Clinical Evaluation Report

For

SARS-CoV-2 Antigen Rapid Test (Immunochromatography)

Qingdao Hightop Biotech Co., Ltd.

1 Research Summary

Clinical institutions conduct clinical validation tests on products of SARS-CoV-2 Antigen Rapid Test（Hereinafter referred to as assessment reagent）which is registered for the first time. Proving the clinical performance of the assessment reagent meets the expected requirements.

A total of 135 patients who were suspected of SARS-CoV-2 are studied. Both nasopharyngeal swab and oropharyngeal swab were collected from same patient.There are 33 cases in the case group, 30 cases are positive tested by the assessment reagent; 102 cases in the control group, 101 cases are negative tested by the assessment reagent. Clinical diagnosis results of assessment reagents: The sensitivity is 90.91%, the specificity is 99.02%, and the overall coincidence rate is 97.04%. The results of two sample types were consistent.

2 Experimental Researchers

Member of the Project	Organization	Title responsibility	responsibility
Jinling Song	Qingdao Hightop Biotech Co., Ltd.	Reagent R&D manager	Major Investigators
Chunmei Pan	Qingdao Hightop Biotech Co., Ltd.	Reagent development engineer	Data collection and analysis, and writing clinical report
Xuemei Zuo	Qingdao Hightop Biotech Co., Ltd.	Reagent development engineer	Review of clinical report
Qin Xue	Qingdao Hightop Biotech Co., Ltd.	QC engineer	experimenter
Mengmeng Du	Qingdao Hightop Biotech Co., Ltd.	QA	Quality control of the project

3 Abbreviation

None.

4 Contents of the report

4.1 Basic Content

4.1.1 Introduction

The novel coronavirus (SARS-CoV-2) belongs to the β coronavirus genus, has an envelope. Its particle is round or elliptic, is often pleomorphic and 60-140 nm in diameter. The crowd is generally susceptible. The main manifestation of onset are pyrexia, debilitation and tussiculation. A few patients are accompanied by nasal congestion, runny nose, diarrhea and other symptoms. The severe cases manifest dyspnea more than a week later, and acute respiratory distress syndrome, septic shock, refractory metabolic acidosis, and coagulation dysfunction are presented rapidly. Some patients only show low fever, slight fatigue, and so on, without pneumonia, and almost recover after a week. The incubation period is generally 3-7 days, with the maximum not exceeding 14 days. Transmission by respiratory droplets is the main route of transmission and can also be spread by contact.

4.1.2 Test purpose

Clinical institutions conduct clinical validation tests on products of SARS-CoV-2 Antigen Rapid Test（Hereinafter referred to as assessment reagent）which is registered for the first time. Proving the clinical performance of the assessment reagent meets the expected requirements.

4.1.3 Test management

The design of the test protocol and various standard operating procedures (SOPs) in the test were jointly completed by Qingdao Hightop Biotech Co., Ltd. and various clinical institutions. Qingdao Hightop Biotech Co., Ltd. is responsible for providing clinical evaluation products. Qingdao Hightop Biotech Co., Ltd. is responsible for the specific implementation of the trial and data management.

4.1.4 Trial design

4.1.4.1 Description of the overall design and plan of the test

This experiment is based on blind and control methods.

The samples from suspected or confirmed patients infected with novel coronavirus, are

selected for blind detection by test reagent. The test results are compared with the RCR results, and the feasibility of application of test reagent in clinical practice is evaluated by judging the clinical sensitivity and specificity of the test reagent.

Prior to the start of the clinical evaluation, the proposer and the clinical evaluation staff shall conduct a preliminary test to make them familiar with and master the applicable instruments, operation methods and technical performance of the product, so as to control the test error to the maximum extent.

4.1.4.1.1 The general process

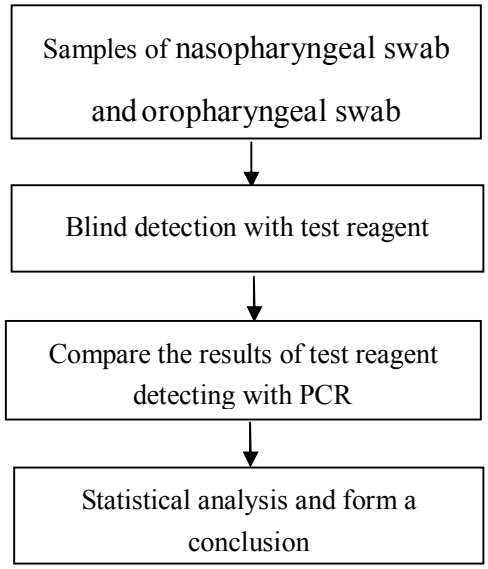
a) The institute prepares nasopharyngeal swab and oropharyngeal swab samples which must be collected from the same patients.

b) The blind test is carried out with the test reagent and the test results are recorded. All the test results are recorded.

c) Any invalid result shall be tested repeatedly. If the result is still invalid, it shall be marked as invalid.

d) Comparing the results of test reagent and PCR by statistical method.

4.1.4.1.2 Test process flow chart



4.1.4.2 Test design and test method selection

4.1.4.2.1 Sample size and the basis for determining sample size

A total of 135 samples are tested. There are 33 cases in the case group, 30 cases are positive tested by the assessment reagent; 102 cases in the control group and 101 cases are negative tested by the assessment reagent.

