# Clinical trial report of in vitro diagnostic reagents

Product name: Diagnostic Kit for IgM/IgG Antibody to 2019-nCoV (Colloidal Gold)

Study start date: February 24, 2020

Study completion date: February 29, 2020

Principal investigator (signature):

Study unit (seal): Chongqing Public Health Medical Center

Person in charge of statistics (signature):

Statistical unit (seal): Chongqing Public Health Medical Center

Sponsor (seal): Bioneovan Co., Ltd

Contact name: Jiang Xin

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Report date: March 1, 2020

Original data storage place: Chongqing Public Health Medical Center

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## Study Summary

Purpose: The main purpose of this clinical trial is to verify through the detection of a lot of clinical trial samples whether the Diagnostic Kit for IgM/IgG Antibody to 2019-nCoV (Colloidal Gold) produced by Bioneovan Co., Ltd has a good correlation with the clinical diagnosis results, and make evaluation and verification according to the measured data to confirm the applicability and accuracy of the reagent in clinical diagnosis.

Methods: By choosing novel coronavirus pneumonia clinical diagnosis criteria for comparison, collect the clinical serum/plasma samples of the hospital, use the Bioneovan reagent for comparative test, record the test results, and fully analyze the inconsistent samples in combination with the patient's epidemiological records, clinical symptoms, prognosis and other information.

Conclusion: The Diagnostic Kit for IgM/IgG Antibody to 2019-nCoV (Colloidal Gold) produced by Bioneovan Co., Ltd has a good correlation with the clinical diagnosis results. The test reagent has good applicability, accuracy and consistency in clinical diagnosis, and the two are equivalent.

Verified by clinical trial, the Diagnostic Kit for IgM/IgG Antibody to 2019-nCoV (Colloidal Gold) produced by Bioneovan Co., Ltd can be used to qualitatively detect the IgM/IgG Antibody to 2019-nCoV in human serum/plasma samples, acting as an auxiliary diagnosis for pneumonia infected by novel coronavirus.

## Trial Investigators

For details, see annex: clinical trial division table

## Abbreviations

(2019-nCoV)IgM/IgG: 2019-nCoV IgM/IgG Antibody.

## 1. Introduction

The 2019 novel coronavirus, or "2019-nCoV", is a new strain of coronavirus that has never been found in humans before. It was discovered due to a viral pneumonia case in Wuhan in 2019 and was named by the World Health Organization on January 12, 2020; Belonging to the novel coronavirus of the genus β, the novel coronavirus has an envelope and round or oval particles, often polymorphic, with a diameter of 60-140nm.Its genetic characteristics are significantly different from those of SARSr-CoV and MERSr-CoV. Current studies show that it has 96% similarity to bat SARS-like coronavirus (bat-SL-CoVZC45), and basically supports that 2019-nCoV comes from bats, but whether there is an intermediate host still needs to be studied. When isolated and cultured in vitro, 2019-nCoV can be found in human respiratory epithelial cells in about 96 hours, while it is found in Vero E6 and Huh-7 cell lines in about 6 days. Novel coronavirus is mainly transmitted through respiratory droplets and contacts. Route of transmission such as aerosol and digestive tract has to be determined yet. Based on findings of current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. Main symptoms are fever, fatigue, and dry cough. A few patients have symptoms such as nasal congestion, runny nose, sore throat and diarrhea, etc.

The test reagent is pre-qualified for the qualitative detection of the Gimp/Iggy Antibody to 2019-nCoV in human serum/plasma samples, and is used as an auxiliary diagnosis for pneumonia infected by novel coronavirus. It has the characteristics of simple operation, rapid diagnosis, high sensitivity and strong specificity. Commissioned by Bioneovan Co., Ltd, conduct clinical trials on the Diagnostic Kit for IgM/IgG Antibody to 2019-nCoV (Colloidal Gold) produced by the company.

