Clinical Validation Report on IVD Kits

Product Name: SARS-CoV-2 (COVID-19) Antibody Test Kit (GICA)

Model and Specifications: 20 tests/kit, packed independently

Type of Clinical Tests: clinical validation

Date of Commence of Clinical Tests: February 14, 2020

Date of Completion of Clinical Tests: February 18, 2020

Validated by: Beijing Aipuyi Medical Inspection Center

Abstract of Research

To evaluate clinical applications of the SARS-CoV-2 (COVID-19) antibody test kit (GICA) produced by Beijing Lepu Medical Technology Co., Ltd. to in-vitro qualitative tests on the content of the SARS-CoV-2 antibody in clinical samples (serum/plasma), a clinical research has been made by Beijing Aipuyi Medical Inspection Center for this test strip. In total, 220 serum samples were selected from clinical ones as the objects of research, with the 2019-nCoV antibody test kit (colloidal-gold) produced by Innovita (Tangshan) Biotechnology Co., Ltd. as a reference product. The objects of research were classified into the positive group and the negative group by comparing test results of these products. Meanwhile, these samples were tested via a test card, to compare the test results of the product tested and those of the reference product, with statistical analysis being made. The coincidence rate of positive/negative and the total coincidence rate of both products were proven higher than 90% in comparison, indicating favorable consistency with the reference product. In the analysis results of Kappa inspection, Kappa was proven >0.8, indicating favorable and high consistency of both methods. Both systems were proven equivalent. The product tested is applicable to auxiliary clinical diagnosis.

I Foreword

As a large family of virus, coronavirus is a single plus strand RNA virus featured by envelopes. As known to us, such virus can trigger major diseases such as cold, Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). SARS-CoV-2 was identified in the cases of viral pneumonia in Wuhan, 2019 and was named officially by WHO on January 12, 2020. As a core protein of SARS-CoV-2, N protein (Nucleocapsid) is a component inside the virus, and is relatively conservative among category-β coronaviruses and is a common tool for diagnosis on coronaviruses. As a key receptor for SARS-CoV-2's entry in the cell, ACE2 is of great significance for research on the virus infection mechanism.

The R&D work concerning the SARS-CoV-2 antibody test kit (GICA) of the Company has been accomplished. To validate the applicability and accuracy of such test strip on clinical applications, clinical validation is carried out. Beijing Aipuyi Medical Inspection Center was entrusted by Beijing Lepu Medical Technology Co., Ltd. with clinical tests of the SARS-CoV-2 antibody test kit (GICA) produced by it. In total, 220 samples were involved in this clinical research.

II Purpose of Research

To validate the applicability and accuracy of the SARS-CoV-2 antibody test kit (GICA) produced by Beijing Lepu Medical Technology Co., Ltd. in clinical applications, a systematic research is required for its clinical properties.

The purpose of research of this clinical test is: calculate the consistency percentage of negative/positive and the total consistency percentage and the Kappa coefficient by making statistics of and analyzing test results through comparative experimental research for the followings for the same clinical sample: the SARS-CoV-2 antibody test kit (GICA) produced by Beijing Lepu Medical Technology Co., Ltd., the product tested, and the 2019-nCoV antibody test kit (colloidal-gold) (registration certificate No.: GXZZ 20203400177) produced by Innovita (Tangshan) Biotechnology Co., Ltd., a reference product. The equivalence between the product tested and the reference product is verified according to the results of statistical analysis, so as to validate the applicability and accuracy of the product tested in auxiliary clinical diagnosis.

The results of this clinical test are important basis for evaluating the effectiveness and safety of the product tested.

III Test Management

1. General introduction to the management structure

This clinical test was undertaken by the clinical unit of Beijing Aipuyi Medical Inspection Center. As the applicant, Beijing Aipuyi Medical Inspection Center is responsible for communications in clinical tests.

2. Quality control in the lab

1) All those engaged in research on clinical tests are proven eligible through qualification examinations and have professional background and capabilities required for clinical tests. All such personnel have been trained before such tests, acquiring comprehensive understanding for the protocol of such tests and specifics of various indexes.

2) As for quality control in the lab, the requirements for quality control specified by the laboratory departments shall be followed, to guarantee standardized test operations.

3) Pre-analysis quality control: the process of sample collection and treatment shall be checked to see whether relevant requirements are met, and whether information such as sample number is correct.

4) The progress and completions of clinical tests shall be regularly checked. Besides, the completeness and accuracy of the information concerning clinical samples shall be checked, and the test results shall be verified.

3. Statistics and data management

1) All the cases included shall be included in the summary on clinical results, and the sample number, age and gender of the subjects shall be recorded in the table. The test personnel will complete the test results of both the reference product and the product tested in the summary on clinical results.

2) The main researchers, test personnel and the sponsor shall review the data jointly upon completion of data entry, and such data shall be locked if without any doubt.

3) The summary on clinical results shall be submitted to those engaged in statistical analysis. The results of statistical analysis obtained shall be included in corresponding part of the clinical report.

4. Storage of materials

The materials related to clinical tests shall be reserved by the test unit and the applicant (one copy each), including the following materials:

The protocol/scheme of clinical tests, the report of clinical tests and the summary on clinical results.

5. Problems identified in research and countermeasures

In clinical tests, the test results of the reference sample and the tested sample are different for a small number of samples. In this case, the qualitative clinical data of such sample shall be adopted or other common test strips clinically produced of the same principle shall be used for repetitive tests.

