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

1. Objective

The CLUNGENE® COVID-19 Antigen Rapid Test Cassette (Nasal Swab) (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 nasal 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 617direct nasal 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 nasal swabs were collected from individual symptomatic (within 7 days of onset) or asymptomatic patients who were suspected of COVID-19. At all locations, one nasal swab was tested directly with the COVID-19 Antigen Rapid Test Cassette (Nasal Swab) 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 Cassette (Nasal Swab) 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≤30 and Ct value≤37).

COVID-19 Antigen		RT-PCR (Ct value≤30)		Total
		Positive	Negative	
CLUNGENE®	Positive	117	3	120
	Negative	3	462	465
Total		120	465	585
PPA (Ct≤30):97.5% (117/120), (95%CI: 92.9%～99.2%)				
NPA: 99.4% (462/465), (95%CI: 98.1%～99.8%)				

COVID-19 Antigen		RT-PCR (Ct value≤37)		Total
		Positive	Negative	
CLUNGENE®	Positive	139	3	142
	Negative	13	462	475
Total		152	465	617
PPA (Ct≤37):91.4% (139/152), (95%CI: 85.9%～94.9%)				
NPA: 99.4% (462/465), (95%CI: 98.1%～99.8%)				

PPA - Positive Percent Agreement (Sensitivity)

NPA - Negative Percent Agreement (Specificity)

6. Conclusion

Taken together, the CLUNGENE® COVID-19 Antigen Rapid Test Cassette (Nasal Swab) had a positive percent agreement (sensitivity) of 97.5% (95%CI: 92.9%～99.2%) with specimens of a Ct count ≤30, 91.4% (95%CI: 85.9%～94.9%) with specimens of a Ct count ≤37, negative percent agreement (specificity) of 99.4% (95%CI: 98.1%～99.8%).