## 2. Study purpose

The main purpose of this clinical trial is to verify through the detection of a lot of clinical trial samples whether the Diagnostic Kit for IgM/IgG Antibody to 2019-nCoV (Colloidal Gold) produced by Bioneovan Co., Ltd has a good correlation with the clinical diagnosis results, and make evaluation and verification according to the measured data to confirm the applicability and accuracy of the reagent in clinical diagnosis.

## 3. Test management

The main investigator is responsible for the clinical trial, and the trial scheme is jointly developed with Bioneovan Co., Ltd. According to the requirements of the test reagent, clinical trial begins after the personnel training is completed. The operation is carried out in strict accordance with the instructions, and the results of the samples to be tested shall be valid when the conditions for judging the results of the instructions are met. At the end of the test, special personnel are assigned to carry out data statistics, sorting and verification. The personnel participating in the verification test have worked in this position for many years and have rich experience.

## 4. Test design

The main purpose of this clinical trial is to verify through the detection of a lot of clinical trial samples whether the Diagnostic Kit for IgM/IgG Antibody to 2019-nCoV (Colloidal Gold) produced by Bioneovan Co., Ltd has a good correlation with the clinical diagnosis results, and make evaluation and verification according to the measured data to confirm the applicability and

accuracy of the reagent in clinical diagnosis.

**4.1 Sample size and basis for determination of sample size**

Clinical trials shall be carried out in qualified clinical trial institutions in accordance with the Measures for the Registration and Management of In-vitro Diagnostic Reagents, the Technical Guidelines on Clinical Trials of In-vitro Diagnostic Reagents and other relevant regulations.

(1) The Diagnostic Kit for IgM/IgG Antibody to 2019-nCoV (Colloidal Gold) produced by Bioneovan Co., Ltd shall be one of the Class III in-vitro diagnostic reagents in accordance with the Measures for the Registration and Management of In-vitro Diagnostic Reagents and the Classification Catalogue of In-vitro Diagnostic Reagents (2013 Edition).

(2) The clinical trial sample size shall be at least 200 serum/plasma samples in accordance with the Key Points for Technical Review of 2019-nCoV Antigen/Antibody Detection Reagent Registration.

(3) The sample size shall also meet the statistical requirements in accordance with the Technical Guidelines on Clinical Trials of In-vitro Diagnostic Reagents. The sample size will be calculated by the single-arm target method in this clinical trial. The possible drop-out and other factors shall also be taken into account to meet the statistical requirements.

- The sample size for confirmed cases of novel coronavirus-infected pneumonia (positive) shall be no less than 120.There shall be no less than 10 cases in different disease processes (e.g. early stage of onset, middle stage of onset and recovery stage after treatment). Consecutive samples shall be collected at different time points from at least 10 cases of novel coronavirus-infected pneumonia, and each case shall at least include the consecutive samples at three time points. The antibody positive conversion process shall be observed in at least two stages among the early stage, middle stage and recovery stage of novel coronavirus infection, and meanwhile, the detection results of each antibody shall have the PCR results in the same stage.
- The sample size for excluded cases of novel coronavirus-infected pneumonia (negative) shall be no less than 80.

**4.2 Inclusion criteria**

- Suspected cases of novel coronavirus (2019-nCoV) infection;
- Remaining samples after routine clinical testing;
- The sample collection and processing shall meet the requirements for standard laboratory operations and product specifications;
- The sample related information shall be complete, including the subject number, age, sex and sample type.

**4.3 Exclusion criteria**

- Severely turbid samples;
- Microbiological contaminated samples;
- Samples that do not meet the requirements for sample collection and processing.

**4.4 Rejection criteria**

- Samples with human error in the clinical trial;
- Other samples that fail to complete the test due to various reasons;
- Any other reasons considered by the principal investigator of each clinical trial institution.

After some samples are excluded or rejected according to the above standards, the sample size must meet the requirements of this protocol.