IV Test Design

1. Overall design of tests and description of the scheme

A proper object of research shall be selected by reference to the *Technical Guidelines for Clinical Research of IVD Kit*. The SARS-CoV-2 antibody test kit (GICA) whose marketing is

approved is adopted as the reference reagent for synchronous comparison through the blind method. The consistency percentage of positive/negative and the total consistency percentage and the Kappa coefficient of the product and the reference reagent shall be analyzed.

Test scheme: 220 cases of serum are selected as the objects of research from clinical cases. The sample is classified into the positive group and the negative group as per the test results of the reference product. Meanwhile, the sample shall be tested via the qualitative test strip tested and the reference one and then the test results of the product tested and the reference product shall be compared, with statistical analysis being made. The consistency percentage of negative/positive and the total consistency percentage and the Kappa coefficient shall be calculated and the applicability and accuracy of the product tested for clinical diagnosis shall be judged based on this. The consistency in diagnosis in test results of the product and the reference product shall be judged through Kappa inspection and analysis. Moreover, the consistency in test results of the serum sample of Beijing Lepu Medical Technology Co. shall be analyzed, and the Kappa coefficient shall be calculated.

2. research methods

1) Collection, saving and transportation methods of sample

The specimen collected shall be used up immediately. Long-term storage of the specimen under room temperature is not allowed. The serum shall be separated out as soon as possible, to avoid hemolysis. The specimen subjected to hemolysis cannot be used any more. The serum/plasma specimen can be saved for three days at 2-8°C. It shall be frozen (-20°C) if long-term storage is required. Repeated freezing and thawing shall be avoided.

3) Determination of the reference methods

The 2019-nCoV antibody test kit (colloidal-gold) (registration certificate No.: GXZZ 20203400177) produced by Innovita (Tangshan) Biotechnology Co., Ltd. is one of the earliest products testing 2019-nCoV antibody whose marketing is approved in China. Such kit is the product adopting the same test (GICA) method as the SARS-CoV-2 antibody test kit (GICA) produced by Beijing Lepu Medical Technology Co., Ltd. and is widely applied clinically. It is generally believed that such kit has superior quality. The purpose and scope of clinical applications of such product are the same as the product tested. Therefore, such product is selected as one of the reference reagents for clinical research.

The sample with inconsistent determination results for the group tested and the reference group in comparative experimental research can be verified through the quantitative clinical results and clinical diagnostic results.

4) Name, specifications, source, batch number, period of validity and storage conditions of all products for clinical research

The name of the product for clinical research is the SARS-CoV-2 antibody test kit (GICA) (10 tests/kit). Such product is provided by Beijing Lepu Medical Technology Co., Ltd. and the batch number is 20CG2501X. Its period of validity is 12 months and the storage condition is 4°C~30°C.

The reference test strip is the 2019-nCoV antibody test kit (colloidal-gold) (20 tests/kit) produced by Innovita (Tangshan) Biotechnology Co., Ltd. and the period of validity is 6 months. The storage condition is 10°C~30°C.

5) Quality control methods

The progress and completions of clinical tests shall be regularly checked. Besides, the completeness and accuracy of the information concerning clinical samples shall be checked, and the test results shall be verified.

6) Methods of clinical tests

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

7) Methods of statistical analysis of clinical research data

A Methods evaluating clinical performance

Whether various indexes can reach the standards of clinical evaluation shall be judged by calculating the consistency percentage of negative/positive and the total consistency percentage in the test results of the product tested and the reference product, to validate the accuracy and applicability of the product in clinical applications. The product tested shall be subject to tests through the sample of different types, with statistics on the results. Meanwhile, different types of sample of the subjects shall be subject to determination by the product tested synchronously, and then the determination results of both shall be compared. The test results recorded shall be subject to statistical analysis upon completion of determination of all clinical samples, to calculate the consistency percentage of negative/positive and the total consistency percentage. Afterwards, equivalence of both shall be evaluated as per these statistical indexes.

B Statistical methods

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

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

8) Standards of clinical evaluation

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

1) Coincidence rate of negative: the sample whose test results are negative for both the product tested and the reference product and the proportion in the sample whose test results are negative for the reference product shall be more than 90%.

2) Coincidence rate of positive: the sample whose test results are positive for both the product tested and the reference product and the proportion in the sample whose test results are positive for the reference product shall be more than 90%.

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

		Reference System Positive	Negative	Total
Test System	Positive	a	b	a+b
	Negative	c	d	c+d
Total		a+c	b+d	a+b+c+d

In general, the formula calculating the coincidence rate of positive/negative is:

Coincidence rate of positive =a/(a+c)*100%

Coincidence rate of negative =d/(b+d)*100%

Total coincidence rate =(a+d)/(a+c+b+d)*100%

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

4) Kappa consistency analysis shall be adopted for statistical analysis of similar reference kits:

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

		Reference System Positive	Negative	Total
Test System	Positive	a	b	a+b
	Negative	c	d	c+d
Total		a+c	b+d	a+b+c+d

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

9) Modification to the scheme during research

N/A

V Results and Analysis of Clinical Tests

In total, 220 test samples (125 for male and 95 for female) are included for the unit and all test samples included are tested. Statistics on test results and those of the product tested are as follows:

Table 1: Statistics on Serum IgG Test Results of the Product Tested and the Reference Product

	Positive Reference Product	Negative Reference Product	Total
Positive product tested	92	1	93
Negative product tested	0	127	127
Total	92	128	220

