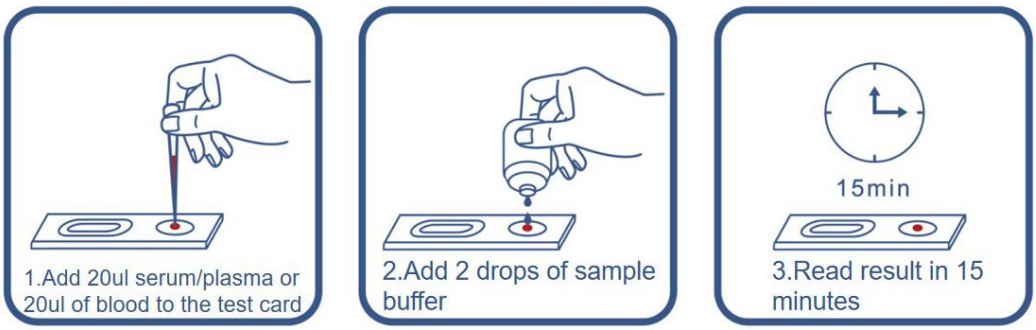
Cassette operation guide:

For serum/plama/whole blood sample.

Step 1: Add 20μl serum/plasma/whole blood to sample well(s) on cassette with a pipette.

Step 2: Add 2 drops sample diluent buffer to sample well(S).

Step 3: Read result within15 minutes visually.



For whole blood from Fingertip:

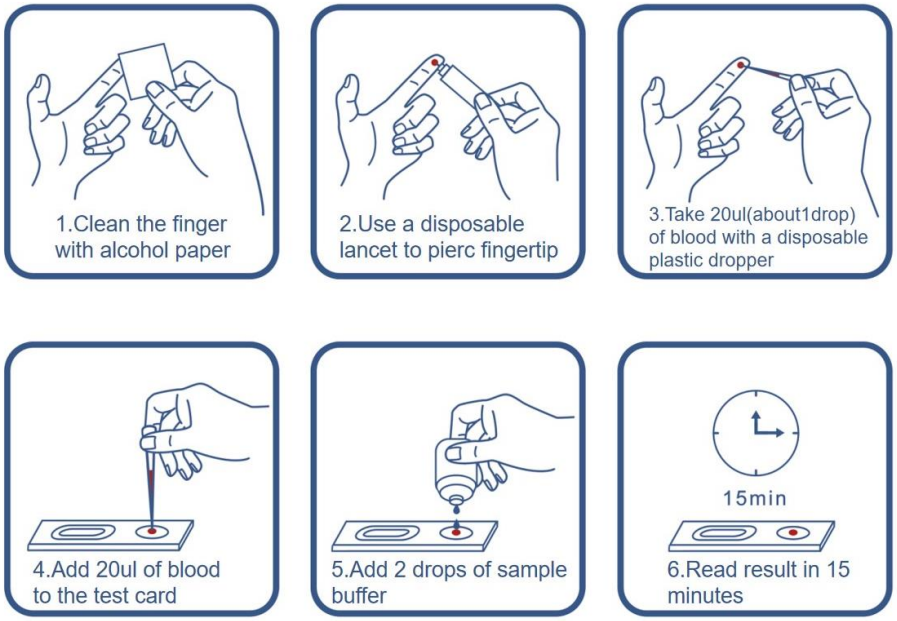
Step 1: Clean a finger with Alcohol Paper or wash hand.

Step 2: Using a Lancet to pierce finger and squeeze finger to get a big blood drop.

Step 3: Add 1 drop or 20 μl blood to the sample well(S) on the cassette a pipette .

Step 4: Add 2 drops sample diluent buffer to sample well(S).

Step 5: Read result within15 minutes.



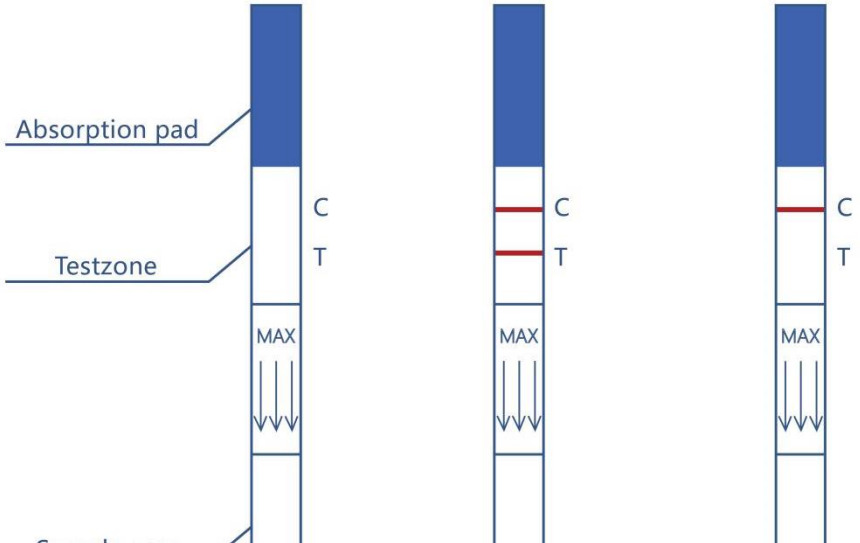
Strip operation guide:

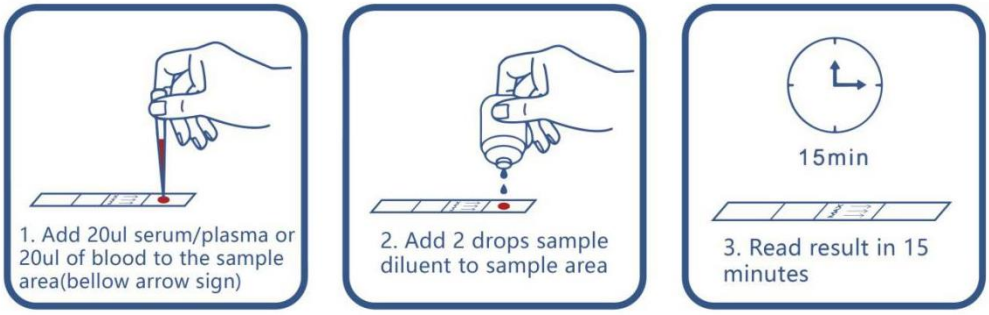
For serum/plama/whole blood sample.

Step 1: Add 20 μl serum/plasma/whole blood to sample area on test strip with a pipette.

Step 2: Add 2 drops sample diluent buffer to sample area on test strip.

Step 3: Wait within15 minutes to read result.





For Finger tip whole blood:

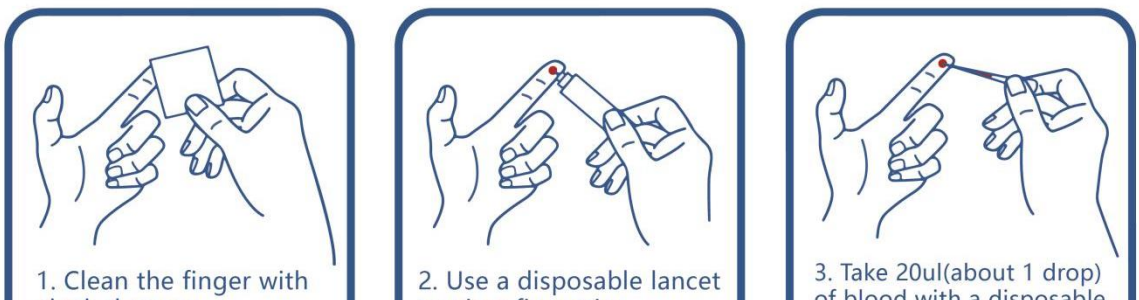
Step 1: Clean a finger with Alcohol Paper or wash hand.

Step 2: Using a Lancet to pierce finger and squeeze finger to get a big blood drop

Step 3: Add 1 drop or 20 μl blood to the sample area with a pipette.

Step 4: Add 2 drops sample diluent buffer to sample area .

Step 5: Read result.within15 minutes.



INTERPRETATION OF RESULTS

POSITIVE

Two red lines appear, the control line (C) and the test line (T). The result is positive.

The intensity of the test line (T) may be less than that of the control line (C); this still means positive result.

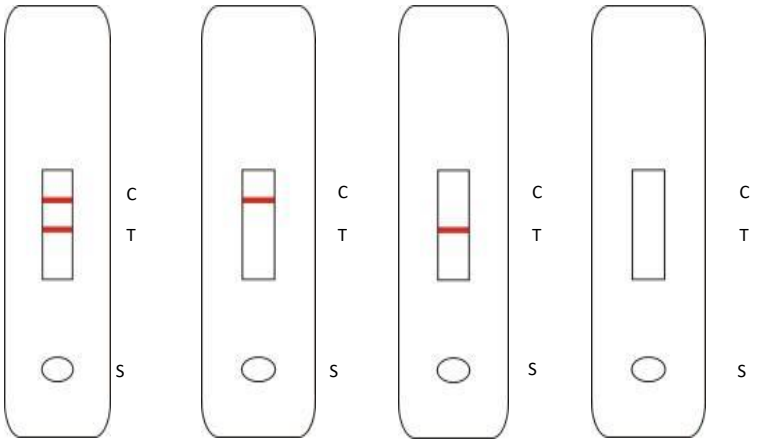


Figure 1 Cassette

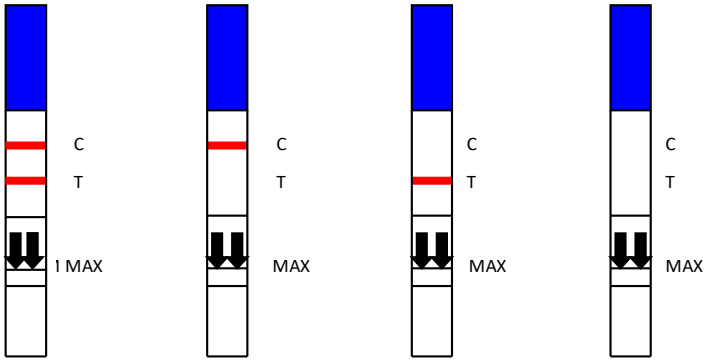


Figure 2 Strip

NEGATIVE

Only the red control line (C) appears. The result is negative.

INVALID

If no red line appears in the position of control line (C), the test result is invalid regardless of color on the test line (T). Review the procedure and repeat the test with a new test device.

LIMITATION OF THE PROCEDURE

This product is only used for primary screen of antibodies against SARS-CoV-2 virus only. D**iagnosis** of COVID-19 infection should not be based on antibody test result alone. Negative antibody test cannot exclude SARS-CoV-2 virus infection.

PERFORMANCE

1. Sensitivity and Specificity:

Based on 634 clinical sera from for medical institutions, 246 sera from confirmed COVID-19 infection patients. 388 negative sera form sera collected from hospitals before June 2019.

Antibody Test Results	COVID-19 clinical diagnosis		
	positive	negative	Total samples
Positive	232	7	239
negative	14	381	395
Total samples	246	388	634

（1）Sensitivity: 232/246=94.3%（2）Specificity:381/388=98.2%

（3）Overall coincidence rate: (232+381)/634=96.7%（4）PPV：
232/(232+7)x100%=97.1%

（5）NPV: 381/(381+14)x100%=96.4%

2. Cross Reactivity:

Not cross react with antibody positive specimen for following microbes:

Specimen Type	**Confirm Method**	**No. Of sample**	**Test Results**
Influenza A IgM	IFA	6	-
Influenza B IgM	IFA	4	-
Parainfluenza IgM	IFA	5	-
SRV IgM	IFA	3	-
Adenovirus IgM	IFA	2	-

Sample type	(+)	(-)
Bilirubin ≤1.2 mmol/L	+	-
Triglyceride ≤ 3 mmol/L	+	-
Hemoglobin ≤ 10 mg/ml	+	-
Rheumatoid factor ≤ 1900 RU/ml	+	-

Mycoplasma Pneumonia IgM	IFA	2	-
Chylamedia Pneumonia IgM	IFA	2	-
HIV IgG	EIA	8	-
HBV IgG	EIA	8	-
HCV IgG	EIA	8	-
Syphilis IgG	EIA	8	-

3. Interference:

No interference observed

REFERENCE

1. Jin Yinghui, Cai Lin; Cheng Jun Shun.Novel coronavirus (2019-nCoV) infection guidance for pneumonia diagnosis and treatment (Standard Version), Chinese PLA medical journal, 1-20

2. Medical expert group of Tongji Hospital Affiliated to Tongji Medical College of Huazhong University of Science and Technology.Novel coronavirus pneumonia diagnosis and treatment guidance (Third Edition), Medical Guidance, 1-9.