4.1.4.2.2 Sample selection basis, criteria of inclusion, exclusion and elimination

4.1.4.2.2.1Sample selection basis

The selected samples are nasopharyngeal swab and oropharyngeal swab samples of patients with suspected or confirmed novel coronavirus infection. According to the PCR results, the patients are divided into case group and control group.

Case group: Samples of patients diagnosed with novel coronavirus infection on the basis of "*The Diagnosis and Treatment Plan for Pneumonia Caused by Novel Coronavirus Infection*", including samples of patients with different clinical severity and stages of disease.

Control group: samples from patients infected with novel coronavirus are excluded on the basis of "*The Diagnosis and Treatment Plan for Pneumonia Caused by Novel Coronavirus Infection*".

4.1.4.2.2.2 Criteria for sample inclusion

(1) No age limit;

(2) No gender limit;

(3) Complete information file, including: sample ID number, name, gender, age, department, PCR result, sample type and sampling date.

4.1.4.2.2.3 Criteria for sample exclusion

(1) Samples that have been repeatedly frozen and thawed for more than 3 times;

(2) An insufficient sample size;

(3) A sample with incomplete information;

(4) A sample of duplicate cases.

4.1.4.2.2.4 Criteria for sample elimination

(1) Samples that fail to meet the inclusion criteria and included by mistake.

(2) Samples that meet the inclusion criteria but fail to meet the test plan due to contamination during sample preservation or insufficient sample size caused by human error after inclusion.

4.1.4.2.3 Establishment of Reference Methods

The clinical evaluations were compared with the PCR results, that is, the diagnosis or exclusion of infection is divided into case groups and control groups according to the PCR results, and the clinical sensitivity and specificity of the assessment reagents were evaluated.

4.1.4.2.4 Product Information for clinical evaluations

Assessment reagent

Reagent name: SARS-CoV-2 Antigen Rapid Test

Manufacturer: Qingdao Hightop Biotech Co., Ltd.

Specification: 40 T/ box

Batch number: 200901

Expiry date: 20210908

Storage conditions: 4 - 30℃

4.1.4.2.5 Method of quality control

In the course of this study, Participants must undergo uniform training. Recording methods and standards of judgment should be unified. The whole test process should be operated strictly. The investigator shall faithfully, carefully and carefully record the test results, and all the observations and findings in the clinical evaluation shall be verified to ensure the reliability of the data and ensure that the conclusions in the clinical evaluation are derived from the original data. There are corresponding data management measures in clinical evaluation and data processing stage.

4.1.4.2.6 Statistical analysis method of clinical evaluation data

Statistical analysis is conducted to summarize the results in the form of a four-lattice table, and based on this, the overall coincidence rate, clinical sensitivity, clinical specificity and 95% confidence interval are calculated.

4.1.4.2.7 Modification of scheme during test

None

4.1.5 Clinical evaluation results and analysis

4.1.5.1 Statistics of test reagent tresults and PCR results on nasopharyngeal swab samples

4.1.5.1.1 Statistics result

Statistics of test reagent results and PCR results on nasopharyngeal swab samples

SARS-CoV-2 Antigen Rapid Test	PCR Results		Total
	Positive	Negative	
Positive	30	1	31
Negative	3	101	104
Total	33	102	135

4.1.5.1.2 Analysis of compliance rate

Sensitivity: 90.91% (95%CI: 76.43%-96.86%)

Specificity: 99.02% (95%CI: 94.66%-99.83%)

Total consistent: 97.04% (95%CI:92.63%-98.84%)

4.1.5.2 Statistics of test reagent tresults and PCR results on oropharyngeal swab samples

4.1.5.2.1 Statistics result

Statistics of test reagent results and PCR results on oropharyngeal swab samples

SARS-CoV-2 Antigen Rapid Test	PCR Results		Total
	Positive	Negative	
Positive	30	1	31
Negative	3	101	104
Total	33	102	135

4.1.5.2.2 Analysis of compliance rate

Sensitivity: 90.91% (95%CI: 76.43%-96.86%)

Specificity: 99.02% (95%CI: 94.66%-99.83%)

Total consistent: 97.04% (95%CI:92.63%-98.84%)

4.1.5.3 Statistical analysis on the consistency of results on nasopharyngeal swabs and oropharyngeal swabs

4.1.5.3.1 Statistics result

Statistics of test reagent results and PCR results on total samples

Nasopharyngeal swabs	Oropharyngeal swabs		Total
	Positive	Negative	
Positive	31	0	31
Negative	0	104	104
Total	31	104	135

Positive Percent Agreement: 100%

Negative Percent Agreement: 100%

Overall Percent Agreement: 100%

4.1.6 Discussion and conclusion

SARS-CoV-2 Antigen Rapid Test of Qingdao Hightop Biotech Co., Ltd. was validated in Shandong provincial Chest Hospital and Jiangsu Provincial Center for Disease Control and

prevention. The test process was carried out strictly according to the clinical evaluation plan and standard operating procedures.

4.2 Description of special conditions in clinical evaluations

None.

4.3 Attachment

Statistical Table of Clinical Trial Data