Item	**Formula**	**Results**	95%-L	95%-H
Coincidence rate of negative (%)	a/(a+c)*100%	100.00%	100.00%	100.00%
Coincidence rate of positive (%)	d/(b+d)*100%	99.22%	98.06%	99.88%
Total coincidence rate (%)	(a+d)/(a+b+c+d)*100%	99.55%	98.66%	100.18%
Theoretical coincidence rate Pe:	[(a+b)(a+c)+(c+d)(b+d)]/(a+b+c+d)^2	0.620		
Kappa	(PA-Pe)/(1-Pe)	0.988		

According to Table 1, among the 93 samples of the positive group, 92 are proven positive in the test results of the product tested, and 1 is proven negative. Among the 127 samples of the negative group, 127 are proven negative in the test results of the product tested and 0 is proven positive. Both the coincidence rate of positive/negative and the total coincidence rate are more than 90%, indicating favorable consistency with the reference product. According to the table, the Kappa coefficient = 0.988 (>0.8) in the results of Kappa inspection and analysis, indicating favorable and high consistency of two methods and equivalence of two such systems.

Table 2: Statistics on Serum IgM Test Results of the Product Tested and the Reference Product

	Positive Reference Product	Negative Reference Product	Total
Positive product tested	71	0	71
Negative product tested	2	147	149

Total	73	147	220

Item	Formula	Results	95%-L	95%-H
Coincidence rate of negative (%)	a/(a+c)*100%	97.22%	95.05%	97.92%
Coincidence rate of positive (%)	d/(b+d)*100%	100.00%	100.00%	100.00%
Total coincidence rate (%)	(a+d)/(a+b+c+d)*100%	99.09%	97.83%	99.76%
Theoretical coincidence rate Pe:	[(a+b)(a+c)+(c+d)(b+d)]/(a+b+c+d)^2	0.524		
Kappa	(PA-Pe)/(1-Pe)	0.981		

According to Table 2, among the 71 samples of the positive group, 71 are proven positive in the test results of the product tested, and 0 is proven negative. Among the 149 samples of the negative group, 147 are proven negative in the test results of the product tested and 2 are proven positive. Both the coincidence rate of positive/negative and the total coincidence rate are more than 90%, indicating favorable consistency with the reference product. According to the table, the Kappa coefficient = 0.981 (>0.8) in the results of Kappa inspection and analysis, indicating favorable and high consistency of two methods and equivalence of two such systems.

1. Analysis on Inconsistency in Test Results

S/N	Gender	Age	Product Tested	Reference Product	Clinical Diagnosis
46	Male	57	IgG（+） IgM（-）	IgG（+） IgM（+）	Subsequent visit of pneumonia triggered by COVID-19
62	Male	81	IgG（+） IgM（-）	IgG（+） IgM（+）	Subsequent visit of pneumonia triggered by COVID-19
114	F	70	IgG（+） IgM（-）	IgG（-） IgM（-）	Non-pneumonia triggered by COVID-19

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

VI Discussion and Conclusions

(I) Discussion

The SARS-CoV-2 antibody test card produced by Beijing Lepu Medical Technology Co., Ltd. contains the SARS-CoV-2 recombinant protein (colloidal-gold signs) enveloped on the gold-labeled pad in advance as well as the mouse-anti-human IgG antibody fixed into the test

zone G and the mouse-anti-human IgM antibody fixed into the test zone M and corresponding antibody in the quality control area (C). It can be used for rapid tests on the SARS-CoV-2 antibody in the serum/plasma specimen as well as auxiliary clinical screening of those suffering from pneumonia triggered by COVID-19. This clinical test aims at evaluating the clinical properties of such product. The test conditions are concluded as follows:

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

Test results of the serum sample of the product tested and the reference product: both the coincidence rate of negative/positive and the total coincidence rate are larger than 90%, indicating favorable consistency with the reference product. In the analysis results of Kappa inspection, Kappa was proven >0.8, indicating favorable and high consistency of both methods. Both systems were proven equivalent.

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

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

(II) Test conclusions

By analyzing the test results of the product tested and the reference product, the consistency percentage of negative/positive and the total consistency percentage are proven high. Moreover, according to the results of statistical analysis, there is no remarkable difference in test results of both, indicating favorable consistency in diagnosis and equivalence of two such systems. Meanwhile, the test results of the product tested for the serum and plasma sample of the same patient are completely identical. Therefore, such product is applicable to qualitative clinical analysis on the SARS-CoV-2 antibody in the serum and plasma sample of humans, and can be used for auxiliary diagnosis of those suffering from pneumonia triggered by COVID-19.

VI Special Notes of Clinical Research

N/A

Annex I: Instructions of the Diagnostic Kit for Clinical Tests

I Instructions for the Product Tested

SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)

【Product name】

SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)

【Model】

One test per bag for one person, 20 tests/kit

【Intended Use】

The product is intended for the qualitative detection of antibody content against SARS-CoV-2 in clinical samples (serum/plasma/whole blood).

【Summary】

Coronavirus, as a large virus family, is a single positive stranded RNA virus with envelope. The virus is known to cause major illnesses such as colds, Middle East Respiratory Syndrome (MERS), and Severe Acute Respiratory Syndrome (SARS). The novel virus, now known as SARS-CoV-2, was discovered in Wuhan virus pneumonia cases in 2019, and was officially named by the World Health Organization on January 12, 2020. The core protein of SARS-CoV-2 is the N protein (nucleocapsid), which is a protein component located inside the virus. It is relatively conserved among β-coronaviruses and is often used as a tool for the diagnosis of coronaviruses. ACE2, as a key receptor for SARS-CoV-2 to enter cells, is of great significance for the research of viral infection mechanism.

