COVID-19 Antigen Rapid Test Cassette (Saliva)
Clinical Sensitivity and Specificity Study Report

1. Objective

The CLUNGENE® COVID-19 Antigen Rapid Test Cassette (Saliva) (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 saliva 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 645 direct nasopharyngeal swabs and saliva specimens 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.

One nasopharyngeal swab and one saliva specimen were collected from individual symptomatic (within 7 days of onset) or asymptomatic patients who were suspected of COVID-19. At all locations, saliva specimen was tested directly with the COVID-19 Antigen Rapid Test Cassette (Saliva) according to product instructions for use, and the nasopharyngeal swab was eluted in 3 mL viral transport media and tested with RT-PCR assay for detection of SARS-CoV-2. Nasopharyngeal swabs and saliva specimens 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]). 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 (RT-PCR) test. This product has got CE, NMPA certifications 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≤30 and Ct value≤37)

COVID-19 Antigen		RT-PCR (Ct value≤30)		Total
		Positive	Negative	
CLUNGENE®	Positive	120	2	122
	Negative	4	483	487
Total		124	485	609
PPA (Ct≤30):96.8% (120/124), (95%CI: 92.0%～98.7%)				
NPA:99.6% (483/485), (95%CI: 98.5%～99.9%)				

COVID-19 Antigen		RT-PCR (Ct value≤37)		Total
		Positive	Negative	
CLUNGENE®	Positive	146	2	148
	Negative	14	483	497
Total		160	485	645
PPA (Ct≤37):91.3% (146/160), (95%CI: 85.9%～94.7%)				
NPA: 99.6% (483/485), (95%CI: 98.5%～99.9%)				

PPA - Positive Percent Agreement (Sensitivity)

NPA - Negative Percent Agreement (Specificity)

6. Conclusion

Taken together, the CLUNGENE® COVID-19 Antigen Rapid Test Cassette (Saliva) had a positive percent agreement (sensitivity) of 96.8% (95% CI: 92.0%～98.7%) with specimens of a Ct count ≤30, 91.3% (95%CI: 85.9%～94.7%) with specimens of a Ct count ≤37, and negative percent agreement (specificity) of 99.6% (95% CI: 98.5%～99.9%).