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Clinical Study Report of COVID-19 Antigen Rapid Test Cassette

Ref.: ICOV-502

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Content

1. Summary

83 COVID-19 positive specimens and 121 COVID-19 negative specimens confirmed by PCR and clinical Symptoms were used in clinical study. Commercial PCR served as the reference method for the COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab). The result shows the COVID-19 Antigen Rapid Test Cassette has a high restive sensitivity and high relative specificity when tested with the 204 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 SARS-COV-2. Due to the rapid spread of SARS-CoV-2, 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

Do clinical studies of COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) with the COVID-19 positive specimens and negative specimens which confirmed with PCR method.

4. Materials

- COVID-19 Antigen Rapid Test Cassette
  Test LOT: COV20090001-T
- 83 COVID-19 positive non-frozen specimen confirmed with PCR
- 121 COVID-19 negative non-frozen specimen confirmed with PCR
- PCR brand:
  1.Brand: RealBest RNA SARS-CoV-2: Manufacturer: LLC Vector-Best-Ukraine (CE)
  2.Brand: ACCUPOWER SARS-COV2 REAL-TIME RT-PCR KIT Manufacturer: Bioneer Inc (CE)
- Clinical Sites: 1. Medbioalliance - Ukraine
  2. Reactlab - Ecuador

5. Method

Totally 204 nasopharyngeal swab samples collected from individuals with suspected SARS-CoV-2 infection between 0-7 days after onset of symptom, 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

Method		RT-PCR		Total Results
COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab)	Results	Positive	Negative	
	Positive	80	1	81
	Negative	3	120	123
Total Results		83	121	204
Relative Sensitivity		80/83=96.4%（95%CI*: 89.8%~99.2%）		
Relative Specificity		120/121=99.2%（95%CI*: 95.5%~99.9%）		
Totally accuracy		200/204=98.0%（95%CI*: 95.1%~99.5%） *Confidence Intervals		

8. Conclusion

The relative sensitivity of COVID-19 Antigen Rapid Test was 96.4%, the relative specificity was 99.2% compare with PCR result.

9. References

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