【Measurement Principle】

The product is based on the principle of antigen-antibody reaction and immunoassay technique. The test device contains colloidal gold labeled SARS-CoV-2 recombinant protein, mouse-anti human IgG antibody immobilized in G test area, mouse-anti human IgM antibody immobilized in M test area and the corresponding antibody in quality control area (C).

During the test, when the SARS-CoV-2 IgM antibody level in the sample is at or above the limit of detection of the test, the SARS-CoV-2 IgM antibody in the sample binds to the colloidal gold labeled SARS-CoV-2 recombinant protein which is pre-coated on a gold label pad. The conjugates migrate upward through capillary effect and would be captured by mouse-anti human IgM antibody immobilized in M test area subsequently and this produces a purple-red band appears in the M test area. When the SARS-CoV-2 IgG antibody level in the sample is at or above the limit of detection of the test, the SARS-CoV-2 IgG antibody in the sample binds to the colloidal gold labeled SARS-CoV-2 recombinant protein which is pre-coated on a gold label pad. The conjugates migrate upward through capillary effect and would be captured by mouse-anti human IgG antibody immobilized in G test area subsequently and this produces a purple-red band appears in the G test area. If it is a negative sample, there is not a purple-red band appeared in the M and G test area. Regardless of the presence or absence of the SARS-CoV-2 antibody in the sample, a purple-red band will appear in the quality control area (C). The purple-red band in the quality control area (C) is a criterion for judging whether there is enough sample and whether the chromatography process is normal. It also serves as the internal control standard for reagents.

【Components】

The product contains 20 tests, one IFU (instruction for use) and one lot number card.

For each test, it contains one testing strip, one dropper and one package of desiccant.

The testing strip is composed of one gold standard mat (colloidal gold labeled SARS-CoV-2 recombinant protein), sample mat, cellulose nitrate membrane (Mouse-anti human IgM antibody immobilized in M area, Mouse-anti human IgG antibody immobilized in G area; Goat anti-mouse antibody immobilized in C area), absorbing paper, plastic carrier board.

【Storage and Stability】

It should be stored at 4℃~ 30℃, be kept dry and away from sunlight. The shelf life is 12 months.

For per test strip, it should be used within 1 hour after unsealing.

Production Date and Expiration date are shown in the package label.

【Sample Requirements】

The test strip can be performed with serum/plasma/whole blood.

The blood should be collected by professional medical staff, and it is advised of detecting serum/plasma in priority, and under emergency conditions or special conditions, the whole blood of patients can be used for rapid testing.

After collection of samples, it should be tested immediately. It is forbidden for long time placement of the sample under room temperature. For whole blood sample, if it can not be tested in time, it can preserve for 24 hours between 2 and 8℃. Serum/plasma samples can be preserved for 3 days under temperature between 2 and 8℃, and for long time storage, they should be stored under -20℃, and it should avoided repeated freeze-thaw cycles.

Before testing, the sample must be restored to room temperature, ready for application only after homogeneity.

The sample must be returned to room temperature before testing, and should be used after mixing.

Do not use samples with severe hemolysis, severe lipids, and jaundice.

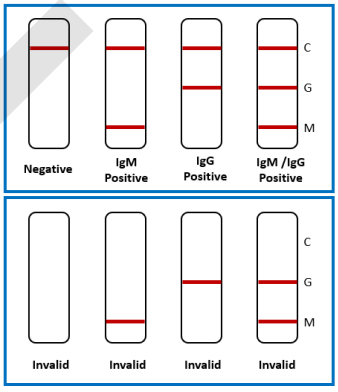
【Test Method】

Please read the instruction for use carefully before performing the test. Before testing, restore the reagents and blood sample to room temperature.

1. Remove the test strip from the packaging reagent bag and use it within 1 hour, especially in an environment with room temperature higher than 30 °C or in high humidity.
2. Place the kit on a clean platform.
   - Serum or plasma sample: Add 10 uL of serum or plasma sample to well A, and then add two drops (about 80 uL) of sample dilution to well B, and start timing.
   - Whole blood sample: Add 20 uL of whole blood sample to sample well A, and then add two drops (about 80 uL) of sample dilution to sample well B, and start timing.
3. Wait for the fuchsia band to appear. The test results should be read within 10-20 minutes. Do not read the results after 20 minutes.

【The Explanation of the Testing Results】

- Positive (+): There appear purple stripes in both quality control area and either area M or G.
- Negative (-): There is only one purple stripe in the quality control area (C), and without purple stripe in either test area M and test area G.
- Invalid: There is no purple stripe in the quality control area (C), indicating incorrect operating procedures or the testing strip has already deteriorated. Under this conditions, it must read the instruction for use again carefully, and then use the new test strips to test again. If the problem still exists, stop using this lot number immediately and contact the local suppliers.



C: Quality Control Line M: IgM Detection line G: IgG Detection line

【Limitation of Procedure】

1. The test results of this product should be comprehensively judged by the physician in combination with other clinical information, and should not be used as the only criterion;
2. The product is used to test the SARS-CoV-2 antibody of the tested sample.

【Product Performance Index】

1 Physical Property

1.1 Appearance

The test card should be clean and integral, no burrs, no damage, no pollution; the material should be firmly attached; the label should be clear and not damaged. The sample buffer should be clear without impurities and flocs.

1.2 Liquid migration speed

The liquid migration speed should be no less than 10mm/min.

1.3 Membrane Strip Width

The membrane strip width of the testing strip should be≥2.5mm.