3. Jiang Yan; Zhao Yang; sun Rong. Overview of technical evaluation criteria of colloidal gold immunochromatography kit, Capital food and medicine, Vol. 24, issue 18, 2017.

4. Wu Hua, Research and implementation of colloidal gold color recognition method, Xi'an University of Science&Technology, 2016.

5. Huang Pei. Establishment of a new rapid detection method for mers-cov, Jilin Agricultural University, 2018.

6. Huang Pei;Han qiuxue;Hu Xingxing.Preparation of the quantum dot immunochromatography test paper of the Middle East respiratory syndrome coronavirus, Chinese Journal of pathogenic biology, June 2018, 13 volumes 557-561.

Index of CE Symbols

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
	Manufacture Date	LOT	Batch number
2℃ 30℃	Temperature scope within which the product is reserved	Σ	Tests per kit
REF	Catalog #		Keep away from sunlight
	Don't use the product when the package is damaged		Biological risks

Manufacturer:

Global WholeHealth Partners Corp

1402 North El Camino Real

San Clemente, CA 9272

Telephone:714-392-9752

Email: cstrongo@gmail.com

Website: www.GWHPCorp.com

Technical dossier: product description

1.Product Introduction

1) Intended use:COVID-19 Antibody Rapid Test Kit (Colloidal Gold Immunochromatography Method) is used for qualitative detection of SARS-CoV-2 virus total antibodies in human whole blood/serum / plasma samples. The test device is intended for professional use only.

2.Product Model:

Cassette: 1 test/pouch,20 tests /box; 1 test/pouch,40 tests /box.

Strip: 1 test/pouch,50 tests /box; 1 test/pouch,100 tests /box.

3.Usage:

SPECIMEN PREPARATION

1) Collection: Collected specimens need not be specially processed. The specimens are collected by the correct medical technology. The serum / plasma specimens are used directly.

2) Storage: The specimen can be stored in the refrigerator for up to 7 days at 4℃.If it needs to be preserved for a long time, it should be frozen at or below - 20 ℃ to preserve, Avoid repeated freeze-thaw cycles.

3) If serum specimen is refrigerated, it must be equilibrated to room temperature before testing. Shake gently and mix well if there is formed sediment in the specimen, it should be removed by centrifugation, and it can be only used after confirming that it is not deteriorated. Severe hemolysis or lipemia specimen cannot be used.

TEST PROCEDURE

4) Test device and specimen should be brought to room temperature (15-30℃) prior to testing. Do not open pouches until ready to perform the assay.

5) Remove the test strips(or cassettes) from the foil pouch. And number them one by one and lay them flatly on the operation bench.

6) Slowly add 20 μl of whole blood/ serum / plasma specimen to the sample well (s) and two drops of sample dilution buffer. Start to calculate the time, and read the result in 10～15 minutes. Do not read after 15 minutes.

INTERPRETATION OF RESULTS

Positive

Two red lines appear, the control line (C) and the test line (T). The result is positive.

The intensity of the test line ("T") may be less than that of the control line ("C"); this still means positive result.

Negative

Only the red control line (C) appears. The result is negative.

Invalid

If no red line appears in the position of control line (C), the test result is invalid regardless of color on the test line (T). Insufficient specimen volume or incorrect procedures are the most likely reasons for control line (C) failure. Review the procedure and repeat the test with a new test device.

4 Contraindications and adverse reactions:

NO.

5 Caution:

7) For in vitro diagnostic use only

8) Please read the instruction inserts carefully before performing the test.Pay attention to the position of the C and the T line.

9) Do not reuse the test device.

10) Do not use expired devices.

11) Once open the pouch, the test should be carried out as soon as possible. The strip (or cassette) should be avoided long time in the air for the reagent will fail after it absorbs moisture.

12) Do not use if the pouch is opened or damaged before testing.

13) All samples and wastes shall be treated as infectious substances.

14) The kit can be stored at room temperature to avoid moisture. The kit stored at low temperature should be balanced to room temperature before opening the pouch for testing.

15) Shelf-life of the kit is 18 months.

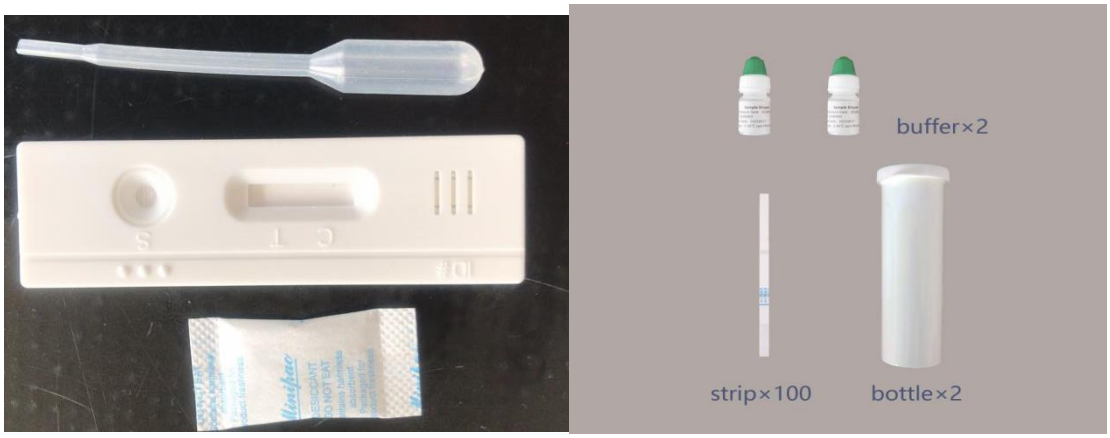
6.Classification

Base on intended use and definition of categorization, and according to 98/79/EC, Annex III, this product is classified to others.

7.Conformity Assessment Procedure

According to 98/79/EC, the conformity assessment procedures of annex IV is applicable to this product.

4 - Technical dossier: product images



5 - Technical dossier: risk management report (ISO 14971)

Chapter 1 Summary

1. Introduction

1.1 Product principle and intended use

Principle COVID-19 Antibody Rapid Test Kit (Colloidal Gold immunochromatography method）takes the nucleoprotein of COVID-19 as the coating antigen and labeling antigen, and apply the double antigen sandwich principle to test the specificity antibody of COVID-19 （including IgM,IgG,IgA） in clinical samples. Colloidal gold is labeled with COVID-19 antigen and mouse IgG, NC membrane is coated with COVID-19 antigen (test line T) and Sheep anti mouse IgG (quality control line C). When the positive sample is tested, COVID-19 antibody in the sample is combined with the colloidal gold labeled antigen to form a complex. Because of the chromatography, the complex moves forward along the strip. When passing through the test line, the complex is combined with the pre-coated antigen to form a sandwich and the color is appeared, while the gold labeled mouse IgG continues forward and reacts with the quality control line. Negative samples will be only colored at the quality control line.

Intended use:COVID-19 Antibody Rapid Test Kit (Colloidal Gold）is used for qualitative detection of COVID-19 total antibodies in human whole blood/serum / plasma samples.The test device is intended for professional use only.

1.2 Product composition

Components: The test strip (or cassette) is sealed in a foil pouch,One dropper and The package of desiccant

Raw material:

Main active materials： COVID-19 antigen, Goat anti mouse IgG, mouse IgG.

Main raw and auxiliary materials: nitrocellulose film, colloidal gold binding pad, PVC base plate, absorbent paper, sample pad.

1.3 Production models

Cassette: 1 test/pouch,20 tests /box; 1 test/pouch,40 tests /box.

Strip: 1 test/pouch,50 tests /box; 1 test/pouch,100 tests /box.

Related standards

NO	Standard reference	Standard Title
1	ENISO 18113-1:2011	In vitro diagnostic medical devices—Information supplied by the manufacturer（labeling）Part1 terms，definition，general requirements
2	ENISO 18113-2:2011	In vitro diagnostic medical devices—Information supplied by the manufacturer （labeling） Part2 In vitro diagnostic reagents for professional use
3	EN ISO 23640:2015.	In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents
4	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
5	EN13641：2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
6	EN ISO 15223-1:2016	Medical devices-Symbols to used with medical device labels, labeling and information to be supplied-Part 1 General requirements

2、Purpose of the risk management

The purpose of this risk management review is to analyze the risk assessment of all models of COVID-19 Antibody Rapid Test Kit (Colloidal Gold Immunochromatography Method），and to fully implement the latest "Application of Medical Device Risk Management to Medical Devices" (ENISO14971-2012) to ensure the product's risk management, risk

evaluation and risk control, as well as comprehensive analysis. The acceptability evaluation of the residual risk confirms that the risk of the product has been managed and controlled within acceptable limits.

3. Assignment of responsibilities and authorities of risk management group

Name	Department	Responsibility
Dr. Shujie Cui	Chief Science Officer	Risk Management Leader
Roy salinas	Sales Department	Analyze market information from product management risk. Collect advice information feedback from customers and record risks after production
Mario Adame	Quality Department	Control raw materials quality and purchasing Summarize product quality problem analysis and promote solution problem
Dr. Shujie Cui	R&D Department	Improve the provided product problems by related departments. Improve the provided product problems by related departments.
Mario Adame	Production Department	Collect products risks from production assembling and debugging

Sara Gonzales	Purchasing Department	Be responsible for the risk management activities in the production process, mainly including material procurement management.
Dr. Shujie Cui	Clinical Application	Collect feedback information from clinical application.

Chapter 2 Risk management inputs

1. Acceptable criterion

The risk management team evaluated the risk assessment/risk acceptable criteria formulated in the Risk Management Control Procedure of the company. It believed that the risk acceptance criteria based on the risk management activities still maintained the original criteria. See the following table :

1) Severity level of risks

Level	Code
	1
Minimum harm	2
light minimum harm	3
light harm,	4
medium harm,	5
weight harm	6
causing death	7

2) Occurrence probability of risks

Level name	Code	Frequency
Impossible	1	≥ 1/150000 and ＜ 1/15000

Very Rare	2	≥1/15000 and ＜ 1/2000
Rare	3	≥ 1/2000 and ＜ 1/400
Very seldom	4	≥1/400 and ＜ 1/80
Seldom	5	≥ 1/80 and ＜ 1/20
occasionally	6	≥1/20 and ＜1/8
Sometimes	7	≥1/8 and ＜ 1/3
Often	8	≥1/3 and ＜1/2
Frequently	9	≥1/2

3) Acceptable criterion

Occurrence probability		Severity level						
		1	2	3	4	5	6	7
		No harm	Minimum harm	light minimum harm	light harm	medium harm	weight harm	causing death
Frequently	9	A	R	R	U	U	U	U
Often	8	A	R	R	R	U	U	U
Sometimes	7	A	R	R	R	R	U	U
occasionally	6	A	R	R	R	R	U	U
Seldom	5	A	R	R	R	R	U	U
Very seldom	4	A	A	R	R	R	U	U
Rare	3	A	A	A	R	R	U	U
Very Rare	2	A	A	A	A	R	U	U
Impossible	1	A	A	A	A	A	U	U

Note: A:acceptable risks; R:risks should be reduced by reasonable actions; U:unacceptable risks without analyses risk or benefits

2. Risk management documents

Risks management plan；

Safety characteristics questions listings；

Original risk harm analysis and risk correction actions and residual risk analysis

3. Related documents and records

3.1 Risk management control procedures；

3.2 Product design documents including design drawing, technology and SOP.

Chapter 3 Risk managements

1. Completion of risk management plan

The review team inspected the completion of the risk management plan one by one. Through the inspection of the relevant risk management documents, it was concluded that the risk management plan had been basically implemented.

