# COVID-19 Antigen Rapid Test
# Clinical Sensitivity and Specificity Study Report

## 1. Objective

The CLUNGENE® COVID-19 Antigen Rapid Test (hereinafter referred to as the CLUNGENE Device) manufactured by Hangzhou Clongene Biotech Co., Ltd. is a lateral flow immunoassay intended for the qualitative detection SARS-CoV-2 nucleocapsid antigens in nasopharyngeal swab and oropharyngeal swab from individuals who are suspected of COVID-19 by their healthcare provider.

This study is intended to evaluate the clinical performance, between the CLUNGENE Device and the comparator RT-PCR assay.

## 2. Method

A study of 285 direct nasopharyngeal swabs was performed. The specimens were collected from symptomatic patients suspected of COVID-19 at 3 locations and tested at a single central laboratory.

Two nasopharyngeal swabs were collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. At all locations, one nasopharyngeal swab was immediately frozen at -70℃ for later testing, and the other swab was eluted in 3 mL viral transport media and tested with RT-PCR assay for detection of SARS-CoV-2. A total of 285 retrospective nasopharyngeal swab specimens within a pre-specified date range were selected and then tested by the CLUNGENE Device in a blinded fashion. The operators were blinded to the RT-PCR test results.

The positive percent agreement (PPA) was calculated as 100% x (True Positive/[True Positive+False Negative]). The negative percent agreement (NPA) was calculated as 100% x (True Negative / [True Negative + False Positive]). The 95% (two-sided) confidence interval (CI) was calculated using the Wilson Score Method.

## 3. Comparator method

Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2, manufactured by BGI Genomics Co. Ltd. This product has got CE, NMPA certification and FDA Emergency Use Authorized. A specimen is positive for SARS-CoV-2 if the Ct value of ORF1ab gene is not higher than 37.

## 4. Enrollment criteria (inclusion/exclusion criteria)

4.1 Inclusion criteria

- Individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19.

4.2 Exclusion criteria

- Unable to obtain samples of information needed for the experiment
- Samples that have been contaminated or contaminated during sample storage
- Samples with inappropriate storage conditions

## 5. Result

The results are summarized in the following table.

| COVID-19 Antigen | | RT-PCR | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| **CLUNGENE®** | Positive | 64 | 0 | 64 |
| | Negative | 6* | 215 | 221 |
| Total | | 70 | 215 | 285 |

Positive Percent Agreement (PPA)= 91.4% (64/70), (95%CI: 82.5%～96.0%)

Negative Percent Agreement (NPA) =100% (215/215), (95%CI: 98.2%～100%)

* The 6 discordant specimens (CLUNGENE Device Negative/ Comparator RT-PCR assay Positive) had Ct Values of 34, 36, 35.5, 34, 35 and 33.

The PPA is 98.5% (64/65) (95%CI: 91.8%～99.7%) with specimens of a Ct count ≤33.

**6. Conclusion**

Taken together, the CLUNGENE Antigen Rapid Test had a positive percent agreement (sensitivity) of 91.4% (95% CI: 82.5%～96.0%) and negative percent agreement (specificity) of 100% (95% CI: 98.2%～100%). The PPA is 98.5% (64/65) (95%CI: 91.8%～99.7%) with specimens of a Ct count ≤33.