1.4 Sample buffer volume

The sample buffer volume should be no less than the indicated value.

2 Detection Limit

For the detection of sensitivity reference material, the positive detection rate should be no less than 90%.

3 Negative reference products compliance rate

For the detection of negative reference material, the negative detection rate should be 100%.

4 Positive reference products compliance rate

For the detection of positive reference material, the positive detection rate should be 100%.

5 Precision

For the detection of enterprise reference material P2 and P4, the results should all be positive and the color rendering should be uniform.

6 Analysis Specificity

6.1 Cross-reactivity: This test device has no cross reactivity with endemic human coronavirus OC43 antibody, influenza A virus antibody, influenza B virus antibody, respiratory syncytial virus antibody, adenovirus antibody, EB virus antibody, measles virus antibody, cytomegalovirus antibody, rotavirus antibody, norovirus antibody, mumps virus antibody, varicella-zoster virus antibody, and mycoplasma pneumoniae antibody.

6.2 Interfering substances:

The test results do not be interfered with the substance at the following concentration:

bilirubin concentration ≤250 μmol/l; triglycerides concentration≤15 mmol/l; hemoglobin concentration ≤10 g/dL; rheumatoid factor concentration≤80RU/ml; anti-mitochondrial antibody concentration≤80 U/mL; antinuclear antibody concentration ≤80U/mL; the total IgG concentration ≤14g/L.

The test results do not be influenced by the following substance: α-interferon, zanamivir, ribavirin, oseltamivir, and paramivir, Lopinavir, ritonavir, abidol, levofloxacin, azithromycin, ceftriaxone, meropenem, tobramycin, histamine hydrochloride, phenylephrine, oxymetazoline, sodium chloride (containing Preservatives), beclomethasone, dexamethasone, flunisolide, triamcinolone, budesonide, mometasone and fluticasone.

【Precautions】

1. The test device is to be used as an aid in the diagnosis of SARS-Cov-2. Do not use expired products.
2. Do not freeze or use after the expiration date (see the packaging for the expiration date).
3. Avoid excessive temperature and humidity in the experimental environment. The reaction temperature should be 15-30 °C and the humidity should be below 70%.
4. The package bag contains desiccant, and it should not be taking orally.
5. It is recommended to use fresh blood for the sample collection. It is not recommended to use high-fat chyle, jaundice, and high rheumatoid factor samples. Do not use hemolyzed samples.
6. When testing, please wear protective clothing, gloves and eye shields.
7. Do not use the test card with broken single packaging, unclear marks, and past the expiration date.
8. Dispose of used specimens, test cards and other waste in accordance with relevant local laws and regulations.

【Explanation of Symbols】

	DO NOT USE IF PACKAGE IS DAMAGED		CONSULT INSTRUCTIONS FOR USE
	DO NOT REUSE		EXPIRY DATE
4℃ 30℃	TEMPERATURE LIMIT		DATE OF MANUFACTURER
	MANUFACTURER	LOT	BATCH CODE
	KEEP AWAY FROM SUNLIGHT		KEEP DRY
IVD	*IN VITRO* DIAGNOSTIC MEDICAL DEVICE	CE	CE MARK
EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN		

【References】

[1] Aiping Wu, Yousong Peng, Baoying Huang, Xiao Ding, Xianyue Wang, Genome Composition and Divergence of the Novel Coronavirus (SARS-CoV-2) Originating in China. Cell Host & Microbe 27, March 11, 2020

[2] Diagnostic and Treatment Protocol for COVID-19 (Provisional 5th Edition, Amendment Edition), 2020.2.8.

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Annex II: Data of Clinical Tests

I Serum

Sample No.	Gender	Age	Product Tested Test Results	Reference Product Test Results
1	F	45	IgG（+） IgM （+）	IgG（+） IgM（+）
2	M	66	IgG（+） IgM（-）	IgG（+） IgM（-）
3	M	36	IgG（+） IgM（+）	IgG（+） IgM（+）
4	F	44	IgG（-） IgM（-）	IgG（-） IgM（-）
5	F	54	IgG（+） IgM（+）	IgG（+） IgM（+）
6	M	65	IgG（+） IgM（-）	IgG（+） IgM（-）
7	M	69	IgG（+） IgM（+）	IgG（+） IgM（+）
8	M	74	IgG（-） IgM（-）	IgG（-） IgM（-）
9	F	25	IgG（+） IgM（-）	IgG（+） IgM（-）
10	M	53	IgG（+） IgM（+）	IgG（+） IgM（+）
11	F	33	IgG（-） IgM（-）	IgG（-） IgM（-）
12	M	28	IgG（-） IgM（-）	IgG（-） IgM（-）
13	M	42	IgG（-） IgM（-）	IgG（-） IgM（-）
14	F	77	IgG（-）	IgG（-）

			IgM（-）	IgM（-）
15	M	82	IgG（-） IgM（-）	IgG（-） IgM（-）
16	F	36	IgG（-） IgM（-）	IgG（-） IgM（-）
17	M	64	IgG（+） IgM（-）	IgG（+） IgM（-）
18	M	26	IgG（+） IgM（+）	IgG（+） IgM（+）
19	F	35	IgG（+） IgM（+）	IgG（+） IgM（+）
20	M	62	IgG（-） IgM（-）	IgG（-） IgM（-）
21	F	83	IgG（-） IgM（-）	IgG（-） IgM（-）
22	F	52	IgG（-） IgM（-）	IgG（-） IgM（-）
23	F	46	IgG（-） IgM（-）	IgG（-） IgM（-）
24	M	91	IgG（-） IgM（-）	IgG（-） IgM（-）
25	M	46	IgG（+） IgM（+）	IgG（+） IgM（+）
26	F	32	IgG（-） IgM（-）	IgG（-） IgM（-）
27	F	30	IgG（-） IgM（-）	IgG（-） IgM（-）
28	M	29	IgG（+） IgM（+）	IgG（+） IgM（+）
29	F	66	IgG（-） IgM（-）	IgG（-） IgM（-）
30	F	31	IgG（+） IgM（+）	IgG（+） IgM（+）

