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 770 direct nasopharyngeal swabs was performed. The specimens were prospectively collected from patients in community meeting Department of Public Health definition of a suspected COVID-19 case and being tested for SARS-CoV-2 part of routine medical care at 5 locations and tested at a single central laboratory.

Two nasopharyngeal swabs were collected from individual symptomatic (within 7 days of onset) or asymptomatic patients who were suspected of COVID-19. At all locations, one nasopharyngeal swab was tested directly with the COVID-19 Antigen Rapid Test according to product instructions for use, and the other swab was eluted in 3 mL viral transport media and tested with RT-PCR assay for detection of SARS-CoV-2. Swabs were randomly assigned to testing with the COVID-19 Antigen Rapid Test or RT-PCR assay and were tested by operators who were blinded to the RT-PCR test result.

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]). Accuracy was calculated as 100% x ([True Positive+ True Negative] /Total sample Qty). 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., is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test. 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 and the Ct value of human housekeeping gene β-Actin is not higher than 35.

4. Enrollment criteria (inclusion/exclusion criteria)

4.1 Inclusion criteria

- Patients in community meeting Department of Public Health definition of a suspected COVID-19 case and being tested for SARS-CoV-2 part of routine medical care.
- Symptomatic (within 7 days of onset) or asymptomatic patients 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.

The RT-PCR cycle threshold (Ct) is the relevant signal value. Lower Ct value indicate higher viral load. The

sensitivity was calculated for the different Ct value range (Ct value≤33 and Ct value≤37).

COVID-19Antigen		RT-PCR (Ct value≤33)		Total
		Positive	Negative	
CLUNGENE®	Positive	145	2	147
	Negative	3	593	596
Total		148	595	743
PPA (Ct≤33): 98.0% (145/148), (95%CI: 94.2%～99.3%)				
NPA: 99.7% (593/595), (95%CI: 98.8%～99.9%)				
Accuracy: 99.3%((145+593)/743), (95%CI: 98.4%～99.7%)				

COVID-19Antigen		RT-PCR (Ct value≤37)		Total
		Positive	Negative	
CLUNGENE®	Positive	161	2	163
	Negative	14	593	607
Total		175	595	770
PPA (Ct≤37): 92.0% (161/175), (95%CI: 87.0%～95.2%)				
NPA: 99.7% (593/595), (95%CI: 98.8%～99.9%)				
Accuracy: 97.9%((161+593)/770), (95%CI: 96.6%～98.7%)				

PPA - Positive Percent Agreement (Sensitivity)

NPA - Negative Percent Agreement (Specificity)

6. Conclusion

Taken together, the CLUNGENE® COVID-19 Antigen Rapid Test had a positive percent agreement (sensitivity) of 98.0% (95%CI: 94.2%～99.3%) with specimens of a Ct count ≤33, 92.0% (95%CI: 87.0%～95.2%) with specimens of a Ct count ≤37, negative percent agreement (specificity) of 99.7% (95%CI: 98.8%～99.9%), and accuracy of 99.3% (95%CI: 98.4%～99.7%) with specimens of a Ct count ≤33, 97.9% (95%CI: 96.6%～98.7%) with specimens of a Ct count ≤37.