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Clinical Study Report of COVID-19 Antigen Rapid Test

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1. Summary

70 COVID-19 positive specimens and 60 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 sensitivity and high relative specificity when tested with the 130 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: COV20120037
- 60 COVID-19 positive non-frozen nasal swab specimen.
- 70 COVID-19 negative non-frozen nasal swab specimen
- PCR brand:
GSD NovaPrime(R) COVID-19
- Clinical Sites:
MEGALAB in Spain

5. Method

Totally 130 nasal 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	65	0	65
	Negative	5	60	65
Total		70	60	130
Relative Sensitivity		92.9% (95%CI*: 84.1%~97.6%)		
Relative Specificity		>99.9% (95%CI*: 94.0%~100%)		
Accuracy		96.2% (95%CI*: 91.3%~98.7%)		

8. Conclusion

The relative sensitivity of COVID-19 Antigen Rapid Test (Swab) was 92.9%, the relative specificity was > 99.0% compare with PCR result in this clinical study.

9. References

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