31	M	95	IgG（+） IgM（+）	IgG（+） IgM（+）
32	M	34	IgG（+） IgM（+）	IgG（+） IgM（+）
33	F	55	IgG（+） IgM（+）	IgG（+） IgM（+）
34	F	82	IgG（-） IgM（-）	IgG（-） IgM（-）
35	M	40	IgG（+） IgM（+）	IgG（+） IgM（+）
36	M	57	IgG（+） IgM（+）	IgG（+） IgM（+）
37	M	37	IgG（+） IgM（-）	IgG（+） IgM（-）
38	F	27	IgG（-） IgM（-）	IgG（-） IgM（-）
39	M	56	IgG（+） IgM（+）	IgG（+） IgM（+）
40	F	87	IgG（+） IgM（+）	IgG（+） IgM（+）
41	M	73	IgG（-） IgM（-）	IgG（-） IgM（-）
42	M	59	IgG（+） IgM（+）	IgG（+） IgM（+）
43	F	25	IgG（-） IgM（-）	IgG（-） IgM（-）
44	F	43	IgG（+） IgM（+）	IgG（+） IgM（+）
45	M	31	IgG（-） IgM（-）	IgG（-） IgM（-）
46	**M**	**57**	**IgG（+）** **IgM（-）**	**IgG（+）** **IgM（+）**
47	M	66	IgG（-）	IgG（-）

			IgM（-）	IgM（-）
48	M	72	IgG（-） IgM（-）	IgG（-） IgM（-）
49	M	51	IgG（-） IgM（-）	IgG（-） IgM（-）
50	F	54	IgG（-） IgM（-）	IgG（-） IgM（-）
51	F	49	IgG（-） IgM（-）	IgG（-） IgM（-）
52	M	68	IgG（+） IgM（+）	IgG（+） IgM（+）
53	F	29	IgG（+） IgM（-）	IgG（+） IgM（-）
54	F	58	IgG（-） IgM（-）	IgG（-） IgM（-）
55	F	55	IgG（-） IgM（-）	IgG（-） IgM（-）
56	F	42	IgG（+） IgM（+）	IgG（+） IgM（+）
57	M	39	IgG（+） IgM（+）	IgG（+） IgM（+）
58	M	51	IgG（-） IgM（-）	IgG（-） IgM（-）
59	F	33	IgG（-） IgM（+）	IgG（-） IgM（+）
60	F	46	IgG（+） IgM（+）	IgG（+） IgM（+）
61	M	54	IgG（-） IgM（+）	IgG（-） IgM（+）
62	**M**	**81**	**IgG（+）** **IgM（-）**	**IgG（+）** **IgM（+）**
63	F	19	IgG（-）	IgG（-）

			IgM（-）	IgM（-）
64	M	37	IgG（+） IgM（+）	IgG（+） IgM（+）
65	M	48	IgG（-） IgM（-）	IgG（-） IgM（-）
66	F	72	IgG（+） IgM（+）	IgG（+） IgM（+）
67	F	66	IgG（+） IgM（-）	IgG（+） IgM（-）
68	M	47	IgG（+） IgM（+）	IgG（+） IgM（+）
69	M	62	IgG（+） IgM（+）	IgG（+） IgM（+）
70	M	58	IgG（+） IgM（+）	IgG（+） IgM（+）
71	F	83	IgG（+） IgM（+）	IgG（+） IgM（+）
72	M	65	IgG（-） IgM（-）	IgG（-） IgM（-）
73	F	37	IgG（-） IgM（-）	IgG（-） IgM（-）
74	M	55	IgG（-） IgM（-）	IgG（-） IgM（-）
75	F	38	IgG（-） IgM（-）	IgG（-） IgM（-）
76	M	47	IgG（+） IgM（+）	IgG（+） IgM（+）
77	M	81	IgG（-） IgM（-）	IgG（-） IgM（-）
78	F	37	IgG（-） IgM（-）	IgG（-） IgM（-）
79	F	35	IgG（-） IgM（-）	IgG（-） IgM（-）

80	M	42	IgG（-） IgM（-）	IgG（-） IgM（-）
81	M	77	IgG（-） IgM（-）	IgG（-） IgM（-）
82	M	30	IgG（+） IgM（+）	IgG（+） IgM（+）
83	F	36	IgG（-） IgM（-）	IgG（-） IgM（-）
84	M	58	IgG（+） IgM（+）	IgG（+） IgM（+）
85	F	71	IgG（+） IgM（+）	IgG（+） IgM（+）
86	M	64	IgG（+） IgM（-）	IgG（+） IgM（-）
87	M	57	IgG（-） IgM（-）	IgG（-） IgM（-）
88	F	86	IgG（-） IgM（-）	IgG（-） IgM（-）
89	M	42	IgG（+） IgM（-）	IgG（+） IgM（-）
90	F	83	IgG（-） IgM（-）	IgG（-） IgM（-）
91	M	52	IgG（+） IgM（+）	IgG（+） IgM（+）
92	M	79	IgG（-） IgM（-）	IgG（-） IgM（-）
93	F	45	IgG（-） IgM（-）	IgG（-） IgM（-）
94	M	40	IgG（+） IgM（+）	IgG（+） IgM（+）
95	F	88	IgG（+） IgM（+）	IgG（+） IgM（+）
96	M	64	IgG（+）	IgG（+）

