Tigsun COVID-19 Antigen Rapid Test
Clinical Validation Report

Product name: Tigsun COVID-19 Antigen Rapid Test
Model & specification: 1 test/kit, 1 Individual package
Type of clinical trial: Clinical validation
Start date of clinical trial: Nov. 2, 2020
Completion date of clinical trial: Mar. 3, 2021

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Abstract

To evaluate the Tigsun COVID-19 Antigen Rapid Test (the "Tigsun Kit" for short) produced by Beijing Tigsun Diagnostics Co.,Ltd. ("the Company" for short) for clinical application in qualitative detection of the content of SARS-CoV-2 antigen in clinical samples (nasal swab samples), The medical institutions conducted a clinical study on the test cassette contained therein. A total of 516 nasal swab samples were collected in this clinical trial, including 190 positive samples and 326 negative samples confirmed by the COVID-19 diagnosis and treatment protocol. The Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) (the "Reference Kit" for short) produced by Sansure Biotech Inc. was used as a reference kit. Based on the test result of the Reference Kit, the study objects were divided into 2019-nCoV positive group and 2019- nCoV negative group. At the same time, these samples were tested with the Test Kit, and the test results of the Test Kit and the Reference Kit were compared and statistically analyzed. The results showed that the diagnostic specificity of the Test Kit is 99.39%, the sensitivity is 97.89%, the total coincidence rate is 98.84% . The above results show a good consistency between the Test Kit and the Reference Kit.

1. Introduction

Since December 2019, continuous surveillance on influenza and relevant diseases had been carried out, and several patients with viral pneumonia had been found and diagnosed with viral pneumonia/pulmonary infection. Relevant viruses were typed for detection. On January 7, 2020, the laboratory detected a novel coronavirus. The "2019 novel coronavirus (2019-nCoV)" was identified in the viral pneumonia cases and named by the World Health Organization (WHO) on January 12, 2020. The 2019-nCoV infected cases typically have symptoms like fever, fatigue, dry cough as the main respiratory syndrome, and gradually develop dyspnea. Severe patients presented with acute respiratory distress syndrome, septic shock, refractory metabolic acidosis, and coagulation dysfunction. Some patients had mild onset symptoms, but no fever. Most patients had good prognosis, while a few patients were critically ill and even died.

The incubation period of 2019-nCoV infection is 1-14 days, with an average of about 5 days.Some of those infected may have no symptoms at all but still be contagious; Most of the patients will rapidly deteriorate into severe pneumonia, respiratory distress, asphyxia, etc. A small proportion of patients infected with 2019-nCoV may die. In addition, 2019-nCoV has been reported to attack the nervous system and the male reproductive system. Therefore, 2019-nCoV infection early screening is of great significance for controlling the epidemic and the transition from mild to severe.

COVID-19 antigen can be detected approximately 0 to 7 days after infection (with or without symptoms), which is earlier and more direct than antibody detection. Compared to nucleic acid detection is faster and more convenient.

2. Objective

To evaluate the Tigsun kit suitability and accuracy, Nasal specimens were collected and tested and obtained results were compared with the clinical diagnosis results and PCR, to evaluate the sensitivity, specificity and other indicators of the product, and to verify the accuracy of the product, so as to determine whether it meets the requirements of safety and effectiveness.

3. Design of the trial

3.1 Overall design and scheme description of the trial

At least 2 nasal swabs samples shall be collected for each subject after enrollment,

one collected for PCR detection and one collected for antigen test. Samples for PCR test are Blinded before testing, and unblinded after all test are finished.
After the specialist have collected the nasal sample, 516 patients were chosen in all.

3.2 Trial design and study method selection

3.2.1 Sample size and sample size determination basis

To ensure that the results are statistically significant, sufficient positive samples should be covered in this evaluation, such as no less than 150 positive samples of nasal swabs.

3.2.2 Sample selection criteria, inclusion criteria, exclusion criteria

3.2.2.1 Selection basis

This product is intended used for qualitatively testing COVID-19 antigens in human nasal specimens.
Clinical sensitivity study samples can be selected from the patients with Covid-19 symptoms within seven days of the onset of symptoms. specimens collected by nasal swab that meet the inclusion criteria.
Clinical specificity study samples can be selected from the asymptomatic people without specific information of Exposure risk.

3.2.2.2 Inclusion criteria

A. Have been to the high risk area or have close contact with the confirmed person within 30 days.

B. Have more than one and with mild or moderate symptoms, such as fever, cough, sore throat, unexplained muscle pain, nausea, nasal congestion, headache, diarrhea, palpitations, chest tightness, White lung.

C. Asymptomatic people

D. Without any risk information of exposure to COVID-19.

3.2.2.3 Exclusion criteria

1)The collection time of samples is more than 7 days from the symptom onset

2)The patient is in Serious life-threatening symptoms

3) The collection time of samples is not clear, or clinical information is missing;

4) Insufficient sample size due to error during test operation;

5) Samples such as those contaminated during specimen transport were found before the test operation;

6) Samples were frozen for storage.

