# Clinical General Report

# SARS-CoV-2 Ag Test (Lateral Flow Method)

**COVID-19 Antigen Rapid Test (Swab)**

**CONFIDENTIAL**

**Test Time:** June 24, 2020~June 21, 2020

**Clinical Trial Medical Unit:** Yeungnam University Medical Center

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**Report Date:** June 29, 2020

Completion Instructions:

1. Clinical trial institutions and researchers should conduct clinical trials strictly in accordance with the clinical trial protocol in a serious and responsible manner, and compile clinical trial reports impartially and objectively.

2. Clinical trial institutions and researchers should be responsible for the authenticity and science of the trial report.

# CLINICAL TRIAL REPORT

## Abstract of Research

According to the requirements of rules of IVDD, COVID-19(SARS-CoV-2) Antigen test (Lateral Flow Method), developed by Zhejiang Anji Saianfu Biotech Co., Ltd., need to undergo clinical trial to determine whether it meets the use requirement or intended use.

This trial used clinical diagnostic results of patients as reference, conducted clinical application trial on COVID-19(SARS-CoV-2) Antigen test (Lateral Flow Method) developed by Zhejiang Anji Saianfu Biotech Co., Ltd， examined the safety and effectiveness of reOpenTest reagent.

Selected samples in this trial included human Nasal and Throat swab samples. In this trial 130 samples were totally selected. The trial result is summarized as follows:

### 1.Analysis of Test Result

### (1) Study method

Tests were performed according to instruction for use of COVID-19 Ag Test' with residual

nasopharyngeal swab (NPS)s in VTM (Viral Transport Medium) from 30 positive patients

confirmed by real-time PCR method and 100 negative persons confirmed by real-time PCR.

①Model name/manufacturer for VTM: ESwapTM 482C (COAPN Diagnostic Inc)

T-SWAB TRANSPORTTM CTM (Noble Bio)

②Real-time PCR: Allplex 2019-nCoV assay (Seegene Inc, EUA approved)

③Storage temperature for the specimens in VTM: stored at -70℃ within 3 months

### （2）Specimen information

①Inclusion criteria

i. The specimen is confirmed with real-time PCR

②Exclusion criteria

i. Specimens with unclear PCR results
ii. Specimen information is unclear.
iii. Contaminated specimens
iv. Insufficient specimens to test
v. eNAT ™ (COAPN Diagnostic Inc) medium specimens

### (3) Acceptance Criteria

Control line should be appeared.