2. Residual Risks Evaluation

Identification of known or predictable hazards and evaluation of risks:

All reasonable hazards and their cause were identified and the resulting risks have been evaluated. All of the data have been documented in the above tables before the required measures for the risk diminution have been defined and a final evaluation has been carried out.

From the above table ,we know ,it is proposed that actions should be taken to decrease risks. After taking actions, these risks have been acceptable from the above table.

From the clinical research data in China, there are some possible risks about clinical application, we know from the these clinical cases, the occurred risks don't produced serious results. So we have taken corresponding actions for each possible risk. After actions, all clinical risks can been accepted. Except clinical risks, from the above evaluation,

other risks cannot cause serious advent events, so we think all risks can be accepted through reevaluation.

Overall residual risk evaluation

In this risk analysis the "present state" of the device has been evaluated. Having carried out the evaluation of the product, the risk of appearance of a no-acceptable fault is quite low. Each single residual risk has been evaluated and documented, and its result shows that is acceptable. The product construction, its function as well the application under normal conditions does not represent any risk for the user.

The review team conducted a comprehensive analysis of all residual risks and undesirable side effects, and think there is no contradictory effect on individual risk control measures, all individual residual risks are acceptable; Warning review: there is no contradictory among warnings, so each warning does not low other warning effect; Instruction for use: it is operational, and following the advice of instruction for use user can operate the device to realize its intended use. Reviewing experts including clinical doctors consider that when individual risk effect together ,that product can screen patient's disease, his benefits are greater than risks, therefore comprehensive residual risks are acceptable.

3.Post-production information

For the device has not been marketed, so there is no risks information from the post-production. If new risk will be founded, relative technicians should re-analyse, re-evaluate and control.

Chapter 4 Risk management conclusion

From the above steps, risk team think that all activities have been appropriately carried out in the risk plan. According to risk plan's requirements, manufacturer analyzed all kinds

of hazards and possible reasons during the application of COVID-19 Antibody Rapid Test Kit (Colloidal Gold), and took correction actions to reduce risk. Then they evaluated residual risks acceptability. All evaluations' results show that residual risks are acceptable. Risk team concludes that COVID-19 Antibody Rapid Test Kit (Colloidal Gold Immunochromatography Method) can effectively screen patients' diseases. With comparison of possible risks, patients' benefits are greater than risks from products use. So the product overall residual risks are acceptable.

And manufacture also made PMS procedures, and they can effectively supervise and collect all risks from post-market in time, then analyze possible reasons and take actions, to improve product quality and make risks be acceptable scope.

Annex： risk management documents

1. Identification of qualitative and quantitative characteristics；

2.Original risk harm analysis and risk correction actions and residual risk analysis

Annex 1: Identification of qualitative and quantitative characteristics

1	Intended use and how to use	COVID-19 Antibody Rapid Test Kit (Colloidal Gold immunochromatography method) is used for qualitative detection of COVID-19 total antibodies in human serum / plasma samples. The test device is intended for professional use only.
2	Is the medical device intended to be implanted?	No
3	Intended to contact patient or other person	It will contact user.
4	What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	Components: The test strip (or cassette) is sealed in a foil pouch, One dropper and one package of desiccant Raw material: Main active materials：COVID-19 antigen, Goat anti mouse IgG, mouse IgG. Main raw and auxiliary materials: nitrocellulose film, colloidal gold binding pad, PVC base plate, absorbent paper, sample pad.

5	Is energy delivered to or extracted from the patient?	No
6	Are substances delivered to or extracted from the patient?	Yes, It will extract blood from patients body.
7	Are biological materials processed by the medical device for subsequent re-use ,transfusion or transplantation?	Yes. No special preparation is needed for the collected samples. Then the correct medical technology is used to collect the samples. The serum / plasma samples need to be centrifuged and the supernatant is extracted for detection.
8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	No
9	Is the medical device intended to be routinely cleaned and disinfected by the user?	No
10	Is the medical device intended to modify the patient environment?	No
11	Are measurements taken?	Yes
12	Is the medical device interpretative?	No
13	Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	No
14	Are there unwanted outputs of energy or substances?	Yes, Chemical pollution of toxic chemical reagents, potential biological pollution of samples, environmental pollution of non recyclable packaging or plastics.
15	Is the medical device susceptible to environmental influences?	Yes This product will be affected by high temperature and other environment.
16	Does the medical device influence the environment?	Yes, Chemical pollution of toxic chemical reagents, potential biological pollution of samples, environmental pollution of non recyclable packaging or plastics.
17	Are there essential consumables or accessories associated with the medical device?	No
18	Is maintenance or calibration necessary?	No
19	Does the medical device contain software?	No.
20	Does the medical device have a restricted shelf-life?	Storage conditions:2-30℃ 18 month
21	Are there any delayed or long-term use effects?	No

22	To what mechanical forces will the medical device be subjected?	No
23	What determines the lifetime of the medical device?	Antigen, antibody and other bioactive substances, storage and transportation process.
24	Is the medical device intended for single use?	single-used
25	Is safe decommissioning or disposal of the medical device necessary?	Yes. The used reagent, the remaining used sample and the used empty reagent bottle shall be treated as the biological infectious waste
26	Does installation or use of the medical device require special training or special skills?	The device is used by professionals.
27	How will information for safe use be provided?	Instruction use
28	Will new manufacturing processes need to be established or introduced?	No
29	Is successful application of the medical device critically dependent on human factors such as the user interface?	No
29.1	Can the user interface design features contribute to use error?	No
29.2	Is the medical device used in an environment where distractions can cause use error?	No
29.3	Does the medical device have connecting parts or accessories?	No
29.4	Does the medical device have a control interface?	No
29.5	Does the medical device display information?	No
29.6	Is the medical device controlled by a menu?	No
29.7	Will the medical device be used by persons with special needs?	The device will be used by qualified doctors.
29.8	Can the user interface be used to initiate user actions?	No
30	Does the medical device use an alarm system?	NO.
31	In what way(s) might the medical device be deliberately misused?	Yes. Mixed use of expired products and different reagent batches.
32	Does the medical device hold data critical to patient care?	No
33	Is the medical device intended to be mobile or portable?	No.
34	Does the use of the medical device depend on essential performance?	Yes

35	Which grade is the MD software.	No
H.2.1	Identification of intended uses	
H.2.1.1	General IVO medical devices for laboratory or point of care examinations have two users: (1) an operator who performs the examination, and (2) a healthcare provider who receives, interprets and acts on the results. In the case of IVO medical devices for self-testing, the patient could be the only user. Identification of intended uses should consider the objective intent of the manufacturer with respect to both elements of use: (1) use of the IVO medical device to produce an examination result, and (2) use of the examination result to reach a decision on the diagnosis, treatment or monitoring of a patient.	COVID-19 Antibody Rapid Test Kit (Colloidal Gold Immunochromatography method) is used for qualitative detection of COVID-19 total antibodies in human whole blood/serum / plasma samples. The test device is intended for professional use only. Test results are not the only basis
H.2.1.2	Intended use The intended use of an IVD medical device can include the measurement system, analyte, kind-of-property, sample matrix, examination procedure (qualitative, semi-quantitative or quantitative), type of operator and site of use.	measurement system :immunological Reaction; Analyte:COVID-19 antibodies(IgG/IgM/IgA) ; sample matrix: serum / plasma ; examination procedure: quantitative; Type of operator: professional ; site of use: Hospital .Doctors, Clinics
H.2.1.3	Indications for use The indications for use include the medical applications and patient populations for which the IVD medical device is intended	In vitro Qualitative detection of COVID-19 total antibodies in human whole blood/serum / plasma samples Applied population :no limit.
H.2.2	Identification of possible use errors	
H.2.2.1	Use errors	Inappropriate reagents or sample matrix are used; expired products are used; different reagent batches are mixed.
H.2.2.2	Examples of possible use errors by laboratory personnel	
H.2.2.3	Examples of possible use errors by healthcare providers	This product is intended to be used to assist in the diagnosis of diseases. Doctors use IVD test results as the basis for diagnosis. This product is intended to assist in the diagnosis of diseases, and doctors use IVD test results to screen certain diseases in the population.

H.2.2.4	Examples of possible use errors by patients in self-testing	The device belongs to professional use
H.2.3	Identification of characteristics related to safety	
H.2.3.1	General In addition to chemical, mechanical, electrical and biological characteristics in common with other medical devices, IVD medical devices have performance characteristics that determine the accuracy of the examination results. Failure to meet the performance characteristics required for a specific medical use could result in a hazardous situation that should be evaluated for risk to patients.	Velocity of liquid moving，Minimum detectable amount，Consistency of positive references，Consistency of negative references，Reproducibility.
H.2.3.2	Performance characteristics of quantitative examination procedures	No
H.2.3.3	Performance characteristics of qualitative examination procedures	The device is used to qualitatively detect COVID-19 in human whole blood/serum / plasma samples.
H.2.3.4	Dependability characteristics	The device is used for qualitative detection of COVID-19 total antibodies in human whole blood/serum / plasma samples T
H.2.3.5	Ancillary patient information	The test results of this product need to be combined with other diagnostic information of the patient in order to make an appropriate explanation.
H.2.4	Identification of known and foreseeable hazards	
H.2.4.1	Hazards to the patient	Incorrect results
H.2.4.2	Relationship to performance characteristics	See identifications of performance characteristics related to safety
H.2.4.3	Identifying hazards in fault conditions	Stability failure (storage, transportation, in use), the purchased raw materials fail to meet the performance required by the design, the storage conditions of raw materials are incorrect, the expired raw materials are used, the reaction system is incorrect, the precision is invalid, and the non-specific is invalid.
H.2.4.4	Identifying hazards in normal use	The undesired influence of other components (interference factors) in the sample matrix.

Annex 2.Original risk harm analysis and risk correction actions and residual risk analysis

D1. Biological and chemical hazards								
1	Bio-contamination	Positive Specimen can cause biological contamination.	5	3	15	Define the disposal method of positive specimen	Instruction for use	5
2	Chemical pollution of toxic chemicals	toxic chemicals can cause biological contamination.	5	3	15	Define the disposal method of chemicals	Instruction for use	5
3	Incorrect formulation(chemical composition)	Product cannot detect specimens				Compile Products technical requirements	**Products technical requirements** **product test**	5
D2. Environmental hazards and contributory factors								
1	Storage or operation outside prescribed environmental conditions	Influenced on device lifetime and accuracy	3	4	12	Control the process of storage	Product labeling Instruction for use	
2	Contamination due to waste products and /or device disposal	Free disposal of waste product can contaminate the environment.	3	4	12	Should give clear indication of method of waste products and device disposal	Instruction for use	

D3. Hazards resulting from incorrect output of energy and substances								
1	Bio-contamination	Positive specimen can cause biological contamination.	5	3	15	Define the disposal method of positive specimen	Instruction for use	5
2	Chemical pollution of toxic chemicals	toxic chemicals can cause biological contamination.	5	3	15	Define the disposal method of chemicals	Instruction for use	5
D4. Hazards related to the use of the device and contributory factors								
1	Inadequate labeling	Inadequate labeling does not conformed to standards ,misguide users.	3	5	15	Design labeling should be conformed to requirements of ENISO15223-1：2016，ENISO 18113-1:2011，ENISO 18113-2:2011	Labeling	
2	Inadequate operating instructions 如： ▪ inadequate specification of accessories ▪ inadequate specification of pre-use checks ▪ over-complicated operating instructions	users can not correctly use the deice ，	4	5	10	Product instruction for use should be conformed to requirements of ENISO 18113-1:2011，ENISO 18113-2:2011	design documents Training record	
3	Use by unskilled/untrained personnel	It may cause not to correctly detect specimen	4	3	12	Qualified doctors will use the device.	Training Recording	
4	Inadequate warning of hazards likely with re-use of single use devices	The deice is usable, and may cause to bio-contamination	4	3	12	Waring Label should be conformed to the requirements of ENISO15223-1:2016	Product labeling	4