			IgM（-）	IgM（-）
97	M	17	IgG（+） IgM（-）	IgG（+） IgM（-）
98	F	62	IgG（-） IgM（-）	IgG（-） IgM（-）
99	F	42	IgG（-） IgM（-）	IgG（-） IgM（-）
100	M	53	IgG（-） IgM（-）	IgG（-） IgM（-）
101	M	62	IgG（-） IgM（-）	IgG（-） IgM（-）
102	F	38	IgG（-） IgM（-）	IgG（-） IgM（-）
103	F	78	IgG（-） IgM（-）	IgG（-） IgM（-）
104	M	56	IgG（-） IgM（-）	IgG（-） IgM（-）
105	M	36	IgG（-） IgM（-）	IgG（-） IgM（-）
106	M	48	IgG（-） IgM（-）	IgG（-） IgM（-）
107	F	70	IgG（-） IgM（-）	IgG（-） IgM（-）
108	M	84	IgG（+） IgM（+）	IgG（+） IgM（+）
109	F	64	IgG（-） IgM（-）	IgG（-） IgM（-）
110	M	58	IgG（-） IgM（-）	IgG（-） IgM（-）
111	M	55	IgG（-） IgM（-）	IgG（-） IgM（-）
112	F	51	IgG（-）	IgG（-）

			IgM（-）	IgM（-）
113	F	33	IgG（-） IgM（-）	IgG（-） IgM（-）
114	**F**	**70**	**IgG（+）** **IgM（-）**	**IgG（-）** **IgM（-）**
115	M	45	IgG（+） IgM（+）	IgG（+） IgM（+）
116	M	49	IgG（+） IgM（+）	IgG（+） IgM（+）
117	F	36	IgG（-） IgM（-）	IgG（-） IgM（-）
118	F	34	IgG（+） IgM（-）	IgG（+） IgM（-）
119	F	43	IgG（-） IgM（-）	IgG（-） IgM（-）
120	M	74	IgG（+） IgM（+）	IgG（+） IgM（+）
121	M	38	IgG（-） IgM（-）	IgG（-） IgM（-）
122	F	48	IgG（+） IgM（+）	IgG（+） IgM（+）
123	F	36	IgG（-） IgM（-）	IgG（-） IgM（-）
124	M	54	IgG（-） IgM（-）	IgG（-） IgM（-）
125	M	71	IgG（+） IgM（+）	IgG（+） IgM（+）
126	M	55	IgG（+） IgM（-）	IgG（+） IgM（-）
127	F	19	IgG（+） IgM（+）	IgG（+） IgM（+）
128	M	65	IgG（-） IgM（-）	IgG（-） IgM（-）

129	F	40	IgG（-） IgM（-）	IgG（-） IgM（-）
130	M	71	IgG（+） IgM（+）	IgG（+） IgM（+）
131	M	33	IgG（+） IgM（+）	IgG（+） IgM（+）
132	M	38	IgG（-） IgM（-）	IgG（-） IgM（-）
133	F	54	IgG（-） IgM（-）	IgG（-） IgM（-）
134	F	35	IgG（-） IgM（-）	IgG（-） IgM（-）
135	M	86	IgG（+） IgM（+）	IgG（+） IgM（+）
136	M	48	IgG（+） IgM（-）	IgG（+） IgM（-）
137	F	39	IgG（+） IgM（+）	IgG（+） IgM（+）
138	M	56	IgG（-） IgM（-）	IgG（-） IgM（-）
139	M	89	IgG（+） IgM（-）	IgG（+） IgM（-）
140	F	44	IgG（-） IgM（-）	IgG（-） IgM（-）
141	F	77	IgG（-） IgM（-）	IgG（-） IgM（-）
142	M	76	IgG（-） IgM（-）	IgG（-） IgM（-）
143	M	62	IgG（-） IgM（-）	IgG（-） IgM（-）
144	M	49	IgG（-） IgM（-）	IgG（-） IgM（-）
145	F	84	IgG（+）	IgG（+）

			IgM（+）	IgM（+）
146	M	40	IgG（-） IgM（-）	IgG（-） IgM（-）
147	F	36	IgG（+） IgM（+）	IgG（+） IgM（+）
148	M	80	IgG（-） IgM（-）	IgG（-） IgM（-）
149	M	72	IgG（-） IgM（-）	IgG（-） IgM（-）
150	M	37	IgG（+） IgM（+）	IgG（+） IgM（+）
151	F	16	IgG（-） IgM（-）	IgG（-） IgM（-）
152	M	85	IgG（+） IgM（+）	IgG（+） IgM（+）
153	F	53	IgG（+） IgM（-）	IgG（+） IgM（-）
154	M	22	IgG（+） IgM（-）	IgG（+） IgM（-）
155	M	16	IgG（-） IgM（-）	IgG（-） IgM（-）
156	F	51	IgG（+） IgM（-）	IgG（+） IgM（-）
157	F	78	IgG（-） IgM（-）	IgG（-） IgM（-）
158	M	73	IgG（-） IgM（-）	IgG（-） IgM（-）
159	M	38	IgG（+） IgM（+）	IgG（+） IgM（+）
160	M	56	IgG（-） IgM（-）	IgG（-） IgM（-）
161	F	37	IgG（-）	IgG（-）

