

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 $100\% \times (\text{True Positive} / [\text{True Positive} + \text{False Negative}])$. The negative percent agreement (NPA) was calculated as $100\% \times (\text{True Negative} / [\text{True Negative} + \text{False Positive}])$. 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 \leq 30 and Ct value \leq 37)

COVID-19 Antigen		RT-PCR (Ct value \leq 30)		Total
		Positive	Negative	
CLUNGENE[®]	Positive	120	2	122
	Negative	4	483	487
Total		124	485	609

PPA (Ct \leq 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 \leq 37)		Total
		Positive	Negative	
CLUNGENE[®]	Positive	146	2	148
	Negative	14	483	497
Total		160	485	645

PPA (Ct \leq 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 \leq 30, 91.3% (95%CI: 85.9% ~94.7%) with specimens of a Ct count \leq 37, and negative percent agreement (specificity) of 99.6% (95% CI: 98.5% ~99.9%).