5.	Insufficient publicity of limitations	Leading to doctors' wrong judgment	4	3	12	Instruction for use should explain test method limitation of the device	Instruction for use	4
	D5. Hazards arising from functional failure, maintenance and aging							
1	Inadequate maintenance	Inappropriate storage actions will cause devices invalid	4	4	16	Should indicate correct storage condition	Instruction for use	
2	Lack of adequate determination of end of device life	May reduce end of device life and test accuracy	3	6	18	Purchase control the antigen and antibody quality and make out appropriate storage conditions.	Raw materials test procedure . Instruction for use	3
3	Inadequate packaging(contamination and /or deterioration of the device)	Destroyed package maybe damage the products	3	6	18	Package Design should be conformed to product requirements	Product package validation report	3
	D6. Hazards arising from manufacturing process							
1	Purchasing Process	Nonconforming raw materials may cause not realize intended use	4	4	16	Should strictly control the raw materials quality.	Raw materials incoming inspection procedure and Raw materials incoming inspection test report.	
2	Inappropriate operation in Key processing /Special procedure	May cause the device quality and measurement accuracy	4	4	16	Package process should be validate ,and should train operators about SOP.	Package technology validation report and SOP . Operators have been trained.	
3	Outgoing Quality Control	If the quality of outgoing devices is non-conformed ,it may cause delay patient test.	4	5	20	Compile OQC procedure ensure the device quality	OQC procedure and OQC report.	
4	Personal qualification	Nonconforming operators may cause the device to be non-conformed.	4	3	12	Operators should be trained about the Operation instruction .	Train plan and train record about the operators.	
5	Production Environment	Nonconforming production Environment may effect on products quality.	3	4	12	Workshop should be 10^{5}class clean room and production environment procedure should be compiled.	Production environment procedure and clean room test report	

6	Equipment/Facilities	Nonconforming Equipment/facilities may effect on products quality.	4	4	16	Production Equipment/facilities procedure should be compiled.	Facilities control procedure, Equipment instruction and maintain record		
7	Measurement equipment	Nonconforming measurement equipment may effect on products accuracy and mistake test result.	4	4	16	Measurement equipment procedure should be compiled.	Measurement Equipment procedure, Equipment instruction and maintain record		
8	Transportation and storage	Nonconforming transportation and storage condition may effect on product performance.	4	3	12	Correct transportation and storage condition should be validated	Transportation and storage condition evaluation report		
9	Packaging	Broken package Device maybe invalid	4	4	16	Reasonable packaging technology	Package validation test report Package SOP	4	
D7 Hazards arising from Design & Development process									
1	Choose inadequate raw materials	Raw material is not qualified for performance .Cause to misjudge the results.	4	3	12	The raw materials should meet the requirements of	Raw Test report	4	
2	Choose inadequate package materials	Broken package will contaminate product	4	6	24	Package Design should be conformed to requirements of product technical requirements	Product package validation report	4	
D8 Hazards arising from clinical application									
1	Clinical users	Nonconforming clinical doctors may cause to incorrectly use it and misjudge	4	4	16	Clinical doctors should be qualified after trained	Doctor certification		
2	Contaminated for operation	Broken package and invalidation Device maybe invalid	4	4	16	Should use intact package and valid device	product labeling		
D9. Additional hazards to in vitro diagnostic medical devices									

1	Inappropriate reagents or sample matrix are used	It leads to the instability of the test results and makes the user unable to make a correct judgment.	4	4	16	Should strictly control the raw materials quality . Instruction for use should define specimen requirements	Raw materials incoming inspection procedure and Raw materials incoming inspection test report. Interfere research report and instruction for use.
2	expired products are used	It leads to the instability of the test results and makes the user unable to make a correct judgment.	4	4	16	Labeling should define products validation	Product Labeling
3	Batch inhomogeneity, batch-to-batch inconsistency	It leads to the instability of the test results and makes the user unable to make a correct judgment.	4	4	16	Pay attention to representativeness and stability during sampling inspection	Finished product inspection specification and Stability Research Report
4	Doctors use IVD test results as the basis for diagnosis.	Doctors Incorrect use will cause to wrong cure method.	4	4	16	Define use method of the device	Instruction for use
5	Doctors use IVD test results to screen certain diseases in the population.	Incorrect test result will cause to screen inappropriate patients	4	4	16	Define judgement method of detection results	Instruction for use
6	Patients incorrect detection results.	Incorrect test result will cause inappropriate screen and delay patients treatment.	4	4	16	Define judgement method of detection results	Instruction for use
7	Stability problems (in storage, in shipping, in use, after first opening of the container)	The expected results are not correct due to the failure of product stability study;	4	4	16	Establish stability study requirements document and conduct stability study	Stability study report
7	The purchased raw materials fail to meet the design requirements	It leads to the instability of the test results and makes the user unable to make a correct judgment.	4	4	16	Should strictly control the raw materials quality . Instruction for use should define specimen requirements	Raw materials incoming inspection procedure and Raw materials incoming inspection test report. Interfere research report and instruction for use.

8	Incorrect storage conditions of Raw materials.	Inappropriate storage actions of raw materials will cause Nonconforming devices	4	4	16	Should indicate raw materials correct storage condition	Raw materials Storage Management SOP
9	Use invalid raw materials	Invalid storage actions of raw materials will cause Nonconforming devices	4	4	16	◦ Should indicate raw materials correct storage life time	◦ Raw materials Storage Management SOP
10	the reaction system is incorrect,	It will cause Nonconforming devices and invalid detection results.	4	4	16	Reaction system should be verified.	Reaction system verification report.
11	the precision is invalid	Invalid precision will cause inappropriate screen and delay patients treatment.	4	4	16	Performance evaluation should be conformed to EN13612-2002	Performance evaluation report
12	the non-specificity is invalid.	Invalid non-specificity will cause inappropriate screen and delay patients treatment.	4	4	16	Performance evaluation should be conformed to EN13612-2002	Performance evaluation report
13	The undesired influence of other components (interference factors) in the sample matrix.	It will cause inappropriate screen and delay patients treatment.	4	4	16	Should study samples interference	Interference research report
14	Common interfering factors	Temperature out of range can affect test results	4	4	16	Storage condition should be defined in instruction for use.	Instruction for use
15	Carry-over effects	Invalid regent will cause inaccuracy test results	4	4	16	Validation date should be defined in instruction for use and labeling.	Labeling and Instruction for use
16	Specimen identification errors	Sample markers will cause inaccuracy test results	4	4	16	It should prompt the user to correctly mark the sample in the instruction for use	Instruction for use
17	Problems related to taking, preparation and stability of specimens	If the prepared sample is unqualified, the storage time is too long after sample processing, and the measuring range of the pipette is not correct during sample aspirating, the test result may be inaccurate	4	4	16	Clearly describe the precautions for sample operation in the manual, and prompt the user to store the sample	Instruction for use

18	Inadequate specification of prerequisites	Changes in the formulation of reagents and test strips may cause to change test values	4	4	16	Prepare according to the formulation of reagents and test strip related raw materials specified in the production SOP	Production SOP	

Abbreviations used

RE:Risk Evaluation S:Severity O: Risk frequency for the device during life. RL:Risk Level RRM:Risk Reduction Measure NH:New hazard generated ALOR:Acceptable Level of Risk

6 - Technical dossier: list of technical standards adopted

NO	Standard reference	Standard Title
1.	EN ISO 13485:2016	Medical devices—Quality management systems—Requirements for regulatory purposes
2.	EN ISO 14971:2012	Medical devices-Application of risk management to medical devices
3	ENISO 18113-1:2011	In vitro diagnostic medical devices—Information supplied by the manufacturer（labeling）Part1 terms，definition，general requirements
4	ENISO 18113-2:2011	In vitro diagnostic medical devices—Information supplied by the manufacturer（labeling）Part2 In vitro diagnostic reagents for professional use
5	EN ISO 23640:2015.	In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents
6	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
7	EN13641：2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
8	EN ISO 15223-1:2016	Medical devices-Symbols to used with medical device labels, labeling and information to be supplied-Part 1 General requirements

7 - Technical dossier: performance study

1.Evaluation Purpose

The purpose is to evaluate whether COVID-19 Antibody Rapid Test Kit produced by Global WholeHealth Partners Corp. meets product technical requirements.

2.Evaluation Scheme

COVID-19 Antibody Rapid Test Kit was evaluated by physical examination, minimum detection limit, negative coincidence rate, positive coincidence rate and repeatability of the product, respectively. These parameters are the contents of Product Technical Requirements

Such as the followings:

Research product Batch:20200201、20200202、20200203 model: cassette.

/strp

Auxiliary materials and instruments:

Negative specimens

Minimum detection limit reference, prepared by Cui

Positive reference，prepared by Cui

Negative reference，prepared by Cui

Repetitive reference, prepared by Cui

Timer, Vernier caliper

2.1 Physical examination

2.1.1Appearance

Requirements: the packing box shall be clean and tidy with complete components; the identification shall be correct; the product name, batch number, and validity period shall be clear; the instructions shall be clear and complete.

Methods :the contents of inner and outer package and label of the finished kit were checked.

2.1.2 Width of Strip

Requirements: Strip width ≥3.0mm

Method: Randomly select 3 pieces strips to be tested from each of the three batches finished products, tear the packaging bag and take out the strips, Then use vernier caliper to measure the strips width.

2.1.3Velocity of liquid moving

Requirements:≥20mm/min

Method: Randomly select 9 pieces strips to be tested from each of the three batches finished products, tear the packaging bag and take out the strips, test with Negative specimens, and start to use stopwatch when adding specimens, and stop timing when the specimens move to the end of absorbent paper.

2.2Minimum detectable amount

Requirements: test with minimum detectable amount:L1 is strongly positive，L2 is positive,L3 is weakly positive,L4 is negative.

Method: Randomly select 4 pieces strips to be tested from each of the three batches finished products, tear the packaging bag and take out the strips, test with Minimum detection limit reference, and observe the results within 10 minutes to 15 minutes.

2.3 Consistency of negative references:

Requirements: Test 10 negative references，the results are（-/-）10/10。

Method: Randomly select 1 pieces strips to be tested from each of the three batches finished products, tear the packaging bag and take out the strips, test with negative references, and observe the results within 10 minutes to 15 minutes.

2.4 Consistency of positive references

Requirements: Test 5 positive references, the results are（+/+）5/5.

Method: Randomly select 5 pieces strips to be tested from each of the three batches finished products, tear the packaging bag and take out the strips , test with positive references, and observe the results within 10 minutes to 15 minutes.

2.5Reproducibility

Requirements: Test precision reference (n = 10)，the results are all positive,and uniform chromaticity.

Method: Randomly select 10 pieces strips to be tested from each of the three batches finished products, tear the packaging bag and take out the strips , test with repetitive reference, and observe the results within 10 minutes to 15 minutes.

3.Evaluation data

3.1Appearance

Table 1 Test results for Appearance

Lot / Results / No	20200201	20200202	20200203

1	Packing box is clean and tidy with complete components; the identification is correct; the product name, batch number and validity period is clear; and the instructions for use is clear and complete.	Packing box is clean and tidy with complete components; the identification is correct; the product name, batch number and validity period is clear; and the instructions for use is clear and complete.	Packing box is clean and tidy with complete components; the identification is correct; the product name, batch number and validity period is clear; and the instructions for use is clear and complete.
2	Packing box is clean and tidy with complete components; the identification is correct; the product name, batch number and validity period is clear; and the instructions for use is clear and complete.	Packing box is clean and tidy with complete components; the identification is correct; the product name, batch number and validity period is clear; and the instructions for use is clear and complete.	Packing box is clean and tidy with complete components; the identification is correct; the product name, batch number and validity period is clear; and the instructions for use is clear and complete.
3	Packing box is clean and tidy with complete components; the identification is correct; the product name, batch number and validity period is clear; and the instructions for use is clear and complete.	Packing box is clean and tidy with complete components; the identification is correct; the product name, batch number and validity period is clear; and the instructions for use is clear and complete.	Packing box is clean and tidy with complete components; the identification is correct; the product name, batch number and validity period is clear; and the instructions for use is clear and complete.

Results：From the above results, appearance is conformed to product technical requirements.

