COVID-19 Antigen Test

Clinical Sensitivity and Specificity Study Report

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R& D Department
Quality Control Department

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Study Summary

The purpose of this study was to obtain accurate information regarding the clinical performance Sensitivity and Specificity of Artron COVID-19 Antigen Test. The clinical evaluation was carried out for the clinical performance of Artron COVID-19 Antigen Test.

1. Purpose

To validate the clinical performance sensitivity and specificity of Artron COVID-19 Antigen Test.

2. **Reference and Compliance**

FDA guidance for In vitro diagnostic medical device
The present study conformed to all applicable laws and regulations.

3. Materials

- COVID-19 positive specimens were confirmed by RT-PCR. And non-COVID-19 Nasal/Nasopharyngeal Swabs from non-febrile and non-respiratory patients and confirmed non-COVID-19 by RT-PCR.
- Artron COVID-19 Antigen Test, Lot: COV19-Ag-S-1

4. Study Design:

4.1 The clinical performance was evaluated in RT-PCR confirmed COVID-19 infected Nasopharyngeal swab specimens and non-COVID-19 infected Nasopharyngeal Swabs specimens from subjects in the chosen hospitals and clinical laboratories. All the samples should be tested with Artron COVID-19 Antigen Test.

4.2 Test conditions:

- All tests were performed by the clinical technicians in the clinical laboratory according to the manufacturer's instructions using the confirmed samples.
- Visual interpretations of the results of COVID-19 Antigen Test were made independently by the clinical technician.
- The testing center was responsible to summarize the result.

5. Evaluation Criteria

Positive（POS）: Both C and T lines appear regardless of color intensity.
Negative（NEG）: Only C line appears.
Indeterminable (IND): C line appears; T line is so weak that it cannot be determined as positive.
Invalid result（/）: Neither C line nor T line appears.

6. Clinical Results

6.1 Clinical Site One

Results from SANTA ANA HOSPITALS, Manila, Philippines: Evaluation has been done in SANTA ANA HOSPITALS.

The clinical evaluation was carried out for the clinical performance of Artron COVID-19 Antigen Test. Total 38 nasopharyngeal swabs from COVID-19 infected patients and 133 non-COVID-19 infected patients were tested.

Table 1 Artron COVID-19 Antigen Test results

		Results of COVID 19 Ag test		Subtotal
		Positive	Negative	
RT-PCR	Positive	37	1	38
	Negative	0	133	133
Subtotal		37	134	171

Artron COVID 19 Ag Test kit could detect the Nasopharyngeal swabs with high clinical performance sensitivity and specificity listed below:
Sensitivity: 37/38 = 97.3%
Specificity: 133/133 = 100.0%
Total Agreement: (37+133)/171 = 99.4%

Total 38 Nasopharyngeal swabs from SARS-Cov-2 infected patients, and 133 non-SARS-Cov infected patients were tested. Among all of those chosen samples, Artron COVID-19 Ag test kit identified out total 37 SARS-Cov-2 positive from 38 SARS-Cov-2 infected patients' samples; the clinical sensitivity was 97.3%, no false positive from total 133 non-SARS-Cov infected cases, which demonstrated the specificity was 100 %, total agreement is 99.4%

6.2 Clinical Site Two

Results from Clinical lab: Experiments have been done in local Hospitals/Labs in Ahmedabad, Gujarat, India.

The clinical evaluation was carried out for the clinical performance of Artron COVID-19 Antigen Test. Total 56 Nasopharyngeal swabs from COVID-19 infected patients and 68 non-COVID-19 infected patients were tested.

Table 2 Artron COVID-19 Antigen Test results

		Results of COVID 19 Ag test		Subtotal
		Positive	Negative	
RT-PCR	Positive	48	8	56
	Negative	0	68	68
Subtotal		48	76	124

Artron COVID 19 Ag Test kit could detect the Nasopharyngeal swabs with high clinical performance sensitivity and specificity listed below:
Sensitivity: 48/56 = 85.7%
Specificity: 68/68 = 100.0%
Total Agreement: (48+68)/124 = 93.5%

Total 56 Nasopharyngeal swabs from SARS-Cov-2 infected patients, and 68 non-SARS-Cov infected patients were tested. Among all of those chosen samples, Artron COVID-19 Ag test kit identified out total 48 SARS-Cov-2 positive from 56 SARS-Cov-2 infected patients' samples; the clinical sensitivity was 85.7 %, no false positive from total 68 non-SARS-Cov infected cases, which demonstrated the specificity was 100 %, total agreement is 93.5%

7. Conclusion

The sensitivity and specificity of Artron COVID-19 Antigen Test to the positive Nasopharyngeal swab specimens were calculated based on the detection results of RT-PCR. The Artron COVID-19 Antigen test sensitivity >85.7% and specificity is >99.0% respectively, the overall agreement >93.5 %.

8. Report

8.1 Original raw data is archived at Quality Control Department
8.2 The original final report is archived in Quality Control Department.