			IgM（-）	IgM（-）
162	M	46	IgG（+） IgM（+）	IgG（+） IgM（+）
163	F	57	IgG（-） IgM（-）	IgG（-） IgM（-）
164	M	59	IgG（-） IgM（-）	IgG（-） IgM（-）
165	M	41	IgG（-） IgM（-）	IgG（-） IgM（-）
166	M	63	IgG（-） IgM（-）	IgG（-） IgM（-）
167	M	34	IgG（-） IgM（-）	IgG（-） IgM（-）
168	F	48	IgG（+） IgM（+）	IgG（+） IgM（+）
169	F	36	IgG（+） IgM（+）	IgG（+） IgM（+）
170	F	58	IgG（-） IgM（-）	IgG（-） IgM（-）
171	M	40	IgG（-） IgM（-）	IgG（-） IgM（-）
172	M	27	IgG（-） IgM（-）	IgG（-） IgM（-）
173	M	64	IgG（+） IgM（+）	IgG（+） IgM（+）
174	M	38	IgG（-） IgM（-）	IgG（-） IgM（-）
175	F	47	IgG（+） IgM（+）	IgG（+） IgM（+）
176	F	40	IgG（-） IgM（-）	IgG（-） IgM（-）
177	M	82	IgG（+） IgM（+）	IgG（+） IgM（+）

178	M	25	IgG（+） IgM（-）	IgG（+） IgM（-）
179	F	71	IgG（-） IgM（-）	IgG（-） IgM（-）
180	F	46	IgG（-） IgM（-）	IgG（-） IgM（-）
181	M	57	IgG（-） IgM（-）	IgG（-） IgM（-）
182	M	30	IgG（-） IgM（-）	IgG（-） IgM（-）
183	M	52	IgG（+） IgM（+）	IgG（+） IgM（+）
184	F	67	IgG（-） IgM（-）	IgG（-） IgM（-）
185	M	33	IgG（-） IgM（-）	IgG（-） IgM（-）
186	F	53	IgG（+） IgM（+）	IgG（+） IgM（+）
187	M	38	IgG（+） IgM（-）	IgG（+） IgM（-）
188	M	52	IgG（-） IgM（-）	IgG（-） IgM（-）
189	F	46	IgG（-） IgM（-）	IgG（-） IgM（-）
190	M	44	IgG（-） IgM（-）	IgG（-） IgM（-）
191	M	78	IgG（-） IgM（-）	IgG（-） IgM（-）
192	F	87	IgG（-） IgM（-）	IgG（-） IgM（-）
193	F	74	IgG（-） IgM（-）	IgG（-） IgM（-）
194	M	69	IgG（-）	IgG（-）

			IgM（-）	IgM（-）
195	M	46	IgG（-） IgM（-）	IgG（-） IgM（-）
196	F	55	IgG（-） IgM（-）	IgG（-） IgM（-）
197	F	38	IgG（-） IgM（-）	IgG（-） IgM（-）
198	M	53	IgG（-） IgM（-）	IgG（-） IgM（-）
199	M	36	IgG（+） IgM（+）	IgG（+） IgM（+）
200	M	33	IgG（+） IgM（+）	IgG（+） IgM（+）
201	F	28	IgG（+） IgM（+）	IgG（+） IgM（+）
202	M	81	IgG（+） IgM（+）	IgG（+） IgM（+）
203	F	42	IgG（+） IgM（+）	IgG（+） IgM（+）
204	M	70	IgG（-） IgM（-）	IgG（-） IgM（-）
205	M	52	IgG（-） IgM（-）	IgG（-） IgM（-）
206	M	55	IgG（-） IgM（-）	IgG（-） IgM（-）
207	M	28	IgG（-） IgM（-）	IgG（-） IgM（-）
208	F	49	IgG（-） IgM（-）	IgG（-） IgM（-）
209	M	25	IgG（-） IgM（-）	IgG（-） IgM（-）
210	F	53	IgG（-）	IgG（-）

			IgM（-）	IgM（-）
211	F	59	IgG（+） IgM（+）	IgG（+） IgM（+）
212	F	31	IgG（+） IgM（+）	IgG（+） IgM（+）
213	F	48	IgG（-） IgM（-）	IgG（-） IgM（-）
214	M	37	IgG（+） IgM（+）	IgG（+） IgM（+）
215	M	42	IgG（-） IgM（-）	IgG（-） IgM（-）
216	M	56	IgG（+） IgM（-）	IgG（+） IgM（-）
217	M	34	IgG（-） IgM（-）	IgG（-） IgM（-）
218	F	79	IgG（-） IgM（-）	IgG（-） IgM（-）
219	F	67	IgG（-） IgM（-）	IgG（-） IgM（-）
220	M	58	IgG（+） IgM（+）	IgG（+） IgM（+）

Note: “—” – negative sample; “+”- positive sample.

III Information of the Sample with Inconsistent Test Results

The sample with inconsistent test results in the comparative test shall be re-confirmed through the results of clinical diagnosis. The records are as follows:

S/N	Gender	Age	Product Tested	Reference Product	Clinical Diagnosis
46	**M**	**57**	**IgG（+） IgM（-）**	**IgG（+） IgM（+）**	
62	**M**	**81**	**IgG（+） IgM（-）**	**IgG（+） IgM（+）**	
114	**F**	**70**	**IgG（+） IgM（-）**	**IgG（-） IgM（-）**	