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Clinical Study Report of COVID-19 Antigen Rapid Test

Ref.: ICOV-502

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Content

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1. Summary

70 COVID-19 negative specimens with clinical symptoms and asymptomatic were used in this clinical study. Commercial RT-PCR served as the reference method for the COVID-19 Antigen Rapid Test (Swab). The result shows the COVID-19 Antigen Rapid Test has a high relative specificity when tested with the 70 specimens.

2. Background

Coronaviruses are a large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus in 2019 causes coronavirus disease COVID-19.[1] The new coronavirus is called 2019-nCoV or COVID-19. Due to the rapid spread of COVID-19, COVID-19 is now a pandemic affecting many countries globally. As of May 24th, there were 5.2 million confirmed cases worldwide and 337 000 reported deaths [2]. The clinical presentation of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.[3]

3. Objective

Test the performance of COVID-19 Antigen Rapid Test (Swab) in collecting clinical swab specimens compare with PCR results.

4. Materials

- COVID-19 Antigen Rapid Test (Swab)
  Lot: COV20090001-T
- 70 COVID-19 negative non-frozen nasopharyngeal swab specimen
- PCR brand:
  BGI 2019-nCoV RT-qPCR
- Clinical Sites:
  Hospital in China

5. Method

Totally 70 nasopharyngeal swab specimens collected from different individuals with suspected COVID-19 infection between 0-7 days after onset of symptom and asymptomatic donors, then tested with PCR and COVID-19 antigen rapid test respectively.

6. Operation Method

Operation method can be referred to package insert provided in the kits.

7. Test Results

Table: Clinical Study Result from Nasal Swab Specimen

COVID-19 Antigen Rapid Test		RT-PCR		Total
		Positive	Negative	
COVID-19 Antigen	Positive	0	1	1
	Negative	0	69	69
Total		0	70	70
Relative Sensitivity		/		
Relative Specificity		98.6% (95%CI*:92.3%~99.9%)		
Accuracy		98.6% (95%CI*:92.3%~99.9%)		

8. Conclusion

The relative specificity of COVID-19 Antigen Rapid Test (Swab) was 98.6% compare with PCR result in this clinical study.

9. References

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3. World Health Organization (WHO). Coronovirus. https://www.who.int/health-topics/coronavirus