3.2 Strip width

Table 2 Test results of strip width

Lot / No / Results	20200201	20200202	20200203
1	4.01 mm	3.99 mm	4.00 mm
2	4.02 mm	3.98 mm	4.00 mm
3	4.00 mm	4.02 mm	3.99 mm

Results： All f strip widths are greater than 3.0mm，so they are conformed to product technical requirements.

3.3Velocity of liquid moving

Table 3 Test results of Velocity of liquid moving

Lot / No / Results	20200201	20200202	20200203
1	41.8mm/min	42.0mm/min	42.0mm/min

2	42.9mm/min	44.8mm/min	43.1mm/min
3	45.8mm/min	42.1mm/min	41.8mm/min

Results：All velocities of liquid moving are no less than 20mm/min.so they are conformed to product technical requirements.

3.4Minimum detectable amount

Table 4 Test results of Minimum detectable amount

Lot / Reference / Results	20200201	20200202	20200203
L1	+	+	+
L2	+	+	+
L3	+	+	+
L4	-	-	-

Results：L1,L2,L3 and L4 are all in accordance with specified requirements ,so Minimum detectable amount is conformed to product technical requirements.

3.5 Consistency of negative references

Table 5 Test results of Consistency of negative references

Lot / Reference / Results	20200201	20200202	20200203
N1	-	-	-

N2	-	-	-
N3	-	-	-
N4	-	-	-
N5	-	-	-
N6	-	-	-
N7	-	-	-
N8	-	-	-
N9	-	-	-
N10	-	-	-

Results：all results are negative, so consistency of negative references is product technical requirements.

3.6Consistency of positive references

Table 6 Consistency of positive references of Test results

Lot / Reference / Results	20200201	20200202	20200203
P1	+	+	+
P2	+	+	+
P3	+	+	+
P4	+	+	+
P5	+	+	+

Results：All results are positive, so consistency of positive references is conformed to product technical requirements。

3.7Reproducibility

Table 7 Test results of Reproducibility

Lot / Reference / Results	20200201	20200202	20200203
J	+	+	+
J	+	+	+
J	+	+	+
J	+	+	+
J	+	+	+
J	+	+	+
J	+	+	+
J	+	+	+
J	+	+	+
J	+	+	+

Results：Cassette Batch 20200201、20200202、20200203 are separately used Reproducibility references ， Results are all positive and uniform chromaticity. So Reproducibility is conformed to product technical requirements.

3.8 Sensitivity, Specificity, Interference studies.

3.8.1 Sensitivity Study：

Clinical sample comparison test: Since the emergency nature of “out break”, there are

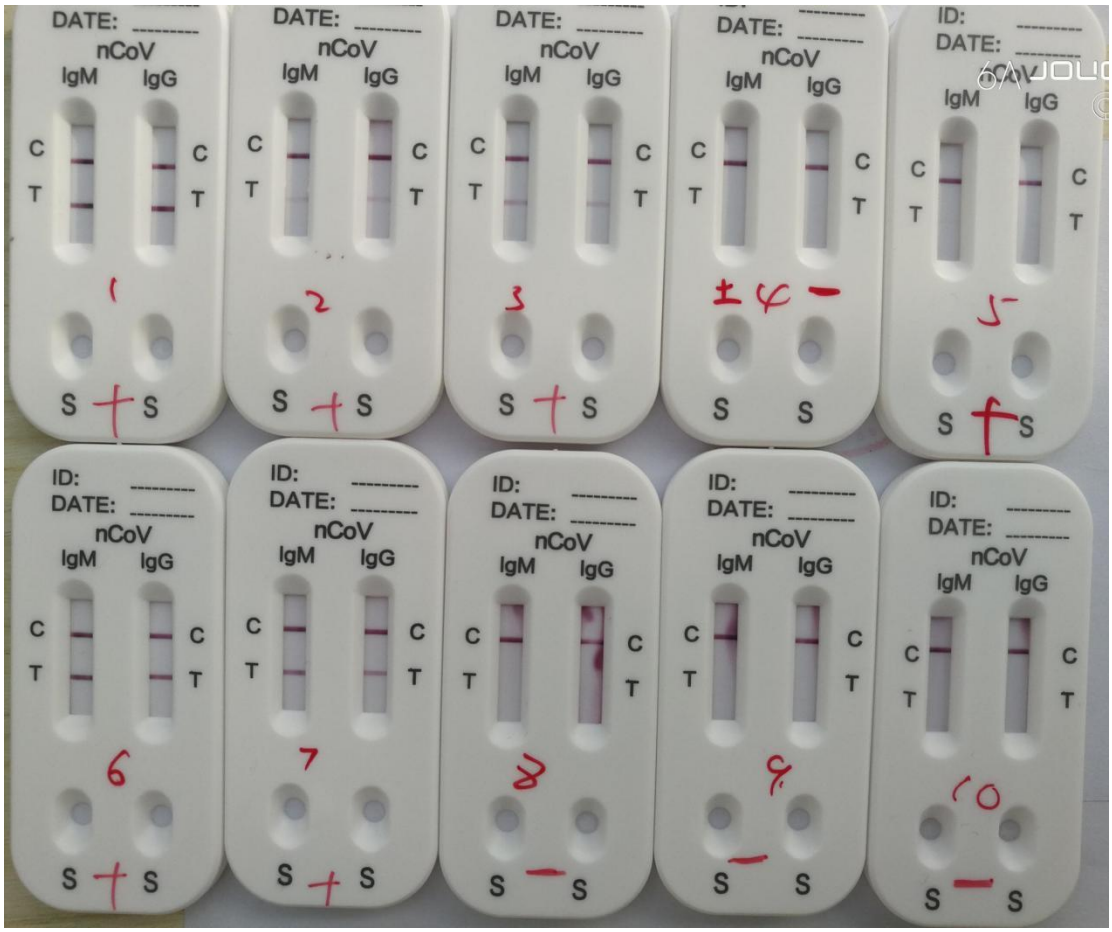
lack of conventional serum panels available to do comprehensive sensitivity studies. What are available currently in China sera from ***PCR*** diagnosed patients. In china, two companies have chines FDA cleared antibody rapid test(Colloidal Gold Method). We **purchased the IgM/IgG antibody test kit from Innovita** CO. LTD(cFDA approval no:202340017) as a predicate to compare the sensitivity with our test kits.

Fist, 10 PCR confirmed patient specimen has collected from 302 Beijing Hospital. Test procedures are followed through the instruction of use from Innovate 2019-nCOV antibody test kit(the predicate) and Global WholeHealth Partners Corp COVID-19 Antibody Test Kit(the test kit. Lot 20200203). Results are listed at Table 1.

NO / Result		1	2	3	4	5	6	7	8	9	10
Test	IgM/ IgG	+	+	+	+	+	+	+	+	+	+
Predicate	IgM	+	+	+	+	+	+	+	–	–	–
	IgG	+	+	+	–	+	+	+	–	–	–

Table-1 10 positive sera test results

Global antibody test results



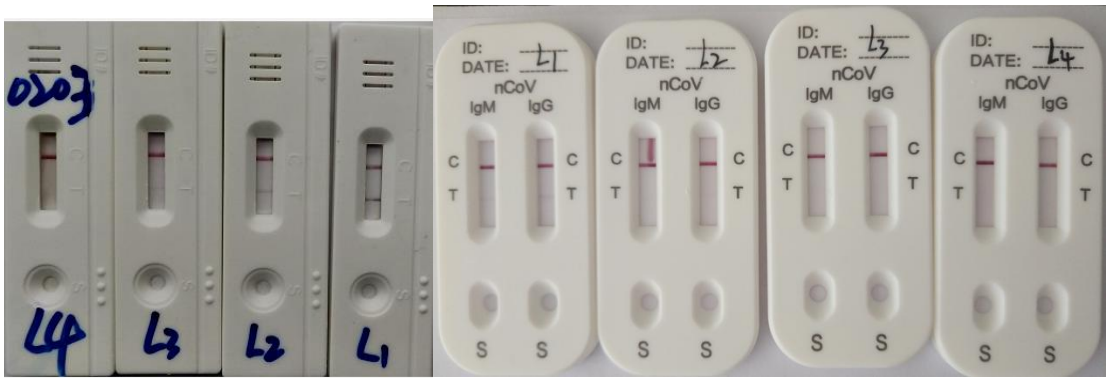
Innovita IgM/IgG antibody test results

Summary: Global's bio Antibody Rapid test, which detect total antibodies specific for CORVID-19 virus demonstrated a superior sensitivity compared with a Chinese FDA cleared rapid test.

3.8.2 Sensitivity control study:

Select a relative strong positive sample, Diluted with negative sera and tested with Innovita antibody kit and Global antibody kit.

	L1	L2	L3	L4
Dilution	1:25	1:50	1:100	negative
Global	+	+	+	-
INNOVITA IgM	+	+	-	-
INNOVITA IgG	+	+	-	-



Global Innovita

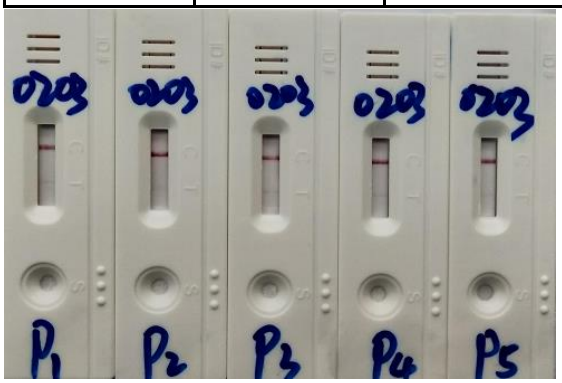
Conclusion: Global antibody can detect L1-L3. This sensitivity panel has been used as sensitivity test controls for each lot of product.

3.8.3 Positive Control Study:

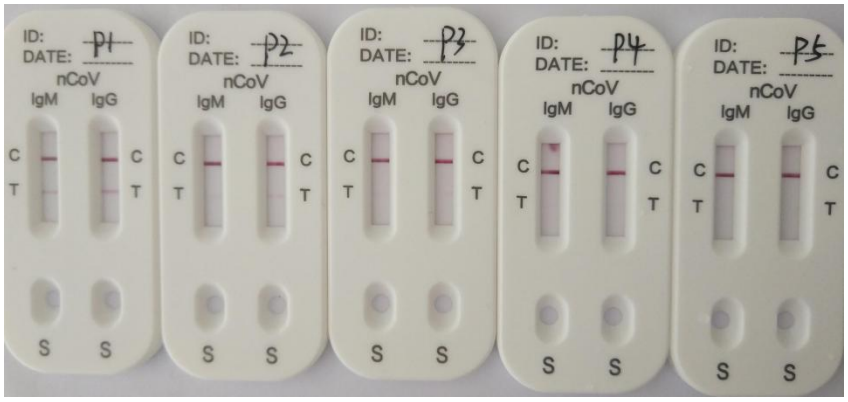
5 individual positive sera has been selected to make a positive control panel. Labeled as

P1,P2,P3,P4,P5.

	P1	P2	P3	P4	P5
Global	+	+	+	+	+
Innovita IgM	+	+	+	+	+
Innovita IgG	+	+	+	+	+



Global



Innovita

5 positive has been selected for positive control panel and strong, intermediate and weak positive are included.

3.8.4 Precision Control:

1 intermediate positive specimen has be used for precision control study. This precision control is named J. Each lot will be tested 10 repeats.

3.8.5 Negative control study:

10 sera from health subjects collected before the outbreak of CORVID-19, from 2018-6,2019. This panel serves negative control for each lot.

Global

Innoviat

Both Global and Innovita antibody test kits are all negative in test results.

So the company's control panel has been selected and reserved for QC of each lot product.

