

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 $100\% \times (\text{True Positive} / [\text{True Positive} + \text{False Negative}])$. The negative percent agreement (NPA) was calculated as $100\% \times (\text{True Negative} / [\text{True Negative} + \text{False Positive}])$. Accuracy was calculated as $100\% \times ((\text{True Positive} + \text{True Negative}) / \text{Total sample Qty})$. 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 \leq 33 and Ct value \leq 37).

COVID-19Antigen		RT-PCR (Ct value \leq 33)		Total
		Positive	Negative	
CLUNGENE®	Positive	145	2	147
	Negative	3	593	596
Total		148	595	743

PPA (Ct \leq 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 \leq 37)		Total
		Positive	Negative	
CLUNGENE®	Positive	161	2	163
	Negative	14	593	607
Total		175	595	770

PPA (Ct \leq 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 \leq 33, 92.0% (95%CI: 87.0%~95.2%) with specimens of a Ct count \leq 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 \leq 33, 97.9% (95%CI: 96.6%~98.7%) with specimens of a Ct count \leq 37.