**4.5 Sample collection, storage and transportation methods**

Serum samples shall be collected from veins by conventional methods; plasma sample processing methods: heparin solution, sodium citrate solution or EDTA solution may be used to anticoagulate blood. Serum or plasma samples may be stored at 2~8 ℃ for 5 days, and stored at -20 ℃ for more than 5 days. If repeated sample freezing and thawing, the number of freeze-thaw cycles shall not exceed 3.The test result of hemolysis samples shall be invalid. For samples containing suspended fibrin or polymer, it is recommended to take the supernatant for testing after centrifugation. Hemolysis samples cannot be tested. There shall be no other microbial contamination in the test samples. The sample transfer box must have a special mark. After removal from the sealed bag, the samples must be disinfected by ultraviolet light or 75% ethanol spray. Before use, please equilibrate the test samples at room temperature for more than 30 minutes. The frozen samples shall be mixed before testing. Serum or plasma samples may be heat-inactivated, and the test results are stable after heat-inactivation.

**4.6 Operating steps**

The operation shall be in strict accordance with the product instructions of the manufacturer.

**4.7 Related information of clinical trial reagents**

4.7.1 Test reagents

- Name: Diagnostic Kit for IgM/IgG Antibody to 2019-nCoV (Colloidal Gold)
- Source: Bioneovan Co., Ltd
- Product batch number: 202002004
- Specification/model: 20 tests/box
- Expiry date: February 21, 2021
- Sample type: Serum/plasma

4.7.2 Nucleic acid reagents

- Name: Diagnostic Kit for Nucleic Acid to 2019-nCoV (Fluorescent PCR Method)
- Sample type: pharyngeal swab, sputum or alveolar lavage fluid

**4.8 Clinical diagnostic criteria**

4.8.1 Suspected cases

Conduct the comprehensive analysis by combining the following historical epidemiology and clinical pictures:

4.8.1.1 Historical epidemiology

(1) Have a travel history or residence history in Wuhan and surrounding areas, or other communities with reported cases within 14 days before the onset of illness;

(2) Have a history of exposure to novel coronavirus infected patients (positive results of nucleic acid testing) within 14 days before the onset of illness;

(3) Had been exposed to patients with fever or respiratory symptoms from Wuhan and surrounding areas, or from communities with reported cases within 14 days before the onset of illness;

(4) Clustering outbreak.

4.8.1.2 Clinical pictures

(1) Fever and/or respiratory symptoms;

(2) With the imaging features of the aforementioned novel coronavirus pneumonia:

(3) The total count of leukocytes is normal or decreased, or the lymphocyte count normal is decreased in the early stage of onset of illness.

Patients have any one of the historical epidemiology and meet any two of the clinical pictures. If there is no clear historical epidemiology, patients meet three of the clinical pictures.

4.8.2 Confirmed cases

Suspected cases with one of the following etiology evidences:

• Real-time f luorescent R T-PCR detection shows positive novel c oronavirus nucleic a cid testing results;

• Viral gene sequencing is highly homologous to known novel coronaviruses.

**4.8 Quality control of clinical trials**

4.8.1 Formulate standard operating procedures for clinical trials.

4.8.2 Ensure that the rights and interests of the subjects in the clinical trial are protected, the test records and reported data are accurate and complete, and ensure that the trial follows the approved protocol and relevant laws and regulations.

4.8.3 Maintain and enhance the reliability and validity of data.

4.8.4 In the process of statistical analysis, the statistical analysis plan specifies the statistical analysis of clinical trials from a more technical and detailed perspective, thereby further controlling the quality of system analysis implementation.

4.8.5 Audit and Inspection. In case of problems, give feedback in a timely manner, find the reasons, and ensure the smooth progress of the trial.

**4.9 Statistical analysis method of clinical research data**

During the trial, the results shall be recorded on the original record form for such trial. The original record form shall include the sample number / medical record number, gender, age, sample type, collection time, trial results, assessment reagents and clinical diagnosis results.

Upon the completion of the trial, the clinical research unit will organize the trial data and conduct statistical analysis on such trial data. The statistical analysis summarizes the results in the form of a 2X2 table, and calculates the clinical sensitivity, clinical specificity, clinical total coincidence rate and 95% confidence interval. According to the results, the consistency of the assessment reagents and clinical diagnostic criteria will be evaluated. Conclusions will be drawn and the clinical trial report will be completed by the clinical research units.