## 2. RESULT

### 1) Positive specimen (n=30)

| No. | Specimen collection date | Medium | Days after symptom onset | Day of PCR testing | Result of Real-time RT-PCR | | | COVID-19 Ag |
|---|---|---|---|---|---|---|---|---|
| | | | | | E | RdRP | N | Result |
| 1 | 2020-02-28 | CTM | 4 | 2020-02-29 | 18.18 | 20.57 | 21.64 | Positive |
| 2 | 2020-02-28 | CTM | 2 | 2020-02-29 | 20.07 | 21.50 | 22.80 | Positive |
| 3 | 2020-02-28 | CTM | 7 | 2020-02-29 | 24.68 | 26.62 | 27.48 | Positive |
| 4 | 2020-02-28 | CTM | 7 | 2020-02-29 | 16.04 | 17.18 | 17.93 | Positive |
| 5 | 2020-02-28 | CTM | 2 | 2020-02-29 | 16.38 | 17.28 | 19.01 | Positive |
| 6 | 2020-02-28 | CTM | 7 | 2020-02-29 | 20.96 | 21.97 | 23.59 | Positive |
| 7 | 2020-02-28 | CTM | 5 | 2020-02-29 | 21.93 | 23.31 | 24.46 | Positive |
| 8 | 2020-02-29 | CTM | No symptom | 2020-02-29 | 31.92 | 28.95 | 30.97 | Negative |
| 9 | 2020-02-28 | CTM | 5 | 2020-03-01 | 12.82 | 15.01 | 16.60 | Positive |
| 10 | 2020-02-28 | CTM | 3 | 2020-03-01 | 19.57 | 21.43 | 23.08 | Positive |
| 11 | 2020-02-29 | CTM | 7 | 2020-03-01 | 25.35 | 26.46 | 27.78 | Positive |
| 12 | 2020-02-29 | CTM | 7 | 2020-03-01 | 24.02 | 25.26 | 25.86 | Positive |
| 13 | 2020-02-29 | CTM | 7 | 2020-03-02 | 31.04 | 38.43 | 33.94 | Negative |
| 14 | 2020-03-01 | CTM | 8 | 2020-03-02 | 11.80 | 14.69 | 16.34 | Positive |
| 15 | 2020-03-01 | CTM | 5 | 2020-03-03 | 17.47 | 20.15 | 20.24 | Positive |
| 16 | 2020-03-01 | CTM | 14 | 2020-03-03 | 28.49 | 30.50 | 31.27 | Negative |
| 17 | 2020-03-02 | CTM | 5 | 2020-03-03 | 23.15 | 24.44 | 25.16 | Positive |
| 18 | 2020-03-02 | CTM | 5 | 2020-03-03 | 15.32 | 16.68 | 18.89 | Positive |
| 19 | 2020-03-01 | CTM | 8 | 2020-03-03 | 25.61 | 27.91 | 28.27 | Positive |
| 20 | 2020-03-02 | CTM | No symptom | 2020-03-03 | 24.64 | 25.07 | 27.79 | Positive |
| 21 | 2020-03-02 | CTM | 2 | 2020-03-03 | 21.73 | 23.42 | 24.55 | Positive |
| 22 | 2020-03-02 | CTM | 8 | 2020-03-03 | 17.29 | 18.71 | 20.22 | Positive |
| 23 | 2020-03-02 | CTM | 11 | 2020-03-03 | 21.57 | 22.79 | 23.62 | Positive |
| 24 | 2020-03-02 | CTM | 3 | 2020-03-04 | 22.24 | 24.54 | 25.17 | Positive |
| 25 | 2020-03-02 | CTM | 3 | 2020-03-04 | 24.37 | 27.13 | 26.40 | Positive |
| 26 | 2020-03-02 | CTM | 9 | 2020-03-04 | 22.46 | 23.80 | 25.02 | Positive |
| 27 | 2020-03-02 | CTM | No symptom | 2020-03-04 | 24.75 | 26.58 | 27.93 | Positive |
| 28 | 2020-03-02 | CTM | No symptom | 2020-03-04 | 26.88 | 28.29 | 29.40 | Positive |
| 29 | 2020-03-03 | CTM | 1 | 2020-03-04 | 26.46 | 29.34 | 29.73 | Positive |
| 30 | 2020-03-03 | CTM | 5 | 2020-03-04 | 16.18 | 17.99 | 20.34 | Positive |