Control Panel Composition

Description	Number	Name	QC criteria
Positive control	5	P1-P5	+ 5/5
Negative Control	10	N1-N10	- 10/10
Sensitivity Control	4	L1,L2,L3,L4	L1,L2 + L3 +/- L4 -
Precision	1	J	Repeat10times All +, Uniform in color strength

Sample type	Results	
Bilirubin 1259 μmol/L	-	
Triglyceride 2027 μmol/L	-	
Hemoglobin 2mg/ml	-	
Rheumatoid factor 1900 RU/ml	-	

Interference Studies

3.8.6 Specificity Studies

Specimen Type	Confirm Method	No. Of sample	CORVID-19 antibody Test Results
Influenza A IgM	IFA	6	-
Influenza B IgM	IFA	4	-
Parainfluenza IgM	IFA	5	-
SRV IgM	IFA	3	-
Adenovirus	IFA	2	-
Mycoplasma Pneumonia IgM	IFA	2	-
Chylamedia Pneumonia IgM	IFA	2	-
HIV IgG	EIA	8	-
HBV IgG	EIA	8	-
HCV IgG	EIA	8	-
Syphilis IgG	EIA	8	-

For other corona virus antibody positive cross reactivity tests, we have not yet finished due to difficulties to find positive patient samples. This data will be submitted later.

420 negative sera specimen were collected between 2019.1-2019.5 from several hospitals stored at -20 C°. Those samples were collected form outbreak of CORVID-19, assumed to be negative for infection of CORID-19. Exclude for severe hemolysis, lipemia samples, total 402 were used to perform specificity experiment.

Total sample	Result (+)	Result(-)
402	7	395

Note： the positive is determined by any very faint or ghost line appeared at test line.

Specificity： 398/402=98.2%

4.Evaluation conclusion

By testing Physical examination, Minimum detectable amount, Consistency of negative references, Consistency of positive references, Reproducibility, these parameters from three continuous batches, 20200201,20200202 and 20200203,are all conformed to each performances in Product Technical Requirements.

Annex: test results pictures:

−　　+　　+　　+

Figure 1 Batch 20200201Minimum detectable amount

+　　+　　+　　+　　+

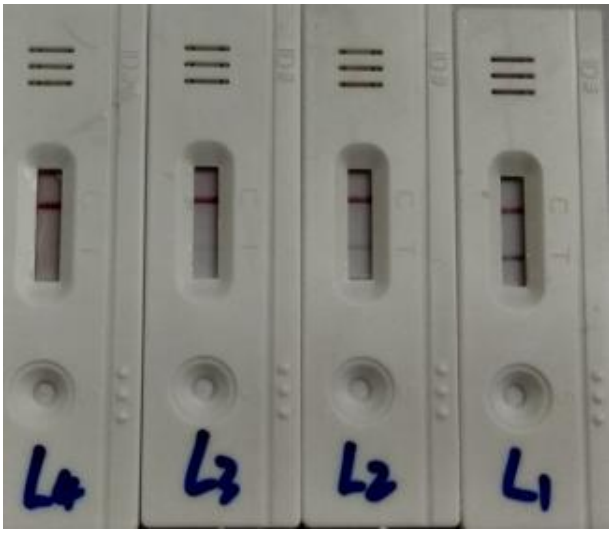
Figure 2 Batch 20200201Consistency of positive references

– – – – – – – – – –

Figure 3 Batch 20200201Consistency of negative references

+ + + + + + + + + +

Figure 4 Batch 20200201 Reproducibility



− + + +

Figure 5 Batch 20200202Minimum detectable amount

+ + + + +

Figure 6 Batch 20200202Consistency of positive references

– – – – – – – – – –

Figure 7 Batch 20200202Consistency of negative references

+ + + + + + + + + +

Figure 8 Batch 20200202Reproducibility

− + + +

Figure 9 Batch 20200203Minimum detectable amount

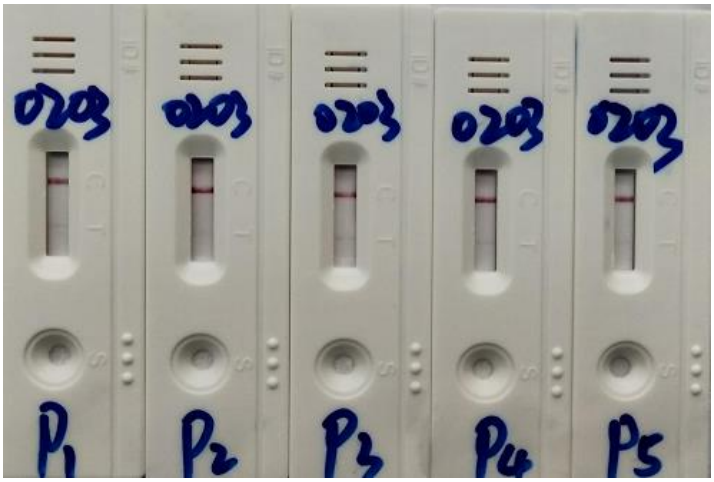


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Figure 10 Batch 20200203Consistency of positive references

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Figure 11 Batch 20200203Consistency of negative references

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Figure 12 Batch 20200203Reproducibility

8 - Technical dossier: performance study - product stability

Contents

1.0 Purpose

The purpose of the stability test is to demonstrate the stability of COVID-19 Antibody Rapid Test Kit(Colloidal Gold immunochromatography method). The test is designed for the evaluation of the test strip's performance characteristics in a long time period.

2.0 References

The study was conducted based on the requirements of the Enterprise Product Technical Requirements.

3.0 Compliance

The present study conformed to all applicable laws and regulations.

4.0 Study Scheme and results for Reagent Real-time Stability

4.1 Scheme

Test sample:

COVID-19 Antibody Rapid Test Kit (Colloidal Gold immunochromatography method)

Model: Cassette/strip

Lot Number: 20200201 Manufacture Date: 18/01/2020

Lot Number: 20200202 Manufacture Date: 20/01/2020

Lot Number: 20200203 Manufacture Date: 28/01/2020

Test condition

Temperature: 25°C

Humidity: normal state

Test date and duration

Duration: 3,6,9,12,15,18,20,22,24,26 months

Reagent Storage Condition:

2～30°C , sealed and avoid light

Test Performances Characteristics and Evaluation Criteria

Minimum detectable amount：L1 is strongly positive，L2 is positive,L3 is weakly

positive,L4 is negative.

Consistency of positive references：（+/+）5/5.

Consistency of negative references：（-/-）10/10.

Reproducibility：the results all positive, and uniform chromaticity.

If any one of the Performances is not conformed to the above Criteria, stop the experiment and prepare the next test.

4.2 Test results

Table 1 Test results of Minimum detectable amount

Batch	20200201	20200202	20200203
the first time	L1、L2、L3 are positive,L4 is negative ,compliant with Minimum detectable amount.	L1、L2、L3 are positive,L4 is negative ,compliant with Minimum detectable amount.	L1、L2、L3 are positive,L4 is negative ,compliant with Minimum detectable amount.
Test Date	20/1/2020	25/01/2020	30/1/2020

Table 2 Test results of Consistency of negative references

Batch	20200201	20200202	20200203
The first time	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.
Test Date	20/1/2020	25/01/2020	30/1/2020

Table 3 Test results of Consistency of positive references

Batch	20200201	20200202	20200203
The first time	The positive compliance rate was 5/5, which met the requirements of the product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of the product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of the product positive compliance rate.
Test Date	20/1/2020	25/01/2020	30/1/2020

Table 4 Test results of repeatability

Batch	20200201	20200202	20200203
The first time	The test results were all positive and consistent in color, which met the requirements of product repeatability.	The test results were all positive and consistent in color, which met the requirements of product repeatability.	The test results were all positive and consistent in color, which met the requirements of product repeatability.
Test Date	20/1/2020	25/01/2020	30/1/2020

4.3 Conclusion

Based on the results of real-time stability study: three consecutive batches of COVID-19 Antibody Rapid Test Kit (Colloidal Gold Immunochromatography Method)（Batch number：20200201、20200202、20200203）should be sealed and stored at 2～30°C in the avoiding sunlight for 26 months. The product performance Characteristics were tested in the 3,6,9,12,15,18,20,22,24,26 months. So far, only first time real-time stability observation record has been finished, and the experimental results are all in accordance with the Characteristics specified in the technical requirements. We will continue to carry out the follow-up stability study for 26 months. If the test results still meet the requirements, our company will determine its validity

period as 24 months, and the later stability study data will be supplemented during the review process.

5.0 Study Scheme and results for Reagent Accelerated Stability

5.1 Scheme

Test sample:

COVID-19 Antibody Rapid Test Kit (Colloidal Gold immunochromatography method)

Model: Cassette/strip

Lot Number:20200201/20200202/20200203

Test condition

Temperature: 25°C

Humidity: normal state

Test date and duration

Duration: 7,14,20,25 days

Reagent Storage Condition:

37°C , sealed and avoid light

Test Performances Characteristics and Evaluation Criteria

Minimum detectable amount ：L1 is strongly positive，L2 is positive,L3 is weakly positive,L4 is negative.

Consistency of negative references:（-/-）10/10

Consistency of positive references:（+/+）5/5.

Repeatability all positive and uniform chromaticity.

If any one of the Performances is not conformed to the above criteria,stop the experiment and prepare the next test.

5.2 Test results

Table 5 Detection result of Minimum detectable amount

Batch	20200201	20200202	20200203
Day 1	L1、L2、L3 are positive，L4 is negative，compliant with Minimum detectable amount	L1、L2、L3 are positive，L4 is negative，compliant with Minimum detectable amount.	L1、L2、L3 are positive，L4 is negative，compliant with Minimum detectable amount.
Test Date	20/01/2020	25/01/2020	30/01/2020
Day 7	L1、L2、L3 are positive，L4 is negative，compliant with Minimum detectable amount	L1、L2、L3 are positive，L4 is negative，compliant with Minimum detectable amount.	L1、L2、L3 are positive，L4 is negative，compliant with Minimum detectable amount.
Test Date	27/01/2020	01/02/2020	06/02/2020
Day 14	L1、L2are positive，L3、L4 are negative，compliant with Minimum detectable amount	L1、L2、L3 are positive，L4 is negative，compliant with Minimum detectable amount.	L1、L2、L3 are positive，L4 is negative，compliant with Minimum detectable amount.
Test Date	03/02/2020	08/02/2020	13/02/2020
Day 20	L1、L2are positive，L3、L4 are negative，	L1、L2、L3 are positive，L4 is negative，	L1、L2、L3 are positive，L4 is negative，

	compliant with Minimum detectable am ount	compliant with Minimum detectable am ount.	compliant with Minimum detectable am ount.
Test Date	09/02/2020	14/02/2020	19/02/2020
Day 25	L1、L2are positive，L3 、 L4 are negative ， compliant with Minimum detectable am ount	L1、L2、L3 are positive ，L4 is negative ， compliant with Minimum detectable am ount.	L1、L2、L3 are positive ，L4 is negative ， compliant with Minimum detectable am ount.
Test Date	14/02/2020	19/02/2020	24/02/2020

Note：Batch:20200201 ,20200202,20200203 was stored at 37℃ for 25 days separately.

Table 6 Test result of Consistency of negative references

Batch	20200201	20200202	20200203
Day 1	The negative compliance rate is 10/10, which meets the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.
Test Date	20/1/2020	25/01/2020	30/01/2020
Day 7	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.
Test Date	27/1/2020	01/02/2020	06/02/2020

Day 14	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.
Test Date	03/02/2020	08/02/2020	13/02/2020
Day 20	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.
Test Date	09/02/2020	14/02/2020	19/02/2020
Day 25	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.
Test Date	14/02/2020	19/02/2020	24/02/2020

Note：Batch:20200201,20200202,20200203 was stored at 37℃ for 25 days separately.

Table7 Test result of Consistency of positive references

Batch	20200201	20200202	20200203
Day 1	The positive compliance rate was 5/5, which met the requirements of	The positive compliance rate was 5/5, which met the requirements of	The positive compliance rate was 5/5, which met the requirements of

	product positive compliance rate.	product positive compliance rate.	product positive compliance rate.
Test Date	20/1/2020	25/01/2020	30/01/2020
Day 7	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.
Test Date	27/1/2020	01/02/2020	06/02/2020
Day 14	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate./
Test Date	03/02/2020	08/02/2020	13/02/2020
Day 20	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.
Test Date	09/02/2020	14/02/2020	19/02/2020
Day 25	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.
Test Date	14/02/2020	19/02/2020	24/02/2020

Note：Batch:20200201,20200202,20200203 was stored at 37℃ for 25 days separately.