4.9.1 Serum/plasma samples

[Evaluation M ethod] T he c linical s ensitivity, clinical s pecificity, t otal c linical c oincidence rate and 95% confidence interval of serum/plasma samples are evaluated using clinical diagnostic criteria as controls.

4.9.2 Samples of patients with different courses of disease

[Evaluation M ethod] The stratified analysis is performed for patients with different disease courses.

4.9.3 Continuous collection of samples at different times

[Evaluation method] For the continuous samples collected at different times of patients with pneumonia infected with novel coronavirus, evaluate the statistical results of the comparisons of testing by using the assessment reagent and the nucleic acid reagent, and evaluate the detection ability and window phase of the investigational in vitro diagnostic reagent for novel coronavirus infection.

4.9.4 For samples whose results from the test by using the assessment reagent are inconsistent with those of the clinical diagnostic criteria, the full analysis will be conducted by combining patient's epidemiological background, clinical symptoms, and disease turnover.

4.9.5 Data analysis calculation formula

| | | Clinical diagnosis results | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| Assessment reagent test results | Positive | A | B | A+B |
| | Negative | C | D | C+D |
| Total | | A+C | B+D | A+B+C+D |

Clinical sensitivity (positive coincidence rate) = A/(A + C) × 100%

Clinical specificity (negative coincidence rate) = D/(B + D) × 100%

Clinical total coincidence rate (total coincidence rate) = (A + D)/(A + B + C + D) × 100%

The calculation formula of Kappa coefficient is as follows:

Kappa=（$P_A$-$P_e$）/（1-$P_e$）

Where, $P_A$ is the "actual agreement rate", $P_e$ is the "theoretical agreement rate". Taking the above table as an example, the calculation method is as follows:

$P_A$=（A+D）/（A+B+C+D）

$P_e$=[（A+B）（A+C）+（C+D）（B+D）]/（A+B+C+D）$^2$

| | |
|---|---|
| Kappa coefficient < 0. | Very weak consistency |
| 0.00< Kappa coefficient< 0.20 | Slightly weak consistency |
| 0.21 < Kappa coefficient< 0.40 | Weak consistency |
| 0.41 < Kappa coefficient< 0.60 | Moderate consistency |
| 0.61 < Kappa coefficient< 0.80 | Strong consistency |
| 0.81 < Kappa coefficient< 1.00 | Very strong consistency |

The calculation formula of clinical sensitivity (positive coincidence rate) 95% confidence interval is shown in Formula (1) ~ Formula (4)

Formula (1) : [(Q1-Q2)/Q3, (Q1+Q2)/Q3]

Formula (2): $Q1=2\times A+1.96^2$

Formula (3): $Q2 = 1.96 \times \sqrt{1.96^2 + 4 \times A \times C/（A + C）}$

Formula (4): $Q3=2\times(A+C+1.96^2)$

The calculation formula of clinical specificity (negative coincidence rate) 95% confidence interval is shown in Formula (5) ~ Formula (8):

Formula (5): [(Q1-Q2)/Q3, (Q1 + Q2)/Q3]

Formula (6): $Q1 = 2 \times D + 1.96^2$

Formula (7): $Q2 = 1.96 \times \sqrt{1.96^2 + 4 \times B \times D/(B + D)}$

Formula (8): $Q3 = 2 \times (B + D + 1.96^2)$

The calculation formula of 95% confidence interval for the total clinical coincidence rate (total coincidence rate) is shown in Formula (9) ~ Formula (12)

Formula (9): [(Q1-Q2)/Q3, (Q1 + Q2)/Q3]

Formula (10): $Q1 = 2 \times (A + D) + 1.96^2$

Formula (11): $Q2 = 1.96 \times \sqrt{1.96^2 + 4 \times (A + D) \times (B + C)/(A + B + C + D)}$