**2) Negative specimens (n=100)**

| No. | Specimen collection date | Medium | Day of PCR testing | Result of Real-time RT-PCR | | | COVID-19 Ag |
|---|---|---|---|---|---|---|---|
| | | | | E | RdRp | N | Result |
| 1 | 2020-03-18 | CTM | 2020-03-18 | - | - | - | Negative |
| 2 | 2020-03-23 | CTM | 2020-03-23 | - | - | - | Negative |
| 3 | 2020-03-23 | CTM | 2020-03-23 | - | - | - | Negative |
| 4 | 2020-03-22 | CTM | 2020-03-22 | - | - | - | Negative |
| 5 | 2020-03-23 | CTM | 2020-03-23 | - | - | - | Negative |
| 6 | 2020-03-14 | CTM | 2020-03-14 | - | - | - | Negative |
| 7 | 2020-03-16 | CTM | 2020-03-16 | - | - | - | Negative |
| 8 | 2020-03-15 | CTM | 2020-03-15 | - | - | - | Negative |
| 9 | 2020-03-17 | CTM | 2020-03-17 | - | - | - | Negative |
| 10 | 2020-03-15 | CTM | 2020-03-15 | - | - | - | Negative |
| 11 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 12 | 2020-03-16 | CTM | 2020-03-16 | - | - | - | Negative |
| 13 | 2020-03-26 | CTM | 2020-03-26 | - | - | - | Negative |
| 14 | 2020-03-26 | CTM | 2020-03-26 | - | - | - | Negative |
| 15 | 2020-03-23 | CTM | 2020-03-23 | - | - | - | Negative |
| 16 | 2020-03-16 | CTM | 2020-03-16 | - | - | - | Negative |
| 17 | 2020-03-23 | CTM | 2020-03-23 | - | - | - | Negative |
| 18 | 2020-03-23 | CTM | 2020-03-23 | - | - | - | Negative |
| 19 | 2020-03-16 | CTM | 2020-03-16 | - | - | - | Negative |
| 20 | 2020-03-23 | CTM | 2020-03-23 | - | - | - | Negative |
| 21 | 2020-03-22 | CTM | 2020-03-22 | - | - | - | Negative |
| 22 | 2020-03-15 | CTM | 2020-03-15 | - | - | - | Negative |
| 23 | 2020-03-23 | CTM | 2020-03-23 | - | - | - | Negative |
| 24 | 2020-03-26 | CTM | 2020-03-26 | - | - | - | Negative |
| 25 | 2020-03-23 | CTM | 2020-03-23 | - | - | - | Negative |
| 26 | 2020-03-18 | CTM | 2020-03-18 | - | - | - | Negative |
| 27 | 2020-03-17 | CTM | 2020-03-17 | - | - | - | Negative |
| 28 | 2020-03-18 | CTM | 2020-03-18 | - | - | - | Negative |
| 29 | 2020-03-24 | CTM | 2020-03-24 | - | - | - | Negative |
| 30 | 2020-03-26 | CTM | 2020-03-26 | - | - | - | Negative |
| 31 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 32 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 33 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 34 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 35 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 36 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 37 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 38 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 39 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 40 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 41 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 42 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 43 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 44 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 45 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 46 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 47 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 48 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 49 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 50 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 51 | 2020-03-27 | CTM | 2020-03-27 | - | - | - | Negative |
| 52 | 2020-03-28 | CTM | 2020-03-28 | - | - | - | Negative |
| 53 | 2020-03-28 | CTM | 2020-03-28 | - | - | - | Negative |
| 54 | 2020-03-28 | ESwab | 2020-03-28 | - | - | - | Positive |

| No. | Specimen collection date | Medium | Day of PCR testing | Result of Real-time RT-PCR | | | COVID-19 Ag |
|---|---|---|---|---|---|---|---|
| | | | | E | RdRp | N | Result |
| 55 | 2020-03-28 | ESwab | 2020-03-28 | - | - | - | Negative |
| 56 | 2020-03-28 | ESwab | 2020-03-28 | - | - | - | Negative |
| 57 | 2020-03-28 | ESwab | 2020-03-28 | - | - | - | Negative |
| 58 | 2020-03-28 | ESwab | 2020-03-28 | - | - | - | Negative |
| 59 | 2020-03-28 | ESwab | 2020-03-28 | - | - | - | Negative |
| 60 | 2020-03-28 | ESwab | 2020-03-28 | - | - | - | Negative |
| 61 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 62 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 63 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 64 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 65 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 66 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 67 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 68 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 69 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 70 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 71 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 72 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 73 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 74 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 75 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 76 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 77 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Positive |
| 78 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 79 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 80 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 81 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 82 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 83 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 84 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 85 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 86 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 87 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 88 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 89 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 90 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 91 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 92 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 93 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 94 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 95 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 96 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 97 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 98 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 99 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |
| 100 | 2020-04-01 | ESwab | 2020-04-01 | - | - | - | Negative |

### 3. DATA ANALYSIS

| | | Real-time RT-PCR | | Total |
|---|---|---|---|---|
| | | + | - | |
| COVID-19 Ag Test | + | 27 | 2 | 29 |
| | - | 3 | 98 | 101 |
| Total | | 30 | 100 | 130 |

- **Sensitivity:** 90.00% (27/30), 95% CI 73.47% to 97.89%
- **Specificity:** 98.00% (98/100), 95% CI 92.96% to 99.76%

## 4. Conclusion

The clinical evaluation for the COVID-19 Ag Test for rapid detection of SARS-CoV-2 antigen was conducted at the Yeungnam University Medical Center in Korea, 130 residual and selected specimens in VTM from persons, who were hospitalized or visited, were tested with comparing to commercialized molecular assays.