Table8 Test results of repeatability

Batch	20200201	20200202	20200203
Day 1	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.
Test Date	20/1/2020	25/01/2020	30/01/2020
Day 7	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.
Test Date	27/1/2020	01/02/2020	06/02/2020
Day 14	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.
Test Date	03/02/2020	08/02/2020	13/02/2020
Day 20	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.
Test Date	09/02/2020	14/02/2020	19/02/2020

Day 25	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.
Test Date	14/02/2020	19/02/2020	24/02/2020

Note：Batch:20200201,20200202,20200203 was stored at 37℃ for 25 days separately.

5.3 Conclusion

Based on the results of accelerated stability study, three consecutive batches of COVID-19 Antibody Rapid Test Kit including Batch 20200201 stored at 37℃ for 25 days, Batch 20200202 and 20200203 stored at 37℃ for 25 days separately. Test the product performance characteristics. The experimental results are all in line with the characteristics specified in the technical requirements.

6.0 Study Scheme and results for Reagent Transport Stability

6.1 Scheme

Test sample:

COVID-19 Antibody Rapid Test Kit (Colloidal Gold immunochromatography method)

Model: Cassette/strip

Lot Number:20200201/20200202/20200203

Test condition

Temperature: 25°C

Humidity: 50-70%

Test date and duration

Duration: 3,5,7 days

Reagent Simulation Transport Condition:

40°C , sealed and avoid light

Test Performances Characteristics and Evaluation Criteria

Minimum detectable amount ：L1 is strongly positive，L2 is positive,L3 is weakly positive,L4 is negative.

Consistency of negative references:（-/-）10/10

Consistency of positive references:（+/+）5/5.

Repeatability all positive and uniform chromaticity.

If any one of the Performances is not conformed to the above Criteria, stop the experiment and prepare the next test.

6.2 Test results

Table 9 The test results of Minimum detectable amount

Batch	20200201	20200202	20200203
Day 3	L1、L2、L3 are positive , L4 is negative , compliant with Minimum detectable am ount	L1、L2、L3 are positive , L4 is negative , compliant with Minimum detectable am ount.	L1、L2、L3 are positive , L4 is negative , compliant with Minimum detectable am ount.
Test Date	20/02/2020	20/02/2020	20/02/2020

Day 5	L1、L2、L3 are positive，L4 is negative，compliant with Minimum detectable amount	L1、L2、L3 are positive，L4 is negative，compliant with Minimum detectable amount.	L1、L2、L3 are positive，L4 is negative，compliant with Minimum detectable amount.
Test Date	22/02/2020	22/02/2020	22/02/2020
Day 7	L1、L2are positive，L3、L4 are negative，compliant with Minimum detectable amount	L1、L2、L3 are positive，L4 is negative，compliant with Minimum detectable amount.	L1、L2are positive，L3、L4 are negative，compliant with Minimum detectable amount.
Test Date	24/02/2020	24/02/2020	24/02/2020

Table 10 Test result of Consistency of negative references

Batch	20200201	20200202	20200203
Day 3	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.
Test Date	20/02/2020	20/02/2020	20/02/2020
Day 5	The negative compliance rate was 10 / 10, which met the requirements of the	The negative compliance rate was 10 / 10, which met the requirements of the	The negative compliance rate was 10 / 10, which met the requirements of the

	product negative compliance rate.	product negative compliance rate.	product negative compliance rate.
Test Date	22/02/2020	22/02/2020	22/02/2020
Day 7	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.
Test Date	24/02/2020	24/02/2020	24/02/2020

Table11 Test result of Consistency of positive references

Batch	20200201	20200202	20200203
Day 3	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.
Test Date	20/02/2020	20/02/2020	20/02/2020
Day 5	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.

Test Date	22/02/2020	22/02/2020	22/02/2020
Day 7	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.
Test Date	24/02/2020	24/02/2020	24/02/2020

Table12 Test results of repeatability

Batch	20200201	20200202	20200203
Day 3	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.
Test Date	20/02/2020	20/02/2020	20/02/2020
Day 5	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.
Test Date	22/02/2020	22/02/2020	22/02/2020
Day 7	The test results were positive and consistent in color, which met the	The test results were positive and consistent in color, which met the	The test results were positive and consistent in color, which met the

	requirements of product repeatability.	requirements of product repeatability.	requirements of product repeatability.
Test Date	24/02/2020	24/02/2020	24/02/2020

6.3 Conclusion

According to the experimental results of transport stability study: COVID-19 Antibody Rapid Test Kit (Batch number: 20200201, 20200202, 20200203) was used to simulation transport stability for 7 days, and product performance characteristics were tested on the 3rd, 5th and 7th days, respectively. The results met product technical requirements .The transport conditions of the kit were determined to be below 30℃.Transport time in high temperature (30-40℃)season shall not exceed 7 days, or transport with necessary actions for lowering the temperature.

7.0 Study Scheme and results for Reagent Open bag Stability

7.1 Scheme

Test sample:

COVID-19 Antibody Rapid Test Kit (Colloidal Gold immunochromatography method)

Model: Cassette/strip

Lot Number:20200201/20200202/20200203

Test condition

Temperature: 25°C

Humidity: normal state

Method:

Pouches were opened and placed at room temperature. Bags will be placed for lasting 10 min, 20 min, 30 min and 35 min, respectively. Then test Performances Characteristic

Test Performances Characteristics and Evaluation Criteria

Minimum detectable amount ：L1 is strongly positive，L2 is positive,L3 is weakly positive,L4 is negative.

Consistency of negative references:（-/-）10/10

Consistency of positive references:（+/+）5/5.

Repeatability all positive and uniform chromaticity.

If any one of the Performances is not conformed to the above Criteria,stop the experiment and prepare the next test.

7.2 Test results

Table 13 Test results of Minimum detectable amount

Batch	20200201	20200202	20200203
open bag	L1、L2、L3 are positive，L4 is negative, compliant with Minimum detectable amount.	L1、L2、L3 are positive，L4 is negative, compliant with Minimum detectable amount	L1、L2、L3 are positive，L4 is negative, compliant with Minimum detectable amount
10min	L1、L2、L3 are positive，L4 is negative, compliant with	L1、L2、L3 are positive，L4 is negative, compliant with	L1、L2、L3 are positive，L4 is negative, compliant with

	Minimum detectable am ount.	Minimum detectable am ount	Minimum detectable am ount
20min	L1、L2、L3 are positive , L4 is negative, compliant with Minimum detectable am ount.	L1、L2、L3 are positive , L4 is negative, compliant with Minimum detectable am ount	L1、L2、L3 are positive , L4 is negative, compliant with Minimum detectable am ount
30min	L1、L2、L3 are positive , L4 is negative, compliant with Minimum detectable am ount.	L1、L2、L3 are positive , L4 is negative, compliant with Minimum detectable am ount	L1、L2、L3 are positive , L4 is negative, compliant with Minimum detectable am ount
35min	L1、L2、L3 are positive , L4 is negative, compliant with Minimum detectable am ount.	L1、L2、L3 are positive , L4 is negative, compliant with Minimum detectable am ount	L1、L2、L3 are positive , L4 is negative, compliant with Minimum detectable am ount
Test Date	23/02/2020	23/02/2020	23/02/2020

Table 14 Test result of Consistency of negative references

Batch	20200201	20200202	20200203
open bag	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.
10min	The negative compliance rate was 10 / 10, which met the requirements of the	The negative compliance rate was 10 / 10, which met the requirements of the	The negative compliance rate was 10 / 10, which met the requirements of the

	product negative compliance rate.	product negative compliance rate.	product negative compliance rate.
20min	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.
30min	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.
35min	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 9 / 10, which met the requirements of the product negative compliance rate.	The negative compliance rate was 10 / 10, which met the requirements of the product negative compliance rate.
Test Date	23/02/2020	23/02/2020	23/02/2020

Table15 Test result of Consistency of positive references

Batch	20200201	20200202	20200203
open bag	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.

10min	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.
20min	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.
30min	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.
35min	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.	The positive compliance rate was 5/5, which met the requirements of product positive compliance rate.
Test Date	23/02/2020	23/02/2020	23/02/2020

Table 16 Test results of repeatability

Batch	20200201	20200202	20200203
open bag	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.
10min	The test results were positive and consistent	The test results were positive and consistent	The test results were positive and consistent

	in color, which met the requirements of product repeatability.	in color, which met the requirements of product repeatability.	in color, which met the requirements of product repeatability.
20min	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.
30min	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.
35min	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.	The test results were positive and consistent in color, which met the requirements of product repeatability.
Test Date	23/02/2020	23/02/2020	23/02/2020

7.3 Conclusion

According to the results of open bag stability study: three consecutive batches of COVID-19 Antibody Rapid Test Kit (Batch number: 20200201, 20200202, 20200203) were placed at room temperature after opening bags, and the product performance characteristics were tested under open bags, placed for 10 min, 20 min, 30 min, 35 min. The results met the technical requirements of the product. So time of the kit open bag stability is finally determined to be 30 min.

8.0 Study Scheme and results for Specimen Stability

8.1 Scheme

Test sample:

COVID-19 Antibody Rapid Test Kit (Colloidal Gold immunochromatography method)

Model: Cassette/strip

Lot Number:20200201/20200202/20200203

Test Specimen:

5 pieces positive specimens of COVID-19 antibody, Number: 36#、37#、38#、39#、40#

5 pieces negative specimens of COVID-19 antibody, Number : 6#、7#、8#、9#、10#.

Test date and duration

Duration: 1,3,5,7 days

Specimen Storage Condition:

2～8°C , sealed and avoid light

Test Performances Characteristics and Evaluation Criteria

Observe whether specimens are changed after 1,3,5,7 days

Observe whether specimens are changed after repeated freezing and thawing.

8.2 Test results

Table 17 Result 1 of the influence on the specimen under the condition of 2 ℃ ~ 8 ℃

Table 18 Result 2 of the influence on the specimen under the condition of2 ℃ ~ 8 ℃

Kit batch	20200201									
Specimen number	36#	37#	38#	39#	40#	6#	7#	8#	9#	10#
Day 1	+	+	+	+	+	-	-	-	-	-
Day 3	+	+	+	+	+	-	-	-	-	-
Day 5	+	+	+	+	+	-	-	-	-	-
Day 7	+	+	+	+	+	-	-	-	-	-
Test Date	Day1:24/02/2020,Day3:26/02/2020,Day5:28/02/2020,Day7:30/02/2020									
Kit batch	20200203									
Specimen	36#	37#	38#	39#	40#	6#	7#	8#	9#	10#
Day 1	+	+	+	+	+	-	-	-	-	-
Day 3	+	+	+	+	+	-	-	-	-	-
Day 5	+	+	+	+	+	-	-	-	-	-
Day 7	+	+	+	+	+	-	-	-	-	-
Test Date	Day1:24/02/2020,Day3:26/02/2020,Day5:28/02/2020,Day7:30/02/2020									

Table 19 Result 3 of the influence on the specimen under the condition of 2 ℃ ~ 8 ℃

Kit batch	20200202

Specimen number	36#	37#	38#	39#	40#	6#	7#	8#	9#	10#
Day 1	+	+	+	+	+	-	-	-	-	-
Day 3	+	+	+	+	+	-	-	-	-	-
Day 5	+	+	+	+	+	-	-	-	-	-
Day 7	+	+	+	+	+	-	-	-	-	-
Test Date	Day1:24/02/2020,Day3:26/02/2020,Day5:28/02/2020,Day7:30/02/2020									

Table 20 Result 4 influence of repeated freezing and thawing on specimen

Kit batch		20200201									
Specimen		36#	37#	38#	39#	40#	6#	7#	8#	9#	10#
Times of freezing and thawing	1	+	+	+	+	+	-	-	-	-	-
	2	+	+	+	+	+	-	-	-	-	-
	3	+	+	+	+	+	-	-	-	-	-
	4	+	+	+	+	+	-	-	-	-	-
	5	+	+	+	+	+	-	-	-	-	-
	6	+	+	+	+	+	-	-	-	-	-
	7	+	+	+	+	+	-	-	-	-	-
	8	+	+	+	+	+	-	-	-	-	-