Formula (12): $Q3 = 2 \times (A + B + C + D + 1.96^2)$

## 5. Clinical research results and analysis

### 5.1 Descriptive analysis

5.1.1 Sample enrollment distribution table

| Sample grouping | Confirmed cases (positive) | Excluded cases (negative) | Total |
|---|---|---|---|
| Cases of samples (unit: case) | 125 | 92 | 217 |

5.1.2 Distribution of samples of patients with different disease courses

| Sample course | Early stage | Interim stage | Recovery stage after treatment | Total |
|---|---|---|---|---|
| Cases of samples (unit: case) | 16 | 24 | 100 | 140 |

Judgment criteria of disease course:

Early stage: 0-7 days after the patient's onset of fever/illness;

Interim stage: 7 to 14 days after the patient's onset of fever/illness;

Recovery stage after treatment: more than 14 days after the patient's onset of fever/illness.

5.1.3 Continuous samples of the same patient collected at different times: a total of 10 cases.

### 5.2 Evaluation of consistency

5.2.1 Analysis and consistency evaluation of serum/plasma sample test results (Table 1 ~ Table 6)

Table 1

| | | Clinical diagnosis results | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| IgG test results | Positive | 104 | 0 | 104 |
| | Negative | 11 | 92 | 103 |
| Total | | 115 | 92 | 207 |

Table 2

| | Clinical sensitivity | Clinical specificity | Total clinical coincidence rate | Kappa value |
|---|---|---|---|---|
| Calculation results | 90.4% | 100.0% | 94.7% | 0.89 |
| 95% CI lower limit | 83.7% | 96.0% | 90.7% | —— |
| 95% CI upper limit | 94.6% | 100.0% | 97% | —— |

Table 3

| | | Clinical diagnosis results | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| IgM test results | Positive | 101 | 0 | 101 |
| | Negative | 14 | 92 | 106 |
| Total | | 115 | 92 | 207 |

Table 4

| | Clinical sensitivity | Clinical specificity | Total clinical coincidence rate | Kappa value |
|---|---|---|---|---|
| Calculation results | 87.8% | 100.0% | 93.2% | 0.87 |
| 95% CI lower limit | 80.6% | 96.0% | 89.0% | —— |
| 95% CI upper limit | 92.6% | 100.0% | 95.9% | —— |

Table 5

| | | Clinical diagnosis results | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| IgM/ IgG test results | Positive | 108 | 0 | 108 |
| | Negative | 7 | 92 | 99 |
| Total | | 115 | 92 | 207 |

Table 6

| | Clinical sensitivity | Clinical specificity | Total clinical coincidence rate | Kappa value |
|---|---|---|---|---|
| Calculation results | 93.9% | 100.0% | 96.6% | 0.93 |
| 95% CI lower limit | 88.0% | 96.0% | 93.2% | —— |
| 95% CI upper limit | 97.0% | 100.0% | 98.4% | —— |

5.2.2 Analysis of test results of patients with different disease courses (Table 7)

Table 7

| | | Clinical diagnosis results | | | Total |
|---|---|---|---|---|---|
| | | Early stage | Interim stage | Recovery stage after treatment | |
| IgG test results | Positive | 4 | 23 | 95 | 122 |
| | Negative | 12 | 1 | 5 | 18 |
| IgM test results | Positive | 9 | 24 | 87 | 120 |
| | Negative | 7 | 0 | 13 | 20 |
| Total | | 16 | 24 | 100 | 140 |

Early detection rate of IgG antibody = 25.0%

Early detection rate of IgM antibody = 56.3%

Detection rate of IgG antibody in the middle stage of the disease = 95.8%

Detection rate of IgM antibody in the middle stage of the disease = 100.0%

Detection rate of IgG antibody in the recovery period after the treatment = 95.0%

Detection rate of IgM antibody in the recovery period after the treatment = 87.0%