The COVID-19 Ag Test showed 90% of sensitivity and 98% of specificity. Among the positive specimens confirmed by real-time PCR, COVID-19 Ag was not detected when the Ct values of each genes in the real-time PCR results were high (weak positive). It is expected that better results were obtained from fresh specimens than from residual specimens.

The limitation of our study was a small number of specimens (positive specimens;30, negative specimens; 100).

# Interference Study Report

**Study Summary**

This study tested the reliability of COVID-19 Antigen Rapid Test Kit (Sars-Cov-2) by spiking potentially interfering substances of high concentration into the tested samples.

**1. Purpose**

The purpose of this test is to evaluate the reliability of COVID-19 Antigen Rapid Test Kit (Sars-Cov-2) under the presence of high concentration interfering substances. Three sequential lots of products are used in this test (Lot No.: 2006008, 2006009, 2006010).

**2. Reference**

The study was performed according to the technology specification of COVID-19 Antigen Rapid Test Kit (Sars-Cov-2)

**3. Method**

3.1 Cross-reactivity on common viruses and bacteria

Spike a healthy Nasal swab sample and a healthy Throat swab sample into saline water, respectively. Prepare the supernatant for subsequent use. MERS-coronavirus, Human coronavirus (NL63), Human coronavirus (229E), Human coronavirus (OC43), Human Adenovirus type 1, Human Adenovirus type 3, Human Adenovirus type 8, Human Adenovirus type 18, Human Adenovirus type 23, Human Adenovirus type 7, Human Adenovirus type 5, Human Adenovirus type 11, Human Parainfluenza virus type 1, Human Parainfluenza virus type 2, Human Parainfluenza virus type 3, Human Parainfluenza virus type 4, Human Rhinovirus type 1, Human Rhinovirus type 14, Human Rhinovirus type 42, Human Metapneumovirus, Respiratory syncytial virus-A, Respiratory syncytial virus-B were confirmed by PCR and ELISA test and clinical diagnostic result and tested with the COVID19 Ag Test Device (swab). Visual interpretations were made at 20 minutes after specimen application. The results are presented in Table 1 below.

**Table 1: Non-Cross-Reacting Compounds**

| | | | |
|---|---|---|---|
| MERS-coronavirus | Neg | Human Adenovirus type 11 | Neg |
| Human coronavirus (NL63) | Neg | Human Parainfluenza virus type 1 | Neg |
| Human coronavirus (NL63) | Neg | Human Parainfluenza virus type 2 | Neg |
| Human coronavirus (229E), | Neg | Human Parainfluenza virus type 3 | Neg |
| Human coronavirus (OC43) | Neg | Human Parainfluenza virus type 4 | Neg |
| Human Adenovirus type 1 | Neg | Human Rhinovirus type 1 | Neg |
| Human Adenovirus type 3 | Neg | Human Rhinovirus type 14 | Neg |
| Human Adenovirus type 8 | Neg | Human Rhinovirus type 42 | Neg |
| Human Adenovirus type 18 | Neg | Human Metapneumovirus | Neg |
| Human Adenovirus type 23 | Neg | Respiratory syncytial virus-A | Neg |
| Human Adenovirus type 7 | Neg | Respiratory syncytial virus-B. | Neg |
| Human Adenovirus type 5 | Neg | | |

**Conclusion:** There was no cross-reaction with above virus at 20minutes.

3.2 Endogenous / Exogenous Material Interference

Prepare the supernatant for subsequent use. Endogenous / exogenous materials with potential interfering effects are spiked in supernatant described above, respectively.

Analytes were spiked into diluting buffer and low positive sample specimen with buffer at the concentrations listed. The specimens were tested in triplicate with 3 lots of test device. Visual interpretations were made at 15 and 20 minutes after specimen application. The results are presented in Table 2 below.

