COVID-19 Antigen Rapid Test
Clinical Sensitivity and Specificity Study Report

1. Objective

The "CLUNGENE® COVID-19 Antigen Rapid Test Cassette" 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.

The clinical performance of the "CLUNGENE® COVID-19 Antigen Rapid Test Cassette" was assessed at clinical sites evaluation with nasopharyngeal swabs obtained from individuals suspected of with COVID-19 infection (within 7 days of onset).

The clinical evaluation including 70 clinical positive specimens from individuals were finally confirmed positive for SARS-CoV-2 virus infection by RT-PCR and 215 clinical negative specimens from individuals were finally confirmed negative for SARS-CoV-2 virus infection by RT-PCR.

2. Method

Regarding the SARS-CoV-2 nucleocapsid antigen detection, testing was performed on 285 clinical nasopharyngeal swab specimens. 70 positive specimens and 215 negative specimens were compared to RT-PCR. We calculate the PPA, NPA with 95%CI.

3. Sample and Collection

3.1 Sample used for RT-PCR and SARS-COV-2 Antigen: nasopharyngeal swab

3.2 Sample Collection: The samples we used for SARS-COV-2 Antigen detection were retrospective samples in the COVID-19 2020 outbreak period and high risk area. For positive sample, we included SARS-CoV-2 Virus infection person with swabs tested RT-PCR confirmed positive. For negative sample, we included the swabs from asymptomatic subjects whom live in high risk area when the epidemic was under control, with swabs tested RT-PCR negative. We blind - coded the samples for testing.

3.3 Sample Storage: Freshly collected specimens were processed and tested in one hour after specimen collection. Specimen stored at 2-8℃ for no more than 24 hours. Store at -70℃ for a long time.

4. Comparator method

Commercialized real-time Polymerase Chain Reaction (RT-PCR) assay with CE mark

5. Operators

They were trained of Operating procedures for CLUNGENE® COVID-19 Antigen Rapid Test Cassette user manual and clinical evaluation protocol.

6. Enrollment criteria (inclusion/exclusion criteria)

6.1 Inclusion criteria

- Individuals suspected of COVID-19 infection tested by SARS-CoV-2 RT-PCR test (within 7 days of onset)
- Confirmed infected by SARS-CoV-2 RT-PCR test
- Asymptomatic subjects underwent SARS-CoV-2 RT-PCR test

6.2 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

7. Result

The results are summarized in the following table.

Table 1: CLUNGENE Device Results versus RT-PCR - SARS-CoV-2

COVID-19 Antigen		RT-PCR		Total
		Positive	Negative	
CLUNGENE®	Positive	64	0	64
	Negative	6*	215	221
Total		70	215	285

Positive Percent Agreement (PPA)= 91.4% (64/70), (95%CI: 82.5%～96.0%)

Negative Percent Agreement (NPA) =100% (215/215), (95%CI: 98.2%～100%)

* The 6 discordant specimens (CLUNGENE Device Negative/ Comparator RT-PCR assay Positive) had Ct Values of 34, 36, 35.5, 34, 35 and 33.

The PPA is 98.5% (64/65) (95%CI: 91.8%～99.7%) with specimens of a Ct count ≤33.

8. Conclusion

The clinical research is a qualitative test comparison to evaluate the clinical use validity and group professional test applicability of the “COVID-19 Antigen Rapid Test Cassette” manufactured by Hangzhou Clongene Biotech Co., Ltd.

For COVID-19 Antigen, when compared to RT-PCR, a statistical comparison was made between the results yielding PPA of 91.4% (95% CI: 82.5%～96.0%), NPA of 100% (95% CI: 98.2%～100%). The PPA is 98.5% (64/65) (95%CI: 91.8%～99.7%) with specimens of a Ct count ≤33.