5.2.3 Continuous samples of the same patient collected at different times

| No. | Subject number | Description of the disease course | Sampling time | Fever/morbidity time | IgG test results | IgM test results | Nucleic acid reagent test results |
|---|---|---|---|---|---|---|---|
| 3 | 1401 | Early stage | 2020.2.15 | 2020.2.8 | - | + | + |
| 4 | 1402 | Interim stage | 2020.2.19 | | + | + | + |
| 5 | 003 | Interim stage | 2020.2.21 | | + | + | - |
| 25 | 1403 | Early stage | 2020.2.4 | 2020.1.29 | - | - | + |
| 26 | 303 | Recovery stage after treatment | 2020.2.19 | | + | + | + |
| 27 | 1404 | Recovery stage after treatment | 2020.2.25 | | + | + | - |
| 34 | 1406 | Early stage | 2020.2.6 | 2020.1.31 | + | - | + |
| 35 | 310 | Recovery stage | 2020.2.19 | Nucleic acid | + | + | + |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | after treatment | | tested positive | | | |
| 36 | 1407 | Recovery stage after treatment | 2020.2.25 | after confirmed diagnosis by relatives | + | + | - |
| 39 | 1408 | Interim stage | 2020.2.8 | 2020.1.31 | - | + | + |
| 40 | 1409 | Interim stage | 2020.2.11 | | + | + | + |
| 41 | 403 | Recovery stage after treatment | 2020.2.17 | | + | + | - |
| 60 | 1410 | Early stage | 2020.2.13 | 2020.2.6 | + | + | + |
| 61 | 603 | Interim stage | 2020.2.19 | Nucleic acid | + | + | + |
| 62 | 1501 | Recovery stage after treatment | 2020.2.22 | tested positive after confirmed diagnosis by relatives | + | + | - |
| 78 | 1507 | Early stage | 2020.2.18 | | - | - | - |
| 79 | 709 | Early stage | 2020.2.19 | 2020.2.13 | - | + | - |
| 80 | 1508 | Interim stage | 2020.2.25 | | + | + | + |
| 124 | 1510 | Early stage | 2020.2.10 | | - | - | - |
| 125 | 1601 | Interim stage | 2020.2.14 | | - | + | + |
| 126 | 1602 | Interim stage | 2020.2.19 | 2020.2.5 | + | + | + |
| 127 | 1205 | Recovery stage after treatment | 2020.2.20 | | + | + | + |
| 132 | 1603 | Early stage | 2020.2.9 | | - | - | - |
| 133 | 1604 | Interim stage | 2020.2.15 | | + | + | + |
| 134 | 1605 | Recovery stage after treatment | 2020.2.21 | 2020.2.6 | + | + | + |
| 135 | 1210 | Recovery stage after treatment | 2020.2.22 | | + | + | + |
| 136 | 1606 | Early stage | 2020.2.14 | | - | + | - |
| 137 | 1607 | Interim stage | 2020.2.18 | 2020.2.7 | + | + | + |
| 138 | 1301 | Recovery stage after treatment | 2020.2.22 | | + | + | - |
| 139 | 1608 | Early stage | 2020.2.14 | 2020.2.8 | - | + | + |
| 140 | 1302 | Interim stage | 2020.2.18 | Nucleic acid | + | + | + |
| 141 | 1609 | Interim stage | 2020.2.21 | tested positive | + | + | + |
| 142 | 1610 | Recovery stage after treatment | 2020.2.23 | after confirmed diagnosis by relatives | + | + | - |

It can be seen from the above results that continuous samples collected at different times for patients with pneumonia infected with novel coronavirus were tested. At the same time, the nucleic acid test results were compared, which fully verifies that the Diagnostic Kit for IgM/IgG A ntibody to 2019-nCoV (Colloidal Gold) of Bioneovan Co., Ltd better reflects the ability to test new coronavirus infection.