3.2.2.4 Criteria for ruling out the abnormal samples from the selected sample

1） Samples that do not meet the requirements of the specimen collection method;

2） Samples that have been dried or contaminated;

3） The diagnostic information of the sample is found to be missing or untraceable before statistics.

4） Samples with incomplete information

3.3 The determination of the comparative method

In order to fully evaluate the clinical performance of this product, NAT and clinical diagnosis results were used as the control.

Product information used in clinical trials:

Item	Test kit	Reference Kit
Product Name	Tigsun COVID-19 Antigen Rapid Test	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)
Specifications	1 test/Box	
Validity& Storage	Stored in a cool and dry place at 2~30℃. Keep away from sunlight, moisture, heat, and frozen condition.Kit contents are stable until the expiration date printed on the outer box. After opening the pouch, the cassette is effective to be used in 1 hour under room temperature (10-30℃) and humidity (<70%).	
Batch No.	14162001	
Manufacturer	Beijing Tigsun Diagnostics Co.,Ltd.	Sansure BioTech Inc

3.4 Clinical evaluation method

The reagents and clinical results are mainly represented in a four-grid table (as shown in Table 1). The table is self-explanatory, that is, it has table titles, table notes and number of cases

SPSS software was used to conduct consistency analysis on the test results of the assessment reagent in clinical results.

4. Results

4.1 Analysis of Clinical Trial

A total of 516 nasal swab samples were selected as the study objects, including 190 positive samples and 326 negative samples confirmed by the COVID-19 diagnosis and treatment protocol. All selected samples were tested.

Consistency statistics for the Tigsun COVID-19 Antigen Rapid Test(Test Kit) produced by the Company and SARS-CoV-2 nucleic acid detection results was carried out to analyze the diagnostic sensitivity, diagnostic specificity, total coincidence rate,

as well as Sensitivity Ct ≤32 and Sensitivity Ct ≤30 of the Test Kit and nucleic acid detection results, and summarize the indicators in the form of four-fold table. The results are as follows:

Table 1 Summary of the Test Kit and Nucleic Acid Detection Results

	Reference kit tested positive	**Reference kit tested negative**	**Total**
Test Kit testedpositive	186	2	188
Test Kit tested negative	4	324	328
Total	190	326	516

Table 2 Summary of Diagnostic Sensitivity and Specificity Results

Item	**Formula**	**Result**	**95% CI**
Diagnostic sensitivity (%)	A /(A+C) ×100%	97.89%	94.71% ~99.19%
Diagnostic specificity(%)	D /(B+D) ×100%	99.39%	97.79%~99.83%
Total coincidence rate (%)	(A+D) / (A+B+C+D) ×100%	98.84%	97.49%~99.47%

Table 3 Summary of PCR Ct≤32 Results with the Test Kit (Sensitivity Ct ≤32 Result)

	Test results of nucleic acid
Test kit	Positive (Ct≤32)
Positive	184
Negative	2
Total	186
Sensitivity	98.92%
95% CI	96.16%~99.70%

Table 4 Summary of PCR Ct≤30 Results with the Test Kit (Sensitivity Ct ≤30 Result)

	Test results of nucleic acid
Test kit	Positive (Ct≤30)
Positive	179
Negative	0
Total	179
Sensitivity	100.00%
95% CI	97.90%~100.00%

Table 5 Data Analysis

Diagnostic Sensitivity (95% CI), N	97.89% (94.71% ,99.19%), 190
Sensitivity Ct ≤32, N	98.92% (96.16%,99.70%), 186
Sensitivity Ct ≤30, N	100.00% (97.90%,100.00%), 179
Diagnostic Specificity (95% CI), N	99.39% (97.79%,99.83%), 326

It can be seen from Table 1 that among the 190 samples in the positive group, 186 cases are positive and 4 cases are negative. Among the 326 samples in the negative group, 324 cases are negative and 2 cases are positive. The diagnostic specificity, diagnostic sensitivity and total coincidence rate are all over 95%, Sensitivity Ct ≤32 is 98.92%, and Sensitivity Ct ≤30 is 100.00%, which indicates that the Test Kit has good diagnostic sensitivity and specificity in clinical performance, and is in good consistency with the Reference Kit.

5. Discussion and Conclusions

A total of 516 patients' Nasal swab were collected in this clinical trial.Tigsun Kit were tested 186 positive out of 190 PCR positive, 324 negative out of 326 PCR negative. Compared with the results of PCR and clinical diagnosis, the clinical sensitivity of Tigsun Kit was 97.89%, the clinical specificity of Tigsun Kit was 99.39%, the total coincidence rate was 98.84%. There was no statistically significant difference between the test results of Tigsun Kit and the clinical diagnosis results, the results of Tigusn Kit were highly consistent with the results of clinical diagnosis and PCR test.

Conclusion: Tigsun COVID-19 Antigen Rapid Test(Test Kit) produced by Beijing Tigsun Diagnostics Co.,Ltd. showed no statistically significant difference between Tigsun Kit test results tested by patients and the clinical diagnosis results, which were highly consistent. That showed Tigsun Kit was safe and effective.