	9	+	+	+	+	+	-	-	-	-	-
	10	+	+	+	+	+	-	-	-	-	-
Test Date	24/02/2020										

Table 21 Results 5 of the influence of repeated freezing and thawing on specimens

Kit batch		20200202									
Specimen		36#	37#	38#	39#	40#	6#	7#	8#	9#	10#
Times of freezing and thawing	1	+	+	+	+	+	-	-	-	-	-
	2	+	+	+	+	+	-	-	-	-	-
	3	+	+	+	+	+	-	-	-	-	-
	4	+	+	+	+	+	-	-	-	-	-
	5	+	+	+	+	+	-	-	-	-	-
	6	+	+	+	+	+	-	-	-	-	-
	7	+	+	+	+	+	-	-	-	-	-
	8	+	+	+	+	+	-	-	-	-	-
	9	+	+	+	+	+	-	-	-	-	-
	10	+	+	+	+	+	-	-	-	-	-

Test Date	24/02/2020

Table 22 Result 6 of the influence of repeated freezing and thawing of card type on specimens

Kit batch		20200203									
Specimen		36#	37#	38#	39#	40#	6#	7#	8#	9#	10#
Times of freezing and thawing	1	+	+	+	+	+	-	-	-	-	-
	2	+	+	+	+	+	-	-	-	-	-
	3	+	+	+	+	+	-	-	-	-	-
	4	+	+	+	+	+	-	-	-	-	-
	5	+	+	+	+	+	-	-	-	-	-
	6	+	+	+	+	+	-	-	-	-	-
	7	+	+	+	+	+	-	-	-	-	-
	8	+	+	+	+	+	-	-	-	-	-
	9	+	+	+	+	+	-	-	-	-	-
	10	+	+	+	+	+	-	-	-	-	-
Test Date		24/02/2020									

8.3 Conclusion

According to the results of specimens stability study： Three consecutive batches of COVID-19 Antibody Rapid Test Kit（Batch number：20200201、20200202、20200203）The test samples were kept at 2 ℃ ~ 8 ℃ for 7 days, and repeated freezing and thawing should not exceed 10 times, which had no effect on the test results.

9 - Technical dossier: performance study - clinical performance

Clinical Agreement Study

Statistical analysis of data

From February 2 to February 10,2020, the specimens of 60 patients were tested in the Fifth Medical Center of PLA General Hospital. The clinical diagnostic information of 60 patients were all "new coronavirus pneumonia". The results of the gold standard RT-PCR reagent test were all positive in 60 cases, and the results of the test reagent were all positive in 60 cases.

From February 16 to February 18, 2020,the specimens of 30 patients were tested at Zhengzhou Center for Disease Control and Prevention . The clinical diagnostic results of 30 patients were all "new coronavirus pneumonia". The results of gold standard RT-PCR reagent test were all positive, and the test reagent’s test results were positive in 29 cases.

From March 8th to March 20th, 75 cases of diagnosed patients at Wuhan Huoshengshan Hospital were tested. 67cases were positive with the test reagent.

From March 12th to March 20th, 81 cases of diagnosed patients at Wuhan women and children hospital were tested.76 cases were positive with the test reagent.

Total tested diagnosed patients were 246 cases from 4 medical institutions and positive for the test device were 232 case.

420 negative sera specimen were collected between 2019.1-2019.5 from several hospitals stored at -20 C°. Those samples were collected before outbreak of CORVID-19, assumed to be negative for infection of CORID-19. Exclude for severe hemolysis, lipemia samples, total 388 were used to perform specificity experiment.

Data Analysis

Antibody Test Results	Clinical diagnosis		
	positive	negative	Total samples
Positive	232	7	239
negative	14	381	395
Total samples	246	388	634

Calculation: (1) Sensitivity: 232/246=94.3%

(2) Specificity:381/388=98.2%

(3) Overall coincidence rate: (232+381)/634=96.7%

(4) PPV： 232/(232+7)x100%=97.1%

(5) NPV: 381/(381+14)x100%=96.4%

10 - Technical dossier: performance study - addresses of manufacturing units

Licensed R&D team: Nexus Alliance Corp.

Telephone: 321-945-4283

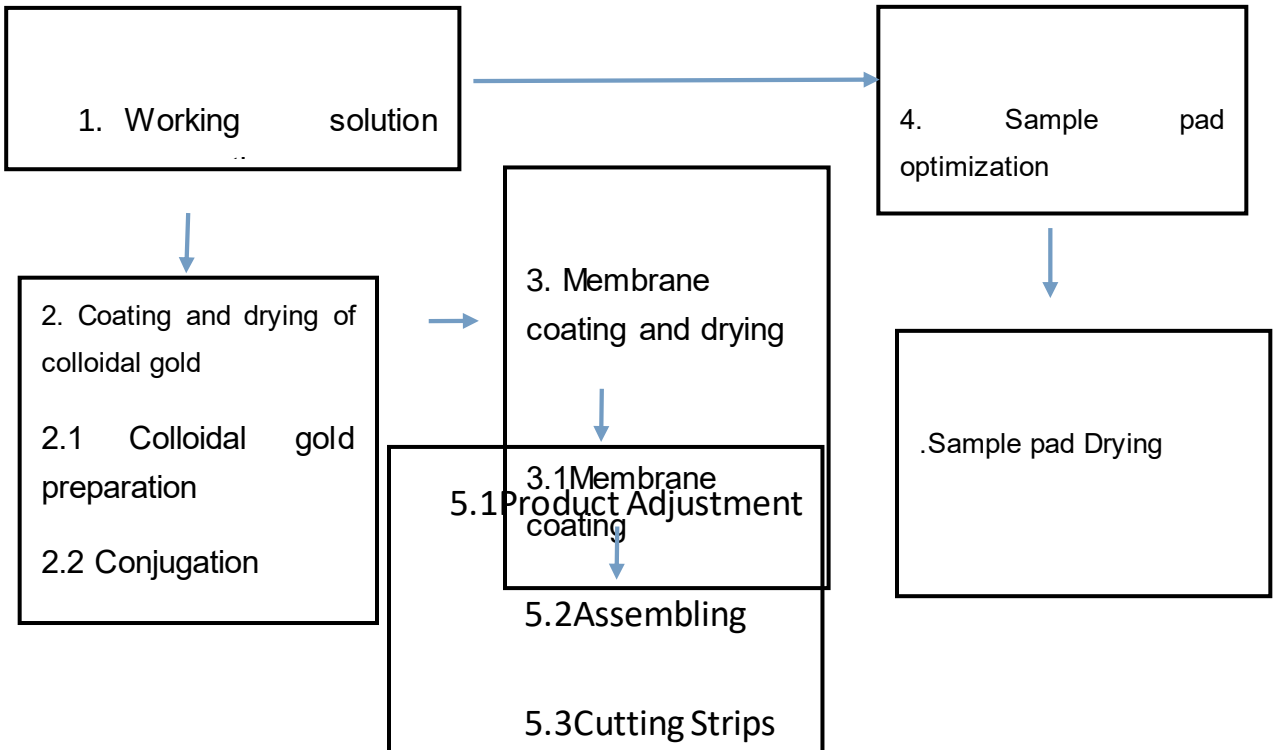
Contact person: Timothy Allen, MD, PhD.

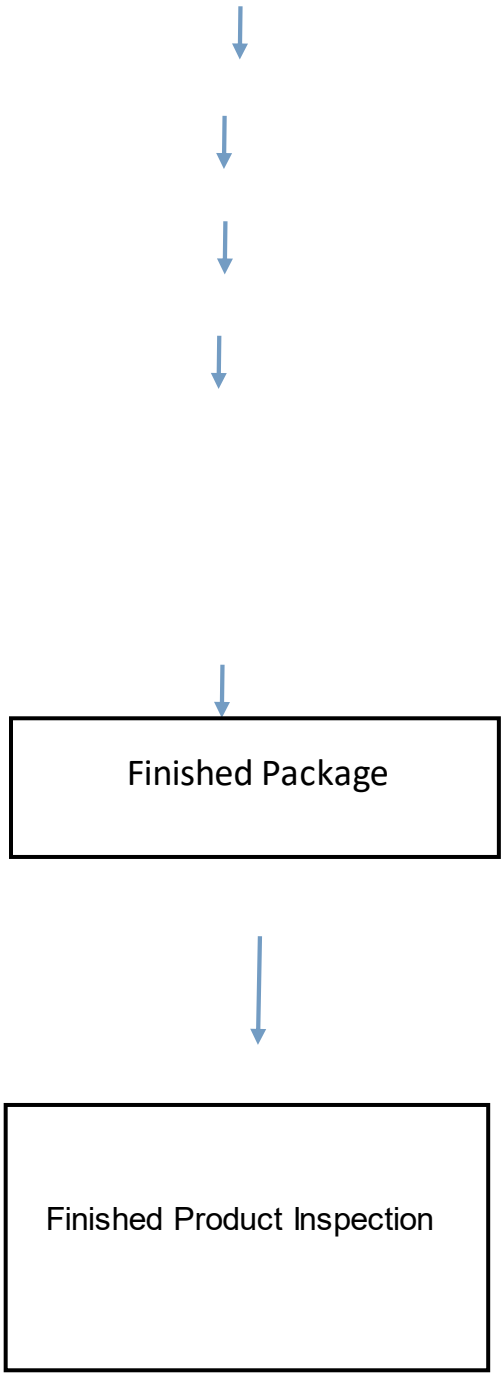
Email: Timothy.Allen@TakeChargemedical.com

Website: www.NexusAllianceBiopharma.com

11 - Technical dossier: performance study - manufacturing processes, containing the flowchart of the product

1Production process flow chart





※：Key procedure.　　☆：Special procedure

Procedure 1,2,3 and 4 are performed in the 10^5Class Cleaning-room, humidity under 30%.

Procedure 5 are performed in the 10^5Class drying Cleaning-room

2 Description of production process flow chart

2.1Working solution preparation

To prepare various solutions for subsequent processes such as colloidal gold coating process and membrane coating process.

2.2Coating and drying of colloidal gold

- Colloidal gold Preparation: Colloidal gold particles were prepared by trisodium citrate dihydrate reduction method.
- Conjugation: conjugation of 2019-nCoV-NF antigen and mouse IgG.
- Centrifugation: Colloidal gold conjugates are precipitated by high-speed centrifugation.
- Conjugate pad preparation: The 2019-nCoV-NF protein colloidal gold conjugates after centrifugation and the mouse IgG colloidal gold conjugate after centrifugation were mixed with dilution buffer(GB) at a certain proportion and evenly coated on the treated glass fibers.
- Drying: Dry the gold conjugate pad.

2.3 Membrane coating and drying

- Membrane coating: The appropriate concentration of 2019-nCoV NC protein and goat anti-mouse IgG were coated on the nitrocellulose membrane by a Jet Sprayer and the test line and quality control line were prepared.
- Membrane drying: drying nitrocellulose membranes.

- Intermediate product inspection

2.4 Intermediate product assembly

- Quality test: combination of prepared conjugated pad and coated membrane were tested to meet the product standards.
- Assembly: The sample pad, colloidal gold conjugate pad, nitrocellulose membrane, water absorbent pad, etc. Are assembled on the PVC base plate.

2.5Intermediate product board inspection

The test strips of intermediate products are inspected in accordance with the standard operating procedures for intermediate products inspection, and then enter the next process after being qualified.

2.6 Finished product assembly

2.6.1 Assemble

- Strip assembly: cut the intermediate board into test strips, and then put the test strips and desiccants into the aluminum foil bags.
- Card type assembly: cut the intermediate sheet into test strips, put the test strips into plastic cards, and then put the plastic cards and desiccants into aluminum foil bags.

2.6.2 Packaging: heat-seal the packaged aluminum foil bags with a sealing machine.

2.6.3 Packaging: Pack the packaged aluminum foil bags and instructions into the packaging box, and seal the label.

2.7 Finished Product Inspection: Inspection is carried out according to the

Standard Operating Procedures for Finished Product Inspection.