5.2.4 Analysis of samples with inconsistent assessment reagents and clinical diagnosis results

According to the clinical trial results, 11 of 115 confirmed cases failed to be tested positive for IgG antibody, with 90.4% clinical sensitivity; 14 cases failed to be tested positive for IgM antibody, with 93.9% IgM/IgG clinical sensitivity; in 92 excluded cases, none were tested positive for IgM/IgG antibodies, with 100.0% IgM/IgG clinical specificity, 92.3% overall IgM/IgG clinical coincidence rate, and 0.93 Kappa value. According to literature reports, the IgM antibody of the novel coronavirus existed in patients for 2-3 weeks, the IgM antibody reached the peak after 1-2 weeks of the patients' onset, and the IgG antibody appeared later than the IgM antibody. According to the patient's epidemiological background, clinical signs and symptoms, disease outcomes and other information, the assessment reagent and clinical diagnosis are highly consistent.

Comprehensive analysis: due to the limitations of its own methodologies, the qualitative auxiliary diagnostic reagents have not yet been completely accurate. There are indeed a very limited number of non-conforming results. The qualitative auxiliary diagnostic results need to be confirmed through other testing methods and diagnostic methods. However, based on the expected use of qualitative auxiliary diagnosis, it can still be accepted clinically.

## 6. Conclusions

The Diagnostic Kit for IgM/IgG Antibody to 2019-nCoV (Colloidal Gold) produced by Bioneovan Co., Ltd has a good correlation with the clinical diagnosis results. The assessment reagent is well applicable, accurate and consistent in clinical diagnosis, and the two are equivalent.

Verified by clinical trial, the Diagnostic Kit for IgM/IgG Antibody to 2019-nCoV (Colloidal Gold) produced by Bioneovan Co., Ltd can be used to qualitatively detect the IgM/IgG Antibody to 2019-nCoV in human serum/plasma samples, acting as an auxiliary diagnosis for pneumonia infected by novel coronavirus.

## 7. Annexes

### 7.1 Main references

### 7.2 Resumes of principal researchers

### 7.3 Division of clinical trials

Appendix

**7.2 Main References**

[1] Measures for the Administration of Registration of In Vitro Diagnostic Reagents (CFDA Order No. 5) [S]

[2] Notice of the China Food and Drug Administration on Issuing the Technical Guiding Principles of Clinical Tests for In Vitro Diagnostic Reagents (No. 16 of 2014) China Food and Drug Administration. September 11, 2014

[3] Key Points of Technical Review for 2019 Novel Coronavirus Antigen/Antibody Detection Reagent Registration in 2019 (Trial), China Food and Drug Administration

[4] Guidelines on the Novel Coronavirus-Infected Pneumonia Diagnosis and Treatment, National Health Commission of the People's Republic of China

| | | | |
|---|---|---|---|
| 2018.11- | Drugs | Phase III clinical trial of the efficacy and safety of ACC007 combined with 3TC + TDF in the treatment of HIV/AIDS | PI |
| 2018.12- | Diagnostic reagents | Mycobacterium tuberculosis MIC drug sensitivity test kit (culture method) | PI |
| 2018.12- | Diagnostic reagents | Non-tuberculous mycobacteria MIC drug sensitivity test kit (culture method) | PI |

Signature of researcher: Date: February 13, 2020

| | | | |
|---|---|---|---|
| 2018.11- | Drugs | Phase III clinical trial of the efficacy and safety of ACC007 combined with 3TC + TDF in the treatment of HIV/AIDS | PI |
| 2018.12- | Diagnostic reagents | Diagnostic kit for mycobacterium tuberculosis MIC drug sensitivity (culture method) | PI |
| 2018.12- | Diagnostic reagents | Diagnostic kit for non-mycobacterium tuberculosis MIC drug sensitivity test kit (culture method) | PI |

Signature of researcher: Date: February 13, 2020

Diagnostic kit for non-mycobacterium

tuberculosis MIC drug sensitivity test kit (culture method)

Appendix

**7.4 Work division of clinical trials**

| Clinical trial personnel | Name of clinical trial institution | Responsibility in clinical trial |
|---|---|---|
| Chen Yaokai | Chongqing Public Health Medical Center | Principal investigator/Head of statistics |
| Xue Chengjun | Chongqing Public Health Medical Center | Sample collection |
| Wang Jing | Chongqing Public Health Medical Center | Test |
| Yang Kun | Chongqing Public Health Medical Center | Sample and reagent management |