COVID-19 Antigen Test

Clinical Sensitivity and Specificity Study Report

Drafted by: Nicolas Ma

Approved by: Jerry Zheng

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ARTRON LABORATORIES INC. Artron CANADA

Management of the study: **Artron Laboratories Inc.**

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
   WHO Instructions and requirements for Emergency Use Listing (EUL)
   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 AntigenTest. 4.2 Test conditions:

   - All tests were performed by the clinical techniciansin 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

Experiments have been done at Santa Ana Hospital, Manila, Philippines

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 = 97.37% (95% CI: 86.19% – 99.93%)
Specificity: 133/133 = 100.0% (95% CI: 97.26% – 100%)
Total Agreement: (37+133)/171 = 99.42%

Total 38 Nasopharyngeal swabs from SARS-Cov-2 infected patients, and 133 non-SARS-Cov-2 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 97.37%, no false positive from total 133 non-SARS-Cov-2 infected cases, which demonstrated the specificity was 100%, total agreement is 99.42%

6.2 Clinical Site Two

Experiments have been done in local private 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 = 85.71% (95% CI: 73.78% – 93.62%)
Specificity: 68/68 = 100.0% (95% CI: 94.72% – 100%)
Total Agreement: (48+68)/124 = 93.55%

Total 56 Nasopharyngeal swabs from SARS-Cov-2 infected patients, and 68 non-SARS-Cov-2 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 85.71%, no false positive from total 68 non-SARS-Cov-2 infected cases, which demonstrated the specificity was 100%, total agreement is 93.55%

6.3 Clinical Site Three

Experiments have been done in Hemolab Clinic, Bucharest, Romania.

The clinical evaluation was carried out for the clinical performance of Artron COVID-19 Antigen Test. This was a prospective study performed over 2 weeks on 303 total subjects.

Table 3 Artron COVID-19 Antigen Test results

		Results of COVID 19 Ag test		Subtotal
		Positive	Negative	
RT-PCR	Positive	30	2*	32
	Negative	0	271	271
Subtotal		30	273	303

*2 inconclusive PCR results counted as presumptive positives

Artron COVID 19 Ag Test kit could detect the Nasopharyngeal swabs with high clinical performance sensitivity and specificity listed below:
Sensitivity: 30/32 = 93.75% (95% CI: 79.19% – 99.23%)
Specificity: 271/271 = 100.0% (95% CI: 98.65% – 100%)
Total Agreement: (30+271)/303 = 99.34%

Table 4 Ct Value for positive RT-PCR Results, Clinical Site Three

Count	30
Median	25
Mode	26
Range	19 – 31

Total 32 Nasopharyngeal swabs from SARS-Cov-2 infected patients, and 271 non-SARS-Cov-2 infected patients were tested. Among all of those chosen samples, Artron COVID-19 Ag test kit identified out total 30 SARS-Cov-2 positive from 32 SARS-Cov-2 infected patients' samples; the clinical sensitivity was 93.75%, no false positive from total 271 non-SARS-Cov-2 infected cases, which demonstrated the specificity was 100%, total agreement is 99.34%

7. Conclusion

Clinical performance of the Artron COVID-19 Antigen Test was evaluated at three clinical sites. A total of 598 subjects were tested, 126 of whom were determined to be SARS-Cov-2 infected. 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 is 91.27% with 95% CI 84.92% – 95.56%, and specificity is 100% with 95% CI 99.22% – 100%. The overall agreement is 98.16 %.

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.