

Clinical Samples Study Report

COVID-19 Antigen Rapid Test Cassette (Swab)

Purpose

Evaluate the performance of Orient gene COVID-19 Antigen Rapid Test Cassette (Swab) for testing clinical samples.

Materials

Orient gene device: COVID-19 Antigen Rapid Test Cassette (Swab)

Lot: 20200313, Exp: 02-2022

Commercial PCR assay: DAAN GENE , 2019 Novel Coronavirus (2019-nCoV) RNA detection kit(PCR Fluorescence probing)

Study design

203 patients exhibiting pneumonia or respiratory symptoms were sequentially enrolled and collected nasopharyngeal (NP) swab samples for testing, each people taken two swab samples at same time, one swab sample for Orient gene device testing, the other swab sample for commercial PCR assay testing. The swab sample were tested in single with Orient gene device, the results were compared to PCR assay results. The information of patients is followed as Appendix-1.

Test site

A total of two investigational sites participated in the study.

Test procedure

Followed the package insert.

Results

Table 1: The COVID-19 Antigen Rapid Test vs PCR

Method		PCR		Total Results
COVID-19 Ag Rapid Test Cassette	Results	Positive	Negative	
	Positive	71	0	71
	Negative	2	130	132
Total Results		73	130	203

Relative Sensitivity: 97.3% (71/73)

Relative Specificity: 100% (130/130)

Accuracy: 99.0% (201/203)

Table 2: Positive results broken down by days since symptom onset

Days Since Symptom Onset	Cumulative PCR Positive(+)	Cumulative Orient Gene COVID-19 Ag Rapid Test Cassette Positive(+)	PPA
1	7	7	100%
2	18	18	100%
3	30	30	100%
4	44	44	100%
5	59	58	98.3%
6	62	60	96.8%
7	70	68	97.1%
8	71	69	97.2%

9	72	70	97.2%
10	73	71	97.3%

Table 3: Orient Gene COVID-19 Ag Performance against the Comparator Method – by Cycle Threshold Counts

Orient Gene COVID-19 Ag Rapid Test Cassette	PCR Results (Ct) of nucleoprotein(N) gene	
	Positive (Ct<30)	Positive (Ct ≥30)
Positive	62	9
Negative	0	2
Total	62	11

Orient Gene COVID-19 Ag Rapid Test Cassette	PCR Results (Ct) of open reading frame(ORF) gene	
	Positive (Ct<30)	Positive (Ct ≥30)
Positive	40	31
Negative	0	2
Total	40	33

Conclusion

The above results showed that:

The Relative Sensitivity of Orient gene COVID-19 Antigen Rapid Test Cassette (Swab) is 97.3% (71/73), Relative Specificity is 100% (130/130) comparison to PCR.

Discussion:

If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended.

Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Line data is attached as Appendix-1.