Clinical Study Report of SARS-CoV-2 Antigen Rapid Test

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Content

1. Summary

We analyzed the SARS-CoV-2 Antigen Rapid Test (Swab) at different locations and at different clinical specimen, as described below.

Nasal swab specimen

316 SARS-CoV-2 positive specimens and 763 SARS-CoV-2 negative specimens with clinical symptoms and asymptomatic were used in this clinical study. Commercial RT-PCR served as the reference method for the SARS-CoV-2 Antigen Rapid Test (Swab). The result shows the AllTest SARS-CoV-2 Antigen Rapid Test has a high restive sensitivity and high relative specificity when tested with the 1079 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

Test the performance of SARS-CoV-2 Antigen Rapid Test (Swab) in collecting clinical swab specimens with suspected SARS-CoV-2 infectious compare with PCR results.

4. Materials

- SARS-CoV-2 Antigen Rapid Test (Swab)
- 316 SARS-CoV-2 positive nasal swab specimen
- 763 SARS-CoV-2 negative nasal swab specimen
- PCR brand:
  1.Brand: R-Biopharm RIDA Gene SARS-CoV-2 real-time PCR kit
  2.Brand: CE marked Seegene Allplex 2019-nCoV Assay
  3.Brand: BioFire COVID-19 Test
- Clinical Sites:
  Different clinical sites in Germany and Slovenia carried on the whole nasal swab clinical study of SARS-CoV-2 Antigen Rapid Test (Swab)

5. Method

Totally 1079 nasal swab specimens collected from different individuals with suspected SARS-CoV-2 infection between 0-7 days after onset of symptom, then tested with RT-PCR and SARS-CoV-2 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 in Germany

SARS-CoV-2 Antigen Rapid Test		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	63	0	63
	Negative	3	100	103
Total		66	100	166
Relative Sensitivity		95.5% (95%CI*: 87.3%~99.1%)		
Relative Specificity		＞99.9% (95%CI*: 96.4%~100%)		
Accuracy		98.2% (95%CI*: 94.8%~99.6%)		

* Confidence interval

Table: Clinical Study Result from Nasal Swab in Slovenia

SARS-CoV-2 Antigen Rapid Test		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	98	0	98
	Negative	10	349	359
Total		108	349	457
Relative Sensitivity		90.7% (95%CI*: 83.6%~95.5%)		
Relative Specificity		＞99.9% (95%CI*: 99.0%~100%)		
Accuracy		97.8% (95%CI*: 96.0%~99.0%)		

* Confidence interval

Table: Clinical Study Result from Nasal Swab in Slovenia

SARS-CoV-2 Antigen Rapid Test		RT-PCR**		Total
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	134	0	134
	Negative	8	314	322
Total		142	314	456
Relative Sensitivity		94.4% (95%CI*: 89.2%~97.5%)		
Relative Specificity		＞99.9% (95%CI*: 99.0%~100%)		
Accuracy		98.3% (95%CI*: 96.7%~99.2%)		

* Confidence interval, ** Qualitative RT-PCR test

Table: Clinical Study Result from Nasal Swab Specimen (Totally)

SARS-CoV-2 Antigen Rapid Test		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	295	0	295
	Negative	21	763	784
Total		316	763	1079
Relative Sensitivity		93.4% (95%CI*: 90.0%~95.8%)		
Relative Specificity		＞99.9% (95%CI*: 99.5%~100%)		
Accuracy		98.1% (95%CI*: 97.0%~98.8%)		

* Confidence interval

8. Conclusion

The relative sensitivity of SARS-CoV-2 Antigen Rapid Test (Swab) was 93.4% (95%CI*: 90.0%~95.8%), the relative specificity was more than 99.9% (95%CI*: 99.5%~100%) compare with PCR result when tested with nasal swab specimen.

9. References

1. Q&A on coronaviruses (COVID-19). https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/q-a-coronaviruses
2. WHO. Coronavirus disease 2019 (COVID-19) Situation Report. https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200524-covid-19-sitrep-125.pdf?sfvrsn=80e7d7f0_2
3. World Health Organization (WHO). Coronovirus. https://www.who.int/health-topics/coronavirus