Clinical Sensitivity and Specificity Study Report

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.

The clinical evaluation including 32 clinical positive specimens from individuals were finally confirmed positive for SARS-CoV-2 virus infection by RT-PCR. 130 clinical negative specimens from individuals were finally confirmed negative for SARS-CoV-2 virus infection by RT-PCR.

1. Method

Regarding the SARS-CoV-2 nucleocapsid antigen detection, testing was performed on 162 clinical nasopharyngeal swab specimens. 32 positive specimens and 130 negative specimens were compared to RT-PCR. We calculate the PPA, NPA with 95%CI.

2. Sample and Collection

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

2.2 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 confirmed SARS-CoV-2 Virus infection person with swabs tested RT-PCR 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.

2.3 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.

3. Comparator method

RT-PCR

4. Operators

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

5. Enrollment criteria (inclusion/exclusion criteria)

5.1 Inclusion criteria

- Individuals suspected of COVID-19 infection tested by SARS-CoV-2 RT-PCR test
- Confirmed infected by SARS-CoV-2 RT-PCR test
- Asymptomatic subjects underwent SARS-CoV-2 RT-PCR test

5.2 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

6. Result

COVID-19 Antigen		RT-PCR		Total
		Positive	Negative	
CLUNGENE®	Positive	27	0	27
	Negative	5	130	135
Total		32	130	162

Positive Percent Agreement (PPA)= 84.38% (27/32), (95%CI: 68.25%～93.14%)

Negative Percent Agreement (NPA) =100% (130/130), (95%CI: 97.13%～100%)

7. 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 84.38% (95% CI: 68.25%～93.14%), NPA of 100% (95% CI: 97.13%～100%).

For COVID-19 Antigen Rapid Test Cassette is intended for the qualitative detection SARS-CoV-2 nucleocapsid antigens. There were still may appear false positive results and negative results. A false negative result can occur if the quantity of antigens for the SARS-CoV-2 virus present in the specimen is below the detection threshold of the assay, or the virus has undergone minor amino acid mutation(s) in the target epitope region recognized by the monoclonal antibodies utilized in the test. Improper specimen collection, improper specimen storage or repeated freezing and thawing of specimens also can lead to inaccurate results.