**Table 2: Interfering Substances**

| Analytes | 2006008 | | 2006009 | | 2006010 | |
|---|---|---|---|---|---|---|
| | Sample | | Sample | | Sample | |
| | Neg. | Pos. | Neg. | Pos. | Neg. | Pos. |
| Phenylephrine | - | + | - | + | - | + |
| Acetylsalicylic | - | + | - | + | - | + |
| Beclomethason | - | + | - | + | - | + |
| Benzocaine | - | + | - | + | - | + |
| Flunisolide | - | + | - | + | - | + |
| Guaiacol | - | + | - | + | - | + |
| Menthol | - | + | - | + | - | + |
| Oxymetazoline | - | + | - | + | - | + |
| Tobramycin | - | + | - | + | - | + |
| Zanamivir | - | + | - | + | - | + |
| Oseltamivir | - | + | - | + | - | + |
| mucous. | - | + | - | + | - | + |
| Whole blood | - | + | - | + | - | + |
| Mouth wash | - | + | - | + | - | + |
| Proteus vulagris | - | + | - | + | - | + |
| Enterococcus | - | + | - | + | - | + |
| Proteus | - | + | - | + | - | + |
| Acinetobacter | - | + | - | + | - | + |
| Salmonella | - | + | - | + | - | + |
| Gardnerella | - | + | - | + | - | + |
| Acinetobacter calcoaceticuscal | - | + | - | + | - | + |
| E.coli | - | + | - | + | - | + |

**Conclusion:** No substances showed any interference with the test. There were no differences observed between the results at 15 minutes and the results at 20 minutes. COVID-19 Antigen shows good reliability in the interference study.

# Limit of Detection Study Report

**Study Summary**

This study tested the limit of detection (LOD) of COVID-19(SARS-CoV-2) Antigen test(ACE2 Receptor Method) on testing SARS-COV-2 antigen

**1. Purpose**

This study was to find out the LOD of COVID-19(SARS-CoV-2) Antigen test. Three sequential lots of products are used in this test (Lot No.: 2006008, 2006009,2006010).

**2. Reference**

The study was performed according to the technology specification of COVID-19(SARS-CoV-2) Antigen test.

**3.Method**

Spike a healthy nasal swab sample and a throat swab sample into saline water, respectively. Prepare the supernatant for subsequent use.Spiked a group of serially diluted SARS-COV-2 Virus culture medium (5.76 x $10^4$ $TCID_{50}$/ml, 2.88 x $10^4$ $TCID_{50}$/ml, 1.44 x $10^4$ $TCID_{50}$/ml, 7.2 x $10^3$ $TCID_{50}$/ml, 3.6 x $10^3$ $TCID_{50}$/ml, 0) in supernatant described above, respectively. Each supernatant are tested 6 times.

**4.Result**

| Sample | nasal swab | | | throat swab | | |
|---|---|---|---|---|---|---|
| | 2006008 | 2006009 | 2006010 | 2006008 | 2006009 | 2006010 |
| 5.76 x $10^4$ $TCID_{50}$/ml | 6/6 | 6/6 | 6/6 | 6/6 | 6/6 | 6/6 |
| 2.88 x $10^4$ $TCID_{50}$/ml | 6/6 | 6/6 | 6/6 | 6/6 | 6/6 | 6/6 |
| 1.44 x $10^4$ $TCID_{50}$/ml | 6/6 | 6/6 | 6/6 | 6/6 | 6/6 | 6/6 |
| 7.2 x $10^3$ $TCID_{50}$/ml | 6/6 | 6/6 | 6/6 | 6/6 | 6/6 | 6/6 |
| 3.6 x $10^3$ $TCID_{50}$/ml | 2/6 | 0/6 | 1/6 | 0/6 | 0/6 | 0/6 |
| 0 | 0/6 | 0/6 | 0/6 | 0/6 | 0/6 | 0/6 |

Test results presented above shows that the Detection limit (LoD) of COVID-19(SARS-CoV-2) Antigen is 7.2 x $10^3$ $TCID_{50}$/ml

**5.Conclusion**

The LOD of COVID-19(SARS-CoV-2) Antigen test meets the requirements in product specification, which supports its feasibility in clinical applications.